

ISOTEST



TECHNICAL MANUAL

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Date	Written by	Reviewed by	Approved by
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1. SAFETY NOTES

1.1. DEFINITIONS AND WARNINGS



 DANGER	Means that failure to apply the correct safety measures will result in death or serious injury.
 WARNING	Means that failure to apply the correct safety measures may result in death or serious injury.
 CAUTION	Means, when placed next to a warning triangle, that failure to apply the correct safety measures may result in mild injury.
CAUTION	Means, when not placed next to a warning triangle, that failure to apply the correct safety measures may result in material damage.
IMPORTANT	Means that, if the COMMENTS in question are not taken into account, an unwanted result or status may be obtained.
COMMENTS	In these documents, "COMMENTS" are used to draw your attention to important information concerning the product or a specific part of the document.
	Means that the reader should consult the user manual to find out the usage procedures and limitations
Qualified personnel	In this manual, "qualified person" refers to a person who is familiar with the installation, assembly, starting-up and use of the equipment, as well as with the risks incurred.
Use of the equipment according to its destination	The equipment should only be used for the applications specified in the manual, with devices and components recommended and approved by Getinge-La Calhène

1.2. GENERAL

 <p>WARNING</p>	<p>This equipment uses hydrogen peroxide, electricity and compressed air.</p> <p>Failure to observe the recommendations and instructions included in this manual may result in serious injury or considerable material damage. Only qualified personnel completely familiarised with all the safety rules and the installation, operation and maintenance procedures set forth in the various manuals is authorised to work on this equipment. The correct and safe operation of this equipment requires installation, use and maintenance in accordance with good engineering practices.</p>
 <p>CAUTION</p>	<p>This equipment should only be used for the purposes indicated by its manufacturer. Unauthorised modifications and the use of spare parts and accessories that are not sold or recommended by the equipment manufacturer may result in fires, electric shocks and injuries.</p>
<p>IMPORTANT</p>	<p>This manual must be kept within reach nearby the equipment, and a copy must be sent to every user. All measurement and testing operations to be performed on the live equipment must comply with the applicable work safety regulations in the country in question. It is advisable to use suitable tools. Before installation and commissioning, please take the time to read the safety instructions and the warnings included in this manual, as well as all the warning labels affixed to the equipment. Please make sure that these warning labels are always readable and replace any missing or damaged labels.</p>

DANGER	<p>Before opening the inner door, it is advisable to make sure that no objects on the work top will interfere with its opening. It is also imperative for the operator handling the door to make sure that the second operator (<i>using the other pair of gloves</i>) has been warned and has not placed his hands under the door. When opening, use one hand to move the handle and place the other hand on the nearest top corner (<i>left-hand side for the operator on the left, right-hand side for the operator on the right</i>) in order to hold the door with two hands while opening it. Failure to observe this instruction may result in injuries to the operator due to impact with the door or his hands getting caught between the door and an object placed on the work top.</p>
CAUTION	<p>When closing one of the two doors (<i>inner door and outer door of the biodecontamination airlock</i>), it is advisable to check that no objects will get caught between the door and the seal. This may cause a leak-tightness fault. The automatic leak test before each biodecontamination cycle may fail in this case, making it impossible to use the device.</p>

1.3. SAFETY INFORMATION

 <p>DANGER</p>	<p>Do not use the ISOTEST isolator in an explosive atmosphere. Only use hydrogen peroxide with a concentration of 35 % as recommended by Getinge-La Calhène</p>
 <p>WARNING</p>	<p>The ISOTEST isolator makes use of hazardous toxic products. The user must take all necessary steps before the proper authorities to have this new equipment included in their safety analysis study. The technicians who will use these machines must have previously undergone a specific adapted training process.</p> <p>When handling hydrogen peroxide, please consult the product toxicity sheet (<i>see appendix</i>).</p> <p>It is compulsory to wear gloves and goggles when handling hydrogen peroxide.</p> <p>Only persons who have been trained in using the ISOTEST isolator are authorised to perform biodecontamination cycles.</p> <p>In the event of a leak of hydrogen peroxide in liquid or gaseous form during a biodecontamination cycle, the operators must press the "EMERGENCY AERATION" button and evacuate the hazard area.</p> <p>An emergency / evacuation procedure must be in place for this purpose.</p> <p>During the biodecontamination phase, the isolators must be connected to an extractor linked directly to the outside of a building to allow aeration. Make sure that the extractors, generally located on the roof, are protected against the rain and sufficiently separated from passage areas and other heating, ventilation and A/C air intakes.</p> <p>The isolator pipes may only be removed after carrying out after the auxiliary isolator aeration phase, taking all necessary precautions in order to compensate for the risk of residual H₂O₂ in the pipes.</p>

**WARNING**

All maintenance operations must be performed after aerating the circuits that contain hydrogen peroxide in gaseous form and purging the circuits in which the sterilant is in liquid form. It is compulsory to rinse with water when removing a component on the injection circuit.

**CAUTION**

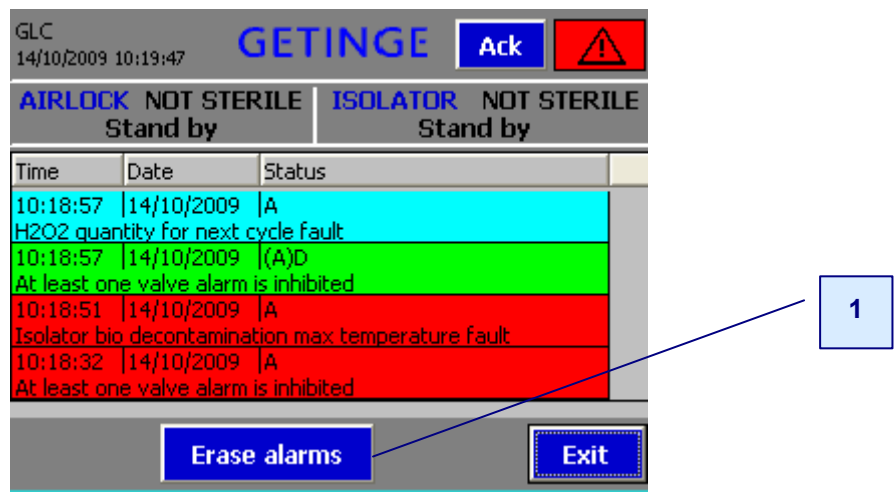
It is advisable to install hydrogen peroxide detectors in the room where the isolator is installed (*acceptable exposure threshold: 1 ppm – 1.4 mg/m³*).

It is advisable to install a luminous signal to show when a biodecontamination phase is in progress to warn operators who want to access the room (*contact available on the terminal block*).

2. PROCESS

2.1. PROCESS ALARMS

Any error occurring during a cycle is displayed in the alarm view and must be acknowledged.



Alarm status:

- A alarm appearing (*in red*).
- (A) D alarm disappearing and acknowledged (*in green*).

Number	Designation
1	Deletes all the alarms in the memory (<i>Access level > = maintenance</i>).

#	Alarm message	Alarm condition	Possible cause	Actions
1	Airlock pressure valve XV04 fault	At all times	<ul style="list-style-type: none"> ♦ Position contacts to be adjusted ♦ Valve malfunction 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
2	Isolator pressure valve XV07 fault	At all times	<ul style="list-style-type: none"> ♦ Position contacts to be adjusted ♦ Valve malfunction 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
3	Airlock flow valve XV01 fault	At all times	<ul style="list-style-type: none"> ♦ Position contacts to be adjusted ♦ Valve malfunction 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
4	Isolator flow valve XV05 fault	At all times	<ul style="list-style-type: none"> ♦ Position contacts to be adjusted ♦ Valve malfunction 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
5	Airlock flow blower M01 fault	In the event of controlling the blower	<ul style="list-style-type: none"> ♦ Blower fault ♦ Continuously variable transmission fault 	Halt blower and the continuous cycle
6	Isolator flow blower M03 fault	In the event of controlling the blower	<ul style="list-style-type: none"> ♦ Blower fault ♦ Continuously variable transmission fault 	Halt blower and the continuous cycle
7	Airlock pressure blower M02 fault	In the event of controlling the blower	<ul style="list-style-type: none"> ♦ Blower fault ♦ Continuously variable transmission fault 	Halt blower and the continuous cycle
8	Airlock blower M02 thermal fault	In the event of controlling the blower	<ul style="list-style-type: none"> ♦ Blower fault ♦ Blower overheated 	Halt blower and the continuous cycle
9	Isolator pressure sensor fault	In cycle after a 15-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	Stops isolator ventilation. Test phase: halts the phase
10	Airlock pressure sensor fault	In cycle after a 15-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	Stops airlock ventilation. Test phase: halts the phase
11	Isolator temperature sensor fault	At any time after a 5-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	Test phase: halts the phase.

#	Alarm message	Alarm condition	Possible cause	Actions
12	Airlock temperature sensor fault	At any time after a 5-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	Test phase: halts the phase.
13	Isolator impossible to put under pressure	Inflation step test phase	<ul style="list-style-type: none"> ♦ Isolator leak-tightness problem ♦ Isolator flow ventilation fault ♦ Isolator flow valve fault 	Halts the test phase
14	Isolator out of specification min. test pressure exceeded	Stabilisation step test phase	<ul style="list-style-type: none"> ♦ Isolator leak-tightness problem ♦ Isolator flow ventilation fault ♦ Isolator flow valve fault 	Halts the test phase
15	Airlock impossible to put under pressure	Inflation step test phase	<ul style="list-style-type: none"> ♦ Airlock leak-tightness problem ♦ Airlock flow ventilation fault ♦ Airlock flow valve fault 	Halts the test phase
16	Airlock out of specification min. test pressure exceeded	Stabilisation step test phase	<ul style="list-style-type: none"> ♦ Airlock leak-tightness problem ♦ Airlock flow ventilation fault ♦ Airlock flow valve fault 	Halts the test phase
17	Isolator bio decontamination min. temperature fault	Isolator biodecontamination phase	<ul style="list-style-type: none"> ♦ Isolator temperature < min. recipe threshold ♦ Sensor fault 	Stops the biodecontamination phase and launches the emergency phase
18	Isolator bio decontamination max. temperature fault	Isolator biodecontamination phase	<ul style="list-style-type: none"> ♦ Isolator temperature > max. recipe threshold ♦ Sensor fault 	No action
19	Isolator production min. pressure fault	Isolator production phase after inhibition duration fault	<ul style="list-style-type: none"> ♦ Isolator pressure < min. recipe threshold ♦ Sensor fault ♦ Ventilation fault 	No action
20	Isolator production max. pressure fault	Isolator production phase after inhibition duration fault	<ul style="list-style-type: none"> ♦ Isolator pressure > max. recipe threshold ♦ Sensor fault ♦ Ventilation fault 	No action

#	Alarm message	Alarm condition	Possible cause	Actions
21	Isolator production min. temperature fault	Isolator production phase	<ul style="list-style-type: none"> ♦ Isolator temperature < min. recipe threshold ♦ Sensor fault 	No action
22	Isolator production max. temperature fault	Isolator production phase	<ul style="list-style-type: none"> ♦ Isolator temperature > max. recipe threshold ♦ Sensor fault 	No action
23	Airlock bio decontamination min. pressure fault	Airlock biodecontamination phase after inhibition duration fault	<ul style="list-style-type: none"> ♦ Airlock pressure < min. recipe threshold ♦ Sensor fault ♦ Compressed-air supply fault 	Stops the biodecontamination phase and launches the emergency phase
24	Airlock bio decontamination max. pressure fault	Airlock biodecontamination phase after inhibition duration fault	<ul style="list-style-type: none"> ♦ Airlock pressure > max. recipe threshold ♦ Sensor fault ♦ Biodecontamination outlet valve fault 	Stops the biodecontamination phase and launches the emergency phase
25	Isolator pressure blower M04 fault	In the event of controlling the blower	<ul style="list-style-type: none"> ♦ Blower fault ♦ Continuously variable transmission fault 	Halt blower and the continuous cycle
26	Airlock door fault	Test phase, biodecontamination, emergency and unload	<ul style="list-style-type: none"> ♦ Position sensor fault ♦ Door locking fault 	Stops the biodecontamination phase and launches the emergency phase Other cases: no action
27	Isolator door fault	Test phase, biodecontamination and production	<ul style="list-style-type: none"> ♦ Position sensor fault 	Stops the biodecontamination phase and launches the emergency phase Other cases: no action
28	Isolator door gasket inflating fault	As soon as the isolator door is closed	<ul style="list-style-type: none"> ♦ Pressure gauge fault ♦ Compressed-air supply fault ♦ Pressure < pressure gauge threshold 	Stops the biodecontamination phase and launches the emergency phase Other cases: no action
29	PC communication fault	At all times	<ul style="list-style-type: none"> ♦ Network cable disconnected ♦ Computer failing or switched off 	Stops the archiving of data
30	Emergency stop fault	At all times	<ul style="list-style-type: none"> ♦ N/A 	Stops the current phase and launches the emergency phase

#	Alarm message	Alarm condition	Possible cause	Actions
31	Isolator biodecontamination min. pressure fault	Isolator biodecontamination phase after inhibition duration fault	<ul style="list-style-type: none"> Isolator pressure < min. recipe threshold Sensor fault Compressed-air supply fault 	Stops the biodecontamination phase and launches the emergency phase
32	Isolator biodecontamination max. pressure fault	Isolator biodecontamination phase after inhibition duration fault	<ul style="list-style-type: none"> Isolator pressure > max. recipe threshold Sensor fault Compressed-air supply fault 	Stops the biodecontamination phase and launches the emergency phase
33	At least one valve alarm is inhibited	At all times	<ul style="list-style-type: none"> User to inhibit a valve alarm 	No action
34	H ₂ O ₂ quantity for next cycle fault	Start of biodecontamination phase	<ul style="list-style-type: none"> Insufficient amount of H₂O₂ for next cycle 	Halts the start of the biodecontamination cycle
35	H ₂ O ₂ vial expiry date fault	Start of biodecontamination phase	<ul style="list-style-type: none"> H₂O₂ past its expiry date 	Halts the start of the biodecontamination cycle
36	H ₂ O ₂ vial presence fault	Start of biodecontamination phase	<ul style="list-style-type: none"> H₂O₂ vial missing RFID system fault RFID chip reading fault 	Halts the start of the biodecontamination cycle
37	Isolator sterilant agent inlet valve XV06 fault	At all times	<ul style="list-style-type: none"> Position contacts to be adjusted Valve malfunction 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
38	Airlock sterilant agent inlet valve XV02 fault	At all times	<ul style="list-style-type: none"> Position contacts to be adjusted Valve malfunction 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
39	Airlock phase abort by operator	At all times	<ul style="list-style-type: none"> Halt requested by user 	Stops the biodecontamination phase and launches the emergency phase Other phases: Stops the current phase
40	Isolator phase abort by operator	At all times	<ul style="list-style-type: none"> Halt requested by user 	Stops the biodecontamination phase and launches the emergency phase Other phases: Stops the current phase

#	Alarm message	Alarm condition	Possible cause	Actions
41	Airlock bio decontamination min. temperature fault	Airlock biodecontamination phase	<ul style="list-style-type: none"> ♦ Airlock temperature < min. recipe threshold ♦ Sensor fault 	Stops the biodecontamination phase and launches the emergency phase
42	Airlock bio decontamination max. temperature fault	Airlock biodecontamination phase	<ul style="list-style-type: none"> ♦ Airlock temperature > max. recipe threshold ♦ Sensor fault 	No action
43	Airlock unloading min. pressure fault	Isolator unloading phase after inhibition duration fault	<ul style="list-style-type: none"> ♦ Airlock pressure < min. recipe threshold ♦ Sensor fault ♦ Ventilation fault 	No action
44	Airlock unloading max. pressure fault	Isolator unloading phase after inhibition duration fault	<ul style="list-style-type: none"> ♦ Airlock pressure > max. recipe threshold ♦ Sensor fault ♦ Ventilation fault 	No action
45	Airlock unloading min. temperature fault	Unloading phase	<ul style="list-style-type: none"> ♦ Airlock temperature < min. recipe threshold ♦ Sensor fault 	No action
46	Airlock unloading max. temperature fault	Unloading phase	<ul style="list-style-type: none"> ♦ Airlock temperature > max. recipe threshold ♦ Sensor fault 	No action
47	Power failure	After the return of power	<ul style="list-style-type: none"> ♦ Master switch off ♦ Power failure 	If the biodecontamination or emergency phases were in progress before the power failure, the isolator starts up in emergency mode. Other cases: no action
48	Airlock door gasket inflating fault	As soon as the airlock door is closed	<ul style="list-style-type: none"> ♦ Pressure gauge fault ♦ Compressed-air supply fault ♦ Pressure < pressure gauge threshold 	Stops the biodecontamination phase and launches the emergency phase Other cases: no action
49	Homogenisation blower M07 fault	Biodecontamination phase after 5 sec	<ul style="list-style-type: none"> ♦ Blower fault ♦ Current-measurement relay fault 	Stops the biodecontamination phase and launches the emergency phase
50	RFID system inhibited	At all times	<ul style="list-style-type: none"> ♦ The user has inhibited the RFID system 	No control of H ₂ O ₂ vial errors. Invalid vial display in the biodecontamination report.

#	Alarm message	Alarm condition	Possible cause	Actions
57	Room H ₂ O ₂ sensor fault	At all times	<ul style="list-style-type: none"> Leak of H₂O₂ gas Leak of liquid H₂O₂ 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
100	PDT01 pressure sensor fault	During the biodecontamination cycle (except condition step) after a 30-sec. delay	<ul style="list-style-type: none"> Sensor is out of scale Sensor incorrectly connected Faulty sensor Check calibration 	No action
101	Airlock humidity sensor fault	During the biodecontamination cycle and in the condition step, after a 5-sec. delay	<ul style="list-style-type: none"> Sensor is out of scale Sensor incorrectly connected Faulty sensor Check calibration 	No action
102	Conditioning timeout fault	During the biodecontamination cycle and at the end of the condition step	<ul style="list-style-type: none"> Humidity set point too low Compressed-air problem Incorrect adjustment of the heating temperature set Vaporiser fault 	Stops the biodecontamination phase and launches the emergency phase
103	Recirculating blower M05 fault	In the event of controlling the blower	<ul style="list-style-type: none"> Blower fault Continuously variable transmission fault 	Stops the biodecontamination phase and launches the emergency phase
104	Recirculating valve XV03 fault	At all times	<ul style="list-style-type: none"> Position contacts to be adjusted Valve malfunction 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
105	Needle positioning fault	At all times	<ul style="list-style-type: none"> Position contacts to be adjusted Faulty sensor 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
109	Vaporiser min. temperature fault	Biodecontamination phase during stabilisation or injection step	<ul style="list-style-type: none"> Incorrect adjustment of the heating temperature set Vaporiser fault Vaporiser temperature < min. recipe threshold 	Stops the biodecontamination phase and launches the emergency phase
110	Vaporiser max. temperature fault	Biodecontamination phase during stabilisation or injection step	<ul style="list-style-type: none"> Incorrect adjustment of the heating temperature set Vaporiser temperature > max. recipe threshold 	Stops the biodecontamination phase and launches the emergency phase

#	Alarm message	Alarm condition	Possible cause	Actions
111	Priming timeout fault	During the biodecontamination cycle and at the end of the priming step	<ul style="list-style-type: none"> ♦ Injection pump fault ♦ FSL02 sensor fault ♦ H₂O₂ vial empty ♦ Leak on H₂O₂ pipe 	Stops the biodecontamination phase and launches the emergency phase
112	Airflow min. fault	During the biodecontamination cycle and the injection and stabilisation step	<ul style="list-style-type: none"> ♦ Flow set point too low ♦ Flow < min. recipe threshold ♦ Pitot tube pressure sensor fault ♦ Recirculating blower fault 	Stops the biodecontamination phase and launches the emergency phase
113	Airflow max. fault	During the biodecontamination cycle and the injection and stabilisation step	<ul style="list-style-type: none"> ♦ Flow set point too high ♦ Flow > max. recipe threshold ♦ Pitot tube pressure sensor fault 	Stops the biodecontamination phase and launches the emergency phase
114	H ₂ O ₂ injection rate fault	During the biodecontamination cycle and the injection and stabilisation step	<ul style="list-style-type: none"> ♦ Injection pump fault ♦ FSL02 sensor fault ♦ H₂O₂ vial empty ♦ Leak on H₂O₂ pipe 	Stops the biodecontamination phase and launches the emergency phase
115	Vaporiser thermal fault	At all times	<ul style="list-style-type: none"> ♦ Incorrect adjustment of the vaporiser heating temperature set ♦ Incorrect vaporiser thermal calibration ♦ Thermal fault 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
116	Vaporiser temperature sensor fault	During the biodecontamination cycle	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	Stops the biodecontamination phase and automatically launches the emergency phase.
117	Room H ₂ O ₂ sensor fault	At any time after a 5-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	Stops the biodecontamination phase and automatically launches the emergency phase. Other phases: no action
118	Airlock high density sensor fault	At any time after a 5-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	No action

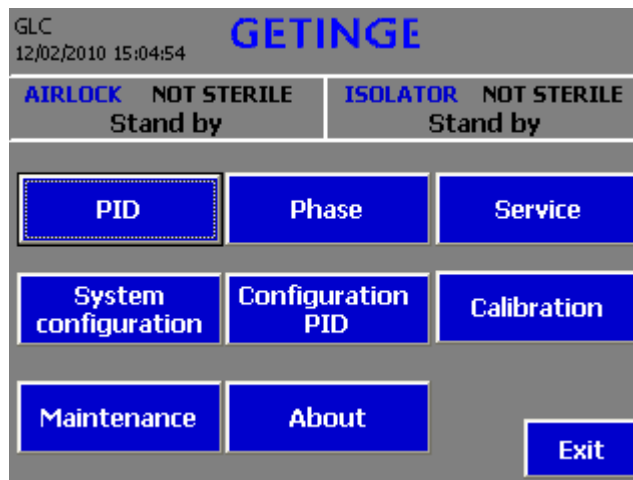
#	Alarm message	Alarm condition	Possible cause	Actions
119	Airlock low density sensor fault	At any time after a 5-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	No action
120	Isolator high density sensor fault	At any time after a 5-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	No action
121	Isolator low density sensor fault	At any time after a 5-second delay	<ul style="list-style-type: none"> ♦ Sensor is out of scale ♦ Sensor incorrectly connected ♦ Faulty sensor ♦ Check calibration 	No action

2.2. CONFIGURATION

2.2.1. Maintenance level adjustment

The following views can be accessed from the main view with at least "maintenance" access level.

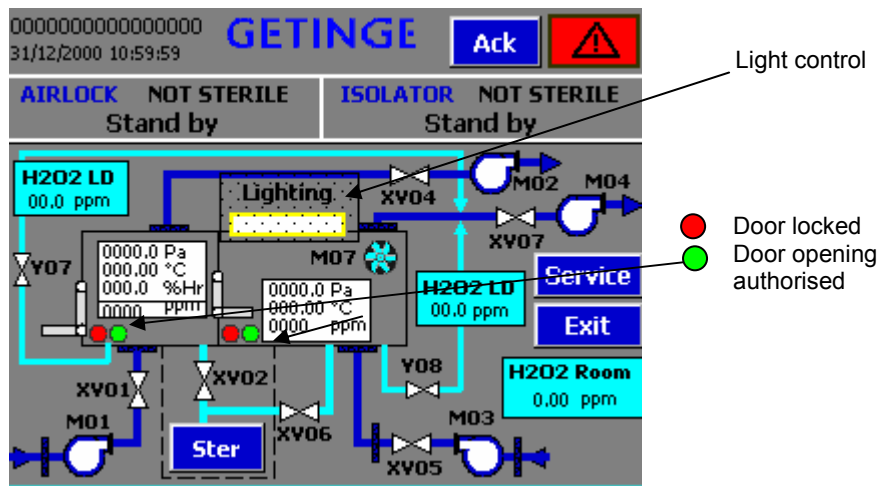
- In the user view, press the "system" button and the following view appears:



PID

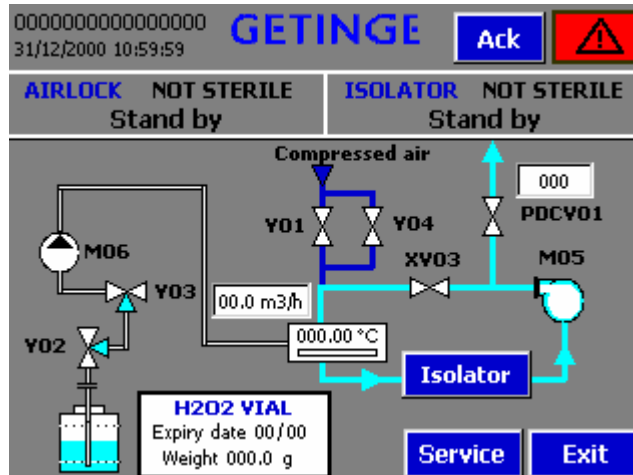
These views show the status of the various actuators.

- Press the "PID" button and the following view appears:



- or ■ Blower in operation or valve open.
- Blower stopped or valve closed.
- (Flashing) Alarm.

- Press the "Ster" button and the following view appears:



- or Blower in operation or valve open.
- Blower stopped or valve closed.
- (*Flashing*) Alarm.

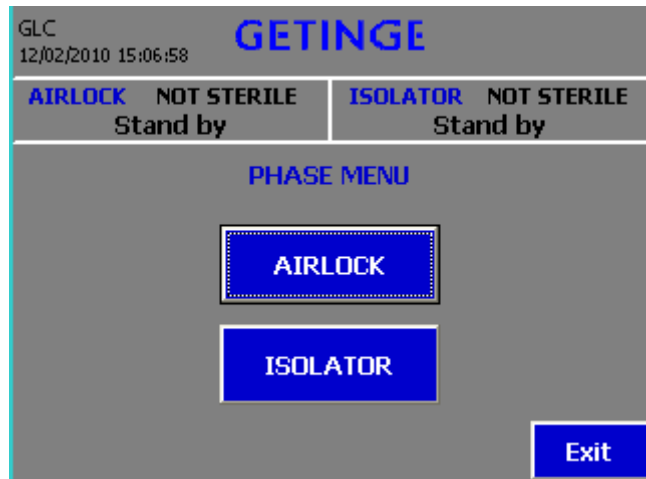
H₂O₂ pipe

- Pump in operation or valve open or presence of H₂O₂ in the pipe
- Pump stopped or valve closed or no H₂O₂ in the pipe.

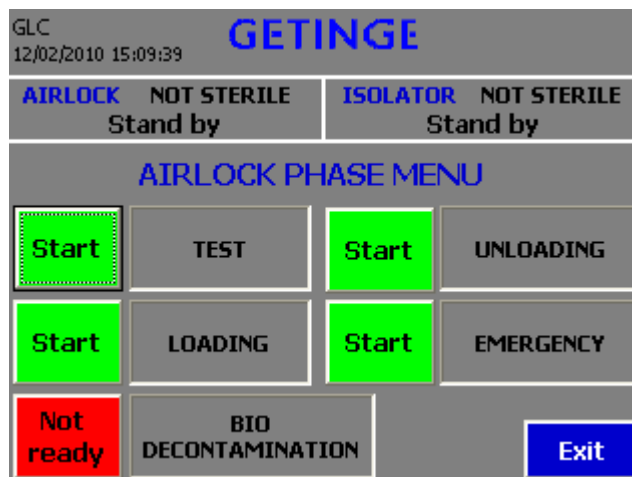
Phase

These views allow a phase to be launched regardless of the process locks.

- Press the "Phase" button and the following view appears:



- Select "Airlock" or "Isolator" and the following view appears:

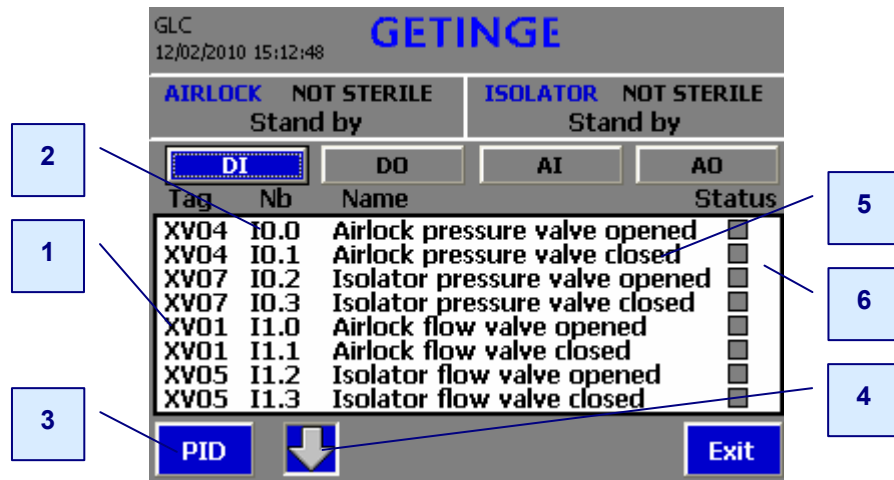


Number	Designation
	Allows the user to launch the phase
	Displays the missing conditions required to launch the phase

Service

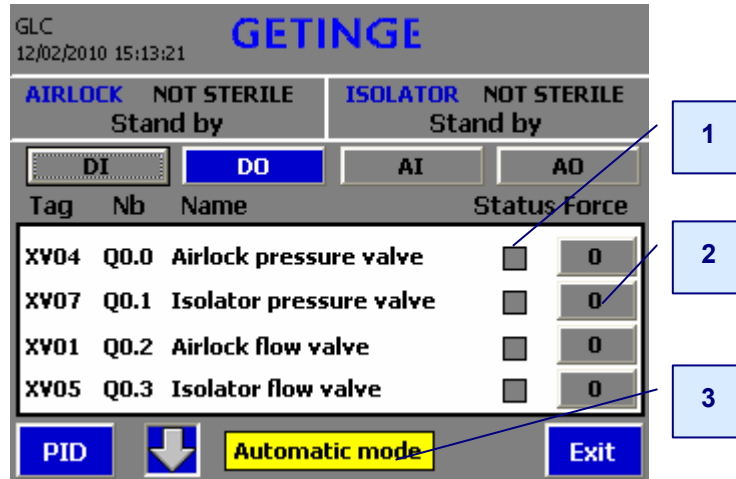
These views can be used to display or force the PLC inputs and outputs.

- Press the "Service" button and the following view appears:



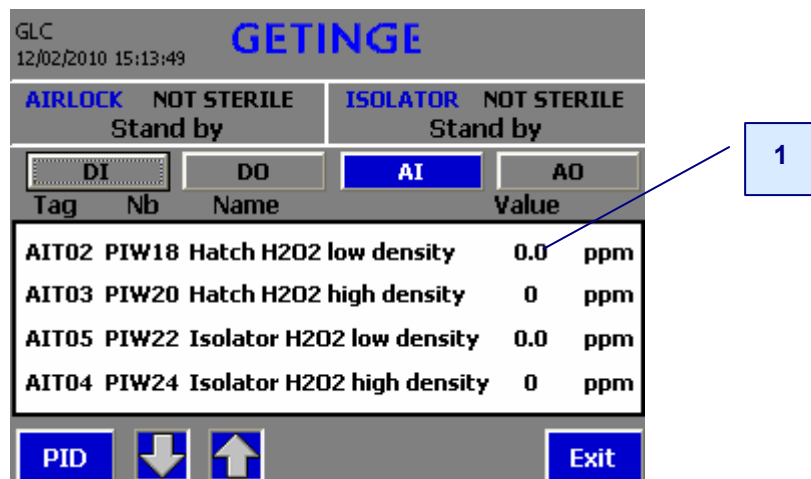
Number	Designation
1	PID tag number
2	PLC input number
3	Provides access to the PID view
4	Provides access to the following inputs
5	PLC input description
6	PLC input status (<input checked="" type="checkbox"/> Input at 1 <input type="checkbox"/> Input at 0)

- Press the "DO" button and the following view appears:



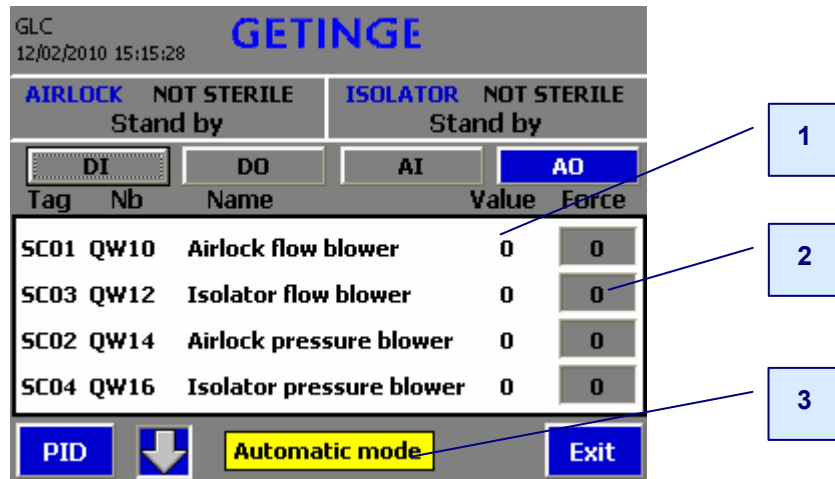
Number	Designation
1	PLC output status (<input checked="" type="checkbox"/> Output at 1 <input type="checkbox"/> Output at 0)
2	Allows the user to force an output
3	Allows the user to select the mode
Automatic mode	Forcing is not possible with a phase in progress
Manual mode	Allows the user to force the outputs

- Press the "AI" button and the following view appears:



Number	Designation
1	Analogue input value

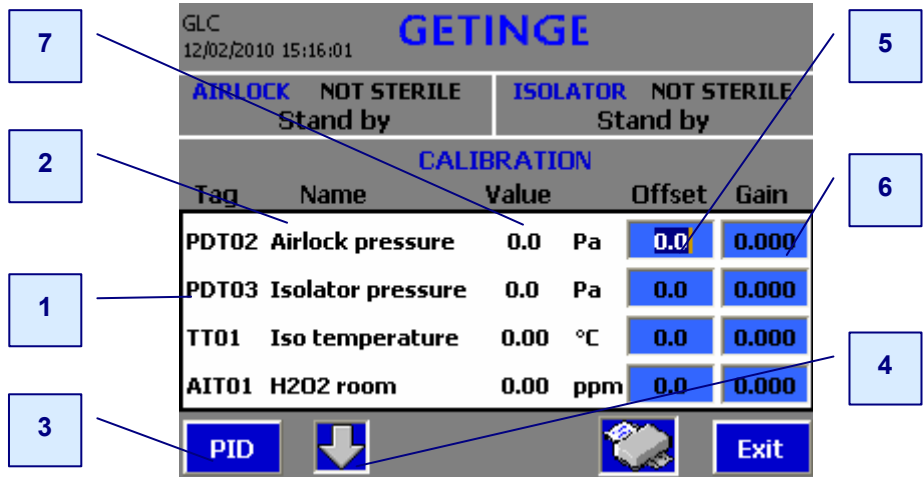
- Press the "AO" button and the following window appears:



Number	Designation
1	Analogue output value
2	Can force an analogue output from 0 to 100 %
3	Allows the user to select the mode
Automatic mode	Forcing is not possible with a phase in progress
Manual mode	Allows the user to force the outputs

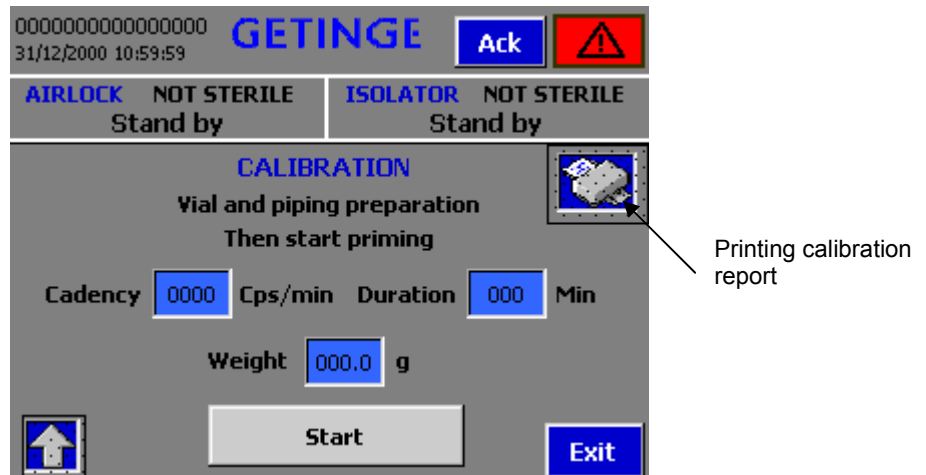
Calibration

These views allow the user to enter the analogue input calibration values. Press the "Calibration" button and the following view appears:



Number	Designation
1	PID tag number
2	Analogue input description
3	Provides access to the PID view
4	Provides access to the following inputs
5	Offset value to be entered
6	Gain value to be entered
7	Real analogue input value

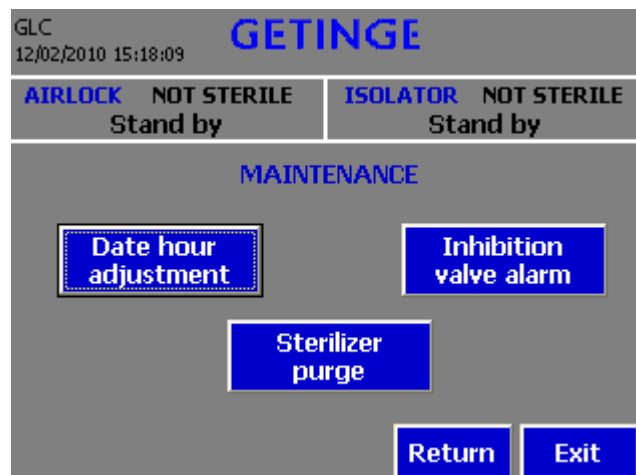
Press the  button and then the  button again to display the following view:



This view is used to calibrate the pump.

- To start a calibration cycle, the operator must follow the instructions on the panel (see chapter 4.1).

Maintenance

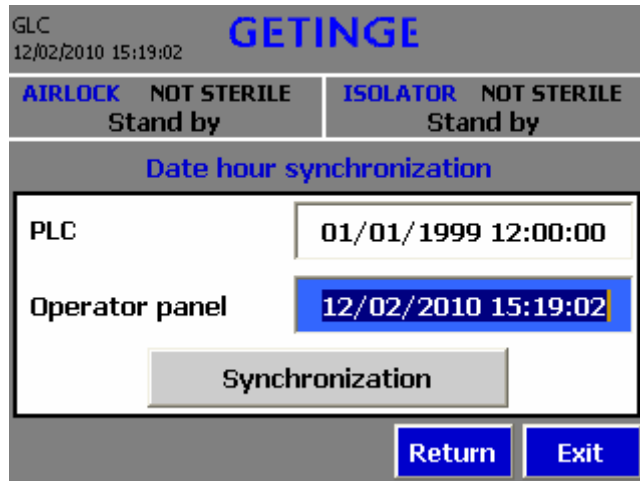


This window provides access to the following views.

Date-time synchronisation

This view allows the user to synchronise the date and time between the PLC and the panel.

- Press the "Maintenance" button followed by "Date-time adjustment" and the following view appears:

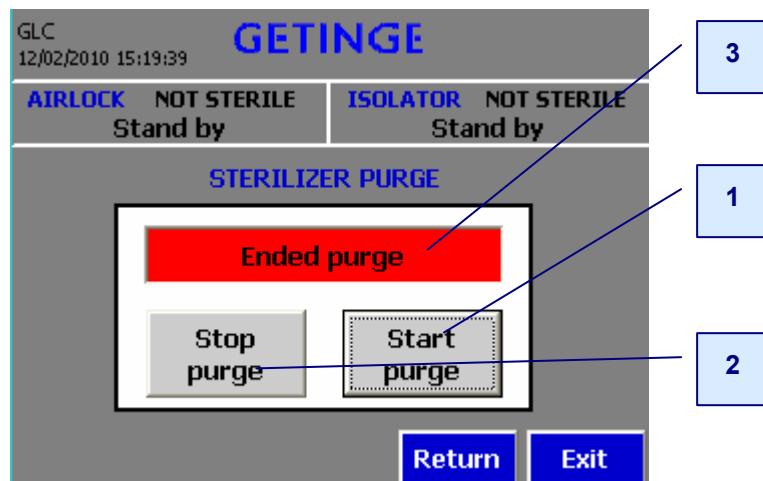


- Enter the date and time of the operator panel and then press "synchronisation".

Sterilizer purge

This view can be used to purge the H₂O₂ pipe.

Press the "Maintenance" button followed by "Sterilizer purge" and the following view appears:

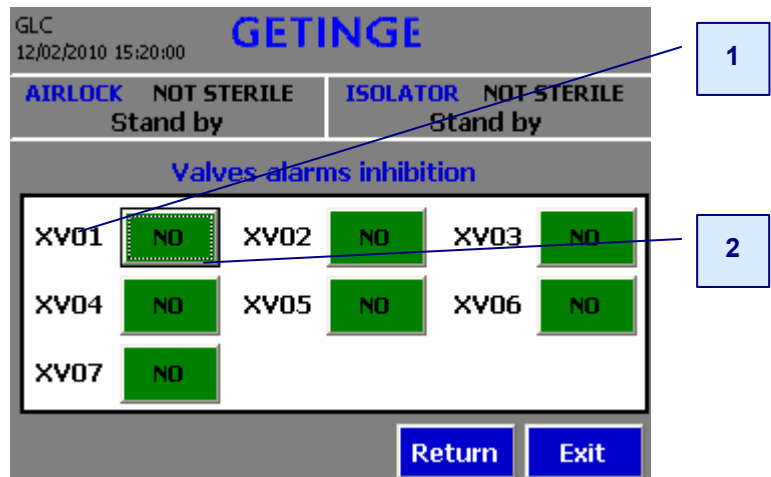


Number	Designation
1	Allows the user to launch the purge
2	Allows the user to stop the purge
3	Purge status

Valve alarms

This view allows the user to inhibit the valve alarms.

- Press the "Maintenance" button followed by "Valve alarm inhibition" and the following view appears:



Number	Designation
1	PID valve tag
2	Allows the user to inhibit an alarm (Yes = <i>alarm inhibited</i>)

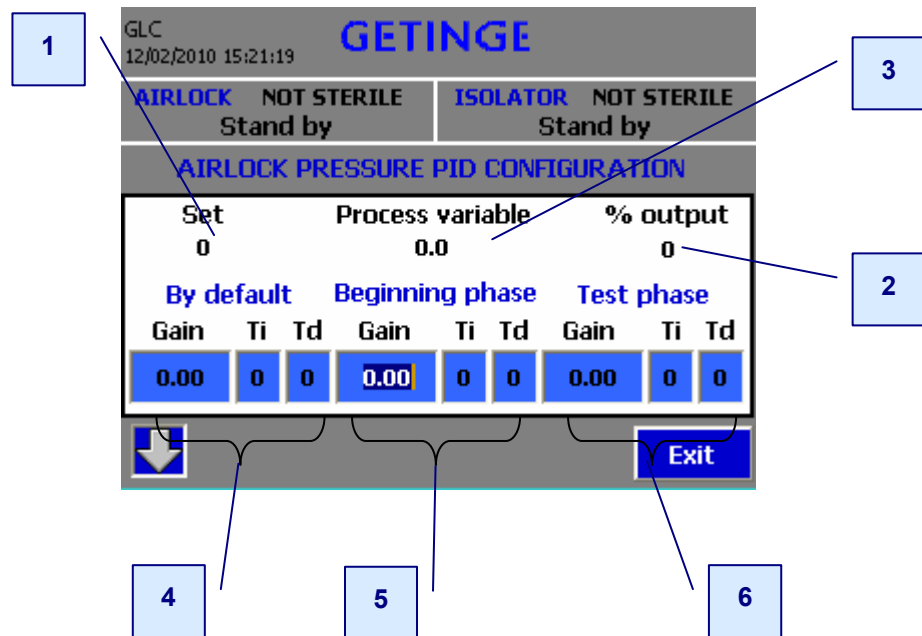
If a valve alarm is inhibited, the following message appears in the main view:

33 At least one valve alarm is inhibited

PID configuration


These views can be used to change the adjustment settings.

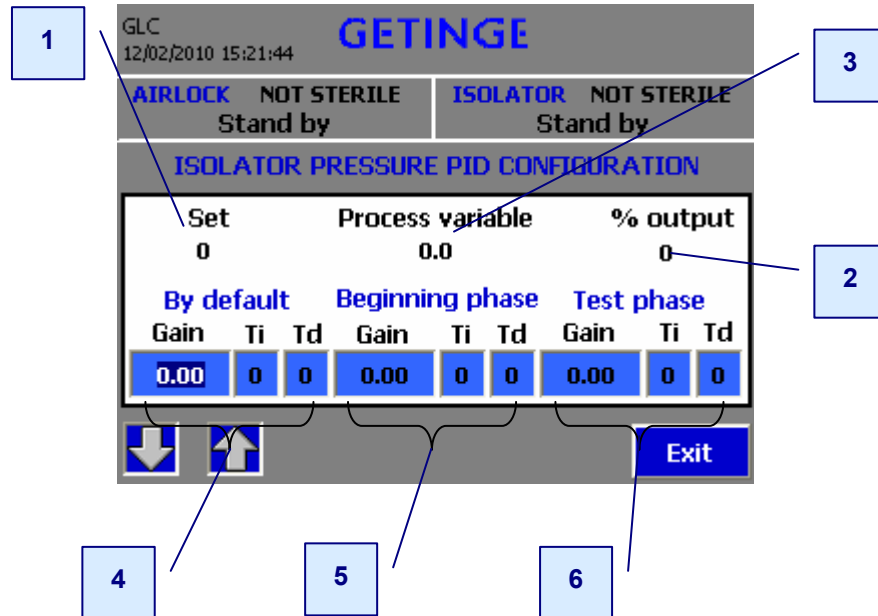
- Press the "PID configuration" button and the following view appears:



This view allows the user to change the airlock pressure adjustment settings.


Number	Designation
1	Pressure set
2	Pressure in the airlock
3	Analogue output value in % (<i>airlock pressure blower</i>)
4	Set of PID parameters for the current phase
5	Set of PID parameters for the start of the phase
6	Set of PID parameters for the test phase

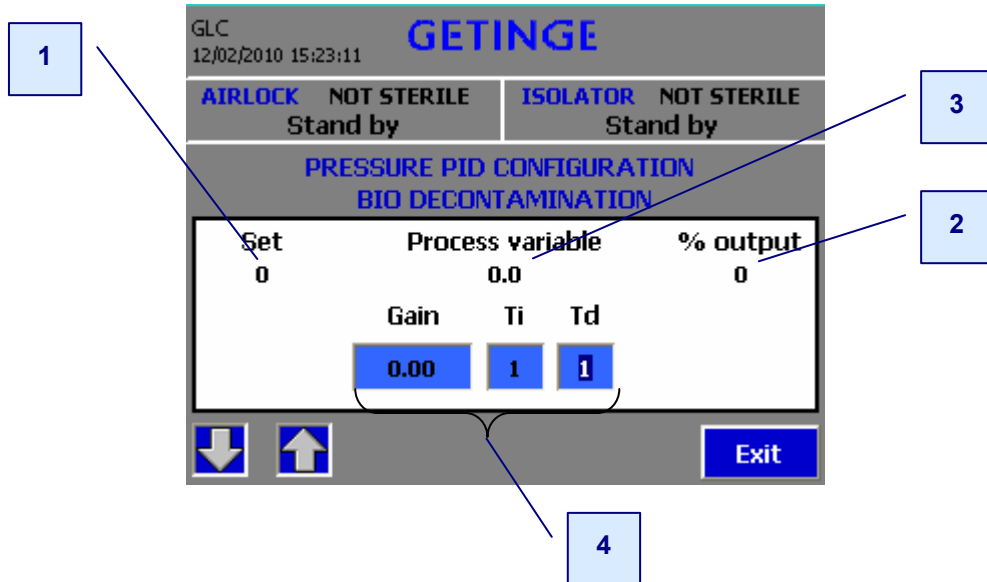
- Press the  button and the following view appears:



This view allows the user to change the isolator pressure adjustment settings.


Number	Designation
1	Pressure set
2	Pressure inside the isolator
3	Analogue output value in % (<i>isolator pressure blower</i>)
4	Set of PID parameters for the current phase
5	Set of PID parameters for the start of the phase
6	Set of PID parameters for the test phase

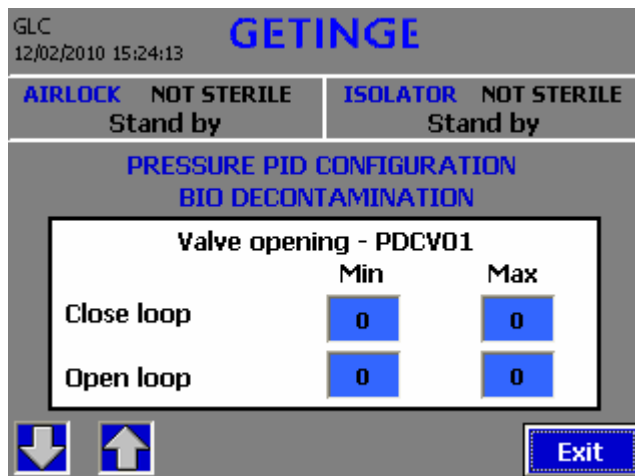
- Press the  button and the following view appears:




This view allows the user to change the biodecontamination pressure adjustment settings.

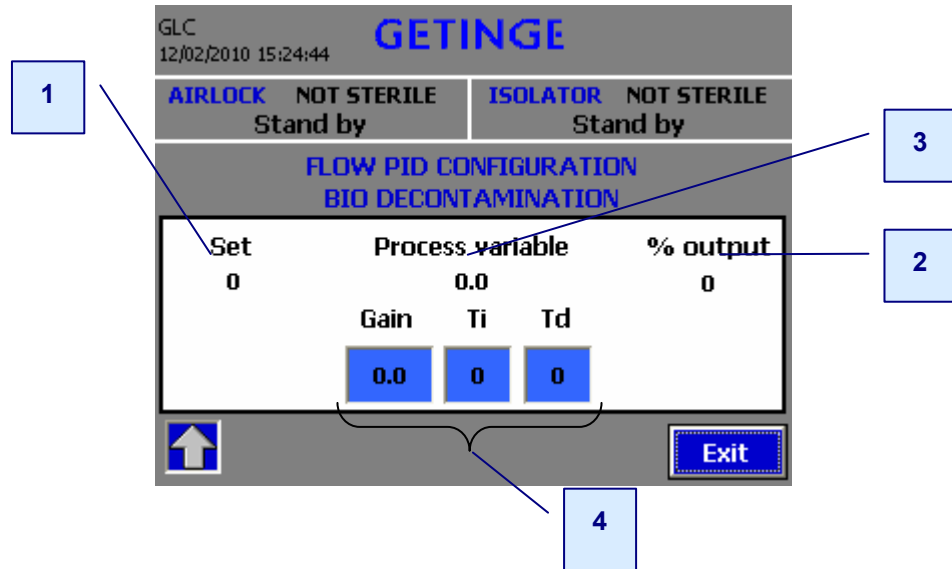
Number	Designation
1	Pressure set
2	Pressure inside the isolator
3	Analogue output value in % (<i>pressure adjustment valve</i>)
4	Set of PID parameters for the current biodecontamination phase

- Press the  button and the following view appears:



This view allows the user to change the opening range of the pressure adjustment valve in the biodecontamination phase for the closed-loop and open-loop cycle.

- Press the  button and the following view appears:



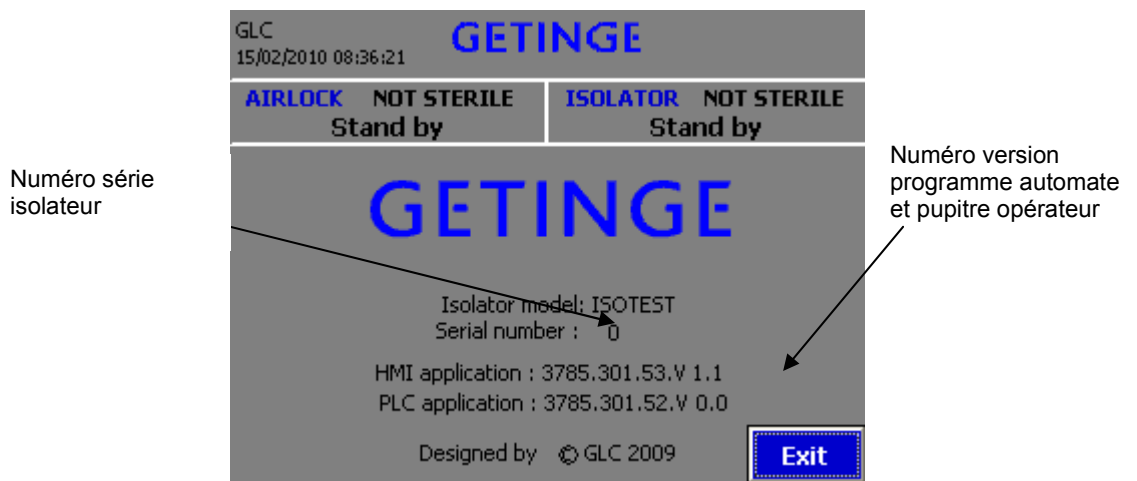
This view allows the user to change the biodecontamination flow adjustment settings.

Number	Designation
1	Flow setting
2	Flow
3	Analogue output value in % (<i>recirculating blower</i>)
4	Set of PID parameters for the biodecontamination flow

About

This view contains system information.

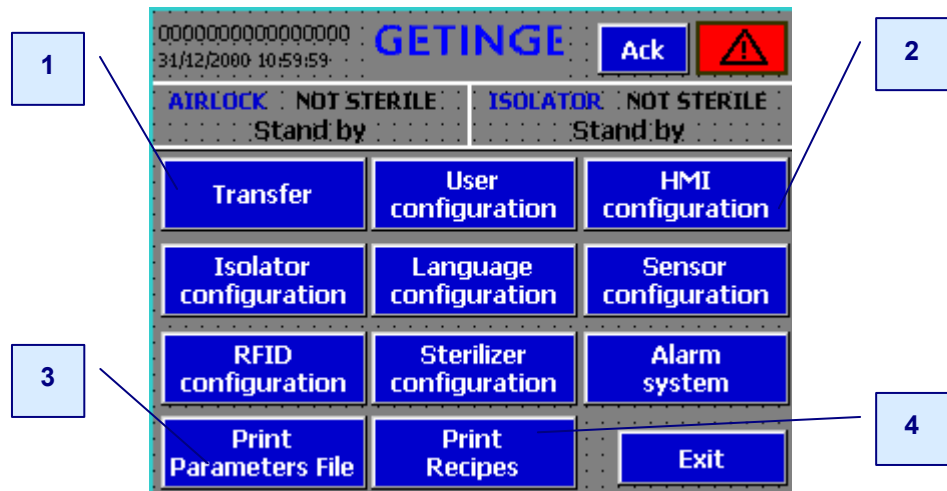
- Press the "About" button and the following view appears:



2.2.2. Administrator adjustment

The following views can be accessed from the main view with at least "administrator" access level.

- In the user view, press the "system" button followed by "system configuration" and the following view appears:

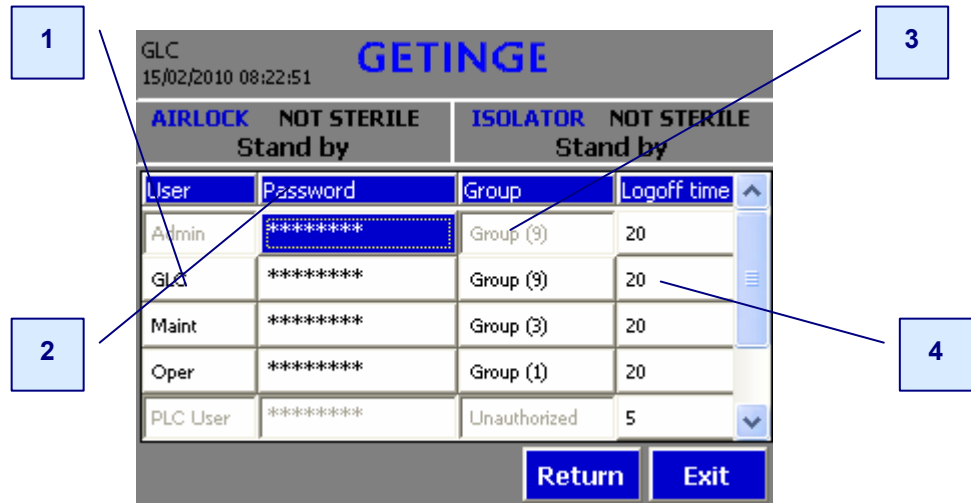


Number	Designation
1	Places the panel in transfer mode
2	Provides access to the "Windows CE" control panel
3	Prints the system parameters
4	Prints the recipes parameters file

User configuration

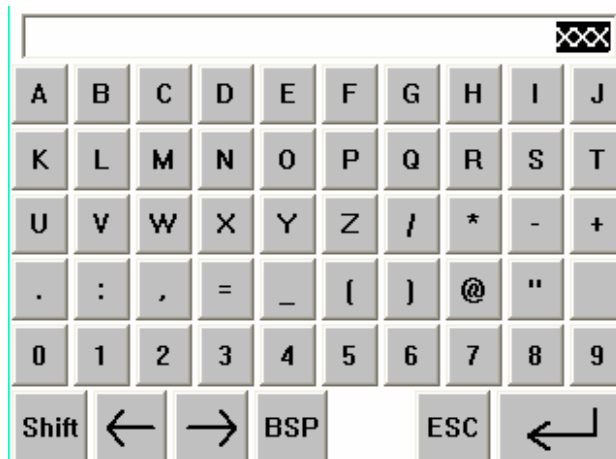
This view can be used to administer users.

- Press the "User configuration" button and the following view appears:



Number	Designation
1	Username field
2	Password field
3	Box for selecting the corresponding access level (<i>operator, validation, maintenance or administrator</i>).
4	Field for entering the connection timeout time (<i>max. 60 minutes</i>).

- To delete a user, double-click on the user to be deleted, and the following pop-up window appears:



- Press the "BSP" button and then confirm. The user is deleted.

Language configuration

This view allows the user to modify the panel language.

- Press the "Language configuration" button and the following view appears:

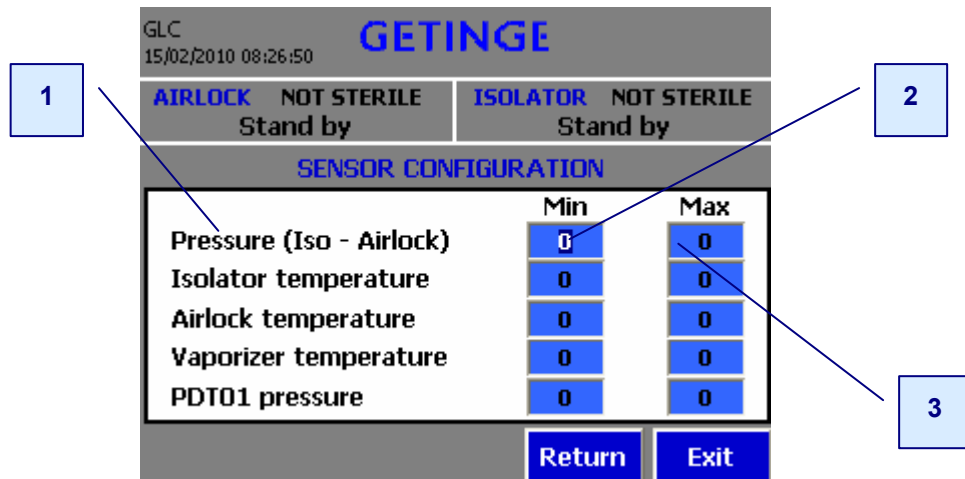


- Press on the chosen language. All the texts and alarms are then displayed in the new language selected.

Sensor configuration

This view allows the user to configure the min. and max. values of the sensors.

- Press the "Sensor configuration" button and the following view appears:

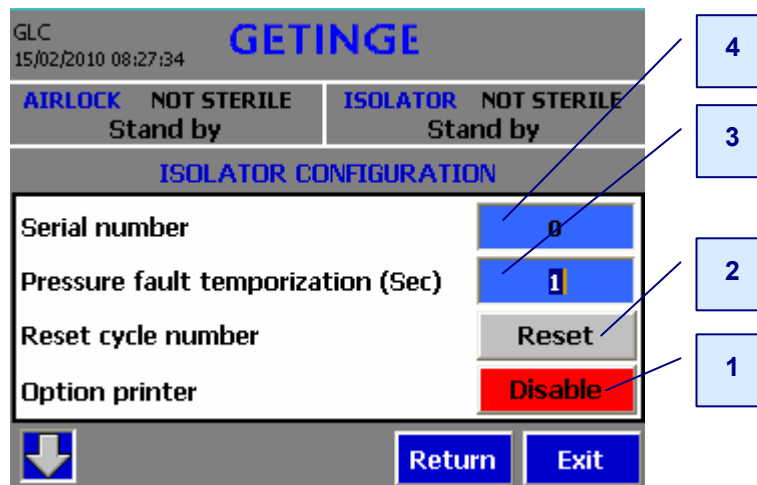


Number	Designation
1	Sensor description
2	Min. value input field
3	Max. value input field


Isolator configuration

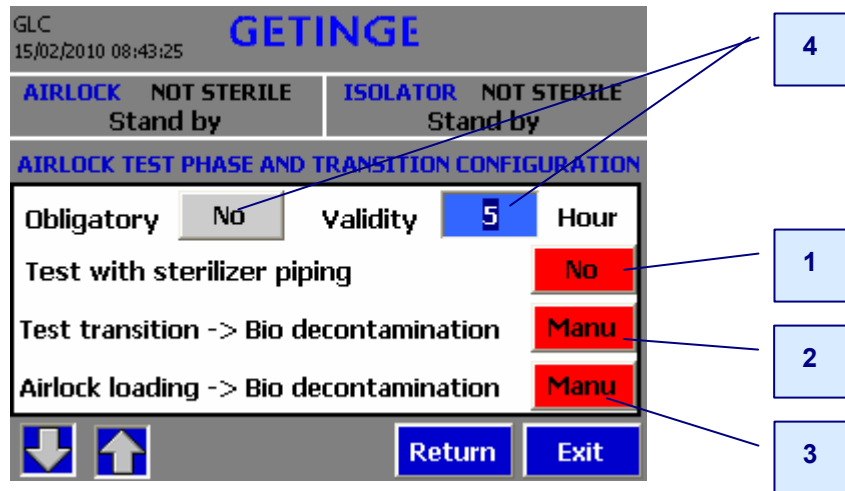
This menu is reserved for persons authorised by Getinge-La Calhène. It can be used to modify the isolator number and define the isolator configuration.

- Press the "Isolator configuration" button and the following view appears:




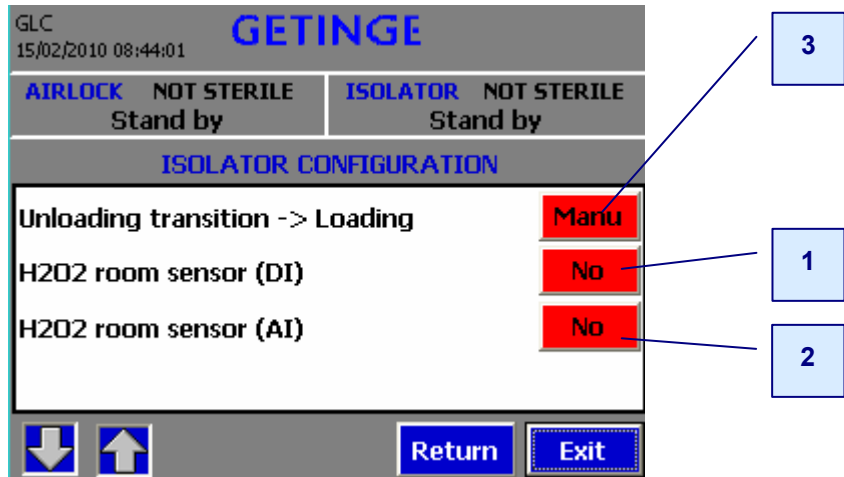
Number	Designation
1	Allows the user to select the printer option
2	Can be used to reset the cycle number
3	Can be used to adjust the pressure fault timer
4	Isolator identification number input field

- Press the  button and the following view appears:




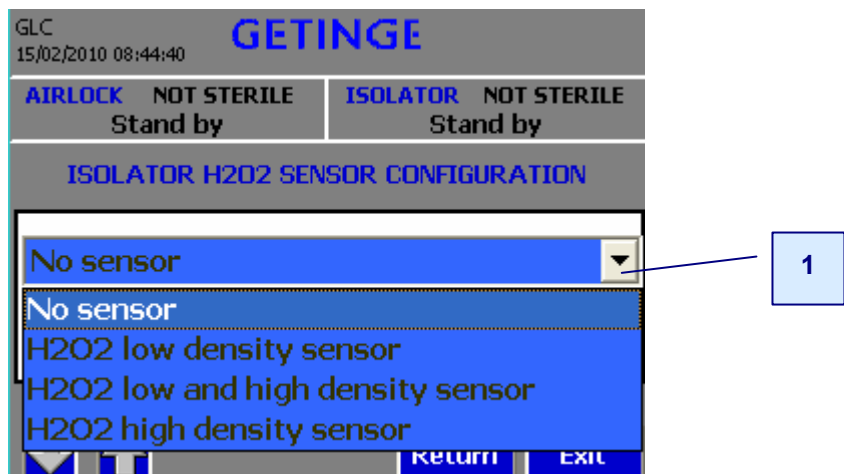
Number	Designation
1	Can be used to conduct the test phase on the sterilizer pipe
2	Allows the selection to be made if the transition from test phase to biodecontamination is automatic. The biodecontamination phase starts automatically following a correct test phase if "Auto" is selected – the biodecontamination phase is started manually by the operator if "Manu" is selected.
3	Allows the selection to be made if the transition from the airlock loading phase to biodecontamination is automatic. The biodecontamination phase starts automatically following the loading phase if "Auto" is selected – the biodecontamination phase is started manually by the operator if "Manu" is selected.
4	Can be used to select whether or not the test phase is compulsory before starting the airlock biodecontamination phase. The test phase will be compulsory before each sterilization if "YES" is selected; the test phase will be compulsory only after the end of each validity period if "NO" is selected.

- Press the  button and the following view appears:




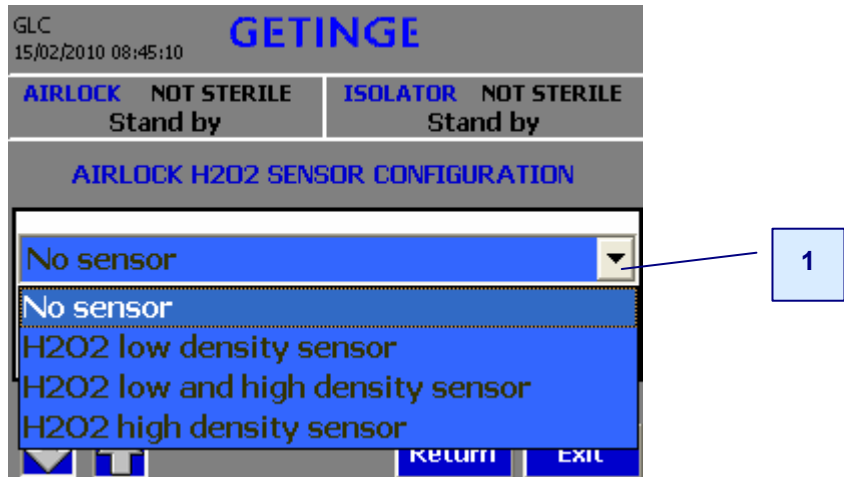
Number	Designation
1	Allows the user to select the room H ₂ O ₂ sensor option (<i>digital input</i>)
2	Allows the user to select the room H ₂ O ₂ sensor option (<i>analogue input</i>)
3	Allows the selection to be made if the transition from the airlock unloading phase to loading is automatic. The loading phase starts automatically after the unloading phase if “Auto” is selected – the loading phase is started manually by the operator if “Manu” is selected.

- Press the  button and the following view appears:




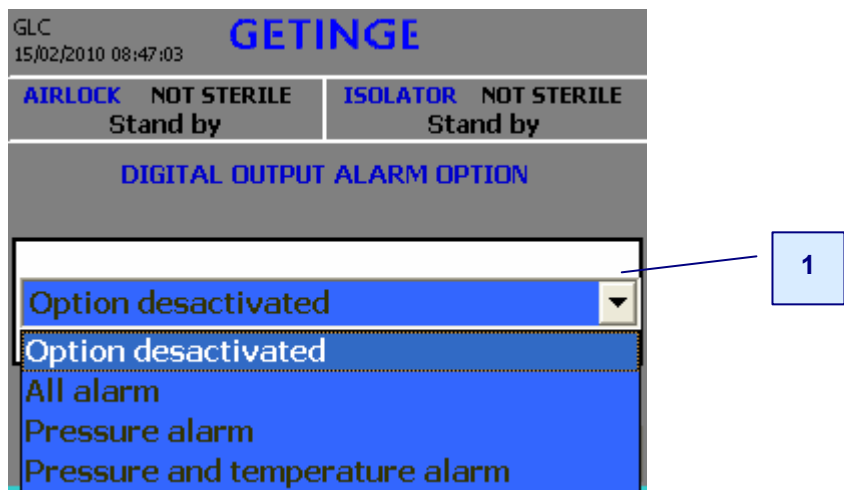
Number	Designation
1	Allows the user to configure the isolator H ₂ O ₂ sensor option

- Press the  button and the following view appears:



Number	Designation
1	Allows the user to configure the airlock H ₂ O ₂ sensor option

- Press the  button and the following view appears:

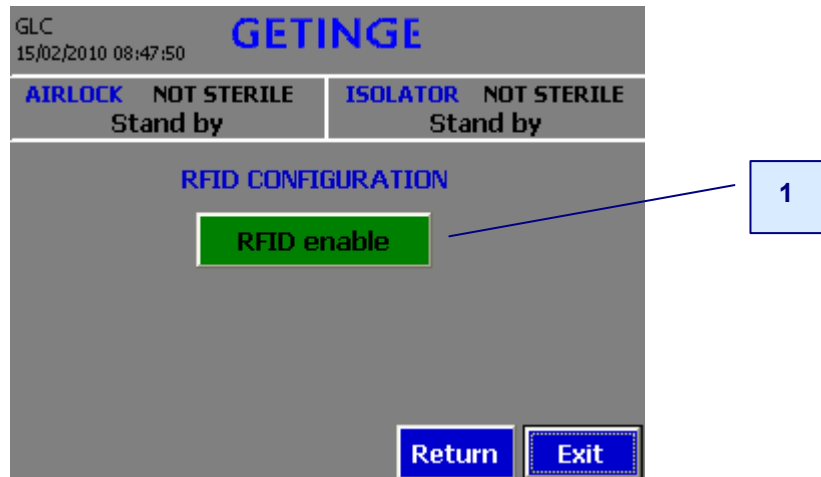


Number	Designation
1	Allows the user to configure the alarm option (<i>digital output</i>)

RFID configuration

This view can be used to deactivate the RFID system for a biodecontamination cycle.

- Press the "RFID configuration" button and the following view appears:

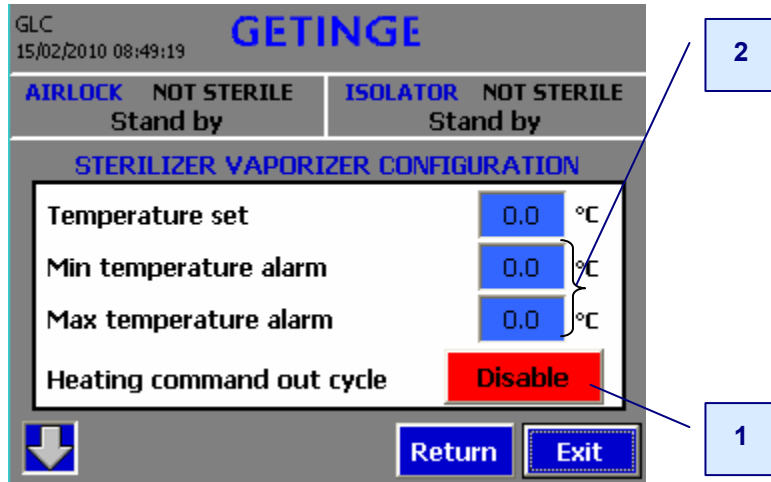


- | | |
|---|---|
| 1 | Can be used to inhibit RFID alarms for a biodecontamination cycle |
|---|---|


Sterilizer configuration

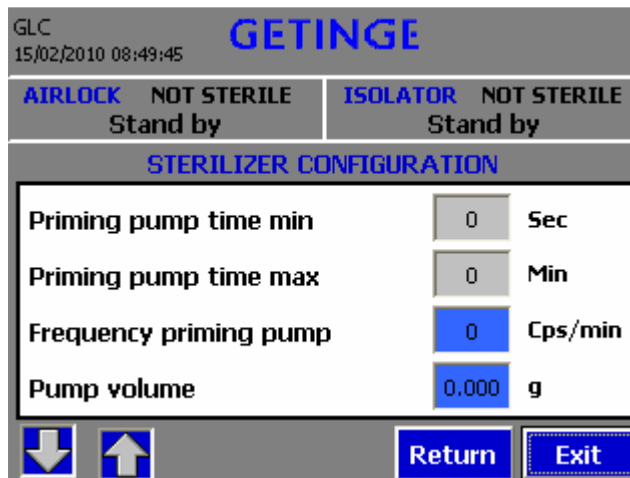
This menu is reserved for persons authorised by Getinge-La Calhène. Can be used to modify / define the sterilizer configuration.

- Press the "Sterilizer configuration" button and the following view appears:




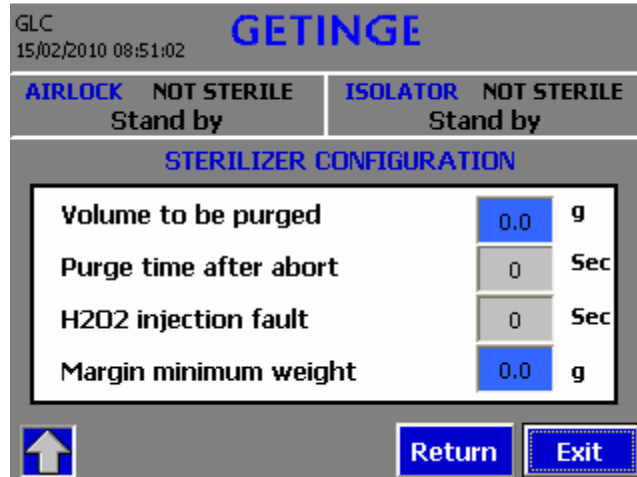
Number	Designation
1	Can be used to select the heating of the vaporiser outside the biodecontamination cycle
2	Vaporiser heating settings

- Press the  button and the following view appears:



- Various sterilizer parameters. The pump volume is determined during the pump calibration.

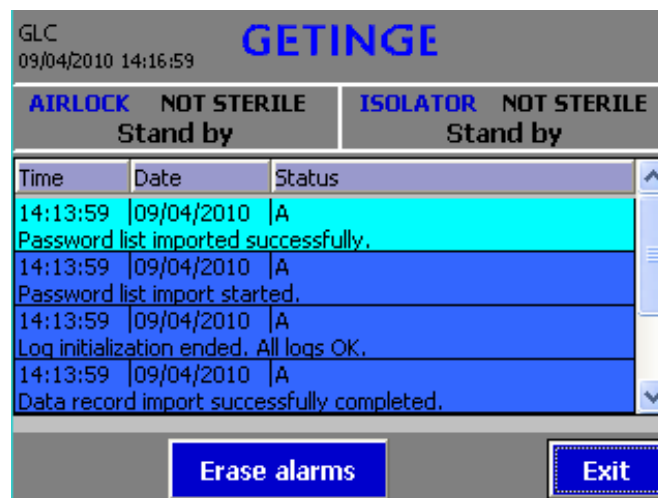
- Press the  button and the following view appears:



- Various sterilizer parameters. The volume to be purged is determined during pump calibration.

System alarm

This view can display any events that occurred during the operation of the installation.



3. MAINTENANCE INSTRUCTIONS

3.1. MAINTENANCE INSTRUCTIONS FOR NON-QUALIFIED PERSONNEL

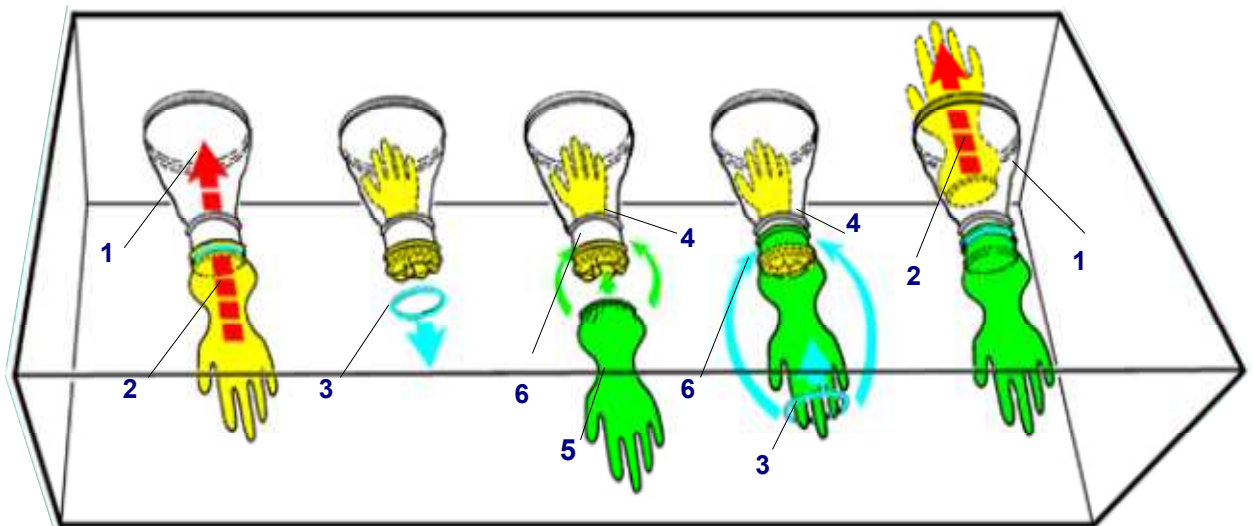
3.1.1. Glove integrity test

Before each sterilization cycle, Getinge-La Calhène recommends checking the integrity of the isolator gloves. The method consists of searching for possible leaks using the Getinge-La Calhène GLT machine or an NH₃ tracer gas.

If the result of the test is "not correct", the glove must be replaced.

The procedure for replacing a glove without breach of containment is as follows:

Installation of gloves for an isolator under positive pressure



- Pull the glove (2) to be replaced inside out into the sleeve (1).
- Remove the tightening ring (3).
- Position the new glove (5) parallel to the cuff ring (4) aligning the axis of the thumb with the seal of the sleeve.
- Install the new glove (5) on the cuff ring (4) up from the bead (6) of the glove to be replaced.
- Place the tightening ring (3) around the glove behind the bead (6).
- Position the bead (6) of the glove and the tightening ring (3) on the end of the cuff ring groove (4).
- Remove the glove (2) from the sleeve (1).
- Extract the glove (2).

Glove storage

- Avoid exposure to natural or artificial light.
- Store them in a dry location with temperatures comprised between 16 and 25 °C.
- Avoid compression stress due to excessive stacking.
- Observe the expiry dates.

Washing and disinfection

Pay close attention when performing these operations. Wash the gloves with distilled water and then blow dry them at a low temperature.

Disinfection must be performed using a method and products that will not damage the materials (*isopropyl alcohol or another disinfectant product*).

Avoid extended exposure to high temperatures. The use of halogenous products is forbidden, especially in concentrated form (*chloroform, bleach, etc.*)

CAUTION	<p>This list is not exhaustive, and it is always preferable to perform a test on one glove before beginning general application of any new method or product.</p> <p>Glove replacement frequency will be determined according to their use and the frequency with which the isolator is sterilized.</p>
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3.2. MAINTENANCE INSTRUCTIONS FOR QUALIFIED PERSONNEL

3.2.1. Testing filter integrity and efficiency

- After each filter removal or replacement, Getinge-La Calhène recommends performing a filter integrity and efficiency test (*at least once a year under normal operating conditions*).
- The operation must be performed by qualified personnel.

3.2.2. Pre-filter cleaning and replacement

Getinge-La Calhène recommends cleaning the pre-filters of the blowers with compressed air at least once a month. Proceed as follows:

- turn the pre-filter anti-clockwise to remove it,
- clean it with compressed air,
- position the pre-filter next to its support, press it and turn it clockwise to re-install it.

Getinge-La Calhène recommends replacing the pre-filters every once six months under normal operating conditions.



WARNING

The blower should never operate without the pre-filter properly installed. This also guarantees its function as a finger guard.

3.2.3. Seal replacement

The seals should be replaced during annual maintenance, if necessary.

The seals in question include the door, window, filter box and DPTE® seals.

This replacement must be performed by qualified personnel.

3.3. **TROUBLESHOOTING FOR QUALIFIED PERSONNEL**

See the alarm messages in chapter 2.1.

After-sales service

Please contact your local GETINGE representative.

4. CALIBRATION AND VERIFICATION

The connection of the instruments is described in detail in electric record no. 3785-301-50. The pump calibration procedure must be performed according to the instructions of chapter 4.1. For further information and for calibration of other instruments, contact the Getinge-La Calhène validation department.

4.1. PUMP

Manufacturer	Type	PID ref.	Calibration frequency
IWAKI	EW	M06	1 year



List of necessary equipment

- full hydrogen peroxide vial
- empty vial,
- scales (*capacity: 250 g – accuracy: 1 g*)
- no. 10 spanner

Procedure

- From the main view of the operator panel, go to the "System" menu.
- Confirm the password.
- Go to the "Calibration" menu.
- Scroll through the pages until you reach the "Pump calibration" page.
- Follow the panel instructions.

Step 1 (*H₂O₂ pipe and vial preparation*)

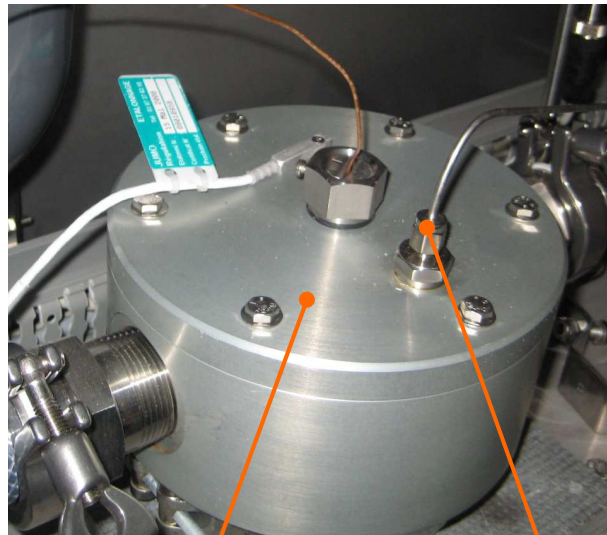
- Check that the central button of the pump is set to 100 %.
- Unscrew the leak-tight connector from the vaporiser.
- Remove the rigid pipe and place it above an empty vial.
- Place a full vial in the sterilizer and lower the needle.
- Press "Start" to start priming.

**DANGER**

The calibration or verification of the pump must always be performed with the heating collar of the vaporiser off. Set the 106Q1 circuit breaker to OFF or deactivate the heating-outside-cycle command in the system configuration menu, sterilizer configuration (*administrator level*). Wait for the vaporiser temperature to drop below 40 °C (*1 to 1:30 hours to drop from 120 °C to 40 °C*).

IMPORTANT

Use only hydrogen peroxide and never water when calibrating the pump.



Vaporiser

Leak-tight
connector

Step 2

- Wait around 1 minute to guarantee priming is complete.
- Press "Stop" to stop priming.

Step 3

- Adjust the settings
 - ♦ No. of cps/min: 100
 - ♦ Duration (*min*): 3
- Determine the vial set point.
- Press "Start" to start calibration (*1st cycle*).

Step 4

- Weigh the vial and enter the value (*example: 38.6 g*)
- Determine the set point of the vial again.
- Press "Start" to continue the calibration (*2nd cycle*).

Step 5

- Weigh the vial and enter the value.
- Determine the set point of the vial again.
- Press "Start" to start purging the injection circuit.

Step 6

- Once the circuit has been purged, press "Stop".
- Weigh the vial and enter the value (*example: 4.3 g*)
- Press the "Validate calibration" button.
- Press the printer button to print the calibration report and then "Exit" or "Start" to resume calibration if necessary.

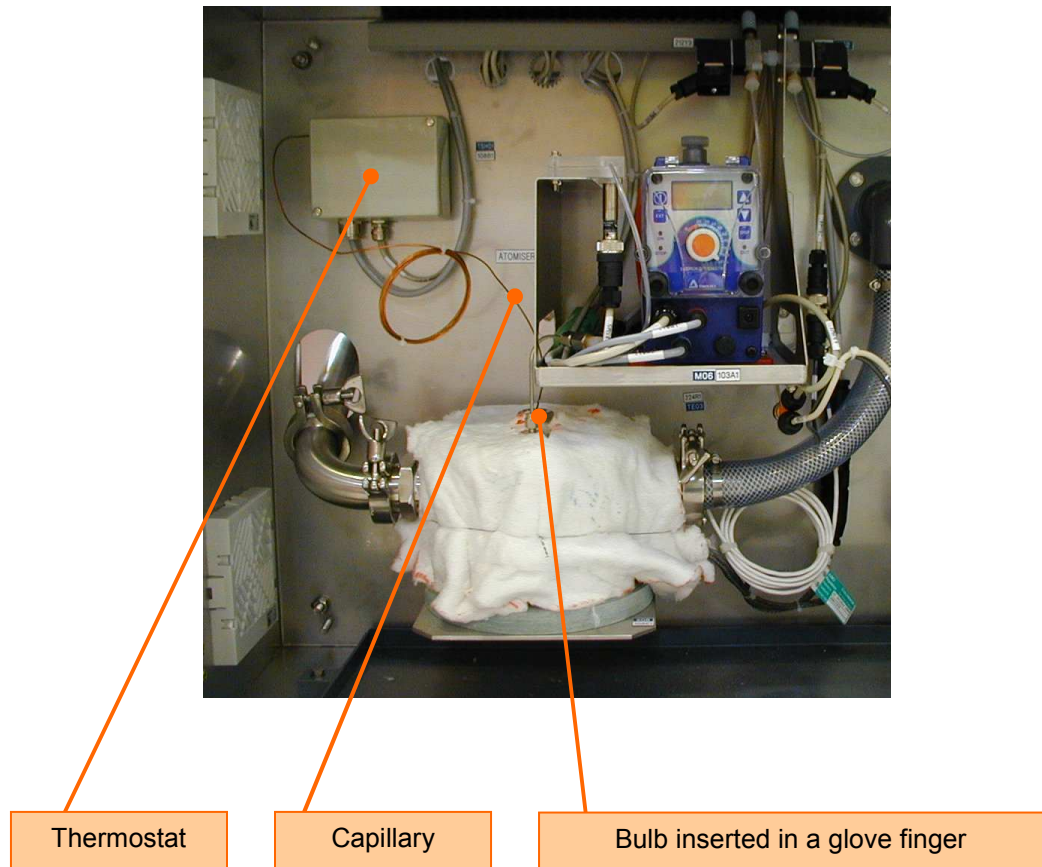
Step 7

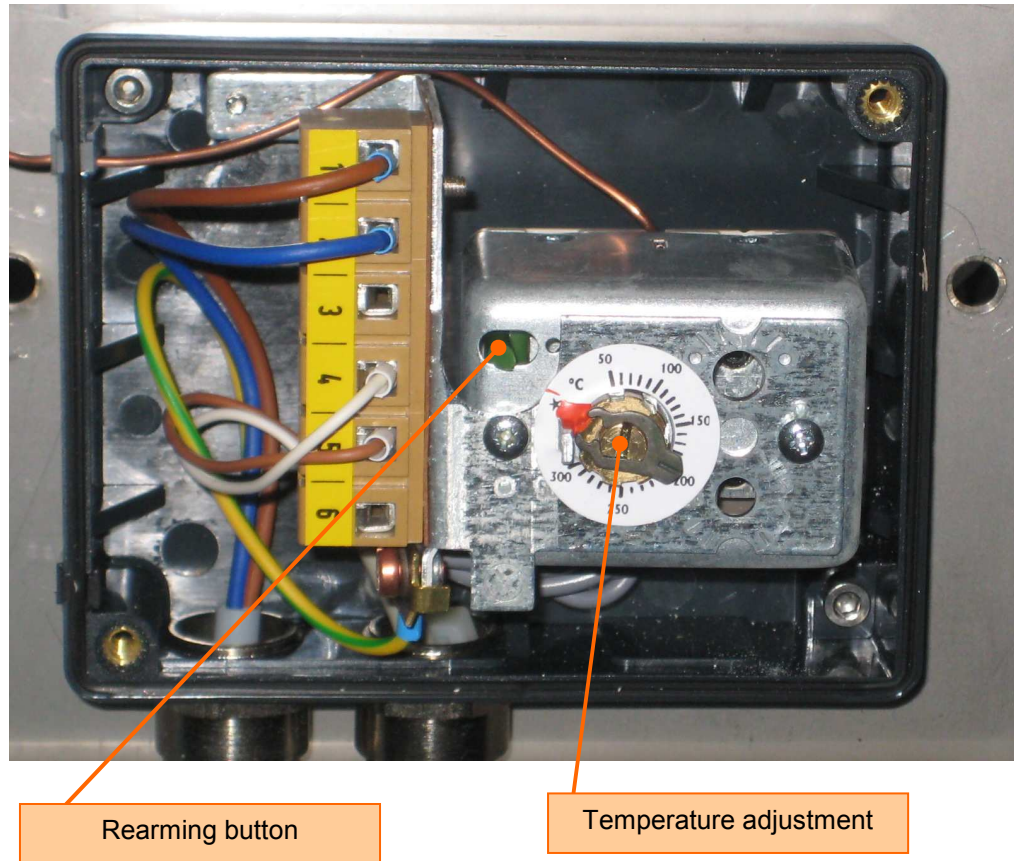
- Re-install the pipe on the vaporiser without forgetting to retighten the leak-tight connector.

4.2. SAFETY THERMOSTAT

Manufacturer	Type	PID ref.	Calibration frequency
JUMO REGULATION	AMTf 54/U	TSH01	6 months

The thermostat is installed at the bottom of the isolator.





If the temperature in the sensor exceeds the set point of **+200 °C**, the electrical circuit is opened and the microswitch is mechanically locked.

When the temperature is lower than the danger temperature minus around 10 % of the extent of the scale, the microswitch can be unlocked manually.

If the ambient temperature on the box and/or capillary is different from the calibrated ambient temperature, the contact point is offset.

- higher ambient temperature = lower contact point.
- lower ambient temperature = higher contact point.

It is advisable to calibrate the thermostat with an ambient temperature comprised between **+19 °C** and **+24 °C**.

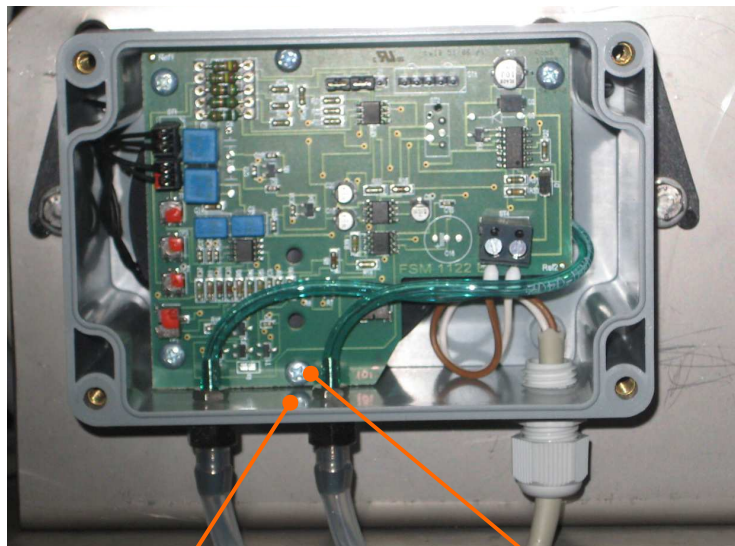
4.3. PRESSURE TRANSMITTERS

Manufacturer	Type	PID ref.	Calibration frequency
JUMO REGULATION	404304	PDT01 – PDT02 – PDT03	1 year



PDT01 pressure transmitter

PDT02 & PDT03 pressure transmitters



Potentiometers PT1 (0 %) and PT2 (100 %)

4.4. TEMPERATURE TRANSMITTER (WORK STATION & AIRLOCK)

Manufacturer	Type	PID ref.	Calibration frequency
PROSENSOR	800PT100	TT01 (<i>work station</i>)	1 year
PROSENSOR	800PT100	TT02 (<i>airlock</i>)	1 year



PT100 sensor with built-in converter (*at the top*)



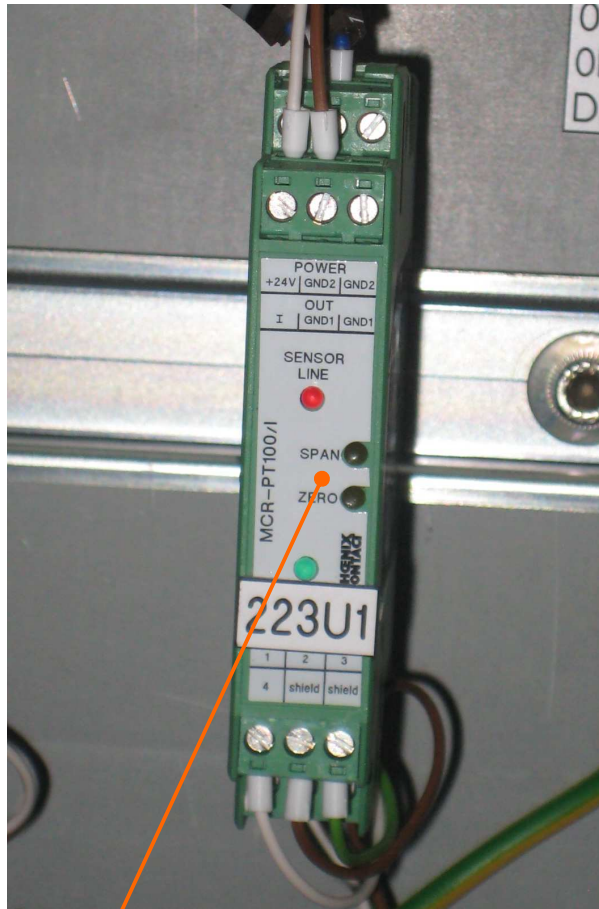
0 % and 100 % potentiometers

4.5. TEMPERATURE TRANSMITTER (STERITRACE II)

Manufacturer	Type	PID ref.	Calibration frequency
PHOENIX CONTACT	2810353	TT03	1 year



Transmitter (installed on the PLC plate at the top)



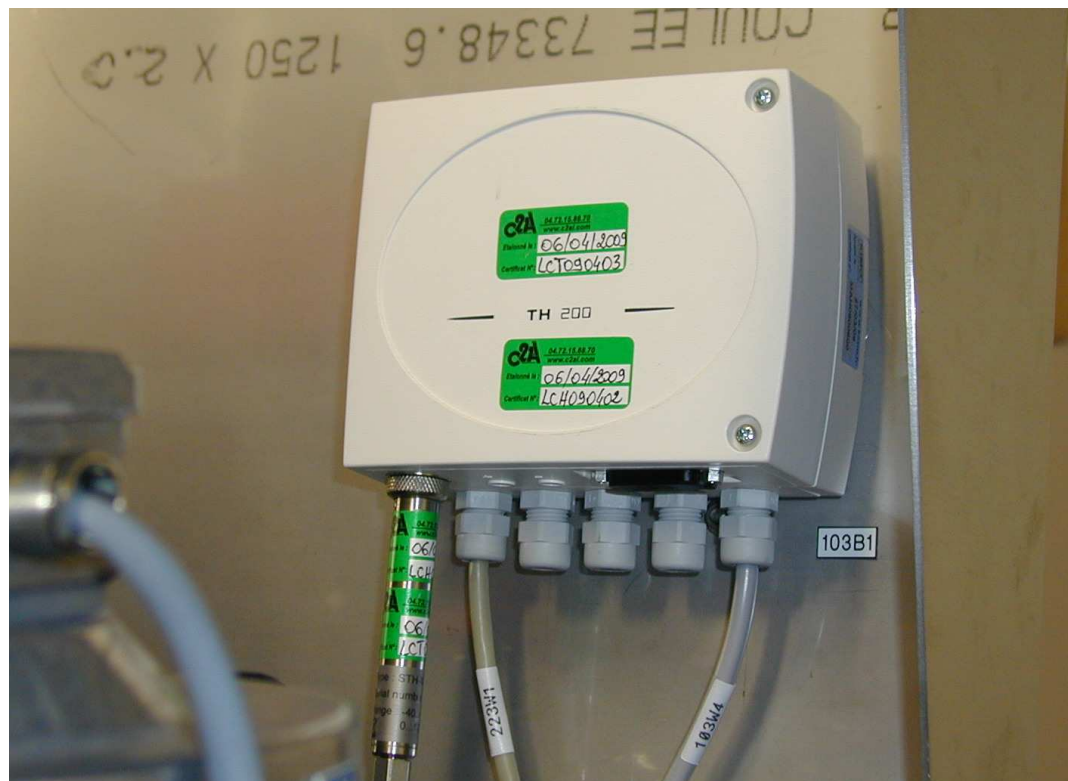
0 % and 100 % potentiometers



PT 100 surface probe connected to the transmitter

4.6. HUMIDITY TRANSMITTER

Manufacturer	Type	PID ref.	Calibration frequency
KIMO	TH200	AT01	1 year



4.7. "EMERGENCY AERATION" BUTTON



"Emergency aeration" button

- Press the button and check that the "Emergency" alarm message appears on the operator panel.

4.8. **ISOLATOR AERATION**

Following the modification of a recipe parameter, it may be necessary to check the efficiency of the aeration phase (see *user manual, chapter "Recipe"*).

Equipment used

- Dräger reactive tubes for H₂O₂ (scale 0 to 3 ppm).
- Dräger manual pump.

Test procedure

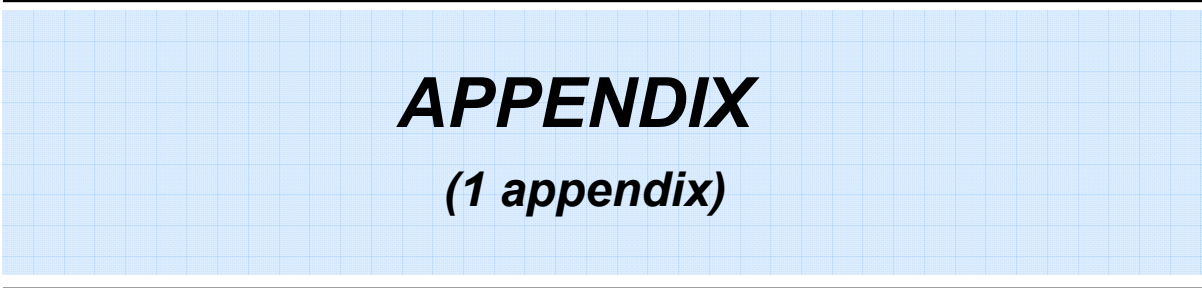
- Position the tool on the extractor sheath and make a hole in the sheath.
- Take a Dräger tube and break the two ends.
- Place the Dräger tube in the pump following the arrow showing the suction direction.
- Place the tube in the extractor pipe.
- Activate the Dräger manual pump 20 times consecutively.
- At the end of the operation, remove the Dräger tube from the exhaust duct.
- The reading will be taken according to the scale shown on the tube and the colour of the white crystals, which initially turn brown in contact with H₂O₂.
- Check that the hydrogen peroxide concentration is less than or equal to 5 ppm.

5. LIST OF SPARE PARTS

Description	Code	Frequency
18 W bulb	16918	2 years
HEPA filter – 6P6 Airlock – air intake and outlet	6604C	1 year
HEPA 1.5P3 HD filter – Isolator – air intake	35257	1 year
HEPA 1.5P3 filter – Isolator – air outlet	23504	1 year
Hypalon sleeve	16285C	/
J3L 190 E seal (DPTE® Beta part)	21819	2 years
J3L 190 I seal (DPTE® Alpha part)	373C	2 years
Kit for replacing 190 J3L lip seals comprising a tool, the replacement procedure, free from particles of cleaning paper and a bottle of silicone	23024C	/
0.2 µm optical filter (compressed-air intake)	33672	1 year
PRV200 pre-filter (airlock)	26239	6 months
PRV160 pre-filter (isolator)	26238	6 months
R48 O-ring seal (for RAC 100)	2285C	2 years
R77 O-ring seal (for RAC 300)	4177C	2 years
Neoprene glove (size 7- sterile, particles removed) (batch of 10)	7,128B	/
H ₂ O ₂ needle	30617	/
Adhesive seal (hatch and window)	18222	/
Pressure intake mini-filter	6599C	1 year
Inflatable seal (airlock door)	24386	/

6. DEFINITION OF THE TECHNICAL TERMS

Work station (or work isolator)	Sealed volume in which the work is performed.
STERITRACE II	Hydrogen peroxide sterilizer (H_2O_2).
Open loop	The sterilizer only takes care of the sterilant intake, the outlet is provided by the isolator extractor.
Closed loop	The sterilizer takes care of the sterilant intake and outlet in the enclosure.
Dust accumulation class	Classification for comparing the airborne contamination levels of one enclosure with another.
Biodecontamination	Sterilization of surfaces using a sterilant in vapour phase.
DPTE® transfer system	Secure transfer system with a double door. The safest method for introducing and eliminating sterile and/or toxic products without breach of containment.
DPTE® ALPHA	Cell clamp / cell door assembly. Fixed part of the DPTE® mounted on the isolator wall.
DPTE® BETA	Container clamp / container door / container body assembly. Mobile part of the DPTE® (<i>for example a container</i>).
DPTE®-DispoBag	System for evacuating waste with no risk of contaminating the environment.
Tubing System	The tubing system has been designed to allow dynamic sterile transfer of equipment or products from inside the isolator to the outside, in a semi-continuous way without breach of containment.
Production phase	Work campaign
Aeration phase	Isolator / airlock aeration to eliminate sterilant vapours.
RFID	Radio Frequency Identification. Radio frequency identification is a method for remotely storing and recovering data using markers called RFID tags or RFID transponders. RFID tags are small objects, such as self-adhesive labels, which can be affixed or added to objects or products or even implanted in living organisms. RFID tags consist of an antenna associated with an electronic chip which allows them to receive and reply to radio requests emitted by the transceiver. These electronic chips contain an identifier and, optionally, additional data.

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APPENDIX
(1 appendix)

HYDROGEN PEROXIDE PRODUCT SHEET



ARKEMA INC.
2000 Market Street
Philadelphia, PA 19103
215-419-7000

HYDROGEN PEROXIDE, VALSTERANE® 35% and 50%

SPECIFICATIONS

	35%		50%	
	Minimum	Maximum	Minimum	Maximum
Hydrogen Peroxide, %	35.0	35.7	50.0	50.7
pH, Apparent	2.4	3.8	1.5	3.0
Color, APHA		10		10
Appearance	Clear		Clear	

PROPERTIES

Active Oxygen, %	16.4	23.5
Specific Gravity @ 20°C		
lb/gal	9.45	9.98
g/mL	1.132	1.195
Boiling Point @ 760 mm Hg, °C	108	114
Freezing Point, °C	-32	-51
Vapor Pressure @ 30°C, mmHg	23	18
Appearance	Clear liquid with a slightly pungent odor	

MISCELLANEOUS

CAS No : 7722-84-1

Valsterane® meets the specifications for hydrogen peroxide as required by the "Food Chemicals Codex" (FCC), 5th Edition. FCC requirements are as follows:

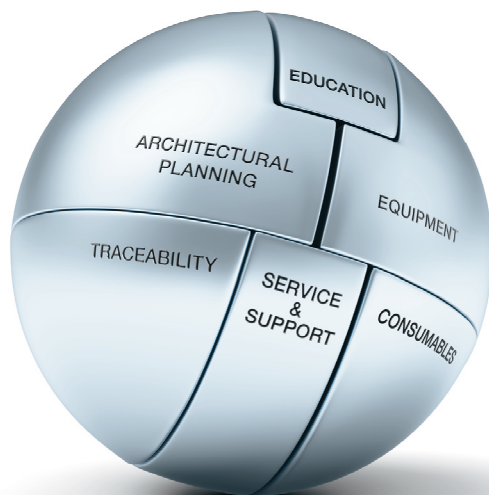
ASSAY:	Within range stated
LEAD, as Pb:	≤ 4 ppm
RESIDUE ON EVAPORATION:	≤ 60 ppm
PHOSPHATE:	≤ 50 ppm
ACIDITY, as H ₂ SO ₄ :	< 0.03%
IRON:	< 0.5 ppm
IIIN:	< 10 ppm

Customer Service: 1.800.346.5757

December 28, 2004

BEFORE HANDLING THIS MATERIAL, READ AND UNDERSTAND THE MSDS (MATERIAL SAFETY DATA SHEET) FOR ADDITIONAL INFORMATION ON PERSONAL PROTECTIVE EQUIPMENT AND FOR SAFETY, HEALTH AND ENVIRONMENTAL INFORMATION.

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