Universitat Autònoma de Barcelona

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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Reference/Réference	MELiSSA Pilot Plant Frame Contract 19445/05/NL/CP
Issue/Edition	0
Revision/Révision	0
Date of issue/Date d'édition	13/02/10
Status/Statut	Final

APPROVAL

Title *Titre*	**Compartment I Functional Test Plan – Step1 and Step2**	Issue *Edition*	0	Revision *Révision*	0

Prepared by *Auteur*	Martinez, N., Peiro, E., Fossen, A. and Godia, F.	Date *Date*	13/02/10
Checked by *Verifié par*	Fossen, A.	Date *Date*	27/02/10
Approved by *Approuvé par*	Gòdia, F.	Date *Date*	27/02/10
Approved by customer *Approuvé par le client*	Lamaze, B.	Date *Date*	13/03/10

CHANGE LOG

Issue/*Edition*	Revision/*Révision*	Status/*Statut*	Date/*Date*
0	0	Final	13/02/10

Distribution List

Name/*Nom*	Company/*Société*	Quantity/*Quantité*
Brigitte LAMAZE	ESA	2 hardcopies + electronic version

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	TN 83.7	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.

- 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. Instructions for maintenance

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.

Table 1. Functional Test Procedures (Step 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	y
N/A	level safety tests	y
	START-UP	
15	Connect N2 to the system	y
5	Influent preparation	n/a
6	Start-up Influent tank VSSL_1000_01	y
7	Filling Influent tank VSSL_1000_01	y
10	Filling Bioreactor VSSL_1007_01 with inoculum	n/a
11	Start-up Bioreactor VSSL_1007_01	y
12	Start-up Bioreactor VSSL_1007_01 feeding	y
26	Active Gas Loop: Start-up	y
20	Passive Gas Loop: Start_up	y
22	Analysis Gas Loop: Start-up	y
23	Analysis Gas Loop: adjust flow rates	n/a

24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_01	n/a
31	Filtration Unit: Installation of dead-end filter LF_1200_03	n/a
33	Filtration Unit: Installation of ceramic membranes LF_1200_01/LF_1200_02	n/a
27	Filtration Unit: Replacement of tube in pump PMP-F-02	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
	SHUT DOWN	
25	Active Gas Loop: Shut down	y
21	Analysis Gas Loop: Shut down	y
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 LF_1200_01/LF_1200_02	n/a
66	SIP Emergency Shutdown	y
	NOMINAL OPERATION	
5	Influent preparation	n/a
7	Filling Influent tank VSSL_1000_01	y
2	Preparation of acid for pH control in Bioreactor VSSL_1007_01	n/a
3	Preparation of base for pH control in Bioreactor VSSL_1007_01	n/a
11	Start-up Bioreactor VSSL_1007_01	
12	Start-up Bioreactor VSSL_1007_01 feeding	
13	Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_01	n/a
71	Bioreactor content sampling	n/a
79	Calibration of pH sensors AT_1011_01 et AT_1011_02	n/a
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
23	Analysis Gas Loop: adjust flow rates	n/a
24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_01	n/a
25	Active Gas Loop: Shut down	y
26	Active Gas Loop: Start-up	y
29	Filtration Unit: (Emergency) Shut down	y
28	Filtration Unit: Calibration of PMP-F-02 flow rate	n/a
27	Filtration Unit: Replacement of tube in pump PMP-F-02	n/a
30	Filtration Unit: Removal of dead-end filter LF_1200_03	n/a

31	Filtration Unit: Installation of dead-end filter LF_1200_03	n/a
32	Filtration Unit: Removal of ceramic membranes LF_1200_01/LF_1200_02	n/a
33	Filtration Unit: Installation of ceramic membranes LF_1200_01/LF_1200_02	n/a
34	Filtration Unit: Start-up in Bypass mode	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
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	y
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	y
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	y
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	y
55	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01 and filtrate line through LF_1200_01/LF_1200_02	y
52	Cleaning of Filtration Unit: backwashing membrane Fi-F-01 / Fi-F-02 using water or cleaning agent	y
58	empty RC01	y
59	empty RC02	y
53	Cleaning of Filtration Unit: Circulation pump PMP-F-01	y
	SIP	
68	SIP of filtrate line 1 and 2	y
69	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate tank VSSL_1204_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.

4.1.2.8. Test deliverables

- 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. Analyses

N/A

4.1.4. Resources specification for the tests

4.1.4.1. Personnel: staff qualification and training needs

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 Annex 3.

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. Facilities : environmental needs, test conditions, interfaces needs, utilities needs

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 RD3.

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 Annex13_hardware_modifications.xls of RD3.

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.

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

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	
	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

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

49	Cleaning of Filtration Unit: retentate side of membrane LF_1200_01 / LF_1200_02		Y
50	Cleaning of Filtration Unit: both retentate and filtrate side of membrane LF_1200_01 / LF_1200_02		Y
51	Cleaning of Filtration Unit: backwash membrane LF_1200_01/LF_1200_02	Y	Y
52	Cleaning of Filtration Unit: backwashing membrane LF_1200_01 using water and cleaning agent		Y
53	Cleaning of Filtration Unit: Circulation pump GP_1201_01		Y
54	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01	Y	Y
55	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01 and filtrate line through LF_1200_01 / LF_1200_02	Y	Y
56	Cleaning of Filtration Unit: automated execution of a sequence of procedures to clean membrane LF_1200_01		Y
45	CIP: nominal stopping of CIP activities		Y
46?	Shut down the System, drain, rinse and clean Bioreactor VSSL_1007_01, Feefing vessel VSSL_1000_01 and Filtration Unit SIP		Y
N/A	Steam utilities start-up		
68	SIP: membrane LF_1200_01 / 02		Y
69	SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01	Y	Y
80	SIP :Purge and sterilize recycle line		Y
81	SIP : Purge and sterilize Harvesting line	Y	Y
82	SIP: Flush recycle line with Steam		Y
83	Filtration Unit: Enter in By Pass Mode automatically when LSH_1206_01 is set		Y
84	SIP membrane, filtrate line and filtrate tank		Y
66	SIP : nominal stopping of SIP activities	Y	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		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

Table 4. Procedures to be updated and validated with TechnoMembranes (in the frame of TN94.66)

33	Filtration Unit: Installation of ceramic membranes 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. Test deliverables

For all the phases, the deliverables are :

- Annotated as-run procedures for the tests (Annex 4 –Bioreactor and Gas loop- and 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 122ºC with a range of ±1 ºC 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. Sample size, frequency, locations

N/A

4.2.3.5. Analyses

N/A

4.2.4. Resources specification for the tests

4.2.4.1. Personnel: staff qualification 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 Annex 8.

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. *Facilities : environmental needs, test conditions, interfaces needs, utilities needs*

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.

Table 6. 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	VSSL_1000_01, VSSL_1007_01, VSSL_1011_01, VSSL_1011_02	Total absence of leackage	Mechanical and Electrical integration	12 h	Check Table
			Filtration Unit	VSSL_1204_01				
			Gas Loop	VSSL_1100_01				
			Cleaning and Sterilisation	VSSL_1209_01, VSSL_1209_02, VSSL_1209_03				
2	Gas Tightness (pressurized with air)	Tanks (mounted on frame with associated instrumentation), tubes	Bioreactor	VSSL_1000_01, VSSL_1007_01, VSSL_1011_01, VSSL_1011_02	Total absence of leackage	Mechanical and Electrical integration	12 h	Check Table
			Filtration Unit	VSSL_1204_01				
			Gas Loop	VSSL_1100_01, VSSL_1100_02				
				Condensate line				
			Cleaning and Sterilisation	VSSL_1209_01, VSSL_1209_02, VSSL_1209_03				
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

			Filtration Unit	FT_1201_01, LSH_1206_01, LSH_1206_02, LT_1206_01, PT_1203_01, PT_1203_02, PT_1203_03, PT_1203_04, PT_1203_05, PT_1203_06, PT_1203_07, PSH_1203_01, AT_1201_01, TT_1205_01, TT_1200_01, TT_1200_02, TT_1200_03, PT_1203_08				
			Gas Loop	AT_1101_01, FT_1101_01, FT_1103_01, FI_1101_01, FI_1101_02, PI_1100_01, PT_1100_01, PT_1101_01, LSH_1102_0, TT_1104_01, PT_1104_01, PT_1100_02,				
			Cleaning and Sterilisation	TT_1208_01, LSH_1209_01, LSL_1209_01, LSH_1209_02, LSL_1209_02				
Test case	**Specifications/ Requirements**	**Instruments**	**Subsystems**	**New TAG**	**Acceptance criteria**	**Schedule**	**Duration**	**Test output**
4	Correct volume measurement	Tanks	Bioreactor	VSSL_1000_01, VSSL_1007_01	Establishment of curve Volume = f(P)	After tests 1, 2 and 3	NA	Check table + calibration curve
			Filtration Unit	VSSL_1204_01				
			Gas Loop	VSSL_1100_02				
			Cleaning and Sterilisation	VSSL_1209_01, VSSL_1209_02				
5	Correct flows and speeds	Pumps and blenders	Bioreactor	GP_1001_01, CP_1002_01, PP_1008_01, BLE_1012_01, BLE_1005_01	Establishement of set points	After Tests 1, 2, 3, 4	NA	Check table + Set points
			Filtration Unit	GP_1201_01, PP_1202_01				
			Gas Loop	PP_1100_01, PP_1101_01, PP_1102_01				

			Cleaning and Sterilisation	CP_1207_01, PP_1209_01, CP_1207_02				

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

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.

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

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 ºC	0,5 < T < 6 ºC 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 ºC	54,5 < T < 55,5 ºC 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

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

- 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

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.

5.2.2.5. *Testing of foreseen software modifications*

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.

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"*** 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).

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 CI 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 CI"? Agree, text amended

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 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 Ok, no problem for us to accept the proposed wording; text amended accordingly.
8/4.1.1.2	***"4.1.1.2. Hazards induced by test item and safety measures to be taken"*** 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). OK anyway those comments have been raised before we agreed on a test plan template. Yes, indeed.
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)

	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	*"All relevant procedures".* Only wording issue: *"All features as described in the relevant procedures"*. 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	"***4.3 Additional hardware tests***". 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 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")
17/Section 4.2.2.4	*"All procedures*". All features addressed by all procedures of Table…...(please complement) OK, completed: *"All features addressed by all procedures of Tables 2-5".*
21/Section 4.2.3.1	"*For the particular case of the sterilisation procedures, 121±1 ºC is the a priori foreseen range* ". For what? Steam produced? Temperature measured somewhere?

	. Better explained in the text: *"For the particular case of the sterilisation procedures, a temperature of 122ºC with a range of ±1 ºC 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"*
28/Section 4.2.6	"*These tests are foreseen to be performed independently on the 3 frames within Functional tests Step2*" If the tests are "within" 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 Already explained in comment on section 4.2. Again, these tests were finally addressed in a different way, so included in Step2 but in a dedicated section.
29/Section 4.2.7	*"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 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	*"The potential presence of residues of the cleaning agent, and its potential effect in the whole MELiSSA loop."* 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."*

	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

TECHNICAL NOTE 94.12

ANNEXES

ANNEX 1

					step 1 functional tests	
EPAS numbers	Sequence of routines	Operator	HMI	status	applicable for step 1	comments/changes from nominal parameters
	EMERGENCY STOPS					
16	Emergency Stop on the RV frame	OP		C	prerequisite	
17	Emergency Stop on the FU frame	OP		C	prerequisite	
18	Emergency Stop of the FU frame on the HM		Y	C	prerequisite	
29	Filtration Unit: (Emergency) Shut down		Y	C	prerequisite	
45	CIP: (Emergency) Shut down of CIP activities		Y	C	prerequisite	
66	(Emergency) Shut down of SIP activities	OP	Y	C	prerequisite	
	CONTROL LOOPS IMPORTANT FOR SAFETY					
N/A	pressure safety tests		n	C	y	check that the control of pressure inside the reactors is working
N/A	level safety tests		n	C	y	check that the control of level inside the reactors is working
	START-UP					
15	Connect N2 to the system	OP		C	y	air
5	Influent preparation	OP			n/a	water
6	Start-up Influent tank VSSL_1000_01	OP	Y	C	y	
7	Filling Influent tank VSSL_1000_01		Y	C	y	temperature setpoint 10ºC
10	Filling Bioreactor VSSL_1007_01 with inoculun	OP			n/a	water
11	Start-up Bioreactor VSSL_1007_01	OP	Y	C	y	
12	Start-up Bioreactor VSSL_1007_01 feeding	OP	Y	C	y	water
26	Active Gas Loop: Start-up		Y	C	y	
20	Passive Gas Loop: Start_up		Y	C	y	
22	Analysis Gas Loop: Start-up		Y	C	y	protection of analyzer from moisture?
23	Analysis Gas Loop: adjust flow rates	OP			n/a	use of CO2 and reference of CH4?
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-02	OP			n/a	
69	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate tank VSSL_1204_01	OP	Y	C	y	
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02		Y	C	y	why not in bypass ?
	SHUT DOWN					
25	Active Gas Loop: Shut down		Y	C	y	
21	Analysis Gas Loop: Shut down		Y	C	y	
19	Passive Gas Loop: Shut down		Y	C	y	
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_0		Y	c	y	
46	Shut down the System, drain, rinse and clean Bioreactor VSSL_1007_01, Feefing vessel VSSL_1000_01 and Filtration Unit		Y		n/a	this procedure is a composite one made of elementary ones that are 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		y	C	y	
	NOMINAL OPERATION					
5	Influent preparation	OP			n/a	water
7	Filling Influent tank VSSL_1000_01		Y	c	y	
2	Preparation of acid for pH control in Bioreactor VSSL_1007_01	OP			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	Y	c		
12	Start-up Bioreactor VSSL_1007_01 feeding	OP	Y	c		
13	Preserve overpressure gas in VSSL_1007_01 into VSSL_1100_0	OP	Y		n/a	
71	Bioreactor content sampling	OP			n/a	
79	Calibration of pH sensors AT_1011_01 et AT_1011_02	OP			n/a	
19	Passive Gas Loop: Shut down		Y	c	y	
20	Passive Gas Loop: Start_up		Y	C	y	
21	Analysis Gas Loop: Shut down		Y	C	y	
22	Analysis Gas Loop: Start-up		Y	C	y	protection of analyzer from moisture
23	Analysis Gas Loop: adjust flow rates	Y			n/a	
24	Analysis Gas Loop: Calibration of gas analyzer AT_1101_0	Y	Y		n/a	
25	Active Gas Loop: Shut down		Y	C	y	
26	Active Gas Loop: Start-up		Y	C	y	
29	Filtration Unit: (Emergency) Shut down		Y	C	y	
28	Filtration Unit: Calibration of PMP-F-02 flow rate	PLC			n/a	
27	Filtration Unit: Replacement of tube in pump PMP-F-02	OP			n/a	
30	Filtration Unit: Removal of dead-end filter LF_1200_02	OP			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 LF_1200_01/LF_1200_02	OP	Y		n/a	
34	Filtration Unit: Start-up in Bypass mode		Y	C	y	
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02		Y	C	y	
37	Filtration Unit: Enter Recycle mode		Y	c	y	switch to other line possible only if valves are replaced?
38	Filtration Unit: Enter Nominal mode		Y	c	y	
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_0		Y	c	y	
40	Drain Filtration Unit: retentate line	OP			n/a	
41	Drain Filtration Unit: inside membranes LF_1200_01/LF_1200_0	OP			n/a	
42	Drain Filtration Unit: filtrate line	OP	Y	c	y	
43	Drain Filtration Unit: entire Filtrate Un	OP			n/a	
44	Fill Filtration Unit with wate				n/a	
	CIP					
45	CIP: (Emergency) Shut down of CIP activities		Y		y	
47	Cleaning Influent tank VSSL_1000_01		Y		n/a	water?
48	Cleaning Bioreactor VSSL_1007_01		Y		n/a	
49	Cleaning of Filtration Unit: retentate side of membrane LF_1200_01/LF_1200_02		Y	c	y	
50	Cleaning of Filtration Unit: both retentate and filtrate side of membrane LF_1200_01/LF_1200_02		Y	c	y	
54	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_0	OP	Y	not finished	y	
55	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01 and filtrate line through LF_1200_01/LF_1200_02		Y	c	y	99
52	Cleaning of Filtration Unit: backwashing membrane Fi-F-01 / Fi-F-02 using water or cleaning agent			c	y	105
58	empty RC01			c	y	109
59	empty RC02			c	y	112
53	Cleaning of Filtration Unit: Circulation pump PMP-F-0			c	y	
	SIP					
68	SIP of filtrate line 1 and 2			c	y	
69	SIP: membrane LF_1200_01/LF_1200_02, filtrate line and Filtrate tank VSSL_1204_01	OP	Y	C	y	

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.		C	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	c	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	c	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		

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		Only controlled valves ?
others				

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		c			
			missing how to add the cooling liquid into the loop		
Procedure			tap water was used for the tests step 1		
Use the HMI to					
1. 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.	05-jun	c	5/6/08 : PR-G-02 = 145 mbar ; PR-G-04=95mbar		
2. Start blender BL-V-01 (set point: 200 rpm): SCI_BL_V_01		c	the value of the speed can be modified on the frequency variator of BL-V-01 inside the electrical cabinet, not through the HMI		
3. Set temperature setpoint to 6°C or another value <= 7°C. Fill HX-V-01 and double jacket with water and antifreeze compound (glycol) if this is not done yet: SCI_V_T_V_01_SP		c	temperature setpoint was changed from 0ºC to 20ºC with T_V_01=15ºC : 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 ?	
4. Start PMP-V-01 : SCI_GP_1001_01_MV1					
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.		nc	the pressure sensor PS-V-03 isnot working		
			to be checked again		

Recommendations / changes	WHEN?	WHO?	Comments
HW modifications			
repair ps-v-03		UAB	
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 int	step2	SHPA	Do you mean the Feedback ? YES
HMI modifications			
more rapid update of compressor state ?		NTE	I will check how it is done and if it is useful
color codes for lines are not clear ; senses of flows neither ;		NTE	
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	
others			

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
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.			missing also fuse F16 to be on		
V-V-01 is closed.		C			
V-V-05 is closed.		c			
V-V-06 is closed.		c			
V-V-07 is on.		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 regulating device (even a safety device)?	Agree : HMI and/or safety	
Procedure					
Initial filling (occurs at start-up, when the influent tank is totally empty)					
1. Connect the dedicated reservoir to valve V-V-02.			Vol V ini = 26L		
2. Open the valve underneath the reservoir and fill it with influent.					
3. Start-up PMP-V-01: SCI_GP_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 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.	05-jun	NC	when V-V-07 was forced to open through PLC, it could not return to closed when V-V-07 was left closed and not forced through PLC, it acted a as pressure relief valve at p=150mbar the role of V-V-04 for pressure regulation was not observed	Sherpa should check the programmation of the V_V_07 behaviour	
5. 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.	05-jun	N/A	these parameters are linked to the WPU (here water) change the stirring speed? Change the temperature setpoint ?	The question was to know which parameters should be used in order to minimize the 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 valve.		c	filling up to Vol=61L, V-V-04 off and then Volume appeared to 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)					
1. Connect the dedicated reservoir to valve V-V-02.					
2. Open the valve underneath the reservoir and fill it with influent.					
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 reservoir. Empty the remaining influent and rinse it.					

Recommendations / changes

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

Important : to be clarify by Sherpa

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)

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-06		NC	V-R-20 is a manual valve not visible on HMI ; p=100 mbar		
2. Flush N2 in the bioreactor byV-G-29		C	where is the bioreactor pressure setpoint for the PLC control of V-G-29?	To be clarified	
3. Start blender BL-R-01 (set point: 220 rpm): SCI_BL_R_01		C	change setpoint is only possible in the electrical cabinet by changing the FVC	Only On/Off in PLC. Speed in the cabinet	
4. Set temperature setpoint to 55°C. Fill HX-R-01 and double jacket with demineralized water if this is not done yet: SCI_R_T_R_01_SP		NC	decalcified water? Not for the tests : tap water the pump is always ON the heating element indication on HMI is not correct : it is always ON even when the electrical heater is OFF		
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_pH_R_01_SP		NC	if pH is above setpoint, PMP R 01 is actuated if pH below setpoint, no action by PMP R 02 it seems the pH control is authorized only when the blender is ON	To be checked by Sherpa. There is a delay between switching from acid to base, due to "dead zone" and controller strategy	
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. 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 L/d). Once nominal liquid volume is reached, one should switch over to volume based control. Nominal volume is around 100L: SCI_V_Feed, SCI_V_Feed_mode_timer or SCI_V_Feed_mode_volume			the switching is made through _mode_timer_S or mode_volume_S		
2. Enable feeding by the button on the HMI: SCI_V_Feed_Enable			the role of this parameter is not really clear and could not be related to the HMI		
3. Use the HMI to set feeding to timer based and to set the amount to feed per day: SCI_V_Feed_mode_timer_S, SCI_V_Feed_Amount_per_day			what are the different roles and possibilities		
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: SCI_V_Feed_volume_SP, SCI_V_Feed_mode_volume_S					

Recommendations / changes WHEN WHO

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

PLC programme modifications
addition of baase is considered? Yes it was tested

HMI modificatinos
temperature control loop should be easy to view with T setpoint and loop T
pH control additions missing I don't think it is useful

pressure setpoint for the bioreactor should appear Not a single SP. More complicated with Active and Passive Strategy

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 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					
1. Make sure V-R-20 is open and N2 is available at around 1 barg at PR-G-06		NC	V-R-20 is a manual valve not visible on HMI ; p bioreactor=103 mbar		
2. Flush N2 in the bioreactor byV-G-29		C	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-G-29 opens up		
3. Start blender BL-R-01 (set point: 220 rpm): SCI_BL_R_01		C	change setpoint is only possible in the electrical cabinet by changing the FVC		
4. Set temperature setpoint to 55°C. Fill HX-R-01 and double jacket with demineralized water if this is not done yet: SCI_R_T_R_01_SP	6/6/08 12:30	NC	it is not possible to activate from HMI the heating ; it was done by forcing the variable HX_R_001 on PLC the heating element indication on HMI is not correct : it is always ON even when the electrical heater is OFF	Temperature is controlled. The heating cannot be 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		
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. 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 L/d). Once nominal liquid	6/6/08 12:35	NC	not done for this part of the tests : the objective was to have a 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 per day: SCI_V_Feed_mode_timer_S, SCI_V_Feed_Amount_per_day					
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: SCI_V_Feed_volume_SP, SCI_V_Feed_mode_volume_S					

Recommendations / changes

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 — Is it necessary ?

PLC programme modifications

addition of baase is considered?

HMI modificatinos

temperature control loop should be easy to view with T setpoint and loop T — agree

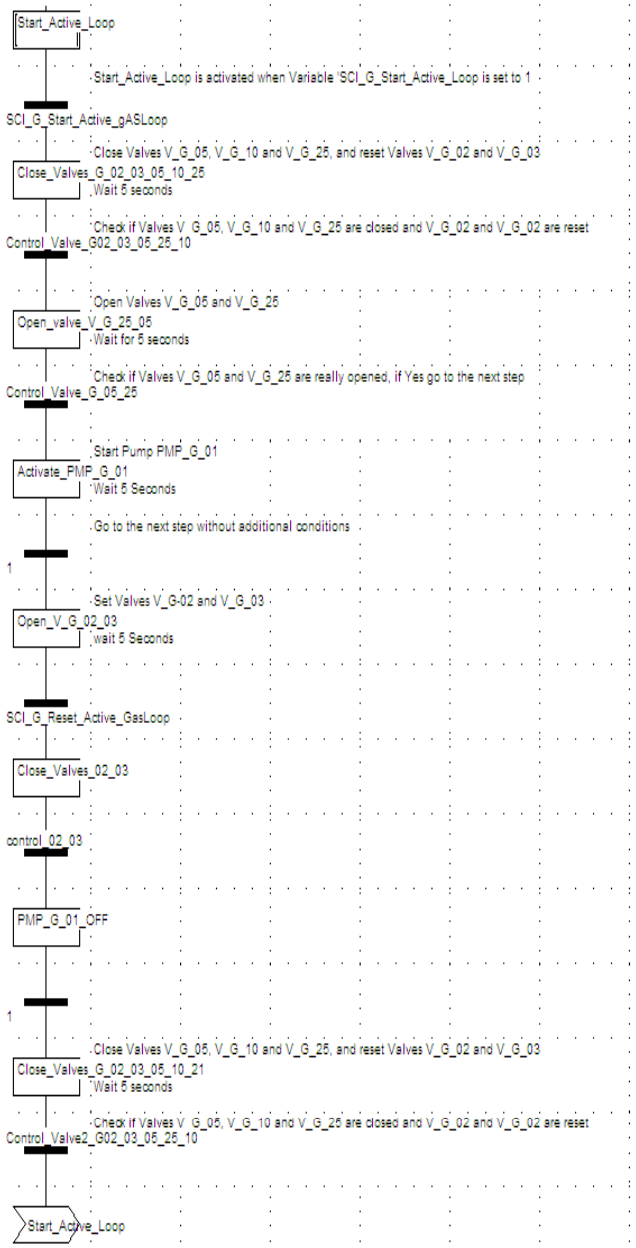
pH control additions missing — see previous answer

pressure setpoint for the bioreactor should appear — no pressure sp

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 comments
1.1. Procedure 26: Active Gas Loop: Start-up					
prerequisite	06/06/2008 12:00		there might be a problem of reverse flow from bioreactor to the active gas loop condensate line through V-G-12		
none in EPAS procedure			V-R-17 and 14 open ; V-R-5 closed ; V-R-13 closed to avoid backflow of water; V-G-11 and V-G-13 closed		
			passive gas loop is ON before starting this procedure (HMI indicatino)		
Scope			(Valves V_G_07 On and V_G_08 Off; PS_G_04 indicates pressure zero)		
Start the active gas loop			Include as prerequisite to check manual valves in R-G-01: V-G-06, V_G_26,		
			Previous condition: R-G-02 at 69 mBar		
Procedure					
Press the button on the HMI: SCI_G_Start_Active_GasLoop		NC	Stop of active gas loop in HMI is not effective even if button STOP changes to red ; START and STOP actions are carried out through the same START button	HMI pb ? Probably because it had to be forced through PLC	
Make sure that V-R-13, -14, and -17 and V-G-11 and -13 are open.		C	ok		
			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		
SCI_G_Start_Active_GasLoop, SCI_G_Reset_Active_GasLoop			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 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**					
Fig : 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 :

- 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
- Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25) are ON
- Run the pump PMP_G_01 — C — OK it started
- Valves S3CV_1100_01_MV, S3CV_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? — I don't know
- Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02, V_G_03) are OFF — nA — not performed
- Stop the pump PMP_G_01 — NA — not performed
- Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, 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-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 control loops

	WHEN	WHO	
Recommendations / changes			
HW modifications			
			??? Pressure indicator for visual control of pressure inside bioreactor
install a PI on bioreactor between 1 barg and 1,2 barg		UAB	
temperture sensor TS-R-01 is OOO it is indicating 0ºC			
repair LS-G-01			
PLC programme modifications		SHERPA	
control of V-G-10 opening?			
HMI modifications		NTE	
Local			
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	C			
V-R-11 is open	06/06/2008 17:00	C			
Procedure			Stop of passive gas loop in HMI is not feasible pushing the button STOP	What do you mean ?	
Press the button on the HMI: SCI_G_PAS_Start		NC	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 PASSIVE GAS LOOP is never used)	Passive always active	
		NC	it seems that V-G-07 is always open ; V-G-08 is always closed whatever the level of pressure above 90mbarg	Sherpa to check. IMPORTANT	
PLC Interface :	06/06/2008 17:00		PS-G-04 cannot measure the pressure above 100mbarg! Preactor=190mbarg		
SCI variables :					
SCI_G_PAS_Start		NC	variable TB_G_PAS cannot be introduced through HMI and it is needed to authorize the passive control loop ; therefore the passive gas loop could not be used before passing only through HMI ; it was forced through PLC	?	
PLC Subroutines : **G_PAS_Start, G_PAS_Esc**					
Fig : PLC procedure: G_PAS_Start					
The subroutine G_PAS_Esc is described on Procedure 19.					

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 To be analysed

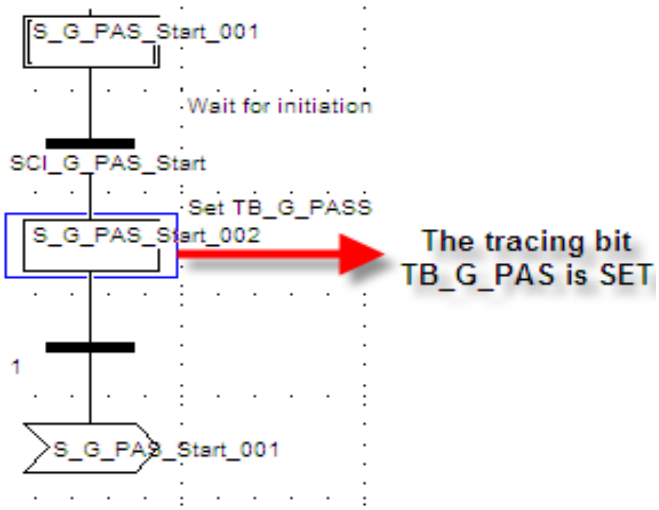
HMI modifications

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 :					
SCI_G_Reset_Active_GasLoop			when forcing this variable from PLC, we could activate 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):					
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 :					
• Input HMI: SCI_G_Reset_Active_GasLoop					
• Valves V_G_02 and V_G_03 are set in OFF		C	ok		
• The pump PMP_G_01 is turn OFF		C	OK it shut down		
• Valves V_G_05, V_G_10 and V_G_25 are set in OFF		C	ok		

	WHEN	WHO
Recommendations / changes		
HW modifications		UAB
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
Remote		
Variables		
others		
User Manual		

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.					
Procedure					
Press the button on the HMI: SCI_G_PAS_Stop	06/06/2008 19:30	NC	ON button has to be pressed to obtain shutdown of 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	OK	
PLC Subroutines : **G_PAS_Stop , G_PAS_Esc**					
Fig : PLC procedure: G_PAS_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	OK	
• This variable begins the PLC procedure G_PAS_Esc		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		
• The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which on state HIGH begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)			it seems that the release of gas was interrupted by the passive shutdown, not started/begun		

Recommendations / changes WHEN WHO

HW modifications

PLC programme modifications
change the variable names

Documentation only ?

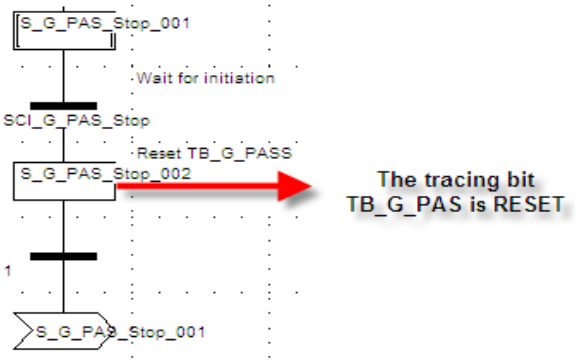
HMI modifications

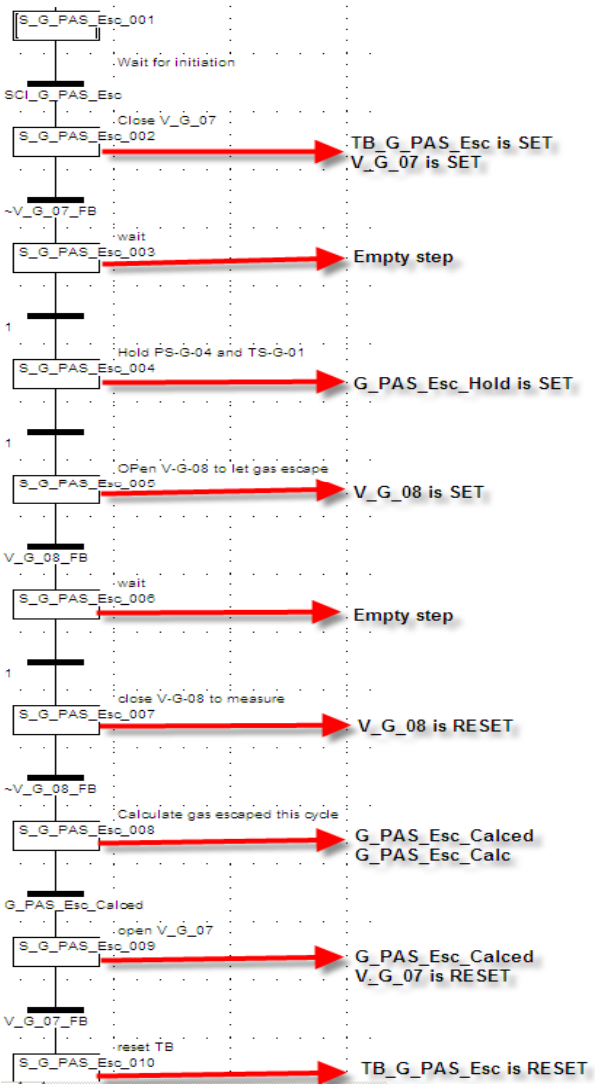
Local
idem remote

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 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	c			
			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		
1. 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.	09-jun				
2. Start blender BL-V-01 (set point: 200 rpm): SCI_BL_V_01		c	blender on		
3. Set temperature setpoint to 6°C or another value <= 7°C. Fill HX-V-01 and double jacket with water and antifreeze compound (glycol) if this is not done yet: SCI_V_T_V_01_SP		c	cooler ON		
4. Start PMP-V-01 : SCI_GP_1001_01_MV1		c	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

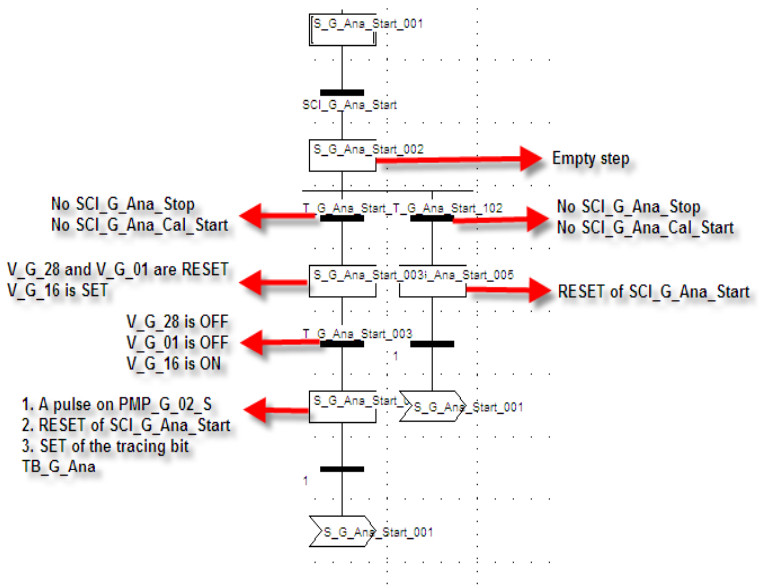
HW modifications
repair ps-v-03 UAB
UAB

PLC programme modifications
step2 SHPA

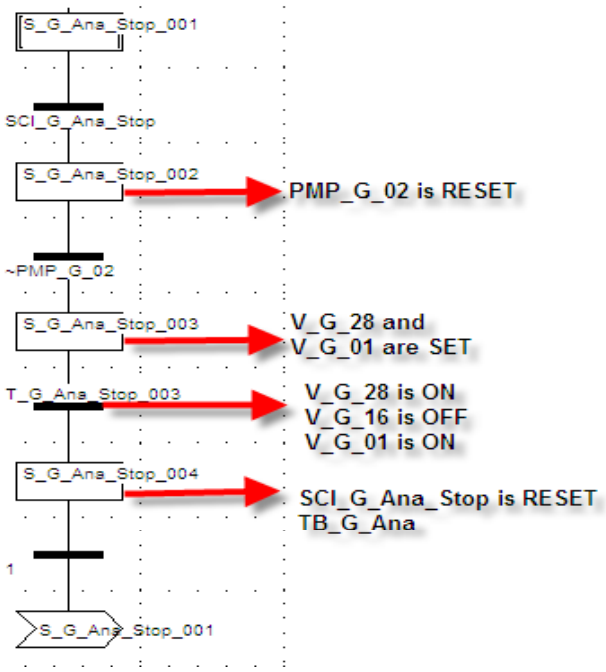
HMI modifications
NTE
NTE
NTE
NTE

others

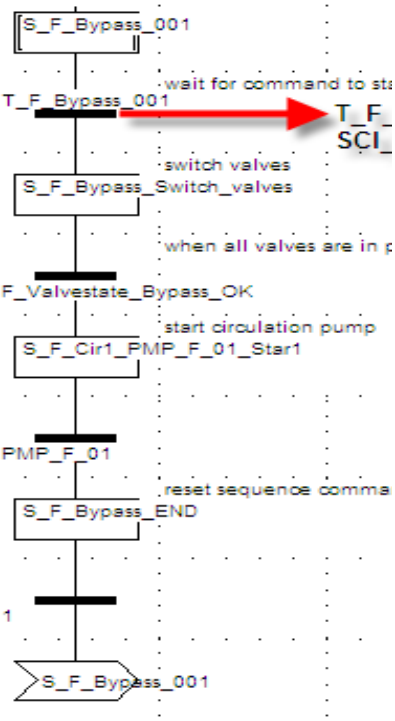
Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. PROCEDURE 22: Analysis Gas Loop: Start-up					
Scope					
Start the analysis gas loop. This part of the gas loop uses PMP-G-02 to create a circulating flow of gas from R-R-01 over the gas analysers.			reactor started up passive control loop ON : PS-G-04 > 100mbarg because active gas loop ON : PS-G-01 = 2,21barg preactor = 153 mbar because a leak was detected in V-G-09 (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					
Make sure V-R-15 and -16 are open. Press the button on the HMI: SCI_G_Ana_Start	09/06/2008 13:30	NC	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 changing value when activating/deactivating the gas analysis loop or is taking when activating the loop the value ON and then switching to OFF		
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.		C	OK both valves V_G_14 and 15 closed but check valve 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		
SCI variables :					
SCI_G_Ana_Start					
PLC Subroutine : **G_Ana_Start**					
		C	V_G28, 01, 16 in the required state		
		C			
		C	ok SCI_G_Ana_Start is reset to OFF		
		C	TB is ON		
			PS_G_02 = 88 mbarg		
			V_G_15 open so that FI reads 0,75 L/Min		
			pressure drops down to 84 mbarg and then goes up again		
			P_R_01 = 79mbarg : there is flow reinjected from the gas analysis loop into the bioreactor		
Fig : PLC procedure: G_Ana_Start					
Recommendations / changes	WHEN	WHO			
HW modifications					
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	
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 comments
1.1. PROCEDURE 21: Analysis Gas Loop: Shut down					
Scope					
Stop the analysis gas loop.					
	09/06/2008 14:14		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 (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		
PLC Interface : ?????			we did not use the PLC interface for this loop		
SCI variables :					
SCI_G_Ana_Stop					
PLC Subroutine : **G_Ana_Stop**					
		C			
		C	the pump is stopped		
		C	ok for 28 and 01		
		C	ok for 28 and 01 and 16		
		C			
			PS_G_02 = 5mbarg to evacuate the venting of N2 from V_G_01 through V_G_15 and V_G_16		
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					
• Valves SV_1101_01_MV, S3CV_1103_02_MV (V_G_28 and V_G_01) are ON, S3CV_1101_01_MV (V_G_16) is OFF					
Recommendations / changes	WHEN	WHO			
HW modifications					
PLC programme modifications					
check the variables used to activate the gas loop from HMI				OK to do	
HMI modificatinos					
local					
change the colours of buttons to reflect started/shut down states					
remote					
idem local					
others					



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, 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. Turbidity can still be monitored by SS-F-01.			SS_F_01 cannot be checked if functional or not, the 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_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:			
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 Bypass mode are set in ON			
• 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



	WHEN	WHO
Recommendations / changes		
HW modifications		
TS_R_01 is going out of range : to be fixed	step2	UAB
V_F_16 is not mounted correctly : to be checked	step2	
the pipes coming from the bioreactor are hot ; it should be warned on these tubes	step2	
same warning on steam pipings	step2	
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
clear identification of the line being used for the filtration		
Remote		
Variables		
others		
User Manual		

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.	10/6/08 15:07		2 blenders ON, influent tank started active gas loop ON : preactor = 80mbarg 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 –which can be useful for maint			SS_F_01 cannot be checked if functional or not, the 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 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:			
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 Bypass mode are set in ON			
• The pump PMP_F_01 starts		C	

	WHEN	WHO
Recommendations / changes		
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	UAB
	step2	
	step2	
	step2	

PLC programme modifications SHERPA

put some ranges in the parameters as an example

HMI modifications NTE

Local

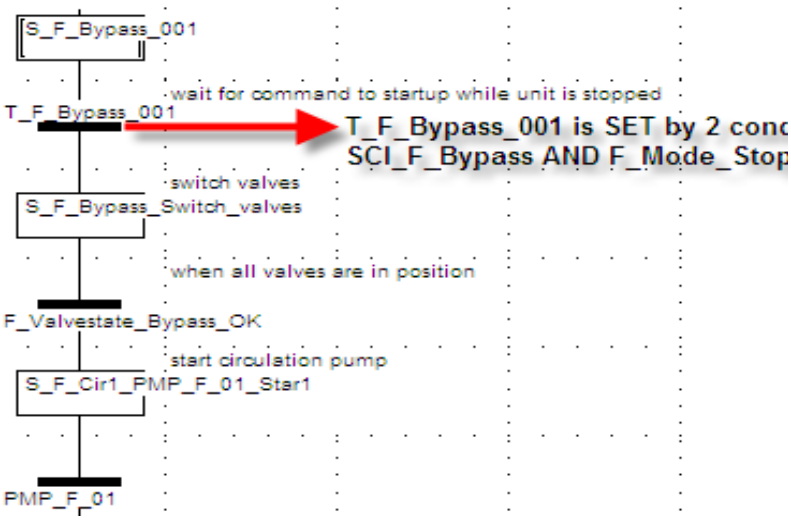
Remote

Variables

others

User Manual

put some example of ranges for the pump PMP_F_01 parameters



Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE 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.	11/6/08 10:15		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 active gas loop ON : preactor = 95mbarg passive gas loop ON analysis loop OFF		
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 –which can be useful for maint			SS_F_01 cannot be checked if functional or not, the 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 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-01 doesn´t run because some variables were manually active: SCI_PMP_F_01_RUN		
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 = 500		
			speed=31,83		
			FS_F_01=7,21 l/min		
			To stop bypass mode is necessary to activate manually SCI-F-Stop		
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:					
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 Bypass mode are set in ON					
• The pump PMP_F_01 starts		C			

Recommendations / changes

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

PLC programme modifications
put some ranges in the parameters as an example

HMI modifications
Local

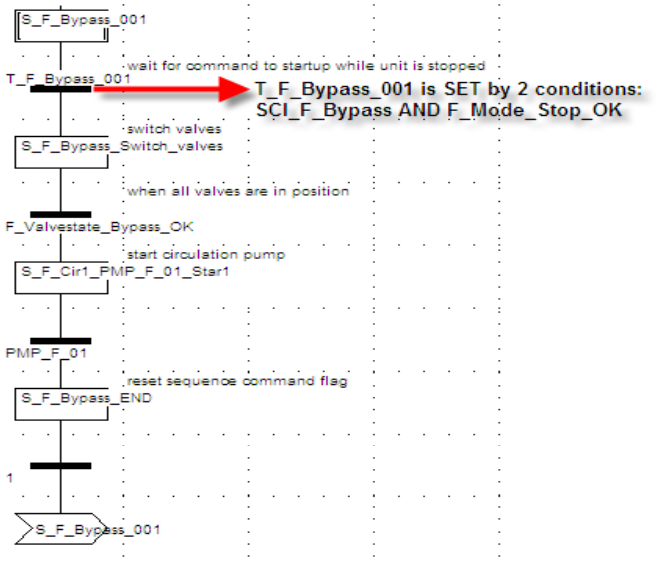
Remote

Variables

others

User Manual
put some example of ranges for the pump PMP_F_01 parameters

WHEN	WHO
step2	UAB
step2	
step2	
step2	
	SHERPA
	NTE



Procedure steps	date/hour	N/NC	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.

10/06/2008 17:56

Procedure

1. Use the HMI to start PLC procedure F_Cir1 or F_Cir2: SCI_F_Cir1 / SCI_F_Cir2
2. Wait for the PLC procedure to finish.
3. 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**

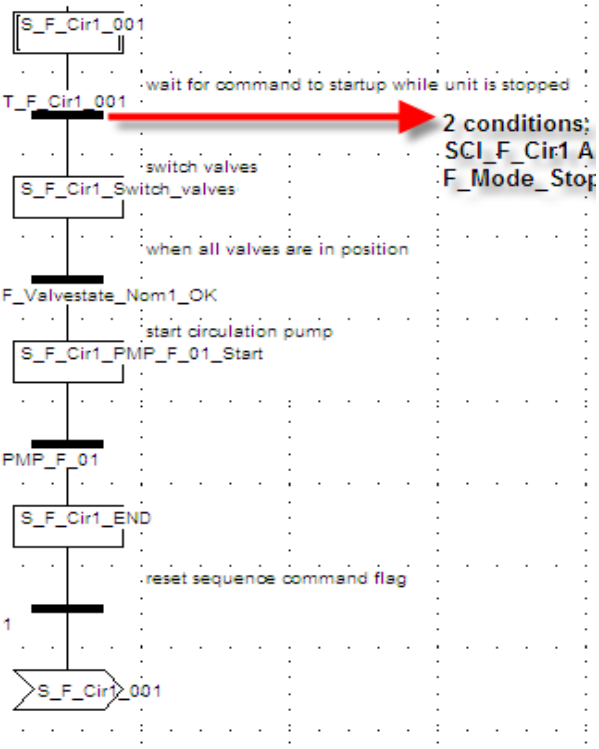
Variables Used (I/O):

SV_1201_01_MV (V_F_01), S3CV_1201_01_MV (V_F_02), S3CV_1201_02 _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), 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_12), SV_1210_03_MV (V_S_13)

Description :

- Input HMI: SCI_F_Cir1
- The operation 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
- All valves involved in the filtration through membrane Fi_F_01 are set in specific state.
- The pump PMP_F_01 starts

NC the button is not working
when forcing SCI_F_Cir1 on PLC : working
flowrate_SP=500 ; speed= 31,8 ; flow=445L/h



nc FORCED THROUGH PLC

C rk : PMP_F_02 is on but it is not running

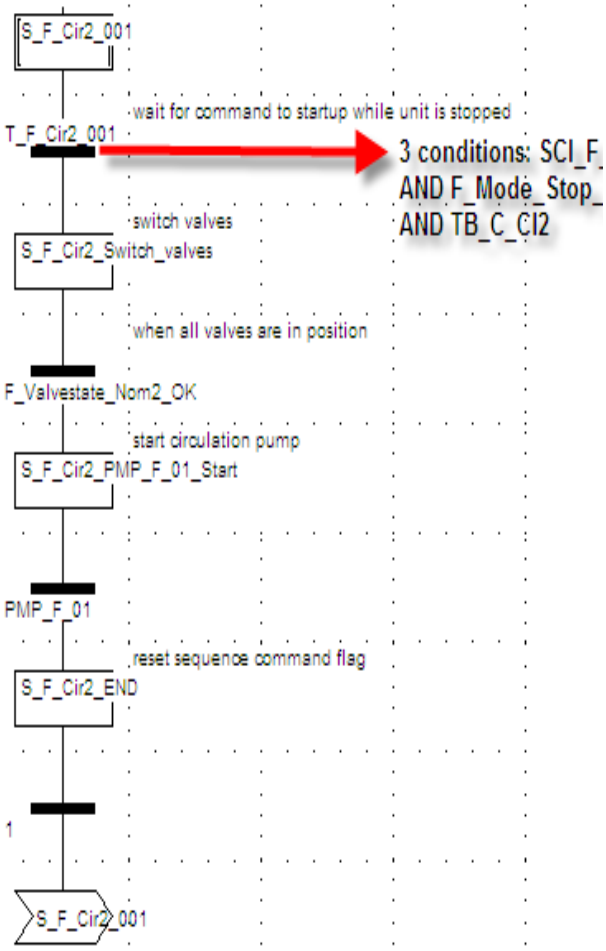
C V_F_01 and 06 ON the others OFF

C see parameters above

PLC Subroutine : **F_Cir2**

Variables Used (I/O):

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), 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)



Description :

- Input HMI: SCI_F_Cir2
- The operation begins with 3 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
  - 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**

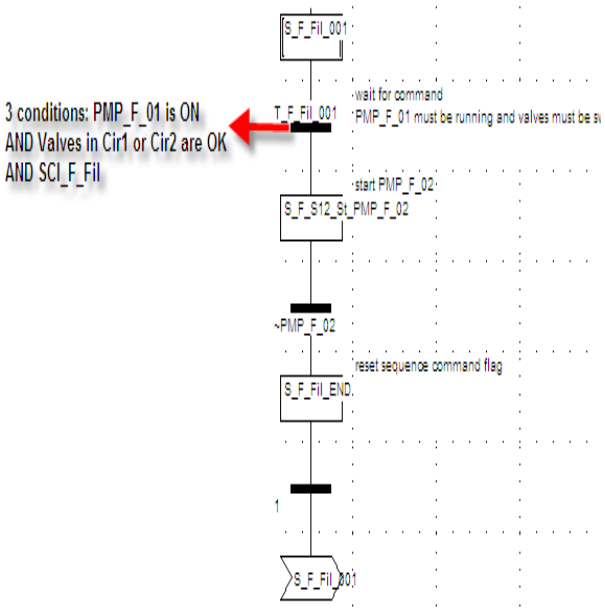
NC forced through PLC

C

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



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
  - PMP_F_01 is ON
  - The state of all valves involved (Cir1 or Cir2) is OK

variables have to be forced through PLC

C

the parameter for pump calibration

F_Filtration_flowrate_cal_factor has to be introduced

before : value=2, then SCI_F_Filtration_rate=300, and

- The pump PMP_F_02 starts
- The condition to end the procedure is that the pump PMP_F_02 is turn OFF

NC PMP_F_02_Speed=600 : the pumps is starting OK

	WHEN	WHO
<u>Recommendations / changes</u>		
HW modifications		UAB
PLC programme modifications		SHERPA
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		NTE
Variables		
others User Manual		

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

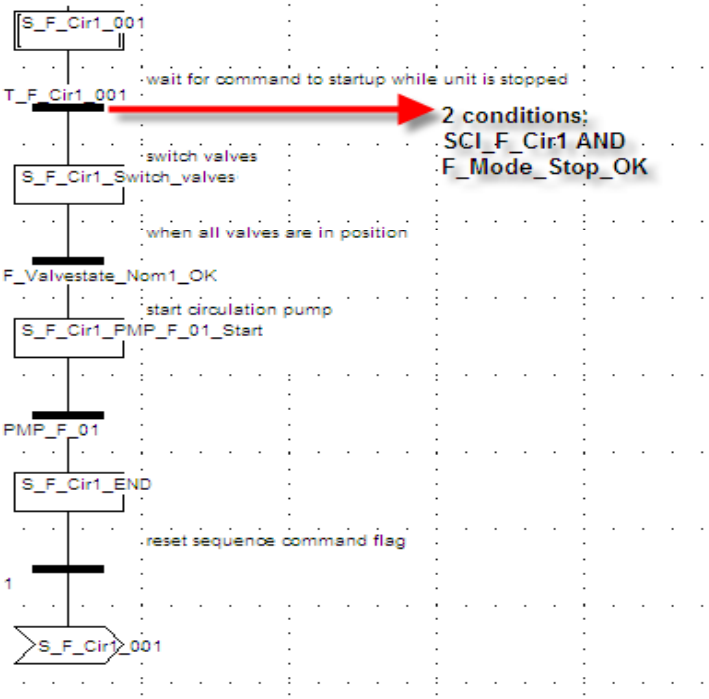
1. Use the HMI to start PLC procedure F_Cir1 or F_Cir2: SCI_F_Cir1 / SCI_F_Cir2
2. Wait for the PLC procedure to finish.
3. Use the HMI to start PLC procedure F_Fil: SCI_F_Fil
4. Wait for the PLC procedure to finish.

The FU is now in nominal filtration mode.

SCI variables : SCI_F_Cir1, SCI_F_Cir2, SCI_F_Fil

PLC Subroutine : **F_Cir1**

NC the button is not working
when forcing SCI_F_Cir1 on PLC : working
flowrate_SP=500 ; speed= 31,8 ; flow=445L/h



Variables Used (I/O):

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), 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_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

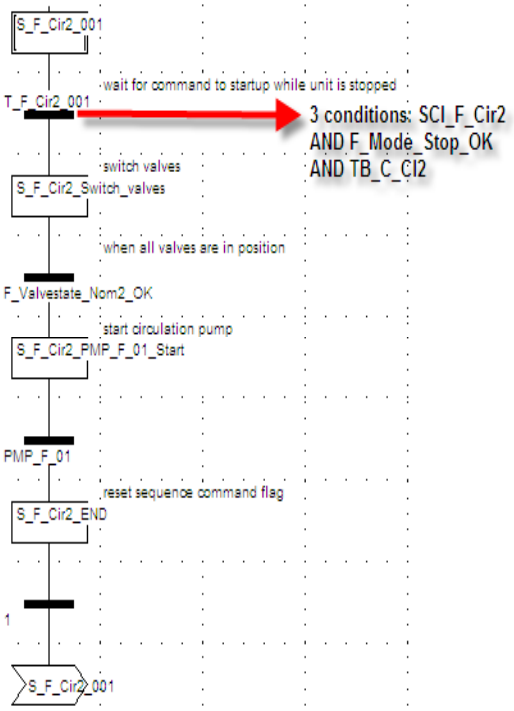
nc FORCED THROUGH PLC

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**



Variables Used (I/O):

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), 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)

Description :

- Input HMI: SCI_F_Cir2
- The operation begins with 3 conditions:
  - Use of the HMI input

11/06/2008 12:28 NC not existing in HMI ; forced through PLC

rk: PMP_F_05 is not existing anymore on the new HW

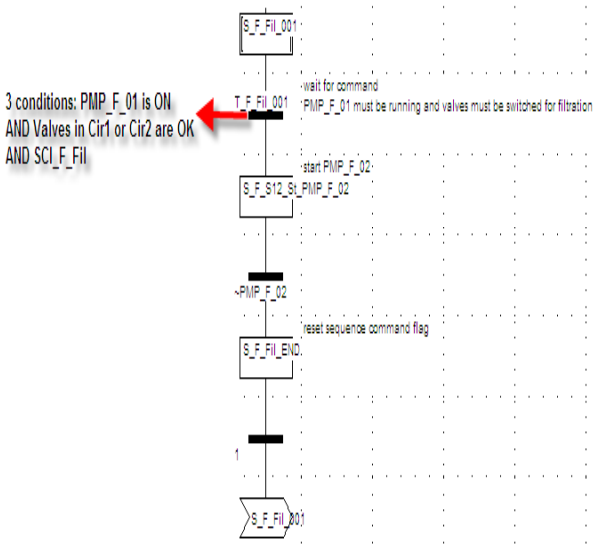
  - F_Mode_Stop_OK: all FU valves are set in OFF (closed), the pumps PMP_F_01 and PMP_F_05 are stopped and the pump PMP_F_02 is ON — C PMP_F_02 can be ON but not spinning if cal_factor=0
  - TB_C_Cl2: the tracing bit is ON — C forced through PLC
- All valves involved in the filtration through membrane Fi_F_02 are set in the specific state. — C V_F_01, 03, 04, 06 ON, the others OFF
- The pump PMP_F_01 starts — NC the pump does not start immediately
  the SCI_PMP_F_01_RUN variable has to be forced

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**

11/06/2008 12:29



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: — variables have to be forced through PLC
  - Use of the HMI input
  - PMP_F_01 is ON
  - The state of all valves involved (Cir1 or Cir2) is OK — C

- The pump PMP_F_02 starts — NC the parameter for pump calibration F_Filtration_flowrate_cal_factor has to be introduced before : value=1, then SCI_F_Filtration_rate=300, and PMP_F_02_Speed=600 : the pumps is starting OK but the relay 17 DO 24V right side in the PLC cabinet is blinking ON/OFF continuously

- The condition to end the procedure is that the pump PMP_F_02 is turn OFF — it seems this routine has no added value because PMP_F_02 is already ON from routines SCI_F_Cir1 or 2
  it seems the reason of the blinking of the relay 17

	WHEN	WHO
Recommendations / changes		
HW modifications		
		UAB
PLC programme modifications check the added value of routine SCI_F_Fil		SHERPA
HMI modifications		NTE
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_F_01 and 02		
Remote see local		
Variables		
others		
User Manual		

Procedure steps	date/hour	N/NC	comments

1.1. Procedure 36: Filtration Unit: Switch from one membrane to the other Fi-F-01 / Fi-F-02

see proc 35

Prerequisite

FU must be filtrating over one of the two membranes in nominal or in recycle mode. The membrane that is switched over from must be cleaned and preserved in clear water if it remains in the membrane module.

Procedure

Use the HMI to

1. Stop the FU: SCI_F_Stop
2. PROCEDURE 35: Filtration Unit: Start up of filtration through membrane Fi-F-01 / Fi-F-02.

SCI variables : SCI_F_Stop, SCI_F_Cir1, SCI_F_Cir2, SCI_F_Fil

PLC Subroutine : **F_Stop, F_Cir1, F_Cir2, F_Fil**

ok made through procedure 35

These subroutines are described above in PROCEDURE 29 and 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

	WHEN	WHO
Recommendations / changes		
HW modifications		UAB
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
Remote		
Variables		
others		
User Manual		

Procedure steps	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 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.

Prerequisite

FU must be filtrating over one of the two membranes in nominal mode.

missing prerequisite : V_R_10 is open!

Procedure

1. Press button 'Recycle mode' on the HMI: SCI_F_Rec, SCI_F_Rec_ERR_Level_High — 10/06/2008 18:54 — 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;

C — 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 ?

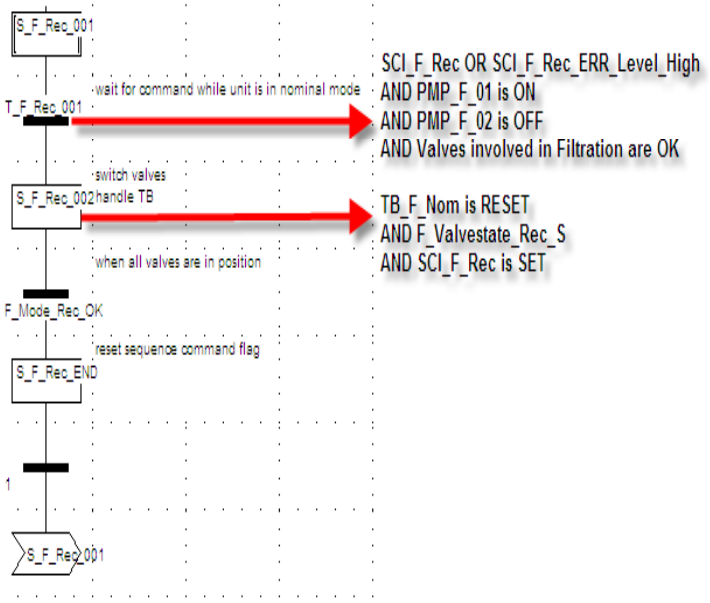
Variables Used (I/O):

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 filtrate to return to the bioreactor R_R_01 instead of harvesting it from the effluent vessel R_F_01

C



WHEN — WHO

Recommendations / changes

HW modifications — UAB

PLC programme modifications — SHERPA

HMI modifications — NTE

Local

present SCI variables on the HMI

Remote

present SCI variables on the HMI

user Manual

missing prerequisite : V_R_10 is open!

Procedure steps	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 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

11/06/2008 13:10 — 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

1. 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

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; setting OFF PMP_F_02 triggered
	NC	PMP_F_01 OFF
	C	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 ?

Variables Used (I/O):

All valves involved in the Filtration (see PROCEDURE 35), S3CV_1202_02_MV (V_F_08)

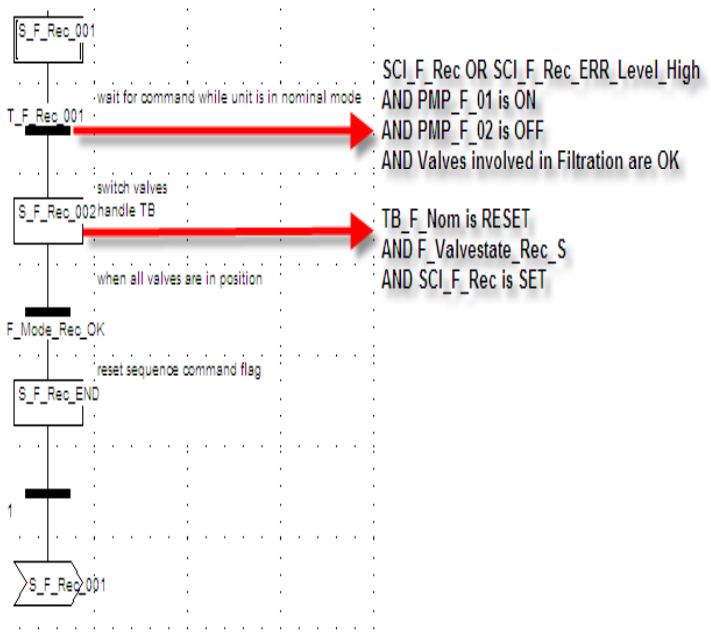
Description:

- Input HMI: SCI_F_Rec or SCI_F_Rec_ERR_Level_High

V_F_08 opened but since PMP_F_01 had stopped, not useful

- 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

NC — 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



WHEN — WHO

Recommendations / changes

HW modifications

UAB

PLC programme modifications
the recirculation mode should be activated automatically when the effluent tank is full (not programmed today)

SHERPA

HMI modifications

NTE

Local

present SCI variables on the HMI

Remote
present SCI variables on the HMI

user Manual
missing prerequisite : V_R_10 is open!

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments

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 recycle mode and the effluent vessel is harvested.

Prerequisite

FU must be filtrating over one of the two membranes in recycle mode.

FU in recylcling mode following proc 37

Procedure

1. Press button 'Nominal mode' on the HMI: SCI_F_Rec, SCI_F_Rec_ERR_Level_High — 10/06/2008 19:34

SCI 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

C

C

C

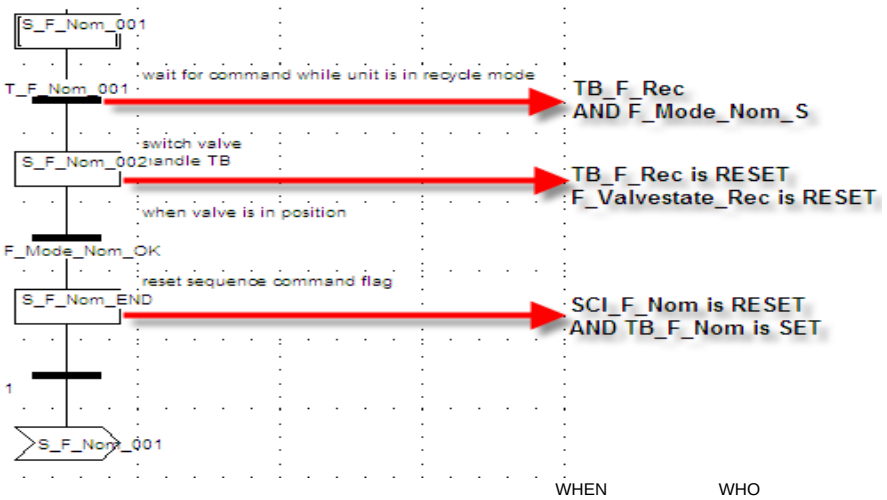
Variables Used (I/O):

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
- F_Mode_Nom_S: the valves involved in Filtration are in position
- 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.

10/06/2008 19:43 C — OK observed V_F_08 returned to OFF



WHEN — WHO

Recommendations / changes

HW modifications — UAB

PLC programme modifications — SHERPA

HMI modifications — NTE

Local

SCI_F_Rec to appear on the screen

Remote

SCI_F_Rec to appear on the screen

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments

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

Procedure

1. Press button 'Nominal mode' on the HMI: SCI_F_Rec, SCI_F_Rec_ERR_Level_High

SCI 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

C

C

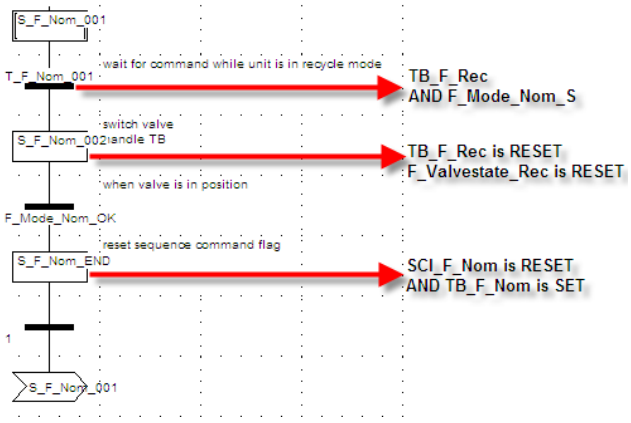
C

Variables Used (I/O):

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
- F_Mode_Nom_S: the valves involved in Filtration are in position
- 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. — 10/06/2008 19:43 — C — OK observed V_F_08 returned to OFF



WHEN — WHO

Recommendations / changes

HW modifications — UAB

PLC programme modifications — SHERPA

HMI modifications — NTE

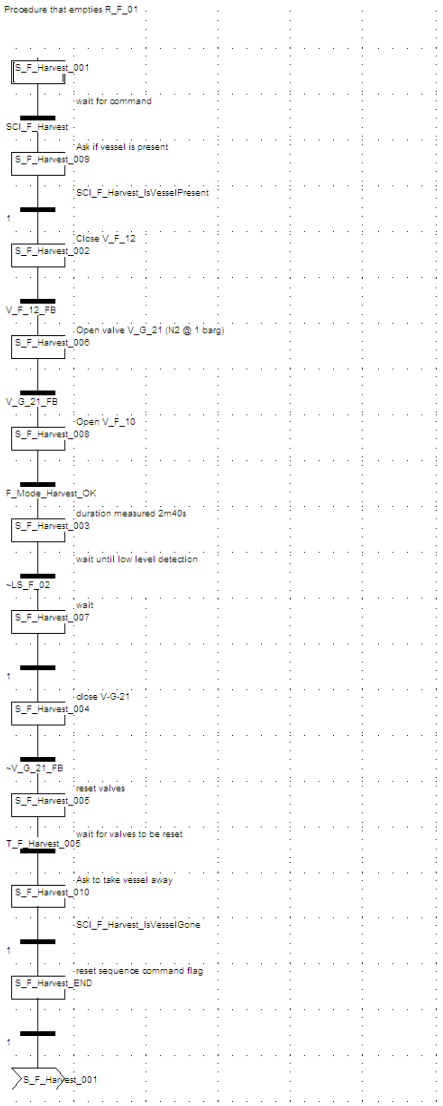
Local

SCI_F_Rec to appear on the screen

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 eventual liquid content in the effluent vessel, for instance cleaning agent left after interruption of a cleaning procedure that includes the effluent vessel.	11/06/2008 14:45		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 effluent=9,12L (LS_F_03=22,9), LS_F_01 and 02 are ON		
Procedure					
1. Make sure tubing connects V-F-10 to a vessel with >= 20 L free space.			after installation, this tubing was connected to the collector to the sewage waters		
2. Press button 'Harvest': SCI_F_Harvest		C			
3. Wait for the PLC procedure to finish. During harvesting the command button is colored green and states 'Harvesting...'					
SCI variables : SCI_F_Harvest_isVesselPresent, SCI_F_Harvest_isVesselGone					
PLC Subroutine : **F_Harvest**					
Fig : PLC procedure: F_Harvest					
			SCI_F:Harvest could be actuated from the HMI		
			SCI_F_Harvest_isVesselPresent, SCI_F_Harvest_isVesselGone are both OFF		
			V_F_10 and V_G_21 opened both		
			PS_F_09 = 0,42 barg		
		NC	SCI_F_Harvest_IsVesselPresent was OFF but did not prevent the following steps		
		C	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 valves are in position					
• The harvest begins and continue until the level switch is OFF		c			
• Valves are RESET and the harvesting vessel is taken off		c			



WHEN WHO

Recommendations / changes

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
modify the tubing downstream V_F_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

PLC programme modifications — SHERPA
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 line

HMI modifications — NTE
Local

Remote

Variables

Others
User Manual

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 40: Drain Filtration Unit: retentate line			change as Drain into Bioreactor		
Scope					
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.					
3. Stop PMP-F-01					
4. Close V-F-06.					
5. Stop PMP-F-02 and start it backwards.					
6. Close V-R-08 when gas starts entering R-R-01.					
7. Stop PMP-F-01					
8. Close V-F-01 and and V-G-20.					
SCI variables :????					
PLC Subroutine : No SFC procedure					
Variables Used (I/O):					
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.					

WHEN WHO

Recommendations / changes

HW modifications

UAB

PLC programme modifications

SHERPA

HMI modifications

NTE

Local

Remote

Variables

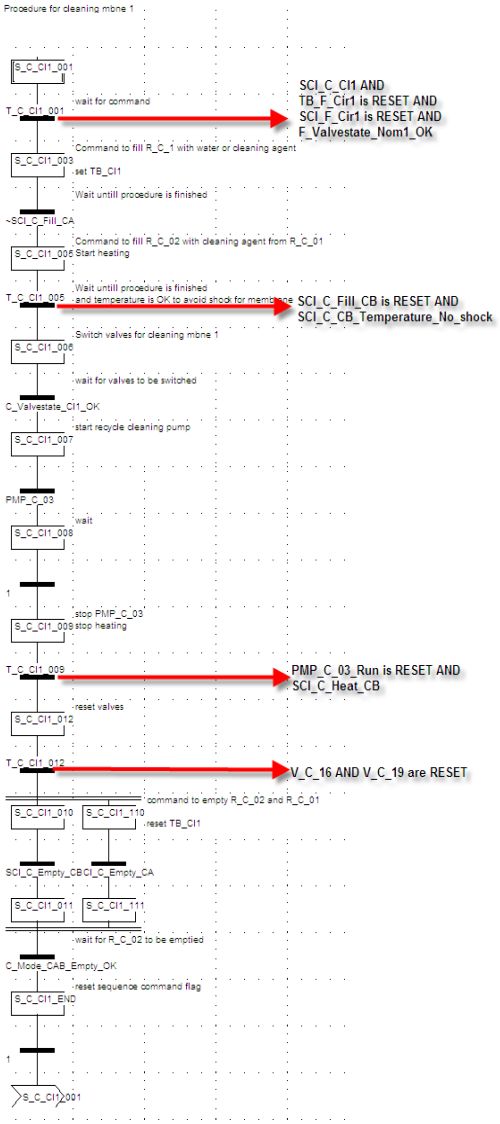
Others

User Manual

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. ***Prerequisite*** The filtration unit must not be running over the membrane that is to be drained. ***Procedure*** 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 ***SCI 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 (I/O):*** 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.					

	WHEN	WHO
Recommendations / changes		
HW modifications		UAB
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
Remote		
Variables		
Others		
User Manual		

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 49: Cleaning of Filtration Unit: retentate side of membrane Fi-F-01 / Fi-F-02					
Scope					
The aim of this procedure is to clean the inside of a membrane. It may be useful to do this on a regular time basis to slow down fouling of the membrane as described in § 7.2.4. This procedure must be used to remove retentate before use of PROCEDURE 50: Cleaning of Filtration Unit: both retentate and filtrate side of membrane Fi-F-01 / Fi-F-02.					
Automated cleaning of the membranes as described in 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.					
Procedure					
Take the precautions and advise on the membranes as they are stated in § 7.2.4.1 in account.	11/06/2008 18:30				
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)			could not be checked		
2. Set the time during which recirculation over R-C-02 is to be done.					
3. Set whether the cleaning solution is to be heated during circulation or not.					
If the use of cleaning agent is desired, fill 2L of it in R-C-03.		NC	this is not taken into account		
Use the HMI to start the procedure C_Cl1 for membrane Fi-F-01 or C_Cl2 for membrane Fi-F-02: SCI_C_Cl1, SCI_C_Cl2. This initiates the actions below:	11/06/2008 18:35				
4. R-C-01 is filled with water and - if desired - cleaning agent: SCI_C_Fill_WA or SCI_C_Fill_CA		C			
5. Content of R-C-01 is pumped into the cleaning buffer R-C-02.		C			
6. PMP-C-03 circulates the contents of the R-C-02 and the piping from V-C-16 (Fi-F-01) resp. V-C-17 (Fi-F-02) to V-C-19 (Fi-F_01) resp. V-C-18 (Fi-F-02), including the retentate side of the membrane:	11/06/2008 18:40	NC	this step has been skipped by the PLC		
7. Normal pressures are:					
8. PS-F-01 / PS-F-04 ~= 1.15 barg to 1.32 barg (increases gradually in time)					
9. PS-F-02 / PS-F-05 ~= 0.14 barg					
10. PS-F-03/ PS-F-06 ~= 0.49 barg					
11. Now cleaning agent can reach particles that could not be rinsed with water. R-C-01 is filled with cleaning agent, which is then squirted into R-R-01: SCI_C_Fill_CA					
12. When the particles are in contact with the cleaning 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 and end without cleaning agent.					
SCI variables : SCI_C_Fill_WA, SCI_C_Cl1, SCI_C_Cl2, SCI_C_PMP_C_01_P, SCI_C_Fill_CA					
PLC Subroutine : **C_Fill_WA, C_Fill_CA,**					
Variables Used (I/O): All variables involved in PROCEDURE 61 and PROCEDURE 62					
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***)		NC	this parameter did not allow to trigger PMP_C_02 to fill RC01 with cleaning agent		
PLC Subroutine : **C_Cl1**					
Fig : PLC procedure: C_Cl1					
Variables Used (I/O): PMP_C_01, V_C_05, V_C_16, V_S_02, V_F_15, V_S_04, V_C_19					
Description: No more description; the procedure is detailed enough.					
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_Cl_Cleaning_agent used to choose to fill R_C_01 with water or cleaning agent.					



Recommendations / changes

HW modifications UAB

PLC programme modifications SHERPA

HMI modifications NTE

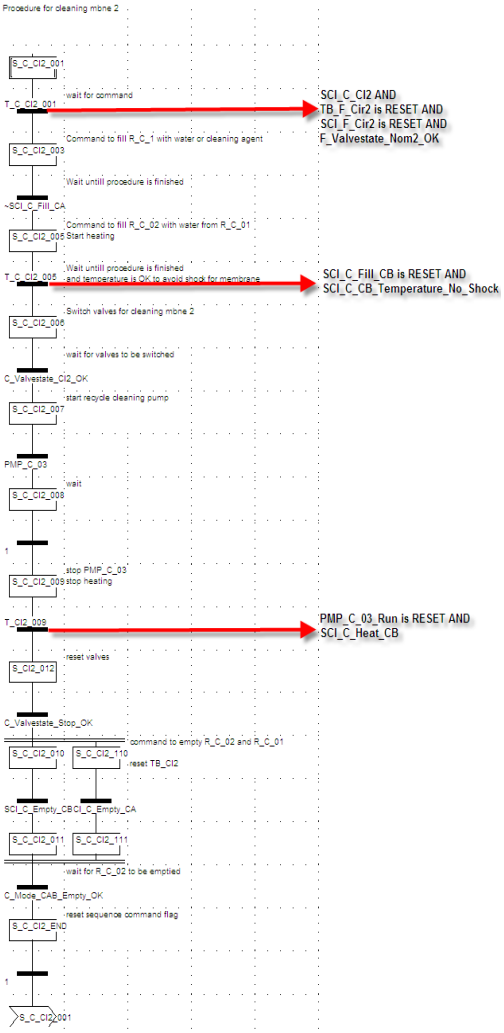
Local

Remote

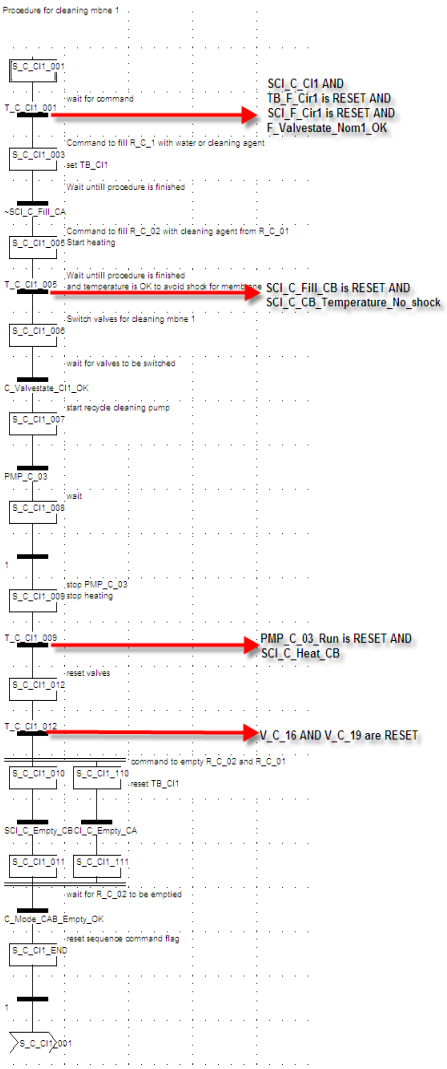
Variables

Others

User Manual



Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 49: Cleaning of Filtration Unit: retentate side of membrane Fi-F-01 / Fi-F-02					
Scope					
The aim of this procedure is to clean the inside of a membrane. It may be useful to do this on a regular time basis to slow down fouling of the membrane as described in § 7.2.4. This procedure must be used to remove retentate before use of PROCEDURE 50: Cleaning of Filtration Unit: both retentate and filtrate side of membrane Fi-F-01 / Fi-F-02.					
Automated cleaning of the membranes as described in 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.					
Procedure					
Take the precautions and advise on the membranes as they are stated in § 7.2.4.1 in account.	12/06/2008 10:00				
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)			SCI_C_Fill_CA_Detergent_Agent_Trigger should be activated in the PLC		
2. Set the time during which recirculation over R-C-02 is to be done.			Several times should be set: Variables C_CI_Time_CI1_1 to _5 should be set (initially they were set to zero by default (attention: when PLC in itializes they will get again their initial values); they were set to 1 min Delay time should also be set: C_01_		
3. Set whether the cleaning solution is to be heated during circulation or not.					
If the use of cleaning agent is desired, fill 2L of it in R C-03.		NC	this is not taken into account		
Use the HMI to start the procedure C_CI1 for membrane Fi-F-01 or C_CI2 for membrane Fi-F-02: SCI_C_CI1, SCI_C_CI2. This initiates the actions below:					
4. R-C-01 is filled with water and - if desired - cleaning 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)		
5. Content of R-C-01 is pumped into the cleaning buffer R-C-02.		C			
6. PMP-C-03 circulates the contents of the R-C-02 and the piping from V-C-16 (Fi-F-01) resp. V-C-17 (Fi-F-02) to V-C-19 (Fi-F_01) resp. V-C-18 (Fi-F-02), including the retentate side of the membrane:		NC	this step has been skipped by the PLC		
7. Normal pressures are:					
8. PS-F-01 / PS-F-04 ~= 1.15 barg to 1.32 barg (increases gradually in time)			Pressures during recirculation: PS_F_01: 0,92; PS_F_02: 0,48; PS_F_03: 0,65 (membrane not installed)		
9. PS-F-02 / PS-F-05 ~= 0.14 barg					
10. PS-F-03/ PS-F-06 ~= 0.49 barg					
11. Now cleaning agent can reach particles that could not be rinsed with water. R-C-01 is filled with cleaning agent, which is then squirted into R-R-01: SCI_C_Fill_CA					
12. When the particles are in contact with the cleaning 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 and end without cleaning agent.					
SCI variables : SCI_C_Fill_WA, SCI_C_CI1, SCI_C_CI2, SCI_C_PMP_C_01_P, SCI_C_Fill_CA					
PLC Subroutine : **C_Fill_WA, C_Fill_CA,**					
Variables Used (I/O): All variables involved in PROCEDURE 61 and PROCEDURE 62					
Description: To choose whether WATER or CLEANING AGENT is used for Filling R-C-01, there i a concept variable: **C_CI_Cleaning_agent** (***C_CI_Cleaning_agent=ON*** , then R-C-01 is filled with ***Cleaning agent*** and ***C_CI_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		
PLC Subroutine : **C_CI1**					
Fig : PLC procedure: C_CI1					
Variables Used (I/O): PMP_C_01, V_C_05, V_C_16, V_S_02, V_F_15, V_S_04, V_C_19					
Description: No more description; the procedure is detailed enough.					
PLC Subroutine : **C_CI2**					
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.					



Recommendations / changes

HW modifications UAB

PLC programme modifications SHERPA

HMI modifications NTE

Local

SCI_C_Fill_CA_Detergent_Agent_Trigger should be activated by a pulse in the HMI

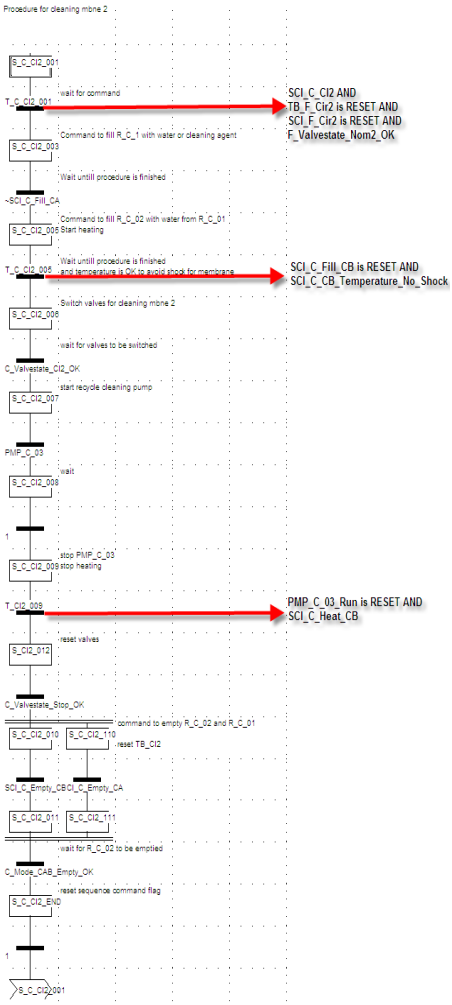
Variables C_CI_Time_CI1_1 to _5 should be set maybe through the local HMI: decissions for cleaning should be fine-tuned by the user from time to time

Remote

Variables

Others

User Manual



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				
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. If the use of cleaning agent is desired, fill 2L of it R-C-03.					
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 initiates the actions below:					
3. R-C-01 is filled with water and - if desired - cleaning agent: SCI_C_Fill_CA		C			
4. 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 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		C			
Normal pressures are:					
• PS-F-01 / PS-F-04 = 0 barg					
• PS-F-02 / PS-F-05 ~= 0 barg					
• PS-F-03 / PS-F-06 ~= 1 barg					
Remove cleaning agent by execution of this procedure with clear water					
SCI variables: SCI_C_BCI1, SCI_C_BCI2, SCI_C_PMP_C_01_P, SCI_C_Fill_CA					
PLC Subroutine: **C_Fill_CA**					
This PLC subroutines is described in PROCEDURE 61					
Variables Used (I/O):					
All variables involved in PROCEDURE 61					
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					
PLC Subroutine: **C_BCI1**					
	12/06/2008				
Fig : PLC procedure: C_BCI1					
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					
PLC Subroutine: **C_BCI2**					

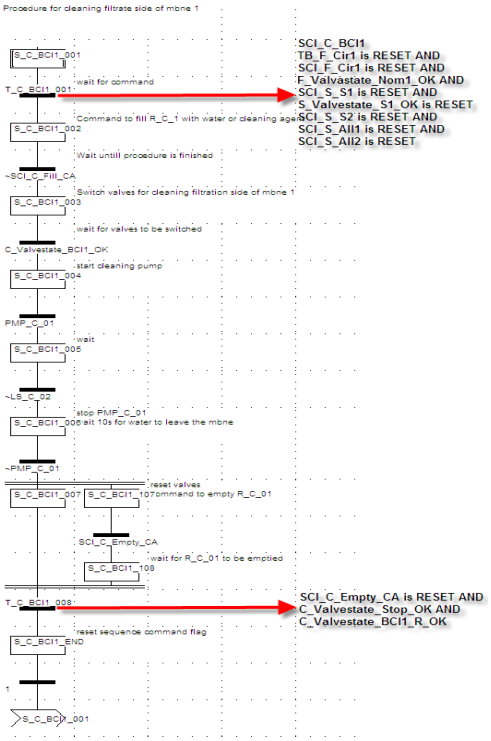
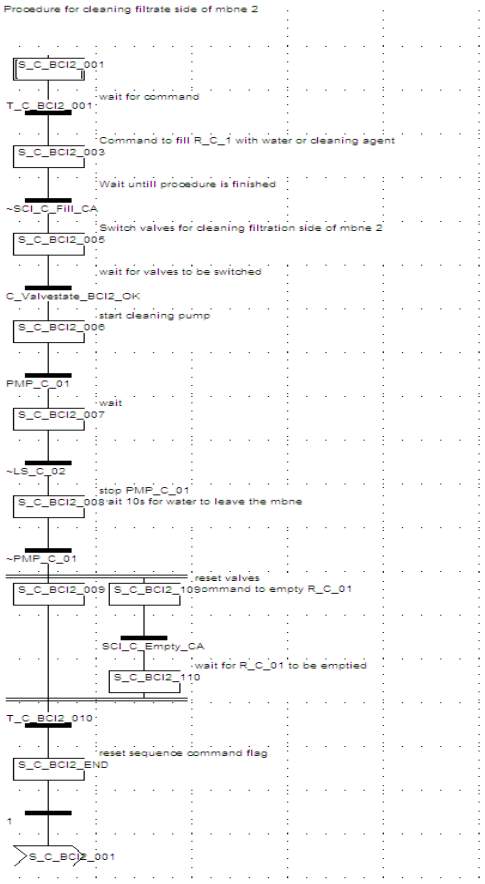


Fig : PLC procedure: C_BCI2



Variables Used (I/O):
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.

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 UAB

PLC programme modifications SHERPA

HMI modifications NTE

Local

Remote

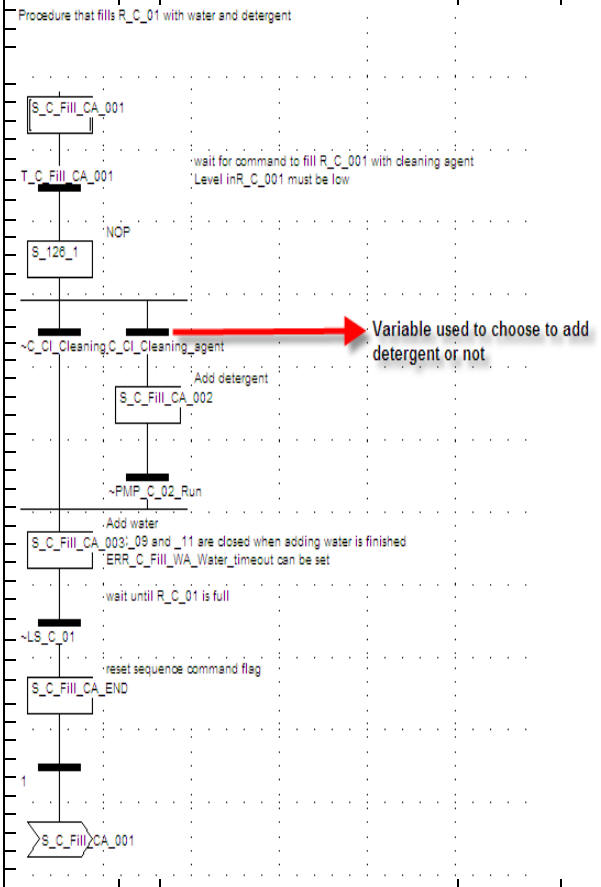
Variables

Others

User Manual

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

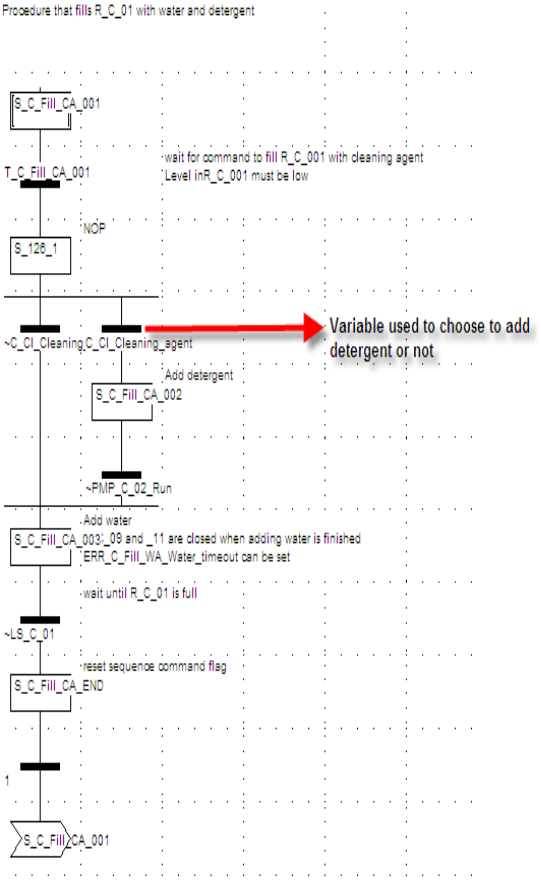
Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 61: Fill cleaning agent into R-C-01					
Scope					
Fill cleaning agent from R-C-03 into R-C-01 and fill it up with water.	12.06.08 12:30				
This procedure can be seen as a 'sub-procedure' in the PLC code that is called from other procedures. It can also be called manually on the HMI.			SCI_C_Fill_CA_Detergent_Trigger should be activated first in the PLC in order to fill the CA before the water PMP_C_03 is run during a time, whereas filling of water is done untile high level is reached (LS-C-01) C_CI_Cleaning_Agent_S should be also activ		
Procedure 1. Fill cleaning agent into R-C-03. 2. Use the HMI to start PLC procedure C_Fill_CA: SCI C Fill CA 3. Wait for the PLC procedure to finish.					
SCI variables : SCI_C_Fill_CA					
PLC Subroutine : **C_Fill_CA**					
Fig: PLC procedure: C_Fill_CA					
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 detailed enough.					



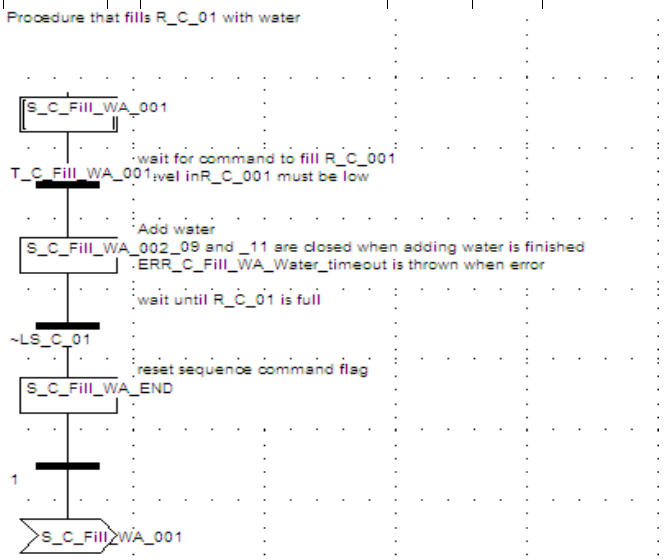
	WHEN	WHO
Recommendations / changes		
HW modifications		UAB
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
Remote		
Variables		
Others		
User Manual		

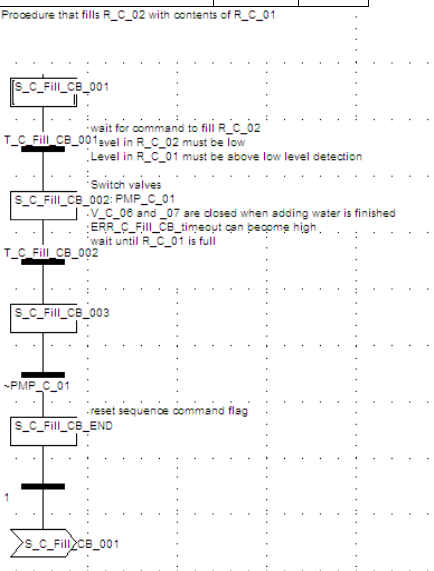
Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 61: Fill cleaning agent into R-C-01					
Scope					
Fill cleaning agent from R-C-03 into R-C-01 and fill it up with water.					
This procedure can be seen as a 'sub-procedure' in the PLC code that is called from other procedures. It can also be called manually on the HMI.		NC	not working : this triggers the addition of water without use of PMP_C_02 (cf. Proc 62)		
		C	OK there was a problem of forced variable preventing the good implementation		
Procedure					
1. Fill cleaning agent into R-C-03.					
2. Use the HMI to start PLC procedure C_Fill_CA: SCI_C_Fill_CA					
3. Wait for the PLC procedure to finish.					
SCI variables : SCI_C_Fill_CA					
PLC Subroutine : **C_Fill_CA**					
Fig: PLC procedure: C_Fill_CA					
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 detailed enough.					

	WHEN	WHO
Recommendations / changes		
HW modifications		UAB
PLC programme modifications		SHERPA
OK working		
HMI modifications		NTE
Local		
add the button to make it ?		
Remote		
Variables		
Others		
User Manual		



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 PLC code that is called from other procedures. It can 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.					
SCI variables : SCI_C_Fill_WA					
PLC Subroutine : **C_Fill_WA**					
Fig: PLC procedure: C_Fill_WA					
Variables Used (I/O): LS_C_02, LS_C_01, V_C_09, V_C_11					
Description: No more explanation, the procedure is detailed enough.					
1.2. Procedure 63: Fill Cleaning agent into R-C-02					
Scope					
Fill the contents from R-C-01 into R-C-02.					
This procedure can be seen as a 'sub-procedure' in the PLC code that is called from other procedures. It can also be called manually on the HMI.	11/06/2008 18:00		initial conditions :R_C_01 full up to high level , R_C_02 empty low level		
Prerequisite					
R-C-01 must contain water or cleaning agent					
Procedure					
1. Use the HMI to start PLC procedure C_Fill_CB: SCI_C_Fill_CB		NC	does not exist on HMI, forced on PLC		
2. Wait for the PLC procedure to finish.					
SCI variables : SCI_C_Fill_CB					
PLC Subroutine : **C_Fill_CB**					
Fig: PLC procedure: C_Fill_CB					
		C	low level in R_C_02, high level in R_C_01		
		C	PMP_C_01 starts		
		NC	wait until R_C_02 is full		
		C	when LS_C_03 is triggered, PMP_C_01 stops		
		NC	before PMP_C_01 stopped, appeared some sparkles inside the electrical cabinet on K4 contactor		
Variables Used (I/O): 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 detailed enough.					





	WHEN	WHO
Recommendations / changes		
HW modifications check contactor K4 in the FU electrical cabinet		NTE/UAB
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
Remote		
Variables		
Others		
User Manual		

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
4. Content of R-C-01 is pumped into the cleaning buffer R-C-02.
5. Valves V-C-14, V-C-15, V-F-02 and V-F-05 are activated.
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.
7. R-C-02 is to be rinsed afterwards. Use PROCEDURE 65: Rinse R-C-02: 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 variables: SCI_C_CLPMP, 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** (***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**

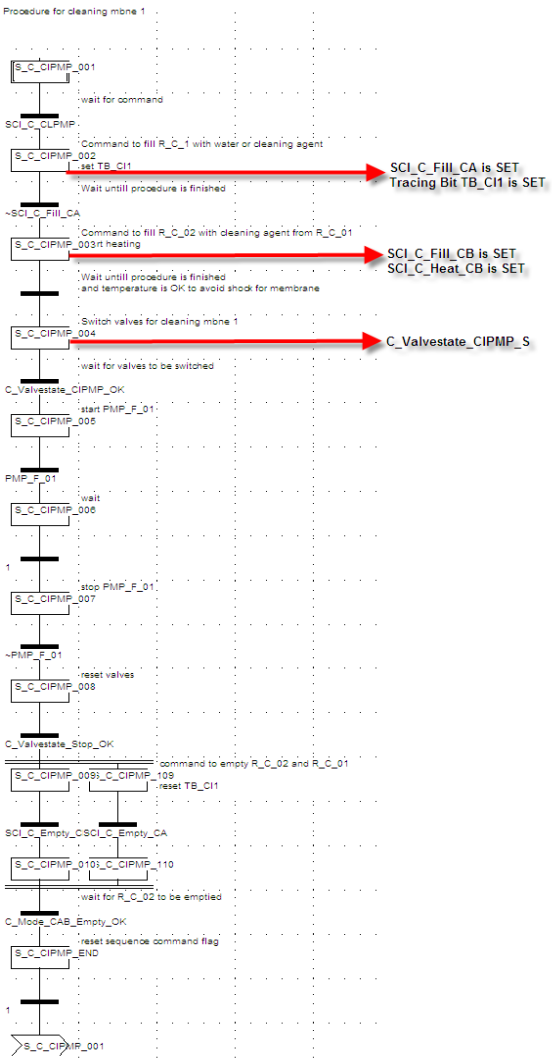


Fig: PLC procedure: C_CLPMP

12/06/2008 C

C

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_Cl_Cleaning_agent used to choose to fill R_C_01 with water or cleaning agent

Recommendations / changes

HW modifications

UAB

PLC programme modifications

step 7 is empty to be completed

SHERPA

HMI modifications

Local

NTE

Remote

Variables

Others

User Manual

1.1. Procedure 52: Cleaning of Filtration Unit: backwashing membrane Fi-F-01 / Fi-F-02 using water or cleaning agent

Scope:

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 51: Cleaning of Filtration Unit: backwash membrane Fi-F-01 / Fi-F-02. Furthermore, PROCEDURE 51 implies removal of F-F-03. This procedure uses water or cleaning agent in R-C-01 and the power of PMP-C-01 to achieve a better flow shock. Do not use cleaning agent.

Prerequisite:

FU must be stopped or be working over the other membrane. Retentate side of the membrane to be backwashed must be rinsed before (use PROCEDURE 49: Cleaning of
Filtration Unit: retentate side of membrane Fi-F-01 / Fi-F-02. If not, drain to V-F-14 or -15 may get clogged.

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.

Use the HMI to start the procedure C_BW1 (Fi-F-01) or C_BW2 (Fi-F-02): SCI_C_BW1 or SCI_C_BW2. This initiates the actions below:

2. R-C-01 is filled with water and - if desired - cleaning agent: SCI_C_Fill_CA
3. Valves V-C-21, V-C-13 and V-F-15 are activated. NC VC19 not VF15
4. PMP-F-01 is activated: SCI_PMP_F_01_RUN

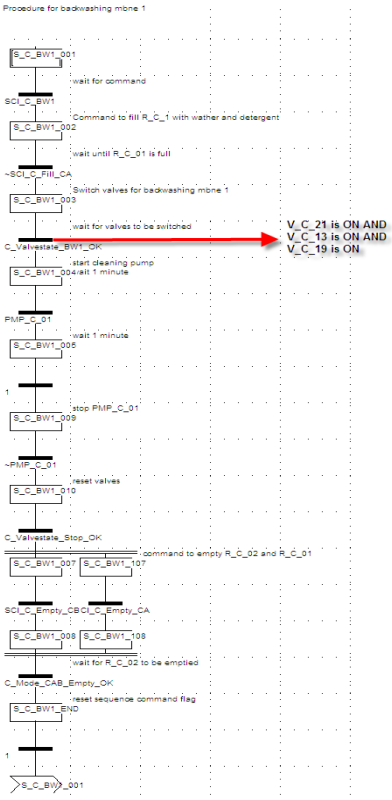
If this procedure is used with cleaning agent, use PROCEDURE 64: Rinse R-C-01 and then this procedure again without cleaning agent in order to remove any cleaning agent from the FU piping and the membrane.

SCI variables : SCI_C_BW1, SCI_C_BW2, SCI_PMP_F_01_RUN, SCI_C_Fill_CA

PLC Subroutine : **C_Fill_CA,**
These PLC subroutines are described in PROCEDURE 61

Variables Used (I/O):
All variables involved in PROCEDURE 61

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_BW1**

Fig: PLC procedure: C_BW1

12/06/2008	c	filled with water in 30s
	c	backwasing paramter was changed from 10 min to 2 min for the test

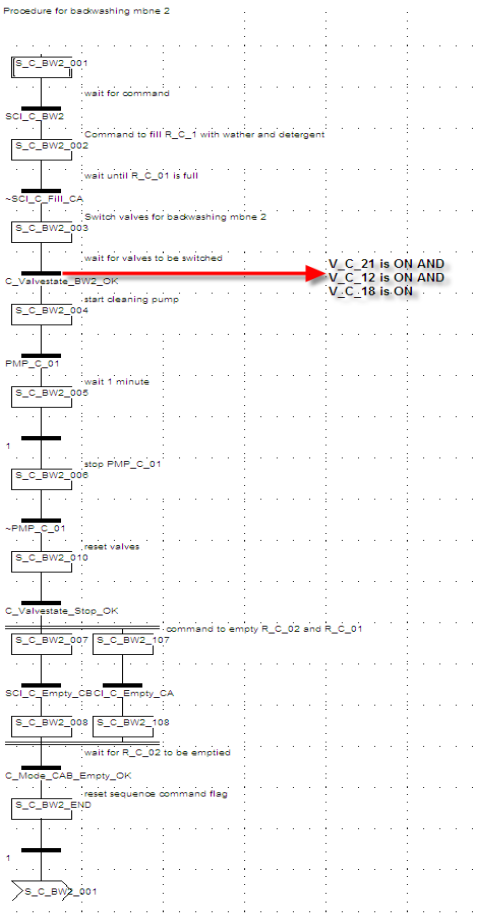
Variables Used (I/O):
V_C_21, V_C_13, V_C_19, PMP_C_01, V_S_04, V_S_06, V_F_15

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

PLC Subroutine : **C_BW2**

Fig: PLC procedure: C_BW2

	C	full in 33s
	C	validation of proc 58 and 59
	NC	error reset BW1 instead of BW2



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

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

HW modifications

UAB	

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

SHERPA	

HMI modifications
Local
add buttons on screen

NTE	

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

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 C
3. Valves V-C-04, V-C-11, V-F-10, V-F-12 and V-F-08 are activated. C
4. PMP-C-01 pushes the contents of the R-C-01 through the nozzle No-C-03 into R-F-01. C
5. R-F-01 is harvested. NC not working to be rewritten

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 : SCI_C_R_F_01, SCI_C_R_F_01_IsCleaningAgent, SCI_F_Harvest, 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** (***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_R_F_01**

Fig: PLC procedure: C_R_F_01

Recommendations / changes

HW modifications

PLC programme modifications
to be rewritten because does not work

HMI modifications
Local
adapt it

Remote

Variables

Others
User Manual

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_Cl_Cleaning_agent used to choose to fill R_C_01 with water or cleaning agent.

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 ?

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

Others
User Manual

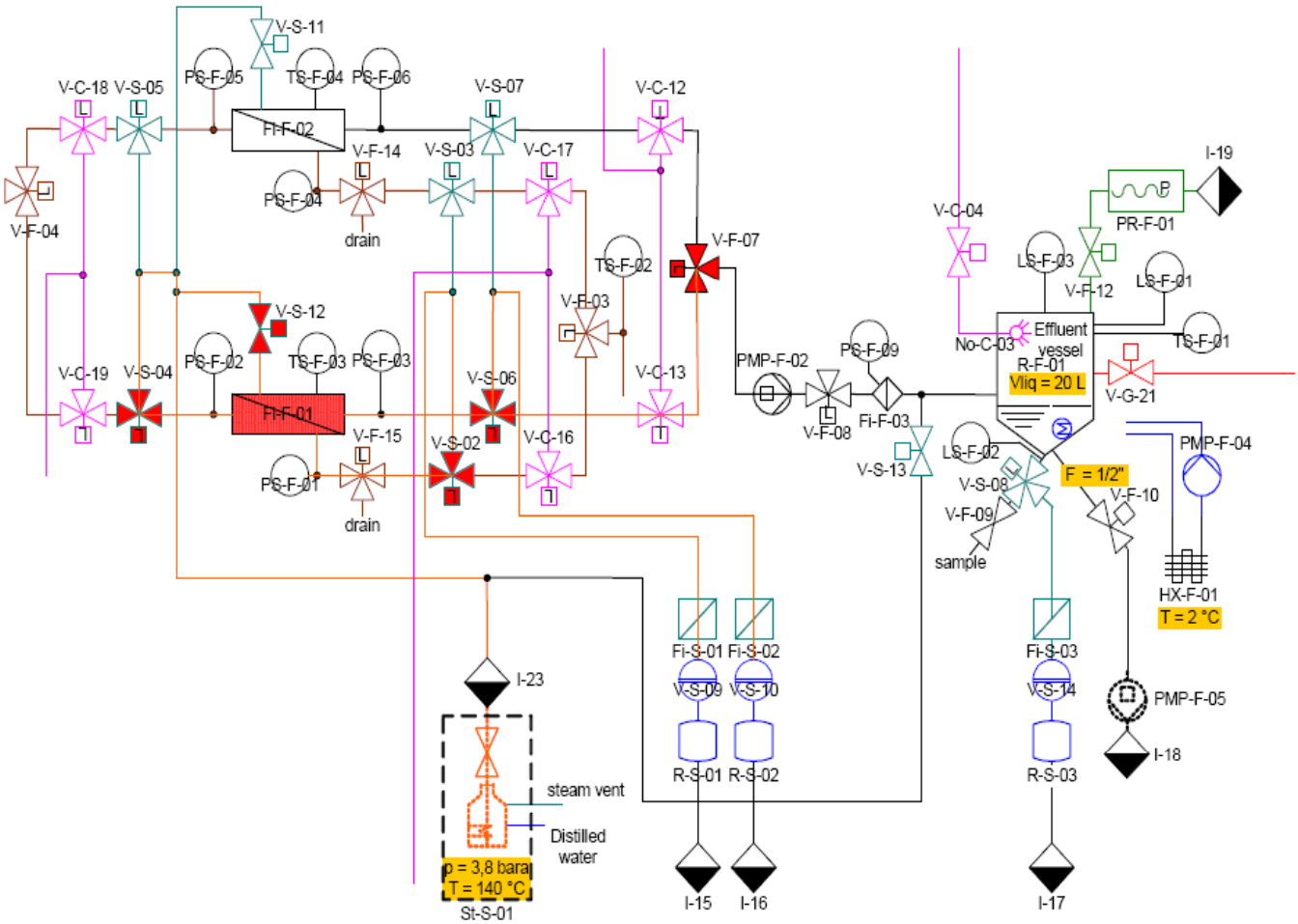
1.1. Procedure 68: SIP: membrane Fi-F-01 / Fi-F-02

13/06/2008

Scope

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 l 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

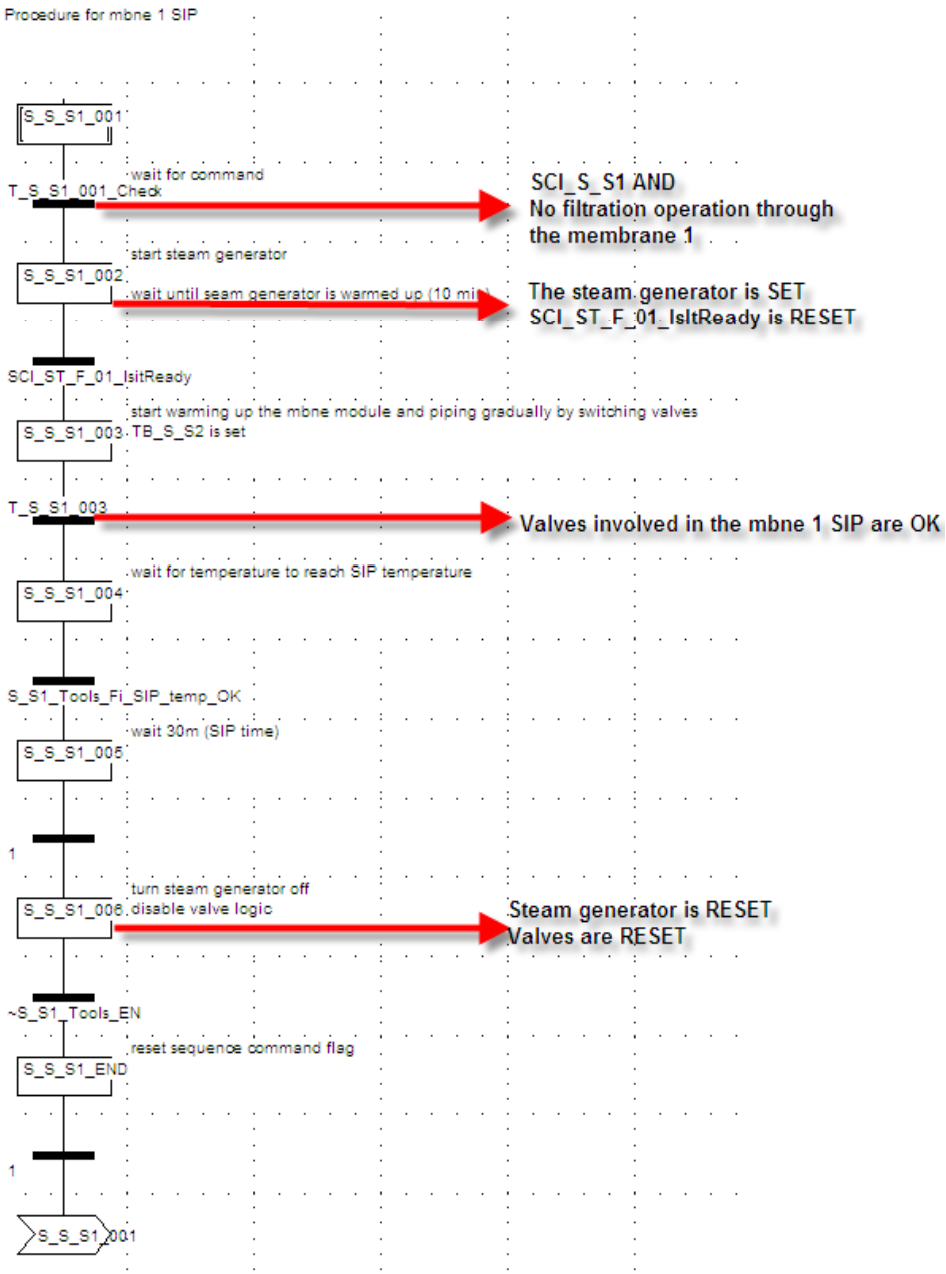
be depressurized using PROCEDURE 67: SIP: Release pressure in St-S-01

SCI variables : SCI_S_S1, SCI_S_S2, SCI_ST_F_01_IsItReady

PLC Subroutine : **S_S1**

12-jun	C	routine checked without steam
13-jun	C	routine checked with steam

Fig: PLC procedure: S_S1

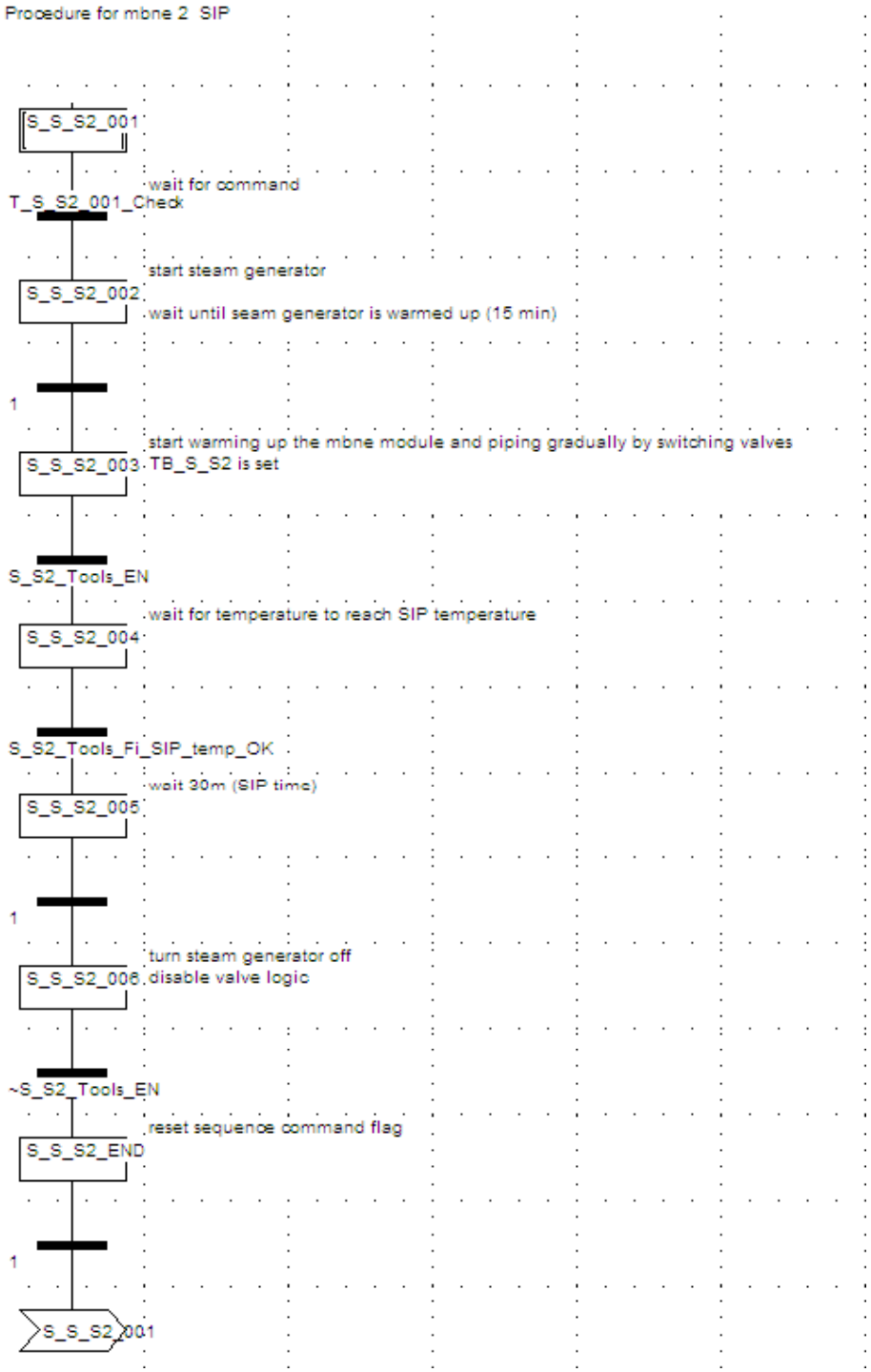


Variables Used (I/O):
V_S_02, V_S_03, V_S_05, V_S_06, V_S_08, V_S_07, V_S_11, V_S_13, V_F_03, V_F_04, V_F_07, V_F_15, ST_S_01

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

PLC Subroutine : **S_S2** 12-jun C checked without steam

Fig: PLC procedure: S_S2



13-jun
ALSO TESTED : EMERGENCY SHUTDOWN PROC67

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

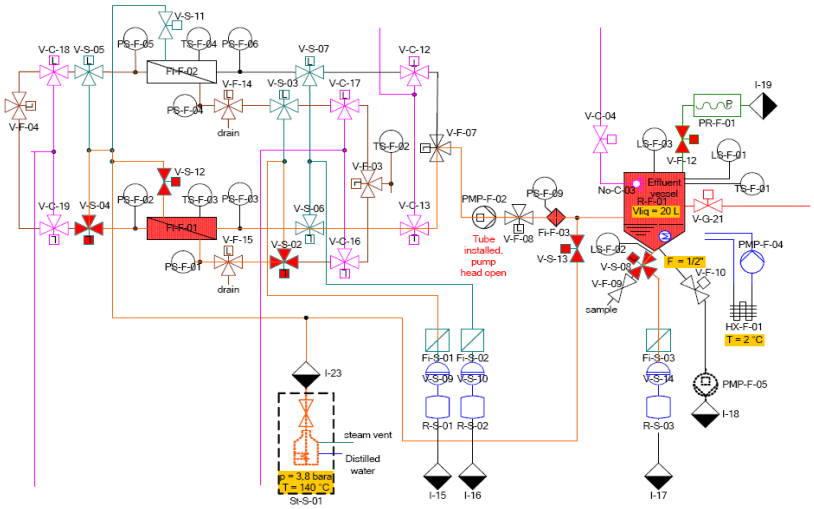
User Manual

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

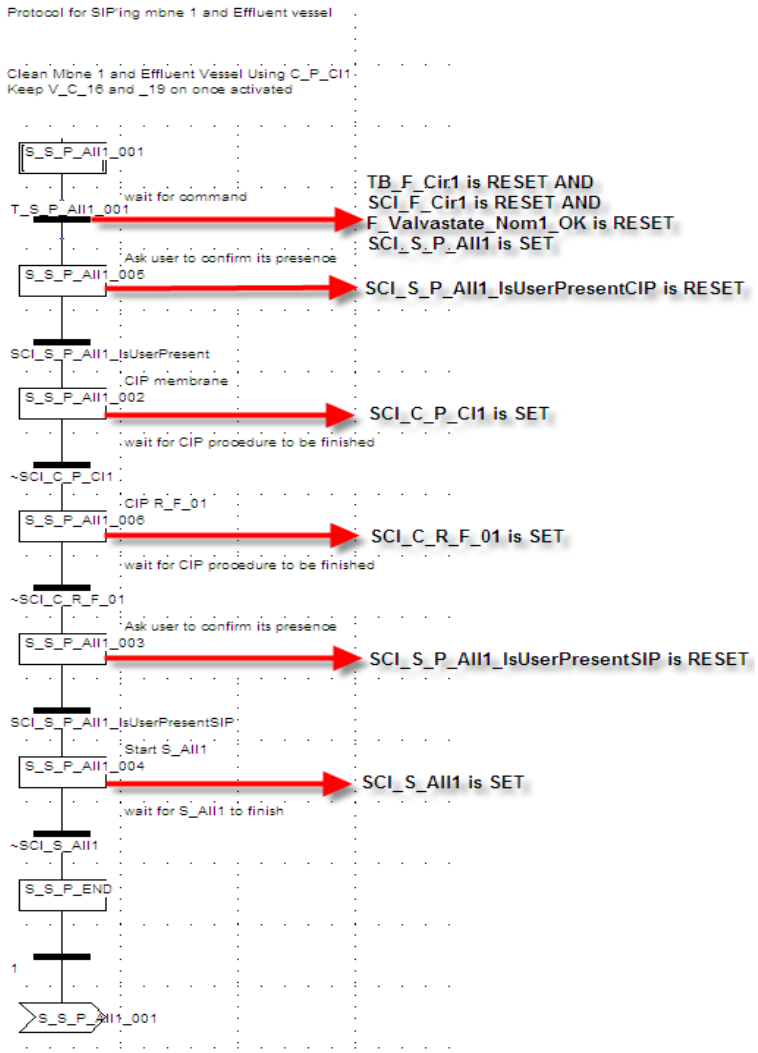
Protocol

1.	Fill the steam generator St-S-01 with 8 l tap water.	13/06/2008	
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-All1 /S-All2 in the PLC): SCI_S_P_All1, SCI_S_All1 / SCI_S_All2	C	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	
6.	Let the PLC know that tSt-S-01 is ready by indicating this on the HMI: 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 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_All1_IsPMP_F_02_Closed

PLC Subroutine : **C_S_P_All1 (protocol)**

Fig: PLC protocol: C_S_P_All1

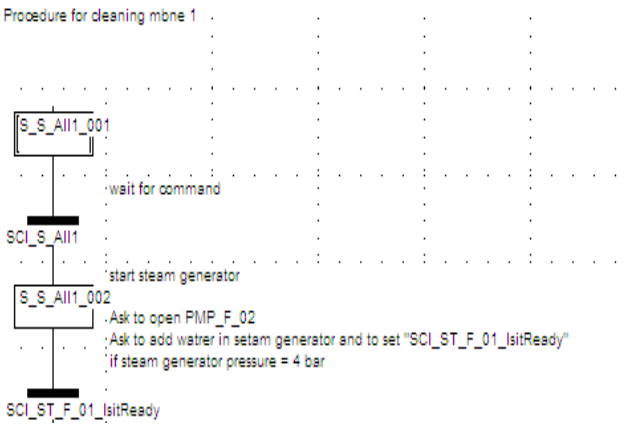


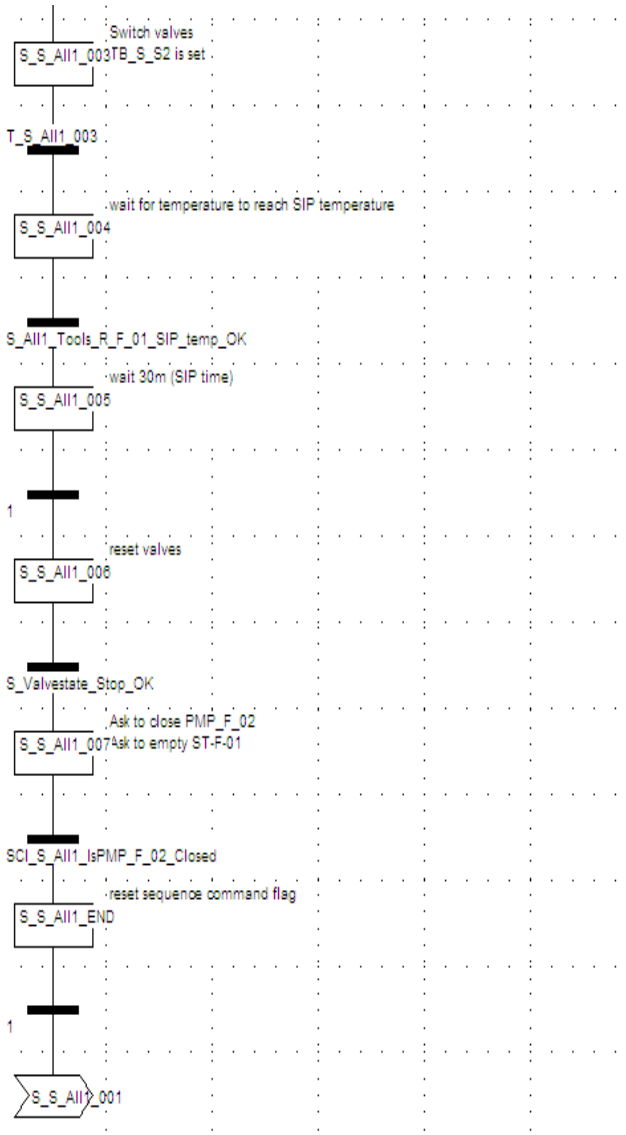
Variables Used (I/O):
All variables involved in PROCEDURE 56 and PROCEDURE 54

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_All1** 13/06/2008 C checked without steam

Fig: PLC procedure: C_S_All1





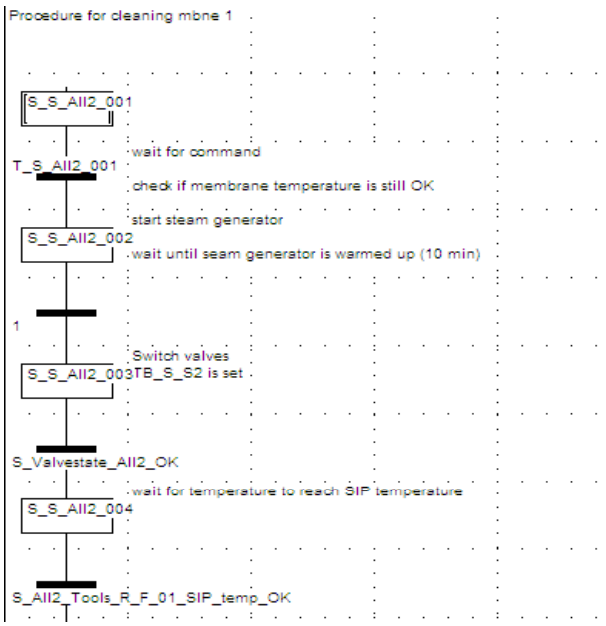
Variables Used (I/O):
V_S_02, V_S_06, V_S_03, V_S_08, V_S_07, V_S_05, V_S_11, V_F_03, V_F_04,

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

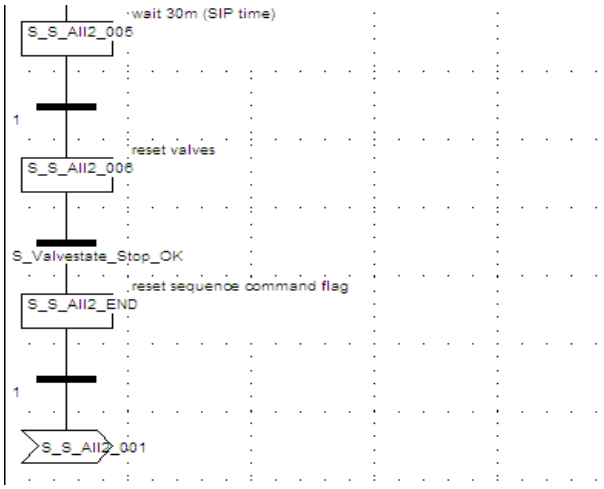
Description: The current procedure is used in the main SIP protocol.

PLC Subroutine : **C_S_All2**

Fig: PLC procedure: C_S_All2



nc nc this transition does not work



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 2nd 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

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 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 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

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE 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.					
3. 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 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		
4. These procedures open the respective drain valve V_F_15 or 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		
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 membrane. It leaves the system via the drain valve.					
6. Wait for the PLC procedure to finish.					
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.					

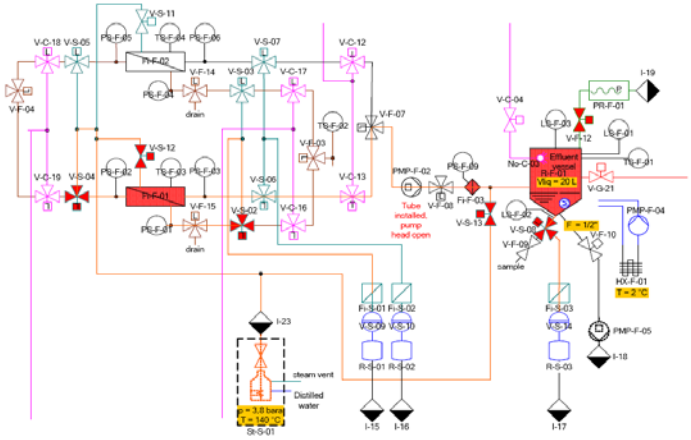
	WHEN	WHO
Recommendations / changes		
HW modifications		
		UAB
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
Remote		
Variables		
Others		
User Manual		

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.

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 l tap water.	16/06/2008	
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-All1 /S-All2 in the PLC): SCI_S_P_All1, SCI_S_All1 / SCI_S_All2	C	it was checked with 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	
6. Let the PLC know that tSt-S-01 is ready by indicating this on the HMI: SCI_ST_F_01_IsItReady	NC	button or question missing, forced through PLC
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		
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_CI1, SCI_C_R_F_01, SCI_S_P_All1_IsUserPresentSIP, SCI_S_All1, SCI_S_All2, SCI_ST_F_01_IsItReady, SCI_S_All1_IsPMP_F_02_Closed

PLC Subroutine : **C_S_P_All1 (protocol)**

Fig: PLC protocol: C_S_P_All1

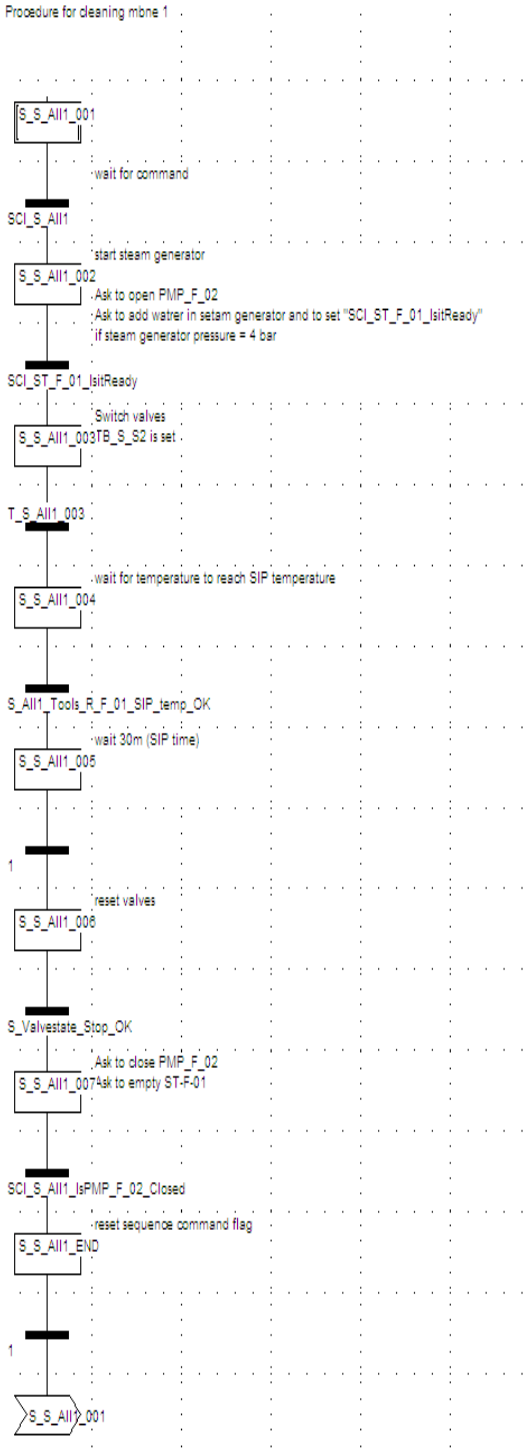
Variables Used (I/O):
All variables involved in PROCEDURE 56 and PROCEDURE 54

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_All1**

16/06/2008 C checked with steam

Fig: PLC procedure: C_S_All1



C 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

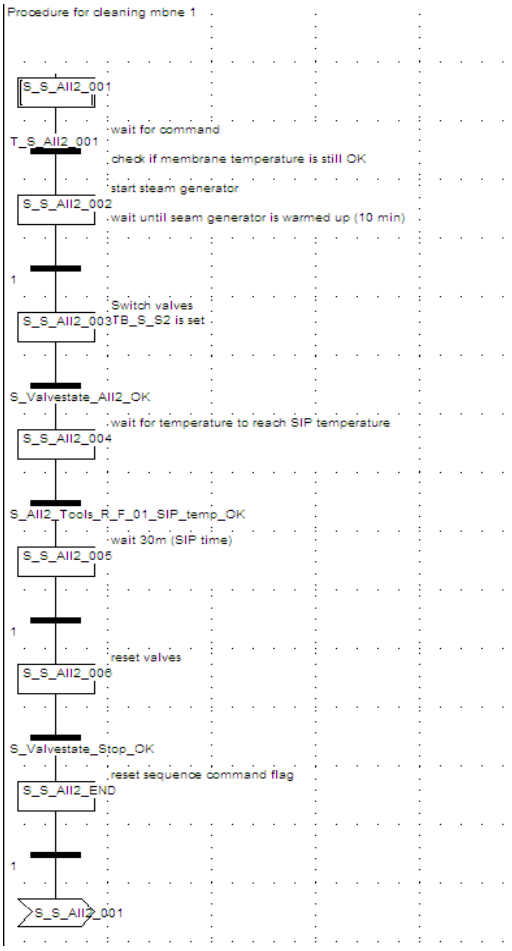
nc this question has to be asked by HMI
this operation requires PPEs

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_All2**

Fig: PLC procedure: C_S_All2



nc	nc	this transition does not work

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 2nd 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 16/06/2008

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

ANNEX 2

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 ~~YES or~~ NO Join this list with priorities	Others members MPP : Enrique Peiro, Raul Moyano SHERPA : Olivier Gerbi

First column-reference Nº is used to check points not conformed

Nº	Description	N/A	OK	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	

S-8	Rules for work at height are respected.	x		
S-9	The work zone is correctly ventilated.		x	
S-10	Peepholes on the process, flow indicators, pressure gauges etc...are 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 (65ºC)
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	

	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	X		
S-21	Adequate dispositions have been taken for handling gas cylinders and other mobile containers	X		
S-22	Gas cylinders are stored in such a way they can be transferred in safety	X		
S-23	Gas flammable cylinders are stored separately	X		

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 ~~YES or~~ NO Join this list with priorities	Others members MPP : Enrique Peiro, Raul Moyano SHERPA : Olivier Gerbi

First column-reference Nº is used to check points that are non compliant

Nº	Description	N/A	OK	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	x		
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	x		
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

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	Result			Remarks
	NA	Y	N	
1. Standards and operating procedures referring to the unit have been established and allow the unit exploitation.		X		
2. Subcontractors procedures, operational specific procedure and subcontractors standards are written in the local language used and/or understood by operators.		X		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.		X		
4. Engineering file (P¬ID, drawings, technical documents) are available and complete		X		
5. Modified documents have followed the revision/approval loop		x		

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)	X			
9. A maintenance plan is enforced for the elements important for safety.		X		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		x		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.		x		
13. The control system documentation (user manual, functional			x	User manual to be updated as a consequence of the

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.		x		
15. In case of alarm activation, the safety positions of actuators are identified and the factory acceptance tests are duly documented.		x		
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.		x		
18. Working license procedures and instructions procedure are ready for implantation.		x		
19. Protection from and detection of fire have been checked.		x		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.	X			
21. Spare parts list with their availability exist.			x	Not critical for starting of functional tests
22. Users can clearly identify the documents that are not controlled		X		

ANNEX 3

Annex 3 – CI Functional Tests Step1: Record of implied personnel

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	CB
Olivier Gerbi	SHERPA	Senior engineer	OG

ANNEX 4

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

	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.

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

Procedure steps	date/hour	N/NC	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	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 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.	26/02/2009	C	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	c	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	c	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		

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	
others			

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.		c			
			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 approximately 90 mbarg.	26-feb	NC	PI_1003_01 = 116 mbar ; PI_1103_01 =2,1barg : THIS SENSOR IS OOO		
2. Start blender BLE_1005_01 (set point: 200 rpm): SCI_BLE_1005_01		c	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 modification		
3. Set temperature setpoint (to 6°C or another value <= 7°C. Fill HX_1002_01 and double jacket with water and antifreeze compound (glycol) if this is not done yet: SCI_TT_1002_01_SP		c	temperature setpoint wasmanually set to 5,2ºC in the morning (using the added switches) in order to give time to cool down		
			change of setpoint from 5ºC to 10ºC : 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		
On initial start up, when liquid level is below connection to S3V_1001_02, GP_1001_01 will no	not c h		the initial condition of the system is that the pump was already full of water		
			to be checked again		
PLC Interface :					

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
others			

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 7: Filling Influent tank VSL2_1000_01					
Scope					
Feed influent to the influent tank.					
Prerequisite					
GP_1001_01 is active except for the initial filling.	26/02/2009	c			
HV_1000_01 is closed.	26/02/2009	C			
HV_1000_02 is closed.	26/02/2009	c			
HV_1000_03 is closed.	26/02/2009	c			
SV_1003_01 is on.	26/02/2009 16:20	c	it is controlled by the PLC but kept closed for the moment		
			PT_1003_01=120mbarg		
Procedure					
Initial filling (occurs at start-up, when the influent tank is totally empty)					
1. Connect the dedicated reservoir to valve H3V_1001_01.			Vol V ini = 55L, manual drain , final volume 51 L with PT=110mbarg, LSH1004_01 is switched off		
2. Open the valve underneath the reservoir and fill it with influent.					
3. Start-up GP_1001_01: SCI_ GP_1001_01_Right			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 frame) to bring the system into feeding mode. This can be checked on the HMI. S3V_1001_02 switches. The pump now withdraws influent and pumps it into VSL2_1000_01.	26-feb	c	Getcake S3V_1001_02 changed position : introduction of water into the influent vessel ; level and pressure readings are increasing add the indication on HMI that GetCake was activated		
4.1 Overpressure safety valve SV_1003_01 now works to vent overpressure in the influent tank without generating an alarm	26-feb	c	indeed opening could be observed to stabilize the pressure between 100 mbarg and 120 mbarg		
4.2 Because HPCV_1003_01 is not capable of releasing the added volume quickly enough.		c	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.		c			
5. Stir the contents in the reservoir and try to have the floating 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.		c			
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 S3V_1001_02 is deactivated. Valve SV_1003_01 returns to its normal function of safety valve.		c			
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)					
1. Connect the dedicated reservoir to valve H3V_1001_01.					
2. Open the valve underneath the reservoir and fill it with influent.					
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. S3V_1001_02 switches. The pump now withdraws influent and pumps it into VSL2_1000_01. Overpressure safety valve SV_1003_01 now works to vent overpressure in the influent tank without generating an alarm, because HPCV_1003_01 is not capable of releasing the added volume quickly enough. Because even with the aid of SV_1003_01 pressure in VSL2_1000_01 increases, S3V_1001_02 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 S3V_1001_02 is deactivated. Valve SV_1003_01 returns to its normal function of safety valve.		c	55L seems to be the maximum level the calibration of volume needs to be done after functional tests		
6. Close the valve underneath the reservoir. Remove the reservoir. Empty the remaining influent and rinse it.					
			done		
PLC Interface :					
SCI variables : SCI_V_GetCake SCI_ GP_1001_01_Right					
PLC Subroutine : V_GetCake (FBD)					

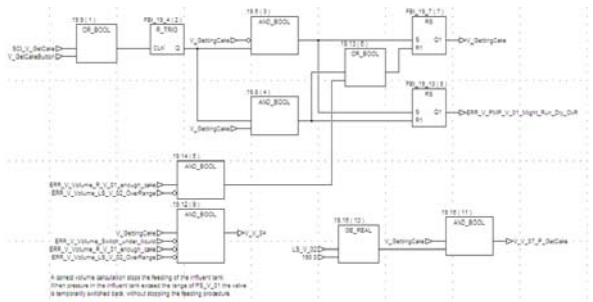


Figure 1: PLC Subroutine (FBD): V_GetCake

Variables Used (I/O):
GP_1001_01_MV1, S3CV_1001_02_MV, SV_1003_01_MV, LSH_1004_01.

Description :

- Input HMI: SCI_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 :
  - o There is not an error of High Level in the influent tank: CL1004_ERR_Vol_Switch_under_liqu is OFF.
  - o There is no alarm about Overpressure (LT_1004_01 > 200mbarg): ERR_Volume_LT_1004_01_OverRange
  - o 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 :
  - o There is not an error of High Level in the influent tank: CL1004_ERR_Vol_Switch_under_liqu is OFF.
  - o There is no alarm about Overpressure (LT_1004_01 > 200mbarg): ERR_Volume_LT_1004_01_OverRange
  - o 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 tanl

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 11: Start-up Bioreactor VSL2_1007_01					
Scope					
Initiate the functions of the bioreactor VSL2_1007_01.					
Prerequisite			why is the GP1001 01 spot on the right blinking in green?		
Bioreactor should 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 activated using the newly installed switch (no use to passs through the electrical cabinet)		
Procedure					
Use the HMI to					
1. Make sure HV_1009_01 is open and N2 is available at around 1 barg		C	working with N2 network supply regulated at 1 barg		
2. Flush N2 in the bioreactor by opening SCV_1103_01		C	this is indeed working		
3. Start blender BLE_1012_01 (set point: 220 rpm): SCI_BLE_1012_01	26/02/2009 17:00	C	change setpoint is only possible in the electrical cabinet by changing the FVC		
4. Set temperature setpoint to 55°C. Fill HX_1008_01 and double jacket with demineralized water if this is not done yet: SCI_TT_1008_01_SP		c	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 question for influent tank cooling loop) LSL 1008 01 on the HMI is not working properly : alarm on Low level, not on level higher than limit		
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 VSL2_1007_01 is too low to reach the pH probes: SCI_AT_1011_SP	26/02/2009 17:10	c	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 if pH below setpoint, no action by PP 1011 02 before lag time of 10 min (programmed in PLC), but then it works it seems the pH control is authorized only when the blender is ON		
PLC Interface :					
SCI variables:					
SCI_BLE_1012_01, SCI_TT_1008_01_SP, SCI_AT_1011_SP					
PLC Subroutine:					
Variables Used (I/O):					
SCV_1103_01_MV, BLE_1012_01_MV, TT_1008_01, TT_1008_02, AT_1011_01, AT_1011_02					
			the switching is made through _mode_timer_S or mode_volume_S		
			the role of this parameter is not really clear and could not be related to the HMI		
			what are the different roles and possibilities		
1.2. Procedure 12: **Start-up Bioreactor VSL2_1007_01 feeding**					
Scope					
Start the feeding function.			default choice for feeding should be volume based		
Prerequisite			"actual volume" should be rephrased "current volume"		
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.			initial volume 93,6 L at 72mbarg chosen mode : volume based, with 6 min=0,1h time interval		

Procedure

1. Use the HMI to set the feeding function to be timer based or volume based. As long as VSL2_1007_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 L/d). Once nominal liquid volume is reached, operator should switch over to volume based control. Nominal volume is around 100L: CL1001_SCI_Feed, CL1001_SCI_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 P>140mbarg, the feeding is switched back to Influent Tank (Pauze_Feed)

2. Enable feeding by the button on the HMI: CL1001_SCI_Feed_Enable
3. Use the HMI to set feeding to timer based and to set the amount to feed per day: CL1001_SCI_Feed_mode_timer_S, CL1001_SCI_Feed_Amount_per_day
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: CL1001_SCI_Feed_volume_SP, CL1001_SCI_Feed_mode_volume_S

PLC Interface:

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),

CL1001_SCI_Feed_volume_SP (volume setpoint of the bioreactor), CL1001_SCI_Feed_Interval_in_hour (time interval between two feeding)

PLC Subroutine: V_Feed (FBD)

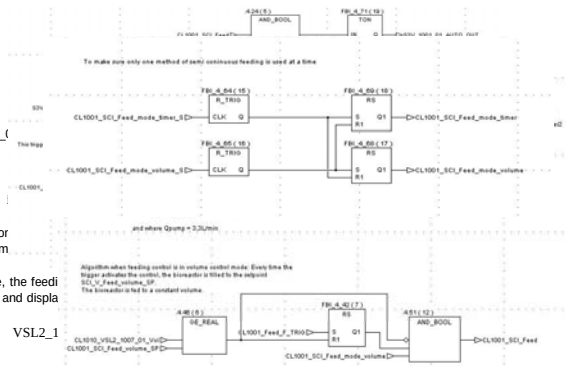


Figure 2: PLC procedure: V_Feed (FBD)

Variables Used (I/O):
LT_1004_01, PT_1003_01, S3V_1001_(GP_1001_01, LSH_1010_01

Description:
· First, the choice of the used mode : CL1001_SCI_Feed_mode_timer_s CL1001_SCI_Feed_mode_volume_s. If Nor VSL2_1007_01 is reached, choose the Volume m

· With HMI button CL1001_SCI_Feed_Enable, the feedi and then the variable CL1001_SCI_Feed is SET and displa
· The valve S3V_1001_01 is open if:
o there is no level error in both VSL2_1 VSL2_1007_01
o The pump GP_1001_01 turn ON
o The variable CL1001_SCI_Feed is in state ON

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					
1. Make sure V-R-20 is open and N2 is available at around 1 barg at PR-G-06		NC	V-R-20 is a manual valve not visible on HMI ; p bioreactor=103 mbar		
2. Flush N2 in the bioreactor byV-G-29		C	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-G-29 opens up		
3. Start blender BL-R-01 (set point: 220 rpm): SCI_BL_R_01		C	change setpoint is only possible in the electrical cabinet by changing the FVC		
4. Set temperature setpoint to 55°C. Fill HX-R-01 and double jacket with demineralized water if this is not done yet: SCI_R_T_R_01_SP	6/6/08 12:30	NC	it is not possible to activate from HMI the heating ; it was done by forcing the variable HX_R_001 on PLC the heating element indication on HMI is not correct : it is always ON even when the electrical heater is OFF		
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		
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. 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 L/d). Once nominal liquid	6/6/08 12:35	NC	not done for this part of the tests : the objective was to have a bioreactor on operation to see the interaction with the gas loop		
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 per day: SCI_V_Feed_mode_timer_S, SCI_V_Feed_Amount_per_day					
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: SCI_V_Feed_volume_SP, SCI_V_Feed_mode_volume_S					

Recommendations / changes

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?

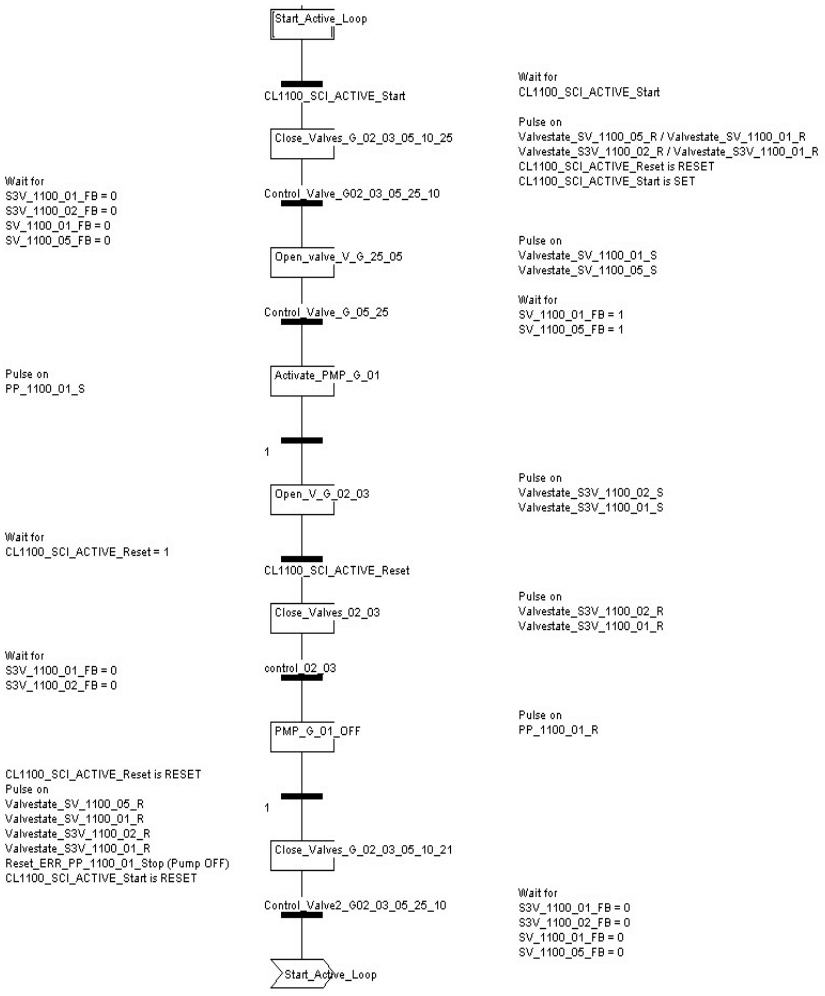
HMI modificatinos
temperature control loop should be easy to view with T setpoint and loop T
pH control additions missing
pressure setpoint for the bioreactor should appear

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 comments
1.1. Procedure 26: Active Gas Loop: Start-up					
Scope					
Start the active gas loop	06/06/2008 12:00		there might be a problem of reverse flow from bioreactor to the active gas loop condensate line through V-G-12		
		NC	no history graph available for gas loop screens (the real time values are working though)		
Procedure					
Press the button on the HMI: CL1100_SCI_Start_Active_GasLoop		C	OK pressed : the green light for active gas loop is working		
Make sure that HV_1007_10, HV_1007_11, HV_1007_14 and HV_1102	26/02/2009 18:20	C	Include as prerequisite to check manual valves in R-G-01: V-06, V_G_26 : checked as well		
		OBS	HMI should have bioreactor pressure indication on the right		
SCI variables :		NC	LSH_1102_01 should not be blinking when no high level is detected?		
CL1100_SCI_Start_Active_GasLoop, CL1100_SCI_Reset_Active_GasLoop		NC	Stop of active gas loop in HMI is not effective even if buttor STOP changes to red ; START and STOP actions are carried out through the same START button		
		C	ok		
PLC Subroutine : **G_Active_Loop**			active gas loop sending gas to reactor maintaining 80 mBa 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 :					
• Input HMI: CL1100_SCI_Start_Active_GasLoop					
• Valves S3V_1100_01_MV, S3V_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					
• Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25) are ON					
• Run the pump PP_1100_01					

- 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

- 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
- Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25) are ON
- Run the pump PMP_G_01 — C — OK it started
- Valves S3CV_1100_01_MV, S3CV_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?
- Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02, V_G_03) are OFF — nA — not performed
- Stop the pump PMP_G_01 — NA — not performed
- Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, 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-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

WHEN — WHO

Recommendations / changes

HW modifications
install a PI on bioreactor between 1 barg and 1,2 barg — UAB — ordered but not mounted
temperture sensor TS-R-01 is OOO it is indicating 0ºC — rechecked : a priori functional
repair LS-G-01 — replaced by another LS that is working

PLC programme modifications — SHERPA
control of V-G-10 opening?

HMI modifications — NTE

Local

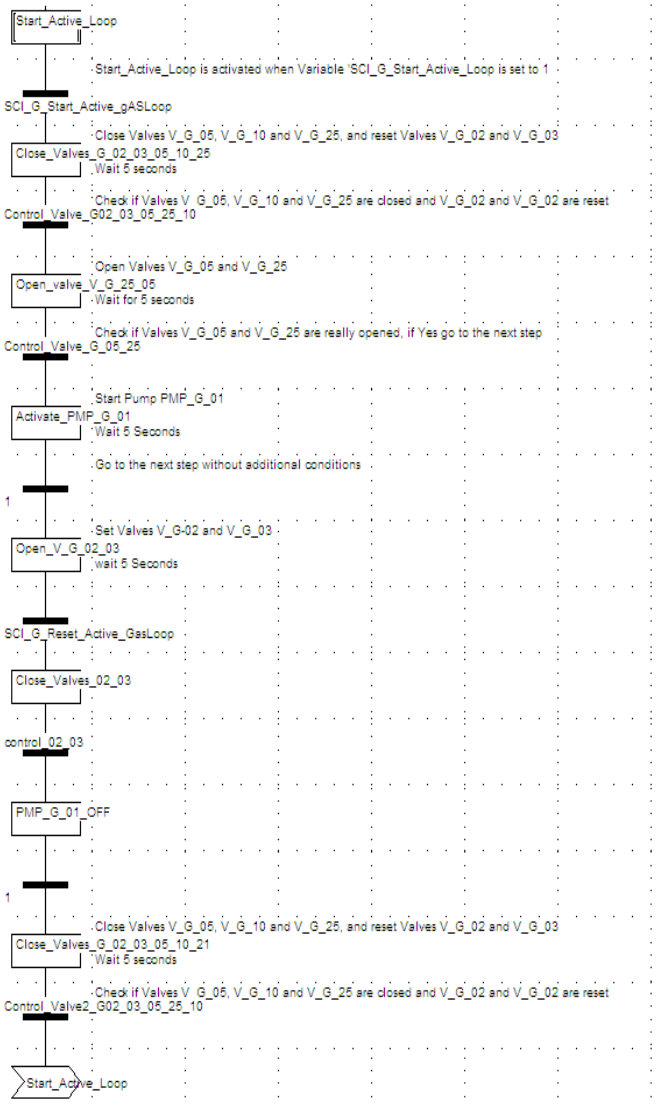
Remote

Variables

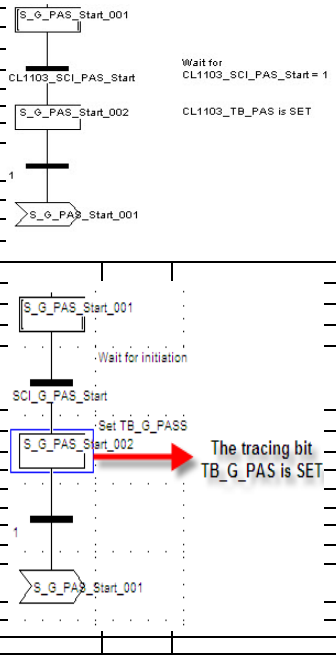
others

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 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.			SV_1100_02 is intially open and SV_1100_03 initially closed		
Pre-requisite					
HV_1009_01 is open	26/02/2009 18:20	C			
HV_1007_08 is open	26/02/2009 18:20	C			
Procedure					
Press the button on the HMI: SCI_G_PAS_Start		c	green light on HMI working		
	26/02/2009 18:45		when PT_1100_01>2500mbarg and PT_1009_01>90mbarg inthe biioreactor, we observe the opening of SV_1100_03 and the closing of SV_1100_02		
SCI variables: SCI_G_PAS_Start					
PLC Subroutines : **G_PAS_Start, G_PAS_Esc**					
Figure 5: PLC procedure: G_PAS_Start					
The subroutine G_PAS_Esc is described on Procedure 19.					
Variables Used (I/O): SV_1100_02_MV, SV_1100_03_MV, PT_1009_01					
Description: • Input HMI: SCI_G_PAS_Start • This variable begins the PLC procedure G_PAS_Esc • The procedure G_PAS_Esc sets the tracing bit TB_G_PAS_Esc which begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)					
Fig : PLC procedure: G_PAS_Start					
The subroutine G_PAS_Esc is described on Procedure 19.					



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	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

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.					
	26/02/2009 18:50	NC	the green light on HMI has disappeared ; yet the compressor remains ON with 2800 mbarg in 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 re		NA	It was not checked		
SCI variables:					
SCI_G_Reset_Active_GasLoop			when forcing this variable from PLC, we could activate 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):					
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:					
• Input HMI: SCI_G_Reset_Active_GasLoop					
• Valves S3V_1100_01 (V_G_02) and S3V_1100_02 (V_G_03) are set in OFF		C	ok		
• The pump PP 1100_01 (PP_1100_01) is turn OFF		C	OK it shut down		
• Valves SV_1100_01(V_G_05), SV_1102_01 (V_G_10) and SV_1100_05 (V_G_25) are set in OFF		C	ok		

	WHEN	WHO
Recommendations / changes		
HW modifications		
		UAB
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
Remote		
Variables		
others		
User Manual		

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.					
Procedure					
Press the button on the HMI: SCI_G_PAS_Stop	06/06/2008 19:30	NC	ON button has to be pressed to obtain shutdown of 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**					

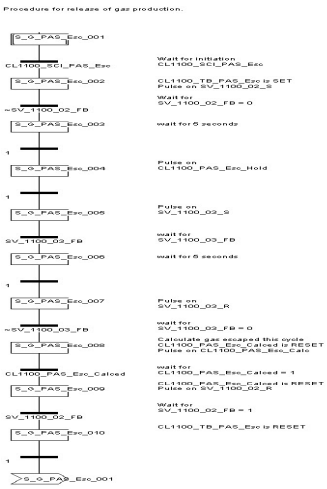


Figure 3 : PLC procedure G_PAS_Stop

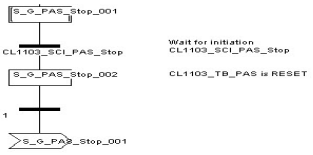
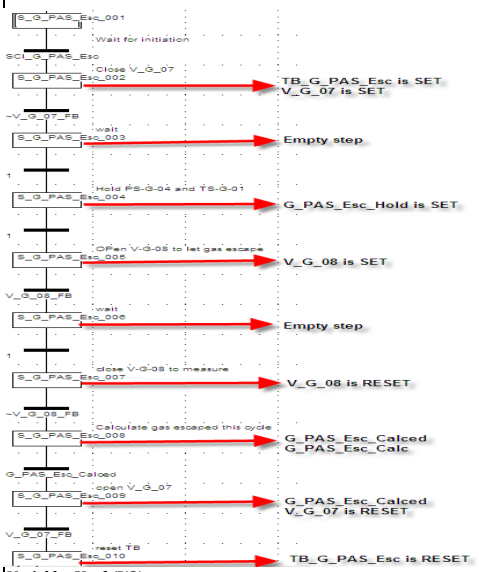


Figure 4: PLC procedure: G_PAS_Esc



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		
• The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which 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		
• The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which on state HIGH begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)			it seems that the release of gas was interrupted by the passive shutdown, not started/begun		

Recommendations / changes WHEN WHO

HW modifications

PLC programme modifications
change the variable names

HMI modifications

Local
idem remote

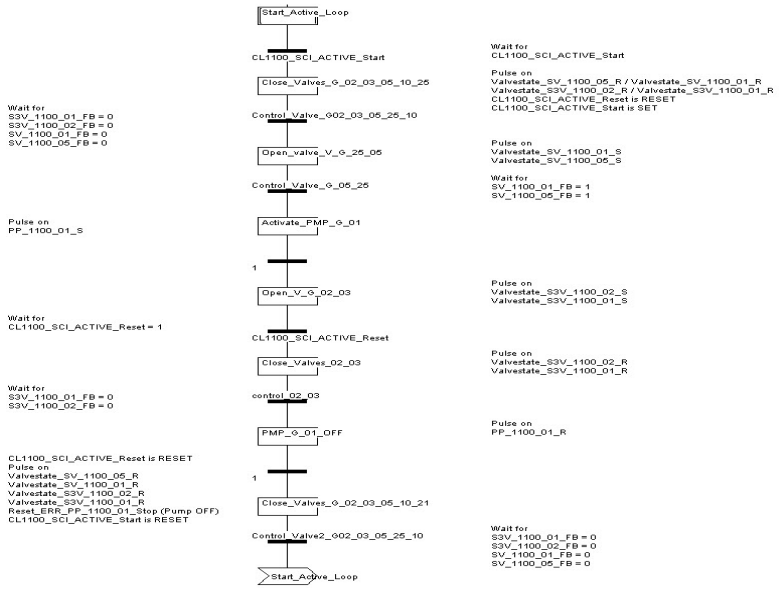
Remote
assign correct roles to ON/OFF buttons on HMI and correct colour codes for state of routine

variables to be seen

others

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		
Start the active gas loop	27/02/2009 9:52	C	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 the menu		
		C	today the history graphs areavailable for gas loop screens (for 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		C	OK pressed : the green light for active gas loop is working		
Make sure that HV_1007_10, HV_1007_11, HV_1007_14 and HV_1102_(	27/02/2009 9:56	C			
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		
SCI variables :		NC	LSH_1102_01 should not be blinking when no high level is detected?		
CL1100_SCI_Start_Active_GasLoop, CL1100_SCI_Reset_Active_GasLoop		NC	Stop of active gas loop in HMI is not effective even if button STOP changes to red ; START and STOP actions are carried out through the same START button		
		C	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					
Description :					
• Input HMI: CL1100_SCI_Start_Active_GasLoop			initial value for pressure PT_1100_01 : 10 mbarg		
• Valves S3V_1100_01_MV, S3V_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					
• Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25) are ON					
• Run the pump PP_1100_01		C	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		C			
• Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02, V_G_03) are OFF					
• Stop the pump PP_1100_01			pump is not a peristaltic one ; it shoud bear other tag (CP)		
• 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
- Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, V_G_25) are ON
- Run the pump PMP_G_01 — C — OK it started
- Valves S3CV_1100_01_MV, S3CV_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?
- Valves S3CV_1100_01_MV, S3CV_1100_02_MV (V_G_02, V_G_03) are OFF — nA — not performed
- Stop the pump PMP_G_01 — NA — not performed
- Valves SV_1100_01_MV, SV_1100_05_MV (V_G_05, 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-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 control loops

Recommendations / changes — WHEN — WHO

HW modifications

install a PI on bioreactor between 1 barg and 1,2 barg — UAB — ordered but not mounted
temperture sensor TS-R-01 is OOO it is indicating 0ºC — rechecked : a priori functional
repair LS-G-01 — replaced by another LS that is working

PLC programme modifications

control of V-G-10 opening? — SHERPA

HMI modifications — NTE

Local

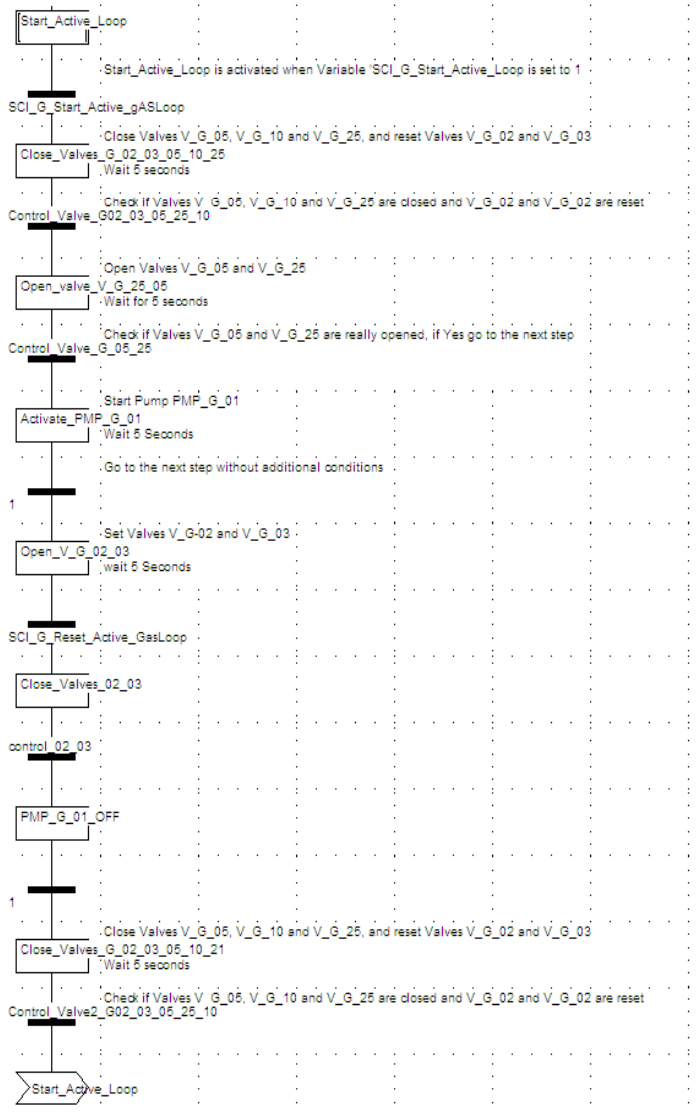
Remote

Variables

others

User Manual

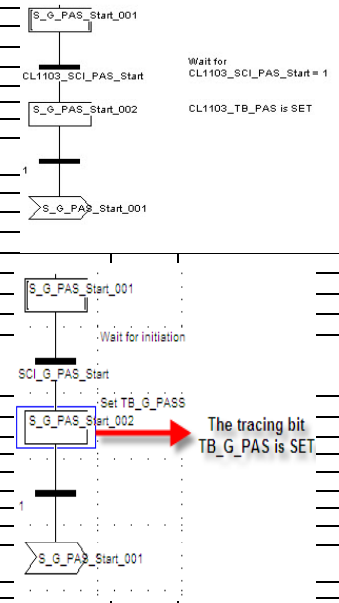
Include as prerequisite to check manual valves in R-G-01: V-G-06, V_G_26,



Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 25: Active Gas Loop: Shut down					
Scope					
Stop the active gas loop.					
	27/02/2009 10:17	NC	both procedure buttons START ACT GL and STOP ACT GL are now green ; the compressor and the valves are in the same position as for START ACT GL		
Procedure			the scale of PT1100 02 should be changed		
Press the button on the HMI: SCI_G_Reset_Active_GasLoop			buttons of procedures are not working OK see previous remark		
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:			SV 1102 01 is not tight		
SCI_G_Reset_Active_GasLoop			SHERPA cl_1100_sci_active_reset was forced and the command for STOP ACT GL was successful (stopping 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:					
• Input HMI: SCI_G_Reset_Active_GasLoop					
• Valves S3V_1100_01 (V_G_02) and S3V_1100_02 (V_G_03) are set in OFF		C	ok		
• The pump PP 1100_01 (PP_1100_01) is turn OFF		C	OK it shut down		
• Valves SV_1100_01(V_G_05), SV_1102_01 (V_G_10) and SV_1100_05 (V_G_25) are set in OFF		C	ok		

	WHEN	WHO
Recommendations / changes		
HW modifications		UAB
PLC programme modifications		SHERPA
HMI modifications		NTE
Local		
Remote		
Variables		
others		
User Manual		

Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
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_1100_02=56 mbarg, PT_1009_01=70mbarg		
Scope			check P sensors calibrations		
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.			PT 1100 01 = 2490 mbarg		
Pre-requisite					
HV_1009_01 is open	27/02/2009 10:04	C			
HV_1007_08 is open	27/02/2009 10:04	C			
			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	c	green light on HMI working		
	27/02/2009 0:00	c	when PT_1100_01>2500mbarg and PT_1009_01>90mbarg inthe bioreactor, we observe the opening of SV_1100_03 and the closing of SV_1100_02		
SCI variables : SCI_G_PAS_Start					
PLC Subroutines : **G_PAS_Start, G_PAS_Esc**					
Figure 5: PLC procedure: G_PAS_Start					
The subroutine G_PAS_Esc is described on Procedure 19.					
Variables Used (I/O): SV_1100_02_MV, SV_1100_03_MV, PT_1009_01					
Description : • Input HMI: SCI_G_PAS_Start • This variable begins the PLC procedure G_PAS_Esc • The procedure G_PAS_Esc sets the tracing bit TB_G_PAS_Esc which begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)					
Fig : PLC procedure: G_PAS_Start					
The subroutine G_PAS_Esc is described on Procedure 19.					



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	replaced

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 19: Passive Gas Loop: Shut down					
Scope					
Stop the passive gas loop.	27/02/2009 10:34		remark : in order to remove the two activated buttons START ACT GL and STOP ACT GL, we push the RESET ALL PROC button : it does not interrupt the current passive gas loop (still active)		
Procedure					
Press the button on the HMI: SCI_G_PAS_Stop	27/02/2009 10:35	C	THE button is working and the square HMI indicator passes from blinking green to continuous grey		
PLC Interface :					
SCI variables : SCI_G_PAS_Stop		c			
PLC Subroutines : **G_PAS_Stop , G_PAS_Esc**					

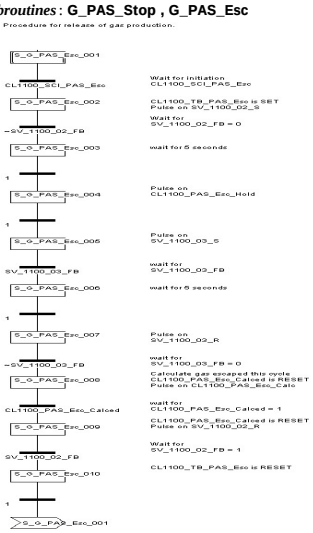
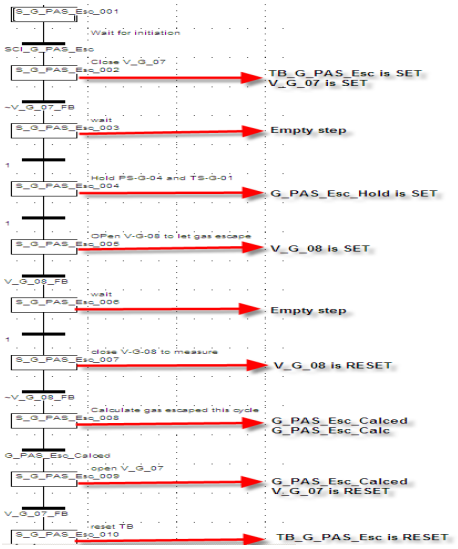



Figure 3 : PLC procedure G_PAS_Stop					
					
Figure 4: PLC procedure: G_PAS_Esc					
					
Variables Used (I/O): SV_1100_02_MV, SV_1100_03_MV (V_G_07 and V_G_08)					
Description :			before stopping, SV 1100 02 and SV 1100 03 are releasing gas to the outlet		
• Input HMI: SCI_G_PAS_Stop					
• This variable begins the PLC procedure G_PAS_Esc		C			
• The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which on state HIGH begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)		c			
• The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which on state HIGH begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)	27/02/2009 10:41	c			

Recommendations / changes 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

others

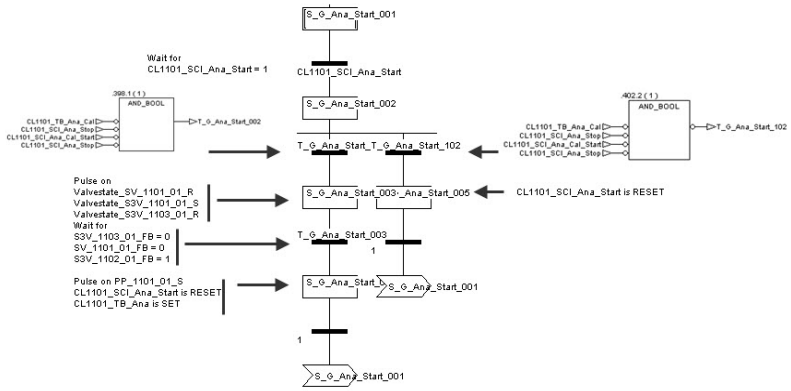
Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 6: Start-up Influent tank VSSL_1000_01					
Scope					
Initiate the functions of the influent tank.					
Prerequisite					
Bioreactor should contain a certain amount of active waste that is strong enough to digest an influent flow.					
V-V-04 must be in position recirculation	09-jun	c			
			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		
1. 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.	09-jun				
2. Start blender BL-V-01 (set point: 200 rpm): SCI_BL_V_01		c	blender on		
3. Set temperature setpoint to 6°C or another value <= 7°C. Fill HX-V-01 and double jacket with water and antifreeze compound (glycol) if this is not done yet: SCI_V_T_V_01_SP		c	cooler ON		
4. Start PMP-V-01 : SCI_GP_1001_01_MV1		c	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

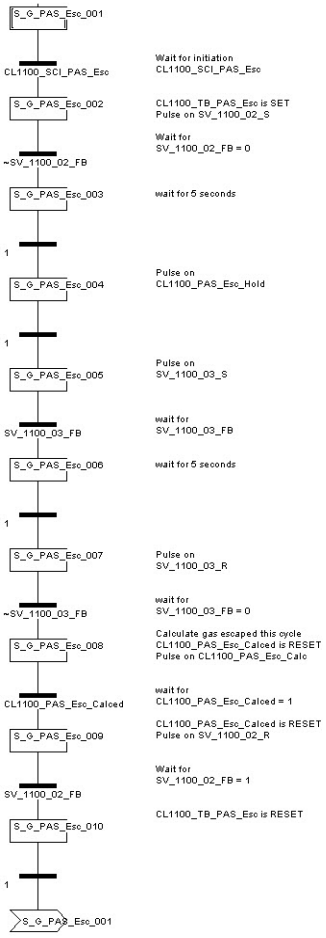
	WHEN?	WHO?	Comments
HW modifications			
repair ps-v-03		UAB	
		UAB	
PLC programme modifications			
	step2	SHPA	
HMI modifications			
		NTE	
		NTE	
		NTE	
		NTE	
others			

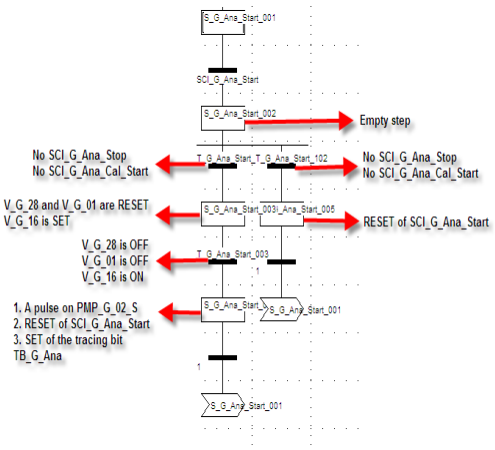
	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 24: Analysis Gas Loop: Calibration of gas analyzer A-G-02					
Scope					
Calibration of the Maihak S 710 Extractive Gas Analyser for CH4 and CO2.			the command should be available only on the local HM screen, the remote HMI screen being used only to start /stop the analysis loop		
Necessities					
Calibration gas at a pressure up to 200mbarg on a 6mm tubing connection. This can be a bottle with a two stage gas pressure regulating valve. Please carefully read the manual for a detailed description on how to use this apparatus.					
Procedure					
The analyzer is calibrated with two calibration gases that contain different percentages of CH4 and CO2. The nominal percentages that are measured should lie between those percentages, so that the analyzer can interpolate to calculate its measurement and does not have to extrapolate. A calibration gas that doesn't contain any CH4 or CO2 can be used, like the N2 from the gas loop. Another calibration gas has to be connected to the gas loop.					
The manual describes from page 135 how to program different calibration procedures.					
Calibration with N2: 1. Stop the analysis loop using PROCEDURE 21: Analysis Gas Loop: Shut down: SCI_G_Ana_Stop 2. Make HPCV_1103_01 sets a pressure not too high for the analysers (PI-G-02 does not exist???). 3. Start Calibration on the HMI: SCI_G_Ana_Cal_Start. S3V_1103_01 (V-G-01) and S3V_1101_01 (V-G-16) switch and provide a N2 flow in the analyzer loop. 4. Calibrate the analyzer as described in its manual.					
Calibration with calibration gas containing known concentration of CH4 and CO2: 1. Set the gas bottle on a pressure around 100 mbarg 2. Connect to the inlet of PP_1101_01 (PMP_G_02) 3. Calibrate the analyzer as described in its manual 4. Disconnect the gas bottle and reconnect the original tube on PP_1101_01 (PMP_G_02) 5. Stop calibration on the HMI: SCI_G_End_Calibration_Gas and start the analysis loop again according PROCEDURE 22: Analysis Gas Loop: Start-up.			these manual operations have not been carried out for the functional tests step 2 ; the calibration gases are not available ; yet a few months ago the functionality of the gas analyzer was chosen		
SCI variables : SCI_G_Ana_Cal_Start, SCI_G_End_Calibration_Gas, SCI_G_Ana_Stop					
PLC Subroutine : **G_Ana_Cal_Start**					
Figure 8: PLC procedure: G_Ana_Cal_Start					
					
Variables Used (I/O): S3CV_1103_02_MV, S3CV_1101_01_MV, PP_1101_01_MV					
Description : • Input HMI: SCI_G_Ana_Cal_Start • The variable SCI_G_Ana_Stop is SET and begins the PLC subroutine G_Ana_Stop (Shut down of the Gas analysis loop) • Valves S3CV_1103_02_MV (V_G_01) is ON, S3CV_1101_01_MV (V_G_16) is OFF • Run the pump PP_1101_01 (PMP_G_02) • The variable SCI_G_End_Calibration_Gas is RESET and stop the calibration of gas analyser AT_1101_01 • The variable SCI_G_Ana_Start is SET and the analysis gas loop can restart					
Questions: • Maybe there is a mistake with PLC procedure: G_Ana_Cal_Start: SCI_G_End_Calibration_Gas is SET instead of RESET. • Why is the pump PP_1101_01 (PMP_G_02) stopped after the SET of SCI_G_Ana_Start? • Explanation of the green underlined sentence.					
end of calibration		NC	it is puitting back S3v 1101 01 and S3V 1103 01 are reset, but the PP 1101 01 is still ON		

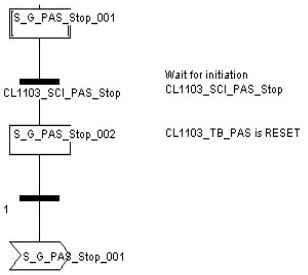
Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. Procedure 22: Analysis Gas Loop: Start-up					
			active gas loop started : worked for a few seconds, but then the compressor was stopped (S3V1100 01 and S3V1100 02 remained open) pb : SCV 1100 01 remained fully open more than 2 seconds because of the aborted/abnormal stopping of active gas loop (it kept its 100% opening value, then the aperture % is not calculated any more)	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	
Scope	27/02/2009 10:50				
			reactor started up 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) preactor = 71 mbarg		
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 gas analysers.	27/02/2009 11:33				
Prerequisite					
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					
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	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 changing value when activating/deactivating the gas analysis loop or is taking when activating the loop the value ON and then switching to OFF		
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.		C	OK both valves V_G_14 and 15 closed but check valve 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		
SCI variables : 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		
• 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		C	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		
		NC	pressure downstream analyzer PT 1101 01 increased up to 170 mbarg and flow FT 1101 01 decreased to 0 L/h		
• This variable begins the PLC procedure G_PAS_Esc			the NRV 1101 01 was taken off because it provoked the increase of pressure downstream the AT 1101 01		
• The procedure G_PAS_Esc resets the tracing bit TB_G_PAS_Esc which on state HIGH begins the subroutine for release of gas production G_PAS_Esc (Passive gas loop)		C	once this replacement is done, the pressure downstream is 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	WHEN	WHO			
HW modifications					
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					

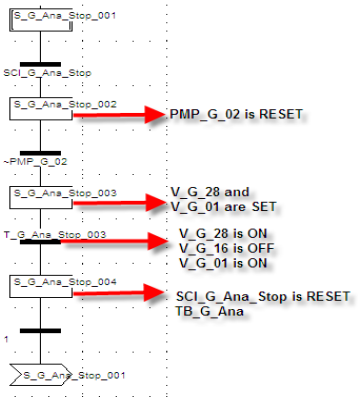


Procedure for release of gas production.







Procedure steps	date/hour	N/NC	comments	SHERPA comments	NTE comments
1.1. PROCEDURE 21: Analysis GaS Loop: Shut down					
Scope					
Stop the analysis gas loop.					
			reactor started up passive control loop ON : PT 1100 02=55mbarg active gas loop ON : PT 1100 01 3180 mbarg		
	27/02/2009 12:42		preactor = 75 mbarg		
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		
PLC Interface : ?????			we did not use the PLC interface for this loop		
SCI variables :					
SCI_G_Ana_Stop					
PLC Subroutine : **G_Ana_Stop**					
		C			
		C	the pump is stopped		
		C	ok for 28 and 01		
		C	ok for 28 and 01 and 16		
		C			
			PS_G_02 = 5mbarg to evacuate the venting of N2 from V_G_01 through V_G_15 and V_G_16		
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					
• Valves SV_1101_01_MV, S3CV_1103_02_MV (V_G_28 and V_G_01) are ON, S3CV_1101_01_MV (V_G_16) is OFF					
Recommendations / changes	WHEN	WHO			
HW modifications					
PLC programme modifications					
check the variables used to activate the gas loop from HMI					
HMI modificatinos					
local					
change the colours of buttons to reflect started/shut down states					
remote					
idem local					
others					

ANNEX 5

Second phase: Step 2 Functional Tests Filtration Unit

EPAS number	Sequence of routines	Operator	HMI	Date	C/NC	Remarks	SHERPA Corrections Date	SHERPA Corrections	Corrections to be done by NTE	NTE Corrections Date	NTE Corrections	MPP Corrections Date	MPP Corrections	Trials after modifications: 1 Date	1 C/NC	1 Remarks	2 Date	2 C/NC	2 Remarks	3 Date	3 C/NC	3 Remarks	4 Date	4 C/NC	4 Remarks	Final status (02/10/09) C/NC
	EMERGENCY STOPS			28/04/2009		Stop button tags are not normalised. Each tag follows a different rule. Are they correct?																				
16	Emergency Stop on the RV frame	Y		28/04/2009	C																					C
17	Emergency Stop on the FU frame	Y		28/04/2009	NC	Emergency button is solely shown in GAS LOOP HMI screen. There is no Emergency button in FILTRATION UNIT, CIP and SIP screens.			Put EMERGENCY BUTTON indicator in FU, CIP nad SIP screens.	06/05/2009	Emergency buttos indicators are in all screens			15/05/2009	C	Considerate name these buttons "INDICATORS" and put both (FU frame button: FU, Gas loop, CIP, SIP and BR									C
18	Nominal stopping of the FU frame on the HMI		Y	28/04/2009	C	Filtration is started with membrane 1. Filtration is stopped with button "STOP FU/CIP/SIP".																				C
29	Filtration Unit: nominal stopping for membrane1 and membrane2		Y	28/04/2009	C	Filtration with membranes 1 and 2 is stopped with the button "STOP FILTRATION".																				C
45	CIP: nominal stopping of CIP activities		Y	28/04/2009	C	CIP activity "FILL VSSL_1209_01 WITH CLEANING AGENT" is started. Nominal stopping with button "CIP(EMERGENCY BUTTON)".			1) In CIP PROCEDURES screen substitute (EMERGENCY) SHUTDOWN button for "CIP (NOMINAL) SHUTDOWN" . In INDICATORS screen subtitute "CIP STOPPED" for " CIP (NOMINAL) SHUTDOWN"	13/05/2009	Done			13/05/2009	C	NTE correction 1) OK									C
66	SIP : nominal stopping of SIP activities	Y	Y	28/04/2009	C	SIP activity "STERILISE LF_1200_01" is started. Nominal stoping with button "SIP(NOMINAL) SHUT DOWN".																				C
	CONTROL LOOPS IMPORTANT FOR SAFETY																									
N/A	level safety tests for Bioreactor, Effluent Vessel, CIP vessels		n	28/04/2009		NA																				NA
N/A	Pumps stopping conditions		n	28/04/2009		NA																				NA
	START-UP																									
15	Connect N2 to the system	Y		28/04/2009	C	Done manually																				C
11	Start-up Bioreactor VSSL_1007_01	Y	Y	28/04/2009		N/A. It is already started																				NA
12	Start-up Bioreactor VSSL_1007_01 feeding	Y	Y	28/04/2009		N/A. At this time Feeding tank is used to maintain C1 Inoculum.																				NA
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02		Y	28/04/2009	C	Each membrane filtration is tested during 2 minutes.																				C
								Comment: PP_1202_01_MV1 has no effect on the power of the pump. The pump can just be started or stopped by changing the speed value. Is this normal?															
	NOMINAL OPERATION					PP_1202_01_MV1 is allways connected and the velocity is regulated by one analogical signal(4-20mA).	04/05/2009																			
29	Filtration Unit: nominal stopping		Y	28/04/2009	C																					C
34	Filtration Unit: Start-up in Bypass mode		Y	28/04/2009	C																					C
29	Filtration Unit: nominal stopping		Y	28/04/2009	C				1) In FU screen, change SPEED % when daily production is changed in the HMI. (SHERPA ask to NTE to correct it on day 11/05/09)															C
35	Filtration Unit: Start-up of filtration through membrane LF_1200_01/LF_1200_02		Y	28/04/2009	C					13/05/2009	Done			13/05/2009	C	NTE correction 1) OK										C
37	Filtration Unit: Enter Recycle mode		Y	28/04/2009	NC	1) Reacycle mode is not entering when Filtration unit is not started. 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 generator. 2) At the end of the procedure, the valve 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 valve SV_1020_03 should be done after the message is confirmed.	04/05/2009	1) Done 2) The pump is so slowly that there is time enough to open the valve.							04/05/2009	C									C
38	Filtration Unit: Enter Nominal mode		Y	28/04/2009	C	Start of membrane 1. Before entering in Nominal mode (from the recycling mode) the recycling line is cleaned/drained with steam. Effluent vessel is filled with water until a volume of 14.09L and 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 draining collector and not to a vessel. This message should also ask if the manual valve HV_1204_02 is opened. After the SIP																			C
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_01		Y	28/04/2009	NC	process there must be a message asking if there is a vessel to collect the filtrate.	04/05/2009	3) Now the vessel message are in the right time. Tested with water.						04/05/2009	C									C
34	Filtration Unit: Start-up in Bypass mode		Y	28/04/2009	C																					C
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_01		Y	28/04/2009	C	Effluent vessel is filled with water until 5.5L and at the end of the procedure volume is 4.11L.																				C
37	Filtration Unit: Enter Recycle mode		Y	28/04/2009	C	FU is stopped. FU is started with membrane 1 and Recycle mode started.																				C
39	Filtration Unit: Harvest Effluent vessel VSSL_1204_01		Y	28/04/2009	C	Effluent vessel is filled with water until the switch LSL_1206_01 is OFF corresponding to a volume in the HMI of 4.11L . At the end of the procedure (and the switch is ON) volume is 4.11L.																				C
	CIP			29/04/2009		(There is water in VSSL_1209_03)																				
61	Fill cleaning agent into VSSL_1209_01			29/04/2009	C	20s. Button "FILL VSSL_1209_01 WITH CLEANIG AGENT"																				C
62	Fill water into VSSL_1209_01			29/04/2009	C	First, tank is emptied. Button "FILL VSSL_1209_01 WITH WATER"																				C
63	Fill cleaning agent into VSSL_1209_02			29/04/2009	C	First, VSSL_1209_01 is emptied. Then it is filled with cleaning agent. Button "FILL VSSL_1209_02".																				C
58	Empty VSSL_1209_01			29/04/2009	C																					C
59	Empty VSSL_1209_02			29/04/2009	C																					C
64	Rinse VSSL_1209_01	y		29/04/2009	C																					C
65	Rinse VSSL_1209_02			29/04/2009	C	First "FILL VSSL_1209_01 WITH WATER" as prerequisite.																				C
60	Clean VSSL_1209_01 and VSSL_1209_02			29/04/2009	C	Cleaning of VSSL_1209_01 is done with the drain opened.																				C
49	Cleaning of Filtration Unit: retentate side of membrane LF_1200_01 / LF_1200_02		Y	29/04/2009	NC	Buttons "CLEANING RETENTATE LF_1200_01" and "CLEANING 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. 2) Does not corresponds with the procedure written by EPAS. 3) After the procedure the retentate line is not drained/rinsed. This is very important because the filtrate line can be contaminated with cleaning agent. 4) First trial: at the end of the procedure the VSSL_1209_01 is not emptied. Second trial: the vessel is emptied correctly. 5)Temperature value of VSSL_1209_02 can not be set. At this moment is not required.	04/05/2009	4) It been retested and is correct for both membranes. But, before stopping the procedure this should be finished. At least the addition of CA.	1), 2), 3) Put a window asking for addition of CA or water	05/05/2009	1), 2), 3) Done. Now is asking for CA or Water.	05/05/2009	C	1)Checked in both membranes and in each screen . JC from NTE commented that the two screens can behave different.									C
50	Cleaning of Filtration Unit: both retentate and filtrate side of membrane LF_1200_01 / LF_1200_02		Y	29/04/2009	NC	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 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. 2) The drawing of the HMI is not correct for T connection between valves SV_1207_07 and SV_1207_03. In FU screen drawing is different but also incorrect.	04/05/2009	2) To be checked with Raul. But, before stopping the procedure this should be finished. At least the addition of CA.	1) Put a window asking for addition of CA or water. 2) Redraw the connections between SV_1207_07 and SV_1207_03 in CIP and FU screens. A drawing with the correct connections has been sent to NTE.	05/05/2009	1), 2), 3) Done. Now is asking for CA or Water.	05/05/2009	C	1)Checked in both membranes and in each screen . JC from NTE commented that the two screens can behave different.									C
51	Cleaning of Filtration Unit: backwash membrane LF_1200_01/LF_1200_02	Y	Y	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, use PROCEDURE 64: Rinse VSSL_1209_01 and then this procedure again without cleaning agent in order to remove any cleaning agent from the FU piping and the membrane" maybe not completely effective.																			C
52	Cleaning of Filtration Unit: backwashing membrane LF_1200_01 using water and cleaning agent		Y	29/04/2009	NC		04/05/2009	1) Related to HMI. But, before stopping the procedure the addition of CA should be finished.	1) Put a window asking for addition of CA or water	05/05/2009	1) Done. Now is asking for CA or Water.	05/05/2009	C	1)Checked in both membranes and in each screen . JC from NTE commented that the two screens can behave different.									C

53	Cleaning of Filtration Unit: Circulation pump GP_1201_01			29/04/2009	NC	1) Not possible to choose water/cleaniq agent in stead of CA. 2) If cleaning agent was used, the operator should use PROCEDURE 64 and 65 for rinsing VSSL_1209_01 VSSL_1209_02, but the pipe have cleaning agent, how we can clean this cleaning agent from the pipe?	04/05/2009	1), 2) Related to HMI. But, before stopping the procedure the addition of CA should be finished.	1), 2) Put a window asking for addition of CA or water	05/05/2009	1), 2) Done. Now is asking for CA or Water.			05/05/2009	C	1)Checked in both membranes and in each screen . JC from NTE commented that the two screens can behave different.									C
54	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01			29/04/2009	NC	1) Not possible to choose water/cleaniq agent in stead of CA. 2) "5. VSL2_1204_01 is harvested (Procedure 39: Harvest Effluent VESSEL VSSL_1204_01): Operator has to confirm manually both following variables for the harvested procedure is completed":. Not say nothing about open the manual valve SV_1204_01 to drain the effluent vessel after the cleaning	04/05/2009	1) Related to HMI. But, before stopping the procedure the addition of CA should be finished. 2) This paragraph has been removed. There is no need to be applied in cleaning procedures.	1) Put a window asking for addition of CA or water	05/05/2009	1) Done. Now is asking for CA or Water.			05/05/2009	C	1)Checked in both membranes in each screen. JC commented that the two screens can behave different. 2) OK									C
55	Cleaning of Filtration Unit: Filtrate tank VSSL_1204_01 and filtrate line through LF_1200_01 / LF_1200_02			29/04/2009	NC	1) "FU must be stopped or be working over the other membrane" is not true: not possible over the other membrane (only one common exit of both membranes). 2) As a prerequisite, the silicone tubing should be released in PP_1202_01. 3) It is not possible to see the pressure in the effluent vessel during the empying of the same. 4) Manual valve operation before emptying the filtrate vessel is not requested by the HMI. 5) "Operator has to confirm manually both following variables for the harvested procedure: CL1201_SCI_Harvest_IsVsslPresent (PLC Address: 000279)" doesn´t match with this procedure. 6) SV_1207_06 is open during CA transfer, incorrectly. 7) Emptying of the filtrate tank is rather slow 8) Button had prod. 06 circulation says "Filtrate side", it should be "Retentate and filtrate sides" 2) SV_1207_09 response is slow opening (problem with the switch now is correct), so CP_1207_02 doesn´t starts, then the step proc. 49 with water (4 step) is aborted, then the procedure do the step 5 but after this step the procedure do more subrrutines of cleaning, ¿it is logical? 3)"Use the HMI to set up how and which procedures / Membrane are to be executed: CL1207_SCI_P_Cl1 = 1 (PLC Address: 000258) CL1207_TB_P_Cl1 = 1 (PLC Address: 000374) CL1207_SCI_P_Cl2 = 1 (PLC Address: 000259) CL1207_TB_P_Cl2 = 1 (PLC Address: 000372) " whats the meaning? you only can select the autocleaning af membrane 1 or membrane 2	04/05/2009	The number of rinsings can be done by repeating the procedure just with water (1 time = 2 rinsings). 1) Document is corrected. 2) Document is corrected. 3) There is no pressure transmitter for this action. 4) There is no need to ask for this, since it is a cleaning procedure. 5) This paragraph has been removed. In cleaning procedures it has no sense. 6) To be checked.					07/05/2009	C	4) OK. 6) Checked. It is not incorrect that valve SV_1207_06 opens for membrane 2.									C (Not possible to clean one membrane while the other is working because there is only one filtrate line)
56	Cleaning of Filtration Unit: automated execution of a sequence of procedures to clean membrane LF_1200_01			29/04/2009	C				1) In "Autocleaning" procedure execution screen substitute "Filtrate side" for "Filtrate/Retentate Side"	13/05/2009	Done			13/05/2009	C	1) OK									C
45	CIP: nominal stopping of CIP activities			29/04/2009	C	OK																					C
46?	Shut down the System, drain, rinse and clean Bioreactor VSSL_1007_01, Feefing vessel VSSL_1000_01 and Filtration Unit		Y	29/04/2009		N/A																					NA
	SIP (with Air)			30/04/2009		Air is used insead of STEAM. Temperautre sensors TT_1200_02/03 doesn't work properly. 1) Pressure units are bar and not mbar. 2) Indicators screen: normalise timer screens with procedures names. 3) Subtitute "Atmpshere" to "Condensate" 4) SIP status should not be Emergency stopped after ending the procedures.			Substitute "Atmosphere" to "Condensate". 4) Substitute the tag lavels of SIP INDICATORS screen for the same tag lavels of the SIP PROCEDURES screen. This is: substitute "SIP (Emergency) Shutdown for "SIP (Nominal) Shutdown"	13/05/2009	Done			13/05/2009	C	NTE corrections 2) and 3) OK									
N/A	Steam utilities start-up	Y		30/04/2009		N/A																					NA
68	SIP: membrane LF_1200_01 / 02			30/04/2009	NC	Button "STERILISE LF_1200_01/02". First message: 60/60/60 seconds. Pressure is not incresing when Air supply is at 1.8bar, but at 4 bar it is OK. Temperature TT_1200_02 is forced to 400ºC 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 line. 3) It is not written in the procedure (it was in EPAS") but in order to protect the membrane of high pressure, at the moment of flushing the steam, steam inlet valves have to be opened and closed untill the pressure is reached.	04/05/2009	1) PT_1203_03/06 for membranes 1/2, respectively. 3) Done.	2) Draw reactor line input to membranes valves SV_1201_05/06 and output valves SV-1201_03/SV_1201_04 in SIP screen to clarify the reactor content lines that are connected to the membranes.	13/05/2009	Done			04/05/2009	NC	For MPP: 1) Membranes Temp sensors don't work properly. 2) After opening Air to the system pressures from membrane 1 were increasing gradually, although valves were closed. Is there a leak somewhere? Temperature set point has changed to 20ºC because the testing is done with air instead of steam. 3) It works, but with 4 bar of air the pressure reached is 1.5bar.	05/05/2009	C	Temperature set point has changed to -1ºC/0ºC 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. Refreshing time of HMI is slower	07/05/2009	C	Retested. Temperature set point has changed to -1ºC/0ºC 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 1.85bar for membrane 2.	13/05/2009	C	NTE correction 2) OK	C
69	SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01	Y	Y	30/04/2009	NC	1) It is not asking for times. 2) SV_1204_01/03 are not opened during the purge. They must open as 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 400ºC, therefore the sterilising process can not be started. 5) N2 line shouldn't be sterilised?	05/05/2009	2) It waits manual valve SV_1204_01 is opened.	1) Put a window to ask for purge/sterilisation/cooling times. Same window that appears in "Protocol of sterilisation for membranes..."	13/05/2009	Done			07/05/2009	C	Temperature set point has changed to -1ºC/0ºC because the testing is done with air instead of steam.	13/05/2009	C	NTE correction 1) OK					C
80	SIP :Purge and sterilize recycle line			30/04/2009	C	60/60/60 seconds. 1) It is not written in the procedure but Should ask Open HV_1204_02. To be checked with STEAM.																					C
81	SIP : Purge and sterilize Harvesting line			30/04/2009	C	Remove "cooling time"??																					C
82	SIP: Flush recycle line with Steam			30/04/2009	NC	60/60/60/60 seconds. 1) Is not written in the procedure but valve SV_1210_10 should not be closed at the end of sterilisation.																					C
66	SIP : nominal stopping of SIP activities			30/04/2009		It doesn't work. N/A	04/05/2009	FU has to be in nominal mode.					11/05/2009	C	FU was started first. Then the procedure was checked with									NA
84	Procedure 84: SIP: membrane LF_1200_01 / LF_1200_02, filtrate line and Filtrate tank VSL2_1204_01			07/05/2009	C	Checked for both membranes. It is not asking for times and CA addition time.	07/05/2009	It uses the last time input. This is normal, but when we know the exact times SHERPA will fix them.																	C

	SIP (with STEAM) 1					Test with STEAM																						
	Steam utilities start-up	Y		12/05/2009	C																						C
68	SIP: membrane LF_1200_01 / 02			12/05/2009	NC	1) There must be a timer during sterilisation time with the condition of temperature >=121ºC.	12/05/2009	1) Done. The timer of sterilisation has a condition of temperature (>=121ºC). 2) control parameters have been optimised. 3) (13/05/09) Restart sterilisation timer when temperature (TT_1200_02/03 or TT_1205_01) decrese to <121ºC 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. 1) Temperatures sensors still doesn't work. TT_1200_02 has been forced to 300-400ºC in order to step to sterilisation phase.	12/05/2009	C	Filtration 1. 180/180/180 seconds. There is no pressure in MPP STEAM line. The STEAM filter in MPP is clogged with iron 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 membrane is to use a maximum temperature ramp of 10ºC/min. Valves are opening and closing during the sterilization time.	13/05/2009	C	Filtration 1. 60/240/60 seconds. 3) Restart timer works correctly if temperature is <121ºC. OK.				C Sterilisation phase has to be checked because TT_1200_02/03 doesn't work properly.
69	SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01	Y	Y	13/05/2009		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 point. It is not written in the procedure but SV_1204_02 should be open during purging time to remove any gas from the upper part of the tank (to be done after manual sterilization is checked). Second trial: Filtration 1: 180/1800/180. Pressure control work correctly. Purge time: Membrane pressure 1.5bar and filtrate line 0.05 bar. Steriliazation phase: Effluent Tank temperature doesn't raise. It gets stable at 88ºC. (jacket 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.	13/05/2009	1) Implementation of restart sterilisation timer when temperature (TT_1200_02/03 or TT_1205_01) decrese to <121ºC.					13/05/2009	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 89ºC.
80	SIP :Purge and sterilize recycle line																										Confirmed in 22/05/09
81	SIP : Purge and sterilize Harvesting line																										Confirmed in 22/05/09
82	SIP: Flush recycle line with Steam																										TBD
66	SIP : nominal stopping of SIP activities																										C
84	LF_1200_02, filtrate line and Filtrate tank VSL2_1204_01																										TBD

	SIP (with STEAM) 2					Test with STEAM																				
	Steam utilities start-up	Y		22/05/2009	C									23/06/2009	C	Filtration 1. 60/120/60. Temperature reached is 112.2ºC and pressure 1.5 bar.										**C**
68	SIP: membrane LF_1200_01 / 02					Checked sterilisation in effluent tank manually. Temperature reached is 92.5ºC . There is a leak in the steam trap LF_1210_03. To be reapaired. But the most important is that vapour is leaking through the jacket. In the previous tests the jacket was closed and							CIFA repaired the jacket of the effleunt	23/06/2009	C	There is a small leak in the 60/60/60. Temperature reached in the tank is 86ºC. There seems to be a leak in the jacket of the effluent tank.										**C** **C** Sterilisation phase has to be checked manually.
69	SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01	Y	Y	22/05/2009	NC	could not be seen. To be repaired by CIFA.					#######	tank.	23/06/2009	NC	To be cheked.										Effluent tank to be repaired
80	SIP :Purge and sterilize recycle line			22/05/2009	NC	100/100/100/100. It is no written in the procedure butCooling time should be removed?																			**C**
81	SIP : Purge and sterilize Harvesting line			22/05/2009	NC	60/60/60. It is not written in the procedure but Should ask open the valve HV_1204_02.																			**C**
82	SIP: Flush recycle line with Steam																								**TBD**
66	SIP : nominal stopping of SIP activities																								**C**
84	LF_1200_02, filtrate line and Filtrate tank VSL2_1204_01																								**TBD**

	SIP (with STEAM) 3					Test with STEAM																				
	Steam utilities start-up	Y		16/09/2009	C									02/10/2009	C											**C**
68	SIP: membrane LF_1200_01 / 02					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										60/180/60. Temperature reached in the tank is 127ºC. Filtration 1 reached 108ºC and										**Confirmed in 22/05/09** **C**
69	SIP: membrane LF_1200_01/02, filtrate line and Filtrate tank VSSL_1204_01	Y	Y	16/09/2009	NC	correct in the PLC. This sensor was changed in MPP by CIFA and does not come from EPAS.	30/09/2009	Changed range of TT_1205_01 to 0-150ºC.						02/10/2009	C	pressure 1.7bar. There was a small leak in the filtrate line to										To be checked after hardware verifications.
80	SIP :Purge and sterilize recycle line																									**Confirmed in 22/05/09**
81	SIP : Purge and sterilize Harvesting line																									**Confirmed in 22/05/09**
82	SIP: Flush recycle line with Steam																									**TBD** To be checked after hardware verifications.
66	SIP : nominal stopping of SIP activities																									**C**
84	SIP: membrane LF_1200_01 / LF_1200_02, filtrate line and Filtrate tank VSL2_1204_01																									**TBD** To be checked after hardware verifications.

ANNEX 6

D= Done
TBD= to be done
TBR= to be repeated
n/a= Not applicable

C= Compliant
NC= Not compliant
pending decision

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	C
	VSSL_1007_01	R_R_01	Vessel	MPP	pag STEP1/2.6	D	C
	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	C
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	C
Cleaning loop	VSSL_1209_01	R_C_01	Vessel	MPP	pag STEP1/2.2	D	C
	VSSL_1209_02	R_C_02	Vessel	MPP	pag STEP1/2.1	D	C
	VSSL_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	C
	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
Filtration unit	VSSL_1204_01	R_F_01	Vessel	MPP	pag STEP1/1.6 pag STEP2/4.1	TBR D	NC C
Gas loop	VSSL_1100_01	R_G_01	Vessel	MPP	pag STEP1/1.4 pag STEP2/4.2	D D	C C
	VSSL_1100_02	R_G_02	Vessel	MPP	pag STEP1/1.8 pag STEP2/4.3	TBR, needs maint. D	NC C
	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	C
	VSSL_1209_02	R_C_02	Vessel	MPP	pag STEP1/1.5	D	C

CORRECT ON_LINE MEASURAMENTS

LOOP	NEW TAG	OLD TAG	ELEMENT	RESPONSIBLE	PROCEDURE	STATUS	RESULTS
Bioreactor	LSH_1004_01	LS_V_01	level swicht	MPP	Tested with water to look the status change	D	C
	PT_1003_01	PS_V_01	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1001_01	PS_V_03	Pressure transducer	CIFA		TBD	
	TT_1002_01	TS_V_01	temperature sensor	CIFA	To be tested with and external thermostatic_bath calibrate by CIFA when Feeding tank is free	TBD	
	TT_1002_02	TS_V_02	temperature sensor	CIFA		TBD	
	LSH_1010_01	LS_R_01	level swicht	MPP	Tested with water to look the status change	D	C
	LT_1010_01	LS_R_02	level swicht	MPP	Tested with water to look the status change	D	C
	LSL_1008_01	LS_R_03	level swicht	MPP	Tested with water to look the status change	D	C
	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	C
	PT_1009_01	PS_R_01	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1009_02	PS_R_02	Pressure transducer	CIFA	CIFA Calibration Report	D	
	TT_1008_01	TS_R_01	temperature sensor	CIFA	pag STEP 2 / 2.3	D	C
	TT_1008_02	TS_R_02	temperature sensor	CIFA	pag STEP 2 / 2.4	D	C
Filtration unit	FT_1201_01	FS_F_01	Flow transducer	CIFA	MPP (pag. Add. Tests)	D	
	LSH_1206_01	LS_F_01	level swicht	MPP	Tested with water to look the status change	D	C
	LSH_1206_02	LS_F_02	level swicht	MPP	Tested with water to look the status change	D	C
	LT_1206_01	LS_F_03	level swicht	MPP	Tested with water to look the status change	D	C
	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	C
	TT_1200_01	TS_F_02	temperature sensor	CIFA	pag STEP 2 / 2.6	D	C
	TT_1200_02	TS_F_03	temperature sensor	CIFA	To be tested with and external thermostatic_bath calibrate by CIFA	TBD	C
	TT_1200_03	TS_F_04	temperature sensor	CIFA	To be tested with and external thermostatic_bath calibrate by CIFA	TBD	C
	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		TBD	
	FI_1101_01	FI_G_01	rotameter	ALCO	New instrument	n/a	n/a
	FI_1101_02	FI_G_02	rotameter	ALCO	New instrument	n/a	n/a
	FI_1100_01	FI_G_03	rotameter	ALCO	New instrument	n/a	n/a
	PI_1100_01	PI_G_01	Manometer	MPP		TBD	
	PT_1100_01	PS_G_01	Pressure transducer	CIFA	CIFA Calibration Report	D	
	PT_1101_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	C
	TT_1104_01	TS_G_01	temperature sensor	CIFA	pag STEP 2 / 2.7	D	C
	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	C
	LSH_1209_01	LS_C_01	level swicht	MPP	Tested with water to look the status change	D	C
	LSL_1209_01	LS_C_02	level swicht	MPP	Tested with water to look the status change	D	C
	LSH_1209_02	LS_C_03	level swicht	MPP	Tested with water to look the status change	D	C
	LSL_1209_02	LS_C_04	level swicht	MPP	Tested with water to look the status change	D	C

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	C
	VSSL_1007_01	R_R_01	Vessel	MPP	pag STEP 2/1.2	D	C
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	C
Cleaning	VSSL_1209_01	R_C_01	Vessel	MPP	pag STEP 2/1.4	D	C
	VSSL_1209_02	R_C_02	Vessel	MPP	pag STEP 2/1.5	D	C

CORRECT FLOWS AND SPEEDS

LOOP	NEW TAG	OLD TAG	ELEMENT	RESPONSIBLE	PROCEDURE	STATUS	RESULTS
Bioreactor	GP_1001_01	PMP_V_01	Gear pump	MPP	Controlet by VDF to be check with a laser tacometer	TBD	
	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	C
	PP_1011_02	PMP_R_02	peristaltic pump	MPP	pag STEP 2 / 3.2	D	C
	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	C
Cleaning	CP_1207_01	PMP_C_01	Centrifugal pump	MPP	pag STEP 2 / 3.4	D	C
	PP_1209_01	PMP_C_02	peristaltic pump	MPP	pag STEP 2 / 3.3	D	C
	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 ….. Mbar*L/s

	UNIT TESTED	TEST number	DATA	VOLUM REACTOR	INITIAL PRESSURE	TEST DURATION	FINAL PRESSURE	REMARKS	RATIO	RESULTS
1,1	VSSL-1007-01 R-R-01	1	30-may	120L	2barg	13h	1,9barg	there is a small gas leak in retractable ph (both of them)	0,25	C
1,2	VSSL-1000-01 R-V-01	1	30-may	60L	2barg	13h	2bargs	No leak	0	C
1,3	VSSL-1209-01 R-C-01	1	30-may	15L	2barg	13h	0,2barg	there is a big gas leak, the gas go to R-C-03 because isn´t valve between the recipients	NC	NC
		2	30-may	15L	1,9barg	2h	1,85barg	there is a small gas leak, the leak identified in pump PMP_C_01	NC	NC
		3	02-jun	15L	2bargs	18h	1barg	there is a small gas leak, the leak identified in pump PMP_C_01	0,23	C
1,4	VSSL-1100-01 R-G-01	1	30-may	10L	2,9barg	2h	0barg	there is a big gas leak identified in the racords, and the V-G-10 is activated and drain the air to the gas colector	NC	NC
		2	30-may	10L	2,9 barg	4h	2,85bargs	there is a small gas leak identified in the valve V-G-10, the valve not closed completly	NC	NC
		3	02-jun	10L	3bargs	18h	2,717bargs	there is a small gas leak identified in the valve V-G-10, the valve not closed completly	0,043	C
1,5	VSSL-1209-02 R-C-02	1	30-may	10L	2barg	13h	0barg	there is a big gas leak, the drain valve V_C_07 was open, and there is a little gas leak in the sensors	NC	NC
		2	30-may	10L	1,9bargs	2h	1,85bargs	there is a small gas leak, the leak indentified in the pump PMP_C_03	NC	NC
		3	02-jun	10L	2bargs	18h	1,5bargs	there is a small gas leak, the leak indentified in the pump PMP_C_03	0,077	C
1,6	VSSL-1204-01 R-F-01	1	30-may	20L	1.9barg	3h	1,85barg	there is a small gas leak identified in V-S-13, the valve isn´t closed completly	NC	NC
		2	02-jun	20L	1,82bargs	42h	1,42bargs	there is a small gas leak identified in V-S-13, the valve isn´t closed completly	0,053	C
1,7	Filtration unit F1	1	02-jun	aprox:15L	2,3bargs	18h	2,78bargs	test failure, thera is a problem in the air inlet, isn´t closed	NC	NC
		2	03-jun	aprox:15L	1,98barg	22h	1,47barg	there is a small gas leak identified in the menbrane Fi_F_01	0,096	C
1,8	VSSL-1100-02 R-G-02	1	03-jun	aprox:300mL	2,38barg	17h	0bargs	ther is a small gas leak in V-G-08 the valve isn´t closed completly	NC	NC

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

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	**C**
2,2	**VSSL-1209-01 R-C_01**	29-may	2barg	14h	0barg		there is a big gas leak, but not liquid leak	**C**

2,3	VSSL-1204-01 R-F-01	29-may	0Barg	14h	0bargs		Impossible to put pressur inside the reactor, the pressur goto the F.U. Not liquid leak	C
2,4	VSSL-1100-01 R-G-01	29-may	2barg	14h	0barg		there is a gas leak, and a small liquid leak in the tubbing	NC
		30-may	2barg	16h	0barg		there is a big gas leak, but not liquid leak	C
2,5	VSSL-1008-01 HX-R-01	29-may	N/A	24h	N/A		OK	C
2,6	VSSL-1007-01 R-R-01	29-may	2barg	14h	1,6barg		there is some small liquid leak in the reactor, located in the retractable fitting (ph),both of them	C
2,7	VSSL-1000-01 R- V-01	29-may	2barg	14h	0,85barg		there is a gas leak located in the Nozzle 1(No-C-1), but not liquid leak	C
2,8	Filtration Unit F1	30-may	2,16barg	4h	1,730barg		there is a gas leak, and a small liquid leak located in Fi-F-03 and in V-S-12	C

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

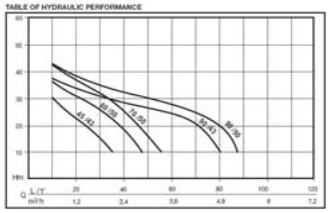
1.7. The pressure inside the reactors is the atmospheric pressure

Success criterion:

2.1. It has not lost of volume

REACTOR TESTED	DATA	INITIAL VOLUM	PROCEDURE TIME	FINAL VOLUM	RESULTS	REMARKS
R_R_01	02-jun	90L	18h	90L	C	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	C	V-V-02 remainig closed

1/



VOLUME TEST STEP 2

INITIAL CONDITIONS:

All the test was do with atmospheric pressure

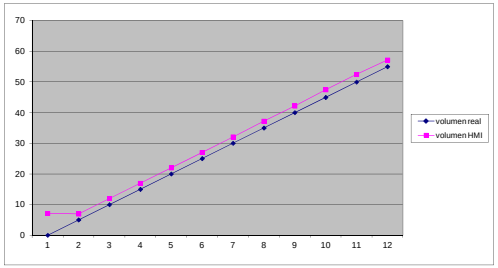
1,1 FEEDING TANK *VSSL-1000-01*

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 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	7,13
5	7
10	11,93
15	16,96
20	22
25	27,02
30	32,06
35	37,2
40	42,2
45	47,45
50	52,47
55	57,2

Swicht upper on betwen 50-55 litres



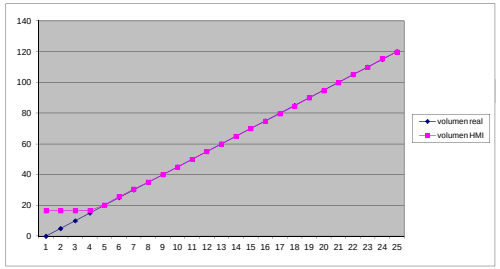
1,2 REACTOR TANK *VSSL-1007-01*

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 litres



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

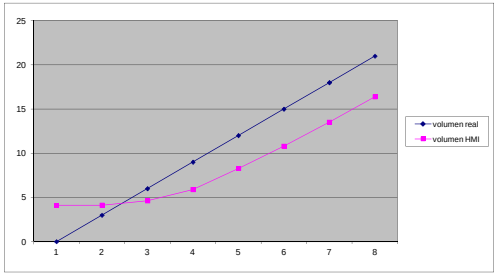
DATE *PROCEDURE:*

16/11/2009 1. Tank is emptied
16/11/2009 2. A volume of 3L is added to the reactor using a graduated plastic glass of 5L
16/11/2009 3. The volume measured in the HMI is taken and compared with the volume added
16/11/2009 4. Water is added until the switch LSH_1206_01 is activated.

16/11/2009

Water volume added to the reactor	Volume measured in the HMI
0	4,11
3	4,13
6	4,62
9	5,90
12	8,27
15	10,82
18	13,54
21	16,40

TBD BY CIFA 5. Adjust LS_1204_01 to the correct measurement with this data



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

DATE *PROCEDURE:*

16/11/2009 1. Tank is emptied
16/11/2009 2. Water is added until the switch LSH_1209_01 is activated.
16/11/2009 3. The tank is emptied until the switch LSL_1209_01 is activated.
16/11/2009 4. The volume of water between switches is measured with 12L graduated bucket.

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 1. Tank is emptied
17/11/2009 2. Water is added until the switch LSH_1209_02 is activated.
17/11/2009 3. The tank is emptied until the switch LSL_1209_02 is activated.
17/11/2009 4. The volume of water between switches is measured with 12L graduated bucket.

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**

17/11/2009 6. 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 obtained.

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

DATE *PROCEDURE:*

18/11/2009 1. Fill the tank with water trying to avoid bubbles by shaking gentle the tank.
18/11/2009 2. Empty the tank and measure the water volume by weight using a tared plastic bottle

Test number	*Bottle Tare (g)*	*Error (g)*	*Bottle weight with water (g)*	*Error (g)*	*Water weight (g)*	*Error (g)*	SD Error
1	34,84	0,1	302,25	0,1	267,4	0,2	0,14
2	34,84	0,1	298,54	0,1	263,7	0,2	0,14
3	34,84	0,1	301,48	0,1	266,6	0,2	0,14
				MEAN	**265,9**		
				SD	2,0		
				RSD (%)	0,7		

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

2/

CORRECT ON-LINE MEASUREMENTS TEST STEP 2

2,1

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

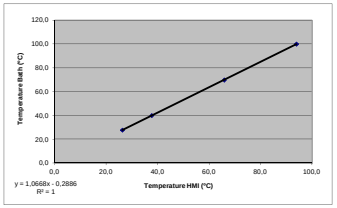
2,2

UNIT TESTED	*CALIBRATION with pH 4.00*	*CALIBRATION with pH 7.00*	*REMARKS*	*RESULT*	*DATE*
AT_1011_02	YES	YES	GOOD RESPONSE	**C**	28/08/2009

2,3

UNIT TESTED	**TT_1008_01**
Description	Bioreactor temperature sensor
Date	08/10/2009
RESULT	T_{real} = 1.07 (T_{HMI}) - 0.29

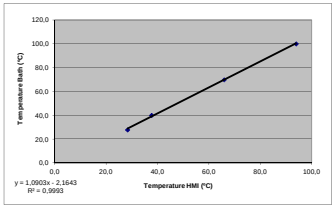
Tested Temperature (ºC)	Temperature HMI (ºC)	Temperature Bath (ºC)
28,0	26,3	27,8
40,0	37,7	40,0
70,0	65,9	69,8
100,0	93,9	100,0



2,4

UNIT TESTED	TT_1008_02
Description	Bioreactor Bath temperature sensor
Date	09/10/2009
RESULT	$T_{real} = 1.09 (T_{HMI}) - 2.16$

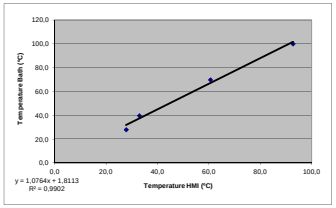
Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
28,0	28,4	27,8
40,0	37,7	40,0
70,0	65,9	69,8
100,0	93,9	100,0



2,5

UNIT TESTED	TT_1205_01
Description	Filtrate tank temperature sensor
Date	09/10/2009
RESULT	$T_{real} = 1.08 (T_{HMI}) + 1.81$

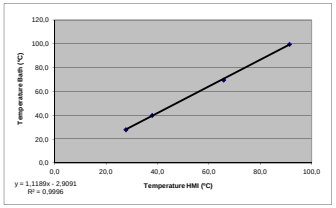
Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
28,0	27,8	28,0
40,0	32,9	39,8
70,0	60,6	69,8
100,0	92,7	100,0



2,6

UNIT TESTED	TT_1200_01
Description	FU temperature sensor
Date	09/10/2009
RESULT	$T_{real} = 1.12 (T_{HMI}) - 2.90$

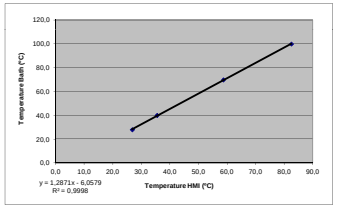
Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
28,0	27,7	28,0
40,0	37,9	40,0
70,0	65,7	69,7
100,0	91,3	99,7



2,7

UNIT TESTED	TT_1104_01
Description	Gas loop temperature sensor
Date	09/10/2009
RESULT	$T_{real} = 1.29 (T_{HMI}) - 6.06$

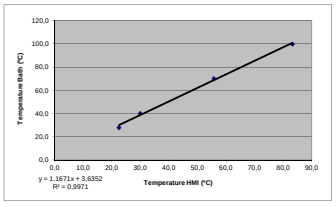
Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
28,0	26,8	28,0
40,0	35,5	40,0
70,0	58,7	69,8
100,0	82,5	99,9



2,8

UNIT TESTED	TT_1208_01
Description	Cleaning temperature sensor
Date	09/10/2009
RESULT	$T_{real} = 1.17 (T_{HMI}) + 3.64$

Tested Temperature (°C)	Temperature HMI (°C)	Temperature Bath (°C)
28,0	22,5	27,9
40,0	29,9	40,1
70,0	55,7	70,0
100,0	83,2	99,8



3/

CORRECT FLOWS AND SPEEDS TEST STEP 2

3,1

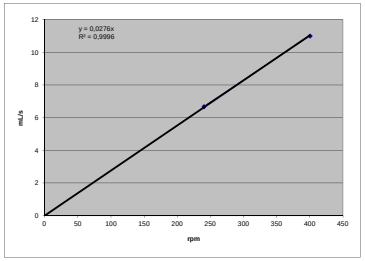
UNIT TESTED	TUBING	TEST number	DATE	MEDIUM	PUMP SPEED	VOLUMETRIC INSTRUMENT	VOLUME (mL)	Volume Error (mL)	TIME (min)	Time error (min)	FLOW (mL/min)	Flow error (mL/min)	Flow error SD based (mL/min)	REMARKS	RESULT
Bioreactor pump PP_1011_01	NORPRENE MASTERFLEX 6412-16 ID 3.1mm	1	28/08/2009	water	Unique	Test tube 10mL ±0.15mL	10,00	0,15	6,63	0,035	1,51	0,031	0,02		C
		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		
										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				

3,2

UNIT TESTED	TUBING	TEST number	DATE	MEDIUM	PUMP SPEED	VOLUMETRIC INSTRUMENT	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
Bioreactor pump PP_1011_02	VITON MASTERFLEX 6404-16 ID 3.1mm (Saint Gobain)	1	28/08/2009	water	Unique	Test tube 10mL ±0.20mL	10,00	0,20	7,42	0,035	1,35	0,03	0,10		C
		2	28/08/2009	water	Unique	Test tube 10mL ±0.15mL	10,00	0,15	7,23	0,035	1,38	0,03	0,02		
		3	28/08/2009	water	Unique	Test tube 10mL ±0.20mL	10,00	0,20	7,57	0,035	1,32	0,03	0,10		
										MEAN	1,35				
										SD	0,03				
	NORPRENE MASTERFLEX 6412-16 ID 3.1mm	4	31/08/2009	water	Unique	Test tube 10mL ±0.15mL	10,20	0,15	7,27	0,035	1,40	0,03	0,02		
		5	31/08/2009	water	Unique	Test tube 10mL ±0.20mL	10,20	0,20	7,00	0,035	1,46	0,04	0,10		
		6	31/08/2009	water	Unique	Test tube 10mL ±0.20mL	10,00	0,20	6,82	0,035	1,47	0,04	0,10	Test repeated. Tubing was overlapped in the	
										MEAN	1,44				
										SD	0,03				

3,3

UNIT TESTED	TUBING	TEST number	DATE	MEDIUM	PUMP SPEED	VOLUMETRIC INSTRUMENT	VOLUME (mL)	Volume Error (±mL)	TIME (s)	Time error (±s)	FLOW (mL/s)	Flow error (mL/s)	Flow error SD based (mL/s)	REMARKS	RESULT
Cleaning pump PP_1209_01	SILICONE OD 8mm ID 2.5 - 3mm	1	28/08/2009	water	240 rpm (Default)	Test tube 100mL ±1.00mL	97,00	1,00	14,6	0,5	6,6	0,3	0,2		C
		2	28/08/2009	water	240 rpm (Default)	Test tube 100mL ±1.00mL	98,00	1,00	14,7	0,5	6,7	0,3	0,2		
		3	28/08/2009	water	240 rpm (Default)	Test tube 100mL ±1.00mL	96,00	1,00	14,3	0,5	6,7	0,3	0,2		
										MEAN	6,67				
										SD	0,02				
		4	31/08/2009	water	400 rpm (Max.)	Test tube 100mL ±1.00mL	88,00	1,00	8,3	0,5	11	1	1		
		5	31/08/2009	water	400 rpm (Max.)	Test tube 100mL ±1.00mL	92,00	1,00	8,5	0,5	11	1	1		
		6	31/08/2009	water	400 rpm (Max.)	Test tube 100mL ±1.00mL	90,00	1,00	8,3	0,5	11	1	1		
										MEAN	11				
										SD	0,12				

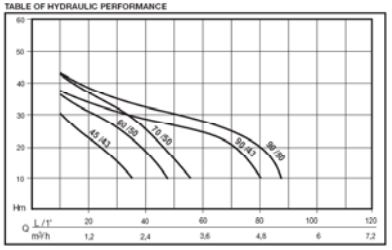


3,4

0,65

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 unitl 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
Cleaning pump CP_1207_01	NOCCHI JETINOX 50/60M	1	16:37:57	16:38:21	24	24	10	25	17/11/2009	C
		2	16:47:04	16:47:28	24	24	10	25	17/11/2009	
		3	-	-	-	-	-	-	-	
							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 unitl 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
Cleaning pump CP_1207_02	NOCCHI JETINOX 50/60M	1	15:23:49	15:24:23	34	32	5,8	11	20/11/2009	C
		2	15:34:25	15:34:56	31	32	5,8	11	20/11/2009	
		3	-	-	-	-	-	-	-	
							MEAN	11		
							Manufacturer range	10 - 48		

3,6

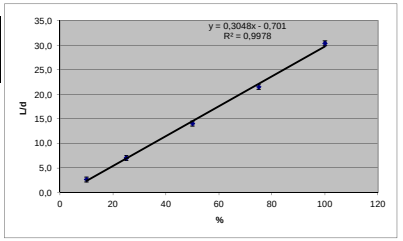
1. The VSSL_1100_01 is used to compress air up to 3.5bar, the maximum pressure of the tank.
2. Check if this pressure is achieved.

UNIT TESTED	Brand & Model
Active Gas Loop pump GCP_1100_01	COMPTOM 1425rpm, 4bar

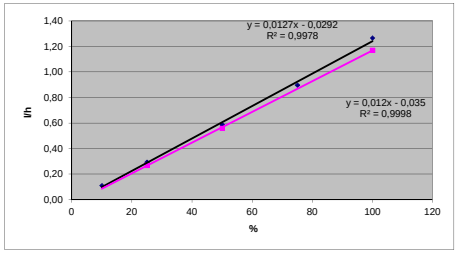
Pressure (bar)	Chrono Time	Time (min)	
1,0	0:00:55	0,92	20/11/2009
2,0	0:02:39	2,65	
3,0	0:07:20	7,33	
3,2	0:15:00	15,00	

3,7

UNIT TESTED	Brand & Model	TUBING	TEST number	DATE	MEDIUM	PUMP SPEED	VOLUMETRIC INSTRUMENT	VOLUME (mL)	Volume Error (±mL)	TIME (s)	Time error (±s)	FLOW (L/d)	Flow error (mL/s)	Flow error SD based (mL/s)	REMARKS	RESULT
Filtrate pump PP_1202_01	Watson Marlow 540U MKII IP55	MARPRENE #14 902.0016.016	1	15/01/2010	water	50	Test tube 25mL ±0.25mL	24,4	0,25	148	0,5	14,2	0,2	0,15		C
			2	15/01/2010	water	50	Test tube 25mL ±0.25mL	24,0	0,25	148	0,5	14,0	0,2	0,15		
			3	15/01/2010	water	50	Test tube 25mL ±0.25mL	23,9	0,25	148	0,5	14,0	0,2	0,15		
											MEAN	14,1				
											SD	0,15				
			4	15/01/2010	water	25	Test tube 25mL ±0.25mL	23,9	0,25	293	0,5	7,0	0,1	0,07		
			5	15/01/2010	water	25	Test tube 25mL ±0.25mL	23,5	0,25	293	0,5	6,9	0,1	0,07		
			6	15/01/2010	water	25	Test tube 25mL ±0.25mL	23,5	0,25	291	0,5	7,0	0,1	0,08		
			7	15/01/2010	water	25	Test tube 25mL ±0.25mL	23,5	0,25	281	0,5	7,2	0,1	0,08		
											MEAN	7,0				
											SD	0,13				
			8	15/01/2010	water	75	Test tube 25mL ±0.25mL	24,4	0,25	98	0,5	21,5	0,3	0,25		
			9	15/01/2010	water	75	Test tube 25mL ±0.25mL	24,6	0,25	98	0,5	21,7	0,3	0,25		
			10	15/01/2010	water	75	Test tube 25mL ±0.25mL	23,6	0,25	95	0,5	21,5	0,3	0,25		
											MEAN	21,6				
											SD	0,12				
			11	15/01/2010	water	100	Test tube 25mL ±0.25mL	24,5	0,25	70	0,5	30,2	0,5	0,38		
			12	15/01/2010	water	100	Test tube 25mL ±0.25mL	24,1	0,25	68	0,5	30,6	0,5	0,39		
			13	15/01/2010	water	100	Test tube 25mL ±0.25mL	24,5	0,25	70	0,5	30,2	0,5	0,38		
											MEAN	30,4				
											SD	0,22				
			14	15/01/2010	water	10	Test tube 25mL ±0.25mL	19,0	0,25	615	0,5	2,67	0,0	0,04		
			15	15/01/2010	water	10	Test tube 25mL ±0.25mL	20,0	0,25	643	0,5	2,69	0,0	0,03		
			16	15/01/2010	water	10	Test tube 25mL ±0.25mL	22,0	0,25	715	0,5	2,66	0,0	0,03		
											MEAN	2,67				
											SD	0,01				



%	l/d	l/h	Flowmeter In line	Flowmeter HMI
50	**14,1**	0,59	0,56	0,56
25	**7,0**	0,29	0,27	0,27
75	**21,6**	0,90		
100	**30,4**	1,27	1,17	1,17
10	**2,7**	0,11		



4/

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	C

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

UNIT TESTED	TEST number	initial DATA	final DATA	VOLUM REACTOR	INITIAL PRESSURE	TEST DURATION	FINAL PRESSURE	REMARKS	RATIO	RESULTS
VSSL-1100-01 R-G-01	1	27/04/2009	27/04/2009	10L	3 Bar	2h	1,6 Bar	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 the gas colector	NC	NC
VSSL-1100-01 R-G-01	2	27/04/2009	29/04/2009	10L	3 Bar	48h	2,4 Bar	there is a small gas leak identified in the V-G-10/SV-1102-04 output	0,6	C

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	1	27/04/2009	28/04/2009	aprox:300mL	2,7 Bar	18h	0,7 Bar	ther is a small gas leak in V-G-08 the valve isn t closed 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	C

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 nº	*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 nº	*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 Nº	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**

ANNEX 7

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 ~~YES or~~ NO Join this list with priorities	Others members MPP : Raul Moyano, Nuria Martinez ; SHERPA : Olivier Gerbi, Christophe Bourg

First column-reference Nº is used to check points not conformed

Nº	Description	N/A	OK	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		X	
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		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	

S-8	Rules for work at height are respected.	X		
S-9	The work zone is correctly ventilated.		X	
S-10	Peepholes on the process, flow indicators, pressure gauges etc...are correctly shielded		X	
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	
S-14	The staff is protected from cold and hot surfaces		X	
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			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	X		
S-21	Adequate dispositions have been taken for handling gas cylinders and other mobile containers	X		
S-22	Gas cylinders are stored in such a way they can be transferred in safety	X		
S-23	Gas flammable cylinders are stored separately	X		

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

Test Phase : C1 functional tests step 2 – Filtration Unit	System Description : Compartment 1 Filtration Unit
Date: 27/04/09	Safety manager : Arnaud Fossen
List of reserves ~~YES or~~ NO Join this list with priorities	Others members MPP : Raul Moyano, Nuria Martinez ; SHERPA : Olivier Gerbi, Christophe Bourg

First column-reference Nº is used to check points that are non compliant

Nº	Description	N/A	OK	NOT OK
E-1	Containment in case of leak, retention walls and drainage are adequate			The platform has holes
E-2	The wastes to be generated in nominal and non nominal operation have been identified and quantified		X	
E-3	Adequate dispositions have been taken for wastes evacuation including cleaning products and solid wastes		X	The list of interfaces has been updated(24/04/09)
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	X		
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

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	Result			Remarks
	NA	Y	N	
1. Standards and operating procedures referring to the unit have been established and allow the unit exploitation.		X		
2. Subcontractors procedures, operational specific procedure and subcontractors standards are written in the local language used and/or understood by operators.		X		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.		X		
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		X		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.		X		
7. A list of elements important for safety is available with their operation range		X		
8. Procedures exist in case the system switches to a degraded mode (in case of failure of one component)	X			
9. A maintenance plan is enforced for the elements important for safety.		X		
10. The safety position of equipments and safety loops in case of alarm triggering have been controlled		X		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 not completed (waiting for the end of the hardware modifications on C1 filtration unit)
12. Mechanical integrity justification exists for every document equipment.			X	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.			X	Draft available for control routine updates.

14. A back up copy control system software to date is stored in a safe place.		X		
15. In case of alarm activation, the safety positions of actuators are identified and the factory acceptance tests are duly documented.		X		
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.		X		
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.		X		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.	X			
21. Spare parts list with their availability exist.		X		It exist a list that have to be completed
22. Users can clearly identify the documents that are not controlled		X		

ANNEX 8

Annex 8 – CI Functional Tests Step2: Record of implied personnel

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	CB
Olivier Gerbi	SHERPA	Senior engineer	OG

MELiSSA

TECHNICAL NOTE 94.12

ANNEX 9

Procedure 40: Drain filtration unit – retentate side (ESA comments on EPAS 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-06
2/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

TECHNICAL NOTE 94.12

ANNEX 10

CIFA Consultoría e Instalaciones Farmacéuticas Alimentarias

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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 220ºC bar, Precisión: ±0.1ºF según rango de temperatura

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

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.

king nutronics corporation™

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

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°F to 600°F, with an accuracy of ±0.5°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°F to 1,200°F, with an accuracy exceeding ±0.15% or ±0.8°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.

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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°F to 250°F, with an unsurpassed accuracy of ±0.1°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.

Performance Specifications

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

[1] 100°F below ambient temperature

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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 Celsius (°C)	Fahrenheit (°F) or Celsius (°C)	Fahrenheit (°F) or 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 (L x W x H)	11" x 7" x 10"	18" x 11" x 14"	18" x 11" x 14"
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
Type	5 x 7 alphanumeric dot-matrix, vacuum-fluorescent type	5 x 7 alphanumeric dot-matrix, vacuum-fluorescent type	5 x 7 alphanumeric dot-matrix, vacuum-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

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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, www.kingnutronics.com/support_page.htm.

PRIMARY STANDARDS

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	-10ºC to -220ºC

ºkosmon, s.a.
CONTROL DE TEMPERATURA

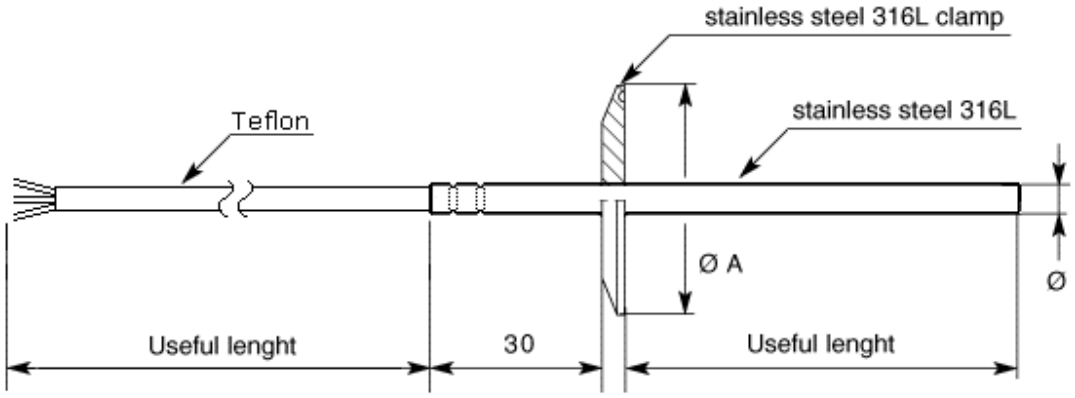
Esplugues, 14-12-2009

INFORME DE CARACTERÍSTICAS TÉCNICAS

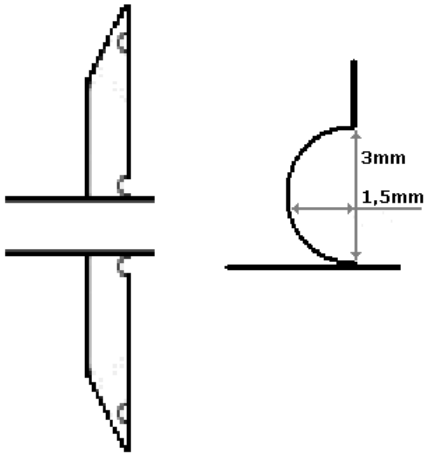
Componentes:
Sonda Pt-100 1/3 DIN Heraeus, D.6X60mm clamp 1" Inox 316, cuello 30mm Inox 316 con 6 mts cable de teflón, 3 hilos.

Código: SPT1/36502

Esquema:



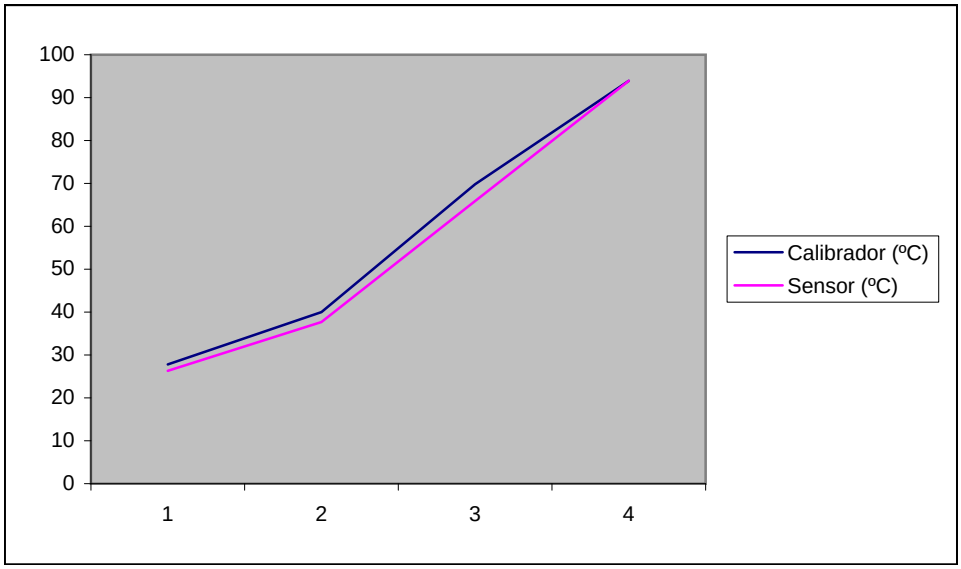
Detalle soldadura:



ºKOSMON S.A.
Dpto. Técnico
Guillén C. C.

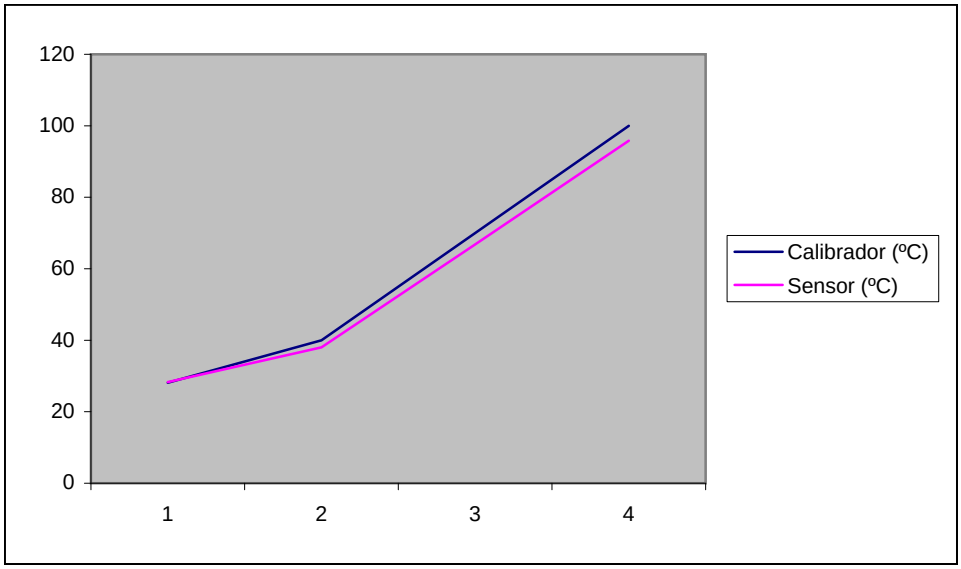
C/ Gall 47 - 3ª Planta P.I. el Gall
Tel: 93 470 64 20 08950 - Esplugues - BARCELONA Fax: 93 480 21 11

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



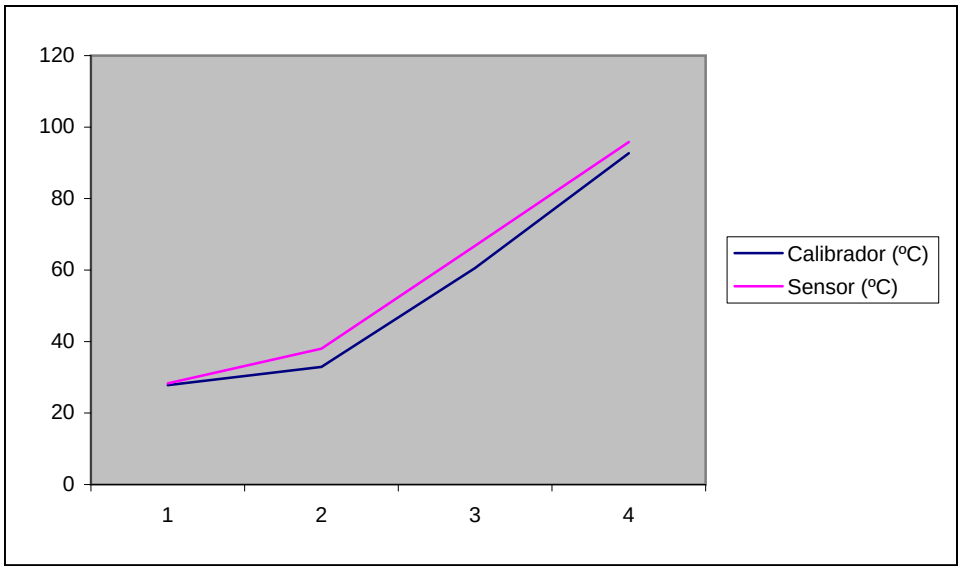
NOTA:
Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-1,5%.

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



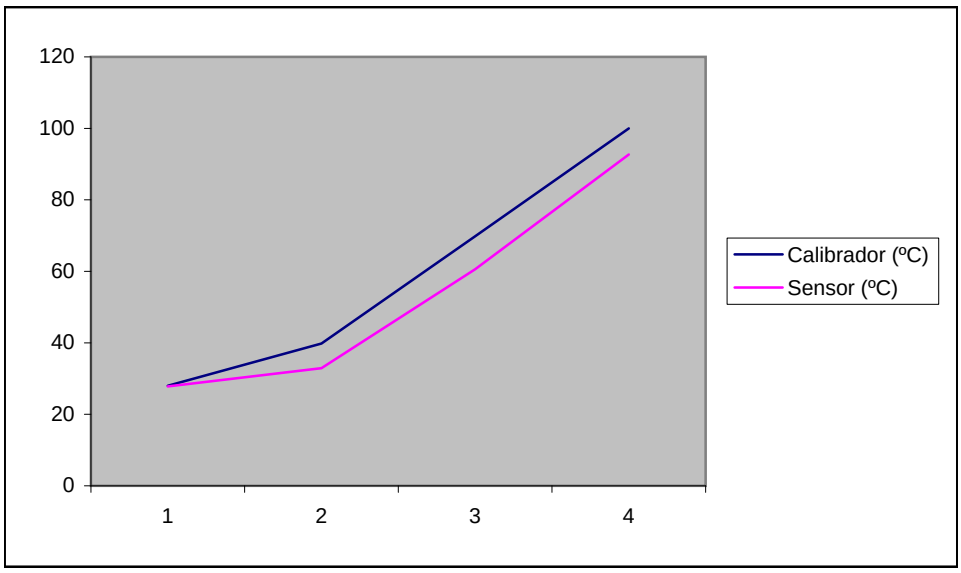
NOTA:
Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-1,5%.

Tag	Marca		Modelo	Rango
TT_1205_01	VEGA			0ºC/150ºC
	Calibrador (ºC)	Sensor (ºC)	Desviación	Desviación media
Input Value 1	28	27,8	0,20%	5,90%
Input Value 2	39,8	32,9	6,90%	
Input Value 3	69,8	60,6	9,20%	
Input Value 4	100	92,7	7,30%	



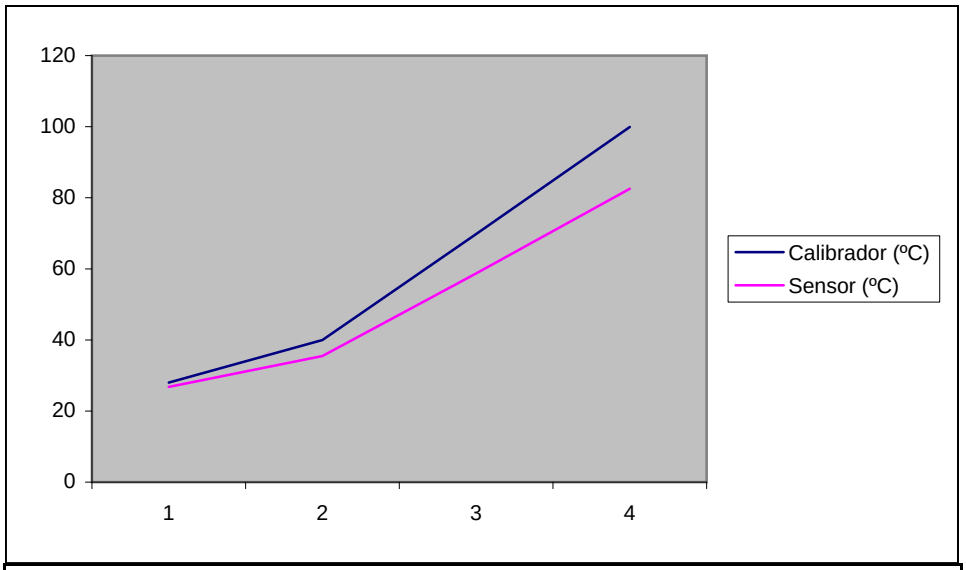
NOTA:
Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-1,5%.

Tag	Marca		Modelo	Rango
TT_1200_01	ENDRESS-HAUSER		TMR 35-A1AADI	0ºC/100ºC
	Calibrador (ºC)	Sensor (ºC)	Desviación	Desviación media
Input Value 1	28	27,8	0,20%	5,90%
Input Value 2	39,8	32,9	6,90%	
Input Value 3	69,8	60,6	9,20%	
Input Value 4	100	92,7	7,30%	



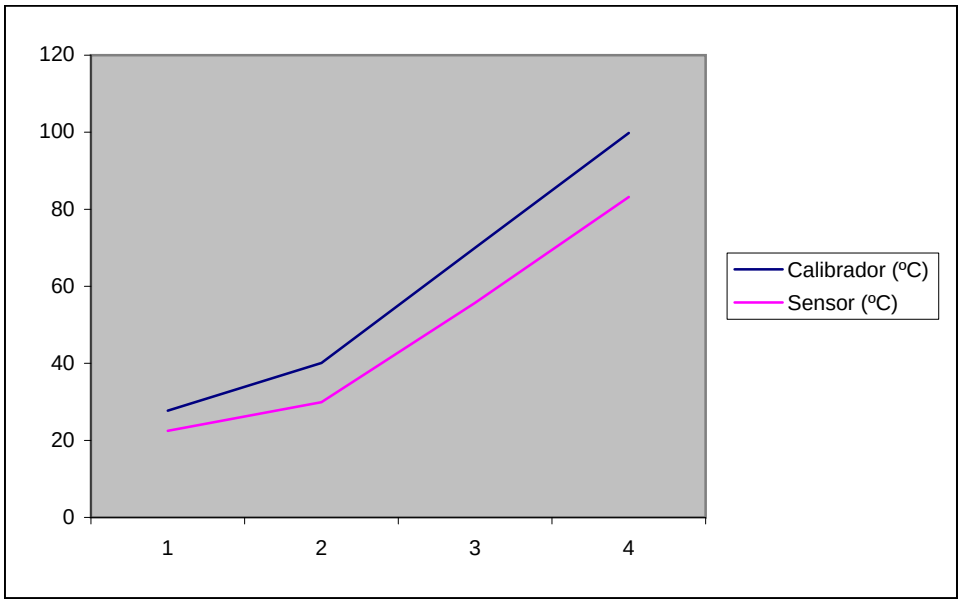
NOTA:
Este elemento debe recalibrarse, ajustar la compensación o substituirse, debido a que su precisión supera el 1-1,5%.

Tag	Marca		Modelo	Rango
TT_1104_01	ENDRESS-HAUSER		OMNIGRAD TST	-50ºC/250ºC
	Calibrador (ºC)	Sensor (ºC)	Desviación	Desviación media
Input Value 1	28	26,8	1,20%	8,54%
Input Value 2	40	35,5	4,50%	
Input Value 3	69,8	58,71	11,09%	
Input Value 4	99,9	82,55	17,35%	



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_1208_01	ENDRESS-HAUSER		OMNIGRAD TST	-50ºC/250ºC
	Calibrador (ºC)	Sensor (ºC)	Desviación	Desviación media
Input Value 1	27,7	22,5	5,20%	11,58%
Input Value 2	40,1	29,9	10,20%	
Input Value 3	70	55,7	14,30%	
Input Value 4	99,8	83,2	16,60%	



NOTA:
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.

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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 ºF a 120 ºF, Efecto temperatura: ±0.004% de Span / ºF, 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)	Accuracy
0/10 Vdc	±0.025% FS
0/30 Vdc	±0.10% FS
0/20mA	±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 keypad 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
N.I.S.T. Traceable certification document provided for base display unit and sensor modules

PRESSURE SENSOR MODULE SPECIFICATIONS

GQS-1

Pressure Types
Gauge, differential & compound

Available Ranges
(See Chart)

Available Accuracies
±0.06 (0/2-0/200 in. H_2O), ±0.07 (0/0.25-0/1 in. H_2O) 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_2O or higher)
±0.02% of span (ranges below 0/1 in. H_2O)

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
Optional: G 1/8 British standard

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

GQS-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° ±3°)
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, non-corrosive gas
0/10-0/10,000 psi ranges: Any medium compatible with 316 SS.

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
Optional: 1/8 NPT female with flush port (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

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

ACCESSORIES

110Vac/60 Hz ac Adapter
220Vac/50 Hz ac Adapter
Contoured protective case
Soft carrying case
Hard carrying case
LPSIIa External 24vdc Loop Power Supply – to power transducers and pressure switch test circuit
SM-1 Voltage Adapter – provides ability to check "live" pressure switches

***Specifications subject to change without notice**

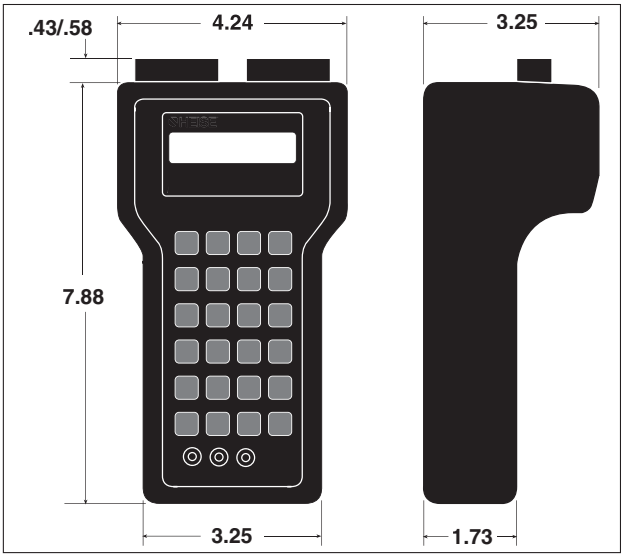
PRODUCT SPECIFICATIONS*

STANDARD RANGES

GQS-2 psi (gauge and absolute pressure)	GQS-1 ˝H_2O (gauge/ differential pressure)	Other Engineering Units**
*5	0.25*	psi
10	0.5*	in. H_2O
15	1.0*	in. Hg
20	2.0*	ftSW
25	3.0*	Bar
30	5.0*	mBar
50	10*	kPa
60	15*	mPa
100	25*	mmHg
150	50*	cmH_2O
200	100*	mmH_2O
250	150*	kg/cm^2
300	200*	User Selectable
500		
600		**Note: Engineering units identified above are accessible through the unit select feature. However, readout will default to the primary unit of measure on start-up. Sensor modules scaled in primary units other than in. H_2O (GQS-1) or psi (GQS-2) are also available.
1000		
1500		
2000		Consult factory.
2500		
3000		
5000		
6000		
7500		
10,000		
vacuum		
5		
10		
15		
compound		
±5	±0.125*	
±10	±0.25*	
±15	±0.5*	
–15/+30	±1.0*	
–15/+60	±1.5*	
	±2.5*	
	±5.0*	
	±7.5*	
	±12.5*	
	±25*	
	±50*	
	±75*	
	±100*	

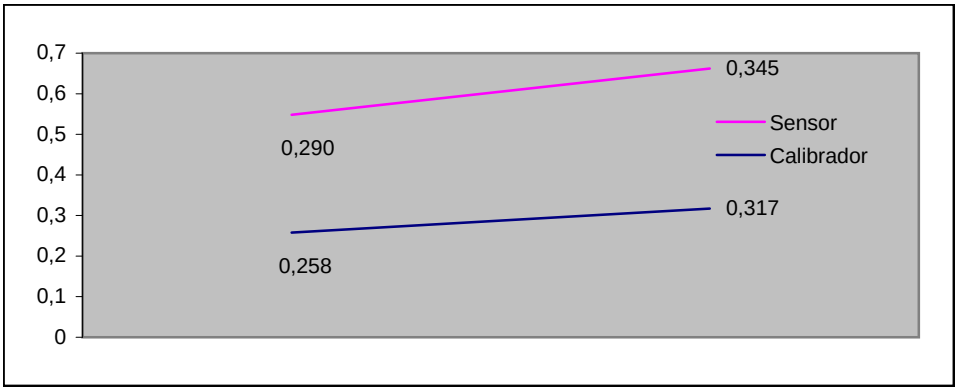
* Non-isolated, for clean dry gas only

DIMENSIONS



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

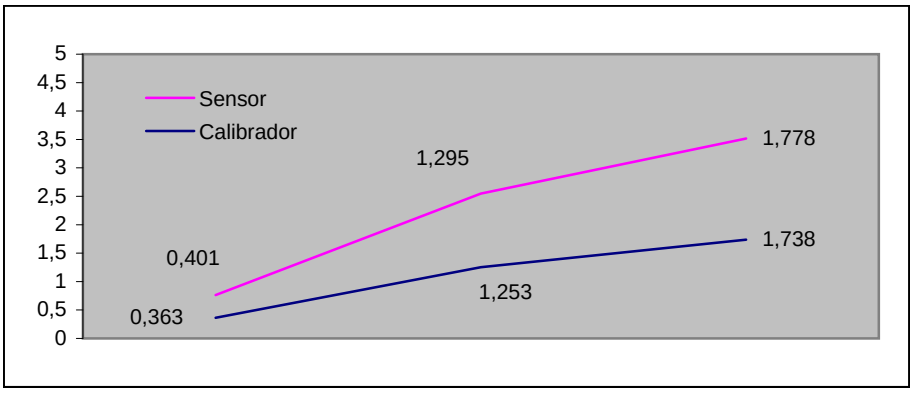
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,258	0,290	11,03%	9,58%
Input Value 2	0,317	0,345	8,12%	



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-1203-06				2 bar

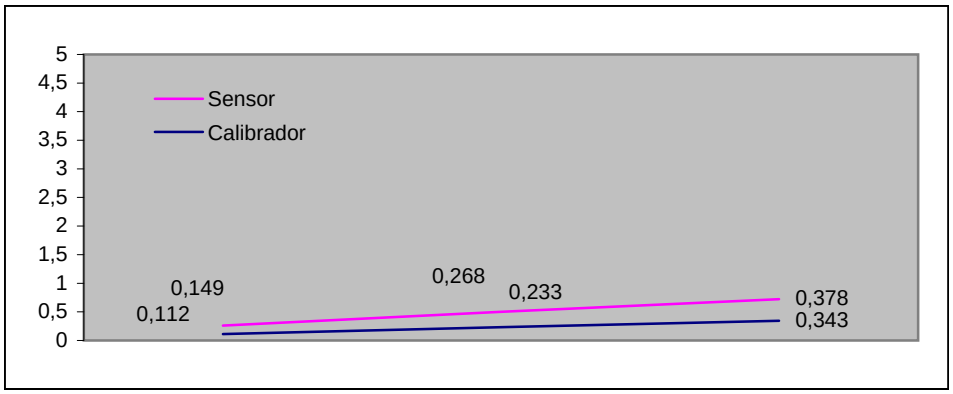
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,363	0,401	9,48%	4,99%
Input Value 2	1,253	1,295	3,24%	
Input Value 3	1,738	1,778	2,25%	



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-1203-03				2 bar

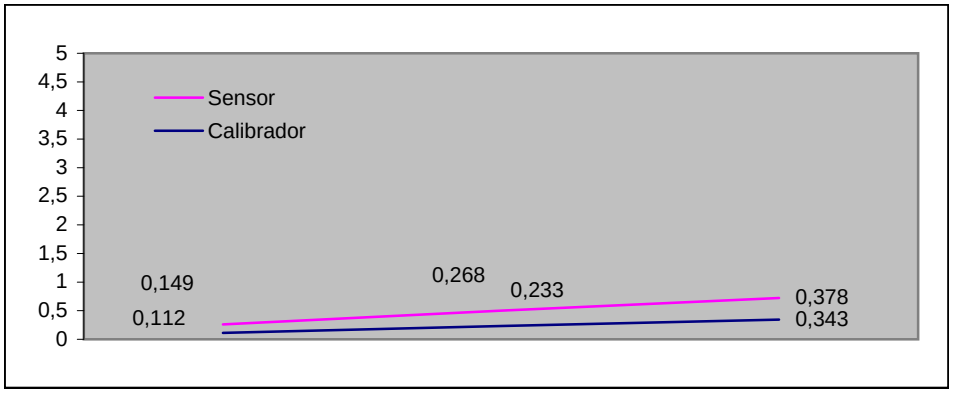
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,112	0,149	24,83%	15,72%
Input Value 2	0,233	0,268	13,06%	
Input Value 3	0,343	0,378	9,26%	



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-1009-02				400 mbar

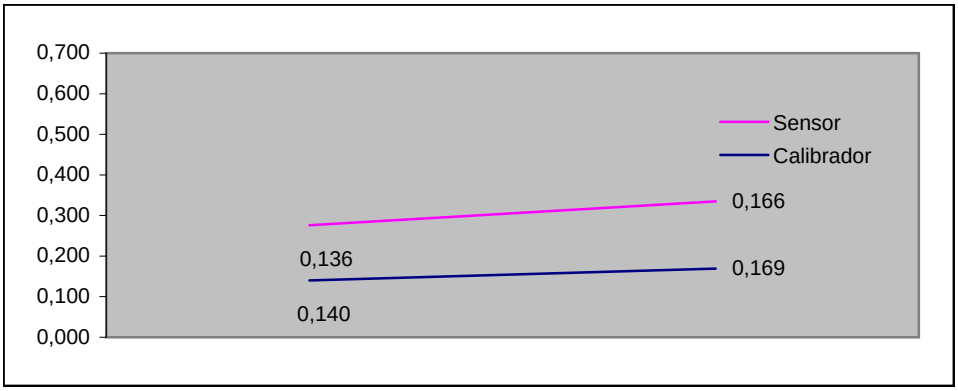
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,392	0,432	9,26%	4,92%
Input Value 2	0,950	0,980	3,06%	
Input Value 3	1,793	1,838	2,45%	



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

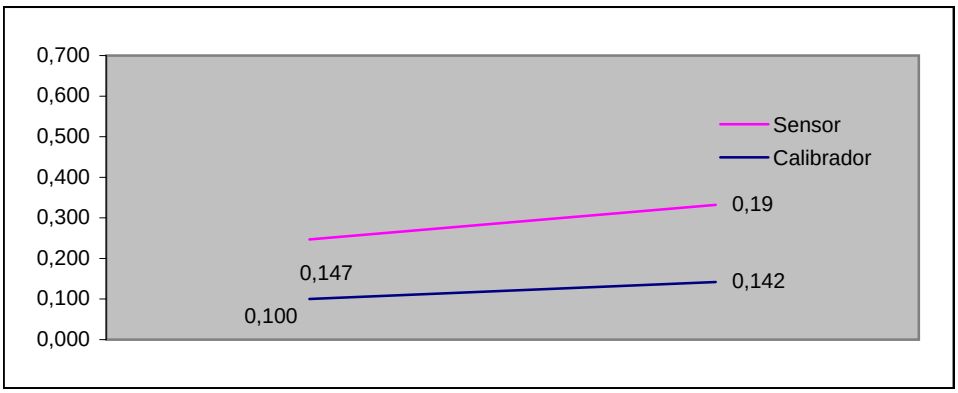
Tag	Marca	Modelo	Rango	Saturación
PT-1009-01				200 mbar

	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%	



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

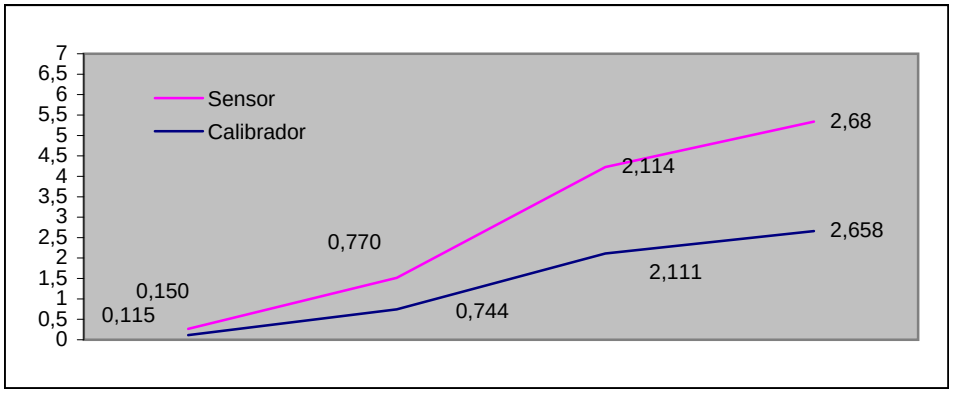
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,100	0,147	31,97%	28,62%
Input Value 2	0,142	0,19	25,26%	



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-1203-01				4 bar

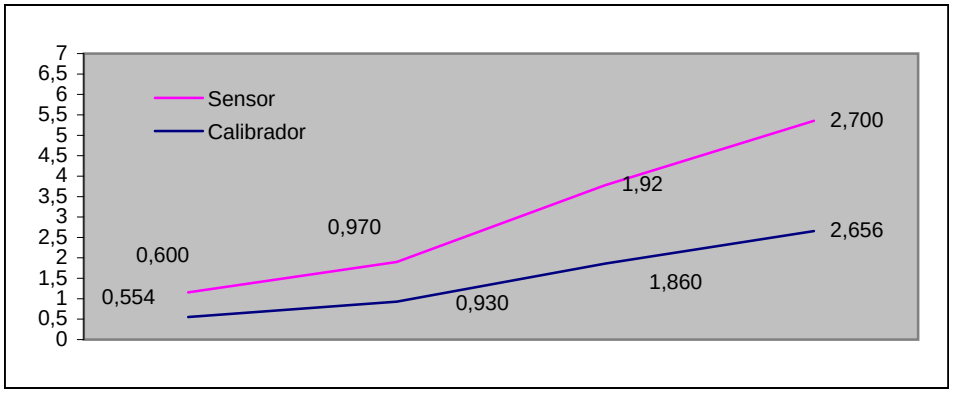
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,115	0,150	23,33%	6,92%
Input Value 2	0,744	0,770	3,38%	
Input Value 3	2,111	2,114	0,14%	
Input Value 4	2,658	2,68	0,82%	



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

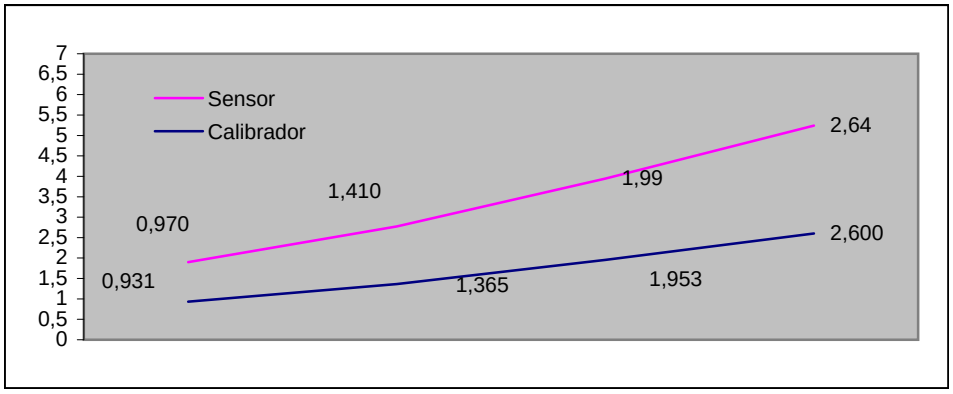
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,554	0,600	7,67%	4,14%
Input Value 2	0,930	0,970	4,12%	
Input Value 3	1,860	1,92	3,12%	
Input Value 4	2,656	2,700	1,63%	



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

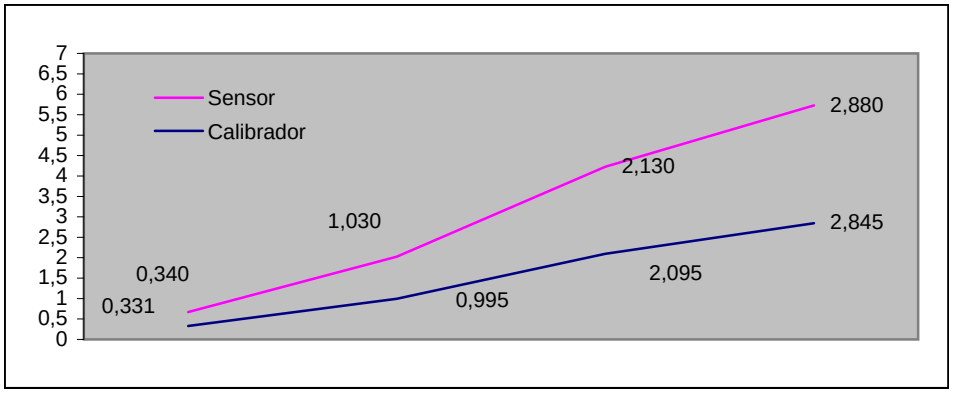
Tag	Marca	Modelo	Rango	Saturación
PT-1203-02				4 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,931	0,970	4,02%	2,65%
Input Value 2	1,365	1,410	3,19%	
Input Value 3	1,953	1,99	1,86%	
Input Value 4	2,600	2,64	1,52%	



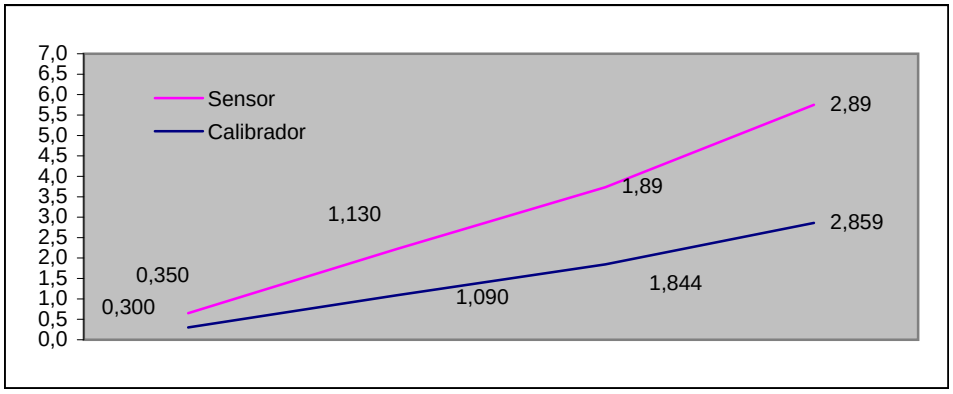
Tag	Marca	Modelo	Rango	Saturación
PT-1203-05				4 bar

	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,331	0,340	2,65%	2,23%
Input Value 2	0,995	1,030	3,40%	
Input Value 3	2,095	2,130	1,64%	
Input Value 4	2,845	2,880	1,22%	



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

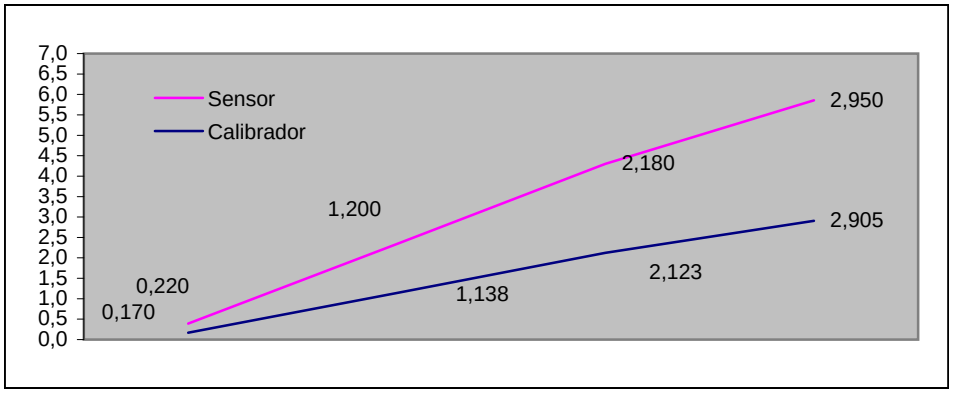
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,300	0,350	14,29%	5,33%
Input Value 2	1,090	1,130	3,54%	
Input Value 3	1,844	1,89	2,43%	
Input Value 4	2,859	2,89	1,07%	



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

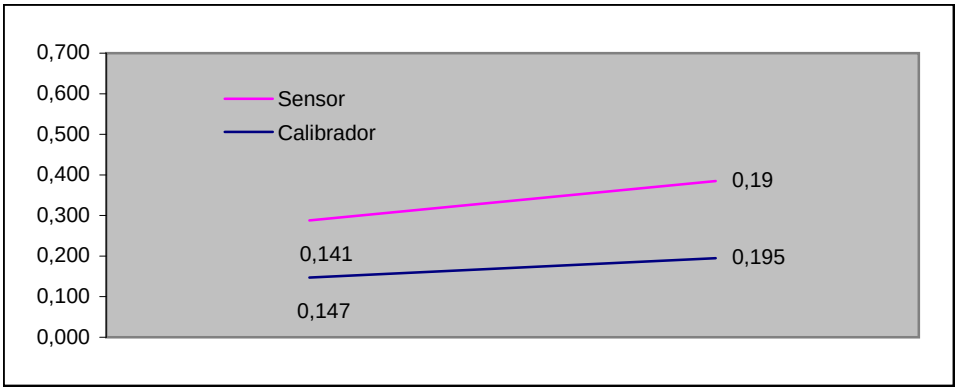
	Calibrador (bar)	Sensor (bar)	Desviación	Desviacion media
Input Value 1	0,170	0,220	22,73%	8,01%
Input Value 2	1,138	1,200	5,17%	
Input Value 3	2,123	2,180	2,61%	
Input Value 4	2,905	2,950	1,53%	



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-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%	



NOTA:
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