





# TECHNICAL NOTE 94.12

### COMPARTMENT I FUNCTIONAL TESTS Step 1 and Step 2

Test Plan Test Protocols Test As Run Procedures Test Report

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#### List of acronyms

CI : compartment I

- MELiSSA: Micro-Ecological Life Support System Alternative
- UAB: Universitat Autònoma de Barcelona
- VFA: volatile fatty acids
- BR: bioreactor
- FU: Filtration unit
- GL: Gas loop
- FBD: Function block diagram
- SFC: Sequential function chart
- HMI: human machine interface



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### 1. Introduction

This Functional Test Plan provides on field tests to verify that CI compartment is installed and operating as specified and meets previously approved functional specifications for its operation, before the system is started up and set onto real operation. In particular, it is oriented to:

- Validate that the CI compartment after connection to Utilities and PLC and Supervision is performing nominally its main functions.
- Identify potential failures / lacks in the current PLC / Supervision programmes
- Identify minor hardware modifications needed before starting the work on control hardware and software up-grade

Functional testing is designed to check installation conditions and to simulate operating conditions to establish a performance baseline providing assurance that the system can be operated at the expected conditions, and additional data for future troubleshooting.

Specifically, these functional tests to be performed will cover part of TN 83.7 test cases: i.e.control of liquid level, section 2.3 page 8, influent/effluent tank temperature, section 2.2 page 7 and gas flowrate, section 2.6 page 11.

The functional tests to check the operation of Compartment I are divided in two steps:

- In the Step1, a functional testing is defined with the control hardware and software as they are at the moment of the initiation of the work. The aim of this step is to identify minor hardware modifications needed before starting the work on control hardware and software up-grade.
- The Step 2 consists in the definition and execution of the functional tests after the implementation of process hardware modifications, and control hardware and software upgrades, for the final acceptance of the Compartment.



### 2. Reference documents

Ref.	Title	Reference	Issue	Date
RD1	EWC Acceptance Review MOM	MOM_EWC_AR_20070619		19/06/07
RD2	EPAS TN 71.10.1 Life Test-Plan and Procedure	TN71.10.1	3	13/07/06
RD3	TN 94.11 Compartment I Integration in MPP	TN 94.11	1	13.02.09
RD4	EPAS EWC User Manual	User Manual	1	12.06.07
RD5	EPAS EWC Scheme	-	-	03.11.06
RD6	TN 83.7 Expertise of level 0 control loops on the 100 L pilot reactor		1	23.10.06
RD7	PID of Compartment 1 after hardware modifications	MPP-PID-10-1001-B1	-	5/1/2010
RD8	CI HMI Software User manual	NTE-MCI-HB-012	1	19/05/09
RD9	Procedures and SFC Analysis	SHERPA TN	1	March 2009

### 3. TASKS DISTRIBUTION

Tasks are distributed among MPP(UAB) and its sub-contractors and suppliers, as described hereafter.

#### MPP(UAB)

- Writes the Functional Test Plan and Protocols.
- Prepares, executes and reviews the Functional Tests
- Reviews and approves of Functional Test Protocol and following reports.
- Verifies that the Utilities equipment is operating in accordance with the requirements defined by manufacturer.

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- Verifies the maintenance and calibration of equipment used for the tests.
- Supervises the Functional tests during execution.
- Reviews the Functional tests data and controls the accordance with acceptance criteria.
- After the performance of the tests, defines any need of hardware modifications.
- Stores and controls all documentation to maintain its integrity.

#### MPP engineering subcontractor (CAMPS PROCESS/CIFA)

- Verifies the complete installation of Utilities and that they are ready for use: prepares of the hardware for the Test Readiness review (Step 1).
- Verifies that the Utilities equipment is operated in accordance with the requirements defined by manufacturer.
- Collaborates with MPP in the design and installation of hardware modifications to assure the Functional Test completion.

#### SHERPA-NTE

- Participates to the Test Readiness Review and test Acceptance Review
- Participates to the tests and resolution of tasks related to PLC and HMI.
- Support UAB during the functional tests addressing control issues. These functional tests to be performed cover part of TN RD6 test cases (i.e. control of liquid level, section 2.3 page 8, influent/effluent tank temperature, section2.2 page 7 and gas flow rate, section 2.6 page 11).
- Cooperate with MPP to write the test Protocols and define the general criteria for the tests, quality requirements and acceptance criteria for tests.
- Participates to the interpretation of the Test Results
- Collaborates with MPP in the design and installation of process modifications to assure the Functional Test completion: implementation of modifications of



PLC program and HMI from Step 1 Test Acceptance Review to Step 2 Test readiness Review.

Each Sub-contractor or supplier is responsible for these tasks in front of MPP(UAB), and UAB has the final responsibility of the coordination, and presents the results to ESA for approval.

### 4. Test Plan

### 4.1. Functional Tests Step 1

4.1.1. Test items

4.1.1.1. Description

Hardware configuration

The basic process description, equipment characteristics and utilities required for Compartment I operation are described in detail in RD3, as well as the installation and checking tasks performed. The P&ID is provided in RD5.

Software configuration

The PLC code structure, control algorithms and procedures, and the description of the supervisor and HMI for Compartment I operation are described in detail in RD3, as well as the installation and checking tasks performed.

Pre-operational Tests

A number of specific tests have to be carried out after the installation that are considered necessary to verify that the equipment was ready for the Functional Tests. They are described in RD3, and consist of:

- Safety valves test
- Liquid tightness test
- Gas tightness test



#### 4.1.1.2. Hazards induced by test item and safety measures to be taken

All people involved in the testing activity must know and observe the rules related to safety required by MPP and UAB.

Any specific precaution and rule that must be observed in the activities related to the execution of this protocol must be pre-determined by the MPP Safety Manager or, where feasible, detailed in the relevant test procedure.

A Safety check-list should be used and compiled prior to the initiation of the tests, considering the acceptance of the critical parameters there indicated as blocking for the testing phase.

The conclusions of the HAZOP on CI carried out in December 2006 (HAZOP-08-1001, issue 0) must be taken into account as inputs for the Functional Tests, being blocking for that phase in case any critical aspect had not been properly assessed.

Tests dedicated to Pressure Safety valves checking and Pressure Safety control, should be carried out first, as a blocking prerequisite for the rest of the Functional Tests.

#### 4.1.1.3. Instructions for operation

Cf User Manual by EPAS

#### 4.1.1.4. <u>Instructions for maintenance</u> N/A

#### 4.1.2. Test strategy

#### 4.1.2.1. Objectives of the tests

In the Step1, functional testing is defined with the control hardware and software as they are at the moment of the initiation of the work. The aim of this step is to identify minor hardware modifications needed before starting the work on control hardware and software up-grade.



#### 4.1.2.2. Approach followed

The functional tests Step 1 are performed on the three modules (bioreactor, filtration unit and gas loop) in only one testing phase, following the sequence described below (section 4.1.2.7), in order to reproduce the main operating procedures already defined by the manufacturer.

#### 4.1.2.3. Applicable requirements

Suitability of procedures to MPP standards, including cleaning and axenicity considerations.

#### 4.1.2.4. Features to be tested

All features as described in the relevant procedures (see Table 1).

#### 4.1.2.5. Features not to be tested

All features which are addressed by procedures considered as not relevant for the purpose of identifying process hardware modifications needed before starting the work on control hardware and software up-grade (see Table 1). Specific hardware tests are postponed to Step2.

#### 4.1.2.6. Success/failure criteria

The success criteria are that the full loop of HMI-PLC-hardware is executing all the semi or fully automated procedures.

#### 4.1.2.7. Test sequence

As the scope of the Functional tests Step1 is, based on the control hardware and software as they are at the moment of the initiation of the work, to identify minor hardware modifications needed, the tests are focused on performing the operation procedures foreseen by EPAS (see RD4), divided in seven main groups:



- Emergency stop procedures
- Control loops important for safety
- Start-up procedures
- Shut-down procedures
- Nominal operation procedures
- Cleaning procedures
- Sterilisation procedures

The detailed list of procedures included in this Step 1 is presented in Table 1.

EPAS numbers	Sequence of routines	applicable for step 1
	EMERGENCY STOPS	
16	Emergency Stop on the RV frame	prerequisite
17	Emergency Stop on the FU frame	prerequisite
18	Emergency Stop of the FU frame on the HMI	prerequisite
29	Filtration Unit: (Emergency) Shut down	prerequisite
45	CIP: (Emergency) Shut down of CIP activities	prerequisite
66	(Emergency) Shut down of SIP activities	prerequisite
	CONTROL LOOPS IMPORTANT FOR SAFETY	
N/A	pressure safety tests	у
N/A	level safety tests	у
	START-UP	
15	Connect N2 to the system	у
5	Influent preparation	n/a
6	Start-up Influent tank VSSL_1000_01	у
7	Filling Influent tank VSSL_1000_01	у
10	Filling Bioreactor VSSL_1007_01 with inoculum	n/a
11	Start-up Bioreactor VSSL_1007_01	у
12	Start-up Bioreactor VSSL_1007_01 feeding	у
26	Active Gas Loop: Start-up	у
20	Passive Gas Loop: Start_up	у
22	Analysis Gas Loop: Start-up	у
23	Analysis Gas Loop: adjust flow rates	n/a

#### **<u>Table 1</u>**. Functional Test Procedures (Step 1)

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24 31	Analysis Gas Loop: Calibration of gas analyzer AT_1101_01 Filtration Unit: Installation of dead-end filter LF 1200 03	n/a n/a
33	Filtration Unit: Installation of ceramic membranes	n/a
27	Filtration Unit: Replacement of tube in pump PMP-F-02	n/a n/a
69	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate tank VSSL_1204_01	y
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02	y y
	SHUT DOWN	
25	Active Gas Loop: Shut down	у
21	Analysis Gas Loop: Shut down	ý
19	Passive Gas Loop: Shut down	y
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_01	y
46		
-	Shut down the System, drain, rinse and clean Bioreactor	
	VSSL_1007_01, Feefing vessel VSSL_1000_01 and Filtration Unit	n/a
32	Filtration Unit: Removal of ceramic membranes	, I
66	LF_1200_01/LF_1200_02	n/a
00	SIP Emergency Shutdown	У
00		У
00	NOMINAL OPERATION	У
5		y n/a
	NOMINAL OPERATION	
5 7 2	NOMINAL OPERATION Influent preparation	n/a
5 7 2 3	NOMINAL OPERATION Influent preparation Filling Influent tank VSSL_1000_01 Preparation of acid for pH control in Bioreactor VSSL_1007_01 Preparation of base for pH control in Bioreactor VSSL_1007_01	n/a y
5 7 2 3 11	NOMINAL OPERATION Influent preparation Filling Influent tank VSSL_1000_01 Preparation of acid for pH control in Bioreactor VSSL_1007_01 Preparation of base for pH control in Bioreactor VSSL_1007_01 Start-up Bioreactor VSSL_1007_01	n/a y n/a
5 7 2 3 11 12	NOMINAL OPERATION Influent preparation Filling Influent tank VSSL_1000_01 Preparation of acid for pH control in Bioreactor VSSL_1007_01 Preparation of base for pH control in Bioreactor VSSL_1007_01 Start-up Bioreactor VSSL_1007_01 Start-up Bioreactor VSSL_1007_01 feeding	n/a y n/a n/a
5 7 2 3 11 12 13	NOMINAL OPERATION Influent preparation Filling Influent tank VSSL_1000_01 Preparation of acid for pH control in Bioreactor VSSL_1007_01 Preparation of base for pH control in Bioreactor VSSL_1007_01 Start-up Bioreactor VSSL_1007_01 Start-up Bioreactor VSSL_1007_01 feeding Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01	n/a y n/a n/a
5 7 2 3 11 12 13 71	NOMINAL OPERATION Influent preparation Filling Influent tank VSSL_1000_01 Preparation of acid for pH control in Bioreactor VSSL_1007_01 Preparation of base for pH control in Bioreactor VSSL_1007_01 Start-up Bioreactor VSSL_1007_01 Start-up Bioreactor VSSL_1007_01 feeding Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01 Bioreactor content sampling	n/a y n/a n/a n/a
5 7 2 3 11 12 13 71 79	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02	n/a y n/a n/a n/a n/a
5 7 2 3 11 12 13 71 79 19	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down	n/a y n/a n/a n/a n/a y
5 7 2 3 11 12 13 71 79 19 20	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Passive Gas Loop: Start_up	n/a y n/a n/a n/a y y y
5 7 2 3 11 12 13 71 79 19 20 21	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Passive Gas Loop: Start_up         Analysis Gas Loop: Shut down	n/a y n/a n/a n/a y y y y
5 7 2 3 11 12 13 71 79 19 20 21 22	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Passive Gas Loop: Shut down         Analysis Gas Loop: Start_up         Analysis Gas Loop: Start-up	n/a y n/a n/a n/a y y y y y
5 7 2 3 11 12 13 71 79 19 20 21 22 23	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Passive Gas Loop: Start_up         Analysis Gas Loop: Start-up         Analysis Gas Loop: Start-up         Analysis Gas Loop: Start-up         Analysis Gas Loop: Start-up	n/a y n/a n/a n/a y y y y y y
5 7 2 3 11 12 13 71 79 19 20 21 22 23 24	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Passive Gas Loop: Start_up         Analysis Gas Loop: Start-up         Analysis Gas Loop: Calibration of gas analyzer AT_1101_01	n/a y n/a n/a n/a n/a y y y y y y n/a n/a
5 7 2 3 11 12 13 71 79 19 20 21 22 23 24 25	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Passive Gas Loop: Start_up         Analysis Gas Loop: Start-up         Analysis Gas Loop: Calibration of gas analyzer AT_1101_01         Active Gas Loop: Shut down	n/a y n/a n/a n/a y y y y y y y n/a n/a y
5 7 2 3 11 12 13 71 79 19 20 21 22 23 24 25 26	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Palysis Gas Loop: Start_up         Analysis Gas Loop: Start-up         Analysis Gas Loop: Calibration of gas analyzer AT_1101_01         Active Gas Loop: Shut down         Active Gas Loop: Shut down         Active Gas Loop: Shut down	n/a y n/a n/a n/a y y y y y y n/a y y y
5 7 2 3 11 12 13 71 79 19 20 21 22 23 24 25 26 29	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Passive Gas Loop: Shut down         Analysis Gas Loop: Start-up         Analysis Gas Loop: Calibration of gas analyzer AT_1101_01         Active Gas Loop: Shut down         Active Gas Loop: Shut down	n/a y n/a n/a n/a y y y y y n/a y y y y y y
5 7 2 3 11 12 13 71 79 19 20 21 22 23 24 25 26	NOMINAL OPERATION         Influent preparation         Filling Influent tank VSSL_1000_01         Preparation of acid for pH control in Bioreactor VSSL_1007_01         Preparation of base for pH control in Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01         Start-up Bioreactor VSSL_1007_01 feeding         Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01         Bioreactor content sampling         Calibration of pH sensors AT_1011_01 et AT_1011_02         Passive Gas Loop: Shut down         Palysis Gas Loop: Start_up         Analysis Gas Loop: Start-up         Analysis Gas Loop: Calibration of gas analyzer AT_1101_01         Active Gas Loop: Shut down         Active Gas Loop: Shut down         Active Gas Loop: Shut down	n/a y n/a n/a n/a y y y y y y n/a y y y

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31	Filtration Unit: Installation of dead-end filter LF_1200_03	n/a
32	Filtration Unit: Removal of ceramic membranes	n/a
33	Filtration Unit: Installation of ceramic membranes	n/a
34	Filtration Unit: Start-up in Bypass mode	у
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02	у
37	Filtration Unit: Enter Recycle mode	у
38	Filtration Unit: Enter Nominal mode	У
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_01	У
40	Drain Filtration Unit: retentate line	n/a
41	Drain Filtration Unit: inside membranes LF_1200_01/LF_1200_02	n/a
42	Drain Filtration Unit: filtrate line	У,
43	Drain Filtration Unit: entire Filtrate Unit	n/a
44	Fill Filtration Unit with water	n/a
	CIP	
45	CIP: (Emergency) Shut down of CIP activities	у
47	Cleaning Influent tank VSSL_1000_01	n/a
48	Cleaning Bioreactor VSSL_1007_01	n/a
49	Cleaning of Filtration Unit: retentate side of membrane LF_1200_01/LF_1200_02	у
50	Cleaning of Filtration Unit: both retentate and filtrate side of membrane LF_1200_01/LF_1200_02	у
54	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01	y
55	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01 and filtrate line through LF_1200_01/LF_1200_02	у
52	Cleaning of Filtration Unit: backwashing membrane Fi-F-01 / Fi-F-02 using water or cleaning agent	у
58	empty RC01	ý
59	empty RC02	ý
53	Cleaning of Filtration Unit: Circulation pump PMP-F-01	y
	SIP	
68	SIP of filtrate line 1 and 2	у
69	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate	
	tank VSSL 1204 01	у
		y

In yellow: procedures involving HMI In orange: procedures carried out by operator without HMI

The protocols for these tests are included in the As-run procedures file.

#### 4.1.2.8. Test deliverables

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- Annotated as run procedures for all the tests including the emergency stops records. (Annex 1).
- Safety, Environment and Ready for Start-Up check lists before the tests (Annex 2)
- HAZOP action list status

#### 4.1.3. Data collection plan – Sampling plan

#### 4.1.3.1. Uncertainty acceptance level

For the Step 1 of Functional Tests, no uncertainty acceptance level has been defined, as the purpose of this step is mainly to check the original hardware and procedures in order to define hardware modifications. Another reason is that calibration of sensors has not yet been performed.

#### 4.1.3.2. Measurement plan

As already implemented on C1 hardware; no additional instrumentation is requested.

#### 4.1.3.3. Sampling and analyses

Neither sampling nor analysis are required for the functional tests step 1.

#### 4.1.3.4. Sample size, frequency, locations

N/A

4.1.3.5. <u>Analyses</u>

N/A

#### 4.1.4. Resources specification for the tests

#### 4.1.4.1. Personnel: staff qualification and training needs

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Qualification Personnel List Report: a personnel list report, indicating the key persons responsible for the Tests, the companies or institutions they belong to, and their approved signatures, should be filled in upon complete execution of this test plan.

The Personnel List Report Form is reported under <u>Annex 3</u>.

#### 4.1.4.2. Hardware: instruments, specific part, hardware for software operation

C1 Hardware as described in RD3

4.1.4.3. Software : verification of software, backup needs

The software used was the Schneider Concept V2.6, also used in EPAS.

4.1.4.4. <u>Facilities : environmental needs, test conditions, interfaces needs, utilities needs</u>

All hardware involved in MPP utilities for C1 as specified in RD3.

#### 4.1.5. Deviations

Records should be maintained for any deviation or abnormalities from this Test Plan and protocols derived (included in the annotated as-run procedures records).

### 4.2. Functional tests Step 2

#### 4.2.1. Test items

#### 4.2.1.1. Description

The test item for functional tests step 2 is the C1 compartment after the implementation of the hardware modifications agreed with ESA and recalled in <u>RD3</u>.

These changes are summarized on the corresponding P&ID (RD7).

The hardware will have passed the following tests that are described in the Hardware Tests document (Annex 6):

Volume test



- Liquid tightness test (Except for the cleaning loop because there were no modification on the hardware involved)
- Gas tightness test

#### 4.2.1.2. Hazards induced by test item and safety measures to be taken

The hazards induced by C1 are summarized in the HAZOP TN-08-1001(0). The actions related to major criticality hazards should be closed before the initiation of the tests sequence.

The test item is reviewed as per the safety and environment check-lists, and there should be only minor reserves remaining open before the tests.

Optionally for the functional tests, the test item is reviewed as per the ready for start-up check-list, and there are only minor reserves remaining open before the tests.

#### 4.2.1.3. Instructions for operation

Cf User Manual by EPAS.

#### 4.2.1.4. Instructions for maintenance

Calibration of the sensors involved is included in the scope of the hardware tests later on described.

#### 4.2.2. Test strategy

#### 4.2.2.1. Objectives of the tests

The objective of the functional tests step 2 is to check that the full operative ensemble C1 hardware - C1 PLC - C1 HMI is working correctly in all the automatic or semi automatic modes specified in the control specification.

These checks will give the final validation of:

- the modifications performed on the hardware of C1 compartment
- the modifications performed on the PLC cabinet



- the modifications of the software performed on the PLC programme
- the modifications on the HMI screens and software

#### 4.2.2.2. Approach followed

In order to optimize the scheduling of the testing versus the status of the C1 hardware modifications, the functional tests step 2 are divided into two main phases: the first one dedicated to Bioreactor and Gas Loop modules, and the second one dedicated to the Filtration Unit module that concentrated the majority of the hardware modifications. Beside these, additional tests are performed on the whole unit: additional hardware tests (volume and flows calibration mainly), automation and control tests, and specific FU tests.

#### 4.2.2.3. Applicable requirements

The requirements for hardware/software modifications were specified by MPP in the Excel table <u>Annex13\_hardware\_modifications.xls of RD3</u>.

They were translated by SHERPA into new PLC procedures and by NTE into new HMI screens communicating with the PLC.

#### 4.2.2.4. Features to be tested

All features addressed by all procedures of Tables 2-5.....

#### 4.2.2.5. Features not to be tested

N/A.

#### 4.2.2.6. Success/failure criteria

The success criteria are that the full loop of HMI-PLC-hardware is executing correctly all the semi or fully automated procedures.

#### 4.2.2.7. Test sequence

The procedures were tested sequentially, according to the lists showed here below.

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#### Table 2. First Phase of Step 2 Functional Tests: Bioreactor and Gas Loop

EPAS			
numbers	Sequence of routines	Operator	НМІ
	EMERGENCY STOPS		
16	Emergency Stop on the RV frame	Y	
17	Emergency Stop on the FU frame	Y	
	CONTROL LOOPS IMPORTANT FOR SAFETY		
N/A	pressure safety tests		n
N/A	level safety tests		n
	START-UP		
15	Connect N2 to the system	Y	
6	Start-up Influent tank VSSL_1000_01	Y	Y
7	Filling Influent tank VSSL_1000_01		Y
11	Start-up Bioreactor VSSL_1007_01	Y	Y
12	Start-up Bioreactor VSSL_1007_01 feeding	Y	Y
26	Active Gas Loop: Start-up		Y
20	Passive Gas Loop: Start_up		Y
22	Analysis Gas Loop: Start-up		Y
24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_01	Y	Y
	SHUT DOWN		
25	Active Gas Loop: Shut down		Y
21	Analysis Gas Loop: Shut down		Y
19	Passive Gas Loop: Shut down		Y
	NOMINAL OPERATION		
7	Filling Influent tank VSSL_1000_01		Y
11	Start-up Bioreactor VSSL_1007_01	Y	Y
12	Start-up Bioreactor VSSL_1007_01 feeding	Y	Y
13	Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01	Y	Y
19	Passive Gas Loop: Shut down		Y
20	Passive Gas Loop: Start_up		Y
21	Analysis Gas Loop: Shut down		Y
22	Analysis Gas Loop: Start-up		Y
24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_01	Y	Y
25	Active Gas Loop: Shut down		Y
26	Active Gas Loop: Start-up		Y
	CIP		
47	Cleaning Influent tank VSSL_1000_01		Y
48	Cleaning Bioreactor VSSL_1007_01		Y

#### Table 3. Second Phase of Step 2 Functional Tests: Filtration Unit

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EPAS			
numbers	Sequence of routines	Operator	HMI
	EMERGENCY STOPS		
16	Emergency Stop on the RV frame	Y	
17	Emergency Stop on the FU frame	Y	
18	Nominal stopping of the FU frame on the HMI		Y
29	Filtration Unit: nominal stopping for membrane1 and membrane2		Y
45	CIP: nominal stopping of CIP activities		Y
66	SIP : nominal stopping of SIP activities	Y	Y
	CONTROL LOOPS IMPORTANT FOR SAFETY		
N/A	level safety tests for Bioreactor, Effluent Vessel, CIP vessels		n
N/A	Pumps stopping conditions		n
	START-UP		
15	Connect N2 to the system	Y	
11	Start-up Bioreactor VSSL_1007_01	Y	Y
12	Start-up Bioreactor VSSL_1007_01 feeding	Y	Y
35	Filtration Unit: Start-up of filtration through membrane		
	LF_1200_01/LF_1200_02		Y
	NOMINAL OPERATION		
29	Filtration Unit: nominal stopping		Y
34	Filtration Unit: Start-up in Bypass mode		Y
29	Filtration Unit: nominal stopping		Y
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02		Y
37	Filtration Unit: Enter Recycle mode		Y
38	Filtration Unit: Enter Nominal mode		Y
39	Filtration Unit: Harvest Effluent vessel VSSL 1204 01		Y
34	Filtration Unit: Start-up in Bypass mode		Y
39			
	Filtration Unit: Harvest Effluent vessel VSSL_1204_01		Y
37	Filtration Unit: Enter Recycle mode		Y
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_01		Y
	CIP		
61	Fill cleaning agent into VSSL_1209_01		Y
62	Fill water into VSSL 1209 01		Y
63	Fill cleaning agent into VSSL_1209_02		Y
58	Empty VSSL_1209_01		Y
59	Empty VSSL_1209_02		Y
64	Rinse VSSL_1209_01		Y
65	Rinse VSSL_1209_02		Y
60	Clean VSSL_1209_01 and VSSL_1209_02		Y



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49	Cleaning of Filtration Unit: retentate side of membrane LF_1200_01 / LF 1200 02	
50	Cleaning of Filtration Unit: both retentate and filtrate side of membrane LF_1200_01 / LF_1200_02	
51		
•	Cleaning of Filtration Unit: backwash membrane LF_1200_01/LF_1200_02	Y
52	Cleaning of Filtration Unit: backwashing membrane LF_1200_01 using water and cleaning agent	
53	Cleaning of Filtration Unit: Circulation pump GP_1201_01	
54	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01	Y
55	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01 and filtrate line through LF_1200_01 / LF_1200_02	Y
56	Cleaning of Filtration Unit: automated execution of a sequence of procedures to clean membrane LF_1200_01	
45	CIP: nominal stopping of CIP activities	
46?	Shut down the System, drain, rinse and clean Bioreactor VSSL_1007_01, Feefing vessel VSSL_1000_01 and Filtration Unit SIP	
N/A	Steam utilities start-up	
68	SIP: membrane LF_1200_01 / 02	
69	SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01	Y
80	SIP :Purge and sterilize recycle line	
81	SIP : Purge and sterilize Harvesting line	Y
82	SIP: Flush recycle line with Steam	
83	Filtration Unit: Enter in By Pass Mode automatically when LSH_1206_01 is set	
84	SIP membrane, filtrate line and filtrate tank	
66	SIP : nominal stopping of SIP activities	Y
31	Filtration Unit: Installation of dead-end filter LF_1200_03	Y
27	Filtration Unit: Replacement of tube in pump PMP-F-02	Y
19	Passive Gas Loop: Shut down	
20	Passive Gas Loop: Start_up	
21	Analysis Gas Loop: Shut down	
22	Analysis Gas Loop: Start-up	
24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_01	Y
0E	Active Gas Loop: Shut down	
25 26	Active Gas Loop: Start-up	

# <u>Table 4</u>. Procedures to be updated and validated with TechnoMembranes (in the frame of TN94.66)



33	Filtration Unit: Installation of ceramic membranes		
55	LF_1200_01/LF_1200_02	Y	Y
32	Filtration Unit: Removal of ceramic membranes LF_1200_01/LF_1200_02	Y	Y

#### Table 5. Maintenance mode procedures

40	Drain Filtration Unit: retentate line	Y	
41	Drain Filtration Unit: inside membranes LF_1200_01/LF_1200_02	Y	
42	Drain Filtration Unit: filtrate line	Y	Y
43	Drain Filtration Unit: entire Filtrate Unit	Y	
44	Fill Filtration Unit with water	Y	
48	Cleaning Bioreactor VSSL_1007_01		Y

In yellow : procedures involving HMI

In orange : procedures carried out by operator without HMI

The protocols for these tests are included in the As-run procedures file.

#### 4.2.2.8. <u>Test deliverables</u>

For all the phases, the deliverables are :

- Annotated as-run procedures for the tests (Annex 4 –Bioreactor and Gas loopand Annex 5 –Filtration Unit-).
- Annotated as-run procedures for the specific hardware tests (Annex 6).
- Safety, Environment and Ready for Start-Up check lists before the tests (Annex 7)
- HAZOP action list status after the hardware change and functional tests

#### 4.2.3. Data collection plan – Sampling plan

#### 4.2.3.1. Uncertainty acceptance level

The calibration of temperature and pressure sensors performed by CIFA and the calibration of flows performed internally in the MPP are used to determine the uncertainty of the corresponding sensors. These results are included in Section 4.3 and Annexes 6 and 10 of the present document. The uncertainty acceptance criteria were not defined previously to the performance of the tests.



For the particular case of the sterilisation procedures, a temperature of 122°C with a range of  $\pm 1$  °C measured in the specific pipeline or tank to be sterilised, is the a priori foreseen acceptance level to consider effective the sterilisation (to be maintained a minimum time of 15 min)

#### 4.2.3.2. Measurement plan

As already implemented on C1 hardware; no additional instrumentation is requested.

#### 4.2.3.3. Sampling and analyses

Neither sampling nor analysis are required for the functional tests step 2.

4.2.3.4. <u>Sample size, frequency, locations</u> N/A

4.2.3.5. Analyses

N/A

#### 4.2.4. Resources specification for the tests

#### 4.2.4.1. Personnel: staff gualification and training needs

Same personnel as for the previous test sequence, involving MPP (UAB), NTE and SHERPA.

A personnel list report, indicating the key persons responsible for the Tests, the companies or institutions they belong to, and their approved signatures, will be filled in upon complete execution of this test plan.

The Personnel List Report Form is reported under <u>Annex 8</u>.

#### 4.2.4.2. Hardware: instruments, specific part, hardware for software operation

C1 Hardware as described in RD3



#### 4.2.4.3. Software : verification of software, backup needs

Same control software as for step 1, HMI software (RD8) and PLC Procedures and SFC Analysis draft document (RD9).

4.2.4.4. <u>Facilities : environmental needs, test conditions, interfaces needs, utilities needs</u>

Same utilities requirements as for step1 tests.



#### 4.2.5. Additional Hardware tests

Other critical points for the objectives of the Functional Tests regarding hardware (Table 6, based on RD2) were not performed in Step1:

- Correct on-line measurements
- Sensors calibration
- Tanks volume calibration
- Pumps flow calibration
- Correct volume measurement
- Correct flows and speeds

These tasks were transferred to Step 2 of Functional Tests, considering they are not critical for the scope of identifying potential lacks in PLC or Supervision and identifying hardware modifications needed before the upgrade. And in particular tanks volume calibration could eventually be simplified or omitted, in the case the calibration of sensors had been already performed and considering that the geometry of the tanks has not been modified.





**<u>Table 6</u>**. Hardware Functional Tests

Test case	Specifications/ Requirements	Instruments	Subsystems	New TAG	Acceptance criteria	Schedule	Duration	Test output
1	Liquid Tightness	Tanks (mounted on frame with associated instrumentation), tubes	Bioreactor Filtration Unit Gas Loop Cleaning and	VSSL_1000_01, VSSL_1007_01, VSSL_1011_01, VSSL_1011_02 VSSL_1204_01 VSSL_1100_01 VSSL_1209_01,	Total absence of leackage	Mechanical and Electrical integration	12 h	Check Table
2	Gas Tightness (pressurized with air)	Tanks (mounted on frame with associated instrumentation), tubes	Sterilisation Bioreactor Filtration Unit Gas Loop Cleaning and Sterilisation	VSSL_1209_02, VSSL_1209_03 VSSL_1000_01, VSSL_1007_01, VSSL_1011_01, VSSL_1011_02 VSSL_1204_01 VSSL_1100_01, VSSL_1100_02 Condensate line VSSL_1209_01, VSSL_1209_02, VSSL_1209_03	Total absence of leackage	Mechanical and Electrical integration	12 h	Check Table
3	Correct on-line measurements	Sensors	Bioreactor	LSH_1004_01, PT_1003_01, PT_1001_01, TT_1002_01, TT_1002_02, LSH_1010_01, LT_1010_01, LSL_1008_01, AT_1011_01, AT_1011_02, PT_1009_01, PT_1009_02, TT_1008_01, TT_1008_02	Calibration performed	Mechanical and Electrical integration	Depending on sensor	Check table

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			Filtration Unit Gas Loop Cleaning and Sterilisation	FT_1201_01, LSH_1206_01,         LSH_1206_02, LT_1203_02,         PT_1203_03, PT_1203_04,         PT_1203_05, PT_1203_06,         PT_1201_01, TT_1205_01,         AT_1201_01, TT_1205_01,         TT_1200_03, PT_1203_08         AT_1101_01, FT_1101_01,         FT_1100_01, PT_1100_01,         FT_1100_01, PT_1100_01,         PT_1100_01, PT_1100_01,         TT_1208_01, LSH_1209_01,         LSL_1209_02				
Test case	Specifications/ Requirements	Instruments	Subsystems	New TAG	Acceptance criteria	Schedule	Duration	Test output
4	Correct volume measurement	Tanks	Bioreactor Filtration Unit Gas Loop Cleaning and Sterilisation	VSSL_1000_01, VSSL_1007_01           VSSL_1204_01           VSSL_1100_02           VSSL_1209_01, VSSL_1209_02	Establishment of curve Volume = f(P)	After tests 1, 2 and 3	NA	Check table + calibration curve
5	Correct flows and speeds	Pumps and blenders	Bioreactor Filtration Unit Gas Loop	GP_1001_01, CP_1002_01, PP_1008_01, BLE_1012_01, BLE_1005_01 GP_1201_01, PP_1202_01 PP_1100_01, PP_1101_01,	Establishement of set points	After Tests 1, 2, 3, 4	NA	Check table + Set points

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	Cleaning and	CP_1207_01, PP_1209_01,		
	Sterilisation	CP_1207_02		
				1

NA: Non applicable

The results of these tests are recorded in Annex 6



#### 4.2.6. Automation and control Functional Tests

These tests are foreseen to be performed independently on the 3 frames within Functional tests Step2, after the hardware tests and when the automation and control functions had been programmed in the PLC. The aim of these tests is to check that the system acts automatically like expected and that the control specifications are respected. The control can then be optimised and validated based on these tests.

The control and automated functions were first defined by EPAS with support of SHERPA for control procedures. The current test plan and test execution and interpretation is to be performed in interaction between UAB and SHERPA, which expertise in control will allow revalidating the compartment control after CI delivery in UAB.

The following is a list of all critical functions for the objectives of this test plan regarding control functional tests:

- Pressure safety
- Level safety
- Temperature control
- Pressure control
- Volume control
- Gas flow control
- pH control
- Cleaning procedure
- Sterilisation procedure
- Mixing

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In all cases the control tests should include checking of the different alarms involved.

Table 7 presents the detailed test plan for automation and control tests foreseen in principle for Step2.

Test case	Function	Subsystem	Constraints	Acceptance criteria	Schedule	Duration	Test output
1	Pressure safety	Bioreactor, Influent tank, filtrate tank, Gas loop, cleaning tanks	P<200 mBar	Gas is released when P> Set point	After hardware tests	3 times	Check list
2	Level safety	Level switches in tanks		Level ≤ stwich	After Test 1	3 times	Check list
3	Temperature control	Influent & Filtrate tanks	Set point: 4 ⁰C	0,5 < T < 6 °C in VSL2_1000_01 and VSL2_1204_01	After Test 1; Filtration Unit and Influent subunits started	4h	Check list + trend record
		Bioreactor	Set point: 55 ⁰C	54,5 < T < 55,5 ℃ in VSL2_1007_01	After tests 1 and 2	4h	Check list + trend record
4	Pressure control	Bioreactor	Set point 90 mBar	P constant ± 5 mBar in VSL2 1007 01	After Test 1; Gas loop tests	1,5h	Check list + trend record
5	Volume control	Bioreactor	Set point 100 L	Constant volume ± 2 L in VSL2_1007_01	After Tests 1 and 2; Subunits started	4h	Check list + trend record
6	Gas flow control	Gas for analysis	Flow rate > 1L/min	Constant flow in FT_1101_01	After Test 1; Gas loop started	1,5h	Check list + trend record
7	pH control	Bioreactor	Set point 5,25	5,1 < pH < 5,4 in VSL2_1007_01	After Test 1	4h	Check list + trend record

#### Table 7. Automation and control test plan (Step 2)

These control tests were already performed in EPAS and the results have been reported in TN 83.7. However, in three cases (i.e. control of liquid level, influent/effluent tank temperature, and gas flow rate), the tests should be re-validated in the MPP.

#### 4.2.7. Testing of foreseen software modifications

Correspond to the pending actions regarding software included in the Compartment I Acceptance Review, as performed in EPAS (RD1):



- Corrective action foreseen in case level switch LS-R-01 goes in alarm: alarm + stop feeding V-V-03 (software/ control algorithm has been updated accordingly)

- Alarm programmed when PS-F-09 increases: for P>0,35 bar for 0,5 d (software/ control algorithm updated accordingly)

The tests foreseen would mean to check that both actions and alarms have been implemented in the control and they are functional.

#### 4.2.8. Filtration unit tests

Because of its specific requirements, it is convenient to separate the FU tests from the others. The FU should be tested according to its requirements after being integrated in the compartment and tested from the hardware, control and automation point of view.

In order to complement the Step 2 of Functional tests, some tests are planned to check the efficiency of the CIP and SIP, also involving process with real broth (CI inoculum broth kept in the fridge from previous bleedings), before starting the real culture.

The tests proposed are the following:

- Efficiency of cleaning: basically to check the increase of pH and change in electro conductivity due to the distribution of NaOH along the circuit. It should involve the following sampling, where feasible:

- Filtrate tank
- Drains
- Pipes
- Cleaning vessels



- Efficiency of rinsing in representative procedures: basically to check the reduction of pH and change in electro conductivity due to the adequate removal of NaOH by water. It should involve the following sampling, where feasible:

- Filtrate tank
- Drains
- Pipes
- Cleaning vessels

- Efficiency of cleaning and rinsing with real broth using a representative procedure: to check the removal of particles basically. It should involve the following sampling, where feasible:

- Filtrate tank
- Drains
- Pipes
- Pumps

- Efficiency of sterilisation with real broth in all filtration procedures: to check by means of sterility controls (culture media plates) the absence of contamination downstream the membrane. It should involve the following sampling, along a period of time of at least one week-:

- Filtrate tank (sampling valve/harvest line)
- Filtrate line (sampling valve)

These tests needed to be harmonised as well with the schedule for the new membrane installation and test plan proposed by Technomembranes (CI test protocol: validation of the filtration unit optimization, TN 94.66). In this sense, the performance of the cleaning and rinsing tests ahead the validation tests of the membrane is acceptable, but the



sterilisation tests with real broth were to be postponed after the membrane had been validated.

### 5. Test Results

### 5.1. Functional Tests Step 1

#### 5.1.1. Annotated as-run procedures

The detailed results of the tests annotated as-run procedures are described in Annex 1. The tests results are presented in the form of tables, including :

- Procedure Steps
- Date/hour
- Compliance of the test
- Comments

Additionally, as a conclusion of each test, the following information regarding recommendations/changes is compiled if applicable, in order to define further hardware/software modifications:

- HW modifications
- PLC programme modifications
- HMI modifications
- Others



#### 5.1.2. Test Conclusions

#### 5.1.2.1. Final stage of Step 1 Functional Tests

The Step 1 of CI Functional tests was carried out, including the SIP tests. The annotated as-run procedures were updated with the results of the last tests and proposals for hardware and software modifications. These updates are included in the file "As-run\_procedures Step1" (Annex 1).

It was decided on the 19.06.08 to stop the functional tests in order to be able to disconnect the PLC and electrical cabinet of CI, for a further modification of the PLC (by NTE) in order to reduce its size.

#### 5.1.2.2. Preliminary revision of CIP and SIP lines and procedures

The revision of CIP and SIP pipelines and procedures was carried out based on the following documents:

"Comments CIP-SIP CI func.tests.doc" (inputs received from ESA), on draining, rinsing and cleaning procedures mainly (Annex 9).

"Hardware\_modifications.xls" (Annex 13 to RD3).

The procedures selected by EPAS for the rinsing and cleaning of the filtration membranes and module have been discussed, and their logic was found not fully clear. As an outcome of the discussion held by MPP and Technomembranes, especially the strategy of backwashing proposed by EPAS was pointed as non optimal. It was however agreed that a comprehensive update on these procedures would imply major hardware modifications. Therefore it was decided to postpone this update and link it to the work on membrane selection to be carried out by Technomembranes in the frame of the WP 94.4 and the corresponding future update.

This update should focus on:

- Reducing, as much as possible, the membranes cleaning frequency.



- Avoiding as much as possible the presence of residues of the cleaning agent..

A critical issue was identified about the CIP and SIP procedures: the path of the flows in the original CI Configuration does not provide guarantee that neither the CIP process nor the SIP process are carried out with the needed quality.. Many dead volumes remain and the purges are not located at an appropriate place along the circuits. This causes on the retentate and filtrate sides potential residues of broth, cleaning agent or non sterilised streams in the ends of some pipelines.

#### 5.1.2.3. Hardware modifications

Annex 13 to RD3 includes the list of hardware modifications identified during the functional tests Step 1. In the right columns, the considerations derived for PLC programming and HMI have been added.

The main modifications correspond to the lack of quality in the CIP and SIP procedures; some others are regarding safety of the operations in CI.

Nevertheless, some definition of details should be fixed with the suppliers and the inputs from them, regarding especially the type of new valves and final layout of piping.

### 5.2. Functional Tests Step 2

#### 5.2.1. Annotated as run procedures

The "as run procedures" of the second step of the functional tests were performed in two steps (see paragraph 4.2.2.2). Therefore, the detailed results are presented in two different files: one dedicated to the Bioreactor and Gas Loop modules in Annex 4, and the second one dedicated to the Filtration Unit module in Annex 5.

The tests results are presented in the form of tables, including :

- Procedure Steps
- Date/hour

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- Compliance of the test
- Comments

Additionally, as a conclusion of each test, the following information regarding recommendations/changes is compiled if applicable, in order to define further hardware/software modifications:

- HW modifications
- PLC programme modifications
- HMI modifications
- Others

#### 5.2.2. Test conclusions

#### 5.2.2.1. Bioreactor ans Gas Loop modules

The results of the testing of all the relevant procedures regarding the Bioreactor and Gas loop showed in general a good performance of the updated PLC procedures and new hardware. The recommendations for NTE and SHERPA included in the "as run procedures" were transferred to them in order for them to implement the necessary changes in the software of the PLC or/and HMI when applicable.

#### 5.2.2.2. Filtration Unit module

The Filtration Unit module functional tests were carried out including SIP tests with air and steam. Nominal operation of the Filtration Unit and the CIP tests were done with water.

As run procedures were performed successfully under minor changes in the HMI screens and the PLC programming. HMI changes were basically focused on the addition of emergency buttons, modifications of alert windows and redrawing of pipes in the SIP screen. The PLC was changed regarding the status of valves, the allert messages and This document is confidential property of the MELiSSA partners and shall not be used, duplicated, modified or transmitted without their authorization

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recognition and the use of water or cleaning agent of the CIP procedures. Also a timer was added in sterilisation procedures.

During the SIP tests, simulated with air, the procedure for sterilisation of membranes was optimised to protect them from strong pressure increases. At this moment steam was flushed to the membranes gradually opening and closing the steam valves until sterilisation pressure was reached.

SIP tests performed with steam were repeated three times, because initially the effluent tank could not reach the sterilisation temperature. However the full operative chain C1 hardware - C1 PLC - C1 HMI was validated when SIP tests were simulated with air.

In order to validate the SIP tests with steam, the effluent tank jacket had to be checked and fixed for leaks and the correct temperature probe range had to be modified in the PLC.

#### 5.2.2.3. Additional Hardware Tests

The results of all the tightness tests, correct on-line measurements and calibrations performed are shown in Annex 6 and in CIFA Calibration reports (Annex 10). These data are required for the adjustment of sensors or even replacement of the same in particular cases where the recalibration is not feasible.

#### 5.2.2.4. Automation and control Functional Tests

Taking into account that almost all of the control loops had been already tested and their behaviour was correct during the Functional tests performed, it was decided to postpone the recording of the particular control loops behaviour on liquid level, influent/effluent tank temperature, and gas flow rate, until a run test is performed in real conditions, to be documented in TN 94.12 Part II.
# **MELiSSA**



## 5.2.2.5. <u>Testing of foreseen software modifications</u>

In both cases included in this section (see 4.5), the checks can only be performed correctly when the run test will be performed in Compartment I, once Steps 1 and 2 of Functional tests had been completed, so they were postponed until then.

## 5.2.2.6. Filtration unit Tests

The fact that cleaning and sterilization procedures involved a lot of conditions to be tested and validated (removal of particles, removal of the cleaning agent; removal of contaminants, maintenance of the sterility) implied to perform these tests in a more detailed way, and prepare dedicated cleaning and sterilisation procedures. They are considered as a stand-alone comprehensive study and therefore the results of these tests will be presented in TN 94.12 Part II..

## 6. General conclusions

The performance of the Compartment I hardware, after the hardware modifications performed in the skid and the Control hardware and software update, was tested for functionality, showing in general a good behaviour regarding hardware, PLC sequences and HMI configuration, although there are still some improvements to be carried out in order to carry out all the procedures in perfect conditions.

Some control tests and cleaning and sterilisation validation tests could not be performed in the frame of these Functional tests (Step 1 and 2), so they will need to be carried out and documented separately.

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## 7. COMMENTS

## TN 94.12: First set of comments

## General comments

As a general remark, we would like to stress that this document is not what we call a Test Plan. A lot of information provided, although of clear interest, is not expected in a Test Plan, and some information which is actually expected in a Test Plan, is missing. An update of the document is mandatory.

This was an old comment corresponding to the previous non updated doc. Agree. In fact some of the information is included even if it corresponds to previous checks on the hardware that are not properly "Functional tests" but inputs for the same. They'd better be included in TN 94.11. So we have splitted the info into the two TNs.

## **Detailed comments**

Page/paragraph	Comment
6/Section 3	
	"Task distribution"
	This paragraph should not be included in a test plan.
	UAB as Prime Contractor is responsible for everything.
	This info looks more like a list of tasks for the performance of various WPs.
	In addition, it is not clear whether ESA approval will requested when appropriate
	We think it's better to maintain it although changing responsibilities according to the new revision of the TN
8/4.1.1.2	"Safety aspects"
0,	Isn t it more relevant to include this info or part of it in the test protocols?
	In our opinion, this should be included also in a test plan even if should be present in the protocols (now in fact are together in the same document).

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28/Table 7	"Test case 6: gas flow control"
	Gas pressure evolution should be recorded during the test
	OK, to be included in the protocol (Step 2 or run test)

## TN 94.12: Second set of comments

## General comments

As a general remark, we would like to stress that this document is not what we call a Test Plan. A lot of information provided, although of clear interest, is not expected in a Test Plan, and some information which is actually expected in a Test Plan, is missing. An update of the document is mandatory.

This was an old comment corresponding to the previous non updated doc. Agree. In fact some of the information is included even if it corresponds to previous checks on the hardware that are not properly "Functional tests" but inputs for the same. They'd better be included in TN 94.11. So we have splitted the info into the two TNs.

OK

## **Detailed comments**

Page/paragraph	Comment
5/Section 1	"This Functional Test Plan provides on field tests to verify that Cl module is installed and operating as specified and meets preapproved functional specifications for control of operating parameters". I realize this wording is a bit restrictive; why "control of ", shouldn't we say "functional specifications for operation of Cl"? Agree, text amended

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# **MELiSSA**



6/Section 3	<ul> <li><i>"Task distribution"</i> This paragraph should not be included in a test plan. UAB as Prime Contractor is responsible for everything. This info looks more like a list of tasks for the performance of various WPs. In addition, it is not clear whether ESA approval will requested when appropriate We think it's better to maintain it although changing responsibilities according to the new revision of the TN I understand you r reasoning but I would suggest to reflect it better in the wording: from a contractual point of view, there is a difference between being in charge of and being responsible for. Please check if the text I propose (here and at the end of the paragraph) suits you</li></ul>
	Ok, no problem for us to accept the proposed wording; text amended accordingly.
8/4.1.1.2	<ul> <li><i>"4.1.1.2. Hazards induced by test item and safety measures to be taken"</i></li> <li>Isn t it more relevant to include this info or part of it in the test protocols?</li> <li>In our opinion, this should be included also in a test plan even if should be present in the protocols (now in fact are together in the same document).</li> <li>OK anyway those comments have been raised before we agreed on a test plan template.</li> <li>Yes, indeed.</li> </ul>
9/Section 4.1.2.1	"The Step 2 will consist in the definition and execution of the functional tests after the implementation of process hardware modifications" I'm not sure that the modifications are only concerning process: the hardware modifications were foreseen in the COO without precise definition, and in fact they regard mainly the process, but some of them regard safety issues, for ex. Remove the word "process" if you prefer (sections 4.1.2.1 and 4.1.2.7)

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	OK, removed.
10/Section 4.1.2.2	"The functional tests Step 1 are performed in one phase". I do not fully understand what is the point you want to highlight there Better explained in the text. In fact, the approach followed was to reproduce progressively the main procedures already defined by EPAS in order to identify the need of hardware/control modifications; it is in contrast with the Step 2 that was performed in two phases to optimise the schedule.
10/Section 4.1.2.4	<i>"All relevant procedures".</i> Only wording issue: <i>"All features as described in the relevant procedures".</i> A feature is not a procedure, strictly speaking Agreed.
10/Section 4.1.2.5	"Not relevant procedures for the purpose of identifying hardware modifications needed before starting the work on control hardware and software up-grade" Amended: "All features which are addressed by procedures considered as not relevant for the purpose of identifying" See my previous comment Agreed.
15/Section 4.2	<ul> <li><i>"4.3 Additional hardware tests"</i>. It is not clear wether 4.3 and followings should be sub-aparagraphs of 4.2, as it seems you consider them as functional tests step 2. Please check</li> <li>In fact, they were performed separately. Anyway, I have included them in Section 4.2 as well but in dedicated subsections, and referred to them in section 4.2.2.2 ("Approach followed")</li> </ul>
17/Section 4.2.2.4	<i>"All procedures"</i> . All features addressed by all procedures of Table(please complement) OK, completed: <i>"All features addressed by all procedures of Tables 2-5"</i> .
21/Section 4.2.3.1	"For the particular case of the sterilisation procedures, 121±1 °C is the a priori foreseen range". For what? Steam produced? Temperature measured somewhere?

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# **MELiSSA**



	Better explained in the text: <i>"For the particular case of the sterilisation procedures, a temperature of 122°C with a range of ±1 °C measured in the specific pipeline or tank to be sterilised, is the a priori foreseen acceptance level to consider effective the sterilisation (to be maintained a minimum time of 15 min"</i>
28/Section 4.2.6	<ul> <li><i>"These tests are foreseen to be performed independently on the 3 frames within Functional tests Step2"</i></li> <li>If the tests are <i>"within"</i> the functional tests step 2, they should be described there. Do you mean that these tests are additional ones however performed at the occasion of Functional tests step 2 or at the end? Please see previous remark on 4.2 and clarify</li> <li>Already explained in comment on section 4.2. Again, these tests were finally addressed in a different way, so included in Step2 but is a distingtion.</li> </ul>
29/Section 4.2.7	in a dedicated section. "Correspond to the pending actions regarding software included in the Compartment I Acceptance Review." To avoid confusion with the AR to be done in the MPP: "Correspond to the pending actions regarding software included in the Compartment I Acceptance Deviaw as performed in EDAS."
	Compartment I Acceptance Review, as performed in EPAS." Agreed.
33/Section 5.1.2.2	"The procedures selected by EPAS for the rinsing and cleaning of the filtration membranes and module have been discussed" To maintain so detailed descrition in the TN?
	I would say yes, otherwise we might lose the traceability of the decision process.
33/Section 5.1.2.2	<i>"The potential presence of residues of the cleaning agent, and its potential effect in the whole MELiSSA loop."</i> This is a very comprehensive study; I would rather phrase this as avoiding, as much as possible, the presence of residues of the Cleaning agent. We are not supposed to duplicate BELISSIMA
	Agreed, text rephrased: "Avoiding as much as possible the presence of residues of the cleaning agent."
36/Section 5.2.2.4	" it was decided to postpone the recording of the particular control loops behaviour on liquid level, influent/effluent tank temperature, and gas flow rate, until a run test is performed in real conditions."

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	To be better defined and included in TN 94.12 Part II
	You made comments but apparently they have still to be addressed by you?
	Text amended accordingly: " it was decided to postpone the recording of the particular control loops behaviour on liquid level, influent/effluent tank temperature, and gas flow rate, until a run test is performed in real conditions, to be documented in TN 94.12 Part II."
37/Section 5.2.2.6	" and prepare dedicated cleaning and sterilisation protocols." I guess we need to clarify among us what we call protocol and procedure; I have the feeling that I am using protocol when you use procedure an vice-versa.
	Understood. Text amended: " and prepare dedicated cleaning and sterilisation procedures."
37/Section 5.2.2.6	"the results of these tests will be presented in a different document." Please include a reference for traceability
	A proposal could be a Part II of this TN 94.12 dedicated to the FU tests and as well including the "run test" foreseen in the previous sections. Text amended accordingly: " the results of these tests will be presented in TN 94.12 Part II."
37/Section 6	As reflected in the previous comments, some tasks are pending to be documented elsewhere. The definition of these documents is not included here, should we foresee the corresponding TNs and reference here?
	Yes. How do you foresee this: new TNs, new version of some existing ones? We can discuss it if you want
	Maybe the best way is to have TN 94.12 Part II, in order to keep the already foreseen numbering in the COO.
	I agree with your proposal of having a separate 94.12 Part II





## Comments on annexes

I just would like to comment that Annex 9 is worded as "I" providing comments: who is "I"? Alain Grasmick? In any case I would suggest to change the format.

As it is explained in the text (Section 5.1.2.2, page 32), this doc. was received from you on 19.08.08, it contained the comments from Pierre on the CIP-SIP procedures (indicated in the title).

# **MELISSA**



# **ANNEXES**

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# **MELISSA**



# ANNEX 1

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						step 1 functional tests	
PAS	Sequence of routines	Operator	нмі	status	applicable for step 1	comments/changes from nominal parameters	
anibers	EMERGENCY STOPS	Sperator	1 11/11	σιαιύδ	Stop 1	uommontarunangea num numinai parameters	
16	Emergency Stop on the RV frame	OP		с	prerequisite		
17	Emergency Stop on the FU frame	OP		c	prerequisite		
18	Emergency Stop of the FU frame on the HM		Y	С	prerequisite		
29 45	Filtration Unit: (Emergency) Shut dowr CIP: (Emergency) Shut down of CIP activities		Y Y	c c	prerequisite prerequisite		
66	(Emergency) Shut down of SIP activitie:	OP	Ý	c	prerequisite		
	CONTROL LOOPS IMPORTANT FOR SAFETY						
N/A	pressure safety tests		n	c c	У	check that the control of pressure inside the reactors is working	
N/A	level safety tests		n	C	У	check that the control of level inside the reactors is working	
	START-UP						
15	Connect N2 to the system	OP		с	v	air	
5	Influent preparation	OP		-	n/a	water	
6 7	Start-up Influent tank VSSL_1000_01 Filling Influent tank VSSL_1000_0'	OP	Y Y	C C	У	temperature setpoint 10°C	
10	Filling Bioreactor VSSL_1007_01 with inoculun	OP	T.	C	y n/a	water	
11	Start-up Bioreactor VSSL_1007_01	OP	Y	С	У		
12 26	Start-up Bioreactor VSSL_1007_01 feeding Active Gas Loop: Start-up	OP	Y Y	C C	y y	water	
20	Passive Gas Loop: Start_ur		Ŷ	С	y		
22 23	Analysis Gas Loop: Start-up Analysis Gas Loop: adjust flow rate:	OP	Y	с	y n/a	protection of analyzer from moisture? use of CO2 and reference of CH4?	
23 24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_0	OP	Y		n/a	?	
31	Filtration Unit: Installation of dead-end filter LF_1200_0	OP			n/a		
33	Filtration Unit: Installation of ceramic membranes LF_1200_01/LF_1200_02	OP	Y		n/a		
27	Filtration Unit: Replacement of tube in pump PMP-F-0/	OP	Ľ		n/a		
69	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate tank	0.0	~	<u> </u>			
	VSSL_1204_01 Filtration Unit: Start-up of filtration through membrane	OP	Y	с	У		
35	LF_1200_01/LF_1200_02		Y	с	у	why not in bypass ?	
	SHUT DOWN						
25 21	Active Gas Loop: Shut dowr Analysis Gas Loop: Shut dowr		Y Y	C C	y v		
21 19	Passive Gas Loop: Shut dowr		Y	c	y y		
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_0		Y	c	ý		
						this procedure is a composite one made of elementary ones that are a	
46	Shut down the System, drain, rinse and clean Bioreactor VSSL_1007_01,						
	Feefing vessel VSSL_1000_01 and Filtration Unit		Y		n/a	tested, it is not useful to test Proc46 within step 1 functional tests	
32	Filtration Unit: Removal of ceramic membranes LF_1200_01/LF_1200_02	OP	Y		n/a		
66	SIP Emergency Shutdown	0.	y.	С	y		
	NOMINAL OPERATION						
5	Influent preparation	OP	~		n/a	water	
7 2	Filling Influent tank VSSL_1000_0' Preparation of acid for pH control in Bioreactor VSSL_1007_01	OP	Y	с	y n/a	water	
3	Preparation of base for pH control in Bioreactor VSSL_1007_01	OP			n/a	water	
11	Start-up Bioreactor VSSL_1007_01	OP OP	Y	с			
12 13	Start-up Bioreactor VSSL_1007_01 feeding Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_0	OP	Y Y	С	n/a		
71	Bioreactor content sampling	OP			n/a		
79 19	Calibration of pH sensors AT_1011_01 et AT_1011_02 Passive Gas Loop: Shut dowr	OP	v	c	n/a v		
20	Passive Gas Loop: Start_ur		Ý	c	y y		
21	Analysis Gas Loop: Shut dowr			C C	У		
22 23	Analysis Gas Loop: Start-u Analysis Gas Loop: adjust flow rate:	Y	Y	ι.	y n/a	protection of analyzer from moisture	
24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_0	Y	Y		n/a		
25 26	Active Gas Loop: Shut dowr Active Gas Loop: Start-up		Y Y	с с	y y		
29	Filtration Unit: (Emergency) Shut dowr		Ŷ	č	y		
28	Filtration Unit: Calibration of PMP-F-02 flow rate Filtration Unit: Replacement of tube in pump PMP-F-0/	PLC OP			n/a		
27 30	Filtration Unit: Removal of dead-end filter LF_1200_0	OP			n/a n/a		
31	Filtration Unit: Installation of dead-end filter LF_1200_0	OP			n/a		
32	Filtration Unit: Removal of ceramic membranes LF_1200_01/LF_1200_02	OP	Y		n/a		
33	Filtration Unit: Installation of ceramic membranes						
33 34	LF_1200_01/LF_1200_02 Filtration Unit: Start-up in Bypass mode	OP	Y Y	с	n/a v		
	Filtration Unit: Start-up of filtration through membrane		Ľ		,		
35	LF_1200_01/LF_1200_02		Y	С	У		
37 38	Filtration Unit: Enter Recycle mode Filtration Unit: Enter Nominal mode		Y Y	c	y v	switch to other line possible only if valves are replaced?	
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_0		Y	с	ý		
40 41	Drain Filtration Unit: retentate line Drain Filtration Unit: inside membranes LF_1200_01/LF_1200_0	OP OP			n/a n/a		
42	Drain Filtration Unit: filtrate line	OP	Y	с	у		
43	Drain Filtration Unit: entire Filtrate Un Fill Filtration Unit with wate	OP			n/a n/a		
44					n/a		
	CIP						
45	CIP: (Emergency) Shut down of CIP activities		Y		у		
47	Cleaning Influent tank VSSL_1000_0		Y		n/a	water?	
48	Cleaning Bioreactor VSSL_1007_01 Cleaning of Filtration Unit: retentate side of membrane		Y		n/a		
49	LF_1200_01/LF_1200_02		Y	с	у		
50	Cleaning of Filtration Unit: both retentate and filtrate side of membrane LF_1200_01/LF_1200_02		~				
54	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_0	OP	Y Y	c not finished	y y		
55	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01 and filtrate line				·		
	through LF_1200_01/LF_1200_02 Cleaning of Filtration Unit: backwashing membrane Fi-F-01 / Fi-F-02 using		Y	с	У		<u>99</u>
52	water or cleaning agent			c	у		105
58	empty RC01			с	у		109
59 53	empty RC02 Cleaning of Filtration Unit: Circulation pump PMP-F-0			c c	y v		
50				3	,		
	SIP SIP of filtrate line 1 and 2						
60		1	I	C	у		
68	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate tank						
68 69		OP	Y	с	у		

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 15: Connect N2 to the system Scope					
N2 must be present at I-06 (PR-G-06) before any function of the Pilot is activated. This will allow pressure regulation and flushing in R-V-01 and R-R-01. It is also necessary for calibration of the analysers, some draining procedures for the filtration unit, for harvesting of R-F-01 and for prevention of underpressure in the later vessel after SIP.		с	for the functional tests step1, N2 replaced by compressed air	C?	
Procedure				-	
Set the regulation of the N2 supply around 1 barg (at no or low flow rate).	04/06/2008	с	4/6/08 : mounting of a manual valve on the air instrument supply to provide 1 barg pressure at i 06		
Connect the frame's N2 connection I-06 to the N2 supply I-06.	05/06/2008	с	5/6/08 : PR-G-02 = 145 mbar ; PR-G-04=95mbar		
This procedure is done by the OPERATOR.					
V-V-07 is on.			this has to be forced through the PC concept interface connected to the PLC		

NTE

step2

Recommendations / changes	WHEN ?	WHO? Comments
HW modifications add a pressure indicator at least temporarily on PR-G-04	step2	UAB
PLC programme modifications N/A		

### HMI modifications

indication of the N2 line on the bioreactor/influent tank

others

Only controlled valves ?

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 6: Start-up Influent tank VSSL_1000_01					
Scope				1	
Initiate the functions of the influent tank.				1	
				1	
Prerequisite					
Bioreactor should contain a certain amount of active waste that is					
strong enough to digest an influent flow.					
V-V-04 must be in position recirculation		с		]	
			missing how to add the cooling liquid into the loop	]	
Procedure			tap water was used for the tests step 1		
Use the HMI to					
<ol> <li>Make sure HV_1003_01 is open and N2 is available at around 1 barg at PC_1103_01, HPCV_1003_01 is set to approximately 110 mbarg and HPCV_1003_02 to approximately 90 mbarg.</li> <li>Start blender BL-V-01 (set point: 200 rpm): SCI_BL_V_01</li> </ol>	05-jun	c	5/6/08 : PR-G-02 = 145 mbar ; PR-G-04=95mbar the value of the speed can be modified on the frequency variator of BL-V-01 inside the electrical cabinet, not through the HMI	-	
<ol> <li>Set temperature setpoint to 6°C or another value &lt;= 7°C. Fill HX.</li> <li>V-01 and double jacket with water and antifreeze compound (glycol) if this is not done yet: SCI_V_T_V_01_SP</li> <li>Start PMP-V-01 : SCI_GP_1001_01_MV1</li> <li>On initial start up, when liquid level is below connection to V-V-04, PMP-V-01 will not run due to dry running protection.</li> </ol>		c	temperature setpoint was changed from 0°C to 20°C with T_V_01=15°C : change in the cooling compressor from ON to OFF, this change is not immediate	What do you mean by Not Immediate ? There is a delay between entering the new setpoint and the triggering off of the cooling compressor Where was changed the SP : from HMI or PLC ?	
The second will not run due to dry running protection.		no	to be checked again	4	

Recommendations / changes	WHEN?	WHO? Comments	
HW modifications repair ps-v-03 V-V-07		UAB	Should it be on HMI ? And/Or used as safety valve ?
PLC programme modifications PLC has reserved a position switch for V-V-07 which is not cabled ; no real i	intestep2	SHPA	Do you mean the Feedback ? YES
HMI modifications more rapid update of compressor state ? color codes for lines are not clear ; senses of flows neither ; for the cooling loop : put the whole line in red if stopped, in blue if active (for add the ps-V-03 value on the HMI screen for influent tank	example)	NTE NTE NTE NTE	I will check how it is done and if it is useful

others

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
Des es dons 7. sun es s					
Procedure 7: Filling Influent tank VSSL_1000_01					
Scope					
Feed influent to the influent tank.					
Prerequisite					
PMP-V-01 is active except for the initial filling.		<u> </u>	missing also fuse F16 to be on		
V-V-01 is closed.		С			
V-V-05 is closed.		c			
V-V-06 is closed.		C	it could be done only forcing it through the PLC ; no access		
			through HMI;		
			why isn't it controlled by the PLC if it is considered a pressure		
V-V-07 is on.		с	regulating device (even a safety device)?	Agree : HMI and/or safety	
Procedure					
Initial filling (appung at start up, when the influent tents is					
Initial filling (occurs at start-up, when the influent tank is					
totally empty)			1/ 11/11 001		
<ol> <li>Connect the dedicated reservoir to valve V-V-02.</li> <li>Open the valve underneath the reservoir and fill it with</li> </ol>			Vol V ini = 26L		
<ol><li>Open the valve underneath the reservoir and fill it with influent.</li></ol>					
3. Start-up PMP-V-01: SCI_ GP_1001_01_MV1					
5. Start-up PMP-V-01. SCI_ GF_1001_01_MV1					
4. Turn switch on panel (on the right of the front side of the					
bioreactor frame) and hold it while pushing the blue button					
(V GetCakeButton) (on the right of the front side of the bioreactor					
frame) to bring the system into feeding mode. This can be checked					
on the HMI. V-V-04 switches. The pump now withdraws influent					
and pumps it into R-V-01. Overpressure safety valve V-V-07 now					
works to vent overpressure in the influent tank without generating					
an alarm, because PR-G-02 is not capable of releasing the added			when V-V-07 was forced to open through PLC, it could not return to closed		
volume quickly enough. Because even with the aid of V-V-07			when V-V-07 was left closed and not forced through PLC, it	Sherpa should check the	
pressure in R-V-01 increases, V-V-04 switches back and forth to			acted a as pressure relief valve at p=150mbar	programmation of the V_V_07	
prevent overpressure.	05-jun	NC	the role of V-V-04 for pressure regulation was not observed	behaviour	
5. Stir the contents in the reservoir and try to have the floating				f The second second second	
portion sucked in to minimise the amount of fragments to amass.			these parameters are linked to the WPU (here water)	The question was to know which parameters should be	
Fill more influent in the reservoir before it is empty and try to avoid			change the stirring speed?	used in order to minimize the	
air to be sucked into the system.	05-jun	N/A	Change the temperature setpoint ?	amount of fragments	
6. When maximum level in the influent tank is reached, the					
system won't allow any more influent to be added and leaves					
feeding mode. This can be checked on the HMI. Valve V-V-04 is					
deactivated. Valve V-V-07 returns to its normal function of safety			filling up to Vol=61L, V-V-04 off and then Volume appeared to		
valve.		С	be 54L in a steady state		
7. Close the valve underneath the reservoir. Remove the					
reservoir. Empty the remaining influent and rinse it.		C			
Nominal filling (occurs when influent liquid level is above the					
minimum)					
<ol> <li>Connect the dedicated reservoir to valve V-V-02.</li> </ol>					
2. Open the valve underneath the reservoir and fill it with					
influent.					
2 Turn audiah an nanal (an its state of the forest its of the					
3. Turn switch on panel (on the right of the front side of the					
bioreactor frame) and hold it while pushing the blue button					
(V_GetCakeButton) (on the right of the front side of the bioreactor					
frame) to bring the system into feeding mode. This can be checked					
on the HMI. V-V-04 switches. The pump now withdraws influent and pumps it into R-V-01. Overpressure safety valve V-V-07 now					
works to vent overpressure in the influent tank without generating					
an alarm, because PR-G-02 is not capable of releasing the added					
volume quickly enough. Because even with the aid of V-V-07					
pressure in R-V-01 increases. V-V-04 switches back and forth to					
prevent overpressure.					
4. Stir the contents in the reservoir and try to have the floating					
portion sucked in to minimise the amount of fragments to amass.					
Fill more influent in the reservoir before it is empty and try to avoid					
air to be sucked into the system.					
5. When maximum level in the influent tank is reached (60 L),					
the system won't allow any more influent to be added and leaves					
feeding mode. This can be checked on the HMI. Valve V-V-04 is					
deactivated. Valve V-V-07 returns to its normal function of safety					
valve.					
6. Close the valve underneath the reservoir. Remove the	1				
reservoir. Empty the remaining influent and rinse it.					

HW modifications - add a purge for the cleaning of the line upstream V-V-02 after introducing the influent

## PLC programme modifications

why an automatic switch to bioreactor decided by PLC while operator wants tofill inlfuent tank

HMI modifications no indication of cooling loop status color codes for lines are not clear ; senses of flows neither ;

others if no purge valve added to the feeding line upstream V-V-02, add a more concentrated medium and then rinse the line with water ? (pb of dilution)

Important : to be clarify by Sherpa

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 11: Start-up Bioreactor VSSL_1007_01					
				•	
Scope				-	
Initiate the functions of the bioreactor R-R-01.					
Prerequisite			missing : FUSE f-14 switched ON		
Bioreactor should contain inoculum or an amount of active waste (minimum 50					
L).	5/6/08 17:00		V=77L		
Procedure					
Use the HMI to					
1. Make sure V-R-20 is open and N2 is available at around 1 barg at PR-G-			V-R-20 is a manual valve not visible on HMI ; p=100		
06		NC	mbar		
			where is the bioreactor pressure setpoint for the		
<ol><li>Flush N2 in the bioreactor byV-G-29</li></ol>		С	PLC control of V-G-29?	To be clarified	
			change setpoint is only possible in the electrical	Only On/Off in PLC. Speed in	
<ol><li>Start blender BL-R-01 (set point: 220 rpm): SCI_BL_R_01</li></ol>		С	cabinet by changing the FVC	the cabinet	
			decalcified water? Not for the tests : tap water		
			the pump is always ON	1	
4. Set temperature setpoint to 55°C. Fill HX-R-01 and double jacket with			the heating element indication on HMI is not correct : it is always ON even when the electrical heater is		
demineralized water if this is not done yet: SCI_R_T_R_01_SP		NC	OFF		
deminieralized water in this is not done yet. 301_K_1_K_01_3P		NC	OFF	L	
5. Make sure Acid bottle contains acid and base bottle contains base. Set pH				To be checked by Sherpa.	
set point to 5.2 or another value if specified. pH control will be automatically			if pH is above setpoint, PMP R 01 is actuated	There is a delay between	
deactivated as long as the liquid volume in R-R-01 is too low to reach the pH			if pH below setpoint, no action by PMP R 02	switching from acid to base,	
probes: SCI_R_pH_R_01_SP			it seems the pH control is authorized only when the blender is ON	due to "dead zone" and	
		INC	biender is ON	controller strategy	
		1			
1.2. Procedure 12: Start-up Bioreactor VSSL_1007_01 feeding					
Scope					
Start the feeding function.					
Prerequisite					
Both bioreactor and influent vessel should be working. Bioreactor should					
contain a certain amount of active waste that is strong enough to digest an					
influent flow.					
Procedure		1		1	
	ĺ	1		1	
1. Use the HMI to set the feeding function to be timer based or volume				1	
based. As long as R-R-01 doesn't contain its nominal volume of liquid, timer		1		1	
			the switching is made through _mode_timer_S or		
based feeding should be applied to feed a certain amount per day (e.g. 2.5		1	mode_volume_S	1	
L/d). Once nominal liquid volume is reached, one should switch over to volume				1	
based control. Nominal volume is around 100L: SCI_V_Feed,				1	
SCI_V_Feed_mode_timer or SCI_V_Feed_mode_volume		I		4	
		1	the role of this parameter is not really clear and	1	
2. Enable feeding by the button on the HMI: SCI_V_Feed_Enable			could not be related to the HMI	4	
		1		1	
3. Use the HMI to set feeding to timer based and to set the amount to feed				1	
per day: SCI_V_Feed_mode_timer_S, SCI_V_Feed_Amount_per_day		1	what are the different roles and possibilities	1	
per day. oor_v_reed_mode_timer_o, oor_v_reed_modent_per_day			what are the different foles and possibilities	1	
4. When nominal volume (100L) is reached, use the HMI to set the volume				1	
to which to feed to 100 and set feeding to volume based mode:				1	
SCI_V_Feed_volume_SP, SCI_V_Feed_mode_volume_S				1	
Joi_v_routine_JF, Joi_v_reeu_mode_volume_J		L	1	1	1

WHEN WHO

HW modifications put a deflector inside the hot water tank to prevent spillings

## PLC programme modifications addition of baase is considered?

 $\begin{array}{l} \mbox{HMI modificatinos} \\ \mbox{temperature control loop should be easy to view with T setpoint and loop T } \\ \mbox{pH control additions missing} \end{array}$ 

pressure setpoint for the bioreactor should appear

others if no purge valve added to the feeding line upstream V-V-02, add a more concentrated medium and then rinse the line with water ? (pb of dilution)

Yes it was tested

I don't think it is useful Not a single SP. More complicated with Active and Passive Strategy

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 11: Start-up Bioreactor VSSL_1007_01				-	
Scope					
Initiate the functions of the bioreactor R-R-01.					
Prerequisite			missing : FUSE f-14 switched ON		
Bioreactor should contain inoculum or an amount of active waste (minimum 50	)				
L).	6/6/08 12:19		V=98L		
			1		
Procedure		-		-	
Use the HMI to				-	
			V-R-20 is a manual valve not visible on HMI ; p		
1. Make sure V-R-20 is open and N2 is available at around 1 barg at PR-G-06		NC	bioreactor=103 mbar where is the bioreactor pressure setpoint for the PLC control	-	
			of V-G-29?		
			V-G-29 is not open (0% aperture) but it was checked that		
			when the pressure inside bioreactor is below than 100mbar, V-	-	
2. Flush N2 in the bioreactor byV-G-29		С	G-29 opens up		
2 Start blander PL D 01 (cet paint: 220 rpm); SCL PL D 01		с	change setpoint is only possible in the electrical cabinet by changing the FVC		
3. Start blender BL-R-01 (set point: 220 rpm): SCI_BL_R_01		C		-	
			it is not possible to activate from HMI the heating ; it was done	Temperature is	
			by forcing the variable HX_R_001 on PLC	controlled. The	
4. Set temperature setpoint to 55°C. Fill HX-R-01 and double jacket with			the heating element indication on HMI is not correct : it is	heating cannot be	
demineralized water if this is not done yet: SCI_R_T_R_01_SP	6/6/08 12:30	NC	always ON even when the electrical heater is OFF	controlled by the user	
5. Make sure Acid bottle contains acid and base bottle contains base. Set pH					
set point to 5.2 or another value if specified. pH control will be automatically					
deactivated as long as the liquid volume in R-R-01 is too low to reach the pH probes: SCI R		NC	not mounted for this test		
		NC	not modified for this test		
	I				
1.2. Procedure 12: Start-up Bioreactor VSSL_1007_01 feeding					
Scope				-	
Start the feeding function.					
		1			
Prerequisite					
Both bioreactor and influent vessel should be working. Bioreactor should					
contain a certain amount of active waste that is strong enough to digest an	1				
influent flow.					
				-	
Procedure					
1. Use the HMI to set the feeding function to be timer based or volume					
based. As long as R-R-01 doesn't contain its nominal volume of liquid, timer					
based feeding should be applied to feed a certain amount per day (e.g. 2.5			not done for this part of the tests : the objective was to have a		
L/d). Once nominal liquid	6/6/08 12:35	NC	bioreactor on operation to see the interaction with the gas loop	Should be clarified	
2. Enable feeding by the button on the HMI: SCI_V_Feed_Enable				-	
	]				
3. Use the HMI to set feeding to timer based and to set the amount to feed		1			
per day: SCI_V_Feed_mode_timer_S, SCI_V_Feed_Amount_per_day					
				1	
4. When nominal volume (100L) is reached, use the HMI to set the volume					
to which to feed to 100 and set feeding to volume based mode:		1			
SCI_V_Feed_volume_SP, SCI_V_Feed_mode_volume_S		1			

HW modifications put a deflector inside the hot water tank to prevent spillings add some switches to acivate BR and IT cooling loops pumps w/o using the electrical cabinet

PLC programme modifications addition of baase is considered?

HMI modificatinos temperature control loop should be easy to view with T setpoint and loop T pH control additions missing pressure setpoint for the bioreactor should appear

others if no purge valve added to the feeding line upstream V-V-02, add a more concentrated medium and then rinse the line with water ? (pb of dilution)

Is it necessary ?

agree see previous answer no pressure sp

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
•					
1.1. Procedure 26: Active Gas Loop: Start-up					
• •					
			there might be a problem of reverse flow from bioreactor to		
prerequisite	06/06/2008 12:00		the active gas loop condensate line through V-G-12		
			V-R-17 and 14 open ; V-R-5 closed ; V-R-13 closed to avoid		
none in EPAS procedure			backflow of water; V-G-11 and V-G-13 closed		
			passive gas loop is ON before starting this procedure (HMI		
			indicatino)		
_			(Valves V_G_07 On and V_G_08 Off; PS_G_04 indicates		
Scope			pressure zero)		
Start the active realizer			Include as prerequisite to check manual valves in R-G-01: V-		
Start the active gas loop			G-06, V_G_26, Previous condition: R-G-02 at 69 mBar	-	
			Previous condition: R-G-02 at 69 mBar		
Procedure		L	Stop of active gas loop in HMI is not effective even if button	HMI pb ? Probably	
			Stop of active gas loop in HMI is not effective even if button STOP changes to red ; START and STOP actions are carried		
Press the button on the HMI: SCI_G_Start_Active_GasLoop		NC	out through the same START button	forced through PLC	
		INC.		loiced through I LC	
Make sure that V-R-13, -14, and -17 and V-G-11 and -13 are open.		с	ok		
		U	Pressure in R-G-01 doesn't increase above 450 mBar.		
			reactor maintaining 80 mBar approx.		
SCI variables :			V-G-09 setpoint moves from zero to 2		
Set futubles .			FI-G-03 is around 16 L/min, stable while the pressure in R-G		
			01 is low, not affected by opening more V-G-04; when		
SCI_G_Start_Active_GasLoop, SCI_G_Reset_Active_GasLoop			pressure is high, flow in FI-G-03 goes to zero		
			Feeding air into V-R-01 from manual valve (not in P&ID) to		
			simulate reactor gas production ; pressure into reactor		
			increased up to 190 mBar (TBC), then V-R-19 opened to		
			maintain pressure. In the meanwhile, pressure in R-G-01		
			increase up to 800 mBar, then up to 1 Bar after some		
			minutes.		
PLC Subroutine : G_Active_Loop					
				4	
Fig : PLC procedure: G_Active_Loop					
		L			
Variables Used (I/O):					
S3CV_1100_01_MV, S3CV_1100_02_MV, SV_1100_01_MV	, ,				
SV_1100_05_MV (V_G_02, V_G_03, V_G_05, V_G_25)	).				
$S_{-1100_{-}05_{-}101}$ (v_d_02, v_d_03, v_d_03, v_d_23)					

Start\_Active\_Loop Start\_Active\_Loop is activated when Variable 'SCI\_G\_Start\_Active\_Loop is set to 1 SCI\_G\_Start\_Active\_gASLoop Close Valves V\_G\_05, V\_G\_10 and V\_G\_25, and reset Valves V\_G\_02 and V\_G\_03 Close\_Valves G\_02\_03\_05\_10\_25 Wait 5 seconds Check if Valves V\_G\_05, V\_G\_10 and V\_G\_25 are closed and V\_G\_02 and V\_G\_02 are reset Velve\_G02\_03\_05\_25\_10 Control Open Valves V\_G\_05 and V\_G\_25 Open\_valve\_V\_G\_25\_05 Wait for 5 seconds Check if Valves V\_G\_05 and V\_G\_25 are really opened, if Yes go to the next step Valve\_G\_05\_25 Control Start Pump PMP\_G\_01 Activate\_PMP\_G\_01 Wait 5 Seconds Go to the next step without additional conditions Set Valves V\_G-02 and V\_G\_03 Open\_V\_G\_02\_03 SCI\_G\_Reset\_Active\_GasLoop Close\_Valves\_02\_03 control\_02\_03 PMP\_G\_01\_OFF Close Valves V\_G\_05, V\_G\_10 and V\_G\_25, and reset Valves V\_G\_02 and V\_G\_03 Close\_Valves G\_02\_03\_05\_10\_21 \_\_\_\_\_\_\_\_Wait 5 seconds Check If Valves V G\_05, V\_G\_10 and V\_G\_25 are closed and V\_G\_02 and V\_G\_02 are reset Control\_Valve2\_G02\_03\_05\_25\_10 Start\_Active\_Loop

<ul> <li>Description :</li> <li>Input HMI: SCI_G_Start_Active_GasLoop</li> <li>Valves S3CV_1100_01_MV, S3CV_1100_02_MV, SV_1100_01_MV, SV_1100_05_MV (V_G_02, V_G_03, V_G_05, V_G_25) are OFF</li> <li>Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V G 25) are ON</li> </ul>			
<ul> <li>Run the pump PMP_G_01</li> <li>Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02, V G 03) are ON</li> </ul>	С	OK it started	
<ul> <li>Input HMI: SCI_G_Reset_Active_GasLoop</li> <li>Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02,</li> </ul>	13:30 NO	C the reset was not performed ; what is the button?	I don't know
<ul> <li>V_G_03) are OFF</li> <li>Stop the pump PMP_G_01</li> <li>Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05,</li> </ul>	nA NA	•	
V_G_25) are OFF		not performed	
Questions: Is V_G_10 really used in this procedure?		not tested since the level sensor LS-G-01 is OOO	
	06/06/2008 18:43	could be tested modifying the upper and lower limits of PS- 01 to actuate on G_Valvestate_V_G_10_P ; working	G.
		V_G_01 is supposed to purge the liquid accumulated in R- 01, why is the value of level sensor LS_G_01 not used ? currently it is just generating an error not used in other control loops	G.
Recommendations / changes	WHEN W	но	
HW modifications			
install a PI on bioreactor between 1 barg and 1.2 barg temperture sensor TS-R-01 is OOO it is indicating 0°C repair LS-G-01	U/	AB	??? Pressure indicator for visual control of pressure inside bioreactor
PLC programme modifications control of V-G-10 opening?	Sł	HERPA	
HMI modifications Local	NT	TE	

Remote

Variables

### others

User Manual

Include as prerequisite to check manual valves in R-G-01: V-G-06, V\_G\_26,

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 20: Passive Gas Loop: Start-					
up					
Scope					
Start the passive gas loop. This part of the gas loop					
uses V-G-07 and V-G-08 to remove excess gas from R-R-					
01 when pressure measured by PS-R-01 is higher than					
90 mbarg.					
Pre-requisite					
V-R-20 is open	06/06/2008 17:00	С			
V-R-11 is open	06/06/2008 17:00				
		-			
			Stop of passive gas loop in HMI is not feasible pushing the		
Procedure			button STOP	What do you mean ?	
			the passive gas loop button on HMI is always green even when this loop is switched OFF (variable = OFF in PLC);		
			the same button on HMI is used to trigger ON/OFF (STOP		
Press the button on the HMI: SCI_G_PAS_Start		NC	PASSIVE GAS LOOP is never used)	Passive always active	
			it seems that V-G-07 is always open ; V-G-08 is always	Sherpa to check.	
		NC	closed whatever the level of pressure above 90mbarg	IMPORTANT	
PLC Interface :	06/06/2008 17:00		PS-G-04 cannot measure the pressure above 100mbarg! Preactor=190mbarg		
I EC Interjuce .	00/00/2008 17.00		i leactor - roombarg		
SCI variables :					
Set fundotes .					
			variable TB_G_PAS cannot be introduced through HMI and i		
			is needed to authorize the passive control loop ; therefore the		
SCI_G_PAS_Start		NC	passive gas loop could not be used before passing only through HMI ; it was forced through PLC	2	
501_0_1 A5_5tart		INC.			
PLC Subroutines : G_PAS_Start, G_PAS_Esc					
I EC Subroutines : O_I A3_Start, O_I A3_ESC					
			ļ		
				4	
				1	
			ļ		
			<u> </u>	1	
Fig. DIC procedures C DAS Start					
Fig : PLC procedure: G_PAS_Start					
Fig : PLC procedure: G_PAS_Start The subroutine G_PAS_Esc is described on Procedure					

HW modifications PS-G-04 is working between 90barg and 100mbarg: change it to have a wider range of measurement from 0 to 200mbarg (for a better volume calculation in case of overpressures above 100mbarg) step 2

PLC programme modifications change use of SCI\_G\_PAS\_Start variable to activate the seque step2

## HMI modifications

Local idem remote

Remote

assign correct roles to ON/OFF buttons on HMI and correct colour codes for state of routine

## variables to be seen

others



Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 25: Active Gas Loop: Shut down					
Scope					
Stop the active gas loop.					
			the compressor was ON with 2220 mbarg in R-G-01 and 150mbarg in R-R-01		
Procedure					
Press the button on the HMI: SCI_G_Reset_Active_GasLoop	06/06/2008 19:15	NC	no button "Reset" on HMI ; to stop the active gas loop, we have to push the same HMI button as for starting it		
If the active gas loop is not to be started up again, gas in R-G-01					
can be released into the bioreactor first by setting the setpoint					
for pressure in R-G-01 to zero.		NA	it was not checked		
SCI variables :			when forcing this variable from PLC, we could activate		
SCI_G_Reset_Active_GasLoop			the sequence	_	
PLC Subroutine: G_Active_Loop described on the next				-	
procedure because the Shut down operation of Active Gas Loop					
is done at the end of this PLC subroutine.					
Variables Used (I/O):					
<i>(umbles esta (1/0)</i> .				_	
S3CV_1100_01_MV, S3CV_1100_02_MV, SV_1100_01_MV,					
SV_1102_01_MV, SV_1100_05_MV (V_G_02, V_G_03,					
V_G_05, V_G_10, V_G_25), PP_1100_01_MV					
Description :					
<ul> <li>Input HMI: SCI_G_Reset_Active_GasLoop</li> </ul>					
<ul> <li>Valves V_G_02 and V_G_03 are set in OFF</li> </ul>		С	ok		
<ul> <li>The pump PMP_G_01 is turn OFF</li> </ul>		С	OK it shut down	]	
<ul> <li>Valves V_G_05, V_G_10 and V_G_25 are set in OFF</li> </ul>		С	ok		

WHO

WHEN

HW modifications

UAB

PLC programme modifications

SHERPA

NTE

HMI modifications Local

Remote

Variables

others

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 19: Passive Gas Loop: Shut down					
Scope					
Stop the passive gas loop.					
<b>—</b>					
Procedure			ON button has to be pressed to obtain shutdown of		
Press the button on the HMI: SCI_G_PAS_Stop	06/06/2008 19:30	NC	passive loop		
	00,00,2000 10.00				
PLC Interface :					
SCI variables :					
			the variable is SCI_G_Stop_Passive_GasLoop but it is		
SCI_G_PAS_Stop		NC	accessible through the HMI	ОК	
PLC Subroutines : G_PAS_Stop , G_PAS_Esc					
Fig : PLC procedure: G_PAS_Stop					
rig : FEC procedure. G_FA3_Stop					
Fig : PLC procedure: G_PAS_Esc					
Variables Used (I/O):					
SV_1100_02_MV, SV_1100_03_MV (V_G_07 and V_G_08)			before stopping, V-G-07 and V-G-08 are releasing gas to		
			the outlet		
Description :					
Input HMI: SCI_G_PAS_Stop		NC	the variable is SCI_G_Stop_Passive_GasLoop but it is accessible through the HMI	ок	
			the effect of this stopping is that V_G_07 and V_G_08	1	
<ul> <li>This variable begins the PLC procedure G_PAS_Esc</li> </ul>		NC?	stop their release of gas out of the R-G-02		
<ul> <li>The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which</li> </ul>					
on state HIGH begins the subroutine for release of gas production			it seems that the release of gas was interrupted by the		
G_PAS_Esc (Passive gas loop)			passive shutdown, not started/begun		

WHO

WHEN

Recommendations / changes

HW modifications

## PLC programme modifications change the variable names

### HMI modifications

Local

idem remote

Remote

assign correct roles to ON/OFF buttons on HMI and correct colour codes for state of routine

## variables to be seen

others





Documentation only ?

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 6: Start-up Influent tank VSSL_1000_01					
Scope					
Initiate the functions of the influent tank.					
Prerequisite					
Bioreactor should contain a certain amount of active waste that is strong					
enough to digest an influent flow.					
V-V-04 must be in position recirculation	09-jun	с			
			missing how to add the cooling liquid into the loop		
Procedure			tap water was used for the tests step1		
Use the HMI to			manual filling up to V=57L		
<ol> <li>Make sure HV_1003_01 is open and N2 is available at around 1</li> </ol>					
barg at PC_1103_01, HPCV_1003_01 is set to approximately 110					
mbarg and HPCV_1003_02 to approximately 90 mbarg.	09-jun				
<ol><li>Start blender BL-V-01 (set point: 200 rpm): SCI_BL_V_01</li></ol>		с	blender on		
<ol> <li>Set temperature setpoint to 6°C or another value &lt;= 7°C. Fill HX-V-</li> </ol>					
01 and double jacket with water and antifreeze compound (glycol) if					
this is not done yet: SCI_V_T_V_01_SP		с	cooler ON		
4. Start PMP-V-01 : SCI_ GP_1001_01_MV1		с	ON		
On initial start up, when liquid level is below connection to V-V-04, PMP-					
V-01 will not run due to dry running protection.			not applicable		

Recommendations / changes	WHEN?	WHO? Comments
HW modifications repair ps-v-03		UAB UAB
PLC programme modifications	step2	SHPA
HMI modifications		NTE NTE NTE NTE

others

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
				SHEN A COMMENTS	
1.1. PROCEDURE 22: Analysis Gas Loop: Start-up					
Scope					
			reactor started up passive control loop ON : PS-G-04 > 100mbarg because		
Start the analysis gas loop. This part of the gas loop uses PMP-G-02			active gas loop ON : PS-G-01 = 2,21barg		
to create a circulating flow of gas from R-R-01 over the gas			preactor = 153 mbar because a leak was detected in V-G-09		
analysers.			(membrane proportional valve)	-	
Prerequisite					
Please make sure to have read the specific gas analyser manual for a					
detailed description on how to use this apparatus.		N/A	the gas analyzer has been shorcircuited for the test		
Procedure				-	
			button is working but on HMI there is no evidence of it : no		
			green on the button; the SCI_G_Ana_Start variable is not		
Make sure V-R-15 and -16 are open. Press the button on the HMI:			changing value when activating/deactivating the gas analysis loop or is taking when activating the loop the value ON and		
SCI_G_Ana_Start	09/06/2008 13:30	NC	then switching to OFF		
If a cold startup of the gas loop is done, close both valves V-G-14			OK both valves V_G_14 and 15 closed but check valve		
and -15 before starting the analysis loop. When PMP-G-02 is			V_G_17 is letting into the loop some gas from bioreactor		
running, open them gradually to adjust the flow rates through the			(PS_G_02 = 150 mbarg) dismounting to check the status of this valve ; thus release of		
analyzers according to PROCEDURE 23: Analysis Gas Loop: adjust			gas in the bioreactor and new pressures are : PBR=80 mbarg		
flow rates.		С	; PS_G_02 = 80 mbarg		
SCI variables :				-	
SCI variables : SCI_G_Ana_Start				1	
				1	
PLC Subroutine : G_Ana_Start				1	
				1	
				1	
		С	V_G28, 01, 16 in the required state		
		0			
		C C	ok SCI_G_Ana_Start is reset to OFF TB is ON		
		C			
			PS_G_02 = 88 mbarg	1	
			V_G_15 open so that FI reads 0,75 L/Min	1	
		<u> </u>	pressure drops down to 84 mbarg and then goes up again	1	
			P_R_01 = 79mbarg : there is flow reinjected from the gas	1	
			analysis loop into the bioreactor		
Fig : PLC procedure: G_Ana_Start				{	
				1	
		<u> </u>		1	
				1	
Recommendations / changes	WHEN	WHO			
HW modifications				1	
V_G_09 to be fixed because it is leaking				]	
V_G_17 to be fixed					
PLC programme modifications					
check the variables used to activate the gas loop from HMI				ok	
				1	
HMI modificatinos				1	
		<u> </u>		1	
local				1	
check the variables used to activate the gas loop from HMI					
remote				1	
idem local		<u> </u>		1	
				-	
others	<u> </u>			1	
		1			



Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. DDOCEDUDE 21. Analysis Cool Churt de		-			
1.1. PROCEDURE 21: Analysis Gas Loop: Shut down Scope					
Stop the analysis gas loop.					
			reactor started up		
			passive control loop ON : PS-G-04 = 80mbarg because		
			active gas loop ON : PS-G-01 = 1,85barg preactor = 79 mbar because a leak was detected in V-G-09		
	09/06/2008 14:14		(membrane proportional valve)		
Procedure			gas analysis loop started		
Press the button on the HMI: SCI_G_Ana_Stop		NC	button is working to trigger the action but stays always in red		
ress the battor of the finit. sol_0_find_stop			ballor to working to anggor the dollor bat only ballways in rea		
PLC Interface : ?????			we did not use the PLC interface for this loop		
SCI variables :					
SCI_G_Ana_Stop					
PLC Subroutine : G_Ana_Stop					
	1	С			
	ł				
		с	the nump is stopped		
	1	Č.	the pump is stopped		
	1				
		С	ok for 28 and 01		
		0	ok for 28 and 01 and 16		
		С	ok for 28 and 01 and 16		
		С			
			PS_G_02 = 5mbarg to evacuate the venting of N2 from V_G_01 through V_G_15 and V_G_16		
			V_G_01 through V_G_15 and V_G_16		
Variables Used (I/O):					
SV 1101 01 MV 52CV 1102 02 MV 152CV 1101 01 MV					
SV_1101_01_MV, S3CV_1103_02_MV and S3CV_1101_01_MV					
Description :					
Input HMI: SCI_G_Ana_Stop	1				
Stop the pump PMP_G_02	1				
<ul> <li>Valves SV_1101_01_MV, S3CV_1103_02_MV (V_G_28 and</li> </ul>	1				
V_G_01) are ON, S3CV_1101_01_MV (V_G_16) is OFF					
	ļ				
Recommendations / changes	WHEN	WHO			
HW modifications					
PLC programme modifications					
check the variables used to activate the gas loop from HMI				OK to do	
	1				
HMI modificatinos		<u> </u>			
local					
change the colours of buttons to reflect started/shut down states					
remote idem local	+				
	1				
others					
others	I	I	1		



Procedure steps	date/hour	N/NC	comments
1.1. Procedure 34: Filtration Unit: Start up in Bypass mode			
Scope			
Start the FU over in bypass mode. In this mode both membranes are bypassed.	09/06/2008 16:30		
Retentate is circulated over piping and flexible hose from and to R-R-01.	09/00/2008 10:30		
which also includes PMP-F-01, FS-F-01 and SS-F-01. Membranes and entire			
filtrate side of the FU are now physically cut off from the rest of the system -which can be useful for maintenance reasons -while PMP-F-01, and piping			
with its contents is kept on temperature and particles are kept in suspension	'		SS_F_01 cannot be checked if functional or not, the
Turbidity can still be monitored by SS-F-01.			measurement reading is always the same
Prerequisite			
FU must be stopped. The membrane that is switched over from must be			
cleaned and preserved in clear water if it remains in the membrane module.			missing prerequisite : the manual valves V-R-08 and 09 should be opened
Procedure 1. Use the HMI to start PLC procedure F_Bypass: SCI_F_Bypass		-	
2. Wait for the PLC procedure to finish.			
The FU is now in bypass mode, which can be checked on the HMI.			
SCI variables : SCI_F_Bypass		nc	the HMI button has no action
			when forced through PLC the sequence is launched
			for the aperture of the valves but the pump is not started
PLC Subroutine : F_Bypass			
			the parameter SCI_PMP_F_01_RUN is preventing the start-up of the pump ; when forced to 1, the pump is
			authorized to start but the velocity parameter is
			staying at 0, and cannot be changed
Variables Used (I/O):			
SV_1201_01_MV (V_F_01), S3CV_1201_01_MV (V_F_02)			
S3CV_1201_04_MV (V_F_05), SV_1203_01_MV (V_F_13), SV_1201_02_NV (V_F_05), S2CV_1201_05_MV (V_F_13),			
SV_1201_02_MV         (V_F_06),         S3CV_1201_05_MV         (V_F_14),           S3CV_1201_06_MV         (V_F_15),         S3CV_1201_08_MV         (V_F_17).			
SV_1103_01_MV (V_G_20)			
Description : • Input HMI: SCI_F_Bypass			
The Bypass mode begins with 2 conditions:			
• Use of the HMI input			
• F_Mode_Stop_OK: all FU valves are set in OFF (closed), the pumps PMP_F_01 and PMP_F_05 are stopped and the pump PMP_F_02 is ON			
<ul> <li>All valves involved in Bypass mode are set in ON</li> </ul>			
The pump PMP_F_01 starts		NC	this needs an input SCI_PMP_F_01_RUN from the HMI that has to be forced through the PLC
		-	· · ·
			S_F_Bypass_001
			wait for command to sta
			T_F_Bypass_001
			SCI_
Becommendations / changes	WHEN	WHO	S_F_Bypass_Switch_valves
Recommendations / changes			
HW modifications TS_R_01 is going out of range : to be fixed	step2	UAB	when all valves are in p
V_F_16 is not mounted correctly : to be checked	step2	0/12	F_Valvestate_Bypass_OK
the pipes coming from the bioreactor are hot ; it should be warned on these tubes same warning on steam pipings	step2 step2		start circulation pump
		0	S_F_Cir1_PMP_F_01_Star1
PLC programme modifications		SHER	
HMI modifications		NTE	
Local		INTE	PMP_F_01
clear identification of the line being used for the filtration			reset sequence comma
			S_F_Bypass_END
Remote			
			1
Variables			
			S_F_Bypass_001
others			

Procedure steps	date/hour	N/NC	comments
			Comments
1.1. Procedure 34: Filtration unit: Start up in Bypass mode			
Scope			
			2 blenders ON, influent tank started
Start the FU over in bypass mode. In this mode both membranes are			active gas loop ON : preactor = 80mbarg
bypassed.	10/6/08 15:07		passive gas loop ON
Retentate is circulated over piping and flexible hose from and to R-R-01,			
which also includes PMP-F-01, FS-F-01 and SS-F-01. Membranes and entire			
filtrate side of the FU are now physically cut off from the rest of the system			SS_F_01 cannot be checked if functional or not, the
-which can be useful for maint			measurement reading is always the same
Prerequisite			
FU must be stopped. The membrane that is switched over from must be			
			missing prerequisite : the manual valves V-R-08 and 09
cleaned and preserved in clear water if it remains in the membrane module.			should be opened
Procedure			
1. Use the HMI to start PLC procedure F_Bypass: SCI_F_Bypass			
2. Wait for the PLC procedure to finish.			
The FU is now in bypass mode, which can be checked on the HMI.			
SCI variables : SCI_F_Bypass		nc	the HMI button has no action
			when forced through PLC the sequence is launched for the
			aperture of the valves but the pump is not started
PLC Subroutine : F_Bypass			
			the parameter SCI_PMP_F_01_RUN is preventing the start-
			up of the pump ; when forced to 1, the pump is authorized to
			start but the velocity parameter is staying at 0, and cannot
			be changed
			the frequency variator is giving an error ERR_R_PMP_F_01_Freq_Drive
			the frequency variator was checked : it is OK ; it seems the
			analog output for speed is not going to the freq. variator
			this problem was identified : the value specified to the freq
			variator is too small to start-up the pump which returns an
			error
			change of parameters with higher values
			Flowrate = 1000
			speed=63,66
			FS_F_01=16 l/min
Variables Used (I/O):			
SV_1201_01_MV (V_F_01), S3CV_1201_01_MV (V_F_02),			
S3CV_1201_04_MV (V_F_05), SV_1203_01_MV (V_F_13),			
SV_1201_02_MV (V_F_06), S3CV_1201_05_MV (V_F_14),			
S3CV_1201_06_MV (V_F_15), S3CV_1201_08_MV (V_F_17),			
SV_1103_01_MV (V_G_20)			
Description :			
Input HMI: SCI_F_Bypass			
The Bypass mode begins with 2 conditions:			
<u> </u>			
• Use of the HMI input			
• F_Mode_Stop_OK: all FU valves are set in OFF (closed), the pumps			
PMP_F_01 and PMP_F_05 are stopped and the pump PMP_F_02 is ON			
All valves involved in Bypass mode are set in ON			
• The pump PMP_F_01 starts		С	
	1	1.	1

Recommendations / changes	WHEN	WHO
HW modifications FS_G_01 is showing 3L/min when no flow is passing through and 1,6L/min when there is flow : to be recalibrated	step2 step2 step2 step2 step2	UAB

## PLC programme modifications

SHERPA

put some ranges in the parameters as an example

## **HMI** modifications

Local

Remote

Variables

others

User Manual

put some example of ranges for the pump PMP\_F\_01 parameters

NTE			
S_F_Bypass_001			• • •
T_F_Bypass_001	d to startup while T_F_Bypass SCI_F_Bypa	_001 is SE	T by 2 conc
switch valves S_F_Bypass_Switch_valves	//	· · · · ·	
when all valves a F_Valvestate_Bypass_OK	are in position	· · · · ·	
start circulation p	bump	· · · · ·	· · · · · · · · · · · · · · · · · · ·
PMP_F_01	· · · · ·	· · · ·	· : · ·

Procedure steps	date/hour	N/NC	comments	SHERPA comments NTE cor	nments
1.1. Procedure 34: Filtration unit: Start up in Bypass mode					
Scope					
			Vreactor = 74L (setpoint=80L), preactor = 70mbarg		
			2 blenders ON, influent tank started		
			V-V-03 activated from the PLC to fill reactor up to 82 L		
Next the Efference is because and the this work have been been as			active gas loop ON : preactor = 95mbarg		
Start the FU over in bypass mode. In this mode both membranes are			passive gas loop ON		
hypassed.	11/6/08 10:15	5	analysis loop OFF	4	
Retentate is circulated over piping and flexible hose from and to R-R-01,					
which also includes PMP-F-01, FS-F-01 and SS-F-01. Membranes and entire					
iltrate side of the FU are now physically cut off from the rest of the system			SS_F_01 cannot be checked if functional or not, the		
which can be useful for maint			measurement reading is always the same	-	
		_		4	
Prerequisite		_		4	
U must be stopped. The membrane that is switched over from must be					
terrenden al and an el trada a contra 1600 a constructor terretaria a contra da terretaria.			missing prerequisite : the manual valves V-R-08 and 09 should		
leaned and preserved in clear water if it remains in the membrane module.			be opened	-	
<u>, , , , , , , , , , , , , , , , , , , </u>				4	
Procedure		+ +		4	
Use the HMI to start PLC procedure F_Bypass: SCI_F_Bypass				4	
Wait for the PLC procedure to finish.				4	
he FU is now in bypass mode, which can be checked on the HMI.				4	
				4	
CI variables : SCI_F_Bypass			the HMI button has no action	4	
			when forced through PLC the sequence is not launched for the		
			aperture of the valves		
			SCI_F_Bypass is On but F-Mode_Stop_OK is off due to PMP F 02 manually activated		
			PMP_F_02 manually activated PMP-F-01 doesn't run because some variables were manually		
			active: SCI_PMP_F_01_RUN		
LC Subroutine : F_Bypass					
			the parameter SCI_PMP_F_01_RUN is preventing the start-up	1	
			of the pump ; when forced to 1, the pump is authorized to start		
			but the velocity parameter is staying at 0, and cannot be		
			changed		
			the frequency variator is giving an error		
			ERR_R_PMP_F_01_Freq_Drive		
			the frequency variator was checked : it is OK ; it seems the		
			analog output for speed is not going to the freq. variator this problem was identified : the value specified to the freq	4 1	
			this problem was identified . the value specified to the field		
			variator is too small to start-up the pump which returns an error		
			change of parameters with higher values	4	
			Flowrate = 500	1	
		:	speed=31,83	1	
			FS_F_01=7,21 l/min		
			To stop bypass mode is necessary to activate manually SCI-F-		
			Stop	-	
/ariables Used (I/O):					
SV_1201_01_MV (V_F_01), S3CV_1201_01_MV (V_F_02),					
3CV_1201_04_MV (V_F_05), SV_1203_01_MV (V_F_13),		1 1			
$V_1201_02_MV$ (V_F_06), S3CV_1201_05_MV (V_F_14),		1 1			
$V_1^2 = 1201_2 = 0.05 \text{ MV}$ (V_1_00), $S_2 = 0.05 \text{ MV}$ (V_1_14), $S_3 = 0.05 \text{ MV}$ (V_1_14), $S_3 = 0.05 \text{ MV}$ (V_1-14), $S_3 = 0.05 \text{ MV}$ (V_1		1 1			
$V_{1103_01_WV} (V_{G_20})$		1 1			
Y_1105_01_IVI Y (Y_0_20)		+ +		4	
		1 1		4 1	
Description :				4 1	
Input HMI: SCI_F_Bypass				1	
The Bypass mode begins with 2 conditions:					
Use of the HMI input				1	
F_Mode_Stop_OK: all FU valves are set in OFF (closed), the pumps	l			1	
MP_F_01 and PMP_F_05 are stopped and the pump PMP_F_02 is ON		1 1			
	1	+ +		4	
All valves involved in Bypass mode are set in ON				4	
The pump PMP_F_01 starts		С			
ecommendations / changes	WHEN	WHO	S_F_Bypass_001	•	
Coominemations / changes				•	
IW modifications			in the state of the second	·	
S_G_01 is showing 3L/min when no flow is passing through and 1,6L/min when			T_F_Bypass_001		
here is flow : to be recalibrated	step2	UAB	I_F_Bypass	001 is SET by 2 con	
	step2			ss AND F_Mode_Sto	p_OK
	step2		switch valves		
	step2		S_F_Bypass_Switch_valves	•	
		o=-			
LC programme modifications		SHERF	A		
ut some ranges in the parameters as an example					
IMI modifications		NTE	F_Valvestate_Bypass_OK	•	
Local		INTE			
			start circulation pump		
			S_F_Cir1_PMP_F_01_Star1		
				-	

PMP\_F\_01

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S\_F\_Bypass\_001

S\_F\_Bypass\_END

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Remote

Variables

others

User Manual put some example of ranges for the pump PMP\_F\_01 parameters

1.1. Procedure 35: Filtration Unit: Start up of filtration through
membrane Fi-F-01 / Fi-F-02

Scope: Start the FU over one of the two membranes.

### Procedure

Procedure step

1. Use the HMI to start PLC procedure F\_Cir1 or F\_Cir2: SCI\_F\_Cir1 / SCI\_F\_Cir2

- Wait for the PLC procedure to finish.
   Use the HMI to start PLC procedure F\_Fil: SCI\_F\_Fil
- 4. Wait for the PLC procedure to finish.
- The FU is now in nominal filtration mode.

SCI variables : SCI\_F\_Cir1, SCI\_F\_Cir2, SCI\_F\_Fil

PLC Subroutine : F\_Cir1

## Variables Used (I/O):

SV_1201_01_MV	(V F 01),	S3CV_1201_01_MV	(V_F_02),
S3CV_1201_02 _N			(V_F_06),
S3CV_1202_01_MV	(V_F_07),	S3CV_1201_06_MV	(V_F_15),
S3CV_1201_07_MV	(V_F_16),	S3CV_1201_08_MV	(V_F_17),
SV_1103_01_MV	(V_G_20),	SV_1207_03_MV	(V_C_04),
S3CV_1207_02_MV	(V_C_13),	S3CV_1207_04_MV	(V_C_15),
S3CV_1207_05_MV	(V_C_16),	S3CV_1207_08_MV	(V_C_19),
S3CV_1210_01_MV	(V_S_02),	S3CV_1210_03_MV	(V_S_04),
S3CV_1210_05_MV	(V_S_06),	S3CV_1210_06_MV	(V_S_07),
SV_1210_02_MV (V_S	S_12), SV_1210_	_03_MV (V_S_13)	

## **Description** :

• Input HMI: SCI\_F\_Cir1

- The operation begins with 2 conditions:
- o Use of the HMI input
- o F\_Mode\_Stop\_OK: all FU valves are set in OFF (closed), the pumps
- PMP\_F\_01 and PMP\_F\_05 are stopped and the pump PMP\_F\_02 is ON
- All valves involved in the filtration through membrane Fi\_F\_01 are set in specific state.
- The pump PMP\_F\_01 starts

PLC Subroutine : F\_Cir2

## Variables Used (I/O):

SV_1201_01_MV	(V_F_01),	S3CV_1201_01_MV	(V_F_02),
S3CV_1201_02 _M	IV (V_F_03),	S3CV_1201_03_MV	(V_F_04),
S3CV_1201_04 _N	$V (V_F_{05})$	), SV_1201_02_MV	(V_F_06),
S3CV_1202_01_MV	(V_F_07),	SV_1203_01_MV	(V_F_13),
S3CV_1201_05_MV	(V_F_14),	S3CV_1201_07_MV	(V_F_16),
S3CV_1201_08_MV	(V_F_17),	SV_1103_01_MV	(V_G_20),
SV_1207_02_MV	(V_C_02),	S3CV_1207_01_MV	(V_C_12),
S3CV_1207_03_MV	(V_C_14),	S3CV_1207_04_MV	(V_C_15),
S3CV_1207_06_MV	(V_C_17),	S3CV_1207_07_MV	(V_C_18),
S3CV_1210_02_MV	(V_S_03),	S3CV_1210_04_MV	(V_S_05),
S3CV_1210_05_MV	(V_S_06),	S3CV_1210_07_MV	(V_S_08),
SV_1210_02_MV (V_	S_12)		

	NC the button is not working	
	when forcing SCI_F_Cir1	
	flowrate_SP=500 ; speed	l= 31,8 ; flow=445L/h
	S_F_Cir1_001	
		· · · · · ·
	T_F_Cir1_001 wait for command to startup	
		2 conditions:
	switch valves	SCI_F_Cir1 A F_Mode_Stor
	S_F_Cir1_Switch_valves	mode_otol
	when all valves are in positi	on
		: :
	F_Valvestate_Nom1_OK	
	start circulation pump S_F_Cir1_PMP_F_01_Start	
(V_F_02),		· · ·
(V_F_06), (V_F_15),		
$(V_F_{13}),$ $(V_F_{17}),$	PMP_F_01	· ·
(V_C_04),	<u> </u>	
(V_C_15), (V_C_19),	S_F_Cir1_END	· · ·
(V_S_04),	reset sequence command fil	· · · · · · ·
(V_S_07),		
	1	
		· · ·
	<u>&gt;S_F_Cir</u> }_001	
	nc FORCED THROUGH PL	
the pumps		6
SON	C rk : PMP_F_02 is on but i	it is not running
1 are set in	C V_F_01 and 06 ON the o	thers OFF
	C see parameters above	
	S_F_Cir2_001	· ·
		· ·
	wait for command to startup while	unit is stonned
	T_F_Cir2_001	
		3 conditions: SCI_F
	switch valves	AND F_Mode_Stop_
	S_F_Cir2_Switch_valves	AND TB_C_CI2
	when all valves are in position	
	when an varies are in position	
	F_Valvestate_Nom2_OK	· ·
	start circulation pump	
	S_F_Cir2_PMP_F_01_Start	· ·
		· ·
(V_F_02),	PMP_F_01	 
$(V_F_04),$	reset sequence command flag	
(V_F_06), (V_F_13),	S_F_Cir2_END	· ·
$(V_F_{16}),$		
(V_G_20), (V_C_12),		
(V_C_15),		
(V_C_18), (V_S_05),	· · ·	
$(V_S_{00}),$ $(V_S_{00}),$		
	∑s_F_Cir2≥001	· · · · · ·

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10/06/2008 17:56

### **Description** :

- Input HMI: SCI\_F\_Cir2
- The operation begins with 3 conditions:
- o Use of the HMI input
- $\circ~$  F\_Mode\_Stop\_OK: all FU valves are set in OFF (closed), the pumps PMP\_F\_01 and PMP\_F\_05 are stopped and the pump PMP\_F\_02 is ON
- TB\_C\_Cl2: the tracing bit is ON
- All valves involved in the filtration through membrane  $Fi_F_{02}$  are set in the specific state.
- The pump PMP\_F\_01 starts

## Question:

- 1. Why is the state of the valve V\_C\_02 used here?
- 2. The variable TB\_C\_Cl2 is used once (only read), so never SET or RESET whereas there is a tracing bit TB\_Cl2 used in PLC subroutine C\_Cl2 (it is SET and then RESET later)

## PLC Subroutine : F\_Fil

- NC forced through PLC
- C farmed through DL
- C forced through PLC
- C V\_F\_01, 03, 04, 06 ON, the others OFF
- NC the pump does not start immediately
- the SCI\_PMP\_F\_01\_RUN variable has to be forced

3 conditions: PMP_F_01 is ON AND Valves in Cir1 or Cir2 are OK AND SCI F_Fil	•wait for command T_F_FI_001 PMP_F_01 must be running and valves must be si
	start PMP_F_02 S_F_S12_St_PMP_F_02
	~PINP_F_02
	reset sequence command flag
	1
	S_F_FIL)201

variables have to be forced through PLC

the parameter for pump calibration

F\_Filtration\_flowrate\_cal\_factor has to be introduced before : value=2, then SCI\_F\_Filtration\_rate=300, and

PMP\_F\_02\_Speed=600 : the pumps is starting OK

С

NC

Variables Used (I/O):

See above;

The variables involved depend on the type of the filtration: if the filtration is through membrane Fi\_F\_01 or Fi\_F\_02

### Description :

- Input HMI: SCI\_F\_Fil
- The operation begins with 3 conditions:
- Use of the HMI input
- o PMP\_F\_01 is ON
- o The state of all valves involved (Cir1 or Cir2) is OK

• The pump PMP\_F\_02 starts

- The condition to end the procedure is that the pump  $PMP\_F\_02$  is turn OFF
- WHEN
   WHO

   Recommendations / changes
   UAB

   HW modifications
   SHERPA

   HMI modifications
   NTE

### HMI modifications Local

introduce on the screen the buttons corresponding to the variables used in the three procedures above introduce on a screen the parameters for PMP\_F01 and 02

Remote see local

300 10041

## Variables

others

Procedure steps	date/hour	N/NC comments	SHERPA comments	NTE comments
1.1. Procedure 35: Filtration Unit: Start up of filtration through membrane Fi-F-01 / Fi-F-02				
Scope: Start the FU over one of the two membranes.	11/06/2008 11:	25		
Procedure 1. Use the HMI to start PLC procedure F_Cir1 or F_Cir2: SCI_F_Cir1 /				
SCL_F_Cir2 2. Wait for the PLC procedure to finish. 3. Use the HMI to start PLC procedure F_FiI: SCL_F_FiI 4. Wait for the PLC procedure to finish. The FU is now in nominal filtration mode.		NC the button is not working when forcing SCL_F_Cir1 on PLC : working flowrate_SP=500 ; speed= 31,8 ; flow=445L/h		
SCI variables : SCI_F_Cir1, SCI_F_Cir2, SCI_F_Fil	S_F_Cir1	001		
PLC Subroutine : F_Cir1	· · · ·		unit is stopped	· · · · ·
	T_F_Cir1_0		2 conditions	
	· · ·	switch valves Switch_valves	SCI_F_Cir1 / F_Mode_Sto	
		when all valves are in position	· · · · ·	· · · · ·
	F_Valvestat	e_Nom1_OK		
	S_F_Cir1	start circulation pump _PMP_F_01_Start :	- - -	•
		• • • • • • • • • •		
	PMP_F_01	· · · · · · · · · · · ·		
Variables Used (1/O):	S_F_Cir1	END	•	•
SV_1201_01_MV (V_F_01), S3CV_1201_01_MV (V_F_02), S3CV_1201_02 _MV (V_F_03), SV_1201_02_MV (V_F_06), S3CV_1202_01_MV (V_F_07), S3CV_1201_06_MV (V_F_15), S3CV_1201_07_MV (V_F_16), S3CV_1201_08_MV (V_F_17), SV_1103_01_MV (V_G_20),		reset sequence command flag		
SV_1207_03_MV (V_C_04), S3CV_1207_02_MV (V_C_13), S3CV_1207_04_MV (V_C_15), S3CV_1207_05_MV (V_C_16),	1	· · · · · · · · · · · · ·		
S3CV_1207_08_MV         (V_C_19),         S3CV_1210_01_MV         (V_S_02),         S3CV_1210_03_MV         (V_S_04),         S3CV_1210_05_MV         (V_S_06),         S3CV_1210_05_MV         (V_S_06),         S3CV_1210_02_MV         (V_S_12),         (V_S_12), <th(v_s_12),< th=""></th(v_s_12),<>		r <u>}</u> 001		•
SV_1210_03_MV (V_S_13)				
Description : Input HMI: SCI_F_Cir1 The operation begins with 2 conditions:				
<ul> <li>Use of the HMI input</li> <li>F_Mode_Stop_OK: all FU valves are set in OFF (closed), the pumps</li> </ul>		nc FORCED THROUGH PLC		
<ul> <li>PMP_F_01 and PMP_F_05 are stopped and the pump PMP_F_02 is ON</li> <li>All valves involved in the filtration through membrane Fi_F_01 are set in specific state.</li> <li>The pump PMP_F_01 starts</li> </ul>		C rk : PMP_F_02 is on but it is not running C V_F_01 and 06 ON the others OFF C see parameters above		
PLC Subroutine : F_Cir2	S F Cir2 001	C see parameters above		
		· · · · ·		
	T_F_Cir2_001	wait for command to startup while unit is stopped 3 conditions: SC		
		AND F_Mode_St		
	S_F_Cir2_Swit	switch valves AND TB_C_CI2		
		when all valves are in position		
	F_Valvestate_No	m2_OK		
	S_F_Cir2_PM	start circulation pump P_F_01_Start		
Variables Used (I/O):	PMP_F_01			
SV_1201_01_MV (V_F_01), S3CV_1201_01_MV (V_F_02), S3CV_1201_02 _MV (V_F_03), S3CV_1201_03_MV (V_F_04), S3CV_1201_04 _MV (V_F_05), SV_1201_02_MV (V_F_06), S3CV_1202_01_MV (V_F_07),	S_F_Cir2_END	reset sequence command flag		
SV_1203_01_MV         (V_F_13),         S3CV_1201_05_MV         (V_F_14),           S3CV_1201_07_MV         (V_F_16),         S3CV_1201_08_MV         (V_F_17),           SV_1103_01_MV         (V_G_20),         SV_1207_02_MV         (V_C_02),		· · · · · · · · · · · · · · · · · · ·		
$\begin{array}{llllllllllllllllllllllllllllllllllll$				
S3CV_1207_07_MV (V_C_18), S3CV_1210_02_MV (V_S_03), S3CV_1210_04_MV (V_S_05), S3CV_1210_05_MV (V_S_06), S3CV_1210_07_MV (V_S_08), SV_1210_02_MV (V_S_12),		· · · · · · · · · · · · · · · · · · ·		
\$3CV_1210_07_MV (V_\$_08), \$V_1210_02_MV (V_\$_12)	S_F_Cir2_00	01		
	<u></u> ر			

Description : • Input HMI: SCI_F_Cir2 • The operation begins with 3 conditions:			:					
<ul> <li>O Use of the HMI input</li> <li>F_Mode_Stop_OK: all FU valves are set in OFF (closed), the pumps</li> </ul>	11/06/2008 12:28	NC	not existing in HMI ; forced throu rk: PMP_F_05 is not existing any		ew HW			
<ul> <li>PMP_F_01 and PMP_F_05 are stopped and the pump PMP_F_02 is ON</li> <li>TB_C_Cl2: the tracing bit is ON</li> <li>All valves involved in the filtration through membrane Fi_F_02 are set in</li> </ul>		C C	PMP_F_02 can be ON but not sp forced through PLC					
<ul> <li>In the specific state.</li> <li>The pump PMP_F_01 starts</li> </ul>		C NC	V_F_01, 03, 04, 06 ON, the othe the pump does not start immedia the SCI_PMP_F_01_RUN variab	ately	rced			
Question: 1. Why is the state of the valve V_C_02 used here?								
<ol> <li>The variable TB_C_Cl2 is used once (only read), so never SET or RESET whereas there is a tracing bit TB_Cl2 used in PLC subroutine C_Cl2 (it is SET and then RESET later)</li> </ol>				S_F_Fil_00	1:	•		· · ·
PLC Subroutine : F_Fil	11/06/2008 12:29	3 6	conditions: PMP_F_01 is ON	T_F_Fil_001	wait for comman PMP_F_01 mus		valves must be s	witched for filtration
		AND Valves in Cir1 or Cir2 are OK AND SCI_F_Fil			start PMP_F_02			
				S_F_S12_S	t_PMP_F_02	•	•	· · ·
					: · · · · · · · · · · · · · · · · · · ·			· · · · · · · · · · · · · · · · · · ·
				~PMP_F_02	: :			· · · ·
				S_F_FII_EN	ireset sequence D.	command flag	•	· · ·
Variables Used (1/0):				1		•	•	
See above; The variables involved depend on the type of the filtration: if the filtration is					i sa sa s s			 
through membrane Fi_F_01 or Fi_F_02 Description :				<u>/s_f_fil</u> z		•	•	• •
<ul> <li>Input HMI: SCI_F_Fil</li> <li>The operation begins with 3 conditions:</li> <li>Use of the HMI input</li> </ul>			variables have to be forced throu	igh PLC				
<ul> <li>PMP_F_01 is ON</li> <li>The state of all valves involved (Cir1 or Cir2) is OK</li> </ul>		С	the parameter for pump calibration	on				
		NC	F_Filtration_flowrate_cal_factor I before : value=1, then SCI_F_Fil PMP_F_02_Speed=600 : the put	tration_rate=30	00, and			
• The pump PMP_F_02 starts			but the relay 17 DO 24V right sid is blinking ON/OFF continuously it seems this routine has no adde PMP_F_02 is already ON from ro	le in the PLC c ed value becau	abinet se			
- The condition to end the procedure is that the pump PMP_F_02 is turn OFF			it seems the reason of the blinkir					
Recommendations / changes.	VHEN	WHC	D					
HW modifications		UAB	1					
PLC programme modifications check the added value of routine SCI_F_Fil		SHE	RPA					
HMI modifications Local		NTE						
introduce on the screen the buttons corresponding to the variables used in the three procedures above introduce on a screen the parameters for PMP_F_01 and 02								
Remote see local								

Variables

others

Procedure steps	date/hou	r N/NC comments
<b>1.1. Procedure 36: Filtration</b> Unit: Switch from or membrane to the other Fi-F-01 / Fi-F-02 <i>Prerequisite</i>	ne	see proc 35
FU must be filtrating over one of the two membranes in nominal or recycle mode. The membrane that is switched over from must be clear and preserved in clear water if it remains in the membrane module.		
<b>Procedure</b> Use the HMI to 1. Stop the FU: SCI_F_Stop 2. PROCEDURE 35: Filtration Unit: Start up of filtration through membra Fi-F-01 / Fi-F-02.	ane	
SCI variables : SCI_F_Stop, SCI_F_Cir1, SCI_F_Cir2, SCI_F_Fil		
<i>PLC Subroutine</i> : F_Stop, F_Cir1, F_Cir2, F_Fil These subroutines are described above in PROCEDURE 29 and PROCEDU 35	IRE	ok made through procedure 35
Variables Used (I/O):		
The same variables as variables involved in F_Stop, F_Cir1, F_Cir2, F_Fil		
Question: The procedure seems not complete because the switch could be done directly by the HMI buttons: SCI_F_S12, SCI_F_S21. The corresponding PLC subroutines F_S12 and F_S21 exist	De	
Recommendations / changes	WHEN	WHO
HW modifications		UAB
PLC programme modifications		SHERPA
HMI modifications Local		NTE
Remote		
Variables		
others		

Procedure steps	date/nour	N/NC	comments	SHERPA comments	NIE comments
1.1. Procedure 37: Filtration Unit: Enter Recycle mode Scope Switch V-F-08 to recycle the produced filtrate back to the bioreactor instead of leading it into the effluent vessel. This procedure is called automatically when the effluent vessel is full. It might be used before CIP and SIP procedures for the effluent vessel R-F-01. Precequisite FU must be filtrating over one of the two membranes in nominal mode. Procedure 1. Press button 'Recycle mode' on the HMI: SCI_F_Rec,			missing prerequisite : V_R_10 is open!		
SCI_F_Rec_ERR_Level_High	10/06/2008 18:5	4 NC	no recycling mode on the HMI		
SCI variables : SCI_F_Rec, SCI_F_Rec_ERR_Level_High PLC Subroutine : F_Rec					
		c	PMP_F_02 was set OFF but continued to run; the only way to stop the flow was to set the cal factor to 0; these parameters were set manually through PLC PMP_F_02 was actuated through PLC why is the recycling mode asking for PMP_F_02 to be stopped while the filtrate has to be sent again to the		
Variables Used (I/O): All valves involved in the Filtration (see PROCEDURE 35), S3CV_1202_02_MV (V_F_08) Description: Input HMI: SCL_F_Rec or SCL_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced filtrate to return to the bioreactor R_R_01 instead of harvesting it from the effluent vessel R_F_01		с	bioreactor through PMP_F_02 ?		SCI_F_Rec OR SCI_F_Rec_ERR_Level_High AND PMP_F_01 is ON AND PMP_F_02 is OFF AND Valves involved in Filtration are OK TB_F_Nom is RESET AND F_Valvestate_Rec_S AND SCI_F_Rec is SET
Recommendations / changes	WHEN	WHO	r_mode_rec_on reset sequence command fi	a0	
HW modifications		UAB		-• . 	
PLC programme modifications		SHERPA	1 <b>+</b>	•	
HMI modifications Local		NTE	∑s_F_Re⊋001	· · · · · · · · · · · · · · · · · · ·	
present SCI variables on the HMI			<u>/</u> /		

user Manual missing prerequisite : V\_R\_10 is open!

Remote present SCI variables on the HMI

	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 37: Filtration Unit: Enter Recycle mode Scope					
Switch V-F-08 to recycle the produced filtrate back to the pioreactor instead of leading it into the effluent vessel. This procedure is called automatically when the effluent vessel is full. It might be used before CIP and SIP procedures for the effluent		)	line 1 of FU is ON		
Prerequisite FU must be filtrating over one of the two membranes in nominal mode.			missing prerequisite : V_R_10 is open!		
Procedure I. Press button 'Recycle mode' on the HMI: SCI_F_Rec, SCI_F_Rec_ERR_Level_High	11/06/2008 13:11	NC	no recycling mode on the HMI		
CI variables : SCI_F_Rec, SCI_F_Rec_ERR_Level_High					
LC Subroutine : F_Rec					
		с	PMP_F_02 was set OFF but continued to run; the only way to stop the flow was to set the cal factor to 0;		
		NC	setting OFF PMP_F_02 triggered PMP_F_01 OFF		
		С	these parameters were set manually through PLC		
			PMP_F_02 was actuated through PLC why is the recycling mode asking for PMP_F_02 to be stopped while the filtrate has to be sent again to the		
			bioreactor through PMP_F_02 ?		
All valves involved in the Filtration (see PROCEDURE 35),					
all valves involved in the Filtration (see PROCEDURE 35), 3CV_1202_02_MV (V_F_08) Description:			V_F_08 opened but since PMP_F_01 had stopped, not useful		
Il valves involved in the Filtration (see PROCEDURE 35), 3CV_1202_02_MV (V_F_08) <b>escription:</b> Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced Itrate to return to the bioreactor R_R_01 instead of harvesting it		NC	V_F_08 opened but since PMP_F_01 had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should be used to reprogram the routine		
Il valves involved in the Filtration (see PROCEDURE 35), 3CV_1202_02_MV (V_F_08) <b>escription:</b> Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced Itrate to return to the bioreactor R_R_01 instead of harvesting it		NC	had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should		CI F Rec OR SCI F
Il valves involved in the Filtration (see PROCEDURE 35), 3CV_1202_02_MV (V_F_08) escription: Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced trate to return to the bioreactor R_R_01 instead of harvesting it om the effluent vessel R_F_01	WHEN	NC	had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should be used to reprogram the routine	it is in nominal mode AN	CI_F_Rec OR SCI_F ID PMP_F_01 is ON ID PMP_F 02 is OF
Il valves involved in the Filtration (see PROCEDURE 35), 3CV_1202_02_MV (V_F_08) Description: Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced Itrate to return to the bioreactor R_R_01 instead of harvesting it om the effluent vessel R_F_01 ecommendations / changes_	WHEN		had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should be used to reprogram the routine	it is in nominal mode AN AN AN TE	ND PMP_F_01 is ON ND PMP_F_02 is OF ND Valves involved 3_F_Nom is RESET
Il valves involved in the Filtration (see PROCEDURE 35), 3CV_1202_02_MV (V_F_08) Description: Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced Itrate to return to the bioreactor R_R_01 instead of harvesting it om the effluent vessel R_F_01 ecommendations / changes. W modifications LC programme modifications te recirculation mode should be activated automatically when the	WHEN	WHO	had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should be used to reprogram the routine S_F_Rec_001 switch valves S_F_Rec_002 switch valves S_F_Rec_002 switch valves S_F_Rec_002 switch valves are in positi	AN AN TE AN	ND PMP_F_01 is ON ND PMP_F_02 is OF ND Valves involved
Il valves involved in the Filtration (see PROCEDURE 35), 3CV_1202_02_MV (V_F_08) escription: Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced trate to return to the bioreactor R_R_01 instead of harvesting it om the effluent vessel R_F_01 ecommendations / changes. W modifications = recirculation mode should be activated automatically when the fluent tank is full (not programmed today) WI modifications	WHEN	WHO UAB	had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should be used to reprogram the routine	it is in nominal mode AN AN AN TE AN AN	ND PMP_F_01 is ON ND PMP_F_02 is OF ND Valves involved 3_F_Nom is RESET ND F_Valvestate_Re
All valves involved in the Filtration (see PROCEDURE 35), S3CV_1202_02_MV (V_F_08) Description: Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced iltrate to return to the bioreactor R_R_01 instead of harvesting it rom the effluent vessel R_F_01 Recommendations / changes IW modifications PLC programme modifications he recirculation mode should be activated automatically when the effluent tank is full (not programmed today)	WHEN	WHO UAB SHERPA	had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should be used to reprogram the routine	it is in nominal mode AN AN AN TE AN AN	ND PMP_F_01 is ON ND PMP_F_02 is OF ND Valves involved 3_F_Nom is RESET ND F_Valvestate_Re
iltrate to return to the bioreactor R_R_01 instead of harvesting it rom the effluent vessel R_F_01 Recommendations / changes_ HW modifications PLC programme modifications he recirculation mode should be activated automatically when the siffluent tank is full (not programmed today) HMI modifications Local	WHEN	WHO UAB SHERPA	had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should be used to reprogram the routine	it is in nominal mode AN AN AN TE AN AN	ND PMP_F_01 is ON ND PMP_F_02 is OF ND Valves involved 3_F_Nom is RESET ND F_Valvestate_Re
All valves involved in the Filtration (see PROCEDURE 35), S3CV_1202_02_MV (V_F_08) Description: Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High The valve V_F_08 is SET in position to allow the produced iltrate to return to the bioreactor R_R_01 instead of harvesting it rom the effluent vessel R_F_01 Recommendations / changes W modifications PLC programme modifications he recirculation mode should be activated automatically when the ffluent tank is full (not programmed today) IMI modifications Local present SCI variables on the HMI Remote	WHEN	WHO UAB SHERPA	had stopped, not useful the simple setting/resetting of F_Valvestate_Rec_S/R is needed to open or close the V_F_08 : this should be used to reprogram the routine	it is in nominal mode AN AN AN TE AN AN	ND PMP_F_01 is ON ND PMP_F_02 is OF ND Valves involved 3_F_Nom is RESET ND F_Valvestate_Re

If the FU is working in recycle mode, this procedure switches V-F. 08 back to its nominal position to re-enter nominal filtration mode, where the produced filtrate is lead to the effluent vessel. This procedure is called automatically when the unit is in recycle mode and the effluent vessel is harvested.		
<b>Prerequisite</b> FU must be filtrating over one of the two membranes in recycle		
mode.		FU in recylcling mode following proc 37
<b>Procedure</b> 1. Press button 'Nominal mode' on the HMI: SCI_F_Rec, SCI_F_Rec_ERR_Level_High	10/06/2008 19:34	
<i>SCI</i> variables : SCI_F_Rec, SCI_F_Rec_ERR_Level_High, SCI_F_Nom		
PLC Subroutine : F_Nom		
	NC	SCI_F_Rec does not exit on the HMI but it could be forced ON through PLC
	С	
	C	
	С	
Variables Used (I/O): All valves involved in the Filtration (see PROCEDURE 35), S3CV_1202_02_MV (V_F_08)		
<ul> <li>Description:</li> <li>Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High</li> <li>F_Mode_Nom_S: the valves involved in Filtration are in position</li> <li>F_Valvestate_Rec is RESET means the valve V_F_08 is SET in position OFF to leave Recycle mode and to lead the produced filtrate into Effluent vessel R_F_01.</li> </ul>	10/06/2008 19:43 C	OK observed V_F_08 returned to OFF
S_F_Nom_001 wait for command while unit is in recycle mode T_F_Nom_001 switch valve S_F_Nom_002undle TB	TB_F_Rec AND F_Mode_Nom	
	TB_F_Rec is RESET F_Valvestate_Rec i	s RESET
F_Mode_Nom_OK reset sequence command flag	SCI_F_Nom is RESE AND TB F Nom is 1	
<u>&gt;s_F_Nor</u> _001	•	
Recommendations / changes	WHEN WHO	
HW modifications	UAB	
	UAB	
PLC programme modifications	SHERPA	A
HMI modifications	NTE	
Local SCI_F_Rec to appear on the screen		

date/hour

N/NC comments

SHERPA comments NTE comments

Procedure steps

mode Scope

1.1. Procedure38: Filtration Unit: Enter Nominal
		· · · · ·
1.1. Procedure38: Filtration Unit: Enter Nominal mode Scope		
If the FU is working in recycle mode, this procedure switches V-F- 08 back to its nominal position to re-enter nominal filtration mode, where the produced filtrate is lead to the effluent vessel. This procedure is called automatically when the unit is in r	11/06/2008 13:20	line 1 of FU is in use with recycling mode
Prerequisite FU must be filtrating over one of the two membranes in recycle mode.		FU in recycling mode following proc 37
<b>Procedure</b> 1. Press button 'Nominal mode' on the HMI: SCI_F_Rec, SCI_F_Rec_ERR_Level_High		
<b>SCI variables</b> : SCI_F_Rec, SCI_F_Rec_ERR_Level_High, SCI_F_Nom		
PLC Subroutine : F_Nom		
	NC	SCI_F_Rec does not exit on the HMI but it could be forced ON through PLC
	С	
	С	
	С	
S_F_Nom_001 TB_F_Rec AND F_Mod switch valve s_F_Nom_002/sindle TB TB_F_Rec TB_F_Rec TB_F_Rec TB_F_Rec TB_F_Rec TB_F_Rec S_F_Nom_002/sindle TB TB_F_Rec S_F_Nom_002/sindle TB TB_F_Rec S_F_Nom_002/sindle TB S_F_Nom_O2/sindle TB	ode_Nom_S	OK observed V_F_08 returned to OFF
<u>}S_F_Nop}_001</u>		
Recommendations / changes	HEN WHO	
HW modifications	UAB	
PLC programme modifications	SHEF	RPA
PLC programme modifications HMI modifications Local	SHEF	RPA

Remote SCI\_F\_Rec to appear on the screen

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 39: Filtration Unit: Harvest Effluent vessel R-F-01					
Scope Harvest the effluent production contained in the effluent vessel R-F-01.					
This procedure can also be used to evacuate any aventual liquid content in the effluent vessel, for instance cleaning agent left after interruption of a cleaning procedure that includes the effluent vessel.			missing prerequisite : manual valve downstream V_F_10 and upstream FI-S-03		
The vent V-F-12 is closed and 1 barg pressurized N2 is applied by V-G-21 to evacuate liquid through V-F-10.			for the tests, the N2 is replaced by air instrument 1,5barg initial conditions : PS F_09 = 0,145barg, vol		
Procedure			effluent=9,12L (LS_F_03=22,9), LS_F_01 and 02 are ON		
<ol> <li>Make sure tubing connects V-F-10 to a vessel with</li> <li>= 20 L free space.</li> </ol>			after installation, this tubing was connected to the collector to the sewage waters		
<ol> <li>Press button 'Harvest': SCI_F_Harvest</li> <li>Wait for the PLC procedure to finish. During narvesting the command button is colored green and tates 'Harvesting'</li> </ol>		С			
-					
CCI variables : CCI_F_Harvest_isVesselPresent, CCI_F_Harvest_isVesselGone					
PLC Subroutine : F_Harvest					
Fig : PLC procedure: F_Harvest			$\begin{array}{l} SCI_{}F\text{-Harvest could be actuated from the HMI}\\ SCI_{}F_{}\text{-Harvest}_{}is/vessel/cosent,\\ SCI_{}F\text{-Harvest}_{}is/vessel/cone are both OFF\\ V_{}F_{}10 and V_{}6_{}21 opened both\\ \underline{PS}_{}F_{}09 = 0.42 barg \end{array}$		
		NC	SCI_F_Harvest_IsVesselPresent was OFF but did not prevent the following steps		
		с	V=4,1L (LS_F_03 = 0), LS_F_02 switched from ON to OFF, triggering the closing of V_F_10 and V_G_21		
Variables Used (I/O): V_F_12, V_G_21, V_F_10					
Description: Input HMI: SCI_F_Harvest The Vessel for harvesting must be present and					
<ul> <li>The vessel for harvesting must be present and valves are in position</li> <li>The harvest begins and continue until the level</li> </ul>					
switch is OFF Valves are RESET and the harvesting vessel is taken		c			
off Recommendations / changes_	WHEN	c WHO	l	<u> </u>	
HW modifications section of soft tubing between V_G_21 and gas filter for					
effluent tank to be replaced by metal section of hose between filter and effluent tank to be modified to preserve axenicity : replace by metal		UAB			

Procedure that empties R_F_01						i.			
						1			1
S_F_Harvest_001						1			
						÷			÷
wait for command						1			÷
SCLE Happest						1			
Ask if vessel is present	1		1			1			1
177 6						1			
SCI_F_Harvest_IsVesselPreser	<u>, 1</u>	•		• •	• •			• •	
			- 1			1			
Close V_F_12									
									1
V_F_12_FB									
V_F_12_FB Open valve V_G_21 (N2 @ 1 i S_5 Harvert 008	barg)	• •	11	• •	• •			• •	
S_F_Harvest_006									
			÷			÷.			÷
						÷			÷
V_G_21_FB	1.		. 1			1			÷
Open V_F_10 S_F_Harvest_008						:			
	-		÷			÷			÷
		• •			• •			• •	
F_Mode_Harvest_OK						1			
duration measured 2m40s	- ÷ +		÷÷	• •	• •		• •	• •	
	-		-			÷			÷
wait until low level detection	÷.,		- 1			÷			÷
wait until low level detection									
~LS_F_02 			. :			÷			÷
wait S_F_Harvest_007						÷			
						1			
1 <b></b>	-		÷			÷			÷
dose V-G-21			1	• •	• •	1		• •	1
S_F_Harvest_004						1			
	4.		- 1						÷
						÷			
~V_G_21_FB									
reset valves		• •		• •	• •			• •	-
S_F_Harvest_005			•	• •	• •			• •	-
reset valves S_F_Harvest_005		•••		•••				•••	
S_F_Harvest_005		•••		•••				•••	
S_F_Harrest_005		· ·		· ·	•••			•••	
T_F_Harver_005								• •	
reset valves S_F_Hanvest_008 T_F_Hanvest_008 Ask to take vessel avey S_F_Hanvest_010		· ·		· ·	· ·			· ·	
reset talvés     reset talvés     reset talvés     reset talvés     reset talvés to be reset     reset talvés to be reset     reset talvés to talvé velset avey     reset talvés to talvé velset avey     reset talvés to talvé velset avey		· ·		· ·	· ·			· ·	
Inset valves           S_F_Hanest_000           Maint for valves to be reset		· ·		· ·	· ·			· ·	
Inset valvés S_F_Harver_000 Ask to (ské vesse) avay S_F_Harver_010 S_F_HAV S_F_F S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV S_F_FAV		· ·		· ·	· ·			· ·	
Inset tables		· ·		· ·	· ·			· ·	
SF_Harvet_0     SF_Harvet_0     SF_Harvet_0     SF_Harvet_0     SF_Harvet_0     SF_Ftarvet_0     SF_Fta		· · ·		· · ·	· · ·			· · ·	
Inset tables		· · ·		•••				· · ·	
Inset tables		· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·	· · ·			· · ·	
SE_Hanvet_008     As to take vessel anay     SE_Hanvet_010     As to take vessel anay     SE_Hanvet_010     SELF_Hanvet_10Vessel@one     SELF_Hanvet_010     SELF		· · ·		· · ·	•••			· · ·	
As to take vessel array S_F_Harvest_005 As to take vessel array S_F_Harvest_010 SCL_F_Harvest_INVesselBone CL_F_Harvest_INVesselBone S_F_Harvest_INVESSelBone S_F_Harvest_INVESSE S_F_Harvest_INVESSE S_F_Harvest_INVESSE S_F_Harvest_INVESSE S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_HARVEST S_F_F_HARVEST S_F_F_HARVEST S_F_F_HARVEST S_F_F_HARVEST S_F_F_F_F_F_F_F_F_F_F_F_F_F_F_F_F_F_F_F		· · ·		· · ·	· · · · · · · · · · · · · · · · · · ·			· · ·	

HW modifications section of soft tubing between V_G_21 and gas filter for effluent tank to be replaced by metal section of hose between filter and effluent tank to be modified to preserve axericity: replace by metal modify the tubing downstream V_E_10 in order to allow also the collection of filtrate in a dedicated vessel, and not to be obliged to send it to the sewage, with an additional manual valve or diaphragm valve	UAB
PLC programme modifications include additional user written parameters for presence/absence of vessel to recover the effluent possible improvement : activate V_F_08 in order to isolate effluent tank from filtrate	SHERPA

HMI modifications NTE Local

Remote

Variables

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 40: Drain Filtration Unit: retentate				1	
line Scope			change as Drain into Bioreactor	-	
Drain the retentate line of the FU. If the purpose is to shut down				-	
and clean the entire system, use PROCEDURE 46: Shut down the System, drain, rinse and clean Bioreactor R-R-01, Feeding					
vessel R-V-01 and Filtration unit. The description below may need adaptation as it is never been				-	
executed before.				-	
Prerequisite					
FU is stopped (can be done by procedures 17 or 29)					
Procedure				-	
1. Drain the retentate in the FU at the pressure side of PMP-F- 01 via R-R-01 by opening V-F-06 and V-G-20. If the hose at V-R-					
09 is connected and V-R-09 is open, the liquid will be pushed into the bioreactor. Switch both V-F-03 and -04 to empty the					
second membrane. Switch both V-F-02 and -05 to drain the					
bypass piece. 2. Close V-R-09.				-	
<ol> <li>Stop PMP-F-01</li> <li>Close V-F-06.</li> </ol>				-	
5. Stop PMP-F-02 and start it backwards.				-	
<ol> <li>Close V-R-08 when gas starts entering R-R-01.</li> <li>Stop PMP-F-01</li> </ol>				-	
8. Close V-F-01 and and V-G-20.				-	
SCI variables :????				-	
PLC Subroutine : No SFC procedure					
Variables Used (I/O):					
$V_{F_{0}}^{(1)}$ V_F_6, V_G_20, V_F_03, V_F_04, V_F_02, V_F_05,					
PMP_F_01, PMP_F_02, V_F_01				-	
Description: No more description; the procedure is explicit				-	
enough.					
Recommendations / changes	WHEN	WHO			
HW modifications					
The modifications		UAB			
PLC programme modifications		SHER	PA		
HMI modifications Local		NTE			
Remote					
Variables					
·······					

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 41: Drain Filtration Unit: inside membranes Fi-F-01/Fi-F-02 Scope					
Drain and rinse the retentate inside one membrane of the FU.					
<b>Prerequisite</b> The filtration unit must not be running over the membrane that is to be drained.					
<b>Procedure</b> 1. Dilute the retentate with water using PROCEDURE 49: Cleaning of Filtration Unit: retentate side of membrane Fi-F-01 / Fi-F-02: SCI_C_Cl1 or SCI_C_Cl2					
2. Drain the retentate in the FU by actuating V-C-19 and V-F- 15 (Fi-F-01) or V-F-14 (Fi-F-02): SCI_C_V_C_19_S, SCI_C_V_C_18_S, SCI_C_CB_to_drain1, SCI_C_CB_to_drain2					
<i>SCI</i> variables : SCI_C_Cl1, SCI_C_Cl2, SCI_C_V_19_S, SCI_C_18_S, SCI_C_CB_to_drain1, SCI_C_CB_to_drain2					
PLC Subroutine : No SFC procedure					
Variables Used (1/0): All variables used in PROCEDURE 49, V_C_19, V_F_15, V_C_18, V_F_14					
Description: No more description; the procedure is explicit enough.					
Recommendations / changes	WHEN	WHO	<u>.</u>		
HW modifications		UAB			

PLC programme modifications

HMI modifications Local NTE

SHERPA

Remote

Variables

$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$					SHERPA	NTE			
atter determined with a first of the data of th	rocedure steps	date/hour	N/NC	comments					
Control of the control of the index of	.1. Procedure 49: Cleaning of Filtration								
a more deep services is to too be not and out of the notation	Init: retentate side of membrane FI-F-01 / FI-F- 2								
<pre>tetrace. Track to under the other set register tetrace. Track to under the other set register tetrace to under tetrace to under tetrace to under tetrace tetrace to under tetrace to under tetrace to under tetrace tetrace to under tetrace to under tetrace to under tetrace tetrace to under tetrace to under tetrace to under tetrace tetrace to under tetrace to under tetrace to under tetrace tetrace to under tetrace t</pre>	Scope								
be basis basis down loong of the methode is a divergence of the control of the	he aim of this procedure is to clean the inside of a								
Socked # 1.2.4. The provider many by out is included starting the more many of the socket	nembrane. It may be useful to do this on a regular me basis to slow down fouling of the membrane as								
and of Brandson Unit both Indicate and these interview and address of the matrixes of the matr	escribed in § 7.2.4. This procedure must be used to								
home and a large of the submarks of a reaction is a source of a reaction is the source of a reaction is the source of the reaction is the reaction is the reaction is the source of the reaction is the rea	leaning of Filtration Unit: both retentate and filtrate								
CICCULUME, ACCOUNTS, CLAR AND ALL CLAR AND	le of membrane Fi-F-01 / Fi-F-02.								
contain the subject of productions to determine to determine the subject of	utomated cleaning of the membranes as described in								
Pile 5 method       Image: Status 10 / 2011         Status 10 / 2011       Image:	xecution of a sequence of procedures to clean								
Seeding     Image: Control of the interview of t	embrane Fi-F-01 / Fi-F-02 will call this procedure in the PLC a number of times								
an be granted by 7.2 million and the methodenes of the product is to be a second of the product is									
yr e Staffer         10000011001           Staffer         10000001001001           Staffer         1000000100000000000000000000000000000	rocedure								
the full to stury the view first proceeds is to temporal and the stury from the proceeds is to temporal operation of the stury opera	ake the precautions and advise on the membranes as	11/06/2008 19:20							
SSL_Classing Apert define whether dear is the two darking by the production or n.	e the HMI to set up how this procedure is to be	11/00/2008 18:30							
bit is but out (SLC_Chamma, Jupent: - all) or main (SLC_Chamma, Jupent:									
Set if the metadary which indication one PC- to a distance of all products of the PC- the ord diaming grant is dorked. III. 2 of the R- the ord diaming grant is dorked. III. 2 of the R- No. In the Month Is start the product CCL for product PC-OL for the Month III. 2 of the R- Source of all products the contents of the R-COL the PC-OL for Ideal Water of the R-COL for Ideal Water of the R-COL the PC-OL for Ideal Water of the R-COL for Ideal Water of the R-COL the PC-OL for Ideal Water of the R-COL for Ideal Water of t	ter is to be used (SCI_C_Cleaning_Agent = off) or								
b B b deck.         Image: Solution is to be heads         Image: Solution is to be heads           w dot decking synth decked. If 2, d in Res.         Image: Solution is to be heads         Image: Solution is to be heads            Image: Solution is to be heads         Image: Solution is to be heads         Image: Solution is to be heads            Image: Solution is to be heads         Image: Solution is to be heads         Image: Solution is to be heads            Image: Solution is to be heads         Image: Solution is to be heads         Image: Solution is to be heads            Image: Solution is to be heads         Image: Solution is to be heads         Image: Solution is to be heads            Image: Solution is to be heads         Image: Solution is to be heads         Image: Solution is to be heads            Image: Solution is to be heads         Image: Solution is to be heads         Image: Solution is to be heads            Image: Solution is to be heads         Image: Solution is to be heads         Image: Solution is to be heads               Image: Solution is to be heads			-	coula not be checked					
Transfer: SCI_CII, VA SPLC_CII, SCI_CCII, SCIII, SCI_CCII, SCI_CCIII, SCIII, SCIII, SCIIII, SCIIII, SCIIII, SCIIII, SCIIII, SCIIII, SCIIIII, SCIIIII, SCIIIII, SCIIIII, SCIIIIIIIIII	is to be done.		<u> </u>						
35.       No       No <t< td=""><td>ring circulation or not.</td><td></td><td> </td><td></td><td></td><td></td><td></td><td></td><td></td></t<>	ring circulation or not.								
a the life up dark the product C_01 for L_011.5(L_02.C_02 The initiates headon to be the second to the second to be the C_011.5(L_02.C_02.C_02.C_01.5) initiates headon to be the the life to the control to the lower of G_02.0.       Image to the the life to the control to the life to the lower of G_02.0.         MP-02 directions the contents of the R_00 C 02.0.       Image to the the life to the lower of G_02.0.       Image to the the life to the control to the life to the lower of G_02.0.         MP-02 directions the contents of the R_00 C 02.0.       Image to the the life to the control to the life to the life to the life to the control to the life to the life to the life to the control to the life to the life to the life to the control to the life to the life to the life to the control to the life to the life to the life to the life to the control to the life to the control to the life to the life to the life to the control to the life to the control to the life to the			NC	this is not taken into account					
method is FLO or C.20 for membrane FLO2       1060200 it 50         Control of C-D in Must be detroined       0         method parts FLO_FLI, WA SOLCFLIGA       0         Control of C-D in SUL C-D in SUL C-D in SUL C-PLIGA       0         MP-C-D control of C-D in SUL C-D in SUL C-PLIGA       0         In SUL C-D in SUL C-D in SUL C-PLIGA       0         In SUL C-D in SUL C-D in SUL C-PLIGA       0         In SUL C-D in SUL C-D in SUL C-PLIGA       0         In SUL C-D in SUL C-D in SUL C-PLIGA       0         In SUL C-D in SUL C-D in SUL C-PLIGA       0         In SUL C-D in SUL C-D in SUL C-PLIGA       0         In SUL C-D in SUL C									
R.C.D. In first with water and - if detect- ming apert SLC_PR_MA or SLC_PIL       Image: SLC_PR_MA         DAME_05 circulates the contents of the RC_O2 in the paper for VC_D1 (Pri-CO) Normal papers stC_PR_MA       Image: SLC_PR_MA         DAME_05 circulates the contents of the RC_O2 in the paper for VC_D1 (Pri-CO) Normal papers stC_PR_MA       Image: SLC_PR_MA         Normal papers stC_PR_MA       Image: SLC_PR_MA       Image: SLC_PR_MA         Normal stC_PR_MA       Image: SLC_PR_MA       Image: SLC_PR_MA       SLC_PR_MA         Normal stC_PR_MA       Image: SLC_PR_MA       Image: SLC_PR_MA       SLC_PR_MA       SLC_PR_MA         Normal sto Ima	mbrane Fi-F-01 or C_Cl2 for membrane Fi-F-02:								
androg agent Sci LC, FIL, WA & SCI LC, Chi LCA Control of R-C03 inclusions the contents of the R-C02 diffe period prom VC-16 (Fil-10) resp. V-C1 (Fil-10) LOBOODE 18:0/CC Provide a state base in the result of t		11/06/2008 18:35							
ther R-C 02.      C      Dep C 03 includes the contents of the R-C 02     difference contents     difference contents     difference contents     difference contents     difference contents     difference contents     difference	aning agent: SCI_C_FIII_WA or SCI_C_FIII_CA		с						
Ithe paint from VC-16 (FI-50) resp. VC-18 (FI-50) resp.			с						
11b by byte (b) (F) (F) (F) (F) (F) (F) (F) (F) (F) (F	PMP-C-03 circulates the contents of the R-C-02								
Juding the relevance side of the membrane:       Interpretation been adapted by the PLC.         Interpretation:       Interpretation:         SP-67 // PS-60 - = 0.16 barg       Interpretation:         PS-67 // PS-60 - = 0.16 barg       Interpretation:         Interpretation:       Interpretation:         PS-67 // PS-60 - = 0.16 barg       Interpretation:         Interpretation:       Interpretation:         PS-67 // PS-60 - = 0.16 barg       Interpretation:         Interpretation:       Interpretation:         PS-67 // PS-60 - = 0.16 barg       Interpretation:         Interpretation:       Interpretation:         PS-67 // PS-60 - = 0.16 barg       Interpretation:         Interpretation:	d the piping from V-C-16 (Fi-F-01) resp. V-C-17 (Fi-F								
Normal pressure are:       SC-10 / PS-C 4 - 1.15 karg to 1.32 barg         PS-F0 / PS-F0 / PS-F0 - 2.44 barg         Toroise gradually in time)         Now densing agent can read particles that could         It be rised with value R-C0-15 filled with densing agent         It be rised with value R-C0-15 filled with densing agent         It be rised with value R-C0-15 filled with densing agent         It be rised with value R-C0-15 filled with value ragin         It be rised with value R-C0-15 filled with value ragin         It with be structure filled with value ragin         It with be structure filled with value ragin         It with be structure filled with value ragin         It with value R-C0-15 filled with value ragin         It with value R-C0-15 filled with value ragin         It with be structure filled with value ragin         It with value R-C0-15 filled with value ragin         It with value R-C0-15 filled with value ragin         It with value R-C0-15 filled with value ragin         It with be structure filled with value ragin         It with be structure filled with value ragin         It with walue R-C0-15 filled with value ragin         It with walue R-C0-15 filled with walue ragin         It with walue R-C0-15 filled with walue ragin         It with walue R-C0-15 filled with walue ragin         It with walue ragin		11/06/2008 18:40	NC	this step has been skipped by the PLC					
Transes galadaly in time) PS-620 /PS-620 - 0.44 barg PS-620 /PS-620 /PS-620 - 0.44 barg PS-620 /PS-620 /PS-620 - 0.44 barg PS-620 /PS-620	Normal pressures are: PS-E-01 / PS-E-04 == 1.15 barg to 1.32 barg								
PS-F-04/PS-F06 -= 0.49 barg Now dealing agent on reach particles that could be rined with water. R-0.16 filled with dealing C_FIIL_CA When the particles are in contact with the ning agent for some time they soak off and can be contact with water agent the bioractic in filled with water agent for some time they soak off and can be contact with water agent the bioractic in filled with water agent for some time they soak off and can be contact with water agent for some time they soak off and can be contact with water agent the bioractic in filled with water agent for some time they soak off and can be contact with water agent for some time they soak off and can be contact with water agent for some time they soak off and can be contact with water agent for some time they soak off and can be contact with a particles are removed for some time they soak off and can be contact with a particles are removed for some to be they soak off and can be contact with a particles are removed for some to water off a log 2 with some source of a source of a some source of a source of	reases gradually in time)								
Lbe integration to not denote the spatial with cleaning agent contract with the moning agent for some time they sold of and can be noted with water. R-C-01 Is filled with water agent and C-D_C_FIL_QA.  When the particles are in contact with the moning agent for some time they sold of and can be noted with water. R-C-01 Is filled with water agent and C-D_C_FIL_QA.  When the particles are removed in PROCEDURE 61 and C-D_C_COLORING agent for sole of the moning agent in C-D_C_FIL_QA.  C Subroutine: C_C11  Fig: PIC procedure: C_C1  F							Procedure for cleaning mbne 1		
end, which is then squiried into R-R-01       SCL C (14 AND         L_CPILCA       SCL C (14 AND         aning agent for some time they soak off and can be noned with water agant       SCL C (14 AND         BL C (15 BLG with water agant       SCL C (14 AND         The interactor is finded with water agant       SCL C (14 AND         The water with a particles are in contact with the aning agent       SCL C (14 AND         The interactor is finded with water agant       SCL C (14 AND         The water with a particles are removed       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C FILWA       SCL C (14 AND         L_CPMP_CO IP, SCL C (10 AND       SCL C (14 AND         L_CPMP_CO (17)       SCL C (14 AND         L_CPMP_CO (17)       SCL C (14 AND         SCL C (10 AND       SCL C (14 AND									•
When the particles are in contact with the aning agent for some time they soak off and can be noved with water agent due bioreactor is fined. SLC_LTM_WA       SLC_CTAL RES         SCL_CTAL RES       SCL_CCL STAL       SCL_CCL STAL         Partifies proceed with water agent       SCL_CCL STAL       SCL_CCL STAL         If a partifies or conved       SCL_CCL STAL       SCL_CCL STAL         If a partifies proceed with water agent       SCL_CCL STAL       SCL_CCL STAL         If a partifies proceed with water agent       SCL_CCL STAL       SCL_CCL STAL         If a partifies proceed with water agent       SCL_CCL STAL       SCL_CCL STAL         If a partifies proceed with water agent       SCL_CCL STAL       SCL_CCL STAL         If a partifies proceed with water agent       SCL_CCL STAL       SCL_CCL STAL         If a partifies proceed with water agent       SCL_CCL STAL       SCL_CCL STAL         If a partifies proceed with water agent       SCL_CCL STAL       SCL_CCL STAL         If a water agent and the partifies are removed       SCL_CCL STAL       SCL_CCL STAL         If a water agent agent agent water agent age	ent, which is then squirted into R-R-01:								· · · · · ·
When the particles are in contact with the noned with water R-C01 is filled with water again the bioreactic braining agent. Sol. C, C11, SC1, C	I_C_FIIL_CA						<u>s_c_cn_ou</u>	-	SCI_C_CI1 AND
noved with water R-C-11 is filled with water again the bioreactic is filled. With water again dent without cleaning agent. <i>I variables</i> : SCLC_FIL_UMA peat this procedure until all particles are removed dent without cleaning agent. <i>I variables</i> : SCLC_FIL_CA, <i>I variables</i> : I variables involved in PROCEDURE 61 and OCEDURE 62 scription: To choose whether WATER or a concept variable: C_CCLCancing_agent <i>C_CLCanning_agent.OV</i> , then R-C-01 is filled with anding agent and C_CLCancing_agent <i>C_CLCanning_agent.OV</i> , then R-C-01 is filled with water only) <i>C_Subroutine</i> : C_C11 <i>Fig</i> : PLC proceedure: C_C11							wait for command		TB F Cir1 is RESE
peat this procedure until all particles are removed d end without cleaning agent. T variables: SCI_C_FIIL_CA, SCI_C_CII_SCI_C_CI2 L_C_PMP_CCO1.P, SCI_C_FIIL_CA, riables Used (I/O): 1 variables involved in PROCEDURE 61 and CCEDURE 62 scription: To choose whether WATER or a concept variables: C_CCLCenning_agent C_CO1.pdf bit in the parameter 6d not allow to trigger PMP_C_C0 NC to fill RCO1 with deaning agent C_CO1.pdf bit in the parameter 6d not allow to trigger PMP_C_C0 NC to fill RCO1 with deaning agent C_CO1.pdf bit in the parameter 6d not allow to trigger PMP_C_C0 NC to fill RCO1 with deaning agent SCI_C_CIL_DOS	moved with water. R-C-01 is filled with water again								F_Valvestate_Nom
d end without cleaning agent.  T variables: SCI_C_FII_CA.  SC Jobroutine: C_FII_CA.  L'All control of the second o							S C CI1 003	vater or cleaning ag	ent
I variables: SCL_C, Fill_VMA, SCL_C, Cl1, SCL_C, Cl2,									
I and miles: SUC_D_IN_WA, SUC_DI, SUC_DLZ,         C. Subroutine: C_FIIL_WA, C_FIIL_CA         C. Subroutine: C_FIIL_WA, C_FIIL_CA         I variables involved in PROCEDURE 61 and         I variables involved in PROCEDURE 61 and         I variables involved in PROCEDURE 61 and         I comments of the procedure is used for Filling R-Co1, there are an expression is 0x10 with ideaning agent of the intervalues to be swithed         C. Subroutine: C_C1C         EANING AGENT is used for Filling R-Co1, there are and C_C_CLEAning agent-OFF         NC       to fill RC01 with deaning agent         NC       to fill RC01 with deaning agent         Fig: PLC procedure: C_C11       Image: C_C1         riables Used (I/0):       Image: C_C1         realware used Used in the procedure is       Image: C_C1         Solution with water only )       Image: C_C1         RC Cultion       Image: C_C1         Rig: PLC procedure: C_C11       Image: C_C1         riables Used (I/0):       Image: C_C1         RP_C_C10, V_C_C16, V_S_D2, V_F_15, Image: C_C1       Image: C_C1         RP_C_C10, V_C_C16, V_S_D2, V_F_15, Image: C_C10, C_C2       Image: C_C10, C_C10					1				•
C Subroutine: C_FIILWA, C_FIILCA,       Image: C_FIILWA, C_FIILCA,       Image: C_FIILWA, C_FIILCA,         triables Used (I/O):       Image: C_FIILWA, C_FIILCA,       Image: C_FIILWA, C_FIILCA,         1 variables involved in PROCEDURE 61 and       Image: C_FIILWA, C							Command to fill R_C_02 with	cleaning agent from	n R_C_01
riables Used (I/O):       With utili procedure is finited         variables involved in PROCEDURE 61 and       SCI_C_FII_CB is f         scription:       To choose whether WATER or a concept variable:       Sci_C_CI_CB         a concept variable:       C_C_CI_CB       Sci_C_CI_CB         C_COLOR       NC       to fill RC01 with deaning agent       Sci_C_CI_CB         NC       to fill RC01 with deaning agent       Sci_C_CI_CB       Sci_C_CI_CB         Fig: PLC procedure:       C_CI1       Sci_C_CI_CB       Sci_C_CI_CB         riables Used (I/O):       Sci_C_CI_CB       Sci_C_CI_CB       Sci_C_CI_CB         PMP_C_C_03, V_C_19       Sci_C_CI_CB       Sci_C_CI_CB       Sci_C_CI_CB         Sci_CI_C_190       Sci_CI_C_CB       Sci_CI_C_CB       Sci_CI_C_CB         Sci_CI_C_190       Sci_CI_C_CB       Sci_CI_CB       Sci_CI_CB         Sci_CI_DB<									
riables Used (I/O):       SCI_C_CB_Tempe         variables involved in PROCEDURE 61 and DCEDURE 61 and DCEDURE 62       Solido values for cleaning more 1         seription:       To choose whether WATER or EANING AGENT is used for Filling R-C-01, there a concept variable:       Sc_C1_CCE         a concept variable:       C_C1Ceaning_agent       Sc_C1_CCE         a concept variable:       C_C1Ceaning_agent       Sc_C1_COE         C_C1Ceaning_agent=00, then R-C-01 is filled with aning agent and C_C1. Cleaning_agent       Sc_C1_COE         C_Subroutine:       C_C11       Sc_C1_COE         Fig:       PLR_C_05, V_C_16, V_S_02, V_F_15.       Sc_C1_OE         riables Used (I/O):       Sc_C1_02       Sc_C1_COE         riables Used (I/O):       Sc_C1_02       PLR_C_03, V_C_16, V_S_02, V_F_15.         seription:       No more description; the procedure is       Sc_C1_C1_OE	o sassoanne : o_i m_wA, o_rm_oA,						Wait untill procedure is finishe	id id shock for memb <b>a</b>	
variables involved in PROCEDURE 61 and DCEDURE 62 seription: To choose whether WATER or EANING AGENT is used for Filling R-C-01, there a concept variable: C_CLCleaning agent (C_Cleaning agent-00, then R-C-01 is filled with aning agent and C_CL_Cleaning agent=0F n R-C-01 is filled with water only) C Subroutine: C_Cl1 Fig: PLC procedure: C_Cl2 Fig: PLC procedure: C_Cl2 Fig: PLC procedure: C_Cl2 Fig: PLC procedure: C_Cl3 Fig: PLC procedure: C_Cl3 Fig: PLC procedure: C_Cl4 Fig: C	riables Used (I/O):		-						SCI_C_CB_Temper
scription: To choose whether WATER or EANING AGENT is used for Filling R-C-01, there a concept variable: C_CLCleaning_agent C_Cleaning_agent=0V, then R-C-01 is filled with saming_agent and C_CL_Cleaning_agent=0FF n R-C-01 is filled with water only) C Subroutine: C_Cl1 Fig: PLC procedure: C_Cl1 riables Used (I/O): riables Used (I/O):	l variables involved in PROCEDURE 61 and				1		-Switch valves for cleaning mb S_C_CI1_006	ne 1	
scription: To choose whether WATER or EANING AGENT is used for Filling R-C-01, there a concept variable: C_CLCleaning_agent CL_Cleaning_agent=OFF n R-C-01 is filled with water only) C Subroutine: C_Cl1 Fig: PLC procedure: C_Cl2 Fig: PLC procedure: Fig: PLC procedure: Fig: PLC procedure: Fig: PLC procedure: Fig: Fig: PLC procedure: Fig: Fig: Fig: Fig: Fig: Fig: Fig: Fig	DCEDURE 62						wait for valves to be switched		
Arrynon: To cooked windler wATER of the procedure is         EANING AGENT is used for Filing R-Co1, there a concept variable: C_CI_Cleaning_agent=OFF a concept variable: C_CI_Cleaning_agent=OFF a R-Co1 is filled with water only)         C Subroutine: C_CI1         Fig: PLC procedure: C_CI2         Fig: PLC procedure: C_CI4					1			-	
a concept variable: C_CLCleaning_agent CL_Cleaning_agent=OV, then R-C-01 is filled with aning agent and C_CLCleaning_agent=OFF n R-C-01 is filled with water only) C Subroutine: C_Cl1 Fig: PLC procedure: C_Cl1 riables Used (I/O): PLC_01, V_C_05, V_C_16, V_S_02, V_F_15, S_04, V_C_19 SCI_CL_08 SCI_CL		1					start recycle cleaning pump		
searing agent and C_CI_Cleaning_agent=OFF       NC       this parameter dd not allow to trigger PMP_C_02         NC       to fill RC01 with cleaning agent       PMP_C_02         C Subroutine: C_Cl1       Image: C_Cl1       Image: C_Cl1         Fig: PLC procedure: C_Cl1       Image: C_Cl1       Image: C_Cl1         riables Used (I/O):       Image: C_Cl1       Image: C_Cl1       Image: C_Cl1         science       Image: C_Cl1       Image: C_Cl1       Image: C_Cl1         riables Used (I/O):       Image: C_Cl1       Image: C_Cl1       Image: C_Cl1         Science       Image: C_Cl1       Image: C_Cl1       Image: C_Cl1         riables Used (I/O):       Image: C_Cl1       Image: C_Cl1       Image: C_Cl1         science       Image: C_Cl1       Image: C_Cl1       Image: C_Cl1	a concept variable: C_Cl_Cleaning_agent		1				S_C_CI1_007		-
m.R-C-01 is filled with water only )       NC       to fill RC01 with deaning agent       Image: Control of the c				this parameter did not allow to trigger PMP C 02					
C Subroutine: C_Cl1 Fig: PLC procedure: C_Cl1 riables Used (I/O): IP_C_01, V_C_05, V_C_16, V_S_02, V_F_15, S_04, V_C_19 seription: No more description; the procedure is SC_CL_Description: Test values SC_CL_Description: Test values SC_SC_SC_SC_SC_SC_SC_SC_SC_SC_SC_SC_SC_S			NC	to fill RC01 with cleaning agent			PMP_C_03		
C Subroutine: C_Cl1									
riables Used (I/O):	C Subroutine : C_Cl1				1				
rriables Used (I/O): MP_C_01, V_C_05, V_C_16, V_S_02, V_F_15, 								-	
riables Used (I/O): AP_C_01, V_C_05, V_C_16, V_S_02, V_F_15, S_04, V_C_19 Scription: No more description; the procedure is Scription: No more description; the procedure is	Fig : PLC procedure: C_Cl1						1 stop PMP C 03		· · · · · · ·
MP_C_01, V_C_05, V_C_16, V_S_02, V_F_15,	ninklas Vand (VO).						S_C_CI1_009 stop heating		•
LS_04, V_C_19	uriables Used (I/O): MP_C_01, V_C_05, V_C_16, V_S_02, V_F_15,								
scription: No more description; the procedure is			<u> </u>				T_C_CI1_009	-	PMP_C_03_Run is R SCI C Heat CB
	scription: No more description: the procedure is	l	I			1			
							S_C_CI1_012		

PLC Subroutine : C\_Cl2

Fig : PLC procedure: C\_Cl2

Variables Used (I/O): PMP\_C\_01, V\_C\_05, V\_C\_17, V\_S\_03, V\_F\_14, V\_S\_05, V\_C\_18

Description: No more description; the procedure is detailed enough.

Questions: The SCI variable SCI\_C\_Cleaning\_Agent doesn't exist BUT there is another Concept variable: C\_CI\_Cleaning\_agent used to choose to fill R\_C\_01 with water or cleaning agent.

 
 T\_C\_CIT\_019
 PMP\_C\_03\_Run is RESET AND SCI\_C\_Heat\_CB

 S\_C\_CIT\_012
 V\_C\_16 AND V\_C\_19 are RESET

 S\_C\_CIT\_010
 S\_C\_CIT\_010

 S\_C\_CIT\_010
 S\_C\_CIT\_010

 S\_C\_CIT\_010
 S\_C\_CIT\_010

 S\_C\_CIT\_010
 S\_C\_CIT\_010

 S\_C\_CIT\_010
 S\_C\_CIT\_010

 S\_C\_CIT\_011
 S\_C\_CIT\_011

 V\_MINT OF R\_C\_022 to be empled

 C\_MORE\_CAB\_Empty\_OK

 S\_C\_CIT\_END

 Image: S\_C\_CIT\_END

S\_C\_C12001

## Recommendations / changes

HW modifications

	UAB	
		Procedure for cleaning mbne 2
PLC programme modifications	SHERPA	<u></u>
		S_C_C12_001
		wait for command SCI C CI2 AND
HMI modifications	NTE	TE F Cir2 is RESET AND
Local		SCI_F_Cir2 is RESET AND Command to fill R_C_1 with water or cleaning agent F_Valvestate_Nom2_OK
		8_C_C12_003
		Walt untill propedure is finished
Remote		-SCI_C_FIIL_CA
		Command to fill R_C_02 with water from R_C_01
Variables		S_C_CI2_005 Start heating
		Wait untill procedure is finished
Others		T_C_CI2_005 and temperature is OK to avoid shock for membrane SCI_C_Fill_CB is RESET AND SCI_C_CB_Temperature_No_Shock
User Manual		Switch valves for cleaning mone 2
		S_C_CI2_006
		wait for valves to be switched
		C_Valvestate_CI2_OK start recycle cleaning pump
		S_C_CI2_007
		PMP_C 03
		wait S_C_C12_008

PMP\_C\_03 mit S\_C\_02\_09 S\_C\_02\_09 mit S\_C\_02\_09 min T\_02\_09 C\_Valvestee\_slop\_0K S\_C\_02\_01 S\_C\_02\_02 S\_C\_02\_01 S\_C

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 49: Cleaning of Filtration				1	
Init: retentate side of membrane Fi-F-01 / Fi-F- 12					
ope				Ť	
e aim of this procedure is to clean the inside of a mbrane. It may be useful to do this on a regular					
ne basis to slow down fouling of the membrane as scribed in § 7.2.4. This procedure must be used to					
nove retentate before use of PROCEDURE 50: eaning of Filtration Unit: both retentate and filtrate				+	
de of membrane FI-F-01 / FI-F-02.				ŧ	
utomated cleaning of the membranes as described n PROCEDURE 56: Cleaning of Filtration Unit:					
utomated execution of a sequence of procedures to lean membrane Fi-F-01 / Fi-F-02 will call this					
rocedure in the PLC a number of times.				+	
rocedure				ł	
ake the precautions and advise on the membranes					
s they are stated in § 7.2.4.1 in account. se the HMI to set up how this procedure is to be	12/06/2008 10:00			ł	
xecuted: . SCI_C_Cleaning_Agent defines whether clear				ł	
vater is to be used (SCI_C_Cleaning_Agent = off) or leaning agent (SCI_C_Cleaning_Agent = on)			SCI_C_Fill_CA_Detergent_Agent_Trigger should be activated in the PLC		
			Several times should be set: Variables C_CI_Time_CI1_1 to _5 should be set (initially		
<ol> <li>Set the time during which recirculation over R-C-</li> </ol>			they were set to zero by default (attention: when PLC in itializes they will get again their initial		
<ul> <li>Set the time during which reciculation over k-c-</li> <li>i2 is to be done.</li> <li>Set whether the cleaning solution is to be heated</li> </ul>			values); they were set to 1 min Delay time should also be set: C_01_	ł	
<ol> <li>Set whether the cleaning solution is to be neated luring circulation or not.</li> <li>f the use of cleaning agent is desired, fill 2L of it in R</li> </ol>				ļ	
-03. Ise the HMI to start the procedure C_CI1 for		NC	this is not taken into account	ļ	
nembrane Fi-F-01 or C_Cl2 for membrane Fi-F-02:					
CI_C_CI1, SCI_C_CI2. This initiates the actions elow:					
. R-C-01 is filled with water and - if desired - leaning agent: SCI_C_Fill_WA or SCI_C_Fill_CA		c	working just with water: see procedure 61: this triggers the addition of water without use of PMP_C_02 (cf. Proc 62)		
. Content of R-C-01 is pumped into the cleaning uffer R-C-02.		с С	PMP_0_02 (dl. P100 62)	ł	
		C		+	
<li>PMP-C-03 circulates the contents of the R-C-02 ind the piping from V-C-16 (Fi-F-01) resp. V-C-17 (Fi- Page 10 - 20 - 20 - 20 - 20 - 20 - 20 - 20 -</li>					
<ul> <li>-02) to V-C-19 (Fi-F_01) resp. V-C-18 (Fi-F-02), ncluding the retentate side of the membrane:</li> </ul>		NC	this step has been skipped by the PLC	ļ	
Normal pressures are:			Pressures during recirculation: PS_F_01: 0,92;	ł	
<ol> <li>PS-F-01 / PS-F-04 ~= 1.15 barg to 1.32 barg increases gradually in time)</li> </ol>			PS_F_02: 0,48; PS_F_03: 0,65 (membrane not installed)		
. PS-F-02 / PS-F-05 ~= 0.14 barg 0. PS-F-03/ PS-F-06 ~= 0.49 barg				ł	
<ol> <li>Now cleaning agent can reach particles that could not be rinsed with water. R-C-01 is filled with cleaning</li> </ol>					
gent, which is then squirted into R-R-01: CI_C_Fill_CA				ļ	
2. When the particles are in contact with the					
leaning agent for some time they soak off and can be removed with water. R-C-01 is filled with water					
again and the bioreactor is rinsed: SCI_C_Fill_WA Repeat this procedure until all particles are removed				ł	
and end without cleaning agent.				I	
CI variables : SCI_C_Fill_WA, SCI_C_CI1, SCI_C_CI2,					
SCI_C_PMP_C_01_P, SCI_C_FIII_CA				ł	
PLC Subroutine : C_FIII_WA, C_FIII_CA,				ŧ	
				ł	
Variables Used (I/O): All variables involved in PROCEDURE 61 and				ł	
PROCEDURE 62				ł	
Description: To choose whether WATER or CLEANING AGENT is used for Filling R-C-01, there i					
a concept variable: C_Cl_Cleaning_agent C_Cl_Cleaning_agent=ON, then R-C-01 is filled					
with Cleaning agent and					
C_Cl_Cleaning_agent=OFF, then R-C-01 is filled with		NC	this parameter did not allow to trigger PMP_C_02 to fill RC01 with cleaning agent		
				Ī	
PLC Subroutine : C_Cl1				Ť	
Fig : PLC procedure: C_Cl1				ŧ	
				Ŧ	
Variables Used (I/O):				ŧ	
PMP_C_01, V_C_05, V_C_16, V_S_02, V_F_15, V_S_04, V_C_19				ļ	
Description: No more description; the procedure is				1	
detailed enough.					

## PLC Subroutine : C\_Cl2

Fig : PLC procedure: C\_CI2

# Variables Used (I/O): PMP\_C\_01, V\_C\_05, V\_C\_17, V\_S\_03, V\_F\_14, V\_S\_05, V\_C\_18

Description: No more description; the procedure is detailed enough.

Questions: The SCI variable SCI\_C\_Cleaning\_Agent doesn't exist BUT there is another Concept variable: C\_CI\_Cleaning\_agent used to choose to fill R\_C\_01 with water or cleaning agent.

S\_C\_CI1\_110 .reset TB\_CI1 mpty\_CBCI\_C\_Empty\_CA C\_Mode\_CAB\_Empty\_OK reset sequence command flag S\_0

. . S\_C\_C12001

## Recommendations / changes

HW modifications

PLC programme modifications

HMI modifications NTE Local SCI\_C\_FRI\_CA\_Detergent\_Agent\_Trigger should be activated by a pulse in the HMI Variables C\_CI\_Time\_CI1\_1 to \_5 should be set maybe through the local HMI: decissions for cleaning should be fine-tuned by the user from time to time

UAB

SHERPA

Remote Variables

Procedure for cleaning mbne 2	
<u>5.C.CI2.001</u>	
T_C_CI2_001 TB_F_Cir2_is RESET J SCI_F_Cir2_is RESET J	AND
Command to fill R_C_1 with water or cleaning agent F_Valvestate_Nom2_	
Walt until procedure is finlaned	
Command to fill R_C_02 with water from R_C_01	
T_C_CI2_005 and temperature is OK to avoid shock for membrane SCI_C_FIII_CB is RE: SCI_C_CB_Temperature	
Suitch valves for deaning mone 2	
weit for valves to be switched C_Valvestete_CI2_OK	
start recycle cleaning pump S_C_C12_007	
PNP_C_03 	
1	
T_CI2.009 SCI C Heat CB	ESET AND
SUL_INST Valves	
C_Velvestele_Stop_OK	
S_C_CI2_010 S_C_CI2_110	
SCLC_Empty_CBCLC_Empty_CA	
wait for R_C_02 to be emptied	
reset sequence command flag	
∑ <u>s_c_a</u> 2)oo1	

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments	
1.1. Procedure 50: Cleaning of Filtration Unit: both						
retentate and filtrate side of membrane Fi-F-01 / Fi-F-02 Scope						
The aim of this procedure is to clean the entire membrane and the						
membrane module. It is not per se sufficient for a thorough cleaning of the membranes inside because the flow rate is not as big as in						
e.g. PROCEDURE 49, which results in a lower shear for						
PROCEDURE 56: Cleaning of Filtration Unit: automated execution of a sequence of procedures to clean membrane Fi-F-01 / Fi-F-02 will						
call this procedure in the PLC a number of times.						
Prerequisite						[
Retentate side should be at least rinsed before execution of this procedure. The drain on V-F-14 or -15 may get clogged if this is not						
done.	12/06/2008 12:30					
Procedure:						
Take the precautions and advise on the membranes as they are stated in § 7.2.4.1 in account.						
Use the HMI to set up how this procedure is to be executed:	15:25					
<ol> <li>SCI_C_Cleaning_Agent defines whether clear water is to be used</li> </ol>						
(SCI_C_Cleaning_Agent = off) or cleaning agent (SCI_C_Cleaning_Agent = on)						
<ol> <li>If the use of cleaning agent is desired, fill 2L of it R-C-03.</li> </ol>						
Use the HMI to start the procedure C_BCI1 for membrane Fi-F-01 or C_BCI2 for membrane Fi-F-02: SCI_C_BCI1, SCI_C_BCI2. This						
A. R-C-01 is filled with water and - if desired - cleaning agent:						
SCI_C_FIII_CA		с				
<ol> <li>The content of R-C-01 is pumped via V-C-21 and V-C-13 (Fi_f- 01) or V-C-12 (Fi-F-02) through some filtrate piping into the filtrate</li> </ol>						Procedure for cleaning filtrate side of mone 1 .
side of the membrane. It leaves the membrane module via V-S-12						
(Fi-F-01) or V-S-11 (Fi-F-02) and goes through a pie Normal pressures are:		С				SCL_C_BCI1 TB_F_Cirt is RESET AND SCL_F_Cirt is RESET AND SCL_F_Cirt is RESET AND
<ul> <li>PS-F-01 / PS-F-04 = 0 barg</li> <li>PS-F-02 / PS-F-05 = 0 barg</li> </ul>						wait for command
<ul> <li>PS-F-02 / PS-F-05 ~= 0 barg</li> <li>PS-F-03 / PS-F-06 ~= 1 barg</li> </ul>						T_C_BCI1_001 S_Valvestate_S1_OK is RESET
Remove cleaning agent by execution of this procedure with clear water						S. Valvestate_S1_OK is RESET command to fill R_C_1 with water of cleaning age &CL_S. S2 is RESET AND S.C_BCIT_002
						SCI_S_AII2 is RESET
SCI variables: SCI_C_BCI1, SCI_C_BCI2, SCI_C_PMP_C_01_P, SCI_C_FIII_CA						-sci_c_fiil_ca
						Suvitoh valves for cleaning filtration side of mone 1 S_C_BCI1_003
PLC Subroutine : C_FIIL_CA This PLC subroutines is described in PROCEDURE 61						wait for valves to be switched
Variables Used (I/O):						C_Velvestate_BCI1_OK
All variables involved in PROCEDURE 61						S_C_BCI1_004
Description: To choose whether WATER or CLEANING AGENT is used for Filling R-C-01, there is a concept variable:						PMP_C_01
C_Cl_Cleaning_agent (C_Cl_Cleaning_agent=ON, then R-C-01 is						S_C_BC11_005
filled with <i>Cleaning agent</i> and <i>C_Cl_Cleaning_agent=OFF</i> , then R- C-01 is filled with						
						~LS_C_02 stop PMP_C_01
PLC Subroutine : C_BCI1						S_C_BCI1_000 sit 10s for water to leave the mbne
	12/06/2008					~PMP. C. 01
Fig : PLC procedure: C_BCI1						
						SCI_C_Empty_CA
Variables Used (I/O):						
PMP_C_01, V_C_21, V_C_13, V_S_06, V_S_04, V_S_12, V_C_19						
Description: No more description, the procedure is enough detailed						T_C_BCI1_008 C_Valvestate_Stop_OK AND C_Valvestate_BCI1_R_OK
						reset sequence command flag S_C_BCI1_END
PLC Subroutine : C_BCl2		<u> </u>				
						∑s_c_в¢p_001

## Fig : PLC procedure: C\_BCI2

# Variables Used (UO): V\_C\_21, V\_C\_12, V\_S\_07, V\_S\_11, V\_S\_05, V\_C\_18 Description: No more description, the procedure is detailed enough. Image: Comparison of the comparis

better explain that there is 1 min of timer for letting out the liquid bewteen low level sencor and the drain valve

Procedure for cleaning filtrate side of mbne 2				
				1
	1 1 1 1			1.1
S_C_BCI2_001				
wait for command	1	1.1	• •	1.1
T_C_BCI2_001				
	:			
S_C_BCI2_003	er or cleaning	agent		1
3_0_8012_003				
Wait untill procedure is finished	: · · · ·	1 1 1	• •	- ÷
~SCI_C_FIII_CA				
Switch valves for cleaning filtration	on side of mb	ne 2		
3_6_8012_000				
wait for valves to be switched	<u>.</u>	· · ·		- ÷
·	:			
C_Valvestate_BCI2_OK	1			
S_C_BCI2_008	:			
3_0_8012_000	:	1		1
	1 1 1 1	· : ·	• •	1.1
	:	:		
PMP_C_01	1			. :
S_C_BCI2_007	1	1		1
3_6_8612_007	:	:		
	1	1.11		10.1
				1
~LS_C_02				
stop PMP_C_01 S C BCI2 008 ait 10s for water to leave the mi	hne			
		-		-
		- i -	• •	1
	-	-		-
~PMP_C_01				
S_C_BCI2_009 S_C_BCI2_109ommand to en	noty R C 01			1
	1.1.1.1	· : ·		
	:	:		1
SCI_C_Empty_CA	1			1.1
s c BCI2 110	to be emptie	id :		1
				1
· · · · · · · · · · · · · · · · · · ·	:	· : ·	• •	1.1
T_C_BCI2_010	-			
	1			
reset sequence command flag	-			
	:			
	1.1.1.1		· ·	·
	-			
1	÷			
	1			1
S_C_BC≥_001	1			
	• • • •		• •	

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 61: Fill cleaning agent into	R-C-01				
Scope Fill cleaning agent from R-C-03 into R-C-01 and fill it					
up with water. This procedure can be seen as a 'sub-procedure' in	12.06.08 12:30		SCI_C_Fill_CA_Detergent_Trigger should be		
This procedure can be seen as a sub-procedure in			activated first in the PLC in order to fill the CA before the water		
the PLC code that is called from other procedures. It			PMP_C_03 is run during a time, whereas filling of water is done untile high level is reached (LS-C-		
can also be called manually on the HMI.			01) C_CI_Cleaning_Agent_S should be also activ		
Procedure	Procedure that fills	R_C_01	with water and detergent	I	
<ol> <li>Fill cleaning agent into R-C-03.</li> <li>Use the HMI to start PLC procedure C_Fill_CA:</li> </ol>	-				
SCI_C_Fill_CA 3. Wait for the PLC procedure to finish.	<u> </u>		· · · · · · · · · · · · · · · · · · ·		
S. Wait for the PLC procedure to finish.	S_C_FIII_CA_00	1	· · · · ·		
SCI variables : SCI_C_FIII_CA			wait for command to fill R_C_001 with cleaning ag	ent	
	T_C_FIIL_CA_001		Level inR_C_001 must be low		
PLC Subroutine : C_Fill_CA			· · · · · · · · · · · · · · · · · · ·		
Fig: PLC procedure: C_Fill_CA	S_128_1		· · · · ·		
			<u> </u>		
			Variable use	ed to choose to	add
	- ~C_CI_Cleaning.C	_CI_Cle	aning_agent detergent or		
	Fli	S_C_Fi	Add detergent		
	F				
			· · · ·		
		PMP_C	02_Run		
		ld water 3;_09 a	nd _11 are closed when adding water is finished		
			ill_WA_Water_timeout can be set		
	wa	it until I	R_C_01 is full		
	_~LS_C_01		· · ·		
	S_C_FIII_CA_EN		ence command flag		
	1				
	S_C_FIII_CA_(	001			
Variables Used (I/O):					
LS_C_02, LS_C_01, V_C_09, V_C_11, PMP_C_02					
Description: No more explanation, the procedure is det	ailed enough				
	WHEN	wно	·	- <u></u>	
Recommendations / changes					
HW modifications		UAB			
PLC programme modifications		SHER	PA		
HMI modifications		NTE			
Local					

Others User Manual

Remote Variables

				SHERPA	NTE
Procedure steps	date/hour	N/NC	comments	comments	comments
1.1. Procedure 61: Fill cleaning agent into	R-C-01				
Scope					
Fill cleaning agent from R-C-03 into R-C-01 and fill it					
up with water. This procedure can be seen as a 'sub-procedure' in the					
PLC code that is called from other procedures. It can					
			not working : this triggers the addition of water		
also be called manually on the HMI.		NC	without use of PMP_C_02 (cf. Proc 62) OK there was a problem of forced variable		
		с	preventing the good implementation		
Procedure					
<ol> <li>Fill cleaning agent into R-C-03.</li> <li>Use the HMI to start PLC procedure C_Fill_CA:</li> </ol>					
SCI_C_FIII_CA					
<ol><li>Wait for the PLC procedure to finish.</li></ol>					
SCI variables : SCI_C_FIII_CA					
PLC Subroutine : C_FIII_CA					
Fig: PLC procedure: C_Fill_CA					
Variables Used (I/O):					ļ
LS_C_02, LS_C_01, V_C_09, V_C_11, PMP_C_02		-			
Description: No more explanation, the procedure is deta	ailed enou	gh.			
		Ĭ			
	WHEN	WHO	Procedure that fills R_C_01 with water and detergent		
Recommendations / changes					
HW modifications					
		UAB	S C Fill CA 001		
PLC programme modifications		SHER	PA wait for command to fill R_C	001 with cleaning age	ent .
		0	T_C_FIII_CA_001 Level inR_C_001 must be lo		
OK working			· · ·		
			NOP		
HMI modifications Local		NTE	S_126_1		
add the button to make it ?			<u> </u>		
				Variable use	d ta abaaaa ta
			~C_CI_Cleaning.C_CI_Cleaning_agent	detergent or	d to choose to
Remote			Add detergent	detergent of	
			S_C_FIII_CA_002		
Variables					
Others			~PMP_C_02_Run	: :	
User Manual					
			Add water S_C_Fill_CA_003:_09 and _11 are closed when adding wat	er is finished	
			ERR_C_Fill_WA_Water_timeout can be set		
			wait until R_C_01 is full		
			~LS_C_01		
			reset sequence command flag		
			S_C_FIII_CA_END		
			1 <b></b> : : :		
			· · · · · · · · · · · · · · · · · · ·		
			S_C_FIII2CA_001		

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments			
1.1. Procedure 62: Fill water into R-C-01								
Scope Fill water into R-C-01.								
This procedure can be seen as a 'sub-procedure' in the					1			
PLC code that is called from other procedures. It can	Procedure th	at fil	Is R_C_01 with water		· .			
also be called manually on the HMI.				:	:			
Procedure 1. Use the HMI to start PLC procedure C_Fill_WCA:								
SCI_C_Fill_WA 2. Wait for the PLC procedure to finish.	S C Fill		001	:	:			
2. Wait for the red procedure to missin	[5_C_FIII_	1		:	:			
SCI variables : SCI_C_Fill_WA		. :	wait for command to fill R_C_00	11 - L - L - L - L - L - L - L - L - L -	· · :	· ·		- 3
PLC Subroutine : C_Fill_WA	T_C_Fill_W		01:vel inR_C_001 must be low		:			
Fig: PLC procedure: C_Fill_WA		:			:			
			Add water				•	
	S_C_FIII_		002_09 and _11 are closed whe ERR_C_Fill_WA_Water_timeout					
		. :						
			wait until R_C_01 is full					
	~LS_C_01	:			:			
		<u> </u>	reset sequence command flag	: · ·	••••	• •	•	•
	S_C_Fill_	WA_	END	:	:			
		. :		;	;			
		:	:		:			
	1	:	:	:				
		• •				• •		•
	S_C_Fil	Nviz	A 001	:				
Variables Used (I/O): LS_C_02, LS_C_01, V_C_09, V_C_11								
Description: No more explanation, the procedure is det	ailed enough				<b> </b>			
1.2. Procedure 63: Fill Cleaning agent into					-			
Scope Fill the contents from R-C-01 into R-C-02.								
This procedure can be seen as a 'sub-procedure' in the					<u> </u>			
PLC code that is called from other procedures. It can			initial conditions :R_C_01 full up to high level ,					
also be called manually on the HMI.	11/06/2008 18:00		R_C_02 empty low level					
Prerequisite								
R-C-01 must contain water or cleaning agent								
Procedure								
<ol> <li>Use the HMI to start PLC procedure C_Fill_0</li> <li>Wait for the PLC procedure to finish.</li> </ol>	CB: SCI_C_FIII_CB	NC	does not exist on HMI, forced on PLC					
SCI variables : SCI_C_FIII_CB								
501 / M MB/05 - 501_0_, m_05								
PLC Subroutine : C_Fill_CB								
Fig: PLC procedure: C_Fill_CB								
··· <b>3</b> ····· <b>b</b> ············· <b>b</b> ··· <b>b</b> ·········								
		С	low level in R_C_02, high level in R_C_01					
		С	PMP_C_01 starts					
		NC	wait until R_C_02 is full					
		С	when LS_C_03 is triggered, PMP_C_01 stops					
			before PMP_C_01 stopped, appeared some sparkles inside the electrical cabinet on K4					
		NC	contactor					
					<u> </u>			
		<u> </u>			<u> </u>			
Variables Used (I/O):					<b> </b>			
PMP_C_01, LS_C_02, LS_C_04, V_C_07, V_C_05, V_C_06, V_C_11								
Description: No more explanation, the procedure is det	ailed enough	-			+			
			Proceedings (Sect 201- D. O. 00, 100- 1	n of B. C. C.f.	<u> </u>	I		
Recommendations / changes	WHEN	WHO	Procedure that fills R_C_02 with conten	a or R_C_01	:			
Recommendations / changes_								
HW modifications check contactor K4 in the FU electrical cabinet		NTE/L	JAB SC FILL CB 001	:	÷			
PLC programme modifications		SHER	the second se	IR_C_02 be low				
			Level in R_C_01 must	be above low le				
HMI modifications		NTE	Switch valves S_C_Fill_CB_002: PMP_C_01				•	
Local		ALC	U_C_06 and _07 are o ERR_C_Fill_CB_timeo	losed when addi	ng water is fin hioh	ished		
			wait until R_C_01 is fu T_C_Fill_CB_002	ll			•	
Remote					÷			
						• • •	•	
Variables			S_C_FIII_CB_003	:	:			
Others						• • •		
Others User Manual			~PMP_C_01	:	:			
			reset sequence comma	nd flag	· · ·	• • •		
			S_C_FIII_CB_END		:			
					-			
			S_C_FIII2CB_001		÷			
				:	:			

## 1.1. Procedure 53: Cleaning of Filtration Unit: Circulation pump PMP-F-01 Scope:

This procedure may be used to dilute the retentate in PMP-F-01 and some of the retentate piping with water, and then again to clean PMP-F-01 and some of the retentate piping. This is done by filling R-C-02 with water or cleaning agent and then circulating over it. It might be useful before disassembling PMP-F-01, SS-F-01 or FS-F-01 for maintenance.

## Prerequisite

FU must be stopped prior to execution of this procedure.

## Procedure

Use the HMI to set up how this procedure is to be executed: 1. SCI\_C\_Cleaning\_Agent defines whether clear water is to be used (SCI\_C\_Cleaning\_Agent = off) or cleaning agent (SCI\_C\_Cleaning\_Agent = on)

2. Set the time during which recirculation over R-C-02 is to be done. If the use of cleaning agent is desired, fill 2L of it in R-C-03.

Use the HMI to start the procedure C\_CLPMP: SCI\_C\_CLPMP. This initiates the actions below:

3. R-C-01 is filled with water and - if desired - cleaning agent: SCI\_C\_Fill\_CA

Content of R-C-01 is pumped into the cleaning buffer R-C-02. Valves V-C-14, V-C-15, V-F-02 and V-F-05 are activated. 4.

5.

6. PMP-F-01 circulates the contents of the R-C-02 and the piping from V-C-15 to V-F-02 through the bypass piping, via V-F-05 and V-C-14 back to R-C-02.

R-C-02 is to be rinsed afterwards. Use PROCEDURE 65: Rinse R-C-02: 7 SCI\_C\_Rinse\_CB. If cleaning agent was used, first rinse R-C-01 with PROCEDURE 64: Rinse R-C-01: SCI C Rinse CA.

SCI\_C\_FIII\_CA, SCI variables : SCI C CLPMP. SCI C Rinse CA. SCI\_C\_Rinse\_CB

PLC Subroutine : C\_Fill\_CA, C\_Rinse\_CA, C\_Rinse\_CB

These PLC subroutines are described in PROCEDURE 61, PROCEDURE 64 and PROCEDURE 65

## Variables Used (I/O):

All variables involved in PROCEDURE 61, PROCEDURE 64 and PROCEDURE 65

Description: To choose whether WATER or CLEANING AGENT is used for Filling R-C-01, there is a concept variable: C\_Cl\_Cleaning\_agent (C\_Cl\_Cleaning\_agent=ON, then R-C-01 is filled with Cleaning agent and C\_Cl\_Cleaning\_agent=OFF, then R-C-01 is filled with water only)

## PLC Subroutine : C CLPMP

## Fig: PLC procedure: C\_CLPMP

12/06/2008 C

С

UAB

SHERPA

NTE

## Variables Used (I/O):

V\_C\_15, V\_F\_02, V\_F\_05, V\_C\_14, V\_F\_16, PMP\_F\_01, V\_F\_17

Description: No more description, the procedure is detailed enough.

Questions: The SCI variable SCI\_C\_Cleaning\_Agent doesn't exist BUT there is another Concept variable: C\_CI\_Cleaning\_agent used to choose to fill R\_C\_01 with water or cleaning agent

## Recommendations / changes

W modifications		
0		

PLC programme modifications step 7 is empty to be completed

HMI modifications Local

Remote

н٧

## Variables





		Procedure for backwashing mbne 1
Proc52	12/06/2008	
1.1. Procedure 52: Cleaning of Filtration Unit: backwashing membrane		S_C_BW1_001
Fi-F-01 / Fi-F-02 using water or cleaning agent		wait for command
Scope:		SCI_C_BW1
Important for the effectiveness of backwashing is to achieve a quick rise in flow rate (and therefore pressure difference. This can not be achieved with PROCEDURE		Command to fill R_C_1 with wather and detergent
51: Cleaning of Filtration Unit: backwash membrane Fi-F-01 / Fi-F-02. Furthermore,		S_C_BW1_002
PROCEDURE 51 implies removal of F-F-03. This procedure uses water or cleaning		wait until R C 01 is full
agent in R-C-01 and the power of PMP-C-01 to achieve a better flow shock. Do not		~SCI_C_FIILCA
use cleaning agent.		Switch valves for backwashing mbne 1
Prerequisite:		S_C_BW1_003
FU must be stopped or be working over the other membrane. Retentate side of the		wait for valves to be switched V_C_21 is ON AND
membrane to be backwashed must be rinsed before (use PROCEDURE 49: Cleaning		C_Valvestate_BW1_OK
of Filtration Unit: retentate side of membrane Fi-F-01 / Fi-F-02. If not, drain to V-F-14		start cleaning pump
or -15 may get clogged.		S_C_BW1_004/ait 1 minute
Dra aardurau		[
Procedure: Use the HMI to set up how this procedure is to be executed:		PMP_C_01
<ol> <li>SCI_C_Cleaning_Agent defines whether clear water is to be used</li> </ol>		welt 1 minute
(SCI_C_Cleaning_Agent = off) or cleaning agent (SCI_C_Cleaning_Agent = on)		S_C_BW1_005
If the use of cleaning agent is desired, fill 2L of it in R-C-03.		
In the use of cleaning agent is desired, in 22 of it in 16-0-05.		, <del></del>
Use the HMI to start the procedure C_BW1 (Fi-F-01) or C_BW2 (Fi-F-02):		stop PMP_C_01
SCI_C_BW1 or SCI_C_BW2. This initiates the actions below:		S_C_BW1_009
<ol><li>R-C-01 is filled with water and - if desired - cleaning agent: SCI_C_Fill_CA</li></ol>		
<ol> <li>Valves V-C-21, V-C-13 and V-F-15 are activated.</li> </ol>	NC VC19 not VF15	~PMP_C_01
<ol> <li>PMP-F-01 is activated: SCI_PMP_F_01_RUN If this procedure is used with cleaning agent, use PROCEDURE 64: Rinse R-C-01</li> </ol>		.reset valves
and then this procedure again without cleaning agent, use PROCEDURE 04: Rinse R-C-01		S_C_BW1_010
cleaning agent from the FU piping and the membrane.		
		C_Valvestate_Stop_OK
SCI variables : SCI_C_BW1, SCI_C_BW2, SCI_PMP_F_01_RUN, SCI_C_FIII_CA		command to empty R_C_02 and R_C_01
PLC Subroutine : C_Fill_CA,		
These PLC subroutines are described in PROCEDURE 61		SCI_C_Empty_CBCI_C_Empty_CA
Variables Used (I/O):		S C BW1 008 S C BW1 108
All variables involved in PROCEDURE 61		
		wait for R_C_02 to be emptied
Description: To choose whether WATER or CLEANING AGENT is used for		C_Mode_CAB_Empty_OK
Filling R-C-01, there is a concept variable: C_Cl Cleaning agent		reset sequence command flag S_C_BW1_END
rinning it-c-or, mere is a concept variable. C_CI_Cleaning_agent		
(C_Cl_Cleaning_agent=ON, then R-C-01 is filled with Cleaning agent and		
C_Cl_Cleaning_agent=OFF, then R-C-01 is filled with water only)		>s_c_BW}_001
		/

PLC Subroutine : C\_BW1

Fig: PLC procedure: C\_BW1

12/06/2008 c	filled with water in 30s	

	12/06/2008 C	nied with water in 305	
	с	backwasing paramter was changed	
	с	backwasing paramter was changed	
			Procedure for backwashing mbne 2
Variables Used (I/O): V_C_21, V_C_13, V_C_19, PMP_C_01, V_S_04, V_S_06, V_F_15			(S_C_BW2_001
Description: No more description, the procedure is detailed enough.			wait for command
PLC Subroutine : C_BW2			SCI_C_BW2 Command to fill R_C_1 with wather and detargent
Fig: PLC procedure: C_BW2			S_C_BW2_002
			~sci_c_Fiii_cA
			Suffer valves for backwashing mbne 2 Suffer valves for backwashing mbne 2
			valit for valves to be switched V_C_21 is ON AND
	с	full in 33s	start cleaning pump S_C_BW2_004
	Ũ		
	с	validation of proc 58 and 59	PMP_C_01
			1
	NC	error reset BW1 instead of BW2	
			~PhIP1
Variables Used (I/O): V_C_21, V_C_12, V_C_18, PMP_C_01, V_S_05, V_S_07, V_F_14			S_C_BW2_010
Description: No more description, the procedure is detailed enough.			C_Valvestate_Stop_OK
Questions: The SCI variable SCI_C_Cleaning_Agent doesn't exist BUT there is another Concept variable: $C_{\rm CI}_{\rm C}$ leaning_agent used to choose to fill R_C_01 with			C_BW2_007 S_C_BW2_107
another concept variable: c_c_leaning_agent used to choose to fill R_c_of with water or cleaning agent.			SCL_C_Empty_CBCL_C_Empty_CA
			S_C_BW2_008 S_C_BW2_108
Recommendations / changes			wait for R_C_02 to be emptied C_Mode_CAB_Empty_OK
HW modifications	UAB		S_C_BW2_END
PLC programme modifications add initial values for variables otherwise they are all reset error for line 2 : RESET of BW1 to be modified into RESET of BW2	SHERP/	A	1
HMI modifications	NTE		/=
Local add buttons on screen			
Remote			
add buttons on screen			

Variables

Others User Manual the procedure is to transfer cleaning agent from RC01 to RC02 through V\_C\_21, V\_C\_13, V\_C\_19 in the code of PLC, it is possible to use or not cleaning agent

12/06/2008

С

С

С

NC

not working to be rewritten

## 1.1. Procedure 54: Cleaning of Filtration Unit: Filtrate tank R-F-01

#### Scope:

This procedure cleans and rinses the effluent vessel R-F-01.

## Prerequisite

FU must be stopped or be put into recycle or bypass mode prior to execution of this procedure. R-F-01 must be harvested.

#### Procedure

Use the HMI to set up how this procedure is to be executed:

1. SCI\_C\_Cleaning\_Agent defines whether clear water is to be used

 $(SCI\_C\_Cleaning\_Agent = off) \ or \ cleaning \ agent \ (SCI\_C\_Cleaning\_Agent = on)$ 

If the use of cleaning agent is desired, fill 2L of it in R-C-03. Connect the drain outlet of R-F-01 to a vessel that can hold the contents of R-C\_01

(15 L) before using the HMI to start the procedure C\_R-F-01: SCI\_C\_R\_F\_01. This initiates the actions below: 2. R-C-01 is filled with water and - if desired - cleaning agent: SCI\_C\_Fill\_CA

- Valves V-C-04, V-C-11, V-F-10, V-F-12 and V-F-08 are activated. PMP-C-01 pushes the contents of the R-C-01 through the nozzle No-C-03 into 3.
- 4.
- R-F-01 R-E-01 is harvested 5

If this procedure is used with cleaning agent, use PROCEDURE 64: Rinse R-C-01 and then this procedure several times without cleaning agent in order to remove any cleaning agent from R-F-01.

 $SCI \ variables: {\tt SCI\_C\_R\_F\_01}, \ {\tt SCI\_C\_R\_F\_01\_IsCleaningAgent}, \ {\tt SCI\_F\_Harvest}, \ {\tt SCI\_C\_R\_F\_01}, \ {\tt SCI\_C\_R\_F\_01\_IsCleaningAgent}, \ {\tt SCI\_F\_Harvest}, \ {\tt SCI\_C\_R\_F\_01}, \ {\tt SCI\_C\_R\_F\_01\_IsCleaningAgent}, \ {\tt SCI\_F\_Harvest}, \ {\tt SCI\_S\_C\_R\_F\_01\_IsCleaningAgent}, \ {\tt SCI\_F\_Harvest}, \ {\tt SCI\_C\_R\_F\_01\_IsCleaningAgent}, \ {\tt SCI\_F\_Harvest}, \ {\tt SCI\_C\_R\_F\_01\_IsCleaningAgent}, \ {\tt SCI\_F\_Harvest}, \ {\tt SCI\_S\_C\_R\_F\_01\_IsCleaningAgent}, \ {\tt SCI\_S\_01\_IsCleaningAgent}, \ {\_ SCI\_S\_01\_IsCleaningAge$ SCI\_C\_Fill\_CA, SCI\_C\_Rinse\_CA, SCI\_C\_Rinse\_CB

## PLC Subroutine : C\_Fill\_CA, C\_Rinse\_CA, C\_Rinse\_CB

These PLC subroutines are described in PROCEDURE 61, PROCEDURE 64 and PROCEDURE 65

#### Variables Used (I/O):

All variables involved in PROCEDURE 61, PROCEDURE 64 and PROCEDURE 65

Description: To choose whether WATER or CLEANING AGENT is used for Filling R-C-01, there is a concept variable:  $C_CL_Cleaning_agent$  and  $(C_CL_Cleaning_agent=0N)$ , then R-C-01 is filled with *Cleaning agent* and C\_Cl\_Cleaning\_agent=OFF, then R-C-01 is filled with water only)

## PLC Subroutine : C\_R\_F\_01

## Fig: PLC procedure: C\_R\_F\_01

Variables Used (I/O):

V\_S\_07, V\_F\_12, V\_F\_10, V\_C\_04, V\_S\_13, V\_F\_08, V\_C\_11, PMP\_C\_01, LS C 02

Description: No more explanation, the procedure is detailed enough.

Questions: The SCI variable SCI\_C\_Cleaning\_Agent doesn't exist BUT there is another Concept variable: C\_CI\_Cleaning\_agent used to choose to fill R\_C\_01 with water or cleaning agent.

## Recommendations / changes

HW modifications

PLC programme modifications to be rewritten because does not work

HMI modifications Local

adapt it

Remote

Variables



12/06/2008

Proc 55

## Recommendations / changes

**HW modifications** 

# PLC programme modifications

cleaning of line 2 to be written authorize two options with and without cleaning agent check transition 32 on line 1 : final rinsing is not correct

# **HMI modifications**

Local

## Remote

Variables

# Others

User Manual

emphasize that the PMP\_F\_02 should not have its tube clamped do we want cleaning agent by default or not ?

Proc 66 - emergency shutdown of SIP

13/06/2008

Emergency stop tried while being in Proc68 on line 1 there was a little delay (5s) on the return to closed position of VS04

## Recommendations / changes

**HW modifications** 

**PLC programme modifications** 

HMI modifications Local

Remote

Variables

# **1.1. Procedure 68:** SIP: membrane Fi-F-01 / Fi-F-02 *Scope*

13/06/2008

The membranes are CIP on a regular basis in order to prolong their lifetimes. After every CIP procedure the filtrate side of the membrane must be made sterile again. To avoid big pressure differences over the membrane also the retentate side of the membrane is included in the process.



## Fig: Sterilization of Filtration Unit: membrane Fi-F-01 / Fi-F-02

The above figure shows the parts sterilized in case of Fi-F-01. All orange colored piping and parts are heated by steam. Red filled valves are actuated during the procedure. V-F-07 is normally closed because the system is filtrating over mbne 2.

## Prerequisite

• The CIP procedure for both membrane sides (must precede this procedure). The entire filtrate line, including effluent vessel and the membrane inside membrane must contain only water and gas.

• The filter Fi-F-03 is also to be sterilized and must be present in the module.

- Tube must be installed on filtration pump PMP-F-02. This is a good time to replace the tube by a new one.
- The pump head on PMP-F-02 must be open so that the tube is not clamped.

Cooling agent must be removed from the double jacket on the effluent vessel

R-F-01. Use the red handle valves and a recipient. Leave open the valves that

close this jacket to release any steam from remaining agent during SIP

## Protocol

1. Fill the steam generator St-S-01 with 8 I tap water.

- 2. Switch the main switch and the two green switches on St-S-01 to 1.
- 3. Use the HMI to start the procedure (S-ET1 /S-ET2 in the PLC): SCI\_S\_S1 / SCI\_S\_S2
- The PLC activates the steam generator
- 4. Wait until pressure in St-S-01 is 4 barg. This can be checked on its built in pressure indicator.
- 5. Make sure the valve on top of St-S-01 (that connects to the FU) is entirely open.
- 6. Let the PLC know that the St-S-01 is ready by indicating this on the HMI: SCI\_ST\_F\_01\_IsItReady
- The PLC switches valves in order to gradually increase pressure and temperature in the membranes and other parts. When temperature / pressure is the desired SIP value a timer starts. Temperature / pressure is kept above this value for the necessary period of time.
- Then St-S-01 is switched off and valves are switched back.
- 7. Wait for the PLC routine to finish (cfr. HMI).
- 8. Close the valve on St-S-01.
- 9. Open the If no another SIP action is foreseen the pressure vessel should

Fig. DI C procedures C C1

be depressurized using PROCEDURE 67: SIP: Release pressure in St-S-01

SCI variables : SCI\_S\_S1, SCI\_S\_S2, SCI\_ST\_F\_01\_IsItReady



12-jun Croutine checked without steam13-jun Croutine checked with steam

Fig: PLC pro	cedure: 5_51
Procedure for mbne 1 SIP	
· · ·	· · ·
S_S_S1_001	· · ·
	: :
· · · · · · · · · · · · · · · · · · ·	
T_S_S1_001_Check	SCI_S_S1 AND
	No filtration operation through
	the membrane 1
start steam generator	
S_S_S1_002 wait until seam generator is warmed up (10 mi	The steam generator is SET
. wait until seam generator is warned up (10 mil	SCI_ST_F_01_IsltReady is RESET
	SCI_ST_P_OT_INIGADA IN RESET
SCI_ST_F_01_lsitReady	· · ·
start warming up the mbne module and piping g	radually by switching valves
S_S_S1_003 TB_S_S2 is set	
T_S_S1_003	Valves involved in the mbne 1 SIP are OK
	valves involved in the hibite 1 SIF are OK
wait for temperature to reach SIP temperature	
S_S_S1_004	
	· · ·
S_S1_Tools_Fi_SIP_temp_OK	
wait 30m (SIP time)	
S_S_S1_005	· · · ·
	· · ·
· · · · · · · · · · · · · · · · · · ·	; ;
turn steam generator off S_S_S1_006.disable valve logic	Steam generator is DECET
	Steam generator is RESET
· · · · · · · · · · · · · · · · · · ·	Valves are RESET
~S_S1_Tools_EN	
reset sequence command flag	
S_S_S1_END	: : : : : : : : : : : : : : : : : : :
	: : :
>s_s_s1_x001	
$\angleF$ , , ,	· ·

Variables Used (I/O):

V\_S\_02, V\_S\_03, V\_S\_05, V\_S\_06, V\_S\_08, V\_S\_07, V\_S\_11, V\_S\_13, V\_F\_03, V\_F\_04, V\_F\_07, V\_F\_15, ST\_S\_01

Description: No more explanation, the procedure is detailed enough.

## PLC Subroutine : S\_S2

## 12-jun C checked without steam

## Fig: PLC procedure: S\_S2

Procedure for mbne 2 SIP	· · ·			
	• •	•		
<u></u>				
S_S_S2_001				
<u> </u>				
wait for comma	nd · · · · · · ·			
T_S_S2_001_Check			•	
				•
	: .	:	:	:
start steam gene	erator			•
S_S_S2_002 wait until seam	generator is warmed u	up (15 min)	:	
1			:	
	the mine medule at	ad pipipa aredually by a	witching values	· •
S_S_S2_003 TB_S_S2 is set	o the mone module at	nd piping gradually by s	witching varves	
				•
		•		
S_S2_Tools_EN				
wait for tempera	ture to reach SIP tem	nerature		
S_S_S2_004	to reach oir ten	perature .		•
0_0_02_004.				
			· · · · · · ·	
				•
S_S2_Tools_Fi_SIP_temp_OK				
wait 30m (SIP t	ime)			
S_S_S2_005				•
	: .	:	:	:
				•
			:	
1				
turn steam gene	erator off			
S_S_S2_006 disable valve lo				•
				· :
~S_S2_Tools_EN				
~5_52_100I5_EN				
reset sequence	command flag			
S_S_S2_END				
	· · ·			
1				
			•	
S_S_S2_001	· · ·	•	•	. 13-jun
				ALSO TESTED : EMERGENCY SHUTDOWN F
		•	-	. ALGO TEGTED . LIVIERGENGT GHUTDOWN P

Variables Used (I/O):

V\_S\_02, V\_S\_06, V\_S\_13, V\_S\_03, V\_S\_08, V\_S\_06, V\_S\_04, V\_S\_12, V\_F\_03, V\_F\_04, V\_F\_07, V\_F\_15, ST\_S\_01

Description: No more explanation, the procedure is detailed enough.

## Question:

1. Is it a manual operation: Switch the main switch and the two green switches on St-S-01 to 1?

2. The valves involved in this subroutines is not defined explicitly; are they V\_S\_02, V\_S\_06, V\_S\_13, V\_S\_03, V\_S\_08, V\_S\_06, V\_S\_04, V\_S\_12, V\_F\_03, V\_F\_04, V\_F\_07, V\_F\_15?

## Recommendations / changes

## **HW modifications**

sensor TS\_F\_03 to be checked not possible to reach the 121C setpoint : check the The procedure guarantees the adequate sterilisation of the pipes (both retentate and filtrate) from the steam inlet to the drain of condensate, but: - The drain of condensate in the filtrate line (via V-S-06) is far from the end of the pipe (V-F-07), so this end is a "cul de sac" even if V-C-13 is closed. - The steam inlet in the retentate line (via V-S-04) is also far from the begginning of the pipe (V-F-04), even that in this case V-S-04 is opening discontinuously to maintain pressure in the line, so partially letting the steam arrive until V-F-04. - There is not any vacuum breaking operation in the end of the procedure, so its critical to start the filtration immediately after the sterilisation to avoid vacuum in the line, unless an external supply of nitrogen would be provided

The kind of valves used (ball valves) all along retentate and filtrate sides is not the best for axenicity

The screwed connections are risky for axenicity

## **PLC programme modifications**

add the button/question for confirmation of steam presence

## **HMI** modifications

Local

do we want to be able to mpdify locally the sterilization temperature setpoint?

## Remote

Variables

## Others

User Manual

# **1.1. Procedure 69:** SIP: membrane Fi-F-01 / Fi-F-02, filtrate line and Filtrate tank R-F-01

## Scope

Before starting filtration over a membrane it is useful to -after cleaning -sterilize the entire filtrate line in order to avoid contamination of eventual reproducing species that may have past the membrane in very small amounts during the previous batch. The retentate side of the membrane is also put under steam pressure because pressure and temperature differences between both sides of the membrane increase the chance for it to break.

# Fig: Sterilization of Filtration Unit: membrane Fi-F-01, filtrate line and Filtrate tank

R-F-01



The above figure shows the parts sterilized in case of Fi-F-01. All orange colored piping

and parts are heated by steam. Red filled valves are actuated during the procedure

## Prerequisite

The CIP procedures for both membrane sides and effluent vessel must precede this procedure. The entire filtrate line, including effluent vessel and the membrane inside membrane must contain only water and gas.

The filter Fi-F-03 is also to be sterilized and must be present in the module.

Tube must be installed on filtration pump PMP-F-02. This is a good time to replace the tube by a new one.

The pump head on PMP-F-02 must be open so that the tube is not clamped.

Cooling agent must be removed from the double jacket on the effluent vessel R-F-01. Use the red handle valves and a recipient. Leave open the valves that close this jacket to release any steam from remaining agent during SIP

## Protocol

1. Fill the steam generator St-S-01 with 8 I tap water.	13/06/2008	
<ol><li>Switch the main switch and the two green switches on St-S-01 to 1.</li></ol>		
<ol><li>Use the HMI to start the procedure (S-All1 /S-All2 in the PLC): SCI_S_P_All1,</li></ol>		
SCI_S_AII1 / SCI_S_AII2	С	it was checked both without steam
The PLC activates the steam generator	NC	MPP with own MPP steam circuit
4. Wait until pressure in St-S-01 is 4 barg. This can be checked on its built in pressure		
indicator.	na	
5. Make sure the valve on top of St-S-01 (that connects to the FU) is entirely open.		
	na	
<ol><li>Let the PLC know that tSt-S-01 is ready by indicating this on the HMI:</li></ol>		
SCI_ST_F_01_IsItReady	NC	button or question missing
The PLC switches valves in order to gradually increase pressure and temperature in the		
membranes and other parts. When temperature / pressure is the desired SIP value a		
timer starts. Temperature / pressure is kept above this value for the necessary period of	1	
time.		
Then St-S-01 is switched off and valves are switched back.	na	
Wait for the PLC routine to finish (cfr. HMI).		
Close the valve on St-S-01.		
Open the If no another SIP action is foreseen the pressure vessel should be		
depressurized using PROCEDURE 67: SIP: Release pressure in St-S-01	NC	done by hand on the MPP steam circuit

SCI	variables :	SCI_S_P_All1,	SCI_S	P_All1_IsUserPresentCIP,
SCI_S_P_	All1_IsUserPresent,	SCI	_C_P_Cl1,	SCI_C_R_F_01,
SCI_S_P_	All1_IsUserPresentSIP,	SCI_S_All1,	SCI_S_All2,	SCI_ST_F_01_IsItReady,
SCI_S_All	1_IsPMP_F_02_Closed			

## PLC Subroutine : C\_S\_P\_All1 (protocol)

Fig: PLC protocol: C\_S\_P\_All1



## Variables Used (I/O):

All variables involved in PROCEDURE 56 and PROCEDURE 54

*Description:* This is the main protocol for SIP. The procedures C\_P\_Cl1, C\_R\_F\_01, C\_S\_All1 are called inside the main protocol.

## PLC Subroutine : C\_S\_AII1

13/06/2008 C

checked without steam

## Fig: PLC procedure: C\_S\_All1



Switch valves	
S_S_AII1_003TB_S_S2 is set .	· · ·
T_S_AU1_003	
wait for temperature to reach SI	
	e temperature
S_S_AII1_004	
· ·	
S_AII1_Tools_R_F_01_SIP_temp_OK	
wait 30m (SIP time)	
S_S_AII1_005	
1	
· · ·	
reset valves	
S_S_AII1_008	
5_5_XIII_000	
· · ·	
S_Valvestate_Stop_OK	
Ask to close PMP_F_02	
S_S_AII1_007Ask to empty ST-F-01	
<u> </u>	
SCI_S_AII1_IsPMP_F_02_Closed	
<ul> <li>reset sequence command flag</li> </ul>	
S_S_AII1_END	
· · ·	
1	
$\leftarrow$ $\perp$ $\downarrow$ $\downarrow$ $\downarrow$ $\downarrow$	
S S AII \$ 001 ·	
<u></u>	

## Variables Used (I/O):

V\_S\_02, V\_S\_06, V\_S\_03, V\_S\_08, V\_S\_07, V\_S\_05, V\_S\_11, V\_F\_03, V\_F\_04,

V\_F\_07, V\_F\_08, V\_F\_10, V\_F\_12, V\_F\_15, V\_C\_à4, V\_G\_21, ST\_S\_01, PMP\_F\_02

Description: The current procedure is used in the main SIP protocol.

## *PLC Subroutine* : C\_S\_AII2

## Fig: PLC procedure: C\_S\_AII2

cedure for cleaning mbne 1						
				•		
		•		•		
		•		•		
					• •	•
_S_AII2_001						
_3_All2_001						
U .				•		
wait for comm	3	. : .		: .		
5 AII2 001	and			:		
check if memb	rane temperat	ure is still (	эк			
				: .		
start steam ger	reator			•		
S All2 002				:		
wait until seam	n generator is v	varmed up	(10 min)			
	-					
	:	· : ·		: :	• •	
· ·	•	•		•		
				:		
Switch valves				: :	· ·	
S All2 003TB_S_S2 is se	· ·	•		•		
_S_AII2_00316_5_521556	1.	•		•		
;				:		
	A					
·	•	•		•		
/alvestate_All2_OK						
wait for tempe	rature to reach	SIP temp	erature			
_S_AII2_004				•		
				:		
					• •	
AII2_Tools_R_F_01_SIP_te	i ok					
AII2_100IS_R_F_01_SIP_te	mp_OK	•		•		
		. : .		: .		

nc

nc

this transition does not work

wait 30m (SIP time)	
1 reset valves	
S_S_AII2_006	
S_Valvestate_Stop_OK	
s_S_AII2_END	

Variables Used (I/O):

 $V\_S\_02, \ V\_S\_06, \ V\_S\_03, \ V\_S\_08, \ V\_S\_06, \ V\_S\_04, \ V\_S\_12, \ V\_F\_03, \ V\_F\_04,$ 

V\_F\_07, V\_F\_14, V\_F\_08, V\_F\_10, V\_F\_12, V\_C\_04, V\_G\_21, ST\_S\_01

**Description:** The current procedure must be used in the main SIP protocol for the  $2^{nd}$  membrane. BUT this protocol doesn't exist.

Question:

1. Is it a manual operation: Switch the main switch and the two green switches on St-S-01 to 1?

2. The PLC subroutines S\_P\_All1 (protocol) is the protocol corresponding to the current

procedure and the SFC procedure S\_All1 is called inside this protocol; why not S\_P\_All2?

made for line 1 only

13/06/2008

Recommendations / changes

## HW modifications

tank, but:

VS08 is connected to PLC but not to any fluid circuit - use as spare? The procedure in this case guarantees the complete sterilization of the line including the filtrate

- The "cul de sac" comment in Proc. 68 for V-S-04 is also applicable here.

- Tha fact that two steam inlets are coming at the same time into the R-F-01(one from V-S-04 through the filter Fi-F-03 and the other from V-S-13) make not obvious the adequacy of the procedure both for the sterilisation and for the resistance (based on deltaP) of the Filter Fi-F-03.

- The phase of vacuum braking after sterilisation is also missing in Proc. 69, and in this case to start-up a procedure of filtration seem not enough to break vacuum quickly in R-F-01, so it would be needed to have an entrance of nitrogen in R-F-01 in the end of the procedure.

The kind of valves used (ball valves) all along retentate and filtrate sides is not the best for axenicity

The screwed connections are risky for axenicity; this is specially critical if PTFE ribbon is used, wich is quite common in the connections to R-F-01

## PLC programme modifications

modify PLC program to be in agreement with absence of VS08 on hardware check for line 2 code seems incomplete

## HMI modifications

Local

add a question or button to confirm good state of PMPF 02 connection add all  $% \left( {{\rm buttons}} \right)$  buttons

Remote

see local

Variables

User Manual

## Others

the procedure has to be modified to take into account that VS08 is not connected to effluent vessel and that VF10 is used to purge and to drain add instructions for steam circuit maintenance after use of steam

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
Procedure steps	date/nour	N/NC	comments	comments	comments
1.1. Procedure 42: Drain Filtration Unit: filtrate line					
Scope					
Get liquid out of the part of the filtration piping starting at the effluent vessel and going via filtrate side to retentate side of the					
membrane Fi-F-01 of Fi-F-02.					
Prerequisite					
Effluent vessel R-F-01 must be empty					
Procedure					
1. Unlock the tubing in PMP-F-02.					
2. Make sure that the steam valve on the steam generator is					
entirely closed.					
<ol> <li>Use the HMI to start PLC procedure C_Drain_All1 if filtrate line including mbne 1 is to drained or C_Drain_All2 if filtrate line</li> </ol>					
including mbne 2 is to be drained: SCI_C_CB_to_drain1,					
SCI_C_CB_to_drain2	16/06/2008 12:11	nc	the button has no action		
<ol> <li>These procedures open the respective drain valve V_F_15 or</li> <li>14 status of the number of th</li></ol>					
V-F-14 at the bottom of the membrane module and valves V-S-04 and -12 or respectively V_S_5 and -11.			the procedure was followed manually step by step		
			The procedure was rollowed manually step by step		
5. Then V-G-21 is activated to put pressure from the N2 line on					
the effluent vessel and push the liquid out of the filtration line,					
through a piece of the SIP piping and the retentate side of the					
<ul><li>membrane. It leaves the system via the drain valve.</li><li>6. Wait for the PLC procedure to finish.</li></ul>					
SCI variables : SCI_C_CB_to_drain1, SCI_C_CB_to_drain2					
PLC Subroutine : No SFC procedure BUT maybe procedure must					
be created					
Variables Used (I/O):					
V_F_14, V_F_15, V_S_04, V_S_12, V_S_05, V_S_11, V_G_21					
Description: No more description; the procedure is explicit					
enough.					
		14/11/2			
Recommendations / changes	WHEN	WHO			
HW modifications		UAB			
		UAD			
PLC programme modifications		SHER	ΡΔ		
		SHER			

NTE

HMI modifications Local

Remote

Variables

# 1.1. Procedure 69: SIP: membrane Fi-F-01 / Fi-F-02, filtrate line and Filtrate tank R-F-01 Scope

Before starting filtration over a membrane it is useful to –after cleaning –sterilize the entire filtrate line in order to avoid contamination of eventual reproducing species that may have past the membrane in very small amounts during the previous batch.

# Fig: Sterilization of Filtration Unit: membrane Fi-F-01, filtrate line and Filtrate tank



The above figure shows the parts sterilized in case of Fi-F-01. All orange colored piping and parts are heated by steam. Red filled valves are actuated during the procedure

## Prerequisite

The CIP procedures for both membrane sides and effluent vessel must precede this procedure. The entire filtrate line, including effluent vessel and the membrane inside membrane must contain only water and gas.

The filter Fi-F-03 is also to be sterilized and must be present in the module. Tube must be installed on filtration pump PMP-F-02. This is a good time to replace the tube by a new one.

The pump head on PMP-F-02 must be open so that the tube is not clamped.

Cooling agent must be removed from the double jacket on the effluent vessel R-F-01. Use the red handle valves and a recipient. Leave open the valves that close this jacket to release any steam from remaining agent during SIP

## Protocol

1. Fill t	he steam generator	St-S-01 with 8 I tap w	vater.	16/06/2008	
2. Swite	ch the main switch	and the two green swi	itches on St-S-01 to 1.		
3. Use	the HMI to start the	e procedure (S-All1 /S-	All2 in the PLC): SCI_S_P_All1,		
SCI_S_AI	I1 / SCI_S_AII2			С	it was checked with steam
The PLC a	activates the steam	generator		NC	MPP with own MPP steam circuit
4. Wait	until pressure in St	-S-01 is 4 barg. This c	an be checked on its built in		
pressure	indicator.			na	
5. Make	e sure the valve on	top of St-S-01 (that co	onnects to the FU) is entirely open.	na	
6. Let t	he PLC know that t	St-S-01 is ready by inc	licating this on the HMI:	na	
	_01_IsItReady	or o or is ready by inc	actually this of the finit.	NC	button or question missing, forced through PLC
	,	rder to gradually incre	ase pressure and temperature in		
			e / pressure is the desired SIP value		
			ve this value for the necessary		
period			,		
Then St-S	S-01 is switched off	and valves are switch	ed back.	na	
Wait for t	the PLC routine to fi	inish (cfr. HMI).			
Close the	valve on St-S-01.				
Open the	If no another SIP a	action is foreseen the p	pressure vessel should be		
depressu	rized using PROCED	URE 67: SIP: Release	pressure in St-S-01	NC	done by hand on the MPP steam circuit
SCI	variables :	SCI_S_P_AII1,	SCI_S_P_All1_IsUserPresentCIP,		

SCI\_S\_P\_AII1\_IsUserPresent, SCI\_C\_P\_CI1, SCI\_C\_P\_CI1, SCI\_C\_R\_F\_01, SCI\_S\_P\_AII1\_IsUserPresentSIP, SCI\_S\_AII1, SCI\_S\_AII2, SCI\_ST\_F\_01\_IsItReady, SCI\_S\_AII1\_IsPMP\_F\_02\_Closed

## PLC Subroutine : C\_S\_P\_AII1 (protocol)

## Fig: PLC protocol: C\_S\_P\_All1



## Variables Used (I/O): All variables involved in PROCEDURE 56 and PROCEDURE 54

*Description:* This is the main protocol for SIP. The procedures C\_P\_Cl1, C\_R\_F\_01, C\_S\_All1 are called inside the main protocol.

## PLC Subroutine : C\_S\_AII1

Fig: PLC procedure: C\_S\_All1 Procedure for cleaning mbne 1 . S\_S\_AII1\_001 wait for command SCI\_S\_AII1 start steam generator S\_S\_AII1\_002 Ask to open PMP\_F\_02 Ask to add watrer in setam generator and to set "SCI\_ST\_F\_01\_IsitReady" if steam generator pressure = 4 bar SCI\_ST\_F\_01\_IsitReady Switch valves S\_S\_AII1\_003TB\_S\_S2 is set 003 T\_S\_AII1 wait for temperature to reach SIP temperature S\_S\_AII1\_004 S\_AII1\_Tools\_R\_F\_01\_SIP\_temp\_OK wait 30m (SIP time) S\_S\_AII1\_005 reset valves S\_S\_AII1\_006 S\_Valvestate\_Stop\_OK Ask to close PMP\_F\_02 S\_S\_AII1\_0074sk to empty ST-F-01 SCI\_S\_AII1\_IsPMP\_F\_02\_Closed reset sequence command flag S\_S\_AII1\_END ∕s\_s\_aii<u>}</u>001

Variables Used (I/O):

 $V\_S\_02, \ V\_S\_06, \ V\_S\_03, \ V\_S\_08, \ V\_S\_07, \ V\_S\_05, \ V\_S\_11, \ V\_F\_03, \ V\_F\_04,$  $V_F_07, \ V_F_08, \ V_F_10, \ V_F_12, \ V_F_15, \ V_C_{a4}, \ V_G_{21}, \ ST_S_{01},$ PMP\_F\_02

Description: The current procedure is used in the main SIP protocol.

16/06/2008 C

checked with steam

timer set to 30 min in order to observe the process there is a regulation of pressure inside the line obtained thanks to the opening/closinf of steam feeding valves V\_S\_04, V\_S\_12, V\_S\_13

it was indeed observed that V\_S\_06 remains closed in order to force the steam from V\_S\_12 to V\_F\_10

OK the valves return to their closed position except for the feed valves that still regulate pressure

nc

С

this question has to be asked by HMI this operation requires PPEs

## $\textit{PLC Subroutine}: C\_S\_AII2$

Fig: PLC procedure: C\_S\_AII2

Procedure for cleaning mbne 1							
	•						
·				•			
S_S_AII2_001							
wait for comma T_S_AII2_001	nd						
	ane temperature i	s still OK					
start steam gen	erator						
wait until seam	generator is warm	ed up (10 min)					
1							
Switch valves							
Switch valves S_S_AII2_003TB_S_S2 is set		:					
	· · · · · ·						
S_Valvestate_All2_OK	:						
wait for tomor	ature to reach SIP	tomocraturo			nc	nc	this transition does not work
S_S_All2_004	atore to reach on-	temperature					
				•			
S_AII2_Tools_R_F_01_SIP_ter							
wait 30m (SIP t	ime)			•			
S_S_A112_005							
	•						
reset valves							
S_S_A112_006							
	:						
S_Valvestate_Stop_OK							
	- - 	:					
reset sequence	command flag						
	command flag	• • • • • • •					
reset sequence	command flag						
reset sequence	command flag		· · · ·				
reset sequence	command flag						
S_S_AII2_END	command flag			•			
S_S_AII2_END	command flag		· · · · ·				
S_S_AII2_END	command flag						

## Variables Used (I/O):

V\_S\_02, V\_S\_06, V\_S\_03, V\_S\_08, V\_S\_06, V\_S\_04, V\_S\_12, V\_F\_03, V\_F\_04,

## V\_F\_07, V\_F\_14, V\_F\_08, V\_F\_10, V\_F\_12, V\_C\_04, V\_G\_21, ST\_S\_01

**Description:** The current procedure must be used in the main SIP protocol for the 2<sup>nd</sup> membrane. BUT this protocol doesn't exist.

## Question:

1. Is it a manual operation: Switch the main switch and the two green switches on St-S-01 to 1?

2. The PLC subroutines S\_P\_All1 (protocol) is the protocol corresponding to the current procedure and the SFC procedure S\_All1 is called inside this protocol; why not S\_P\_All2?

## made for line 1 only

## **Recommendations / changes**

## HW modifications

VS08 is connected to PLC but not to any fluid circuit - use as spare? The procedure in this case guarantees the complete sterilization of the line including the filtrate tank, but: - The "cul de sac" comment in Proc. 68 for V-S-04 is also applicable here.

- Tha fact that two steam inlets are coming at the same time into the The kind of valves used (ball valves) all along retentate and filtrate sides is not the best for axenicity The screwed connections are risky for axenicity; this is specially critical if PTFE ribbon is used, wich is quite common in the connections to R-F-01 check the steam traps status check the PMP\_F\_02 silicone tube

replace the silicone tubing between VG21 and the effluent tank

## PLC programme modifications

modify PLC program to be in agreement with absence of VS08 on hardware check for line 2 code seems incomplete

## HMI modifications

Local add a question or button to confirm good state of PMPF 02 connection add all buttons

Remote see local

#### Variables Others

User Manual the procedure has to be modified to take into account that VS08 is not connected to effluent vessel and that VF10 is used to purge and to drain

add instructions for steam circuit maintenance after use of steam

## 16/06/2008

# **MELISSA**



# ANNEX 2

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**MELISSA** 



# 1. HYGIENE AND SAFETY CHECK-LIST

Test Phase : C1 functional tests step 1	System Description : Compartment 1
Date: 28/05/08	Safety manager : Arnaud Fossen
List of reserves <u>YES or NO</u>	Others members
Join this list with priorities	MPP : Enrique Peiro, Raul Moyano
-	SHERPA : Olivier Gerbi

First column-reference N° is used to check points not conformed

N⁰	Description	N/A	ОК	NOT OK
S-1	Adequate safety equipments and staff protection exist and are located in the right place. Are included: fire-extinguisher, eyes-washers , safety shower, breathing masks, fire alarm, first aid kit , body harness, protection against electric current etc)	Breathing mask body harness,	fire-extinguisher, safety shower, fire alarm, first aid kit , protection against electric current	Eye washer not accessible enough
S-2	Access to safety equipment and fire protection is clear		x	
S-3	An appropriate solution has been found to the exposition of noise problems (85 dbA)		x	
S-4	Illumination is appropriate		x	
S-5	catwalks and ladders allow a safe access to every level	x		
S-6	All ladders are equipped with fences or chain at access points	x		
S-7	Platforms or floors to work are well protected and have a good leveling		x	





# **TECHNICAL NOTE**

S-8	Rules for work at height are respected.	х		
S-9	The work zone is correctly ventilated.		x	
S-10	Peepholes on the process, flow indicators, pressure gauges etcare correctly shielded		x	To check spyholes seals
S-11	Panels indicate the dangers existing in the work area and provide appropriate instructions		x	
S-12	Exits and evacuation paths are clearly indicated		x	
S-13	The layout of the equipments is acceptable from the point of view of their height, their accessibility and the availability of elevation devices		x	Access to Utilities is relatively difficult
S-14	The staff is protected from cold and hot surfaces			The hot water tank is not insulated yet (65°C)
S-15	Tank legs or lower parts are fireproof		x	
S-16	Material Safety Data Sheets are available		x	
S-17	The tanks and all instruments are properly tagged			New tagging in progress
S-18	The construction/installation phase is over and the equipment is ready for use. The scaffolds have been dismantled, the rubbish have been cleaned up, the construction tools have been removed from the process.		x	
S-19	The steps for preparing and executing the maintenance have been taken in		x	





# **TECHNICAL NOTE**

	order to reduce as much as possible the risks for the staff		
S-20	The capacity of the elevation devices is clearly indicated on the equipment	Х	
S-21	Adequate dispositions have been taken for handling gas cylinders and other mobile containers	Х	
S-22	Gas cylinders are stored in such a way they can be transferred in safety	х	
S-23	Gas flammable cylinders are stored separately	х	

Enumerate difference that have been corrected before the start:

Enumerate difference that have been / will be corrected after the start:

S-1: tap water supply is anyway accessible near the reactors; eyewasher will be relocated; acceptable for the tests

S-10: checked: OK

S-13: Utilities layout is conditioned by the available space in the room; acceptable for the tests having special care for the needed operations on the rack (more than one people always involved)

S-14 : it is not hot enough and accessible enough to be a threat for people during the tests ; acceptable for the tests

S-17: PID available according to the existing TAGs




## 2. Environment CHECK-LIST

Test Phase : C1 functional tests step 1	System Description : Compartment 1
Date: 28/05/08	Safety manager : Arnaud Fossen
List of reserves <u>YES or NO</u>	Others members
Join this list with priorities	MPP : Enrique Peiro, Raul Moyano
	SHERPA : Olivier Gerbi

First column-reference N° is used to check points that are non compliant

Nº	Description	N/A	ОК	NOT OK
E-1	Containment in case of leak, retention walls and drainage are adequate		x	
E-2	The wastes to be generated in nominal and non nominal operation have been identified and quantified	х		
E-3	Adequate dispositions have been taken for wastes evacuation including cleaning products and solid wastes	x		
E-4	Drains are been clearly identified «Rainwater»or «Process» according to the case. Plans are up to date		x	
E-5	Genetically Modified Organisms are identified	х		
E-6	The authorizations for animal experimentation have been granted	x		

Enumerate differences that have been corrected before the start: N/A

Enumerate differences that have been corrected after the start:  $N\!/\!A$ 





## **TECHNICAL NOTE**

## 3. CHECK-LIST for "READY for START UP" REVIEW

Phase : functional tests step 2

System Description \_\_\_\_\_Compartment I

Date \_28/05/08\_\_\_\_\_

Safety Manager/ safety Officer \_Arnaud Fossen\_ Team members \_\_MPP : Enrique Peiro, Raul Moyano ;SHERPA : Olivier Gerbi

Description	Re	Result		Result		Result		esult Remarks		Remarks
	NA	Y	Ν							
1. Standards and operating procedures referring to the unit have been established and allow the unit exploitation.		Х								
2. Subcontractors procedures, operational specific procedure and subcontractors standards are written in the local language used and/or understood by operators.		Х		The procedures are available in English, understood by the personnel involved in the tests						
3. Operating procedures describe the steps required to execute specific activities on the process.		Х								
4. Engineering file (P¬ID, drawings, technical documents) are available and complete		Х								
5. Modified documents have followed the revision/approval loop		х								





6. Records indicate that documents have been duly-examined before the start of operations.		x		
7. A list of elements important for safety is available with their operation range		X		Three safety valves that have been tested for their triggering pressure level Level alarms on influent and bioreactor tanks are working
8. Procedures exist in case the system switches to a degraded mode (in case of failure of one component)	Х			
9. A maintenance plan is enforced for the elements important for safety.		Х		The safety valves have been checked ahead of the tests
10. The safety position of equipments and safety loops in case of alarm triggering have been controlled		х		This is part of the testing sequence
11. Process risks have been assessed, and the recommendations to mitigate them are documented. The implementation of these actions is documented.			x	Laboratory Hazard Analysis MPP-TN-07-0001(3) and C1 HAZOP MPP-TN-07-1001(0) are available. Update of C1 HAZOP to be completed after the potential hardware modifications to be defined
12. Mechanical integrity justification exists for every document equipment.		х		
13. The control system documentation (user manual, functional			x	User manual to be updated as a consequence of the





# **TECHNICAL NOTE**

description of control) is up to date and available.				functional tests conclusions
14. A back up copy control system software to date is stored in a safe place.		х		
15. In case of alarm activation, the safety positions of actuators are identified and the factory acceptance tests are duly documented.		х		
16. A risk analysis for the working place has been performed.		x		Hazard analysis of the laboratory and inspection by UAB Safety Officer
17. In case of emergency, interventions and evacuation procedure are ready for implementation.		х		
18. Working license procedures and instructions procedure are ready for implantation.		х		
19. Protection from and detection of fire have been checked.		х		Yearly routine inspection coordinated by UAB/ETSE maintenance team
20. Operators have been trained for the specific operational procedures and their training/certification is documented.	Х			
21. Spare parts list with their availability exist.			х	Not critical for starting of functional tests
22. Users can clearly identify the documents that are not controlled		х		

# **MELISSA**



# ANNEX 3

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Name	ORGANIZATION	Function	Initials
Raúl Moyano	MPP	Maintenance Technician	RM
Nuria Martinez	MPP	Bioprocess engineer	NM
Enrique Peiro	MPP	Technical Manager	EP
Arnaud Fossen	MPP	ESA Operational Representative	AF
Chistophe Bourg	SHERPA	Engineer	СВ
Olivier Gerbi	SHERPA	Senior engineer	OG

## Annex 3 - CI Functional Tests Step1: Record of implied personnel

# **MELISSA**



# ANNEX 4

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						step 1 functional tests	step 2 fu	Inctional tests BR+GL
EPAS numbers	Sequence of routines	Operator	нмі	status	applicable for step 1	comments/changes from nominal para	ble for step 2	comments/changes from nominal parameters
	EMERGENCY STOPS	Γ						
16	Emergency Stop on the RV frame	OP		С			у	
17 18	Emergency Stop on the FU frame Emergency Stop of the FU frame on the HMI	OP	Y	C C			у У	
29 45	Filtration Unit: (Emergency) Shut down CIP: (Emergency) Shut down of CIP activities		Y Y	с с с с				
66	(Emergency) Shut down of SIP activities	OP	Ý	č				
	CONTROL LOOPS IMPORTANT FOR SAFETY							
N/A	pressure safety tests		n	С	v	check that the control of pressure insid	v	
N/A	level safety tests		n	c	ý	check that the control of level inside the		
	START-UP							
15	Connect N2 to the system	OP		С	v	air		Some NC (NM)
5	Influent preparation Start-up Influent tank VSSL_1000_01	OP OP	Y		n/a	water		
6 7	Filling Influent tank VSSL_1000_01		Y	C C	y y	temperature setpoint 10°C	у У	Some NC (NM)
10 11	Filling Bioreactor VSSL_1007_01 with inoculum Start-up Bioreactor VSSL_1007_01	OP OP	Y		n/a v	water	v	Some NC (NM)
12	Start-up Bioreactor VSSL_1007_01 feeding Active Gas Loop: Start-up	OP	Y	C	ý	water	ý	Some NC (NM)
26 20	Passive Gas Loop: Start_up		Ϋ́	с с с с с с	y y		у У	Some NC (NM) Some NC (NM)
22 23	Analysis Gas Loop: Start-up Analysis Gas Loop: adjust flow rates	OP	Y	С	n/a	protection of analyzer from moisture? use of CO2 and reference of CH4?	у	Some NC (NM)
24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_01	OP	Y		n/a	?	у	Some NC (NM)
31	Filtration Unit: Installation of dead-end filter LF_1200_03 Filtration Unit: Installation of ceramic membranes	OP						
33 27	LF_1200_01/LF_1200_02 Filtration Unit: Replacement of tube in pump PMP-F-02	OP OP	Y		n/a n/a			
69	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate tank	-			1/a			
	VSSL_1204_01 Filtration Unit: Start-up of filtration through membrane	OP	Y					
35	LF_1200_01/LF_1200_02		Y	С		why not in bypass ?		Some NC (NM)
	SHUT DOWN							
25	Active Gas Loop: Shut down		Y	С				
20 21 19	Analysis Gas Loop: Shut down Passive Gas Loop: Shut down		Y Y	с с				Some NC (NM) Some NC (NM)
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_01		Ϋ́	L				Some NC (NM)
46	Shut down the System, drain, rinse and clean Bioreactor VSSL_1007_01, Feefing vessel VSSL_1000_01 and Filtration Unit		Y					
32	Filtration Unit: Removal of ceramic membranes							
	LF_1200_01/LF_1200_02	OP	Y					
	NOMINAL OPERATION							
_								
5 7	Influent preparation Filling Influent tank VSSL_1000_01	OP	Y		n/a	water		
2 3	Preparation of acid for pH control in Bioreactor VSSL_1007_01 Preparation of base for pH control in Bioreactor VSSL_1007_01	OP OP			n/a n/a	water water		
11	Start-up Bioreactor VSSL_1007_01	OP	Y	с	174	Water		
12 13	Start-up Bioreactor VSSL_1007_01 feeding Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01	OP OP	Y Y	с				
71 79	Bioreactor content sampling Calibration of pH sensors AT_1011_01 et AT_1011_02	OP OP						
19	Passive Gas Loop: Shut down	01	Y					
20 21	Passive Gas Loop: Start_up Analysis Gas Loop: Shut down		Y Y	C C				
22 23	Analysis Gas Loop: Start-up Analysis Gas Loop: adjust flow rates	v	Y	С	n/a	protection of analyzer from moisture		
24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_01	Ŷ	Y		174			
25 26	Active Gas Loop: Shut down Active Gas Loop: Start-up		Y Y	C C				
29 28	Filtration Unit: (Emergency) Shut down Filtration Unit: Calibration of PMP-F-02 flow rate	PLC	Y	С	n/a			
27	Filtration Unit: Replacement of tube in pump PMP-F-02	OP			n/a			
30 31	Filtration Unit: Removal of dead-end filter LF_1200_03 Filtration Unit: Installation of dead-end filter LF_1200_03	OP OP			n/a n/a			
32	Filtration Unit: Removal of ceramic membranes	OP	Y		n/a			
33	Filtration Unit: Installation of ceramic membranes							
34	LF_1200_01/LF_1200_02 Filtration Unit: Start-up in Bypass mode	OP	Y Y	С	n/a			
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02		v	С				
37	Filtration Unit: Enter Recycle mode		Ý	с		switch to other line possible only if valv	es are re	
38 39	Filtration Unit: Enter Nominal mode Filtration Unit: Harvest Effluent vessel VSSL_1204_01		Y Y	с				Some NC (NM) Some NC (NM)
40 41	Drain Filtration Unit: retentate line Drain Filtration Unit: inside membranes LF_1200_01/LF_1200_02	OP OP						Not recorded
42	Drain Filtration Unit: filtrate line	OP	Y					
43 44	Drain Filtration Unit: entire Filtrate Unit Fill Filtration Unit with water	OP						
	CIP	1						
45 47	CIP: (Emergency) Shut down of CIP activities Cleaning Influent tank VSSL_1000_01		Y Y			water?		
48	Cleaning Bioreactor VSSL_1007_01 Cleaning of Filtration Unit: retentate side of membrane		Y					
49	LF_1200_01/LF_1200_02		Y	1				Some NC (NM)
50	Cleaning of Filtration Unit: both retentate and filtrate side of membrane LF_1200_01/LF_1200_02		Y					
54	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01	OP	Ŷ					
55	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01 and filtrate line through LF_1200_01/LF_1200_02		Y					
	SIP							
69	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate tank VSSL_1204_01	OP	Y					
61	CIP FU	1	1	I	1	I	I	Some NC (NM)
62 63	CIP FU CIP FU							Some NC (NM) Some NC (NM)
								x /

c c

с

Procedure steps	date/hour	N/NC	comments	SHERPA comments
emergency stop buttons				
Scope				

Bioreactor

2 emergency stop buttons working correctly the display on the HMI is indicating the emergency stop

Gas Loop 4 emergency stop buttons located on Filtration Unit skid are working correctly

the display on HMI is not working

2.1. Valve opening at the pressure indicated by the manufacturer.

		INPUT	OPEN VALVE	EPAS CALIBATED		
VALVE TESTED	DATA				REMARKS	RESULTS
		PRESSURE	PRESSURE	PRESSURE		
					The manometer used hasn't	
					mbarg divisions, and not	
RV_1003_01	26-feb	5 barg	500 mbarg	500mbarg	have a calibrated certificate	С
					The manometer used hasn't	
					mbarg divisions, and not	
RV_1009_01	26-feb	5 barg	510mbarg	500mbarg	have a calibrated certificate	С

RV\_1100\_01

26-feb 5 barg

3200 mbarg 3500 mbarg

when actuated, the relief valve is not going back to its position and is leaking it is acceptable for the tests

comments

## Level safety

Influent tank

manual activation of the GetCake procedure initial volume : 25L HMI animation is OK on remote HMI, GetCake procedure is not allowed because it should be done on the local HMI

general remark on blender and pump buttons there is no confirmation asked for activation/deactivation

55,15 L : LSH is activated blinking white/yellow automatically the valve S3v\_1001\_02 was automatically switched to recirculation position

general remark the tags on the screen ten dto disappear from the screen even when selected

Procedure steps	date/hour	N/NC	comments	SHERPA comments	
Flocedule steps	uale/nour	IN/INC	continents	SHERFA COMMENTS	INTE COMMENTS
1.1. Procedure 15: Connect N2 to the system				-	
Scope					
N2 must be present at I-06 (PR-G-06) before any function of the Pilot is activated. This will allow pressure regulation and flushing in VSL2_1000_01 and VSL2_1007_01. It is also necessary for calibration of the analysers, some draining procedures for the filtration unit, for harvesting of VSL2_1204_01 and for prevention of underpressure in the later vessel after SIP.		с	for the functional tests step2 BR+GL, N2 replaced by compressed air		
Procedure				-	
Set the regulation of the N2 supply around 1 barg (at no or low flow rate).	26/02/2009	с	26/2/09: mounting of a manual valve on the air instrument supply to provide 1 barg pressure at i 06		
Connect the frame's N2 connection I-06 to the N2 supply I-06.	26/02/2009	с	PI_1003_01=160 mbarg and PI_1103_01=400 mbarg		
		NC	the HPCV 1103 01 seems to be broken		
This procedure is done by the OPERATOR.					
			this has to be forced through the PC concept interface connected to the PLC		
				4	
				4	

Recommendations / changes	WHEN ?	WHO ? Comments
HW modifications add a pressure indicator at least temporarily on PR-G-04	step2	UAB
PLC programme modifications N/A		
HMI modifications indication of the N2 line on the bioreactor/influent tank	step2	NTE

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 6: Start-up Influent tank VSL2_1000_01					
Scope				-	
Initiate the functions of the influent tank.					
				-	
Prerequisite					
Bioreactor should contain a certain amount of active waste that is strong enough to	digest an	N/A			
S3V 1001 02 must be in position.	a geot a	с			
			missing how to add the cooling liquid into the loop		
Procedure			tap water was used for the tests step 2 BR+GL		
Use the HMI to					
1. Make sure HV_1003_01 is open and N2 is available at around 1 barg,					
HPCV_1003_01 is set to approximately 110 mbarg and HPCV_1003_02 to			PI_1003_01 = 116 mbar ;		
approximately 90 mbarg.	26-feb	NC	PI_1103_01 =2,1barg : THIS SENSOR IS OOO		
			the value of the speed can be modified on the frequency		
			variator of BL-V-01 inside the electrical cabinet, not through the HMI		
			please add a confirmation message to acknowledge		
2. Start blender BLE 1005 01 (set point: 200 rpm): SCI BLE 1005 01		с	modification		
3. Set temperature setpoint ( to 6°C or another value $\leq 7$ °C. Fill HX 1002 01		-			
and double jacket with water and antifreeze compound (glycol) if this is not done			temperature setpoint wasmanually set to 5,2°C in the morning	1	
yet: SCI_TT_1002_01_SP		с	(using the added switches) in order to give time to cool down		
			change of setpoint from 5°C to 10°C : the message asking for		
			confirmation is too detailed		
			the decimal figures should be entered using "," and "." is not		
		-	understood	-	
4. Start GP_1001_01 : SCI_ GP_1001_01_Right			see previous comment : please add a confirmation message		
			the initial condition of the system is that the pump was		
On initial start up, when liquid level is below connection to S3V_1001_02, GP_1001_	_01 will no	not c h		1	
			to be checked again	4	
PLC Interface :				J	

SCI variables :

SCI\_BLE\_1005\_01, SCI\_ TT\_1002\_01\_SP, SCI\_GP\_1001\_01\_Right

PLC Subroutine : No. Operator enters values from HMI

### Variables Used (I/O):

BLE\_1005\_01\_MV, TT\_1002\_01, TT\_1002\_02, HX\_1002\_01\_MV, GP\_1001\_01\_MV1, LT\_1004\_01.

WHEN? WHO? Comments

PLC programme modifications PLC has reserved a position switch for V-V-07 which is not cabled ; no real interest in gettin step2

SHPA no position switch, so not cabled same remark for V-R-19

HMI modifications		
more rapid update of compressor state ?	NTE	
color codes for lines are not clear ; senses of flows neither ;	NTE	flows are not shown, but there is no risk of reverse flow
for the cooling loop : put the whole line in red if stopped, in blue if active (for example)	NTE	
add the ps-V-03 value on the HMI screen for influent tank	NTE	PT_1001_01 added

Procedure steps	date/hour	N/NC	comments	SHERPA comments NTE comm
				4
4.4 Prove the Press of the second				
1.1. Procedure 7: Filling Influent tank VSL2_1000_01				-
Scope				4
Feed influent to the influent tank.				-
Prerequisite				-
GP_1001_01 is active except for the initial filling.	26/02/2009	<u>_</u>		-
HV 1000 01 is closed.	26/02/2009			-
HV_1000_02 is closed.	26/02/2009			1
HV 1000 03 is closed.	26/02/2009			1
SV_1003_01 is on.	26/02/2009 16:20		it is controlled by the PLC but kept closed for the moment	1
			PT_1003_01=120mbarg	
Procedure				1
				1
Initial filling (occurs at start-up, when the influent tank is totally	empty)			
<ol> <li>Connect the dedicated reservoir to valve H3V_1001_01.</li> </ol>			Vol V ini = 55L, manual drain , final volume 51 L with PT=110mbarg	, LSH1004_01 is switched off
				1
2. Open the valve underneath the reservoir and fill it with influent.				
<ol> <li>Start-up GP_1001_01: SCI_ GP_1001_01_Right</li> </ol>			pump already running	
4. Turn switch on panel (on the right of the front side of the				
bioreactor frame) and hold it while pushing the blue button				
(V_GetCakeButton) (on the right of the front side of the bioreactor			Getcake S3V_1001_02 changed position : introduction of water into	
frame) to bring the system into feeding mode. This can be checked			the influent vessel ; level and pressure readings are increasing	-
on the HMI. S3V_1001_02 switches. The pump now withdraws				
influent and pumps it into VSL2_1000_01.	26-feb	с	add the indication on HMI that GetCake was activated	
4.1 Overpressure safety valve SV_1003_01 now works to vent			indeed opening could be observed to stabilize the pressure between	h
overpressure in the influent tank without generating an alarm	26-feb	с	100 mbarg and 120 mbarg	
4.2 Because HPCV_1003_01 is not capable of releasing the				
added volume quickly enough.		с	filling up to Volume appeared to be 55L in a steady state	-
4.3 Even with the aid of SV_1003_01, the pressure in				
VSL2_1000_01 increases. S3V_1001_02 switches back and forth to				
prevent overpressure. 5. Stir the contents in the reservoir and try to have the floating		С		-
portion sucked in to minimize the amount of fragments to amass.				
Fill more influent in the reservoir before it is empty and try to avoid				
air to be sucked into the system.				
<ol> <li>When maximum level in the influent tank is reached, the</li> </ol>		C		1
system won't allow any more influent to be added and leaves				
feeding mode. This can be checked on the HMI. Valve				
S3V_1001_02 is deactivated. Valve SV_1003_01 returns to its				
normal function of safety valve.		c		
<ol><li>Close the valve underneath the reservoir. Remove the reservoir.</li></ol>		Ē		1
Empty the remaining influent and rinse it.		с		
19				
Nominal filling (occurs when influent liquid level is above the				1
minimum)				
<ol> <li>Connect the dedicated reservoir to valve H3V_1001_01.</li> </ol>				
2. Open the valve underneath the reservoir and fill it with				1
influent.				
<ol><li>Turn switch on panel (on the right of the front side of the</li></ol>				
bioreactor frame) and hold it while pushing the blue button				
(V_GetCakeButton) (on the right of the front side of the bioreactor				
frame) to bring the system into feeding mode. This can be checked				
on the HMI. S3V_1001_02 switches. The pump now withdraws				1
influent and pumps it into VSL2_1000_01. Overpressure safety		1		1
valve SV_1003_01 now works to vent overpressure in the influent				1
tank without generating an alarm, because HPCV_1003_01 is not		1		1
capable of releasing the added volume quickly enough. Because		1		
even with the aid of SV_1003_01 pressure in VSL2_1000_01		1		1
increases, S3V_1001_02 switches back and forth to prevent		1		1
overpressure.	L	<u> </u>	L	1

c

done

Increases, S3V\_1001\_02 switches back and forth to prevent loverpressure. 4. Slit the contents in the reservoir and try to have the floating portion sucked in to minimise the amount of fragments to amass. Fill more influent in the reservoir before it is empty and try to avoid air to be sucked into the system. 5. When maximum level in the influent tank is reached (60 L), the system word allow any more influent to be added and leaves feeding mode. This can be checked on the HMI. Valve SV\_1001\_02 is deactivated. Valve SV\_1002\_01 returns to its normal function of safety valve. 6. Close the valve underneath the reservoir. Remove the reservoir. Empty the remaining influent and rinse it.

PLC Interface :

SCI variables : SCI\_V\_GetCake SCI\_ GP\_1001\_01\_Right

#### PLC Subroutine : V\_GetCake (FBD)



### Figure 1: PLC Subroutine (FBD): V\_GetCake

Variables Used (I/O): GP\_1001\_01\_MV1, S3CV\_1001\_02\_MV, SV\_1003\_01\_MV, LSH\_1004\_01.

 Description:

 • Input HMI:SCL\_V\_GetCake

 • This variable or the button V\_GetCakeButton starts the PLC procedure V\_GetCake

 • The variable V\_GettingCake is then set at ON that begins the opening of the Controlled valve S3V\_1001\_02 if:

 • There is not an error of High Level in the influent tank:

 CL1004\_ERE\_VOLSwitch\_under\_liquis OFF.

 • There is no alarm about Overpressure (LT\_1004\_01 > 200mbarg): ERR Volume\_LT\_1004\_01\_OverRange

 • There is no alarm on the amount of the cake in the influent tank (VSL2\_1000\_01\_VoL\_Filtered > 60 L

· Then the cake is pumped into the influent tank

The variable V\_gettingCake is then set at ON that begins the opening of the Controlled valve S3V\_1001\_02 if :
 There is not an error of High Level in the influent tank: CL1004\_ERK\_VO15wich\_nuber[Jiqui s OFF.
 There is no alarm about Overpressure (LT\_1004\_01 > 200mbarg): ERR Volume\_LT\_1004\_01\_OverRange
 There is no alarm on the amount of the cake in the influent tank (VSL2\_1000\_01\_Vol\_Filtered > 60 L

Then the cake is pumped into the influent tank

### 55L seems to be the maximum level the calibration of volume needs to be done after functional tests

nts NTE d

ocedure steps	date/hour N/N	comments	SHERPA comments NTE comments
		Commonia	
Procedure 11: Start-up Bioreactor VSL2_1007_01			
functions of the bioreactor VSL2_1007_01.			
site		why is the GP1001 01 spot on the right blinking in green?	
hould contain inoculum or an amount of active waste (min	26/2/09 16:36 N/A	initial volume : 96L at 146 mbarg	
		remark : the heating loop pump for bioreactor can now be activ	vated using the newly installed switch (no use to pass
to			
sure HV_1009_01 is open and N2 is available at around 1		working with N2 network supply regulated at 1 barg	
N2 in the bioreactor by opening SCV_1103_01	c	this is indeed working	
rt blender BLE_1012_01 (set point: 220 rpm):	C	change setpoint is only possible in the electrical cabinet by	
1012_01	26/02/2009 17:00 C	changing the FVC	
		decalcified water? Not for the tests : tap water the pump is always ON	
		the heating element indication on HMI is correct : it is showing	
		when the electrical heater is OFF and ON; could we leave the loop in red and just animate the heating element? (same	
emperature setpoint to 55°C. Fill HX_1008_01 and double		question for influent tank cooling loop)	
th demineralized water if this is not done yet:		LSL 1008 01 on the HMI is not working properly : alarm on	
008_01_SP	C	Low level, not on level higher than limit if pH is above setpoint, acid addition pump PP 1011 01 is	
		actuated	
		it seems that it is not possible to switch from pH probe AT 1011 01 to 1011 02	
sure Acid bottle contains acid and base bottle contains		if pH below setpoint, no action by PP 1011 02 before lag time	
H set point to 5.2 or another value if specified. pH control omatically deactivated as long as the liquid volume in		of 10 min (programmed in PLC), but then it works	
1) is too low to reach the pH probes: SCI_AT_1011_SP	26/02/2009 17:10 c	it seems the pH control is authorized only when the blender is ON	
		-	
:			
S:			
12_01, SCI_TT_1008_01_SP, SCI_AT_1011_SP			
ine:			
uie.			
ed (I/O):			
6_01_MV, BLE_1012_01_MV, TT_1008_01,			
02, AT_1011_01, AT_1011_02		the switching is made through _mode_timer_S or mode_volum	
		the role of this parameter is not really clear and could not be re	elated to the HMI
		what are the different roles and possibilities	
dure 12: Start-up Bioreactor VSL2_1007_01 feeding			
eeding function. te		default choice for feeding should be volume based	
e actor and influent vessel should be working. Bioreactor		"actual volume" should be rephrased "current volume"	
ontain a certain amount of active waste that is strong		initial volume 93,6 L at 72mbarg	
ligest an influent flow.		chosen mode : volume based, with 6 min=0,1h time interval	
the HMI to set the feeding function to be timer based or			
ed. As long as VSL2_1007_01 doesn't contain its nominal liquid, timer based feeding should be applied to feed a			
unt per day (e.g. 2.5 L/d). Once nominal liquid volume is			
rator should switch over to volume based control.			
volume is around 100L: CL1001_SCI_Feed,		the mode coloried upper act collected on the end	
_Feed_mode_timer or CL1001_SCI_Feed_mode_volume		the mode selected was not reflected on the screen the valve S3V_1001_01 opens after 6 minutes;	
		pressure inside bioreactor is controlled at 140mbarg : if	
nable feeding by the button on the HMI: I_Feed_Enable		P>140mbarg, the feeding is switched back to Influent Tank	
I_Feed_Enable is HMI to set feeding to timer based and to set the amount		(Pauze_Feed)	
d per day: CL1001_SCI_Feed_mode_timer_S,			
CI_Feed_Amount_per_day			
nominal volume (100L) is reached, use the HMI to set the			

 When nominal volume (100L) is reached, use the HMI to set the volume to which to feed to 100 and set feeding to volume based mode: CL1001\_SCI\_Feed\_volume\_SP, CL1001\_SCI\_Feed\_wolume\_S PLC Interface:

SCI variables:

SCI Variables: Display: - CL1001\_SCI\_Feed (feed in progress), - CL1001\_SCI\_Feed\_mode\_timer - CL1001\_SCI\_Feed\_mode\_volume, Operator action:

CL1001\_SCI\_Feed\_Enable (ask for feeding bioreactor), CL1001\_SCI\_Feed\_mode\_timer\_S (pulse triggered on rising edge), CL1001\_SCI\_Feed\_mode\_volume\_S (pulse triggered on rising edge), CL1001\_SCI\_Feed\_Amount\_per\_day( Amount to be fed per day in liter in mode timer),

 $\label{eq:cl1001_SCl_Feed_volume_SP} \mbox{(volume setpoint of the bioreactor), Cl1001_SCl_Feed_Interval_in_hour (time interval between two feeding) \end{tabular}$ 

PLC Subroutine: V Feed (FBD)								
				AND_BOOL	FBL 4,71(19)			
				and tool	104			
			ra side and Faadham	· · · · · · · · · · · · · · · · · · ·		AND SOLS OF AUTO OUT		
		To make pure only one me	thad of semi coninuous fee	ding is used at a time				
Figure 0: DLO and states (CDD)								
Figure 2: PLC procedure: V_Feed (FBD)			FBL 4_64(15)		FBI_4_69(10)			
	57N		. R_TRIO		RS			
Variables Used (I/O):		CL1001_SCLFeed_mode_Sin	HELSD CLK Q		5 01	-D-CL1001_SCLFeed_	mode_timer	
LT 1004 01, PT 1003 01, S3V 1001 (					R1			62
	Thisbigs		YEL 4 65(16)		F81_4_00(17)			
GP_1001_01, LSH_1010_01			R_TRIO		RS			
		L1001_SCI_Feed_mode_volu	A SD CLK Q		5 91	-C+CL1001 SCI Feed	mode volume · · ·	
Description:					<u></u> #1			
· First, the choice of the used mode	CL1001,							
CL1001_SCI_Feed_mode_timer_s								
CL1001_SCI_Feed_mode_volume_s. If Nor		and others (	2pump + 3,3L/min					
VSL2_1007_01 is reached, choose the Volume m								
VSEZ_1007_01131cdchcd, choose the volume m								
		Algoithm when feeding contr bigger activates the control, th	of is in volume control mode	Evely firms the				
<ul> <li>With HMI button CL1001_SCI_Feed_Enable, 1</li> </ul>	the feedi	SELV_Feed_volume_SP.						
and then the variable CL1001_SCI_Feed is SET and	nd displa	The binneactor is fed to a con-	dant volume					
The valve S3V 1001 01 is open if:	1.1		400.00	and the second	85	451(12)		
			OE_REAL		2.77	AND_BOOL		
o there is no level error in both	VSL2_1	CL1010 VEL2 1007 01 VelD		1001_Feed_F_TRI0D	5 01		CL1001_SCI_Feed	
VSL2 1007 01		L1001_SCI_Feed_volume_SPD				4 6		
				CL1001_SCI_	feed_mode_volumeD-			
<ul> <li>The pump GP_1001_01 turn ON</li> </ul>								
<ul> <li>The variable CL1001_SCI_Feed is in state ON</li> </ul>	Ň							

Procedure steps	date/hour	N/NC	comments	SHERPA comments NTE comments
				·
1.1. Procedure 11: Start-up Bioreactor VSSL_1007_01				
Scope				
Initiate the functions of the bioreactor R-R-01.				
Prerequisite			missing : FUSE f-14 switched ON	
Bioreactor should contain inoculum or an amount of active waste (minimum				
50 L).	6/6/08 12:19		V=98L	
Procedure				
Use the HMI to				
<ol> <li>Make sure V-R-20 is open and N2 is available at around 1 barg at PR-G</li> </ol>			V-R-20 is a manual valve not visible on HMI ; p	
06		NC	bioreactor=103 mbar	
			where is the bioreactor pressure setpoint for the PLC control	
			of V-G-29? V-G-29 is not open (0% aperture) but it was checked that	
			when the pressure inside bioreactor is below than 100mbar,	
<ol><li>Flush N2 in the bioreactor byV-G-29</li></ol>		С	V-G-29 opens up	
	1	1-	change setpoint is only possible in the electrical cabinet by	1
<ol><li>Start blender BL-R-01 (set point: 220 rpm): SCI_BL_R_01</li></ol>		С	changing the FVC	
			it is not possible to activate from HMI the heating ; it was	]
4. Cat temperature estepint to EE°C. Fill UV D.01 and double isolat with			done by forcing the variable HX_R_001 on PLC	
4. Set temperature setpoint to 55°C. Fill HX-R-01 and double jacket with	( // /00 10 00		the heating element indication on HMI is not correct : it is	
demineralized water if this is not done yet: SCI_R_T_R_01_SP 5. Make sure Acid bottle contains acid and base bottle contains base. Set	6/6/08 12:30	NC	always ON even when the electrical heater is OFF	-
pH set point to 5.2 or another value if specified. pH control will be				
automatically deactivated as long as the liquid volume in R-R-01 is too low				
to reach the pH probes: SCI_R_		NC		
to reach the pH probes: SCI_R_		NC	not mounted for this test	-
		-		-
		_		-
1.2. Procedure 12: Start-up Bioreactor VSSL_1007_01 feeding				
Scope				-
Start the feeding function.				
				-
Prerequisite Both bioreactor and influent vessel should be working. Bioreactor should				4
		1		
contain a certain amount of active waste that is strong enough to digest an		1		
influent flow.				4
Presedure		+		4
<ol> <li>Use the HMI to set the feeding function to be timer based or volume</li> </ol>		+		4
based. As long as R-R-01 doesn't contain its nominal volume of liquid, timer		1		
based feeding should be applied to feed a certain amount per day (e.g. 2.5		1	not done for this part of the tests : the objective was to have	
L/d). Once nominal liquid	6/6/08 12:35	NC	a bioreactor on operation to see the interaction with the gas	
	0/0/08 12:35	NC	loop	4
<ol><li>Enable feeding by the button on the HMI: SCI_V_Feed_Enable</li></ol>				4
3. Use the HMI to set feeding to timer based and to set the amount to		1		
feed per day: SCI V Feed mode timer S, SCI V Feed Amount per day		1		
recuper day. sor_v_recu_mode_timer_s, sor_v_recu_Amount_per_day		+		1
4. When nominal volume (100L) is reached, use the HMI to set the		1		
volume to which to feed to 100 and set feeding to volume based mode:		1		
SCI_V_Feed_volume_SP, SCI_V_Feed_mode_volume_S		1		
	1	1		1
				1

HW modifications put a deflector inside the hot water tank to prevent spillings add some switches to acivate BR and IT cooling loops pumps w/o using the electrical cabinet

# PLC programme modifications addition of baase is considered?

HMI modificatinos temperature control loop should be easy to view with T setpoint and loop T pH control additions missing pressure setpoint for the bioreactor should appear

others if no purge valve added to the feeding line upstream V-V-02, add a more concentrated medium and then rinse the line with water ? (pb of dilution)

Procedure steps	date/hour	N/NC	comments	SHERPA comments NTE comment
	datomodi		oon mone	
1.1. Procedure 26: Active Gas Loop: Start-up				
Scope				
			there might be a problem of reverse flow from bioreactor to	
Start the active gas loop	06/06/2008 12:00		the active gas loop condensate line through V-G-12	
			no history graph available for gas loop screens (the real time	
		NC	values are working though)	
Procedure				
Press the button on the HMI: CL1100_SCI_Start_Active_GasLoop		С	OK pressed : the green light for active gas loop is working	
			Include as prerequisite to check manual valves in R-G-01: V-	
Make sure that HV_1007_10, HV_1007_11, HV_1007_14 and HV_1102	26/02/2009 18:20	С	06, V_G_26 : checked as well	
		OBS	HMI should have bioreactor pressure indication on the right	
		000	LSH 1102 01 should not be blinking when no high level i	
SCI variables :		NC	detected?	
			Stop of active gas loop in HMI is not effective even if buttor	
CL1100_SCI_Start_Active_GasLoop,			STOP changes to red ; START and STOP actions are carried	
CL1100_SCI_Reset_Active_GasLoop		NC	out through the same START button	
			ok	
			active gas loop sending gas to reactor maintaining 80 mBa	
PLC Subroutine : G_Active_Loop			approx. In bioreactor	
Figure 9: PLC procedure: G_Active_Loop				
Variables Used (I/O):				
S3CV_1100_01_MV, S3CV_1100_02_MV, SV_1100_01_MV,				
SV_1100_05_MV (V_G_02, V_G_03, V_G_05, V_G_25),				
PP_1100_01_MV				
				]
Description :				1
<ul> <li>Input HMI: CL1100_SCI_Start_Active_GasLoop</li> </ul>				1
<ul> <li>Valves S3V 1100 01 MV, S3V 1100 02 MV, SV 1100 0</li> </ul>	1 MV SV 1100	05 N	IV (V G 02 V G 03 V G 05 V G 25) are OFF	1
<ul> <li>Valves SV 1100 01 MV, SV 1100 05 MV (V G 05, V G</li> </ul>			1. (1_0_02, 1_0_03, 1_0_03, 1_0_23) are off	
<ul> <li>valves 3v_1100_01_wiv, 3v_1100_05_wiv (v_0_05, v_0</li> <li>Run the pump PP 1100 01</li> </ul>	5_25) are ON			1
<ul> <li>Kun me pump rr_1100_01</li> </ul>				1

Valves S3CV\_1100\_01\_MV, S3CV\_1100\_02\_MV (V\_G\_02, V\_G\_03) are ON •

- Input HMI: SCI\_G\_Reset\_Active\_GasLoop
- Valves S3CV\_1100\_01\_MV, S3CV\_1100\_02\_MV (V\_G\_02, V\_G\_03) are OFF
- Stop the pump PP\_1100\_01
- Valves SV\_1100\_01\_MV, SV\_1100\_05\_MV (V\_G\_05, V\_G\_25) are OFF

Questions: Is V\_G\_10 really used in this procedure?



Description : Input HMI: SCI\_G\_Start\_Active\_GasLoop

<ul> <li>Valves S3CV_1100_01_MV, S3CV_1100_02_MV, SV_1100_01_MV, SV_1100_05_MV (V_G_02, V_G_03, V_G_05, V_G_25) are OFF</li> <li>Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25) are ON</li> </ul>			
<ul> <li>Run the pump PMP_G_01</li> <li>Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02, V G 03) are ON</li> </ul>		С	OK it started
<ul> <li>Input HMI: SCI_G_Reset_Active_GasLoop</li> <li>Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02,</li> </ul>	13:	30 NC	the reset was not performed ; what is the button?
<ul><li>V_G_03) are OFF</li><li>Stop the pump PMP_G_01</li></ul>		nA NA	not performed not performed
<ul> <li>Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25) are OFF</li> </ul>			not performed
Questions: Is V_G_10 really used in this procedure?			not tested since the level sensor LS-G-01 is OOO
	06/06/2008 18:	43	could be tested modifying the upper and lower limits of PS-G- 01 to actuate on G_Valvestate_V_G_10_P ; working
			V_G_01 is supposed to purge the liquid accumulated in R-G- 01, why is the value of level sensor LS_G_01 not used ? currently it is just generating an error not used in other contrc loops
Recommendations / changes	WHEN	WHC	
HW modifications install a PI on bioreactor between 1 barg and 1,2 barg temperture sensor TS-R-01 is OOO it is indicating 0°C repair LS-G-01		UAB	ordered but not mounted rechecked : a priori functional replaced by another LS that is working
PLC programme modifications control of V-G-10 opening?		SHE	RPA
HMI modifications Local		NTE	
Remote			
Variables		Start_	Active Loop
			Start_Active_Loop is activated when Variable 'SCI_G_Start_Active_Loop is set to 1
others User Manual		SCI_G_	
Include as prerequisite to check manual valves in R-G-01: V-G-06, V_G_26,		Close	Close Valves V_G_05, V_G_10 and V_G_25, and reset Valves V_G_02 and V_G_03 Valves_G_02_03_05_10_25
		Control	Check if Valves V. G_05, V_G_10 and V_G_25 are closed and V_G_02 and V_G_02 are reset. Valve_G02_03_05_25_10
			Open Valves V_G_05 and V_G_25
			Wait for 5 seconds
		Control	Check if Valves V_G_05 and V_G_25 are really opened, if Yes go to the next step Valve_G_05_25
		Activa	
			Wait 5 Seconds Go to the next step without additional conditions
		1	Fi i i i
		Open	
		SCI_G	Reset_Active_GasLoop
		 control	· · · · · · · · · · · · · · · · · · ·
		PMP_	

Control

Start\_Active\_Loop

Close Valves V\_G\_05, V\_G\_10 and V\_G\_25, and reset Valves V\_G\_02 and V\_G\_03 Close\_Valves G\_02\_03\_05\_10\_21 \_\_\_\_\_\_\_\_Wait 5 seconds

Check if Valves V\_G\_05, V\_G\_10 and V\_G\_25 are closed and V\_G\_02 and V\_G\_02 are reset /alve2\_G02\_03\_05\_25\_10

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
					•
1.1. Procedure 20: Passive Gas Loop: Start up					
Scope					
Start the passive gas loop. This part of the gas loop uses					
SV_1100_02 and SV_1100_03 to remove excess gas					
from VSL2_1007_01 when pressure measured by PS-R-01 is higher than 90 mbarg.			CV/ 4400, 02 is intight and cV/ 4400, 02 is itight alread		
is nigher than 90 mbarg.			SV_1100_02 is initially open and SV_1100_03 initially closed	-	
Pre-requisite					
HV_1009_01 is open	26/02/2009 18:20	С			
HV_1007_08 is open	26/02/2009 18:20	С			
Procedure					
Press the button on the HMI: SCI_G_PAS_Start		с	green light on HMI working when PT_1100_01>2500mbarg and PT_1009_01>90mbarg	-	
			inthe biloreactor, we observe the opening of SV_1100_03 and		
	26/02/2009 18:45		the closing of SV 1100 02		
SCI variables :			<u> </u>		
SCI_G_PAS_Start	S_G_PAS_Star	_001			
PLC Subroutines : G_PAS_Start, G_PAS_Esc			Wait for		
	CL1103_SCI_PAS	_Start	CL1103_SCI_PAS_Start = 1		
Figure 5: PLC procedure: G_PAS_Start	S_G_PAS_Star	002	CL1103_TB_PAS is SET		
Figure 5: FLC procedure: G_FAS_start					
	— I				
The subroutine G_PAS_Esc is described on Procedure 19.	1				
	S_G_PAS_St	art_001			
Variables Used (I/O):					
SV_1100_02_MV, SV_1100_03_MV, PT_1009_01					
Description :	S_G_PAS_Sta	+ 001			
<ul> <li>Input HMI: SCI_G_PAS_Start</li> </ul>		1_001			
<ul> <li>This variable begins the PLC procedure G_PAS_Esc</li> </ul>					
<ul> <li>The procedure G_PAS_Esc sets the tracing bit</li> </ul>		Vait for initia	tion		
TB_G_PAS_Esc which begins the subroutine for release					
of gas production G_PAS_Esc (Passive gas loop)	SCI_G_PAS_Sta	n .			
		Set TB_G_P	ASS		
	S_G_PAS_Sta	rt_002	The tracing bit	-	
	┝━━┖╘━┳━━┛┦		TB G PAS is SET	-	
	⊨ `` ```			1	
	╞╴╺┻╼╴┊			1	
Fig : PLC procedure: G_PAS_Start	1			]	
				]	
	S G PAS S	tort 001	•		
The subroutine G_PAS_Esc is described on Procedure 19.		lan_oon	· · · · · · · · · · · · · · · · · · ·	4	
	<b>├</b> ──			4	
				1	

HW modifications PS-G-04 is working between 90barg and 100mbarg: change it to have a wider range of measurement from 0 to 200mbarg (for a better volume calculation in case of overpressures above 100mbarg) step 2 replaced

PLC programme modifications change use of SCI\_G\_PAS\_Start variable to activate the sequen step2

#### HMI modifications

# Local idem remote

Remote assign correct roles to ON/OFF buttons on HMI and correct colour codes for state of routine

### variables to be seen

Procedure steps	date/hour	N/NC	comments	SHERPA comments NTE comment
1.1. Procedure 25: Active Gas Loop: Shut down				
Scope				
Stop the active gas loop.				
			the green light on HMI has disappeared ; yet the	
			compressor remains ON with 2800 mbarg in	
	26/02/2009 18:50	NC	VSSL_1100_01 and 150mbarg in VSSL_1100_02	
Procedure			the scale of PT1100 02 should be changed	_
Press the button on the HMI: SCI_G_Reset_Active_GasLoop			buttons of procedures are working OK	
If the active gas loop is not to be started up again, gas in VSSL_	1100_01 can be r	NA	it was not checked	-
SCI variables :				1
			when forcing this variable from PLC, we could activate	1
SCI_G_Reset_Active_GasLoop			the sequence	_
PLC Subroutine: G_Active_Loop described on the nex	+			-
procedure because the Shut down operation of Active Gas Loop				
is done at the end of this PLC subroutine.	,			
s done at the end of this FEC sublodtine.				-
Variables Used (I/O):				-
				-
\$3V_1100_01_MV, \$3V_1100_02_MV, \$V_1100_01_MV				
SV_1102_01_MV, SV_1100_05_MV (V_G_02, V_G_03	,			
V_G_05, V_G_10, V_G_25), PP_1100_01_MV				4
Description :				-
<ul> <li>Input HMI: SCI_G_Reset_Active_GasLoop</li> </ul>				-
<ul> <li>Valves S3V_1100_01 (V_G_02) and S3V_1100_02 (V_G_03)</li> </ul>				-
<ul> <li>values 33v_1100_01 (v_0_02) and 33v_1100_02 (v_0_03) are set in OFF</li> </ul>	)	с	alı	
<ul> <li>The pump PP 1100_01 (PP_1100_01) is turn OFF</li> </ul>		C C	ok OK it shut down	-
		C		4
<ul> <li>Valves SV_1100_01(V_G_05), SV_1102_01 (V_G_10) and</li> </ul>	1	_	1.	
SV_1100_05 (V_G_25) are set in OFF		С	ok	4
	1			1
				1
	1	1		

HW modifications

UAB

PLC programme modifications SHERPA HMI modifications Local NTE

Remote

Variables

others

User Manual

	1		
Procedure steps	date/hour	N/NC	comments
1.1. Procedure 19: Passive Gas Loop: Shut down			
Stop the passive gas loop.			
Procedure			ON button has to be pressed to obtain shutdown of
Press the button on the HMI: SCI_G_PAS_Stop	06/06/2008 19:30	NC	passive loop
PLC Interface :			
SCI variables :			
SCI_G_PAS_Stop		NC	the variable is SCI_G_Stop_Passive_GasLoop but it is accessible through the HMI
PLC Subroutines : G_PAS_Stop , G_PAS_Esc			
<u>[9_0_PAG_</u> Ero_001			
CL1100_SCL_PAS_Ere CL1100_SCL_PAS_Ere			
S_0_PAS_Eco_002 CL100_TB_PAS_Epo to SET Pulse on SV_1100_02_S			
Wash fee oV_1100_02_FB = 0 S_0_FAS_E4<_002 wall for 6 peconds			
Pulse on E_0_PA5_Rsc_004 CL1100_PA5_Esc_Hold			
1			
<u>s_o_PAS_</u> esc_009 SV_1100_03_S w_1100_05_FB SV_1100_03_FD			
50_110_03_14 00_100_00 5_0_PA6_Exc_006 wall for 8 seconds			
· <u>+-</u>			
[0_0_FAG_E6c_007 FUB=100_09_R V_1100_09_R vev_1100_03_FB = 0			
~5V_100_03_FB 0 Calculat gat excepted this syste S_0_FAS isc_DOB CL100_PAS isc_Calce in FEGT Pulse on CL100_PAS isc.Calc			
CL1100_PA5_Ezo_Caloed CL1100_PA5_Ese_Caloed = 1			
5_9_PA5_Exc_000 EL100_FAS_Fax_Called is RERET Walke on SV_1100_02_R Walt for			
sv_1100_02_FB sv_1100_02_FB = 1 			
, +			
<u>_0_P</u> AB_EF0_001			
Figure 3 : PLC procedure G_PAS_Stop			
S_O_PAS_Stop_001			
Wait for initiation CL1103_SCI_PAS_Stop CL1103_SCI_PAS_Stop			
S_G_PAS_Stop_002 CL1103_TB_PAS is RESET			
, —			
S_G-PA8_Stop_001			
Figure 4: PLC procedure: G_PAS_Esc			
S_G_PAS_Esc_001			
Close V_G_07 S_G_PAS_Esc_002 TB_G_PAS_Esc is SET			
-V_G_07 is SET			
S_G_PAS_Exc_003			
Held PS-0-04 and TS-0-01			
G_PAS_Esc_Hold is SET			
OPen V-0-05 to let gas escape     S_0_PAS_Esc_005     V_G_08 is SET			
v_G_08 is SE1			
V_0_05_FB			
Empty step			
1 clase V-0-08 to measure			
V_G_08 is RESET			
-V_G_08_F8 			
G_PAS_Esc_Calced G_PAS_Esc_Calc			
G_PAS_Esc_Calced			
S_G_PAS_Esc_Calced V_G_07 is RESET			
V 0.07 59			
TB_G_PAS_Esc is RESET			
Variables Used (I/O): SV_1100_02_MV, SV_1100_03_MV (V_G_07 and V_G_08)			
Description :			before stopping, V-G-07 and V-G-08 are releasing gas to the outlet
Input HMI: SCI_G_PAS_Stop			
This variable begins the PLC procedure G_PAS_Esc		NC	the variable is SCI_G_Stop_Passive_GasLoop but it is accessible through the HMI
<ul> <li>The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which</li> </ul>			
on state HIGH begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)		NC?	the effect of this stopping is that V_G_07 and V_G_08 stop their release of gas out of the R-G-02
<ul> <li>The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which</li> </ul>			
on state HIGH begins the subroutine for release of gas production			it seems that the release of gas was interrupted by the
G_PAS_Esc (Passive gas loop)			passive shutdown, not started/begun

### HW modifications

# PLC programme modifications change the variable names

## HMI modifications

Local idem remote

Remote assign correct roles to ON/OFF buttons on HMI and correct colour codes for state of routine

variables to be seen

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
				-	
1.1. Procedure 26: Active Gas Loop: Start-up					
Scope			initial pressure bioreactor 70 mbarg ; 10 mbarg in VSSL_1100_01		
			when we start the sequence, the procedures menu shows : STOP ACTIVE GAS LOOP in green ; we push the "RESET ALL PROCEDURES" button and all buttons are now grey in		
Start the active gas loop	27/02/2009 9:52	С	the menu		
			today the history graphs areavailable for gas loop screens (for		
		С	both the real time values and history values)	_	
Procedure		OBS	missing on the screen: HX 1102 01 tag and/or symbol		
Press the button on the HMI: CL1100_SCI_Start_Active_GasLoop		С	OK pressed : the green light for active gas loop is working	1	
Make sure that HV_1007_10, HV_1007_11, HV_1007_14 and HV_1102_	27/02/2009 9:56	С		-	
Include as prerequisite to check manual valves in R-G-01: V-G-06, V_G_26 : checked as well		OBS	HMI should have bioreactor pressure indication on the right		
			LSH_1102_01 should not be blinking when no high level is		
SCI variables :		NC	detected?		
			Stop of active gas loop in HMI is not effective even if button STOP changes to red ; START and STOP actions are carried		
CL1100_SCI_Start_Active_GasLoop, CL1100_SCI_Reset_Active_GasLoop		NC	out through the same START button	-	
		С	ok		
PLC Subroutine : G_Active_Loop			active gas loop sending gas to reactor maintaining 80 mBar approx. In bioreactor	-	
Figure 9: PLC procedure: G_Active_Loop				-	
Variables Used (I/O):					
S3CV_1100_01_MV, S3CV_1100_02_MV, SV_1100_01_MV,					
SV_1100_05_MV (V_G_02, V_G_03, V_G_05, V_G_25),					
PP 1100 01 MV					
				1	
Description :				1	
Input HMI: CL1100_SCI_Start_Active_GasLoop			initial value for pressure PT_1100_01 : 10 mbarg	+	
	MV SV 1100 05	MUC		+	
<ul> <li>Valves S3V_1100_01_MV, S3V_1100_02_MV, SV_1100_01</li> </ul>		IVI V (	v_0_02, v_0_05, v_0_05, V_0_25) are OFF	+	
<ul> <li>Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G</li> </ul>	_25) are ON			1	
<ul> <li>Run the pump PP_1100_01</li> </ul>		С	pump is not a peristaltic one ; it shoud bear other tag (CP)		

С

pump is not a peristaltic one ; it shoud bear other tag (CP)

- Valves S3CV\_1100\_01\_MV, S3CV\_1100\_02\_MV (V\_G\_02, V\_G\_03) are ON C
- Input HMI: SCI\_G\_Reset\_Active\_GasLoop
- Valves S3CV\_1100\_01\_MV, S3CV\_1100\_02\_MV (V\_G\_02, V\_G\_03) are OFF
- Stop the pump PP\_1100\_01
- Valves SV\_1100\_01\_MV, SV\_1100\_05\_MV (V\_G\_05, V\_G\_25) are OFF

Questions: Is V\_G\_10 really used in this procedure?



Description : • Input HMI: SCI_G_Start_Active_GasLoop			
• Valves S3CV_1100_01_MV, S3CV_1100_02_MV,			
SV_1100_01_MV, SV_1100_05_MV (V_G_02, V_G_03, V_G_05, V_G_25) are OFF			
<ul> <li>Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25)</li> </ul>			
are ON			
<ul> <li>Run the pump PMP_G_01</li> <li>Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02,</li> </ul>	(	С	OK it started
• Valves SSCV_1100_01_MV, SSCV_1100_02_MV (V_G_02, V G 03) are ON			
Input HMI: SCI_G_Reset_Active_GasLoop	13:30	NC	the reset was not performed ; what is the button?
<ul> <li>Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02,</li> </ul>			
<ul><li>V_G_03) are OFF</li><li>Stop the pump PMP_G_01</li></ul>			not performed not performed
<ul> <li>Stop the pump 1 Mi _0_01</li> <li>Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25)</li> </ul>	I	1/1	not performed
are OFF			not performed
Questions: Is V_G_10 really used in this procedure?			not tested since the level sensor LS-G-01 is OOO
			could be tested modifying the upper and lower limits of PS-G-
	06/06/2008 18:43		01 to actuate on G_Valvestate_V_G_10_P ; working
			V_G_01 is supposed to purge the liquid accumulated in R-G- 01, why is the value of level sensor LS_G_01 not used ?
			currently it is just generating an error not used in other control
			loops
	WHEN \	wно	
Recommendations / changes			
HW modifications			and and had a structure d
install a PI on bioreactor between 1 barg and 1,2 barg temperture sensor TS-R-01 is OOO it is indicating 0°C	l		ordered but not mounted rechecked : a priori functional
repair LS-G-01			replaced by another LS that is working
PLC programme modifications control of V-G-10 opening?	5	SHER	PA
HMI modifications Local	1	NTE	
Remote			
Remote			
		Sta	rt_Active_Loop
		l	
Variables		·	Start_Active_Loop is activated when Variable 'SCI_G_Start_Active_Loop is set to 1
		_	
others	1	SCI_C	3_Start_Active_gASLoop

User Manual

Include as prerequisite to check manual valves in R-G-01: V-G-06, V\_G\_26,

I						
Start_Active_	Loop			-		
	Start_Active_L	oop is activated w	hen Variable 'S	CI_G_Start_Active	e_Loop is set to 1	
SCL G Start A						· · ·
		Ġ ós ý Ġ io	and V G 25 an	d reset Valves V	G_02 and V_G_0	
Close_Valves	_G_02_03_05_ .Wait 5 seconds	10 25				
Control_Valve_	Check if Valves G02_03_05_25	v g_os, v_g_1 _10	0 and V_G_25 a	re closed and V_	G_02 and V_G_0	2 are reset
		1.1.1.1.1.1	<u>.</u>			
Open_valve_	Open Valves V V_G_25_05 Wait for 5 seco	_G_05 and V_G_	25			• •
				· · · · · · ·	· · · · · · ·	· · · · · ·
Control_Valve_	Check if Valves G_05_25	V_G_05 and V_	3_25 are really (	opened, if Yes go	to the next step	· · ·
	:					
	Start Pump PM	IP_G_01				
Activate_PM	P_G_01 "Wait 5 Second:		:	:		
	Go to the next	step without addit	ional conditions	· · · · ·	•	· · · · · ·
1				:	•	· ·
·	Set Valves V. G	3-02 and V G 03				
Open_V_G_(	02_03					
	wait 5 Seconds					
		:		:	:	
SCI_G_Reset_/	Active_GasLoop	•		:		· ·
		1 · · · ·	: · · · ·	1 · · · ·	: · · · ·	: · · · · :
Close_Valves	_02_03					
control_02_03		•				· ·
PMP_G_01_	OFF	:		:		
				· · · · · · · ·	· · • · · · · ·	· · · · ·
				:		: :
1						
Close_Valves	Close Valves V G_02_03_05_ Wait 5 seconds	_G_05, V_G_10 10_21	and V_G_25, an	d reset Valves V_	G_02 and V_G_03	3
	Check if Valves	ý G 05, V G 1	0 and V_G_25 a	re closed and V	G_02 and V_G_0	2 are reset
Control_Valve2	_G02_03_05_2	5_10				•
	•					
Start_Activ	: - 1000	•				· · ·
Adav	0					

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
				-	
1.1. Procedure 25: Active Gas Loop: Shut down				-	
Scope	-			-	
Stop the active gas loop.				-	
			both procedure buttons START ACT GL and STOP		
			ACT GL are now green ; the compressor and the valves		
	27/02/2009 10:17	NC	are in the same position as for START ACT GL		
Procedure			the scale of PT1100 02 should be changed		
Development the LUML COL O. Development Asthere Oral and			buttons of procedures are not working OK see previous		
Press the button on the HMI: SCI_G_Reset_Active_GasLoop	1100_01_con bo_r		remark	-	
If the active gas loop is not to be started up again, gas in VSSL_	1100_01 can be n	INA	it was not checked	-	
SCI variables :			SV 1102 01 is not tight	1	
Set furmines.			SHERPA cl 1100 sci active reset was forced and the		
			command for STOP ACT GL was successful (stopping		
SCI_G_Reset_Active_GasLoop			of compressor, closing of valves)		
PLC Subroutine: G_Active_Loop described on the next					
procedure because the Shut down operation of Active Gas Loop					
is done at the end of this PLC subroutine.					
Variables Used (I/O):					
S3V_1100_01_MV, S3V_1100_02_MV, SV_1100_01_MV,					
SV_1102_01_MV, SV_1100_05_MV (V_G_02, V_G_03,					
V_G_05, V_G_10, V_G_25), PP_1100_01_MV					
Description :					
<ul> <li>Input HMI: SCI_G_Reset_Active_GasLoop</li> </ul>					
<ul> <li>Valves S3V_1100_01 (V_G_02) and S3V_1100_02 (V_G_03)</li> </ul>					
are set in OFF		С	ok		
<ul> <li>The pump PP 1100_01 (PP_1100_01) is turn OFF</li> </ul>		С	OK it shut down		
<ul> <li>Valves SV_1100_01(V_G_05), SV_1102_01 (V_G_10) and</li> </ul>					
SV_1100_05 (V_G_25) are set in OFF		С	ok	1	
				4	
				4	
	<u> </u>			4	
				1	
	WHEN	WHO			

WHO

HW modifications

UAB

PLC programme modifications

SHERPA NTE

HMI modifications Local

Remote

Variables

others

User Manual

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
				-	
1.1. Broodure 20. Broking Condition					
1.1. Procedure 20: Passive Gas Loop: Start up	27/02/2009 10:04		initial conditions : SV_1100_02 open, SV_1100_03 closed, PT_1	] 1100_02=56 mbarg_PT	1009 01=70mbarg
Scope	21102/2003 10:04		check P sensors calibrations	1100_02=00 mbarg, 1 1	_1005_01=701115419
Start the passive gas loop. This part of the gas loop uses					
SV_1100_02 and SV_1100_03 to remove excess gas					
from VSL2_1007_01 when pressure measured by PS-R-			DT 1100.01 0100 mbase		
01 is higher than 90 mbarg.			PT 1100 01 = 2490 mbarg	-	
				-	
Pre-requisite					
HV_1009_01 is open	27/02/2009 10:04			_	
HV_1007_08 is open	27/02/2009 10:04	С	add the prerequisite: condenser HX1102 02 is ON with pumps	-	
			PP1102 01 and PP 1102 02 ON		
Procedure					
Press the button on the HMI: SCI_G_PAS_Start	27/02/2009 10:08	с	green light on HMI working when PT_1100_01>2500mbarg and PT_1009_01>90mbarg	-	
			inthe bioreactor, we observe the opening of SV_1100_03 and		
	27/02/2009 0:00	с	the closing of SV_1100_02	_	
SCI variables :	to a pro-		·	-	
SCI_G_PAS_Start	S_G_PAS_Star	t_001		-	
PLC Subroutines : G_PAS_Start, G_PAS_Esc			197134	-	
1 De Subroutines : O_FRS_Start, O_FRS_Est	CL1103_SCI_PAS	S_Start	Wait for CL1103_SCI_PAS_Start = 1	-	
Figure 5: PLC procedure: G_PAS_Start	S_G_PAS_Star	t_002	CL1103_TB_PAS is SET	-	
				4	
The subroutine G_PAS_Esc is described on Procedure 19.	1				
	S_G_PA9_St	art_001		_	
Variables Used (I/O):	_			-	
SV_1100_02_MV, SV_1100_03_MV, PT_1009_01				-	
Description :	·			-	
Input HMI: SCI_G_PAS_Start	S_G_PAS_Start	_001		-	
<ul> <li>This variable begins the PLC procedure G_PAS_Esc</li> </ul>			· · · · · · · · · · · · · · · · · · ·	1	
• The procedure G PAS Esc sets the tracing bit	W	ait for initiati	on	-	
TB_G_PAS_Esc which begins the subroutine for release	SCI G PAS Start				
of gas production G_PAS_Esc (Passive gas loop)					
		et TB_G_PA			
	S_G_PAS_Start	_002	The tracing bit		
			TB_G_PAS is SET	-	
	┣ │ ः			1	
	╘╷╺┿╸ः			1	
Fig : PLC procedure: G_PAS_Start				]	
			· · · · · · · · · · · · · · · · · · ·	4	
The subroutine G_PAS_Esc is described on Procedure 19.	S_G_PA9_Sta	art_001			
The subroatile O_FA5_E3C is described on FIOLEddie 17.	<u> </u>			1	
				]	
				]	

replaced

#### Recommendations / changes

HW modifications PS-G-04 is working between 90barg and 100mbarg: change it to have a wider range of measurement from 0 to 200mbarg (for a better volume calculation in case of overpressures above 100mbarg) step 2

PLC programme modifications change use of SCI\_G\_PAS\_Start variable to activate the seque step2

#### HMI modifications

Local idem remote

Remote assign correct roles to ON/OFF buttons on HMI and correct colour codes for state of routine

### variables to be seen

Procedure steps		date/hour	N/NC	comments	SHERPA comments NTE comments
	an Lean. Chut decer		<u> </u>		-
1.1. Procedure 19: Passive G Scope	as Loop: Shut down			remark : in order to remove the two activated buttons START ACT GL and STOP ACT GL, we push the	1
Stop the passive gas loop.		27/02/2009 10:34		RESET ALL PROC button : it does not interrupt the current passive gas loop (still active)	4
Procedure					-
Press the button on the HMI: SCI_G	_PAS_Stop	27/02/2009 10:35	с	THE button is working and the square HMI indicator passes from blinking green to continuous grey	
PLC Interface :					
<i>SCI variables</i> : SCI_G_PAS_Stop			с		
PLC Subroutines : G_PAS_Stop , (					•
5_0_PA5_5zo_001					
	for initiation IOO_SCI_PAS_Exc				-
Wait	100_TB_PAS_Eso is SET • on 8V_1100_02_S for 1100_02_FB = 0				
-9V_1100_02_FB	for 5 seconds				-
S_0_PAS_Esc_004 CL11	* on IOO_PAS_Eso_Hold				-
, —					-
	e on 1100_03_5				
	for 1100_03_FB for 5 seconds				-
5_6_PAS_688_000 Wart	101.0 34 001.03				-
1 5_0_PA5_E#0_007 Puise SV_1	00n 1100_02_R				1
	for 100_03_FB = 0				-
S_0_PAS_Exc_000 CL11 Pulse	ulate gas escaped this cycle 100_PAS_Esc_Calced is RESET e on CL1100_PAS_Esc_Calc				
	for 100_PA5_Eze_Calced = 1 100_PAS_Ese_Calced is RESET = on SV_1100_02_R				-
Wait	e on SV_1100_02_R for 1100_02_FB = 1				-
	100_16_PAS_60 is RESET				
. —					-
29_0_PA9_Ex0_001					
Einen 2. DIC marshar C. DAS	S4				-
Figure 3 : PLC procedure G_PAS_	Stop				-
·					
CL1109_SCLPAS_Step CL11	for initiation 000_SCL_PAS_Stop				-
8_0_PAS_Step_002 CL11	100_TB_PAS is RESET				
					-
'					-
<u>&gt;s_6_PA</u> }_Stop_001					-
					•
Figure 4: PLC pr	rocedure: G_PAS_Esc				-
Wait for initiation					-
SCI_G_PAS_Esc Close V_G_07 S_G_PAS_Esc_002					
	TB_G_PAS_Esc is SET V_G_07 is SET				-
-V_G_07_F8 					-
5_G_PA5_Exc_003	Empty step				
1 Hold PS-0-04 and TS- S_0_PAS_Esc_004	-6-01				•
S_G_PAS_Exc_004	G_PAS_Esc_Hold is SET				1
1 OFen V-G-05 to let ga					-
OPen V-G-05 to let ga	V_G_08 is SET				1
V_G_08_FB					-
S_G_PAS_Esc_006	Empty step				-
S_G_PAS_Exc_007	V_G_08 is RESET				1
-V_G_08_FB					-
Calculate gas escaped	G_PAS_Esc_Calced G_PAS_Esc_Calc				
	G_PAS_Esc_Calc				-
G_PAS_Eso_Caloed open V_G_07 S_G_PAS_Eso_009	G RAS Erc Calcod				-
	G_PAS_Esc_Calced V_G_07 is RESET				-
V_0_07_FB 					1
Variables Used (I/O):	TB_G_PAS_Esc is RESET				4
SV_1100_02_MV, SV_1100_03_M	4V (V_G_07 and V_G_08)				1
				before stopping, SV 1100 02 and SV 1100 03 are	4
Description :				releasing gas to the outlet	4
<ul> <li>Input HMI: SCI_G_PAS_Stop</li> <li>This variable begins the PLC pro-</li> </ul>	ocedure G PAS Esc		с		-
	ets the tracing bit TB_G_PAS_Esc which		5		1
on state HIGH begins the subro	outine for release of gas production				
G_PAS_Esc (Passive gas loop) <ul> <li>The procedure G_PAS_Esc rese</li> </ul>	ts the tracing bit TB_G_PAS_Esc which		C		1
on state HIGH begins the subro	butine for release of gas production				
G_PAS_Esc (Passive gas loop)		27/02/2009 10:41	с		4
					1
					1

WHEN

WHO

HW modifications

# PLC programme modifications change the variable names

HMI modifications

# Local idem remote

# Remote assign correct roles to ON/OFF buttons on HMI and correct colour codes for state of routine

variables to be seen

. Procedure 6: Start-up Influent tank VSSL_1000_01	1			
ope				
ate the functions of the influent tank.				
requisite				
eactor should contain a certain amount of active waste that is				
ng enough to digest an influent flow.				
-04 must be in position recirculation	09-jur	nc		
			missing how to add the cooling liquid into the loop	
cedure			tap water was used for the tests step1	
the HMI to			manual filling up to V=57L	
Make sure HV_1003_01 is open and N2 is available at around	1			
at PC_1103_01, HPCV_1003_01 is set to approximately 110				
arg and HPCV_1003_02 to approximately 90 mbarg.	09-jur			
Start blender BL-V-01 (set point: 200 rpm): SCI_BL_V_01	00 jui		blender on	
Set temperature setpoint to $6^{\circ}$ C or another value <= $7^{\circ}$ C. Fill	HX-	Ŭ		
1 and double jacket with water and antifreeze compound (glyc				
is not done yet: SCI_V_T_V_01_SP	01) 11	с	cooler ON	
Start PMP-V-01 : SCI_GP_1001_01_MV1		c	ON	
initial start up, when liquid level is below connection to V-V-04	,			
P-V-01 will not run due to dry running protection.			not applicable	

Recommendations / changes	WHEN?	WHO? Comments
HW modifications repair ps-v-03		UAB UAB
PLC programme modifications	step2	SHPA
HMI modifications		NTE NTE NTE NTE

		date/hour	N/NC	comments	SHERPA comments NTE comments
1.1. Procedure 24: Analysis Gas Lo	on: Calibration of ass analyzer A.C.		$\vdash$		
02	op. Calibration of gas analyzer A-G-				
Scope				the command should be available only on the local HM	
Calling the state Mailson C 710 Fater that 6				screen, the remote HMI screen being used only to start /stop	
Calibration of the Maihak S 710 Extractive C	sas Analyser for CH4 and CO2.			the analysis loop	
Necessities Calibration gas at a pressure up to 200mba	ra on a 6mm tubing connection. This can				
be a bottle with a two stage gas pressure re	egulating valve.				
Please carefully read the manual for a detai apparatus.	iled description on how to use this				
Procedure The analyzer is calibrated with two calibrati	on gases that contain different				-
percentages of CH4 and CO2. The nominal	percentages that are measured should lie				
between those percentages, so that the ana measurement and does not have to extrapo					
any CH4 or CO2 can be used, like the N2 fr	om the gas loop. Another calibration gas				
has to be connected to the gas loop.					
The manual describes from page 135 how t	o program different calibration procedures.				-
Calibration with N2:					
<ol> <li>Stop the analysis loop using PROCEDU SCI_G_Ana_Stop</li> </ol>	RE 21: Analysis Gas Loop: Shut down:				
<ol><li>Make HPCV_1103_01 sets a pressure r</li></ol>	not too high for the analysers (PI-G-02				
does not exist???). 3. Start Calibration on the HMI: SCI_G_A	na_Cal_Start. S3V_1103_01 (V-G-01) and				-
S3V_1101_01 (V-G-16) switch and provide					
<ol><li>Calibrate the analyzer as described in it</li></ol>	s manual.				
				these manual operations have not been carried out for the functional tests step 2 ; the calibration gases are not available	
Collibration with "hosting				; yet a few months ago the functionality of the gas analyzer	]
Calibration with calibration gas containing k 1. Set the gas bottle on a pressure around			-	was chosen	1
2. Connect to the inlet of PP_1101_01 (PI	MP_G_02)				
<ol> <li>Calibrate the analyzer as described in i</li> <li>Disconnect the gas bottle and reconnect</li> </ol>					
(PMP_G_02) 5. Stop calibration on the HMI: SCI_G_End	d Calibration. Cas and start the analysis				-
loop again according PROCEDURE 22: Analy					
SCI variables :					
SCI_G_Ana_Cal_Start, SCI_G_End_Calibrati	ion_Gas, SCI_G_Ana_Stop				
BLC Submutines C. And. Col. Start					
PLC Subroutine : G_Ana_Cal_Start					
Figure 8: PLC proceed	ure: G_Ana_Cal_Start				-
			<u>ا</u>		
	G_Calibration_Gas		-		
	Waitfor CL1101 SCI Ana Cal Start CL1101_SCI_Ana_Cal_St.		-		
			-		
CL1101_SCI_Ana_Stop is SET	S_393_2		-		
	Wait for CL1101_SCI_Ana_Stop =	0	-		
Pulse on	~CL1101_SCI_Ana_Stop		-		
Valvestate_S3V_1103_01_S Valvestate_S3V_1101_01_R	S_393_3		-		
	Wait for CHECK_VALVES_G_01_16 S3V_1103_01_FB = 1 S3V_1102_01_FB = 0		-		
			-		
Pulse on PP_1101_01_S	START_PUMP_0_02		-		-
	CI 4404 SCI End Calibration Gas Wait for		-		
CL1101_SCI_Ana_Cal_Start is RESET	CL1101_SCI_End_Calibration_Gas Wait for CL1101_SCI_End_Ca reset_calibration	libration_Gas	-		
CL1101_SCI_End_Calibration_Gas is RESET CL1101_SCI_Ana_Start is SET PP_1101_01_R2 is RESET			-		
	, <del></del>		-		-
			-		
	≥0_Calibration_0as		-		
		L	1 -		
Variables Used (I/O):					1
\$3CV_1103_02_MV, \$3CV_1101_01_MV	, PP_1101_01_MV				
Description :					
Input HMI: SCI_G_Ana_Cal_Start	ad basis the DLO I II TO TO I				]
<ul> <li>The variable SCI_G_Ana_Stop is SET a (Shut down of the Gas analysis loop)</li> </ul>	nd begins the PLC subroutine G_Ana_Stop				
<ul> <li>Valves S3CV_1103_02_MV (V_G_01)</li> </ul>	is ON, S3CV_1101_01_MV (V_G_16) is				
OFF • Run the pump PP_1101_01 (PMP_G_02	n				4
	., as is RESET and stop the calibration of gas				
analyser AT_1101_01					4
<ul> <li>The variable SCI_G_Ana_Start is SET and SET and SET and S</li></ul>	nu me analysis yas ioop can restart				]
Questions:		-			]
<ul> <li>Maybe there is a mistake w SCI_G_End_Calibration_Gas is SET instead</li> </ul>	ith PLC procedure: G_Ana_Cal_Start: d of RESET.				
• Why is the pump PP_1101_01 (	(PMP_G_02) stopped after the SET of				1
<ul><li>SCI_G_Ana_Start?</li><li>Explanation of the green underlined sen</li></ul>	tence				4
Explanation of the green underfined sen					1
					4
end of calibration			NC	it is puitting back S3v 1101 01 and S3V 1103 01 are reset, bu	t the PP 1101.01 is still ON
				in a parting back out from or and out from the reset, bu	

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 22: Analysis Gas Loop: Start-up					
Scope	27/02/2009 10:50		the compressor was stopped (S3V1100 01 and S3V1100 02 remained open) pb : SCV 1100 01 remained fully open more than 2 seconds because of the aborted/abnormal stopping of active gas loop	SHERPA made a modification in order to have the calculation of SCV1100 01 aperture rate if active gas loop ON, otherwise zero aperture is the default	
Start the analysis gas loop. This part of the gas loop uses PMP-G- 02 to create a circulating flow of gas from VSL2_1007_01 over the			passive control loop ON : PT 1009 01 : 72 mbarg, PT 1100 02 : 58 mbarg active gas loop OFF : could not be started correctly (Pump is started but then triggered OFF due to too long opening of valves SCV 1100 01 and SV 1100 01, and also the SV 1100 05 cannot be triggered open)		
gas analysers. <b>Prerequisite</b>	27/02/2009 11:33		preactor = 71 mbarg		
Please make sure to have read the specific gas analyser manual for a detailed description on how to use this apparatus.	27/02/2009 11:33		the gas analyzer has been used for the test		
Procedure			button is working but on HMI there is no evidence of it : no		
Make sure V-R-15 and -16 are open. Press the button on the HMI: SCI_G_Ana_Start	27/02/2009 0:00	NC	green on the button; the SCI_G_Ana_Start variable is not changing value when activating/deactivating the gas analysis loop or is taking when activating the loop the value ON and then switching to OFF OK both valves V_G_14 and 15 closed but check valve		
If a cold startup of the gas loop is done, close both valves V-G-14 and -15 before starting the analysis loop. When PMP-G-02 is running, open them gradually to adjust the flow rates through the analyzers according to PROCEDURE 23: Analysis Gas Loop: adjust flow rates.		с	V_G_17 is letting into the loop some gas from bioreactor (PS_G_02 = 150 mbarg) dismounting to check the status of this valve ; thus release of gas in the bioreactor and new pressures are : PBR=80 mbarg ; PS_G_02 = 80 mbarg		
<i>SCI variables</i> : SCI_G_Ana_Start					
PLC Subroutine : G_Ana_Start					
Figure 7: PLC procedure: G_Ana_Start					
Variables Used (I/O): SV_1101_01_MV, S3CV_1103_02_MV and S3CV_1101_01_MV, PP_1101_01_MV					
Description : Input HMI: SCI_G_Ana_Start Run the pump PMP_G_02		C	ok , the FT 1101 01 = 0,64L/h		
<ul> <li>Valves SV_1101_01_MV, S3V_1103_01_MV (V_G_28 and V_G_01) are OFF, S3V_1101_01_MV (V_G_16) is ON</li> </ul>		с	good behaviour of valves S3V 1101 01 and S3V 1103 01, but HMI animation for S3V 1103 01 is not correct when analysis gas loop is started pressure downstream analyzer PT 1101 01 increased up tc		
This variable begins the PLC procedure G_PAS_Esc     The procedure G_PAS_Esc resets the tracing bit		NC	170 mbarg and flow FT 1101 01 decreased to 0 L/ the NRV 1101 01 was taken off because it provoked the increase of pressure downstream the AT 1101 01 once this replacement is done, the pressure downstream is		
TB_G_PAS_Esc which on state HIGH begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)		с	0.25 to 0,50 mbarg??? Check the units of PT1101 01. flowmeter FT 1101 01 is stable at 1,34 L/h		
Fig : PLC procedure: G_Ana_Start					
Recommendations / changes HW modifications	WHEN	WHO			
V_G_09 to be fixed because it is leaking V_G_17 to be fixed					
PLC programme modifications check the variables used to activate the gas loop from HMI					
HMI modificatinos					
local check the variables used to activate the gas loop from HMI remote					
idem local					
others					



Procedure steps	date/hour	N/NC	comments	SHERPA comments NTE comment
1.1. PROCEDURE 21: Analysis Gas Loop: Shut down				
<b>Scope</b> Stop the analysis gas loop.				
Procedure	27/02/2009 12:42		reactor started up passive control loop ON : PT 1100 02=55mbarg active gas loop ON : PT 1100 01 3180 mbarg preactor = 75 mbarg gas analysis loop started	
Press the button on the HMI: SCI_G_Ana_Stop		NC	button is working to trigger the action but stays always in red	
PLC Interface : ?????			we did not use the PLC interface for this loop	
SCI variables :				
SCI_G_Ana_Stop				
PLC Subroutine : G_Ana_Stop	-			
S_G_Ana_Stop_001		с		
SCI_G_Ana_Stop				
S_G_Ana_Stop_002 PMP_G_02 is RESET		С	the pump is stopped	
~PMP_G_02		<u> </u>		
S_G_Ana_Stop_003 V_G_28 and		с	ok for 28 and 01	
V_G_01 are SET				
T_G_Ans_Stop_003 V G_28 is ON		С	ok for 28 and 01 and 16	
V_G_16 is OFF V_G_01 is ON				
S_G_Ana_Stop_004		С		
SCI_G_Ana_Stop is RESET			PS_G_02 = 5mbarg to evacuate the venting of N2 from	
			$V_G_01$ through $V_G_15$ and $V_G_16$	
S_G_Ang_Stop_001				
Variables Used (I/O):				
SV_1101_01_MV, S3CV_1103_02_MV and S3CV_1101_01_MV				
Description :				
Input HMI: SCI_G_Ana_Stop				
Stop the pump PMP_G_02				
<ul> <li>Valves SV_1101_01_MV, S3CV_1103_02_MV (V_G_28 and</li> </ul>				
V_G_01) are ON, S3CV_1101_01_MV (V_G_16) is OFF				
		<u> </u>		
Recommendations / changes_	WHEN	WHO		
HW modifications				
	<u> </u>			
PLC programme modifications				
PLC programme modifications check the variables used to activate the gas loop from HMI		-		
× ,				
HMI modificatinos				1
local		<u> </u>		
change the colours of buttons to reflect started/shut down states	<u> </u>			
remote				
remote idem local	<u> </u>			
others	i	1		1
others				
others				

# **MELISSA**



# ANNEX 5

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#### Second phase: Step 2 Functional Tests Filtration Unit

Secon	Second phase: Step 2 Functional Tests Filtration Unit Trials after modifications Final status (02/10/09)																		
EPAS number	Sequence of routines	Operator H		ite C	/NC Remarks	SHERPA Corrections	Corrections to be done by NTE	NTE	Corrections	MPP Corrections		1	2		3		4		C/NC
	EMERGENCY STOPS		28/04	/2009	Stop button tags are not normalised. Each tag follows a different rule. Are they correct?	Date		Date		Date	Date C/NC	Remarks Date	C/NC Remarks	Date	C/NC Remarks	Date	C/NC F	lemarks	
16	Emergency Stop on the RV frame	Y		2009	C				Emergency			Considerate name these							с
					Emergency button is solely shown in GAS LOOP HMI screen. There is no Emergency button in FILTRATION UNIT, CIP and SIP		Put EMERGENCY BUTTON indicator		buttos indicators are			buttons "INDICATORS" and put both (FU frame button: FU,							
	Emergency Stop on the FU frame Nominal stopping of the FU frame on the	Y	28/04	2009	NC screens. Filtration is started with membrane 1. Filtration is stopped with		in FU, CIP nad SIP screens.	06/05/200	09 in all screens		15/05/2009 C	Gas loop, CIP, SIP and BR							с
18	HMI Filtration Unit: nominal stopping for				C button "STOP FU/CIP/SIP". Filtration with membranes 1 and 2 is stopped with the button														с
29	membrane1 and membrane2		Y 28/04	2009	C "STOP FILTRATION".		1) In CIP PROCEDURES screen												с
							substitute (EMERGENCY) SHUTDOWN button for "CIP												
					CIP activity "FILL VSSL_1209_01 WITH CLEANING AGENT" is		(NOMINAL) SHUTDOWN" . In INDICATORS screen subtitute "CIP												
45	CIP: nominal stopping of CIP activities		Y 28/04	2009	started. Nominal stopping with button "CIP(EMERGENCY C BUTTON)".		STOPPED" for " CIP (NOMINAL) SHUTDOWN"	13/05/200	09 Done		13/05/2009 C	NTE correction 1) OK							с
66	SIP : nominal stopping of SIP activities CONTROL LOOPS IMPORTANT F	Y	Y 28/04	2009	SIP activity "STERILISE LF_1200_01" is started. Nominal stoping C with button "SIP(NOMINAL) SHUT DOWN".														с
	level safety tests for Bioreactor, Effluent Vessel, CIP vessels	UK SAFE		2009	NA														NA
	Pumps stopping conditions START-UP			2009	NA														NA NA
15	Connect N2 to the system Start-up Bioreactor VSSL_1007_01	Y		2009	C Done manually N/A. It is already started														C NA
	Start-up Bioreactor VSSL_1007_01 feeding	, Y		2009	N/A. At this time Feeding tank is used to maintain C1 Inoculum.														NA
	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02				C Each membrane filtration is tested during 2 minutes.														с
						Comment: PP_1202_01_MV1 has no effect on the power of the													
					PP_1202_01_MV1 is allways connected and the velocity is	pump. The pump can just be started or stopped by changing													
29	Filtration Unit: nominal stopping			2009	regulated by one analogical signal(4-20mA). C	04/05/2009 the speed value. Is this normal?													с
	Filtration Unit: Start-up in Bypass mode Filtration Unit: nominal stopping		Y 28/04 Y 28/04		c c														c c
							<ol> <li>In FU screen, change SPEED % when daily production is changed in the HMI. (SHERPA ask to NTE to</li> </ol>												
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02		Y 28/04	2009	C 1) Reacycle mode is not entering when Filtration unit is not started.		correct it on day 11/05/09)	13/05/200	09 Done		13/05/2009 C	NTE correction 1) OK							c
					However, after this sequence: FU stopped - Enter in Recycle mode (Recycle mode is not started) - Start up of FU, the recycle														
					mode is automatically started showing the message referred to the Steam generatically started showing the message referred to the														
					SV_1202_03 opens at the same time apears a message asking if the manual valve HV_1007_07 is already open. The opening of the	1) Done 2) The pump is so slowly													
37	Filtration Unit: Enter Recycle mode		Y 28/04	2009	valve SV_1020_03 should be done after the message is NC confirmed.	that there is time enough to open 04/05/2009 the valve.					04/05/2009 C								с
					Start of membrane 1. Before entering in Nominal mode (from the														
38	Filtration Unit: Enter Nominal mode		Y 28/04	2009	C recycling mode) the recycling line is cleaned/drained with steam. Effluent vessel is filled with water until a volume of 14.09L and														с
					harvest procedure started. 1) The filtrate pump continue working, but as the PT_1203_08 is measuring 0 bar, there will be no														
					production of filtrate due to high pressure in the effluent tank. This should be considered if the calculation of filtrate production is														
					based on the velocity of the pump. 2) The harvest is started and it stops when level is 4.11L in the HMI, but 0L real. This off-set should be corrected? 3) The first message should refer to a														
					should be corrected / 3) The first message should refer to a draining collector and not to a vessel. This message should also ask if the manual valve HV 1204 02 is opened. After the SIP														
39	Filtration Unit: Harvest Effluent vessel VSSL 1204 01		Y 28/04	2009	process there must be a message asking if there is a vessel to NC collect the filtrate.	<ol> <li>Now the vessel message are in 04/05/2009 the right time. Tested with water.</li> </ol>					04/05/2009 C								c
34	Filtration Unit: Start-up in Bypass mode Filtration Unit: Harvest Effluent vessel				C Effluent vessel is filled with water until 5.5L and at the end of the	on our soo are right and. Folded war water.					04/00/2005								č
	VSSL_1204_01				C procedure volume is 4.11L. FU is stopped. FU is started with membrane 1 and Recycle mode														с
37	Filtration Unit: Enter Recycle mode		Y 28/04	2009	C started. Effluent vessel is filled with water until the switch LSL_1206_01 is														с
	Filtration Unit: Harvest Effluent vessel VSSL_1204_01				OFF corresponding to a volume in the HMI of 4.11L . At the end of C the procedure (and the switch is ON) volume is 4.11L.														с
	CIP Fill cleaning agent into VSSL_1209_01			2009	(There is water in VSSL_1209_03) C 20s. Button "FILL VSSL_1209_01 WITH CLEANIG AGENT"														
62	Fill water into VSSL_1209_01		29/04	2009	First, tank is emptied. Button "FILL VSSL_1209_01 WITH C WATER"														с
63	Fill cleaning agent into VSSL_1209_02		29/04	2009	First, VSSL_1209_01 is emptied. Then it is filled with cleaning agent. Button "FILL VSSL_1209_02".														c
59	Empty VSSL_1209_01 Empty VSSL_1209_02 Rinse VSSL_1209_01		29/04	2009 2009 2009															c
65	Rinse VSSL_1209_01 Clean VSSL_1209_02 Clean VSSL_1209_01 and VSSL_1209_02	, ,	29/04	2009	C First "FILL VSSL_1209_01 WITH WATER" as prerequisite. C Cleaning of VSSL_1209_01 is done with the drain opened.														с с
00			20/04	2000	Buttons "CLEANING RETENTATE LF_1200_01" and "CLEANING														0
					RETENTATE LF_1200_02". Pressures are OK. 1) The prerequisite sentence "Define parameters before (see														
					procedure 61 / 62 / 63)" is not understood. The procedure does not ask for any of these 61/62/63 procedures. VSSL_1209_01 is filled														
					with cleaning agent and water, automatically, after a message asking if there is cleaning agent in the VSSL_1209_03.														
					<ol> <li>Does not corresponds with the procedure written by EPAS.</li> <li>After the procedure the retentate line is not drained/rinsed. This is very important because the filtrate line can be contaminated with</li> </ol>	<ol> <li>It been retested and is correct</li> </ol>													
					cleaning agent. 4) First trial: at the end of the procedure the VSSL_1209_01 is not emptied. Second trial: the vessel is emptied	for both membranes. But, before stopping the procedure this should			1), 2), 3) Done. Now is			1)Checked in both membranes and in each screen . JC from							
49	Cleaning of Filtration Unit: retentate side of membrane LF_1200_01 / LF_1200_02		Y 29/04	2009	correctly. 5)Temperature value of VSSL_1209_02 can not be set. NC At this moment is not required.	be finished. At least the addition of 04/05/2009 CA.	1), 2), 3) Put a window asking for addition of CA or water	05/05/200	asking for CA 9 or Water.		05/05/2009 C	NTE commented that the two screens can behave different.							c
					1) The prerequisite sentence "Define parameters before (see														
					procedure 61 / 62 / 63)" is not understood (repeated in other procedures as well). The procedure does not ask for any of these		1) Put a window asking for addition of												
					61/62/63 procedures. VSSL_1209_01 is filled with cleaning agent and water, automatically, after a message asking if there is	2) To be checked with Raul. But,	CA or water. 2) Redraw the connections between SV_1207_07		1), 2), 3)			1)Checked in both membranes							
	Cleaning of Filtration Unit: both retentate and filtrate side of membrane LF_1200_01				cleaning agent in the VSSL_1209_03. 2) The drawing of the HMI is not correct for T connection between valves SV_1207_07 and	before stopping the procedure this should be finished. At least the	and SV_1207_03 in CIP and FU screens. A drawing with the correct		Done. Now is asking for CA			and in each screen . JC from NTE commented that the two							
	/ LF_1200_02 Cleaning of Filtration Unit: backwash				NC SV_1207_03. In FU screen drawing is different but also incorrect.	04/05/2009 addition of CA.	connections has been sent to NTE.	05/05/200	09 or Water.		05/05/2009 C	screens can behave different.							c
51	membrane LF_1200_01/LF_1200_02	T I	1 29/04	2009	C Effectivity not clear; to be checked with real broth. 1) Not possible to choose water in stead of CA. 2) The comment "4. If this procedure is used with cleaning agent,														с
	Cleaning of Filtration Unit: backwashing				2) The comment '4. If this procedure is used with cleaning agent, use PROCEDURE 64: Rinse VSSL_1209_01 and then this procedure again without cleaning agent in order to remove any	1) Related to HMI. But, before			1) Done. Now			1)Checked in both membranes and in each screen . JC from							
52	membrane LF_1200_01 using water and cleaning agent		Y 29/04	2009	cleaning agent without cleaning agent in order to remove any cleaning agent from the FU piping and the membrane" maybe not NC completely effective.	stopping the procedure the 04/05/2009 addition of CA should be finished.	<ol> <li>Put a window asking for addition of CA or water</li> </ol>	05/05/200	is asking for 09 CA or Water.		05/05/2009 C	NTE commented that the two screens can behave different.							c
				1						• •				•		•			

1		1	1		1) Not possible to choose water/cleanig agent in stead of CA.	1	1		1	1				1	I			1	I	
					<ol> <li>If cleaning agent was used, the operator should use PROCEDURE 64 and 65 for rinsing VSSL_1209_01</li> </ol>	1), 2) Related to HMI, But, before		1), 2) Done. Now is asking				Checked in both membranes d in each screen . JC from								
	Cleaning of Filtration Unit: Circulation pump				VSSL_1209_02, but the pipe have cleaning agent, how we can	stopping the procedure the	1), 2) Put a window asking for addition	n for CA or			NTE	E commented that the two								1
53	GP_1201_01		29/04/2009	NC	clean this cleaning agent from the pipe? 1) Not possible to choose water/cleanig agent in stead of CA.	04/05/2009 addition of CA should be finished. 1) Related to HMI. But, before	of CA or water	05/05/2009 Water.	G	05/05/2009	C scre	eens can behave different.							с	
					<ol><li>VSL2_1204_01 is harvested (Procedure 39: Harvest</li></ol>	stopping the procedure the				1		Checked in both membranes								
					Effluent VESSEL VSSL_1204_01): Operator has to confirm manually both following variables for the harvested procedure is	addition of CA should be finished. 2) This paragraph has been		1) Done. Now		1	in e	each screen. JC mmented that the two								
	Cleaning of Filtration Unit: Filtrate tank				completed":. Not say nothing about open the manual valve	removed. There is no need to be	1) Put a window asking for addition of	f is asking for			scre	eens can behave different.								
54	VSSL_1204_01		29/04/2009	NC	SV_1204_01 to drain the effluent vessel after the cleaning	04/05/2009 applied in cleaning procedures.	CA or water	05/05/2009 CA or Water.	0.	05/05/2009	C 2) C	ОК							с	
					1) "FU must be stopped or be working over the other membrane" is	5														
					not true: not possible over the other membrane (only one common exit of both membranes).															
					<ol><li>As a prerequisite, the silicone tubing should be released in</li></ol>	The number of rinsings can be														
					PP_1202_01.	done by repeating the procedure just with water (1 time = 2														
					<ol><li>It is not possible to see the pressure in the effluent vessel during the empying of the same.</li></ol>	rinsings). 1) Document is														
					4) Manual valve operation before emptying the filtrate vessel is not	corrected. 2) Document is														
					requested by the HMI. 5) "Operator has to confirm manually both following variables for	corrected. 3) There is no pressure transmitter for this action, 4)														
					the harvested procedure:	There is no need to ask for this,													с	
	Cleaning of Filtration Unit: Filtrate tank				CL1201_SCI_Harvest_IsVssIPresent (PLC Address: 000279)" doesn 't match with this procedure.	since it is a cleaning procedure. 5 This paragraph has been						DK. 6) Checked. It is not orrect that valve							(Not possible to cle membrane while th	
	VSSL_1204_01 and filtrate line through				<ol><li>SV_1207_06 is open during CA transfer, incorrectly.</li></ol>	removed. In cleaning procedures	t				SV_	_1207_06 opens for							is working because	e there is
55	LF_1200_01 / LF_1200_02		29/04/2009		7) Emptying of the filtrate tank is rather slow	04/05/2009 has no sense. 6) To be checked.			¢.	07/05/2009	C mer	mbrane 2.							only one filtrate	e line)
			1		"Retentate and filtrate sides" 2) SV_1207_09 response is slow opening (problem with the switch		1													
			1		now is correct), so CP_1207_02 doesn't starts, then the step proc.		1													
			1		49 with water (4 step) is aborted, then the procedure do the step 5 but after this step the procedure do more subtrutines of cleaning,	1	1												1	
			1		it is logical? 3)"Use the HMI to set up how and which procedures		1													
			1		Membrane are to be executed: CL1207_SCI_P_CI1 = 1 (PLC Address: 000258)		1													
			1		CL1207_TB_P_Cl1 = 1 (PLC Address: 000374)		1													
			1		CL1207_SCI_P_Cl2 = 1 (PLC Address: 000259)														1	
	Cleaning of Filtration Unit: automated execution of a sequence of procedures to				CL1207_TB_P_Cl2 = 1 (PLC Address: 000372) " whats the meaning? you only can select the autocleaning af membrane 1 or		<ol> <li>In "Autocleaning" procedure execution screen substitute "Filtrate</li> </ol>													
56	clean membrane LF_1200_01		29/04/2009	С	membrane 2		side" for "Filtrate/Retentate Side"	13/05/2009 Done	1	13/05/2009	C 1) C	ОК							с	
45	CIP: nominal stopping of CIP activities Shut down the System, drain, rinse and		29/04/2009	С	ок														с	
	clean Bioreactor VSSL_1007_01, Feefing																			
46?	vessel VSSL_1000_01 and Filtration Unit	Y	29/04/2009		N/A		Substitute "Atmosphere" to	+											NA	
							"Condensate". 4) Substitute the tag													
					Air is used insead of STEAM. Temperautre sensors TT_1200_02/03 doesn't work properly.		lavels of SIP INDICATORS screen for the same tag lavels of the SIP	νr												
					1) Pressure units are bar and not mbar. 2) Indicators screen:		PROCEDURES screen. This is:													
					normalise timer screens with procedures names.		substitute "SIP (Emergency)													
	SIP (with Air)		30/04/2009		<ol> <li>Pressure units are bar and not mbar. 2) Indicators screen: normalise timer screens with procedures names.</li> <li>Subtitute "Atmpshere" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures.</li> </ol>	t	PROCEDURES screen. This is: substitute "SIP (Emergency) Shutdown for "SIP (Nominal) Shutdown"	13/05/2009 Done		13/05/2009	C NTE	E corrections 2) and 3) OK								
N/A	SIP (with Air) Steam utilities start-up	Y	30/04/2009 30/04/2009		normalise timer screens with procedures names. 3) Subtitute "Atmpshere" to "Condensate" 4) SIP status should no	t	substitute "SIP (Emergency) Shutdown for "SIP (Nominal)	13/05/2009 Done		13/05/2009				Temperature set point bes					NA	
N/A		Y			normalise timer screens with procedures names. 3) Subtitute "Atmpshere" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. N/A		substitute "SIP (Emergency) Shutdown for "SIP (Nominal)	13/05/2009 Done	1	13/05/2009	For Ten	MPP: 1) Membranes		Temperature set point has changed to -1°C/0°C because the					NA	
N/A		Y			normalise timer screens with procedures names. 3) Subtitute "Amohere" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NA Button "STERILISE LF_1200_01/02". First message: 60/60/60		substitute "SIP (Emergency) Shutdown for "SIP (Nominal)	13/05/2009 Done	1	13/05/2009	For Ten proj	MPP: 1) Membranes mp sensors don't work perly. 2) After opening Air		changed to -1°C/0°C because the testing is done with air instead of					NA	
N/A		Y			normalise timer screens with procedures names. 5) solutitute "Amplement" to "Condensate" (-) SIP status should not be Emergency stopped after ending the procedures. WN Button "STERILISE LF_1200_01/02". First message: 60/60/60 seconds. Pressure is not increasing when Air supply is at 1.8bar, to at 4 bar it is 00.4. Femperature TT_1200_02 is forced to 40/0°C		substitute "SIP (Emergency) Shutdown for "SIP (Nominal)	13/05/2009 Done	1	13/05/2009	For Ten prop to th	MPP: 1) Membranes		changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside,			Retested. Temperature		NA	
N/A		Y			normalise timer screens with procedures names. 3) Subtitute "Amplement" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures. NNA Button "STERILISE LF_1200_01/02". First message: 60/60/60 sconds. Pressure is not increasing when Air supply is at 1.8bar, but at 6 bar 1 is 0K. Temperature TT_1200_02 is forced to 40/07C but at 6 bar 1 is 0K. Temperature TT_1200_02 is forced to 400/07C		substitute "SIP (Emergency) Shutdown for "SIP (Nominal)	13/05/2009 Done	1	13/05/2009	For Ten prop to th mer grad	MPP: 1) Membranes mp sensors don't work perly. 2) After opening Air he system pressures from mbrane 1 were increasing dually, although valves		changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside, 2 bar of air and condensate traps			set point has changed to -		NA	
N/A		Y			normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures. NM NO STERLISE LF_1200_01/102". First massage: 60/60/60 execonds. Pressure is not increaing when Air supply is at 1,8bar, to at 1 bar it 100. K "Emperature TI", 1200_02 is forced to to complete the sterilisation procedure. TT, 1200_02 is forced to the conding the coding process.		substitute "SIP (Emergency) Shutdown for "SIP (Nominal)	13/05/2009 Done	1	13/05/2009	For Ten prop to th mer grad wer	MPP: 1) Membranes mp sensors don't work perly. 2) After opening Air he system pressures from mbrane 1 were increasing		changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside,					NA	
N/A		Y			normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures. NVA Beaton "STERULSE LF. 1200, 01/02". First message: 60/60/60 assonds Pressure is not increating when Air supply is at 18 asr, that 4 har is 100. K. Empergenuer 17, 1200, 02 is proced to e0/90°C to complete the sterilisation procedure. TT. 1200, 02 is forced to mibinet temperature to complete the cooling process. 1) Which pressure transmitter is used to control the procedure? 1) For NTE: Durw values SV, 1200, 1006 is fill Sereen to clarify		substitute "SIP (Emergency) Shutdown for 'SIP (Nominal) Shutdown" 2) Draw reactor line input to membranes valves SV, 1201_05/06	13052009 Done	1	13/05/2009	For Ten prop to th mer grad wer sorr poir	MPP: 1) Membranes mp sensors don't work perty. 2) After opening Air he system pressures from mbrane 1 were increasing dually, although valves re closed. Is there a leak newhere? Temperature set thas changed to 20°C		changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/12/05 seconds. Tested with the membrane inside, 2 bar of air and condensate traps closed. Drain valve SV_1201_08 is forced to open position to simulate when traps release pressure.		t i	set point has changed to - 1°C/0°C because the testing is done with air instead of steam. 3)		NA	
N/A		Y			normalise timer screens with procedures names. 3) Subtitute "Amplement" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures. NNA Button "STERILISE LF_1200,01/02". First message: 60/60/60 sconds. Pressure is not increasing when Air supply is at 1.8bar, but at 6 bar 1 is 0K. Temperature TT_1200,02 is forced to 40/07C to complete the sterilisation procedure. TT_1200,02 is forced to ambient temperature to complete the cooling process. 1) Which pressure transmitter is used to control the procedure? 2) For NTE: Draw valves SV_1201,05/06 in SIP screen to clarify the reactor content ine. 3) it is not written in the procedure (it was		substitute "SIP (Emergency) Shutdown" <sup>SIP</sup> (Nominal) Shutdown" 2) Draw reactor line input to membranes valves SV, 1201,0506 and output valves SV- 1201,035V (1201,04 F)B zerocet		1	13/05/2009	For Ten prop to th mer grad wer som poir bec with	MPP: 1) Membranes mp sensors don't work perly. 2) After opening Air he system pressures from mbrane 1 were increasing dually, although valves re closed. Is there a leak newhere? Temperature set nt has changed to 20°C ause the testing is done ha ir instead of steam. 3) it		changed to -1°C0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside, 2 bar of air and condensate traps closed. Drain valve SV-1201.06 is forced to open position to simulate when traps release pressure. Pressures reached are 1.9 bar. Valve technology is DK, there was		i i	set point has changed to - 1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7		NA	
	Steam utilities start-up	Y	30/04/2009		normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" (4) SIP status should not be Emergency stopped after ending the procedures. WN Button "STERILISE LF_1200_01/02". First message: 60/60/60 seconds. Pressure is not increasing when Air supply is at 1.8bar, to at 4 bar it is ON. Femperature T_1200_02 is forced to 40/0°C to complete the sterilisation procedure. TT, 1200_02 is forced to mibient temperature to complete the cooling process. 1) Which pressure transmitter is used to control the procedure? 1) Which pressure transmitter is used to control the procedure? 1) Which pressure transmitter is used to control the procedure? 1) Find the 23 bit is on the 3 1 bit on Unition in the gronocedure (6) was in EPASJ but in order to protect the membrane of high pressure, a have to bo	1) PT_1203_03/06 for membranet	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown" 2) Draw nactor fine Input to membrane subvest 52, 120,0566 membrane subvest 52, 120,0566 1201,0359,1201,04 h SIP screen to clarify the reactor content lines the	a			For Ten prop to th mer grad wer som poir bec with wor	MPP: 1) Membranes mp sensors don't work perty. 2) After opening Air he system pressures from mbrane 1 were increasing dually, although valves re closed. Is there a leak newhere? Temperature set nt has changed to 20°C ause the testing is done h air instead of steam. 3) It rks, but with 4 bar of air the		changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside, 2 bar of air and condensate traps closed. Drain valve SV-1201.08 is forced to open position to simulate when traps release pressure. Pressures reached are 1.9 bar. Valve technology is OK, there was a problem with the feedback signal		1	set point has changed to - 1ºC/O°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and			
		Y	30/04/2009	NC	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures. NVA Beatons "STERLUSE LF, 1200, 01/02". First message: 60/60/60 seconds Pressure is not increasing when Air supply is at 1.8ax, and the status status of the status status of the status should be a status of the status of the status of the status to complete the statistisation procedures. TT, 1200, 02 is forced to amplet the statistisation procedures. TT, 1200, 02 is forced to 1) Which pressure transmitter is used to control the procedure (1) 10 FANS the values SV, 1201, 05/06 is fill Screen to clarify the reactor content line. 3) it is not written in the procedure (8) 10 FANS the "Area" to protect the membrane of high pressure, at the moment of flushing the stams, steam inter valves have to be opened and cloced until the pressure is reached.	1) PT_1203,03/06 for membrane 04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown" <sup>SIP</sup> (Nominal) Shutdown" 2) Draw reactor line input to membranes valves SV, 1201,0506 and output valves SV- 1201,035V (1201,04 F)B zerocet				For Ten prop to th mer grad wer som poir bec with wor	MPP: 1) Membranes mp sensors don't work perty. 2) After opening Air he system pressures from mbrane 1 were increasing dually, although valves re closed. Is there a leak newhere? Temperature set nt has changed to 20°C ause the testing is done h air instead of steam. 3) It rks, but with 4 bar of air the	05/05/2009 C	changed to -1°C0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside, 2 bar of air and condensate traps closed. Drain valve SV-1201.06 is forced to open position to simulate when traps release pressure. Pressures reached are 1.9 bar. Valve technology is DK, there was	07/05/2009	1	set point has changed to - 1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7	NTE correction 2) OF		
	Steam utilities start-up	Y	30/04/2009	NC	normalise timer screens with procedures names. 5) Solutite "Amplement" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures. NNA Button "STERILISE LF_1200_01/02". First message: 60/60/60 accords. Pressure is not increasing when Air supply is at 1.80ar, Out at 4 bar is OK. Temperature TT_1200_02 is torced to 400/C to at 4 bar is OK. Temperature TT_1200_02 is torced to 400/C ambient temperature to complete the cooling process. 1) Which pressure transmitter is used to control the procedure? 2) For NTE: Daw values SV, 1201, 0506 is ISI Screen to clarify the reactor content line. 3) it is not written in the procedure (4 was the moment of fluathing the steam, steam inlet valves have to be opened and closed until the pressure is reached. 1) It is not asking for times. 2) SV, 1204_01003 are not opened during the purge. They must open a written in the procedure.	04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown" "SIP (Nominal) Shutdown" 2) Draw reactor line input to membranes valves SV- 1201_03SV_1201_04 in SIP screen to clarify the reactor content lines th are connected to the membranes.	a			For Ten prop to th mer grad wer som poir bec with wor	MPP: 1) Membranes mp sensors don't work perty. 2) After opening Air he system pressures from mbrane 1 were increasing dually, although valves re closed. Is there a leak newhere? Temperature set nt has changed to 20°C ause the testing is done h air instead of steam. 3) It rks, but with 4 bar of air the	05/05/2009 C	changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside, 2 bar of air and condensate traps closed. Drain valve SV-1201.08 is forced to open position to simulate when traps release pressure. Pressures reached are 1.9 bar. Valve technology is OK, there was a problem with the feedback signal	07/05/2009	1	set point has changed to - 1ºC/O°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF		
	Steam utilities start-up	Y	30/04/2009	NC	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NNA Button "STERILISE LF, 1200, 01/02". First message: 60/60/60 accords. Pressure is not increasing when Air supply is at 1.8bar, to at 4 bar it is 00. K Temperature TT, 1200, 02 is forced to ambient temperature to complete the cooling process. 1) Which pressure transmitter is used to control the procedure. 1) Orkich pressure transmitter is used to control the procedure. 1) Orkich pressure transmitter is used to control the procedure. 1) EVA of the TC Toward Status of the transmitter and the transmitter the transmitter is the status of the transmitter the transmitter of the procedure. 1) EVA of the transmitter is used to control the procedure. 1) EVA of the transmitter is used to control the procedure. 10 EVAS but in order to protect the membrane of high pressure, a the proment of futuring the statum, statum liet waves have to be opened and closed until the pressure is reached. 1) I is not asking to frame. 2) EVA, 0,1003 re not opened during the purge. They must copen as written in the procedure.	04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown " 2) Draw reactor line input to membranes valves SV., 1201, 05/06 membranes valves SV., 1201, 05/06 T001, 00/5V, 1201, 04 is 19 screen to carry the reactor content lines the are connected to the membranes. 1) Put a window to ask for	a			For Ten proj to ti mer grav wer som poir bec with wor NC pres	MPP: 1) Membranes mp sensors don't work perify. 2) After opening Air he system pressures from interanet 1 were increasing dually, although valves although valves molecular and the sensor of the molecular and the molecular and the sure the testing is done hair insteed of steem. 3) it sures the testing is done hair insteed of steem. 3) it sure reached is 1.5bar.	05/05/2009 C	changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside, 2 bar of air and condensate traps closed. Drain valve SV-1201.08 is forced to open position to simulate when traps release pressure. Pressures reached are 1.9 bar. Valve technology is OK, there was a problem with the feedback signal	07/05/2009	1	set point has changed to - 1ºC/O°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF		
	Steam utilities start-up	Y	30/04/2009	NC	normalise timer screens with procedures names. 5) Solutite "Amplement" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures. NNA Button "STERILISE LF_1200_01/02". First message: 60/60/60 accords. Pressure is not increasing when Air supply is at 1.80ar, Out at 4 bar is OK. Temperature TT_1200_02 is torced to 400/C to at 4 bar is OK. Temperature TT_1200_02 is torced to 400/C ambient temperature to complete the cooling process. 1) Which pressure transmitter is used to control the procedure? 2) For NTE: Daw values SV, 1201, 0506 is ISI Screen to clarify the reactor content line. 3) it is not written in the procedure (4 was the moment of fluathing the steam, steam inlet valves have to be opened and closed until the pressure is reached. 1) It is not asking for times. 2) SV, 1204_01003 are not opened during the purge. They must open a written in the procedure.	04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown" "SIP (Nominal) Shutdown" 2) Draw reactor line input to membranes valves SV- 1201_03SV_1201_04 in SIP screen to clarify the reactor content lines th are connected to the membranes.	a			For Ten proj to ti mer son poir bec with wor NC Ten	MPP: 1) Membranes mp sensors don't work, perfy: 2) After opening Air he system pressures from horane 1 were increasing dually, although valves e closed. Is there a leak newhere? Temperature set e closed. Is there a leak newhere? Temperature set number of the sensors of the sure reached is 0.5bar.	05/05/2009 C	changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside, 2 bar of air and condensate traps closed. Drain valve SV-1201.08 is forced to open position to simulate when traps release pressure. Pressures reached are 1.9 bar. Valve technology is OK, there was a problem with the feedback signal	07/05/2009	1	set point has changed to - 1ºC/O°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF		
68	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02, filtrate	Ŷ	30/04/2009	NC	normalise timer screens with procedures names. 5) Solutite "Amphere" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NNA Button "STERILISE LF_1200_01/02". First message: 60/60/60 scoods. Pressure is not increasing when Air supply is at 1.8bar, but at 4 bar its DK. Temperature 1T_1200_02 is forced to 400°C. To complete the stellisation procedure, T_1200_02 is forced to any other the stellisation procedure. T_1200_02 is forced to any other the stellisation procedure. T_1200_02 is forced to any other temperature to complete the scooling process. Second 2.1 For TE: Down values SY, 1201, 10506 in SIP scores to carrily the reactor content line. 3) it is not written in the procedure (it was is FPAS) but in order to protect the membrane of thigh pressure, a the moment of flushing the steam, steam inlet valves have to be opened and closed until the pressure is reached. 1) It is not aximg for times. 2) SV_1204_0103 are not opened during the purge. They must open a written in the procedure. 3) In Filtration 1 valve SV_1203, 03 is closed and in Filtration 2 this valve is opened. This valve Should be always opened. 4) TT, 1205_01 can not be forced to 400°C, herefore the sterilising process can not be started.	04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N	For Tem proj to ti mer grad wer sorr poir bec with wor NC pres Ten cha the	MPP: 1) Membranes mp sensors don't work persive 2) After opening Air he system pressures from the system pressures from dually, although valves re closed. Is there a leak mewhere? Temperatures set n has changed to 20°C ause the testing is done thair insteed of steam. 3) it ause the testing is done the same reached is 1.5bar. mperature set point has inged to -15°C/PC because		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< c	
68	Steam utilities start-up SIP: membrane LF_1200_01 / 02	Y Y Y Y Y	30/04/2009	NC	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA NVA NVA NVA NVA NVA NVA NVA	04/05/2009 1/2, respectively. 3) Done.	2) Draw reactor line input to membranes valves SV, 1201 (Nominal) Shutdown? 2) Draw reactor line input to membranes valves SV, 1201 (0.506 and output valves SV, 1201 (0.506 and output valves SV, 1201 (0.507 and output v	a	0	04/05/2009 N	For Tem proj to ti mer grad wer sorr poir bec with wor NC pres Ten cha the	MPP: 1) Membranes mp sensors don't work persive 2) After opening Air he system pressures from the system pressures from dually, although valves re closed. Is there a leak mewhere? Temperatures set n has changed to 20°C ause the testing is done thair insteed of steam. 3) it ause the testing is done the same reached is 1.5bar. mperature set point has inged to -15°C/PC because		changed to -1°C/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside, 2 bar of air and condensate traps closed. Drain valve SV-1201.08 is forced to open position to simulate when traps release pressure. Pressures reached are 1.9 bar. Valve technology is OK, there was a problem with the feedback signal	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF		
68	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01	Y Y Y Y	30/04/2009 30/04/2009 30/04/2009	NC	normalise timer screens with procedures names. 5) Subtitue <sup>2</sup> , Wanneset <sup>4</sup> to <sup>2</sup> Confersati <sup>4</sup> of SIP status should not be Emergency stopped after ending the procedures. NVA Baton <sup>5</sup> STERULSE LF, 1200, 01/02 <sup>2</sup> . First message: 60/60/60 seconds Pressure is not incruing when Air supply is at 1.8bar, but at bar is 100. K. Temperature IT, 1200, 02 is forced to ambient temperature to complete the cooling process. 1) Which pressure transmitter is used to control the procedure 7 2) For NTE: Draw values SV, 1201, 05/66 in SIP screen to clarify the reactor content line. 3) it is not written in the procedure (8 was 1) Brind to asking for times. 2) SV, 1204, 01/03 are not opend during the projes. They must open a switten in the procedure 1) It is not asking for times. 2) SV, 1204, 01/03 are not opend during the projes. They must open a switten in the procedure. 1) It is not asking for times. 2) SV, 1204, 01/03 are not opend withing the projes. They must open a switten in the procedure 1) It is not bay switten opender. 3) In Filtration 1 withe SV, 1203, 03 is closed and in Filtration 2 the willing process can not be started. 5) K2010 is 050060 seconds. 1) Is not written in the procedure busiles 060600606 seconds. 1) Is not written in the procedure busiles 10 K2010. The size of the scientification.	04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N	For Tem proj to ti mer grad wer sorr poir bec with wor NC pres Ten cha the	MPP: 1) Membranes mp sensors don't work persive 2) After opening Air he system pressures from the system pressures from dually, although valves re closed. Is there a leak mewhere? Temperatures set n has changed to 20°C ause the testing is done thair insteed of steam. 3) it ause the testing is done the same reached is 1.5bar. mperature set point has inged to -15°C/PC because		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< c	
68	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02, filtrate	Y Y Y Y	30/04/2009	NC NC	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. WA Button "STERILISE LF_1200_01/02". First message: 60/60/60 seconds. Pressure is not increasing when Air supply is at 1.8bar, to at 4 bar is 100. K Temperature T_1200.02 is forced to 40/0°C to complete the stellisation procedure. TT, 1200.02 is forced to milenit temperature to complete the cooling process. 1) Which pressure transmitter is used to cothol the procedure if the macher content line. 3) It is not within in the procedure (If was in EPAS) but in order to protect the membrane of high pressure, a in EPAS) but in order to protect the membrane of high pressure, a in EPAS) but in order to protect the ammilter lavels have to be opened and closed until the pressure is reached. 1) Is in at asking for times. 2) SIC 120, 0-10103 are not opened during the purge. They must open as written in the procedure 10 / 11.2b3, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 10 / 12.05, 0/1 con both ob al-00°C, therefore the 11 / 12.05, 0/1 con both ob al-00°C, therefore the 12 / 12.05, 0/1 con both ob al-00°C, therefore the 13 / 12.05, 0/1 con both ob al-00°C, therefore the 14 / 15 / 12 / 15 / 12 / 15 / 12 / 15 / 12 / 12	04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N	For Tem proj to ti mer grad wer sorr poir bec with wor NC pres Ten cha the	MPP: 1) Membranes mp sensors don't work persive 2) After opening Air he system pressures from the system pressures from dually, although valves re closed. Is there a leak mewhere? Temperatures set n has changed to 20°C ause the testing is done thair insteed of steam. 3) it ause the testing is done the same reached is 1.5bar. mperature set point has inged to -15°C/PC because		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< c	
68	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01 SIP :Purge and sterilize recycle line	Y Y Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C	normalise timer screens with procedures names. 5) Subtitue "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA NVA NVA NVA NVA NVA NVA NVA	04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N	For Tem proj to ti mer grad wer sorr poir bec with wor NC pres Ten cha the	MPP: 1) Membranes mp sensors don't work persive 2) After opening Air he system pressures from the system pressures from dually, although valves re closed. Is there a leak mewhere? Temperatures set n has changed to 20°C ause the testing is done thair insteed of steam. 3) it ause the testing is done the same reached is 1.5bar. mperature set point has inged to -15°C/PC because		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< c	
68 69 80	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02; filtrate line and Filtrate tank VSSL_1204_01 SIP :Purge and sterilize racycle line SIP : Purge and sterilize Harvesting line	Y Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C	normalise timer screens with procedures names. 5) Subtitue "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA Batton "STERULSE LF. 1200, 01/02". First message: 60/60/60 esconds Pressure is not incruing when Air supply is at 18 atr. but at bar is 100. K. Temperature IT. 1200, 02 is forced to to complete the sterilisation procedure. TT. 1200, 02 is forced to the reactor content is not incruing yathen Air supply is at 18 atr. 1) Which pressure transmitter is used to control the procedure 7. 2) For TTE: Draw values SV, 1201, 05/66 in SIP screen to clarify the reactor content line. 3) it is not written in the procedure (8 was 1) Brits of the transmitter is used to control the procedure (8 2) For TTE: Draw values SV, 1201, 05/66 in SIP screen to clarify the reactor content line. 3) it is not written in the procedure (8 was 1) Brits of the transmitter is used to control the procedure (8 1) It is not asking for times. 2) SV, 1204, 01/03 are not opened during the purge. They wants open a written in the procedure. 3) In Filtration 1 walve SV, 1203, 03 is closed and in Filtration 2 this bit Browed and the sterilisate?" BO600606 seconds. 1) Is not written in the procedure but valve Bo600606 seconds. 1) Is not written in the procedure but valve Bo600606 seconds. 1) Is not written in the procedure but Should ask Open HV, 1204_02. To be checked wth STEAM.	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 SV_1204_01 is opened.	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Tem proj to ti mer grav wer som poir bec with wor NC pres C inst	MPP: 1) Membranes mp sensors don't work, pp sensors don't work, pp sensors don't work, pp sensors don't work, method and a sensor don't work method and a sensor don't work the sensor of the sensor don't work the sensor don't work are instand of statem. 3) it mentor the sensor don't work saure the testing is done testing is done with air testing is done with air test		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< C C C	
68 69 80 81	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01 SIP :Purge and sterilize recycle line	Y Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C NC	normalise timer screens with procedures names. 5) Subtitue "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA NVA NVA NVA NVA NVA NVA NVA	04/05/2009 1/2, respectively. 3) Done.	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Tem proj to ti mer grav wer som poir bec with wor NC pres C inst	MPP: 1) Membranes mp sensors don't work persive 2) After opening Air he system pressures from thomane I were investing thomane I were investing the observation of the sensor re closed. Is there a leak mewhere? Temperatures set nh har instead of steam. 3) it ause the testing is done hair instead of steam. 3) it ause the testing of air the ssure reached is 1.5bar. mperature set point has imped to 15°C/PC because tead of steam.		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< c c	
68 69 80 81	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01 SIP : Purge and sterilize recycle line SIP : Purge and sterilize recycle line SIP : Purge and sterilize Harvesting line SIP : Fush recycle line with Steam SIP : monitorial stopping of SIP activities SIP : membrane	Y Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C NC	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA NVA NVA NVA NVA NVA NVA NVA	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 5V_1204_01 is opened. 04/05/2009 FU has to be in nominal mode. It uses the last time input. This is	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Tem proj to ti mer grav wer som poir bec with wor NC pres C inst	MPP: 1) Membranes mp sensors don't work, pp sensors don't work, pp sensors don't work, pp sensors don't work, method, and the sensors and method, and the sensors and donly, although valves, re closed, is there a leak mewhere? Temperature set name is table to 20°C ause the testing is done table to 20°C and ause the testing is done table to 20°C and ause the testing is done that mperature set point has mged to 15C/PC because testing is done with air tead of steam. was started first. Then the		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< C C C C C	
68 69 80 81 82 66	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01 / 02 SIP: Purge and sterilize recycle line SIP: Purge and sterilize Harvesting line SIP: Purge Sterilize Harvesting line SIP: 1200 01 / 112 000 02 (first an inter an	Y Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C NC	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. WA Button "STERILISE LF, 1200, 01/02". First message: 60/60/60 ascords. Pressure is not increasing when Air supply is at 1.8bar, to at 4 bar it 100. K. Temperature TT, 1200, 02 is forced to 40/0°C to complete the stellisation procedure. TT, 1200, 02 is forced to ambient temperature to complete the cooling process. 1) Which pressure transmitter is used to control the procedure (a prior NET: Draw wess SV, 1201, 00/66 in SIP screent to carrly 1) First to the values SV, 1201, 00/66 in SIP screent to carrly 10 FIRST to the values SV, 1201, 00/66 in SIP screent to carrly 10 FIRST to the values SV, 1201, 00/66 in SIP screent to carrly 10 FIRST to the values SV, 1201, 00/66 in SIP screent to carrly 10 FIRST to the order to 1 hard to when in the procedure (insu- to SIP	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 SV_1204_01 is opened. 04/05/2009 FU has to be in nominal mode.	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Tem proj to ti mer grav wer som poir bec with wor NC pres C inst	MPP: 1) Membranes mp sensors don't work, pp sensors don't work, pp sensors don't work, pp sensors don't work, method, and the sensors and method, and the sensors and donly, although valves, re closed, is there a leak mewhere? Temperature set name is table to 20°C ause the testing is done table to 20°C and ause the testing is done table to 20°C and ause the testing is done that mperature set point has mged to 15C/PC because testing is done with air tead of steam. was started first. Then the		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OP	< C C C C C	
68 69 80 81 82 66	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01 SIP : Purge and sterilize recycle line SIP : Purge and sterilize recycle line SIP : Purge and sterilize Harvesting line SIP : Fush recycle line with Steam SIP : monitorial stopping of SIP activities SIP : membrane	Y Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C NC	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. WA Burton "STERILISE LF_1200_01/02". First message: 60/60/60 seconds. Pressure is not increasing when Air supply is at 1.8bar, to at 4 bar is 100. K Temperature T_1200.02 is forced to to complete the stellisation procedure. TT, 1200.02 is forced to to complete the stellisation procedure. TT, 1200.02 is forced to to complete the stellisation procedure. TT, 1200.02 is forced to the means of the transmitter is used to control the procedure of the means of the transmitter is used to control the procedure of the reador content line. 3) It is not written in the procedure (If was in EPAS) but in order to protect the membrane of high pressure, a the reador content line. 3) It is not written in the procedure. (If was 10 is not asking for times. 2) SV 120, doi:103 ne not opened during the purge. They must open as written in the procedure (If was 10 is not asking control the status opened. 10 is not asking control the status opened. 10 is not asking control the status opened. 10 is not asking to control the status opened. 10 is not asking to means. 3) SV 120, doi:103 ne not opened during the should not be closed at the end of stellisation. 10 SV 2010 should not be closed at the end of stellisation. 11 so closed is 10 is not written in the procedure but Should sk Open H/_120, 40.2. To be checked with STEAM. 11 doesn't work. NA	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 5V_1204_01 is opened. 04/05/2009 FU has to be in nominal mode. It uses the last time input. This is normal, but when we know the	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Tem proj to ti mer grav wer som poir bec with wor NC pres C inst	MPP: 1) Membranes mp sensors don't work, pp sensors don't work, pp sensors don't work, pp sensors don't work, method, and the sensors and method, and the sensors and donly, although valves, re closed, is there a leak mewhere? Temperature set name is table to 20°C ause the testing is done table to 20°C and ause the testing is done table to 20°C and ause the testing is done that mperature set point has mged to 15C/PC because testing is done with air tead of steam. was started first. Then the		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OP	< C C C C NA	
68 69 80 81 82 66 84	Steam utilities start-up SIP: membrane LF_1200_01/02. SIP: membrane LF_1200_01/02. Itrate time and Filtrate tank VSSL_1204_01 SIP :Purge and sterilize recycle line SIP : Purge and sterilize Harvesting line SIP : Purge and sterilize Harvesting line SIP : Purge und sterilize Harvesting line SIP : The three tank VSL2_1204_01	Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C C	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA NVA NVA NVA NVA NVA NVA NVA	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 5V_1204_01 is opened. 04/05/2009 FU has to be in nominal mode. It uses the last time input. This is normal, but when we know the	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Tem proj to ti mer grav wer som poir bec with wor NC pres C inst	MPP: 1) Membranes mp sensors don't work, pp sensors don't work, pp sensors don't work, pp sensors don't work, method, and the sensors and method, and the sensors and donly, although valves, re closed, is there a leak mewhere? Temperature set name is table to 20°C ause the testing is done table to 20°C and ause the testing is done table to 20°C and ause the testing is done that mperature set point has mged to 15C/PC because testing is done with air tead of steam. was started first. Then the		changed to -1*C0*C because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain enables, 2 ber of all and condensate traps of the steam of the steam of the steam when traps release pressure. Pressures reached are 1.9 ber. Valve technology is OK, there was a problem with the feedback signal Refreshing time of HMI is slover	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< C C C C NA	
68 69 80 81 82 66 84	Steam utilities start-up SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01 / 02 SIP: Purge and sterilize recycle line SIP: Purge and sterilize Harvesting line SIP: Purge Sterilize Harvesting line SIP: 1200 01 / 112 000 02 (first an inter an	Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C C	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. WA Burton "STERILISE LF_1200_01/02". First message: 60/60/60 seconds. Pressure is not increasing when Air supply is at 1.8bar, to at 4 bar is 100. K Temperature T_1200.02 is forced to to complete the stellisation procedure. TT, 1200.02 is forced to to complete the stellisation procedure. TT, 1200.02 is forced to to complete the stellisation procedure. TT, 1200.02 is forced to the means of the transmitter is used to control the procedure of the means of the transmitter is used to control the procedure of the reador content line. 3) It is not written in the procedure (If was in EPAS) but in order to protect the membrane of high pressure, a the reador content line. 3) It is not written in the procedure. (If was 10 is not asking for times. 2) SV 120, doi:103 ne not opened during the purge. They must open as written in the procedure (If was 10 is not asking control the status opened. 10 is not asking control the status opened. 10 is not asking control the status opened. 10 is not asking to control the status opened. 10 is not asking to means. 3) SV 120, doi:103 ne not opened during the should not be closed at the end of stellisation. 10 SV 2010 should not be closed at the end of stellisation. 11 so closed is 10 is not written in the procedure but Should sk Open H/_120, 40.2. To be checked with STEAM. 11 doesn't work. NA	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 5V_1204_01 is opened. 04/05/2009 FU has to be in nominal mode. It uses the last time input. This is normal, but when we know the	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Tem proj to ti mer grav wer som poir bec with wor NC pres C inst	MPP: 1) Membranes mp sensors don't work, pp sensors don't work, pp sensors don't work, pp sensors don't work, method, and the sensors and method, and the sensors and donly, although valves, re closed, is there a leak mewhere? Temperature set name is table to 20°C ause the testing is done table to 20°C and ause the testing is done table to 20°C and ause the testing is done that mperature set point has mged to 15C/PC because testing is done with air tead of steam. was started first. Then the		changed to -1*C0/rC because the testing is done with an instead of steam. 3) 15/120/5 seconds. Tested with the membrain ensister (2 bar of air and condensate traps (doed. Drain valves \n.1201; 08 thoroad to open position to simulate with the second pression. Yahe technology is Ok, there was a problem with the feedback signal Refreshing time of HMI is slower NTE correction 1) OK	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< C C C C NA	
68 69 80 81 82 66 84	Steam utilities start-up SIP: membrane LF_1200_01/02 SIP: membrane LF_1200_01/02 SIP: membrane LF_1200_01/02 SIP: Purge and sterilize recycle line SIP: Purge and sterilize Harvesting line SIP: Total terzolo 21, fittal sterilize Procedure 84: SIP: membrane LF_1200_01/11; 200,02, fittals line and Fittrate tank VSL2_1204_01 SIP (with STEAM) 1	Y Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C C	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA NVA NVA NVA NVA NVA NVA NVA	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 5V_1204_01 is opened. 04/05/2009 FU has to be in nominal mode. It uses the last time input. This is normal, but when we know the	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Tem proj to ti mer grav wer som poir bec with wor NC pres C inst	MPP: 1) Membranes mp sensors don't work, pp sensors don't work, pp sensors don't work, pp sensors don't work, method, and the sensors and method, and the sensors and donly, although valves, re closed, is there a leak mewhere? Temperature set name is table to 20°C ause the testing is done table to 20°C and ause the testing is done table to 20°C and ause the testing is done that mperature set point has mged to 15C/PC because testing is done with air tead of steam. was started first. Then the		changed to -1*C0*C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrain sinske, 2 ber of air and condensate traps (doed). Drain values 0, 1201. 08 (doed). Drain values 0, 1201. 08 when traps release pressure and the second are 1.9 ber. Valve technology is Ok, there was a problem with the feedback signal Refreshing time of HMI is slower NTE correction 1) OK	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OP	< C C C C NA	
68 69 80 81 82 66 84	Steam utilities start-up SIP: membrane LF_1200_01/02 SIP: membrane LF_1200_01/02 SIP: membrane LF_1200_01/02 SIP: Purge and sterilize recycle line SIP: Purge and sterilize Harvesting line SIP: Total terzolo 21, fittal sterilize Procedure 84: SIP: membrane LF_1200_01/11; 200,02, fittals line and Fittrate tank VSL2_1204_01 SIP (with STEAM) 1	Y Y Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C C	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA NVA NVA NVA NVA NVA NVA NVA	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 5V_1204_01 is opened. 04/05/2009 FU has to be in nominal mode. It uses the last time input. This is normal, but when we know the	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Temport to the temport of temport	MPP: 1) Membranes progency control work, periny: 2) After opening Air he system pressures from (and and and and and and and and only, although values) re closed. Is there a leak mewhere? Temperature set n has changed to 20°C ause the testing is done hair instead of steam. 3) it ause the testing is done the sure reached is 1.5bar. merature ast point has imped to .15C/PC because treating is done with air testing is done with air test of steam.		changed to -1*C0*C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrain sinkle, 2 bar of air and condensate traps (doed). Drain values 9,1120/1.08 (bar of the testing) of the testing of the when traps release pressure. The technology is Ok, there was a problem with the feedback signal Refreshing time of HMI is slower NTE correction 1) OK	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OF	< C C C C NA	
68 69 80 81 82 66 84	Steam utilities start-up SIP: membrane LF_1200_01/02 SIP: membrane LF_1200_01/02 SIP: membrane LF_1200_01/02 SIP: Purge and sterilize recycle line SIP: Purge and sterilize Harvesting line SIP: Total terzolo 21, fittal sterilize Procedure 84: SIP: membrane LF_1200_01/11; 200,02, fittals line and Fittrate tank VSL2_1204_01 SIP (with STEAM) 1	Y Y	30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009 30/04/2009	NC C C C	normalise timer screens with procedures names. 5) Subtitute "Amplement" to "Condensate" 4) SIP status should no be Emergency stopped after ending the procedures. NVA NVA NVA NVA NVA NVA NVA NVA	04/05/2009 1/2, respectively. 3) Done. 2) It waits manual valve 05/05/2009 5V_1204_01 is opened. 04/05/2009 FU has to be in nominal mode. It uses the last time input. This is normal, but when we know the	substitute "SIP (Emergency) Shutdown or "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) Shutdown "SIP (Nominal) and output valves SV- 1201, 035V, 1201, 04 is SIP screen to clarify the reactor content lines the are connected to the membranes. 1) Put a window to ask for purgetsferilisation for Same window that appears in Protocol of stringstand for	t 1305/2009 Done	0	04/05/2009 N 07/05/2009 1	For Ten Ten grav grav wor wor poi poi poi poi poi poi poi poi tece cha the cha the cha the C prot the cha the C prot the cha the cha the cha the the cha the the cha the the cha the the cha the the cha the the cha the the cha the the cha the cha the the the cha the the the the the the the the the the	MPP: 1) Membranes mp sensors don't work, pp sensors don't work, pp sensors don't work, pp sensors don't work, method, and the sensors and method, and the sensors and donly, although valves, re closed, is there a leak mewhere? Temperature set name is table to 20°C ause the testing is done table to 20°C and ause the testing is done table to 20°C and ause the testing is done that mperature set point has mged to 15C/PC because testing is done with air tead of steam. was started first. Then the		changed to -1*C0*C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Tested with the membrane inside. 2 ber of all and condensate traps in the second of the second steam of the when traps release pressure. Pressures reached are 1.9 bar. Valve technology is Ok, there was a problem with the feedback signal Refreshing time of HMI is slover NTE correction 1) OK Fittration 1.180/180/190 seconds. Fittration 1.180/180/190 seconds.	07/05/2009	1	set point has changed to - 1ºC/0°C because the testing is done with air instead of steam. 3) 15/120/5 seconds. Pressure reached is 1.7 bar for membrane 1 and	NTE correction 2) OP	< C C C C NA	

68 SIP: m	embrane LF_1200_01 / 02		12/05/2009		<ol> <li>There must be a limer during sterilisation time with the condition of temperature &gt;=121°C.</li> </ol>	1) Done. The timer of sterilisation has a condition of temperature (x=121C, 2) control parameters have been optimised. 3) (130/09) Research sterilisation (171_1200,020/03 or TT_1205_01) decreas to <121°C is implemented.		12/05/2009 NC	Test with STEAM at 2.6bar. Filtration 1. 180/600/180 seconds. 2) The increase of pressure is too fast. Valves are opening and closing all the time to maintain the pressure at 1.7 bar. There are no leaks in the line. Checked by valves temperature. J Temperatures TT. 1200.02 has been forced to 3200-400°C in order to step to sterilisation phase.	STEAM line. The STEAM litter in MPP is cloged with inon oxide particles. After cleaning the filter test with 2.1 bar STEAM and 2) control parameters have been optimised. Increase of pressure is much more slowly, OK. Optimal increase velocity to be checked when temperature sensors are correct, because the constrain of the assimum temperature is appoint to the standard standard standard to the standard standard standard closing during the standard in time.	13/05/2009	Filtration 1. 60/240/60 seconds. 3) Restant timer works correctly if temperature is <121°C. C OK.		C Sterilisation phase has to be checked because TT_1200.0203 doesn't work property.				
69 line an 80 SIP :Pu 81 SIP : P 82 SIP: Fi 66 SIP : n	embrane LF_1200_01/02, filtrate d Filtrate tank VSSL_1204_01 urge and stelliza Havesting line urge and stelliza Havesting line urge and stelliza Havesting line orninal stopping of SIP activities 00 UZ trittara line and Hrates tank and Hrates tank	Y Y	13/05/2009	0 F 1 F 2 F 2 F 0 F 0 F 0 F 0 F 0 F 0 F 0 F 0	Test with 2 bar STEAM supply. MPP: SV_1210_12 can not be opened. It doesn't work. The line had to be purged in another open during purging time to remove any gas from the upper part of the start where in the procedure burst SV_1204_02 about be open during purging time to remove any gas from the upper part of the start start and the start of the start and the start of the start start and the start start and the start start and purge time. Membrane pressure 1.5bar and fittrate line 0.05 bar. Stellization phase. Effluent Tark the temperature doesn't raise. It gets stable at 88°C. (acket was drained). Probably higher pressure steam supply is needed and steam pipes internal diameter is too small. To be tested manually with bigger flexible pipes to be provided by CIFA.	1) Implementation of restart sterilisation timer when temperature (TT_1200_02/03 or TT_1205_01) decrese to <121°C.			SHERPA correction 1) OK. For MPP: Sterilisation phase has to be checked manually.					C Sterilisation phase has to be checked manually. Temperature reached is 89°C. Confirmed in 2205099 Confirmed in 2205099 TBD C				
84 VSL2_														TBD				
	SIP (with STEAM) 2	, <u> </u>		Test with STEAM	1 1	· · ·	· · · ·	1	· ·	1 .	,	· · · ·			· · · · · · · · · · · · · · · · · · ·			
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	Steam utilities start-up SIP: membrane LF_1200_01 / 02	Y	22/05/2009	90 C Checked sterilisation in effluent tank manually. Temperature						23/06/2009 C	Filtration 1. 60/120/60. Temperature reached is 112.2°C and pressure 1.5 bar. There is a small leak in the 60/60/60. Temperature							c
69 I	SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01 SIP :Purge and sterilize recycle line			reached is 92.5°C. There is a leak in the steam trap LF_1210_03. To be respectived. But the most important is that vapour is leaking through the jacket. In the previous tests the jacket was closed and 90. C could not be seen. To be repaired by CFA. 100/100/100/100. It is no written in the procedure butCooling time 90. CS should be removed?	nd e			ti	the jacket of the effleunt	t	reached in the tank is 86°C. There seems to be a leak in the jacket of the effluent tank.							C Sterilisation phase has to be checked manually. Effluent tank to be repaired C
82 66	SIP : Purge and sterilize Harvesting line SIP: Flush recycle line with Steam SIP : nominal stopping of SIP activities		22/05/2009	60/60/60. It is not written in the procedure but Should ask open the Valve HV_1204_02.		 	<u>                                     </u>		 									C TBD C
	LF_1200_02, filtrate line and Filtrate tank VSL2_1204_01		'	<u> </u> '	<u>                                      </u>	رر ۱	<u> </u>		'		<u> </u>	Ĺ						TBD
														<del></del>			<del></del>	
	SIP (with STEAM) 3 Steam utilities start-up	+	16/09/2009	Test with STEAM	4'	<b>۱</b>	+'	4'	<b>ا</b> ــــــــــــــــــــــــــــــــــــ	02/10/2009 C	'	·'	+	+		+	+	
68	SIP: membrane LF_1200_01 / 02 SIP: membrane LF_1200_01/02, filtrate			CIFA repaired for a second time the jacket of the effluent tank (july 2009) but temperature in effluent tank still doesn't raise. Test done manually. Probably the range of the sensor TT_1205_01 is not correct in the PLC. This sensor was changed in MPP by CIFA and	d Changed range of TT_1205_01 to	 					60/180/60. Temperature reached in the tank is 127°C. Filtration 1 reached 108°C and pressure 1.7bar. There was a	1						Confirmed in 22/05/09 Confirmed in 22/05/09 To be checked after
80 \$	line and Filtrate tank VSSL_1204_01 SIP :Purge and sterilize recycle line SIP : Purge and sterilize Harvesting line	Y Y	16/09/2009	NC does not come from EPAS.	30/09/2009 0-150°C.				 	02/10/2009 C	small leak in the filtrate line to							hardware verifications. Confirmed in 22/05/09 Confirmed in 22/05/09 TBD To be checked after
82 66	SIP: Flush recycle line with Steam SIP : nominal stopping of SIP activities	<u> </u>	'	<u>                                      </u>	<u>                                     </u>	ا ۱	<u> </u>	<u> </u>	ا ا	<u> </u>	!	<u> </u>						hardware verifications. C
	SIP: membrane LF_1200_01 / LF_1200_02, filtrate line and Filtrate tank VSL2_1204_01	<u> </u>									!							TBD To be checked after hardware verifications.

# **MELISSA**



# ANNEX 6

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#### FUNTIONAL TEST STEP 2 C1

#### LIQUID TIGHTNESS

LOOP	NEW TAG	OLD TAG	ELEMENT	RESPONSIBLE	PROCEDURE	STATUS	RESULTS
Bioreactor	VSSL_1000_01	R_V_01	Vessel	MPP	pag STEP1/2.7	D	С
	VSSL_1007_01	R_R_01	Vessel	MPP	pag STEP1/2.6	D	С
	VSSL_1011_01	R_R_02	Vessel	MPP	N/A bottle 2 liters	n/a	n/a
	VSSL_1011_02	R_R_03	Vessel	MPP	N/A bottle 2 liters	n/a	n/a
	VSSL_1008_01	HX_R_01	Vessel	MPP	pag STEP1/2.5	D	С
Filtration unit	VSSL_1204_01	R_F_01	Vessel	MPP	pag STEP1/2.3	TBR	n/a
Gas loop	VSSL_1100_01	R_G_01	Vessel	MPP	pag STEP1/2.4	D	С
Cleaning loop	VSSL_1209_01	R_C_01	Vessel	MPP	pag STEP1/2.2	D	С
	VSSL_1209_02	R_C_02	Vessel	MPP	pag STEP1/2.1	D	С
	VSSI 1209 03	R C 03	Vessel	MPP	N/A bottle 2 liters	n/a	n/a

#### GAS TIGHTNESS

LOOP	NEW TAG	OLD TAG	ELEMENT	RESPONSIBLE	PROCEDURE	STATUS	RESULTS
Bioreactor	VSSL_1000_01	R_V_01	Vessel	MPP	pag STEP1/1.2	D	C
	VSSL_1007_01	R_R_01	Vessel	MPP	pag STEP1/1.1	D	С
	VSSL_1011_01	R_R_02	Vessel	MPP	N/A bottle 2 liters	n/a	n/a
	VSSL_1011_02	R_R_03	Vessel	MPP	N/A bottle 2 liters	n/a	n/a
					pag STEP1/1.6	TBR	NC
Filtration unit	VSSL_1204_01	R_F_01	Vessel	MPP	pag STEP2/4.1	D	С
					pag STEP1/1.4	D	С
Gas loop	VSSL_1100_01	R_G_01	Vessel	MPP	pag STEP2/4.2	D	С
	VSSL 1100 02				pag STEP1/1.8	TBR, needs maint.	NC
	VSSL_1100_02	R_G_02	Vessel	MPP	pag STEP2/4.3	D	С
	Gas loop	Gas loop	Vessel	MPP	pag STEP1/1.12	D	
Cleaning loop	VSSL_1209_01	R_C_01	Vessel	MPP	pag STEP1/1.3	D	С
	VSSL_1209_02	R_C_02	Vessel	MPP	pag STEP1/1.5	D	С

#### CORRECT ON\_LINE MEASURAMENTS

LOOP	NEW TAG	OLD TAG	ELEMENT	RESPONSIBLE	PROCEDURE	STATUS	RESULTS
Disesset	LSH_1004_01		laural auricht	MPP	Tested with water to look the status	D	С
Bioreactor		LS_V_01	level swicht	CIFA	change CIFA Calibration Report	D	
	PT_1003_01 PT 1001 01	PS_V_01 PS_V_03	Pressure transducer Pressure transducer	CIFA	CIFA Calibration Report	TBD	
	F1_1001_01	F3_V_03	Flessule transuucer	GIFA	To be tested with and external	IBD	
	TT 1002 01				thermostatic bath calibrate by	TBD	
	11_1002_01	TS V 01	temperature sensor	CIFA	CIFA when Feeding tank is free	100	
	TT 1002 02	TS V 02	temperature sensor	CIFA		TBD	
					Tested with water to look the status		
	LSH_1010_01	LS_R_01	level swicht	MPP	change	D	С
	LT_1010_01				Tested with water to look the status	D	С
	L1_1010_01	LS_R_02	level swicht	MPP	change	D	C
	LSL 1008 01				Tested with water to look the status	D	С
		LS_R_03	level swicht	MPP	change	-	
	AT_1011_01	PHS_R_01	PH analyser	MPP	pag STEP 2 / 2.1	TBR, needs maint	NC
	AT_1011_02	PHS_R_02	PH analyser	MPP	pag STEP 2 / 2.2	D	С
	PT_1009_01	PS_R_01	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1009_02 TT 1008 01	PS_R_02 TS R 01	Pressure transducer temperature sensor	CIFA CIFA	CIFA Calibration Report pag STEP 2 / 2.3	D D	С
	TT 1008_01	TS R 02	temperature sensor	CIFA	pag STEP 2 / 2.3	D	c
-	FT_1201_01	FS_F_01	Flow transducer	CIFA	MPP (pag. Add. Tests)	D	U
illiation unit		F3_F_01	FIOW transducer	GIFA	Tested with water to look the status		
	LSH_1206_01	LS_F_01	level swicht	MPP	change	D	С
		20_1_01	ICVCI SWIGHT	IVII I	Tested with water to look the status		
	LSH_1206_02	LS F 02	level swicht	MPP	change	D	С
		20_1_02	lover owient		Tested with water to look the status	_	_
	LT_1206_01	LS_F_03	level swicht	MPP	change	D	С
	PT_1203_01	PS F 01	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT 1203 02	PS_F_02	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1203_03	PS_F_03	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1203_04	PS_F_04	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1203_05	PS_F_05	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1203_06	PS_F_06	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1203_07	PS_F_07	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PSH_1203_01	PS_F_08	Pressure transducer	CIFA	CIFA Calibration Report	D	
	AT_1201_01	SS_F_01	Turbidity sensor	OPTEK/MPP		TBD	
	TT_1205_01	TS_F_01	temperature sensor	CIFA	pag STEP 2 / 2.5	D	С
	TT_1200_01	TS_F_02	temperature sensor	CIFA	pag STEP 2 / 2.6	D	С
	TT_1200_02	TS F 03	temperature sensor	CIFA	To be tested with and external thermostatic_bath calibrate by CIFA	TBD	С
	TT_1200_03		temperatare concer		To be tested with and external thermostatic_bath calibrate by	TBD	С
		TS_F_04	temperature sensor	CIFA	CIFA		
	PT_1203_08	PS_F_09	Pressure transducer	CIFA		TBD	
Gas loop	AT_1101_01	A_G_02	Gas analyser	MAINHAK	To be calibrate by MAINHAK	TBD	
	FT_1101_01	FS_G_01	Flow transducer	IBERFLUID	New instrument	n/a	n/a
	FT_1103_01	FS_G_04	Flow transducer	IBERFLUID	Navy in stay on and	TBD	- 10
	FI_1101_01	FI_G_01	rotameter	ALCO	New instrument	n/a	n/a
	FI_1101_02 FI 1100 01	FI_G_02 FI_G_03	rotameter rotameter	ALCO	New instrument New instrument	n/a n/a	n/a n/a
	PI 1100_01	PI G 01	Manometer	MPP	New Instrument	TBD	n/a
	PT 1100_01	PI_G_01 PS_G_01	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT 1100_01	PS G 02	Pressure transducer	CIFA		TBD	
	LSH_1102_01	LS G 01	level swicht	MPP	Tested with water to look the status change	D	С
	TT_1104_01	TS_G_01	temperature sensor	CIFA	pag STEP 2 / 2.7	D	С
	PT_1100_02	PS_G_04	Pressure transducer	CIFA		D	
Cleaning	TT_1208_01	TS_C_01	temperature sensor	CIFA	pag STEP 2 / 2.8	D	С
	LSH_1209_01	LS_C_01	level swicht	MPP	Tested with water to look the status change	D	С
	LSL_1209_01	LS_C_02	level swicht	MPP	Tested with water to look the status change	D	С
	LSH_1209_02	LS_C_03	level swicht	MPP	Tested with water to look the status change	D	С
	LSL_1209_02	LS_C_04	level swicht	MPP	Tested with water to look the status change	D	С

#### CORRECT VOLUME MEASUREMENTS

LOOP	NEW TAG	OLD TAG	ELEMENT	RESPONSIBLE	PROCEDURE	STATUS	RESULTS
Bioreactor	VSSL_1000_01	R_V_01	Vessel	MPP	pag STEP 2/1.1	D	С
	VSSL_1007_01	R_R_01	Vessel	MPP	pag STEP 2/1.2	D	С
Filtration unit	VSSL_1204_01	R_F_01	Vessel	MPP	pag STEP 2/1.3	D	NC
Gas loop	VSSL_1100_02	R_G_02	Vessel	MPP	pag STEP 2/1.6	D	С
Cleaning	VSSL_1209_01	R_C_01	Vessel	MPP	pag STEP 2/1.4	D	С
	VSSL_1209_02	R_C_02	Vessel	MPP	pag STEP 2/1.5	D	С

#### CORRECT FLOWS AND SPEEDS

LOOP	NEW TAG	OLD TAG	ELEMENT	RESPONSIBLE	PROCEDURE	STATUS	RESULTS
	GP_1001_01				Controlet by VDF to be check with	TBD	
Bioreactor	GF_1001_01	PMP_V_01	Gear pump	MPP	a laser tacometer	IBD	
	CP_1002_01	PMP_V_02	Centrifugal pump	MPP	pag Add. Tests	D	
	PP_1011_01	PMP_R_01	peristaltic pump	MPP	pag STEP 2 / 3.1	D	С
	PP_1011_02	PMP_R_02	peristaltic pump	MPP	pag STEP 2 / 3.2	D	С
	CP_1008_01	PMP_R_03	Centrifugal pump	MPP	pag Add. Tests	D	
	BLE_1012_01	BL_R_01	Blender	MPP	Runnig at max revolutions, checked with laser tacometer (pag Add. Tests)	D	
	BLE_1005_01	BL_V_01	Blender	MPP	Runnig at max revolutions, checked with laser tacometer (pag Add. Tests)	D	
Filtration unit	GP_1201_01	PMP_F_01	Gear pump	MPP	Controlet by VDF to be check with a laser tacometer	TBD	
	PP_1202_01	PMP_F_02	peristaltic pump	MPP	To be tested doin a mathematical equation (volum/time/internal_tub_diameter)	TBD	
Gas loop	GCP 1100 01	PMP G 01	Gas compressor	MPP	pag STEP 2 / 3.6	D	
	PP_1101_01	PMP_G_02	Gas compressor	MPP	To be tested when FT_1101_01 is verified	TBD	
	PP_1102_01	PMP_G_03	peristaltic pump	MPP	To be tested doin a mathematical equation (pressure/time/flow)	TBD	С
Cleaning	CP_1207_01	PMP_C_01	Centrifugal pump	MPP	pag STEP 2/3.4	D	С
	PP_1209_01	PMP_C_02	peristaltic pump	MPP	pag STEP 2 / 3.3	D	С
	CP_1207_02	PMP_C_03	Centrifugal pump	MPP	pag STEP 2 / 3.5	D	C

1/

#### TEST PROCEDURE "Gas tightness" RESULTS

Procedure:

1.1.Close all the manuals and power valves associated to the reactor

1.2. filling the reactors with pressur gas " air"

1.3.Close the reactor and control the tightness

Success criterion:

2.1. The leak mesured will be less that  $\hfill \dots Mbar^*L/s$ 

	UNIT TESTED	TEST number	DATA	VOLUM REACTOR	INITIAL PRESSURE	TEST DURATION	FINAL PRESSURE	REMARKS	RATIO	RESULTS
	VSSL-1007-01	number		REACTOR	FRESSORE	DORATION	FRESSORE	there is a small gas leak in		
1,1	R-R-01	1	30-may	120L	2barg	13h	1,9barg	retractable ph (both of them)	0.25	С
	K-K-01		00 may	1202	Zbaig	1011	1,50419	retractable pri (both or them)	0,20	U
4.0	VSSL-1000-01									
1,2	R-V-01	1	30-may	60L	2barg	13h	2bargs	No leak	0	С
	VSSL-1209-01							there is a big gas leak, the gas		
1,3								go to R-C-03 because isn't		
, -	R-C-01	1	30-may	15L	2barg	13h	0,2barg	valve between the recipients	NC	NC
		2	30-may		1,9barg	2h	1,85barg	there is a small gas leak, the leak identified in pump		
		-	JU-may	15L	1,5barg	211	1,000arg	PMP_C_01	NC	NC
								there is a small gas leak, the		
		3	02-jun	15L	Chorge	18h	1barg	leak identified in pump	0,23	С
		3	02-jun	15L	2bargs	100	Toarg	PMP_C_01	0,23	C
	1001 4400 04				I	1		the sector of the sector field		
	VSSL-1100-01							there is a big gas leak		
1,4								identified in the racords, and		
• • • •								the V-G-10 is activated and	NO	NO
	R-G-01	1	30-may	10L	2,9barg	2h	0barg	drain the air to the gas colector there is a small gas leak	NC	NC
								identified in the valve V-G-10,	NO	NO
		2	30-may	10L	2,9 barg	4h	2,85bargs	the valve not closed completly there is a small gas leak	NC	NC
								identified in the valve V-G-10,	0,043	С
		3	02-jun	10L	3bargs	18h	2,717bargs	the valve not closed completly	,	
	VSSL-1209-02							there is a big gas leak, the		
1,5								drain valve V_C_07 was open, and there is a little gas leak in		
.,0	R-C-02	1	30-may	10L	2barg	13h	0barg	the sensors	NC	NC
								there is a small gas leak, the		
		2	30-may	10L	1,9bargs	2h	1,85bargs	leak indentified in the pump PMP C 03	NC	NC
		-	oo may	102	1,05digo	2	i,cobaigo	there is a small gas leak, the		
		3	02-jun	10L	2bargs	18h	1,5bargs	leak indentified in the pump PMP_C_03	0,077	С
			02 Juli	102	zburgo	1011	1,05dige	1 WI _0_03	0,011	0
	1001 1001 01			1	1	1		the set is a second set of the set		
1,6	VSSL-1204-01							there is a small gas leak identified in V-S-13, the valve		
1,0	R-F-01	1	30-may	20L	1.9barg	3h	1,85barg	isn't closed completly	NC	NC
								there is a small gas leak		
		2	02-jun	20L	1,82bargs	42h	1,42bargs	identified in V-S-13, the valve isn't closed completly	0,053	С
			•	•			-			
17	Filtration well 54							test failure, thera is a problem		
1,7	Filtration unit F1	1	02-jun	aprox:15L	2,3bargs	18h	2,78bargs	in the air inlet, isn't closed	NC	NC
		2						there is a small gas leak identified in the menbrane		-
			03-jun	aprox:15L	1,98barg	22h	1,47barg	Fi F 01	0,096	С
1 0	VSSL-1100-02							ther is a small gas leak in V-G-		
1,8	R-G-02	1	03-jun	aprox:300mL	2,38barg	17h	0bargs	08 the valve isn't closed completly	NC	NC

								there is a small gas leak		
1,9	Sterilization line							identified in V_S_13 the valve	0.000	0
, -		1	04-jun	aprox: 4L	1,913barg	16h	1,45barg	isn't closed completly	0,032	С
								there is a small gas leak to the		
								first filtration unit, some valve		
1,11	Filtration unit F2							used to the change of unit is		
.,								dirty and not closed well (v-f-		
		1	05-jun	aprox:15L	2,219barg	23h	0,97barg	04,v-f-03, v-f-07)	0,221	NC
							r	To prove this gass loop is		
								needed to run the procedure,		
1,12	ACTIVE gass loop	1								
.,								because the valves V-G-02	NC	NC
			06-jun	aprox 11L	N/A	N/A	N/A	and V-G-03 are closed Tested with both valves	NC	NC
		2						opened, there is a small leak		
		-	17-jun	aprox 11L	2,202mbarg	17h	1,038mbarg	but isn't identified	0,063	С
		1								
1,13	PASSIVE gas loop	1	06-jun	aprox: 500mL	2barg	2h	0barg	there are a small gas leak in V- G-08	NC	NC
· · · ·								there is a small leak in the exit		
		2	17-jun	aprox: 500mL	800mbarg	16,5h	0barg	of the V-G-08, the pressure go	NC	NC
								to the gas colector		

1,14	ANALIZER gas loop	1	06-jun	aprox: 300mL	200mbarg	2h	180mbarg	there is a small gas leak in tubbing of gas condenser and action of purging valve	NC	NC	
		2	17-iun	aprox: 300mL	1.5barg	16.5h	1,2barg	there is a small gas leak in tubbing of gas condenser and action of purging valve	0.00151	C	]
		4	17-juli	aprox. SoomE	1,5barg	10,511	1,2baig	action of purging valve	0,00101		_

aprox: the volume is approximate

2/

#### TEST PROCEDURE "Liquid tightness" RESULTS

Procedure:

1.1.Close all the manuals and power valves associated to the reactor

1.2. filli the reactors with Tap water

1.3.increase the pressure inside the reactor with air up to 2 bargs

1.4.Close the reactor and measure pressure

1.5. Measure residual pressure after 12h

1.6.Check for leaks of liquid

#### Success criterion:

2.1. Not leak of liquid

	UNIT TESTED	DATA	INITIAL PRESSUR	TEST TIME	FINISH PRESSUR	VOLUM REACTOR	REMARKS	RESULTS
2,1	VSSL-1209-02 R-C-02	29-may	2barg	14h	0barg		there is a big gas leak, but not liquid leak	с
2,2	VSSL-1209-01 R-C_01	29-may	2barg	14h	0barg		there is a big gas leak, but not liquid leak	С

	VSSL-1204-01					Impossible to put	
0.0						pressur inside the reactor, the	<u> </u>
2,3						pressur goto the	С
	R-F-01	29-may	0Barg	14h	0bargs	F.U. Not liquid leak	
		20 may	obaig	1-111	obaigs	icai	
	VSSL-1100-01					there is a gas	
2,4						leak, and a small liquid leak in the	NC
_, -	R-G-01	29-may	2barg	14h	Obarg	tubbing	
						there is a big gas	•
		30-may	2barg	16h	0barg	leak, but not liquid leak	С
		oo may	Louig	1011	obulg	loan	
2,5	VSSL-1008-01					ок	С
2,0	HX-R-01	29-may	N/A	24h	N/A		U
	VSSL-1007-01					there is some	
						small liquid leak in	
2,6						the reactor, located in the	С
_,0						retractable fitting	
	R-R-01	29-may	2barg	14h	1,6barg	(ph),both of them	
	VSSL-1000-01 R-		1			there is a gas	
	V33E-1000-01 IV					leak located in the	
2,7						Nozzle 1(No-C-1),	С
	V-01	29-mav	2barg	14h	0,85barg	but not liquid leak	
		20 may	Louig		o,oobarg	barnoringara loan	
						there is a gas	
2,8	Filtration Unit F1	30-may	2,16barg	4h	1,730barg	leak, and a small liquid leak located	с
2,0	. addition office 11	oo may	2,100019	117	1,700barg	in Fi-F-03 and in V-	J
						S-12	

#### VOLUM TEST "NOT INCLUDED IN TEST PROCEDURE"

#### Procedure:

1.1.Close all the manual valves associated to the reactor except V-R-18

1.2. fill the influent vessel tank with Tap water using V-V-02 and connect the pump PMP-V-01

1.3. When the tank will be arrived to the maximun volume them the valve V-V-03 opened and pumping the water to the reactor tank

1.4.Wait a minutes to complete the volume nominal in the reactor, when arrived to this point turn the valve V-V-03 to closed position

1.5. close the manual valve V-V-02 and stop the pump.

1.6. Look the volum by HMI and controled this parameter after 12 hours

1.7. The pressure inside the reactors is the atmospheric pressure

#### Success criterion:

2.1. It has not lost of volume

REACTOR TESTED	DATA	INITIAL VOLUM	PROCEDUR E TIME	FINAL VOLUM	RESULTS	REMARKS
R_R_01	02-jun	90L	18h	90L	С	The reactor don't have a volum tightness
R_V_01	02-jun	59.7L	18h	55L	NC	There are a problem with the valve V-V-02, this valve remanig open in the prove and the liquid return out of the sistem traspassing the pump in inverse sense
test2	03-jun	62L	24h	62L	С	V-V-02 remainig closed



**VOLUME TEST STEP 2** 

INITIAL CONDITIONS: All the test was do with atmospheric pressure

#### 1,1 FEEDING TANK VSSL-1000-01

PROCEDURE:

1.1.Close all the manuals valves associated to the reactor except HV-1000-03 1.2. filling to the influent vessel tank Tap water using a bottle volume measures 5 liters 1.3. Look the HMI volum and take the mesurament .4. Repit the points1.2 and 1.3 to arrive to the maximun capacity of the reactor 1.5. Stop the prove when the upper level swicht will be on



#### 1,2 REACTOR TANK VSSL-1007-01

#### PROCEDURE:

1.1.Close all the manuals valves associated to the reactor except HV-10007-18 1.2. filling to the influent vessel tank Tap water using a bottle volume measures 5 liters 1.3. Look the HMI volum and take the mesuramnet 1.4. Repit the points1.2 and 1.3 to arrive to the maximun capacity of the reactor 1.5. Stop the prove when the upper level swicht will be on

Volum liquid Inlet in the reactor	Volum liquid look at HMI	
0	16,61	
5	16,65	
10	16,65	
15	16,7	
20	20,2	
25	25,77	
30	30,72	
35	35,26	
40	40,1	
45	44,95	
50	50,05	
55	55,02	
60	60,05	
65	65,03	
70	70	
75	74,7	
80	79,65	
85	84,6	
90	90,05	
95	94,65	
100	99,8	
105	105,2	
110	109,75	
115	115,36	
120	119,75	Swicht upper on betwen 115-120 li

#### 1,3 EFFLUENT TANK VSSL-1204-01

- DATE PROCEDURE:
- 16/11/2009
- Tank is emptied
   A volume of 3L is added to the reactor using a graduated plastic glass of 5L
   The volume measured in the HMI is taken and compared with the volume added 16/11/2009
- 16/11/2009 16/11/2009 4. Water is added until the switch LSH\_1206\_01 is activated.



TBD BY CIFA 5. Adjust LS\_1204\_01 to the correct measurement with this data









#### 1,4 CLEANING TANK VSSL-1209-01

- DATE PROCEDURE:
- 1. Tank is emptied 16/11/2009
- Water is added until the switch LSH\_1209\_01 is activated. 16/11/2009 16/11/2009
- 3. The tank is emptied until the switch LSL\_1209\_01 is activated.
   4. The volume of water between switches is measured with 12L graduated bucket. 16/11/2009

#### Volume between switches (L) 13,2

16/11/2009 5. The tank is emptied completely and the water volume remaining measured. Volume under LSL switch (L) 3.3 Total volume of the tank (L) 16.5

#### 1,5 CLEANING TANK VSSL-1209-02

DATE PROCEDURE:

- 17/11/2009 17/11/2009
- 1. Tank is emptied 2. Water is added until the switch LSH\_1209\_02 is activated. 17/11/2009
- Water is added than the switch LSL\_1209\_02 is advanced.
   The tank is emptied until the switch LSL\_1209\_02 is advanced.
   The volume of water between switches is measured with 12L graduated bucket. 17/11/2009

Volume between switches (L) 5,7

17/11/2009 5. The tank is emptied completely and the water volume remaining measured.

> Volume under LSL switch (L) 4,3 Total volume of the tank (L) 10

 When water is transferred from VSSL\_1209\_01 to VSSL\_1209\_02 remaing volume in the first tank is 6.5L. This is that a volume of 10L is transferred to VSSL\_1209\_02 confirming the results above 17/11/2009 obtained.

#### 1,6 PASSIVE GAS LOOP TANK VSSL-1100-02

#### DATE PROCEDURE:

- Fill the tank with water trying to avoid bubbles by shaking gentle the tank.
   Empty the tank and measure the water volume by weight using a tared plastic bottle 18/11/2009 18/11/2009
  - Bottle weight Water weight SD Error Test number Bottle Tare (g) Error (g) with water (g) Error (g) (g) Error (g) 34,84 0,1 302,25 0,1 267,4 0,14 0,2 34,84 0,1 298,54 0,1 263,7 0,2 0,14 34,84 0.1 301.48 0,1 266,6 0.2 0.14 MEAN 265,9 2,0 0,7 RSD (%

Water density at 20°C (g/mL)	0,9982071
Volume of water in the tank	
(mL) (±2.0)	266,4

#### 2/

#### CORRECT ON-LINE MEASUREMENTS TEST STEP 2

	UNIT TESTED	CALIBRATION with pH 4.00	CALIBRATION with pH 7.00	REMARKS	RESULT	DATE
2,1	AT_1011_01	YES	YES	BAD RESPONSE. Probably wiring needs maintenance.	NC	28/08/2009

	UNIT TESTED	CALIBRATION with pH 4.00	CALIBRATION with pH 7.00	REMARKS	RESULT	DATE
2,2	AT_1011_02	YES	YES	GOOD RESPONSE	с	28/08/2009

Tested Temperature (°C)

28,0

40.0

70,0

100.0

2.3 UNIT TESTED TT\_1008\_01 Description Bioreactor temperature sensor Date 08/10/2009 RESULT T<sub>real</sub> = 1.07 (T<sub>HMI</sub>) - 0.29



2,4	UNIT TESTED	TT_1008_02	Tested	Temperature HMI (°C)	Temperature Bath (°C)
	Description	Bioreactor Bath temperature sensor	Temperature (°C) 28,0	28.4	27,8
-	Date	09/10/2009			40,0
-	RESULT	T <sub>real</sub> = 1.09 (T <sub>HMI</sub> ) - 2.16	40,0	37,7 65,9	69,8
L		Treal = 1.03 (THM) * 2.10	70,0		
			100,0	93,9	100,0
,5	UNIT TESTED	TT_1205_01	Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
ľ	Description	Filtrate tank temperature sensor	28,0	27,8	28,0
Ī	Date	09/10/2009	40,0	32,9	39.8
ľ	RESULT	T <sub>real</sub> = 1.08 (T <sub>HM</sub> ) + 1.81	70,0	60,6	69,8
L			100,0	92,7	100,0
6	UNIT TESTED	TT_1200_01	Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
[	Description	FU temperature sensor	28,0	27,7	28,0
	Date	09/10/2009	40,0	37,9	40,0
Ī	RESULT	T <sub>real</sub> = 1.12 (T <sub>HM</sub> ) - 2.90	70,0	65,7	69,7
			100,0	91,3	99,7
<b>7</b>	UNIT TESTED	TT_1104_01	Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
	Description	Gas loop temperature sensor	28,0	26,8	28,0
	Date	09/10/2009	40,0	35,5	40,0
	RESULT	T <sub>real</sub> = 1.29 (T <sub>HM</sub> ) - 6.06	70,0	58,7	69,8
-			100,0	82,5	99,9
,8	UNIT TESTED	TT_1208_01	Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
Ī	Description	Cleaning temperature sensor	28,0	22,5	27,9
Ī	Date	09/10/2009	40,0	29,9	40,1
Ī	RESULT	$T_{real} = 1.17 (T_{HMI}) + 3.64$	70,0	55,7	70,0
L		1000 1 1000	100,0	83,2	99.8
			100,0	00,2	55,0

#### CORRECT FLOWS AND SPEEDS TEST STEP 2

	UNIT TESTED	TUBING	TEST number	DATE	MEDIUM	PUMP SPEED	VOLUMETRIC	VOLUME (mL)	Volume Error (mL)	TIME (min)	Time error (min)	FLOW (mL/min)	Flow error (mL/min)	Flow error SD based (mL/min)	REMARKS	RESULT
3,1		NORPRENE MASTERFLEX 6412-16 ID 3.1mm	1	28/08/2009	water	Unique	Test tube 10mL ±0.15mL	10,00	0,15	6,63	0,035	1,51	0,031	0,02		с
			2	28/08/2009	water	Unique	Test tube 10mL ±0.20mL	10,00	0,20	6,50	0,035	1,54	0,04	0,10		
			3	28/08/2009	water	Unique	Test tube 10mL ±0.15mL	8,60	0,15	5,88	0,035	1,46	0,034	0,03		
	Bioreactor pump PP_1011_01										MEAN	1,50				
											SD	0,04				
		VITON MASTERFLEX 6404- 16 ID 3.1mm (Saint	4	31/08/2009	water	Unique	Test tube 10mL ±0.15mL	10,00	0,15	8,03	0,035	1,24	0,02	0,02		
			5	31/08/2009	water	Unique	Test tube 10mL ±0.20mL	10,00	0,20	8,05	0,035	1,24	0,03	0,10		
			6	31/08/2009	water	Unique	Test tube 10mL ±0.15mL	10,00	0,15	7,92	0,035	1,26	0,02	0,02		
											MEAN	1,25				
											SD	0,01				





3,4

1. The procedure "Fill VSSL\_1209\_02" is started

2. The time the pump is ON is monitored in the HMI screen (value in table) and confirmed in-situ

3. The volume transferred by the pump is the volume of the tank VSSL\_1209\_01 until the high switch. This volume is 10L (see 1.5) 4. Work out the flow of the pump and check if it is in the range defined by the manufacturer (See graph)

			HMI Initial	LIMI Eine

UNIT TESTED	Brand & Model	Test number	HMI Initial time	HMI Final time	HMI Time (s)	Chrono Time (s)	Volume flown (L)	Flow (L/min)	Date	Result
		1	16:37:57	16:38:21	24	24	10	25	17/11/2009	с
Cleaning pump CP_1207_01	NOCCHI JETINOX 50/60M	2	16:47:04	16:47:28	24	24	10	25	17/11/2009	
		3		-		-	-		-	I.
							MEAN	25		
							Manufacturer range	10 - 48		

#### 3,5

1. The procedure "Clean Retentate side" membrane 1 is started

2. The time the pump is ON is monitored in the HMI and also in-situ

3. The volume transferred by the pump is the volume of the tank VSSL\_1209\_01 unit! the high switch. This volume is 10L (see 1.5)

4. Work out the flow of the pump and check if it is in the range defined by the manufacturer (See graph)

UNIT TESTED	Brand & Model	Test number	HMI Initial time	HMI Final time	HMI Time (s)	Chrono Time (s)	Volume flown (L)	Flow (L/min)	Date	Result
		1	15:23:49	15:24:23	34	32	5,8	11	20/11/2009	с
Cleaning pump CP_1207_02	NOCCHI JETINOX 50/60M	2	15:34:25	15:34:56	31	32	5,8	11	20/11/2009	
		3		-	-	-	-	-	-	
							MEAN	11		
							Manufacturer range	10 - 48		

#### 3,6

1. The VSSL\_1100\_01 is used to compress air up to 3.5bar, the maximum pressure of the tank. 2. Check if this pressure is achieved.

UNIT TESTED	Brand & Model	Pressure (bar)	Chrono Time	Time (min)
		1,0	0:00:55	0,92
Active Gas Loop pump GCP_1100_01	COMPTOM 1425rpm, 4bar	2,0	0:02:39	2,65
		3,0	0:07:20	7,33
		3.2	0:15:00	15.00

0,65



ĺ	UNIT TE	STED	Brand & Model	TUBING	TEST number	DATE	MEDIUM	PUMP SPEED	VOLUMETRIC	VOLUME (mL)	Volume Error (±mL)	TIME (s)	Time error (±s)	FLOW (L/d)	Flow error (mL/s)	Flow error SD based (mL/s)	REMARKS	RESUL T	35, 30,				y = 0,3048: R <sup>2</sup> = 0,9	(- 0,701 1978	<b>,</b>	
			•		1	15/01/2010	water	50	Test tube 25mL ±0.25mL		0,25	148	0,5	14,2	0,2	0,15		с	25,	o				/		
	Filtrate pump	PP_1202_01	Watson Marlow 54 MKII IP55	MARPRENE #14 902.0016.016	2	15/01/2010	water	50	Test tube 25mL ±0.25mL	24,0	0,25	148	0,5	14,0	0,2	0,15			20,	0			/	1		
					3	15/01/2010	water	50	Test tube 25mL ±0.25mL	23,9	0,25	148	0,5	14,0	0,2	0,15			S 15,	o		_	/			
													MEAN	14,1					10,	0		/				
					P				1	r		1	SD	0,15				-	5,	0						
					4	15/01/2010	water	25	Test tube 25mL ±0.25mL	23,9	0,25	293	0,5	7,0	0,1	0,07			0,0	•	20	40	60	80		20
					5	15/01/2010	water	25	Test tube 25mL ±0.25mL	23,5	0,25	293	0,5	6,9	0,1	0,07		_		0	20	40	%	00		
					6	15/01/2010	water	25	Test tube 25mL ±0.25mL	23,5	0,25	291	0,5	7,0	0,1	0,08		4			1 1=	loumotor In	Eloumotor			
					7	15/01/2010	water	25	Test tube 25mL ±0.25mL	23,5	0,25	281	0,5	7,2	0,1	0,08			%	l∕d	l/h	line	HMI			
													MEAN	7,0					50	14,1	0,59	0,56	0,56			
				1	-		r	[	1				SD	0,13		1		Т	25	7,0	0,29	0,27	0,27			
					8	15/01/2010	water	75	Test tube 25mL ±0.25mL	24,4	0,25	98	0,5	21,5	0,3	0,25		-	75	21,6	0,90					
					9	15/01/2010	water	75	Test tube 25mL ±0.25mL	24,6	0,25	98	0,5	21,7	0,3	0,25		-	100	30,4	1,27	1,17	1,17			
					10	15/01/2010	water	75	Test tube 25mL ±0.25mL	23,6	0,25	95	0,5	21,5	0,3	0,25		1	10	2,7	0,11					
													MEAN SD	21,6 0,12					1,4	40			y =	0,0127x - 0,02	92	
					11	15/01/2010	water	100	Test tube 25mL ±0.25mL	24.5	0.25	70	0.5	30.2	0.5	0.38		1	1,2	20				R <sup>2</sup> = 0,9978	/	
					12	15/01/2010	water	100	Test tube 25mL ±0.25mL		0,25	68	0,5	30,2	0.5	0.39		1	1,0	00						
					13	15/01/2010	water	100	Test tube 25mL ±0.25mL		0.25	70	0.5	30.2	0.5	0.38			0,8	во —					v = 0.012	2x - 0,035
													MEAN	30,4				-	≦ 0,€	60					R <sup>2</sup> = 0	0,9998
													SD	0,22				_	0,4	40			-			
					14	15/01/2010	water	10	Test tube 25mL ±0.25mL	19,0	0,25	615	0,5	2,67	0,0	0,04			0,2	20						
					15	15/01/2010	water	10	Test tube 25mL ±0.25mL	20,0	0,25	643	0,5	2,69	0,0	0,03			0,0		-					
					16	15/01/2010	water	10	Test tube 25mL ±0.25mL	22,0	0,25	715	0,5	2,66	0,0	0,03				0	20	40	60 %	80	100	120
													MEAN	2,67									76			
													SD	0,01												

4/

3,7

#### LIQUID TIGHTNESS STEP 2

These Test only include the vessels that was repaired or dismounting after the first test

4,1	UNIT TESTED	TEST number	initial DATA	final DATA	VOLUM REACTOR	INITIAL PRESSURE	TEST DURATION	FINAL PRESSURE	REMARKS	RATIO	RESULTS
	VSSL-1204-01 R-F-										
	01	1	24/04/2009	27/04/2009	20L	1,55 Bar	70h	1,35 Bar		0,25	С

After this test we detected in the sterilization procedure A internal small leak between the vessel and his jacket. CIFA repaired this internal leak and they did another leak test

4,2

		TESTED		TEST number	initial DATA	final DATA	VOLUM REACTOR	INITIAL PRESSURE	TEST DURATION	FINAL PRESSURE		RATIO	RESULTS
-	VSSL-1100-01		R-G-								there is a big gas leak identified in the racords, and the V-G-10/SV- 1102-04 is activated and drain the air to		
	VSSL-1100-01	01	R-G-	1	27/04/2009	27/04/2009	10L	3 Bar	2h		the gas colector there is a small	NC	NC
	1332-1100-01	01	K-0-	2	27/04/2009	29/04/2009	10L	3 Bar	48h		gas leak identified in the V-G-10/SV- 1102-04 output	0.6	с

#### The valve V-G-10/SV-1102-04 have a internal leak, is necessary repair it. Before this test Cifa did another pressure test

4,3	UNIT TESTED	TEST number	initial DATA	final DATA	VOLUM REACTOR	INITIAL PRESSURE	TEST DURATION	FINAL PRESSURE	REMARKS	RATIO	RESULTS
	VSSL-1100-02 R-G-02								ther is a small gas leak in V-G- 08 the valve isn't closed		
		1	27/04/2009	28/04/2009	aprox:300mL	2,7 Bar	18h	0,7 Bar	completly	NC	NC
	VSSL-1100-02 R-G-02	2	28/04/2009	29/04/2009	aprox:300mL	2.8 Bar	20h	2.6 Bar	We forced to close the output of V-G-08	0.2	с

The valve V-G-8 have a internal leak, is necessary repair it

Additional Tests performed between 12th and 20th January 2010:

#### C1 FLOW PUMP TEST

CP-1008-01 (reactor jacket recirculation pump)

Fill water inside the vssl-1008-1

Test using a volumetric flask

TEST n⁰	Volum ( L )	Duration ( s )
1	3	40,02
2	3	40,31
3	3	39,79
4	3	39,97
5	3	40,4
media	3	40,098

flow calculate: 4.48 L/min

CP-1002-01 (influent jacket recirculation pump)

Fill water inside external vessel and connect the input/output tubbing from the pump

Test using a volumetric flask

TEST n⁰	Volum ( L )	Duration ( s )
1	3	30,19
2	3	31,13
3	3	29,89
4	3	29,67
5	3	30,24
media	3	30,22

flow calculate: 5.95 L/min

#### **BLENDERS VELOCITY TEST**

BLE-1005-01 (influent blender)

Test the real velocity using a tacometer Take the fan protection from the blender and put the tacometer in the axis of the blender

VDF = 50 Hz R.P.M. messured= 1470 rpm

BLE-1012-01 (reactor blender)

Test the real velocity using a tacometer Take the fan protection from the blender and put the tacometer in the axis of the blender

VDF = 55 Hz R.P.M. messured= 1615 rpm

### FLOW TEST FILTRATION UNIT FLOWMETER

FT-1201-01 filtration flowmeter Test performance with Milli Ro water and without membranes

Start the filtration 1 procedure

TEST №	Velocity Set-point HMI	VDF (Hz)	Flow in HMI	Volum (L)	Duration(s)	Flow calculate (L/h)
1	350	15	290	5	60,18	299,1
2	350	15	292	5,1	60,34	304,2
3	350	15	294,5	4,95	60,06	296,7
media			292,16			300
4	450	20	401	7	60,16	418,8
5	450	20	401	7	60,27	418,1
6	450	20	403	7	60,3	417,9
media			401,6			418,26

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# ANNEX 7

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## 1. HYGIENE AND SAFETY CHECK-LIST

Test Phase : C1 functional tests step 2 – Filtration Unit	System Description : Filtration Unit
Date: 27/04/09	Safety manager : Arnaud Fossen
List of reserves <u>YES or NO</u>	Others members
Join this list with priorities	MPP : Raul Moyano, Nuria Martinez ;
_	SHERPA : Olivier Gerbi, Christophe Bourg

First column-reference N° is used to check points not conformed

N٥	Description	N/A	ОК	NOT OK
S-1	Adequate safety equipments and staff protection exist and are located in the right place. Are included: fire-extinguisher, eyes-washers , safety shower, breathing masks, fire alarm, first aid kit , body harness, protection against electric current etc)	Breathing mask, body harness	Fire-extinguisher, eyes-washers, safety shower, fire alarm, first aid kit , protection against electric current	
S-2	Access to safety equipment and fire protection is clear		Х	
S-3	An appropriate solution has been found to the exposition of noise problems (85 dbA)			Noise filters for pneumatic valves have to be implemented.
S-4	Illumination is appropriate		Х	
S-5	catwalks and ladders allow a safe access to every level		X	
S-6	All ladders are equipped with fences or chain at access points	Х		
S-7	Platforms or floors to work are well protected and have a good leveling		X	

S-8	Rules for work at height are respected.	X		
S-9	The work zone is correctly ventilated.		Х	
S-10	Peepholes on the process, flow indicators, pressure gauges etcare correctly shielded		Х	
S-11	Panels indicate the dangers existing in the work area and provide appropriate instructions		Х	
S-12	Exits and evacuation paths are clearly indicated		Х	
S-13	The layout of the equipments is acceptable from the point of view of their height, their accessibility and the availability of elevation devices		Х	
S-14	The staff is protected from cold and hot surfaces		Х	
S-15	Tank legs or lower parts are fireproof		Х	
S-16	Material Safety Data Sheets are available		Х	
S-17	The tanks and all instruments are properly tagged			Only new components have their new tag ; all other ones have their old tag
S-18	The construction/installation phase is over and the equipment is ready for use. The scaffolds have been dismantled, the rubbish have been cleaned up, the construction tools have been removed from the process.		X	
S-19	The steps for preparing and executing the maintenance have been taken in order to reduce as much as possible the risks for the staff		x	

S-20	The capacity of the elevation devices is clearly indicated on the equipment	Х	
S-21	Adequate dispositions have been taken for handling gas cylinders and other mobile containers	Х	
S-22	Gas cylinders are stored in such a way they can be transferred in safety	Х	
S-23	Gas flammable cylinders are stored separately	Х	

Enumerate difference that have been corrected before the start: N/A

Enumerate difference that have been / will be corrected after the start: N/A

## 2. Environment CHECK-LIST

	hase : C1 functional tests step 2 – on Unit	System Description : Compartment 1 Filtration Unit			
	27/04/09	Safety manager : Arnaud Fossen		-	
	reserves <u>YES or NO</u>	Others members			
Join th	is list with priorities	MPP : Raul Moyano, Nuria Martinez ;			
		SHERPA : Olivier Gerbi, Christophe Bourg			
First co	olumn-reference Nº is used to check	points that are non compliant			
N⁰	Description		N/A	ОК	NOT OK
E-1	Containment in case of leak, reter	ntion walls and drainage are adequate			The platform has holes
E-2	The wastes to be generated in no quantified	minal and non nominal operation have been identified and		Х	
E-3	Adequate dispositions have been solid wastes	spositions have been taken for wastes evacuation including cleaning products and			The list of interfaces has been updated(24/04/09)
E-4	Drains are been clearly identified to date	«Rainwater»or «Process» according to the case. Plans are up		Х	
E-5	Genetically Modified Organisms a	are identified	Х		
E-6	The authorizations for animal exp	erimentation have been granted	Х		

Enumerate differences that have been corrected before the start: N/A

Enumerate differences that have been corrected after the start: N/A

## 3. CHECK-LIST for "READY for START UP" REVIEW

Phase : functional tests step 2 – Filtration Unit

System Description \_\_\_\_\_Compartment I Filtration Unit

Date \_27/04/09\_\_\_\_\_

Safety Manager/ safety Officer \_Arnaud Fossen\_

Team members \_\_MPP : Raul Moyano, Nuria Martinez ; SHERPA : Olivier Gerbi, Christophe Bourg

Description		sult		Remarks
	NA	Y	Ν	
1. Standards and operating procedures referring to the unit have been established and allow the unit exploitation.		Х		
2. Subcontractors procedures, operational specific procedure and subcontractors standards are written in the local language used and/or understood by operators.		Х		The procedures are available in English, understood by the personnel involved in the tests. Subcontractors documents are delivered in Spanish.
3. Operating procedures describe the steps required to execute specific activities on the process.		Х		
4. Engineering file (P¬ID, drawings, technical documents) are available and complete		x		PID was updated after the hardware modifications (Last update: 24/04/09) SHERPA document "Procedures and SFC analysis" was updated, draft dated 17/2/09

5. Modified documents have followed the revision/approval loop		Х		Same procedures as in step 1 functional tests for the filtration unit
6. Records indicate that documents have been duly-examined before the start of operations.		Х		
7. A list of elements important for safety is available with their operation range		Х		
8. Procedures exist in case the system switches to a degraded mode (in case of failure of one component)	Х			
9. A maintenance plan is enforced for the elements important for safety.		Х		
10. The safety position of equipments and safety loops in case of alarm triggering have been controlled		Х		This is part of the testing sequence
11. Process risks have been assessed, and the recommendations to mitigate them are documented. The implementation of these actions is documented.			Х	Laboratory Hazard Analysis MPP-TN-07-0001(3) and C1 HAZOP MPP-TN-07-1001(0) are available. Update of C1 HAZOP not completed (waiting for the end of the hardware modifications on C1 filtration unit)
12. Mechanical integrity justification exists for every document equipment.			Х	Certificate for gas loop tank to be provided by CIFA
13. The control system documentation (user manual, functional description of control) is up to date and available.			Х	Draft available for control routine updates.

14. A back up copy control system software to date is stored in a safe place.		Х	
15. In case of alarm activation, the safety positions of actuators are identified and the factory acceptance tests are duly documented.		Х	
16. A risk analysis for the working place has been performed.		Х	Hazard analysis of the laboratory and inspection by UAB Safety Officer
17. In case of emergency, interventions and evacuation procedure are ready for implementation.		Х	
18. Working license procedures and instructions procedure are ready for implantation.		X	EPAS modified procedures to be tested are inside SHERPA document "Procedures and SFC analysis" dated 17/2/09
19. Protection from and detection of fire have been checked.		Х	Yearly routine inspection coordinated by UAB/ETSE maintenance team
20. Operators have been trained for the specific operational procedures and their training/certification is documented.	х		
21. Spare parts list with their availability exist.		Х	It exist a list that have to be completed
22. Users can clearly identify the documents that are not controlled		Х	

# **MELISSA**



# ANNEX 8

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Name	ORGANIZATION	Function	Initials
Raúl Moyano	MPP	Maintenance Technician	RM
Nuria Martinez	MPP	Bioprocess engineer	NM
Enrique Peiro	MPP	Technical Manager	EP
Arnaud Fossen	MPP	ESA Operational Representative	AF
Christophe Bourg	SHERPA	Engineer	СВ
Olivier Gerbi	SHERPA	Senior engineer	OG

# **MELISSA**



# ANNEX 9

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### <u>Procedure 40: Drain filtration unit – retentate side (ESA comments on EPAS</u> procedures received from Pierre Rebeyre on 19.08.08)

The logic of the procedure is not correct. Following sequence is suggested:

Pre-requisite: FU is stopped => PMP-F-01 is also stopped. 1/Close V-F-01 and V-R-08 2/check open V-F-06 and V-R-09 3/open V-G-20 4/switch V-F-03 and V-F-04 for second membrane when gas starts entering the reactor 5/switch V-F-02 and V-F-05 for the bypass branch when gas starts entering the reactor 6/close V-G-20, V-R-09, V-F-06

I do not understand the reason why PMP-F-02 is started backward...Filter Fi-F-03 does not allow reverse flow.

Procedure 41: Drain FU - inside membranes

This procedure flushes retentate out of a membrane with water or cleaning agent. This means the sludge contained within the membrane cannot be recovered. In addition, following procedure 49, as suggested within procedure 41, the diluted sludge is circulated over the membrane. Several draining of R-C-02 and re-fill with clean water/cleaning agent have to be foreseen.

#### Procedure 42: Drain FU – Filtrate lines

The use of SIP lines is likely not to be the best option, but seems un-avoidable given the current hardware config.

Procedure 43: Drain entire FU

This procedure groups procedure 40 and 42. Same comments.

#### Procedure 44: Fill FU with water (i.e. one of the membranes at a time only)

It seems to be possible to perform this operation while filtrating over the second membrane. Basically, the idea is to push both retentate and sludge out of the membrane with water. The mixture sludge + retentate is recovered at the drain port of the membrane module, discarded.

Not sure it is possible to recover the sludge without stopping the FU and execute procedure 40.

Procedure 49 – See comment procedure 41

#### Procedure 50 – See comments procedure 44

#### Procedure 51: backwashing using PMP-F-02 (Filtrate pump)

As filter Fi-F-03 does not allow reverse flow, it shall be removes prior this operation. However, it seems this filter can only be removed if the effluent vessel is empty, thus preventing the possibility form backwashing using filtrate. In any case, the need and efficiency of such procedure remains to be demonstrated, given the fact PMP-F-02 is a peristaltic pump...

#### Procedure 52: Backwashing using water/cleaning agent

Advice is to push the content of the both filtrate and retentate lines to the drain of the membrane module before actually starting this operation. (see comments procedure 41). Nothing is mentioned about duration, pressures, etc.

#### Procedure 53: cleaning of the FU – Circulation pump

Pre-requisite: FU is stopped.

1/ Close V-F-01, V-F-062/execute sequence as suggested by EPAS.3/ DO NOT FORGET TO OPEN V-F-01, V-F-06 AT THE END OF THE SEQUENCE!

This sequence however circulates a mixture of water/cleaning agent and sludge the pump, tubing, turbidity and flow sensors. Need to drain, rinse R-C-02 and re-do the operation until the part of FU containing the pump is cleaned.

#### Procedure 54: Cleaning of filtrate tank

The sequence proposed by EPAS is understood. However, it is not clear how the cleaning agent is prevented form reaching filter Fi-F-03. Addition of a valve between the filter and the filtrate tank?

#### Procedure 55: Cleaning of filtrate tank and filtrate lines

I have doubts this procedure can actually be performed.

Indeed, cleaning agent is pushed to the filtrate tanks, and should be able to go backwards to the retentate side of the membranes, use a piece of SIP tubing, and get out of the membrane module via the drain port.

Is it possible to push the cleaning agent as described above without triggering the pressure relief valve of the filtrate tank?

I have much less difficulties with sterilization procedures actually

# **MELISSA**



# ANNEX 10

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Teià, 21 de Enero de 2010 Ref. CALIBRACION 2.561

Atención Sr. Enrique Peiro MELISSA PROJECT Escuela Técnica Superior de Ingeniería Dpto. Ingeniería Química Campus Universitat Autónoma de Bellaterra 08193-BELLATERRA (BARCELONA)

ASUNTO: Calibración de los sensores de temperatura del módulo C-1, según la normativa vigente UNE-EN ISO 17025 en los apartados 5.10.2 y 5.10.4.

Mediante un baño térmico (del que se adjunta certificado de calibración, del baño mediante sonda patrón), ha ofrecido los siguientes resultados:

-Marca/Modelo: KING NUTRONICS THERMO UNIT 3605 con conexión según elemento.

-Rango: -10 a 220°C bar, Precisión: ±0.1°F según rango de temperatura

-Resolución: 0,1°F, Estabilidad del punto de lectura: ±0.01°F

C.I.F.A. S.L.

Fdo. José Fernández

Director Técnico

## KNC Model 3603-A, 3604-A, and 3605-A Thermo Units



#### **Product Overview**

The Model 3603-A, 3604-A, and 3605-A Thermo Units by King Nutronics Corporation are highly accurate dry well temperature standards designed for testing and calibrating a broad range of thermometers, temperature sensors, thermocouples, RTDs, and temperature switches used in military and industrial applications. Conforming to rigorous U.S. Military specifications, King Nutronics Thermo Units are manufactured in three versions covering the temperature ranges most frequently encountered in field and laboratory settings.

During use, devices to be tested or calibrated are inserted into the dry well of the unit, which is heated or cooled (Model 3605-A only) to the temperature specified by the operator. Close-fitting dry well adapter chucks maximize thermal transfer to the unit under test and minimize the time required for the specified temperature to be reached. Adapter chucks are available for most industrial applications and in sizes conforming to specific U.S. Navy requirements.

All King Nutronics Thermo Units are microprocessor-driven for maximum safety and simplicity of operation. Housed in rugged aluminum carrying cases with storage for additional adapter chucks and accessories, King Nutronics Thermo Units can withstand hard use in workshop, hangar, flight line, shipboard and submarine environments. Like all King Nutronics Instruments, each Thermo Unit can be easily serviced and calibrated in the field, and includes a comprehensive technical manual containing complete troubleshooting and repair instructions, and an illustrated parts breakdown.

The design, operational details, and features of the King Nutronics Model 3603-A, 3604-A, and 3605-A Thermo Units are protected by the following U.S. Patents: 3,699,800; 3,738,174; 3,939,687; 4,075,882; 4,079,618; 4,901,257.



## Model 3603-A Thermo Unit (100°F to 600°F)

Smallest of the Thermo Units manufactured by King Nutronics Corporation, the Model 3603-A is an easy to use self-contained instrument designed to generate, control, measure, and display temperatures from  $100^{\circ}$ F to  $600^{\circ}$ F, with an accuracy of  $\pm 0.5^{\circ}$ F throughout its operating range. The Model 3603-A thermo unit weighs only 12.5 lbs., and is housed in a rugged, compact 11" x 7" x 10" aluminum case, making for easy transport to remote job sites.

A simple ON/OFF switch and a push-button temperature selector control all functions. The measured temperature and other status information is shown on the 16-character digital display.

Four adapter chucks are furnished with the Model 3603-A in the following bore diameters: 1/4", 3/8", 7/16", and 9/16". Other bore diameters are available upon request.





#### Model 3604-A Thermo Unit (100°F to 1200°F)

The Model 3604-A Thermo Unit by King Nutronics Corporation is a self-contained portable dry well temperature calibration system designed to generate, control, measure, and display temperatures from  $100^{\circ}$ F to  $1,200^{\circ}$ F, with an accuracy exceeding  $\pm 0.15\%$  or  $\pm 0.8^{\circ}$ F of the setpoint value, whichever is greater, throughout its operating range.

Incorporating an IEEE-488/GPIB bus, the Model 3604-A Thermo Unit can be operated from a remote terminal using simple commands, or via the user-friendly front panel keypad and display. A convenient built-in dot-matrix printer generates hard copies of test and calibration data.

Two configurations of the Model 3604-A Thermo Unit are available. Part No. 3604A-1-1 includes four adapter chucks in the following bore diameters: 1/4", 3/8", 7/16", and 9/16".

Part No. 3604A-1-101 includes 12 adapter chucks conforming to specific U.S. Navy requirements. Compartments in the carrying case permit up to a dozen adapter chucks to be stored and transported with the instrument.

Each Model 3604-A Thermo Unit also includes an accessory kit containing a dial caliper, a continuity tester, adapter chuck handling tools, an adapter chuck for standard glass thermometers, and an assortment of spare parts. All accessories and parts are stored in the case lid for convenience.



## Model 3605-A Thermo Unit (-40°F to 250°F)

The Model 3605-A Thermo Unit by King Nutronics Corporation is a self-contained portable dry well temperature calibration system based on a Peltier element, which permits the generation and control of temperatures from  $-40^{\circ}$ F to 250°F, with an unsurpassed accuracy of  $\pm 0.1^{\circ}$ F throughout its operating range.

Incorporating an IEEE-488/GPIB bus, the Model 3605-A Thermo Unit can be operated from a remote terminal using simple commands, or via the user-friendly front panel keypad and display. A convenient built-in dot-matrix printer generates hard copies of test and calibration data.



Two configurations of the Model 3605-A Thermo Unit are available. Part No. 3605A-1-1 includes four adapter chucks in the following bore diameters: 1/4", 3/8", 7/16", and 9/16". Part No. 3605A-1-101 includes 12 adapter chucks conforming to specific U.S. Navy requirements. Compartments in the carrying case permit up to a dozen adapter chucks to be stored and transported with the instrument.

Each Model 3605-A Thermo Unit also includes an accessory kit containing a dial caliper, a continuity tester, adapter chuck handling tools, an adapter chuck for standard glass thermometers, and an assortment of spare parts. All accessories and parts are stored in the case lid for convenience.

Characteristics	Specifications			
Model No.	3603-A	3604-A	3605-A	
Temperature range	100°F to 600°F	100°F to 1,200°F	-40°F to 250°F	
	(38°C to 315°C)	(38°C to 649°C)	(-40°C to 121°C) <sup>1</sup>	
Accuracy	±0.5°F	±0.8°F from 100°F to 600°F	±0.1°F	
	throughout range	±0.15% of setpoint	throughout range	
		> 600°F		
Resolution:				
Test mode	0.1°	0.1°	0.1°	
Calibration 0.01°		0.01°	0.01°	
Setpoint stability ±0.15°F		±0.15°F	±0.01°F	
<b>Stabilization time</b> 14 min. max, 75°F to 300°F		30 min. max for a 1,100°F	30 min. max for a 60°F	
	23 min. max, 75°F to 600°F	change from ambient temp.	change from ambient temp.	
Well uniformity	±0.3°F	±0.5°F	±0.5°F	

### **Performance Specifications**

<sup>1</sup> 100°F below ambient temperature



## **General Specifications**

Characteristics	Specifications				
Model No.	3603-A	3604-A	3605-A		
Ambient temp. range:					
Operational	32°F to 120°F	32°F to 120°F	32°F to 120°F		
Storage	-67°F to 167°F	-67°F to 167°F	-67°F to 167°F		
Readout units	Fahrenheit (°F) or	Fahrenheit (°F) or	Fahrenheit (°F) or		
	Celsius (°C)	Celsius (°C)	Celsius (°C)		
Well size	1 " I.D. x 6" deep	1 " I.D. x 6" deep	1 " I.D. x 6" deep		
Case construction	Deep drawn aluminum	Deep drawn aluminum	Deep drawn aluminum		
Case dimensions	11" x 7" x 10"	18" x 11" x 14"	18" x 11" x 14"		
(L x W x H)					
Weight:					
Industrial model	12.5 lbs.	35 lbs.	35 lbs.		
USN model	N/A	44 lbs.	44 lbs.		
Input power:					
Voltage	115 VAC, 50-60 Hz	115 VAC, 50-60 Hz	115 VAC, 50-60Hz		
Current	3.5 Amps	9.0 Amps	5.0 Amps		
Fuse(s)	5 Amps	10 Amps	1 Amp and 5 Amps		

## **Functional Features**

Characteristics	Specifications				
Model No.	3603-A	3604-A	3605-A		
Display:					
No. of characters	16	40	40		
Туре	5 x 7 alphanumeric	5 x 7 alphanumeric	5 x 7 alphanumeric		
	dot-matrix, vacuum-	dot-matrix, vacuum-	dot-matrix, vacuum-		
	fluorescent type	fluorescent type	fluorescent type		
Keypad	N/A	16-key, touch sensitive	16-key, touch sensitive		
Printer	N/A	24 character dot-matrix impact printer with replaceable ribbon cartridge and standard adding machine paper	24 character dot-matrix impact printer with replaceable ribbon cartridge and standard adding machine paper		
Remote interface	N/A	IEEE-STD-488-1978 GPIB	IEEE-STD-488-1978 GPIB		

**∢ing nutronics corporation**<sup>™</sup>



6421 independence avenue, woodland hills, california 91367-2608 • PH. (818) 887-5460 • FAX (818) 887-2766

## CALIBRATION LABORATORY APPROVALS AND CERTIFICATIONS

King Nutronics Corporation's calibration program conforms to ANSI/NCLS-Z540-1-1994, Parts I and II. Additionally, our calibration laboratory and calibration procedures have been audited and approved by the United States Department of the Navy and Lockheed Martin Mission Services.

The U.S. Navy audit by the Joint Naval Audit Certification Team (JNACT) recognizes KNC's calibration program for its satisfactory compliance to criteria set forth in the Naval and Marine Corps Calibration Laboratory Audit Certification Manual, NAVAIR 17-35QAC-01, NAVSEA 04-4734, and USMC TI-4733-35/23. These criteria encompass the relevant requirements of Naval Fleet and SYSCOM Commander Directives.

The JNACT Certificate of Conformance and scope of competency can be viewed on our website, <u>www.kingnutronics.com/support\_page.htm</u>.

Description	Measurement Range
Schwien Model 1025FX110-2 Precision Manometer	0.5 to 110 in-Hg
Ruska Model 2400 Dead Weight Tester	6 to 12,140 psig
Ruska Model 2465 Dead Weight Tester	2 to 700 psig
GE/Pressurements Model P3014-3-P Dead Weight Tester	3 to 150 psig
Hart Scientific Model 5901C-G Triple Point of Water Cell and Dewar Jar	0°C
Rosemount Model 162CE Standard Platinum Resistance Thermometers	-297°F to 1,200°F
Hart Scientific Model 5628 Standard Platinum Resistance Thermometer	-200°C to 660°C
Morehouse Series 1000 Proving Rings	1,000 and 5,000 lbs.
King Nutronics Model 3605	-10°C to -220°C

## **PRIMARY STANDARDS**



Esplugues, 14-12-2009

## **INFORME DE CARACTERÍSTICAS TÉCNICAS**

### **Componentes:**

Sonda Pt-100 1/3 DIN Heraeus, D.6X60mm clamp 1" Inox 316, cuello 30mm Inox 316 con 6 mts cable de teflón, 3 hilos.

**Código:** SPT1/36502

## Esquema:



### Detalle soldadura:



KOSMON S.A. Dpto. Técnico Guillén C. C.

Tel: 93 470 64 20

C/ Gall 47 - 3<sup>a</sup> Planta P.I. el Gall 08950 - Esplugues - BARCELONA

Fax: 93 480 21 11



Tag	Marca		Modelo	Rango
TT_1008_01	ENDRESS-HAUSER		TST-487-1A2B	-50°C/250°C
	Calibrador (°C) Sensor (°C)		Desviación	Desviación media
Input Value 1	27,8	26,3	1,50%	
Input Value 2	40	37,7	2,30%	1.93%
Input Value 3	69,8	65,9	3,90%	1,3370
Input Value 4	93,9	93,9	0,00%	



## NOTA:

Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-1,5%.

Tag	Marca		Modelo	Rango
TT_1008_02	ENDRESS-HAUSER		TST-487-1A2B	-50°C/250°C
	Calibrador (°C) Sensor (°C)		Desviación	Desviación media
Input Value 1	28,1	28,3	-0,20%	
Input Value 2	40	38	2,00%	2,30%
Input Value 3	70	66,8	3,20%	2,30%
Input Value 4	100	95,8	4,20%	




NOTA:						
Este elemento	Este elemento debe recalibrarse, ajustar la compensación o substituirse,					
debido a que	su precisión supe	era el 1-1,5%				
Tag	Marca		Modelo	Rango		
TT_1205_01	VEGA			0°C/150°C		
	Calibrador (°C)	Sensor (°C)	Desviación	Desviación media		
Input Value 1	28	27,8	0,20%			
Input Value 2	39,8	32,9	6,90%	5,90%		
Input Value 3	69,8	60,6	9,20%	5,9076		
Input Value 4	100	92,7	7,30%			



Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-1,5% Tag Marca Modelo Rango TT\_1200\_01 ENDRESS-HAUSER TMR 35-A1AADI '0°C/100°C Calibrador (°C) Sensor (°C) Desviación Desviación media Input Value 1 27,8 28 0,20% Input Value 2 39,8 32,9 6,90% 5,90% Input Value 3 69,8 60,6 9,20%









Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-1,5%.

# NOTA:

Las sondas TT\_1202\_01 y TT\_1202\_02 no se pueden calibrar, porque estaban en servicio en el momento de la calibración Los termopares TT\_1200\_02 y TT\_1200-01, no se pueden calibrar, error de lectura.



Teià, 7 de Diciembre de 2009 Ref. CALIBRACION 2.561

Atención Sr. Enrique Peiro MELISSA PROJECT Escuela Técnica Superior de Ingeniería Dpto. Ingeniería Química Campus Universitat Autónoma de Bellaterra 08193-BELLATERRA (BARCELONA)

ASUNTO: Calibración de los sensores de presión del módulo C-1, según la normativa vigente UNE-EN ISO 17025 en los apartados 5.10.2 y 5.10.4.

Mediante un calibrador manual en línea (del que se adjunta certificado de calibración), ha ofrecido los siguientes resultados:

-Marca/Modelo: HEISE PTE-1 con conexión según elemento.

-Rango: 0.003-25 bar., Precisión: ±0.025, 0.05 o 0.1% de Span

-Compensación de temperatura: 20 °F a 120 °F, Efecto temperatura: ±0.004%

de Span / °F, Sensibilidad: ±0.002% de Span, Repetibilidad: ±0.01% de Span.

C.I.F.A. S.L.

Fdo. José Fernández

Director Técnico

#### **APPENDIX C - PRODUCT SPECIFICATIONS\***

### BASE UNIT PHYSICAL SPECIFICATIONS

Dimensions 7.88 in. (L) x 4.24 in. (W) x 3.25 in. (H)

Weight

Max. 2.2 lbs. w/2 pressure modules installed Case Material

#### High impact ABS

### **Sensor Module Capacity**

2 bays for GQS "Quick Select®" sensor modules Display

2 line LCD, 0.037 in. height per line. Can display simultaneous readings from 2 modules

#### **Electrical Connection**

Miniature recessed banana jacks (one set of test leads provided with each base unit)

#### BASE UNIT OPERATING SPECIFICATIONS

**Operating Temperature Range** Standard: 32° to 120°F Optional: -4 to 120°F

### Storage Temperature

-4° to 158°F Update Rate

130 ms (nominal) with one sensor installed

Resolution ±0.002% of span, 60,000 count (max)

Warm-Up

5 minutes for rated accuracy

### Damping (Measurement Averaging)

Programmable averaging from zero through 16 consecutive readings

#### **Electrical Measurements** 0-50 mA or 0-30 Vdc

Input (volts) 0/10 Vdc 0/30 Vdc 0/20mA 0/50mA	Accuracy ±0.025% FS ±0.10% FS ±0.03% FS
0/50mA	±0.05% FS

# Auto Ranging 10/30 Vdc and 20/50mA

**Temperature Effect Electrical Measurement** ±.001% of Span per °F over compensated range

### Serial Interface

Type: RS-232 Baud Rate: 300, 1200, 2400 or 9600 selectable

### **Field Calibration**

Both Quick Select pressure modules and base unit electronics can be calibrated in the field via prompted kevpad commands

#### Options

Datalogging with Hi-Lo Relay Feature - Datalogging manually or automatically stores up to 715 measured values for upload to PC. Includes upload utility software. Hi-Lo relay feature allows programming of setpoints for activation of alarms or control valves. (Hi-Lo not available with FM approval.) Enhanced LCD – For –4 to 120°F operating range FM Approval - Class 1, Div. 1, Groups A, B, C & D (Not available with CE Mark) CE Mark – EMI/RFI immunity rating (not available

with FM approval)

#### **Power Requirements**

Standard: (2) 9Vdc Alkaline Batteries (provides up to 30 hours operation per set) Optional: 110 or 220 Vac transformer to power calibrator from line power

#### Certification

Revision 4.6 3/2004

N.I.S.T. Traceable certification document provided for base display unit and sensor modules

### PRESSURE SENSOR MODULE SPECIFICATIONS

GOS-1 Pressure Types

Gauge, differential & compound

#### Available Ranges (See Chart)

**Available Accuracies**  $\pm 0.06 (0/2-0/200 \text{ in. H}_20), \pm 0.07 (0/0.25-0/1 \text{ in.}$ H<sub>2</sub>O) or 0.1% of Span

#### Compensated Temperature Range 20°F to 120°F

Temperature Effect

±.004% of Span per °F over compensated range (from reference temperature range of 70° ±3°)

### Repeatability

±0.01% of span (range 0/1 in. H<sub>2</sub>O or higher)  $\pm 0.02\%$  of span (ranges below 0/1 in. H<sub>2</sub>O) Sensitivity

±0.002% of span (typical)

Media Compatibility Clean, dry, non-conductive, non-corrosive gas

#### Under/Overpressure Capability -15 to 50 psi

Maximum Static (line) Pressure 100 psi

**Process Connection** Standard: 1/8 NPT female G 1/8 British standard Optional:

#### Other Options

FM Approved (for use with FM approved base unit) CE Mark (for use with CE Mark rated base unit)

### **GOS-2**

Pressure Types Gauge, absolute, compound & vacuum

#### Available Ranges (See Chart)

Available Accuracies

±0.025, 0.05 or 0.1 % of Span (±0.025 & 0.05% not available on 0/10,000 psi range)

**Compensated Temperature Range** 20°F to 120°F

## Temperature Effect

Standard: ±.004% of Span per °F over the compensated range (from reference temperature of  $70^{\circ} \pm 3^{\circ}$ ) Optional: No additional error due to temperature over the compensated range

## Repeatability

±0.01% of span Sensitivity

### ±0.002% of span (typical)

Media Compatibility

0/5 psi range only: Clean, dry, non-conductive, noncorrosive gas

0/10-0/10,000 psi ranges: Any medium compatible with 316 SS.

- 74-

Optional: Cleaned for Oxygen Service (0/10-0/10,000 psi ranges only)

#### **Overpressure Capability**

200% for ranges up to 1000 psi 150% for ranges over 1000 psi

### Process Connection

Standard: 1/8 NPT female 1/8 NPT female with flush port Optional: (ranges 10 psi and over)

G 1/8 British standard G 1/8 British standard with flush port (ranges 10 psi and over) Welded VCR fitting with standard finish

#### Other Options

FM Approved (for use with FM approved base unit) CE Mark (for use with CE Mark rated base unit)

#### TEMPERATURE INTERFACE MODULES

#### **GOS-RT Series (RTD)**

GQS-RT1 and GQS-RT2 interface modules allow the PTE-1 to measure temperature with an RTD

GQS-RT1: Accommodates Pt100. Ni120. Cu10 and other common 2, 3 or 4 wire probes with resistance outputs of 400 ohms or less. GQS-RT2: Accommodates Pt1000 and other common 2.3 or 4 wire probes with resistance outputs of 4000 ohms or less.

#### Selectable Units of Measure

°C, °F, °K, °R and ohms

Input Receptacle

Accepts TA4F type RTD connector

#### RTD Probes

Pt-100 probes, 6" or 12" length, with or without handle. DIN Class A accuracy. Includes mating TA4F connector.

### Options

FM approved (for use with FM approved base unit) (CE) not available

#### GQS-TC1 (Thermocouple)

**Compatibility** Programmed to provide direct temperature readout from types J, K, T, E, R, S, B & N thermocouples or direct millivolt readout from any thermocouple

### **Reference Junction**

Automatic internal or manual external

### Resolution

Automatic or manually selectable, up to .01°

Units of Measure Selectable; °C, °F, °K, °R and millivolts

#### Receptacle

Accepts "miniature thermocouple connector", Omega® type SMP

#### Options

ACCESSORIES

Soft carrying case

Hard carrying case

110Vac/60 Hz ac Adapter

220Vac/50 Hz ac Adapter

"live" pressure switches

Contoured protective case

FM approved (for use with FM approved base unit) (CE) not available

LPSIIa External 24vdc Loop Power Supply - to

power transducers and pressure switch test circuit

SM-1 Voltage Adapter – provides ability to check

\*Specifications subject to change without notice

## PRODUCT SPECIFICATIONS\*

STANDARD RAM	IGES	
GQS-2 psi (gauge and absolute pressure)	GQS-1 ´H₂O (gauge/ differential pressure)	Other Engineering Units**
*5 10 15 20 25 30 50 60 100 150 200 250 300 500 600 1000 1500 2500 3000 5000 6000 1000 2500 3000 500 000 1500 2500 300 500 500 100 150 250 300 500 500 100 150 250 300 500 500 100 150 250 300 500 500 100 150 250 300 500 500 100 150 250 300 500 500 100 150 250 300 500 500 100 150 250 300 500 500 100 1500 2500 300 500 1000 1500 2500 300 500 1000 1500 2500 3000 500 1000 1500 2500 3000 5000 1000 1500 2500 3000 5000 1500 2500 3000 5000 2500 3000 5000 2500 3000 5000 2500 3000 5000 2500 3000 5000 2500 3000 5000 5000 2500 3000 500	0.25* 0.5* 1.0* 2.0* 3.0* 10* 15* 25* 50* 100* 150* 200*	psi in. H <sub>2</sub> O in. Hg ttSW Bar mBar kPa mHg cmH,0 mmHi <sub>2</sub> O kg/cm <sup>2</sup> User Selectable **Note: Engineering units identified above are accessible through the unit select feature. However, readout will default to the pri- mary unit of measure on start-up. Sensor modules scaled in primary units other than in. H 0 (GOS-1) or psi (GOS-2) are also available. <sup>2</sup> Consult factory.
10 15		
compound		*
±5 ±10 ±15 -15/+30 -15/+60	$\begin{array}{c} \pm 0.125^{*} \\ \pm 0.25^{*} \\ \pm 0.5^{*} \\ \pm 1.0^{*} \\ \pm 1.0^{*} \\ \pm 2.5^{*} \\ \pm 5.0^{*} \\ \pm 7.5^{*} \\ \pm 12.5^{*} \\ \pm 25^{*} \\ \pm 25^{*} \\ \pm 75^{*} \\ \pm 100^{*} \end{array}$	

DIMENSIONS



\* Non-isolated, for clean dry gas only



Tag	Marca	Modelo	Rango	Saturación
PT-1101-01				400 mbar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,258	0,290	11,03%	9.58%
Input Value 2	0,317	0,345	8,12%	9,50%



Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-4%.

Tag	Marca	Modelo	Rango	Saturación
PT-1203-06				2 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,363	0,401	9,48%	
Input Value 2	1,253	1,295	3,24%	4,99%
Input Value 3	1,738	1,778	2,25%	



# NOTA:



Tag	Marca	Modelo	Rango	Saturación
PT-1203-03				2 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,112	0,149	24,83%	
Input Value 2	0,233	0,268	13,06%	15,72%
Input Value 3	0,343	0,378	9,26%	



Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-4%.

Tag	Marca	Modelo	Rango	Saturación
PT-1009-02				400 mbar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,392	0,432	9,26%	
Input Value 2	0,950	0,980	3,06%	4,92%
Input Value 3	1,793	1,838	2,45%	



# NOTA:



Tag	Marca	Modelo	Rango	Saturación
PT-1009-01				200 mbar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,140	0,136	-2,94%	-2.37%
Input Value 2	0,169	0,166	-1,81%	-2,37 /0



Tag	Marca	Modelo	Rango	Saturación	
PT-1003-01				200 mbar	

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,100	0,147	31,97%	<b>28 620</b> /
Input Value 2	0,142	0,19	25,26%	28,62%





Tag	Marca	Modelo	Rango	Saturación
PT-1203-01				4 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,115	0,150	23,33%	
Input Value 2	0,744	0,770	3,38%	6.92%
Input Value 3	2,111	2,114	0,14%	0,9270
Input Value 4	2,658	2,68	0,82%	



# NOTA: Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-4%.

Tag	Marca	Modelo	Rango	Saturación
PT-1203-04				4 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,554	0,600	7,67%	
Input Value 2	0,930	0,970	4,12%	4.14%
Input Value 3	1,860	1,92	3,12%	4,1470
Input Value 4	2,656	2,700	1,63%	



# NOTA:



Tag	Marca	Modelo	Rango	Saturación
PT-1203-02				4 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,931	0,970	4,02%	
Input Value 2	1,365	1,410	3,19%	2.65%
Input Value 3	1,953	1,99	1,86%	2,0070
Input Value 4	2,600	2,64	1,52%	



Тад	Marca	Modelo	Rango	Saturación
PT-1203-05				4 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,331	0,340	2,65%	
Input Value 2	0,995	1,030	3,40%	2.23%
Input Value 3	2,095	2,130	1,64%	2,2370
Input Value 4	2,845	2,880	1,22%	





Tag	Marca	Modelo	Rango	Saturación
PT-1203-08				4 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,300	0,350	14,29%	
Input Value 2	1,090	1,130	3,54%	5.33%
Input Value 3	1,844	1,89	2,43%	5,5576
Input Value 4	2,859	2,89	1,07%	



# NOTA: Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-4%.

Tag	Marca	Modelo	Rango	Saturación
PT-1203-07				4 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,170	0,220	22,73%	
Input Value 2	1,138	1,200	5,17%	8.01%
Input Value 3	2,123	2,180	2,61%	0,0170
Input Value 4	2,905	2,950	1,53%	



# NOTA:



Tag	Marca	Modelo	Rango	Saturación
PT-1100-02				200 mbar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,147	0,141	-4,26%	-3.44%
Input Value 2	0,195	0,19	-2,63%	



Los siguientes elementos no se han podido calibrar, por error de lectura o fallos en la señal del sensor: PT-1001-01, PT-1100-01, PT-1104-01