



Operator Panel Software Detail Design Specification **ISO FLEX-R isolator**

NTA 3015-144 | 007

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Approuvé informatiquement / Electronic signature				

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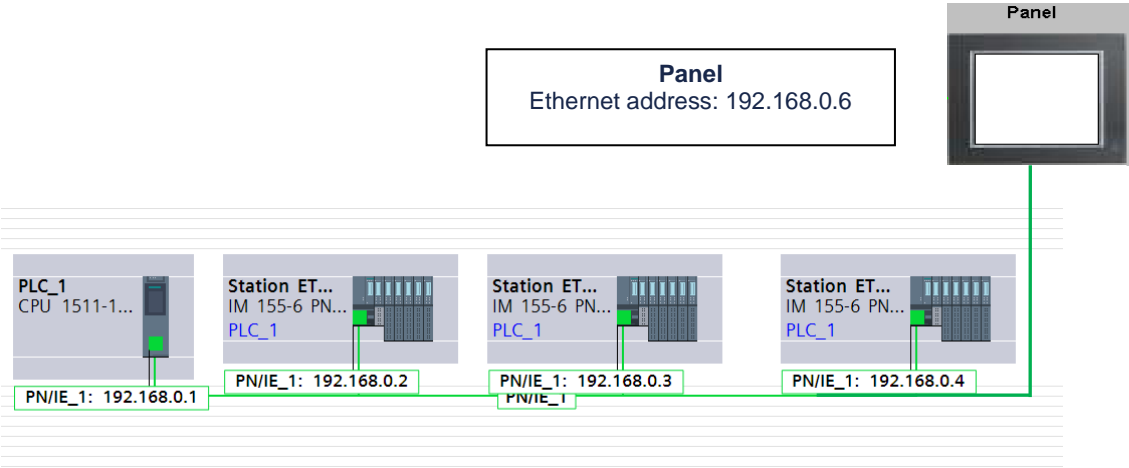
1. Introduction

The purpose of the document is to describe the operator panel functioning.

2. Configuration system

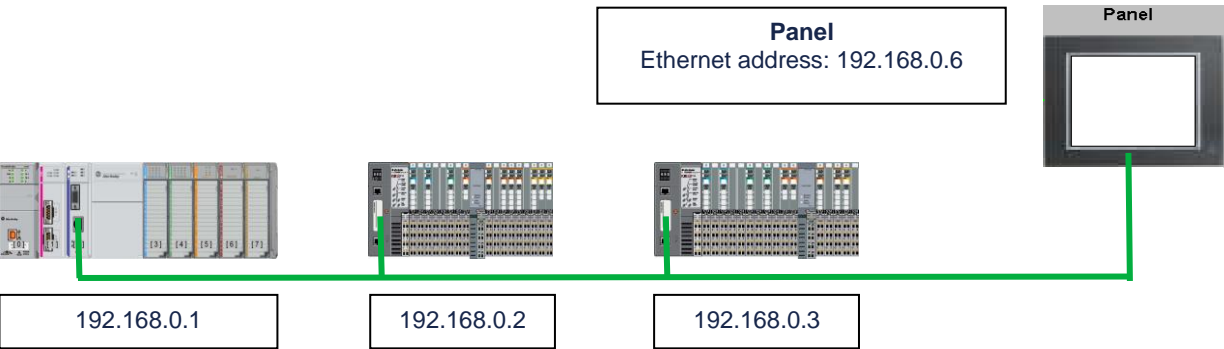
2.1. Siemens PLC–Operator panel communication

The communication between PLC and operator panel is performed by an Ethernet connection.



2.2. Rockwell PLC-Operator panel communication

The communication between PLC and operator panel is performed by an Ethernet connection.



2.3. Hardware system

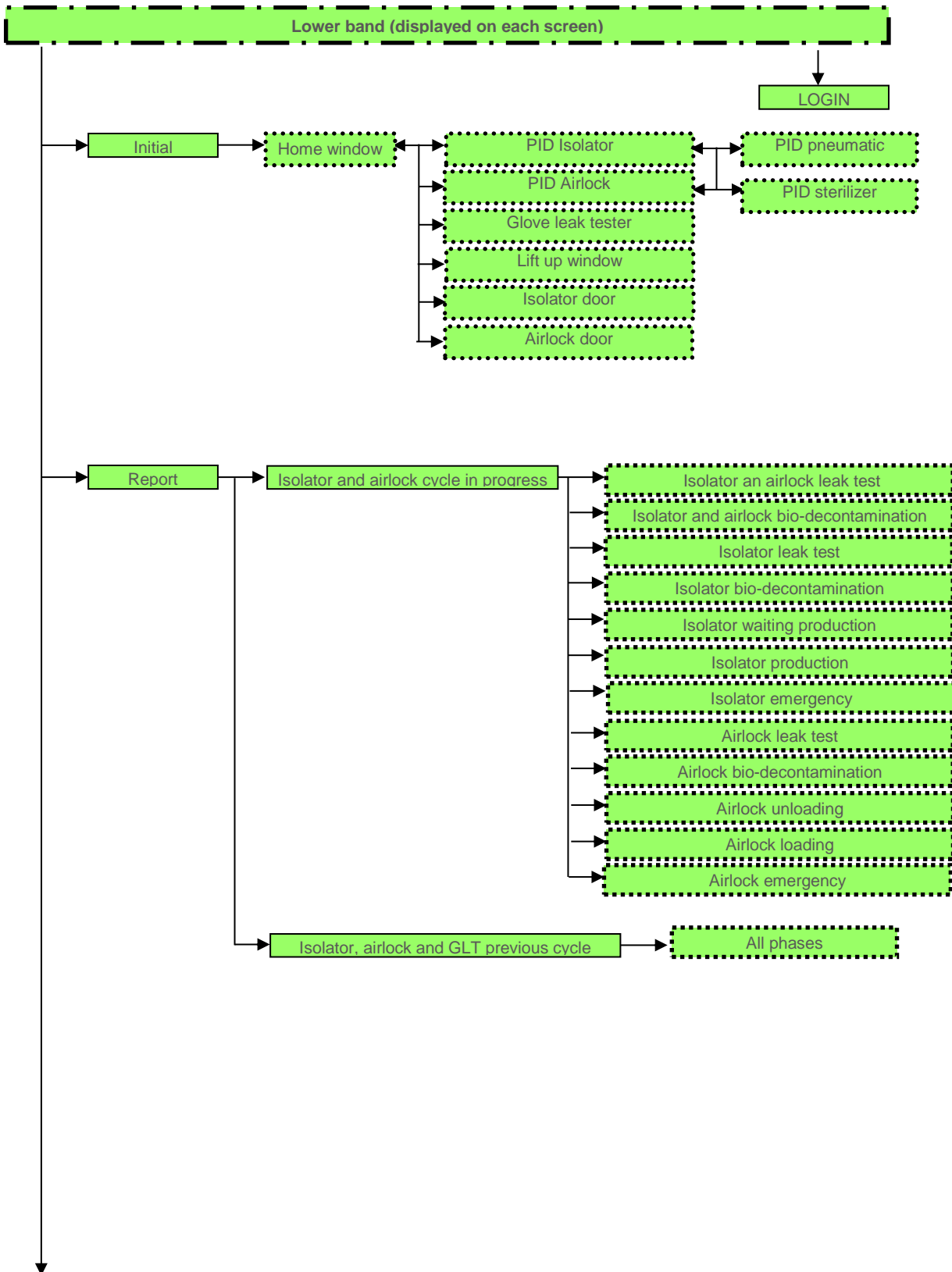
SIMATIC IPC477E PRO, 19" MTouch with 1 hard disk, 3 Ethernet connections:

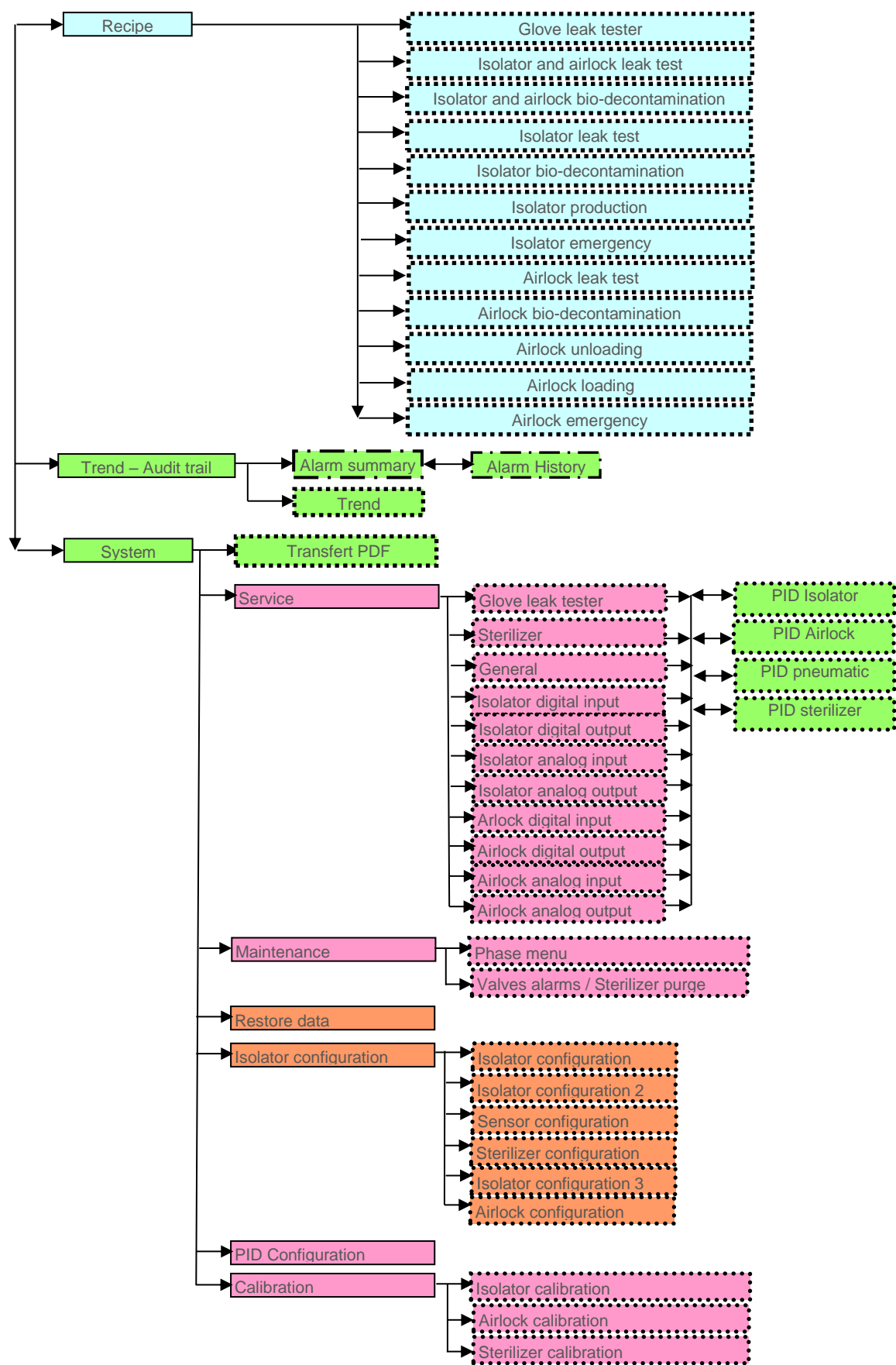
- Resolution 1366*768
- Processor i5-6442EQ CPU 1.90 GHz, 1901 MHz, 4 coeurs.
- RAM 8 Go
- HDD 256 Go

2.4. Software system

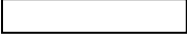

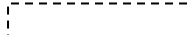




- Windows 10 Enterprise 2016 LTSC, 64 bit
 - Microsoft SQL Server 2012 SP1
 - Wonderware - Archestra System Platform 2014 R2 SP1 – Update 2
-

3. Scada organisation chart


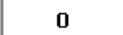







Legend

	Description
	Button
	Screen displaying with commands or fields
	Screen displaying
	Operator level
	Process level
	Maintenance level
	Administrator level


3.1. General

	Description
	Background screen
	Input field
	Alarm (UNACK_ALM) Red
Red	Alarm (UNACK_ALM) Red
Orange	Alarm present and acknowledged (ACK_ALM) Orange
Green	Alarm disappeared and acknowledged (ACK_RTN) Green
	Printing PDF current screen button
	Printing current screen button

3.2. Lower band



Push-button

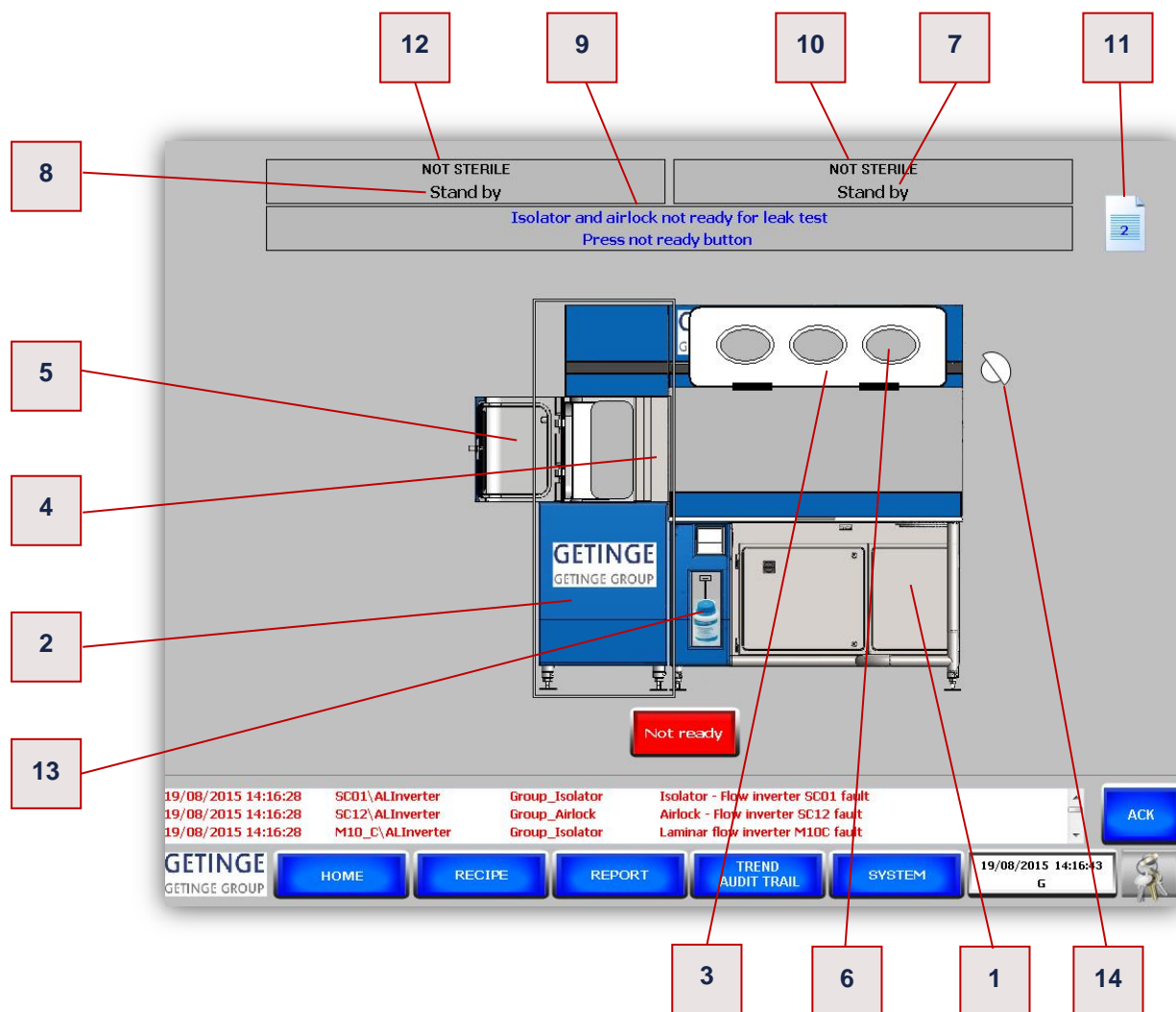
Push-button	Description
Home	Allows the home window opening. Accessible from operator level
Recipe	Allows the recipe windows opening. Accessible from process level
Report	Allows the recipe windows opening. Accessible from operator level
Trend/ Audit trail	Allows the analog value history and alarm window opening. Accessible from operator level
System	Allows the adjustment window opening. Accessible from operator level
Ack	The key is used to acknowledge an alarm message
	Allows the opening or closing of the session (users log in or log off)

Output field








Output field	Description	Format
#####	Operator name connected displaying.	Text (16 alpha numeric characters)
<div><div>UNA... Alarm1</div><div>UNA... Alarm2</div><div>UNA... Alarm3</div></div>	The last alarms are displaying in this box (3 lines).	N/A

3.3. Home

This screen is displayed when the system is started.



Push-button

Push-button	Description
STOP	Allows to stop the isolator or airlock current phase (> operator level with a message box for confirmation)
Not ready	Pressing this button displays the locking conditions (> operator level)
START	Allows to start phase for each corresponding volume (> operator level)
New batch	Allows to start a new batch for the isolator production phase (> operator level)
Batch end	Allows to end a batch for the isolator production phase (> operator level)
	Allows the access to the PID isolator (operator level)
	Allows the access to the PID airlock (operator level)
	Allows the access to the isolator lift up window management (operator level)
	Allows the access to the isolator door management (operator level)
	Allows the access to the airlock door management (operator level)
	Allows the access to the glove leak tester (operator level)
	Allows the access to the reports to be validated (operator level)

Output field

Variable	Description
7	Isolator phase in progress
8	Airlock phase in progress
9	Isolator and airlock. Help text for the operator
10	Isolator status
12	Airlock status
13	Allows the access to H ₂ O ₂ vial values (operator level)
14	Light control (operator level)

3.4. Alarm summary

This screen is used to display the alarm summary.



Push-button

Push-button	Description
Alarm history	Allows to display the alarm history

Output field

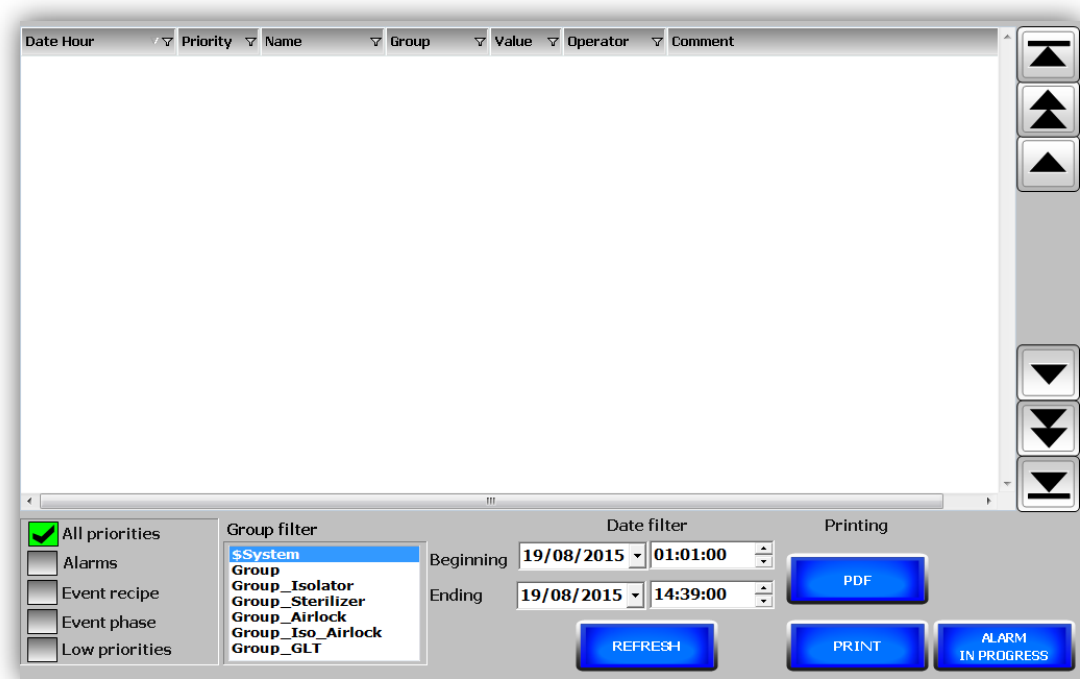
Output field	Description
Date Hour	Operation date & time (alarm appears, disappears and acknowledged)
State	Operation status (UNACK=Not Acknowledged, ACK=Acknowledged)
Name	Alarm name used
Group	Name of the group which the alarm is classified
Comment	Alarm description

List box (alarm group selection)

Output field	Description
Group	Allows to display the Isolator + Airlock + Sterilizer + isolator and airlock + Glove leak tester alarms
Group_Airlock	Allows to display only the airlock alarms
Group_Isolator	Allows to display only the isolator alarms
Group_Iso_Airlock	Allows to display only the isolator and airlock alarms
Group_GLT	Allows to display only the glove leak tester alarms
Group_Sterilizer	Allows to display only the sterilizer alarms

3.5. Alarm history

This screen is used to display the alarm history.



Push-button

Push-button	Description
Refresh	Allows to update the date & time selection and to display the alarm selected
Alarm in progress	Allows to display the alarm summary
All priorities	Allows to display all priorities
alarms	Allows to display high alarm
Event recipe	Allows to display recipe event
Event phase	Allows to display phase event
Low priorities	Allows to display low alarm

Output field

Output field	Description
Date Hour	Operation date & time (alarm appears, disappears and acknowledged)
Priority	Alarm priority
Name	Alarm name used.
Group	Name of the group which the alarm is classified
value	New value
Comment	Alarm description
value	New value

Input field

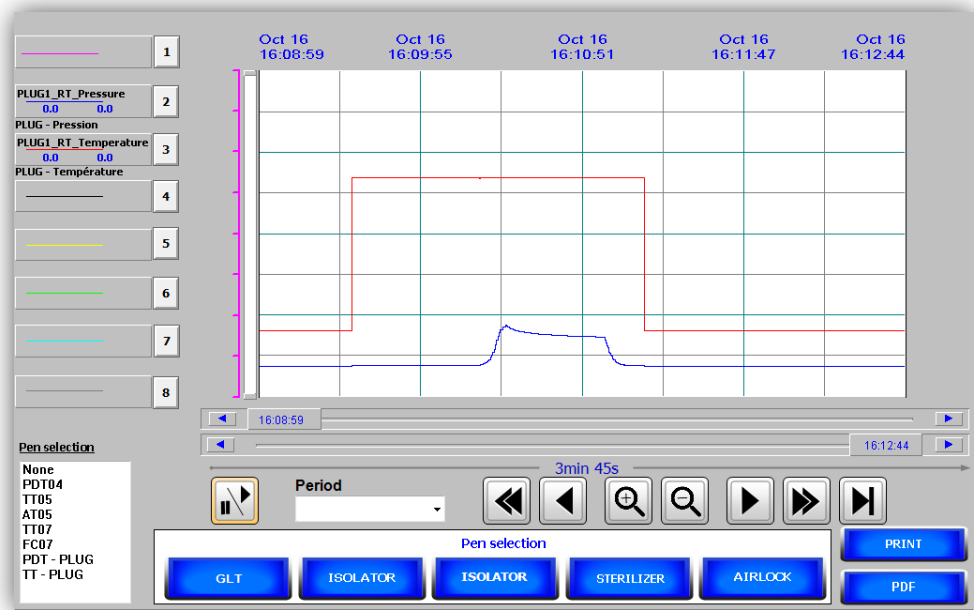
Output field	Description
Beginning	Allows to select the date and time of the alarm starting to display.
Ending	Allows to select the date and time of the alarm ending to display.

List box (alarm group selection)

Output field	Description
\$System	Allows to display all alarms
Group	Allows to display the Isolator + Airlock + Sterilizer + isolator and airlock + Glove leak tester alarms
Group_Airlock	Allows to display only the airlock alarms
Group_Isolator	Allows to display only the isolator alarms
Group_Iso_Airlock	Allows to display only the isolator and airlock alarms
Group_GLT	Allows to display only the glove leak tester alarms
Group_Sterilizer	Allows to display only the sterilizer alarms

3.1. Historical

This screen allows the trends displaying in real time or in history.



Push-button

Push-button	Description
Pen 1 to 8	Allows access to the trends selection
Trend functions	Allows changing the time scale and the pen scale by several tools
GLT	Allows to select the GLT sensors measurement displaying
Filters	Allows to select the filters measurement displaying
Isolator	Allows to select the isolator measurement displaying
Airlock	Allows to select the airlock measurement displaying
Sterilizer H ₂ O ₂ sensor(s)	Allows to select the sterilizer measurement displaying

List box (pen selection)

Output field	Description
Analog input	Allows to select a analog input measurement displaying

Option button (only one option can be selected)

Output field	Description
Real time	Allows the trends displaying in real time
History	Allows the access to the historical trends

3.2. Previous report

This screen is used to display phase report.

ISOLATOR - EMERGENCY

Isolator number : 1236 Date : 17/08/2015 12:25:13

Beginning the : 17/08/2015 12:24:14 Signature : G

Ending the : 17/08/2015 12:24:30 Comments : No comment

User : g Cycle number : 4

GMP parameters

Pressure set : -30 Pa

Pressure min : -200.0 Pa

Pressure max : -200.0 Pa

Pressure average : -200.0 Pa

Pressure stdev : 0.00 Pa

Temperature min : 89.00 °C

Temperature max : 89.00 °C

H2O2 end step : 0.0 ppm

Air velocity min : 0.00 m/s

Air velocity max : 0.00 m/s

Output field

Push-button	Description
1	Name of the phase report
2	Parameter description
3	Output field parameter

Input field

Output field	Description
Start date	Allows to select the date and time of the cycle list to display.
End date	Allows to select the date and time of the cycle list to display.

Push-button

Push-button	Description
Display	Displaying the selected report
Print	Printing the selected report
Refresh	Allows to update the date & time selection and to display the list cycle selected

List box

Output field	Description
Report selection	Allows to select the phase report
Cycle list	Allows to select the cycle

3.3. Current report

This screen is used to display phase report in progress.

1

2

FILLING - TEST

Isolator number : 0

Phase beginning : Date time

User : User

Cycle number : 0

GMP parameters

Cycle beginning : 0.0 Pa

Stabilization 1 pressure: 0.0 Pa

Stabilization 2 pressure: 0.0 Pa

Pressure beginning test : 0.0 Pa

Pressure ending test : 0.0 Pa

Pressure difference : 0.0 Pa/min

Temperature beginning test : 0.00 °C

Temperature ending test : 0.00 °C

Temperature difference : 0.00 Pa/min

Test result : Test result

3

Output field

Push-button	Description
1	Name of the phase report
2	Parameter description
3	Output field parameter

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3.4. Bio-decontamination recipe

This screen allows the bio-decontamination phase recipe adjustment.

1

2

3

RECIPE SELECTION

iso

controle

CREATE RECIPE

Name

CREATE

DELETE RECIPE

Name

DELETE

TRANSFER TO PLC

ISOLATOR - RECIPE BIO DECONTAMINATION

Pressure set (Pa) :

0

Isolator aeration

Min pressure alarm (Pa) :

0

Aeration time set (Min) :

0

Max pressure alarm (Pa) :

0

Blower speed M01 (%) :

0

Pressure alarm inhibition (Sec) :

0

Min temperature alarm (°C) :

0.0

Max temperature alarm (°C) :

0.0

PDF

PRINT

Input or Output field

Push-button	Description
1	Name of the phase recipe
2	Parameter description
3	Input field parameter (accessible from process level)

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Push-button

Push-button	Description
Selection	Displaying the selected recipe. Accessible from process level
Create	Allows the updating the new recipe. Accessible from process level
Delete	Allows deleting the selected recipe. Accessible from process level
Save recipe	Allows the updating recipe. Accessible from process level
Transfer to PLC	Allows the transfer recipe to PLC. Accessible from process level

List box

Output field	Description
Recipe selection	Allows to select the recipe name

3.5. Recipes

This screen allows the parameters adjustment.

2

1

3

CLIMET

Particle 0,5 µm - Max level4000

Particle 5 µm - Max level40

Climet alarm Inhibition (Sec) :60

Measure duration (Min)20

MAS100

Mode (SQS=1 Std=0)1

Volume (Liters) :1000

Measure duration (Min)20

Fractions :2

ISOLATOR - PRODUCTION RECIPE

Pressure set (Pa) :60

Min pressure alarm (Pa) :25

Max pressure alarm (Pa) :75

Pressure alarm Inhibition (Sec) :30

Min temperature alarm (°C) :18.0

Max temperature alarm (°C) :36.0

Blower speed M01 (%) :88

Min air velocity alarm (Pa) :0.36

Max air velocity alarm (Pa) :0.54

Air velocity alarm Inhibition (Sec) :40

Blower speed M03A (%) :80

Blower speed M03B (%) :81

Blower speed M03C (%) :82

PDF

PRINT

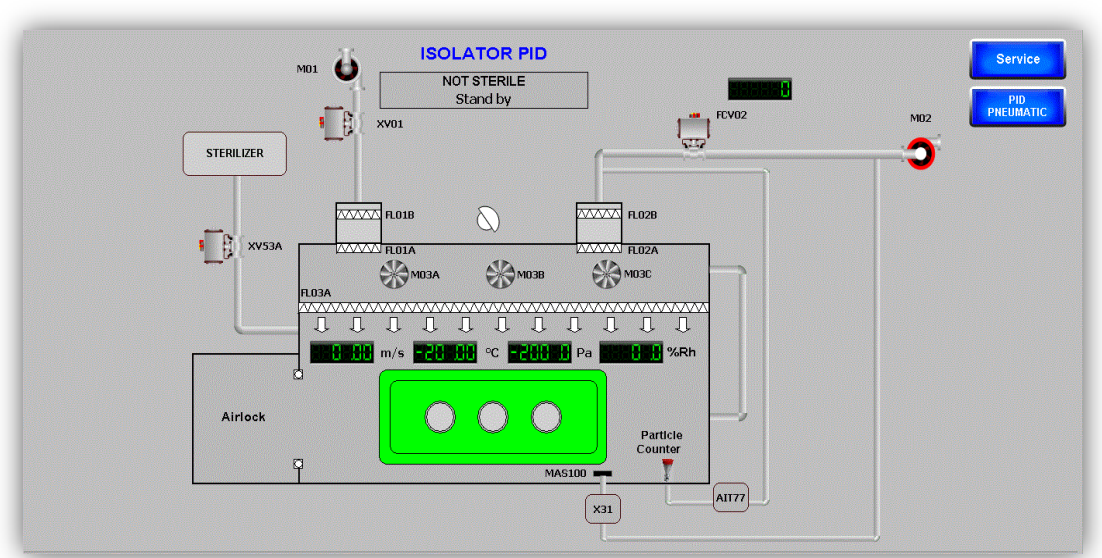
Input or Output field

Push-button	Description
1	Name of the phase recipe
2	Parameter description
3	Input field parameter (accessible from process level)



3.6. PID

This screen allows:

- to display each state of corresponding actuators,
- to display pressure, humidity, temperature, air velocity and H₂O₂.
- to display sterilizer step.



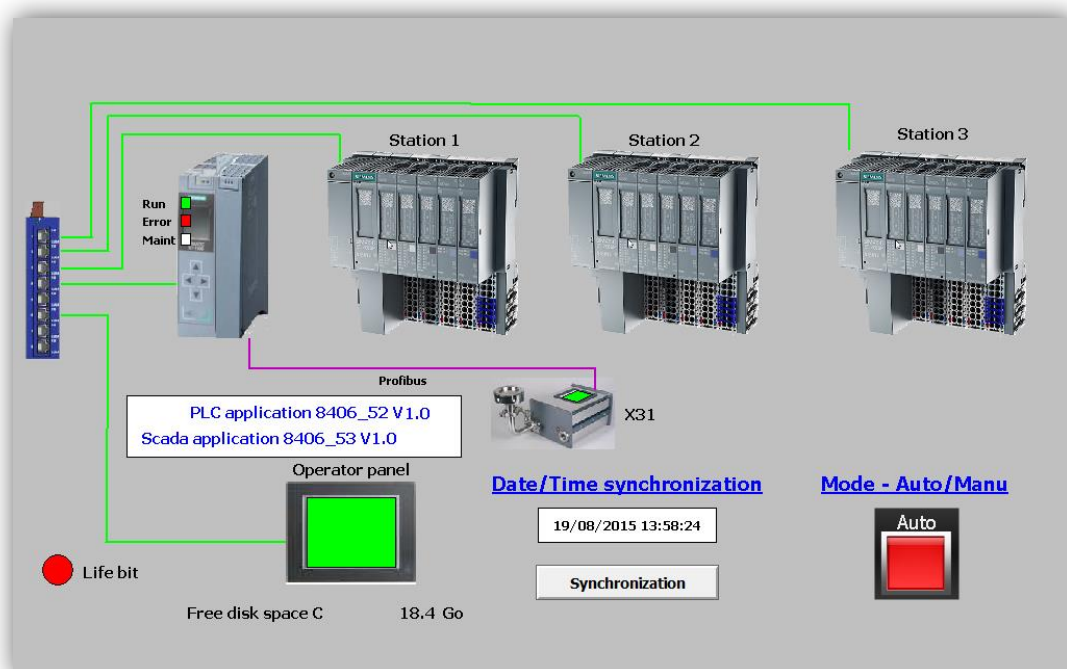
Push-button

Push-button	Description
Airlock	Allows the access to PID airlock
PID pneumatic	Allows the access to PID pneumatic
Service	This button shows the current status of digital input, digital output, analog input, analog output.
Sterilizer	This button show the current status of sterilizer
X31 (MAS100)	This button show the current status of MAS100
AIT77 (Climet)	This button show the current status of Climet
	This button show the filter pressure
	Allows to control the light (operator level)

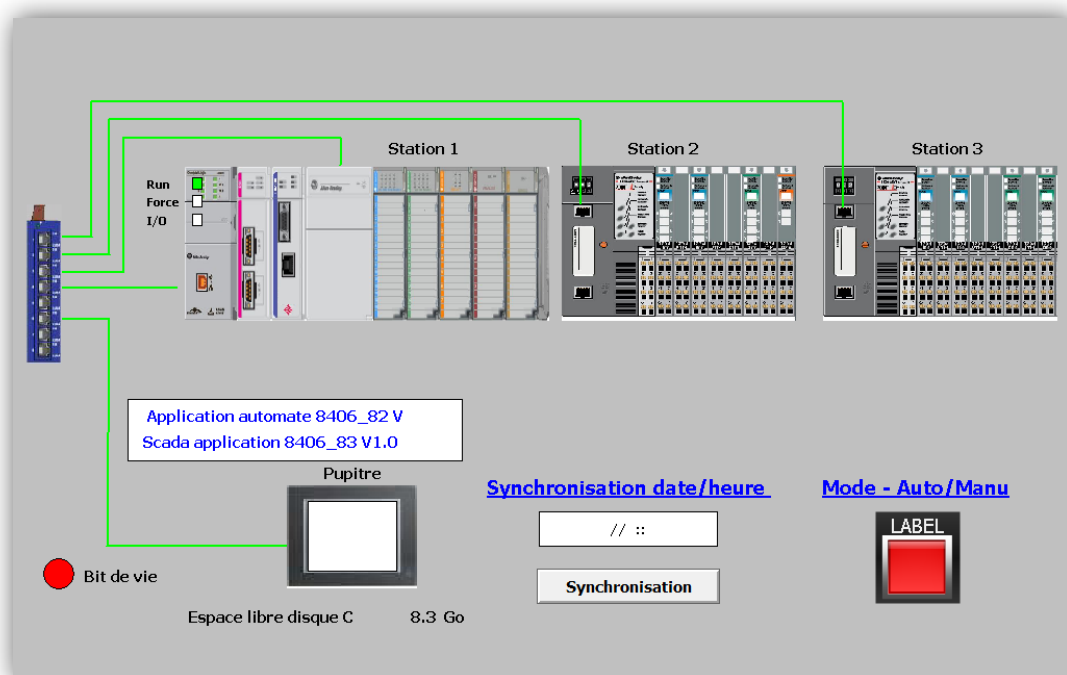
3.7. Siemens and Rockwell services

This screen is used to show the current status of the digital input or digital output or analog input or analog output.



Siemens

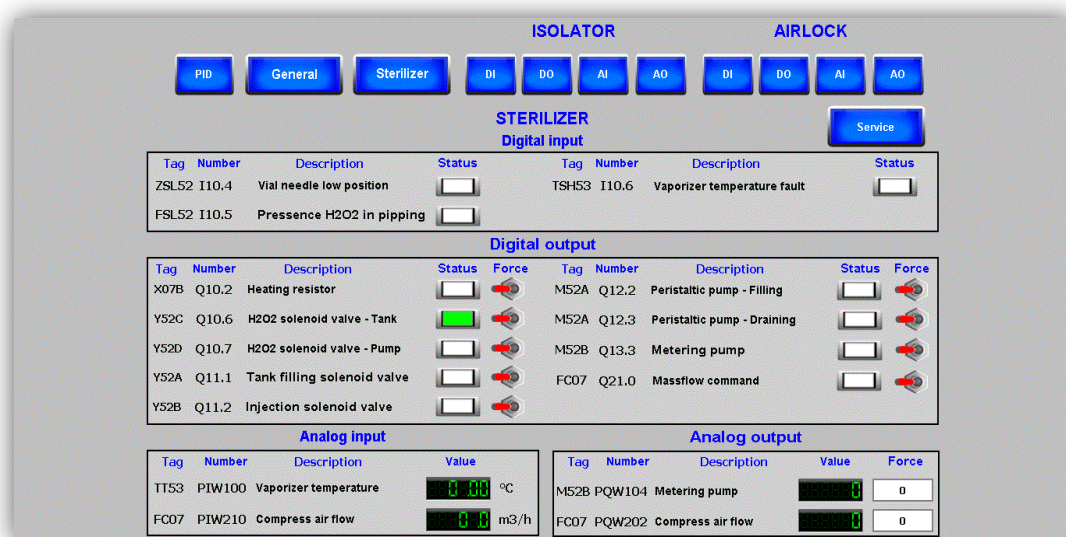


Rockwell







Push-button



Push-button	Description
	Allows the access to show the current status of the digital input or digital output or analog input or analog output (maintenance level)
Synchronization	Allows the user to synchronise the date and time (maintenance level)
	This button is used to select the manual mode (maintenance level)



Push-button

Push-button	Description
	This button is used to force the value of the output (maintenance level)
	Allows the access to the digital input screen (maintenance level)
	Allows the access to the digital output screen (maintenance level)
	Allows the access to the analog input screen (maintenance level)
	Allows the access to the analog output screen (maintenance level)
	Allows the access to show the sterilizer current status of the digital input or digital output or analog input or analog output. (maintenance level)
	Allows the access to show the general current status of the digital input or digital output or analog input or analog output. (maintenance level)
	Allows the access to PID airlock, isolator and sterilizer (maintenance level)

Input or output field

Push-button	Description
	Input field parameter (maintenance level)
	PLC input or output status

3.8. Adjustment menu

This screen is used to select adjustments by a maintenance technician or by administrator.



Push-button

Push-button	Description
Calibration	Allows the access to the calibration menu (maintenance level)
PID configuration	Allows the access to PID configuration (maintenance level)
System configuration	Allows the access to the system configuration (administrator level)
Data restore	Allows the access to restore data view (administrator level)
Maintenance	Allows the access to the maintenance menu (maintenance level)
Service	Allows the access to the I/O status (maintenance level)
Transfer PDF	Allows the access to transfer PDF files (operator level)

3.9. System configuration

This screen is used to select the different adjustments by administrator:

- Isolator serial numbers,
 - Sensors configuration,
 - HMI configuration,
 - Isolator configuration,
 - Sterilizer configuration,
 - Airlock configuration,
 - Data save,
 - Language setting,
 - Logon timeout.
-

4. Password

The system access level contains 5 levels. The structure of the access level is a pyramidal structure (Level0<Level1<Level2<Level3 Etc...).

- Level 0 is for visitor (Groups "Visitor")
- Level 1 is for operator (Groups "Operator")
- Level 2 is for Process (Groups "Supervisor")
- Level 3 is for maintenance (Groups "Maintenance")
- Level 9 is for administrator (Groups "Admin")

These levels allow:

	Level 0	Level 1	Level 2	Level 3	Level 9
Phase control					
Report					
Alarm					
Trend					
Print and transfer PDF files					
Recipe					
Service					
Manage phase in reduce mode					
Calibration					
PID configuration					
Restore data					
Configuring system					

User management includes: change initial password, number of incorrect logon attempts and passwords aging.

Revision history

Date	Version	Description	Written by
18/08/2015	A	First issue (13/319)	S. Chauvin
03/02/2016	B	Issue of software modification (16/067): <ul style="list-style-type: none">• Deletion of the XV13 valve• Addition of the locking airlock door• Addition of the classic airlock views	S. Chauvin
18/05/2016	C	Issue of software modification (16/289): <ul style="list-style-type: none">• Addition of Rockwell PLC software	S. Chauvin
29/03/2017	D	Issue of software modification (17/184): <ul style="list-style-type: none">• Deletion of the XV02 valve• Deletion of the M08 homogenization blower• Modification of the FCV02 valve	S. Chauvin
18/08/2017	E	Issue of software modification (17/386): <ul style="list-style-type: none">• Addition of the glove leak tester plug• Password security management	S. Chauvin
06/11/2019	005	iGLT integration (19/395)	G. Descamps
24/01/2020	006	New presentation + change in 3-digit revision rule according to PQ.DQ.00.04 (20/020)	G. Descamps
20/07/2020	007	Issue of PID tagname standardization (20/241)	E. Delombaerde



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