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ISOTEST

USER MANUAL

Always with you

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REVISION HISTORY

Date	Version	Description	Written by
22.12.2009	A	First issue *(09/186)*	E. Delombaerde
12.02.2010	B	General update *(10/037)*	S. Chauvin
07.07.2010	C	Issue of software modifications *(10/163)* – Addition of: ♦ "Start loading" button ♦ "Waiting production phase" ♦ a screen to select batch number	E. Delombaerde

Date	Written by	Reviewed by	Approved by
07.07.2010	E. Delombaerde	S. Chauvin	D. Papin

CONTENTS

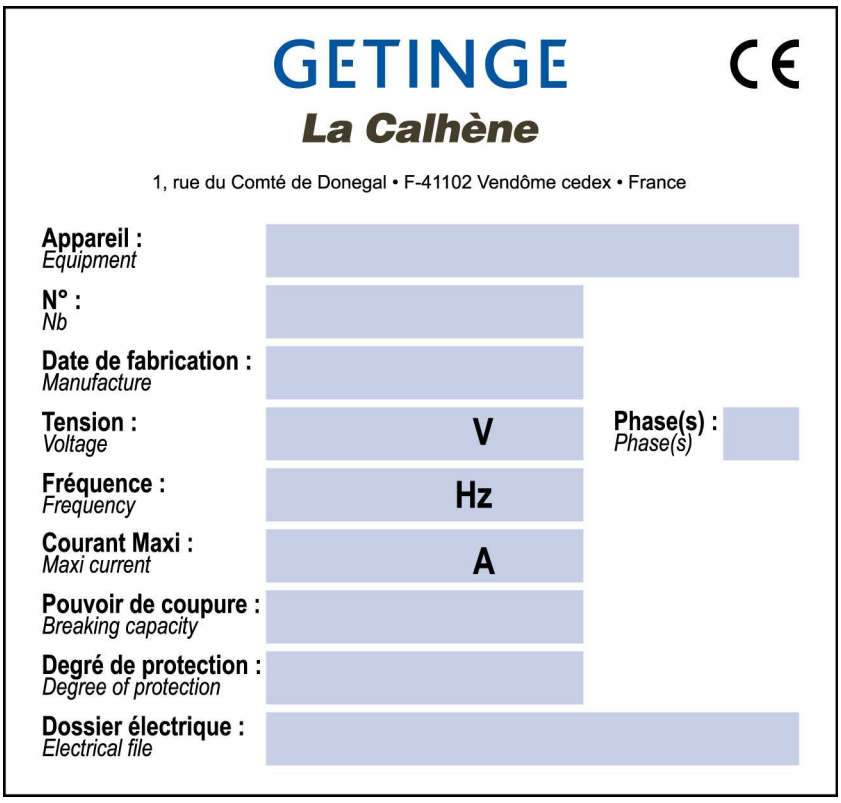
1. IDENTIFICATION

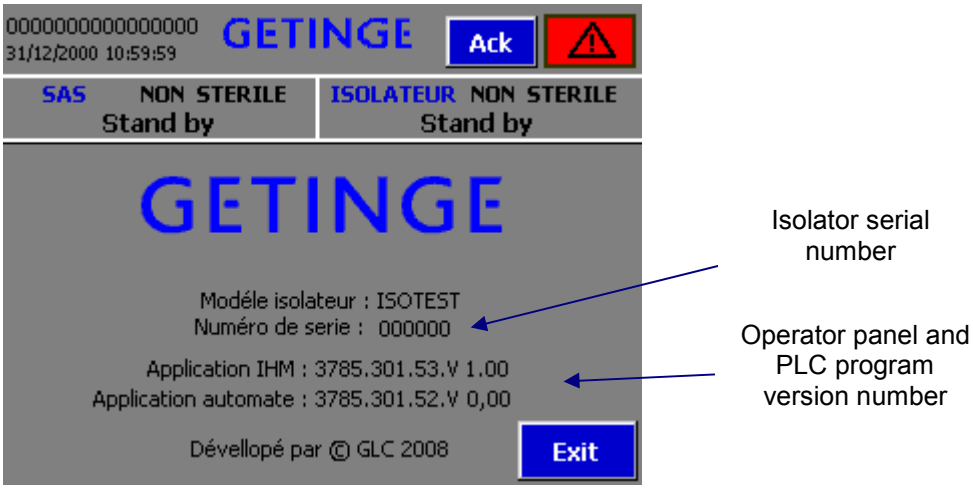
1.1. ISOLATOR BRAND AND DESCRIPTION

ISOTEST	Rigid-wall isolator for the performance of sterility tests (*European version*)

1.2. VERSION OF THE ISOLATOR AND THE SOFTWARE

The isolator is identified by its serial number and by the software version indicated on the operator panel (*see technical manual, configuration chapter*).





1.3. MANUFACTURER'S NAME AND ADDRESS

GETINGE-LA CALHENE	1, rue du Comté de Donegal 41102 Vendôme cedex – France ☎ +33 (0)254 734 747 🖷 +33 (0)254 734 710 www.getinge-lacalhene.com

2. COMPLIANCE REPORT

- EMC directive no. 89/336/EEC modified by directives 91/263/EEC, 92/31/EEC, 93/68/EEC, 92/31/EEC.

- Low voltage directive no. 73/23/EEC.

- Test voltage (*standard test*): as per EN 61 010-1, 2001 issue.
- Overvoltage classification II, pollution level 2

- Electrical safety: as per EN 61 010-1, 2001 issue.

- Electromagnetic compatibility:
  - Emission according to EN 61000-6-4, 2007 issue
  - Immunity according to EN 61000-6-2, 2005 issue

- Personal protective equipment (*gloves*) directive no. 89/686/EEC.

3. SAFETY NOTES

3.1. 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 the reader's 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

3.2. GENERAL

 **WARNING**	This equipment uses hydrogen peroxide, electricity and compressed air. 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.
 **CAUTION**	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.
IMPORTANT	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.
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

4. GENERAL OPERATION AND RANGE OF APPLICATIONS

The ISOTEST isolator is a sealed enclosure which allows its user to perform biodecontamination of various surfaces inside the isolator by chemical means in a closed circuit. The unit is designed and equipped so as to be able to be biodecontaminated using hydrogen peroxide, H_2O_2.

APPLICATION: Rigid-wall isolator for the performance of sterility tests.

The isolator is equipped with a ventilation and filtering module that maintains an overpressure inside the sterile volume while guaranteeing minimum air renewal with HEPA-filtered air. The isolator is furthermore equipped with transfer systems allowing the insertion and removal of sterile equipment and/or products. Handling systems allow the operator to perform operations inside the sterile contained environment from the outside.

These instructions are valid for the ISOTEST *(Rigid-wall stainless-steel isolator with fixed glass window and door)* operating with overpressure and biodecontaminated with hydrogen peroxide, H_2O_2. It consists of a stainless-steel biodecontamination airlock with interlocked doors *(inflatable seals),* a working isolator for performing the sterility test *(using a Millipore Equinox pump or equivalent),* and a ventilation/filtering system.

5. SAFETY INFORMATION

DANGER	Do not use the ISOCYT isolator in an explosive atmosphere. Only use "HYDROCYDE" hydrogen peroxide with a concentration of 35 % as recommended by Getinge-La Calhène
WARNING	The ISOCYT 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. When handling hydrogen peroxide, please consult the product toxicity sheet (*see appendix*). It is compulsory to wear gloves and goggles when handling hydrogen peroxide. Only persons who have been trained in using the ISOCYT isolator are authorised to perform biodecontamination cycles. **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 twice in less than 8 seconds and evacuate the hazard area.** An emergency / evacuation procedure must be in place for this purpose. 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 rain and high winds and sufficiently separated from passage areas and other heating, ventilation and A/C air intakes. 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 H_2O_2 in the pipes.

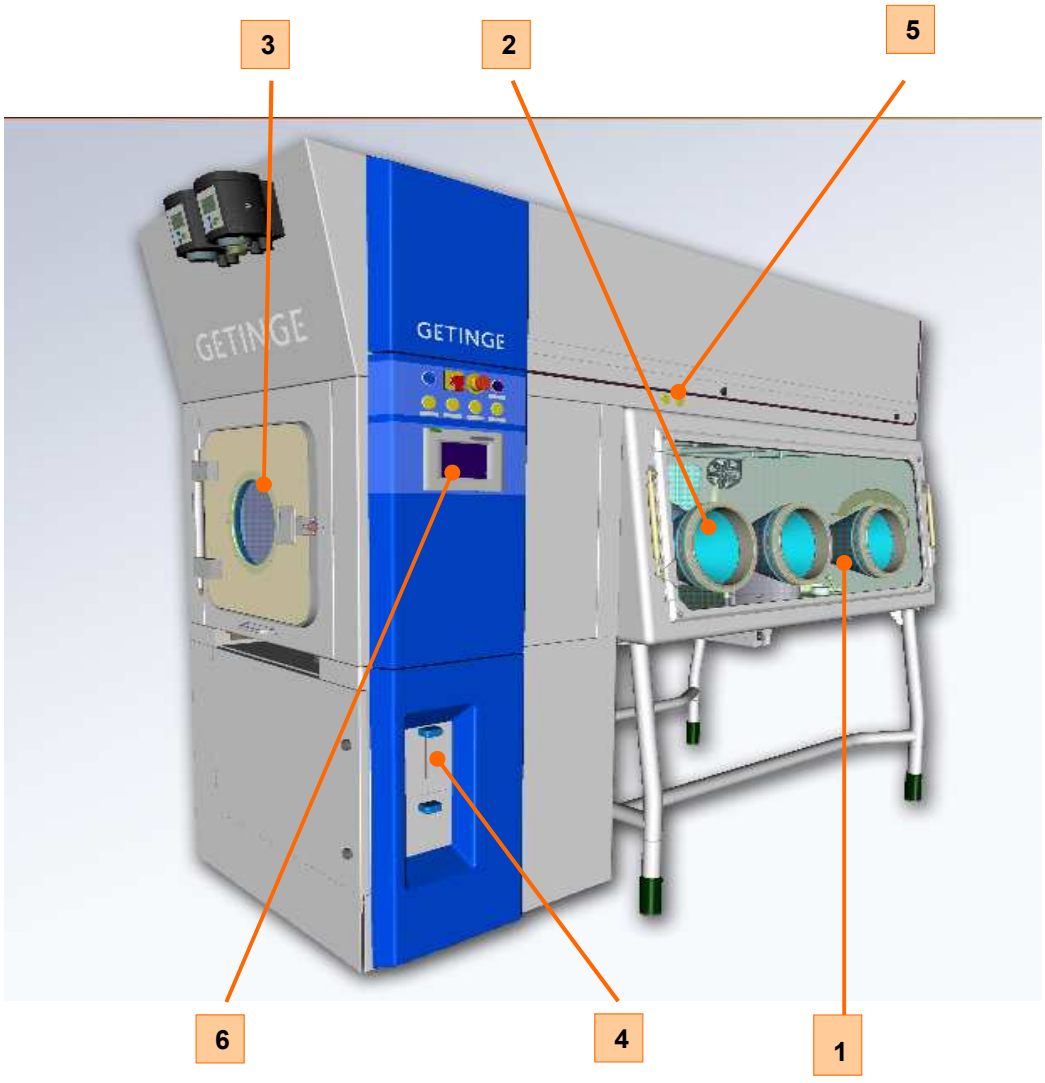
WARNING	All maintenance operations must be performed after aerating the circuits that contain hydrogen peroxide in gaseous form and purging the circuits in which the sterilant is in liquid form. It is compulsory to rinse with water when removing a component on the injection circuit.
CAUTION	It is advisable 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*).
CAUTION	The outer door of the biodecontamination airlock **SHOULD NEVER** be used as a support for setting any type of object, even on a temporary basis. This may affect the adjustment of the door, compromising its seal.
DANGER	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 (*using the other station*) has been warned and has not placed his hands under the door. When opening, use one hand to hold the handle, making sure to operate the door under optimum conditions. 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.
CAUTION	When closing one of the two doors (*inner door and outer door of the biodecontamination airlock*), 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 leak test before a biodecontamination cycle may fail in this case, making it impossible to use the device.

6. COMMISSIONING

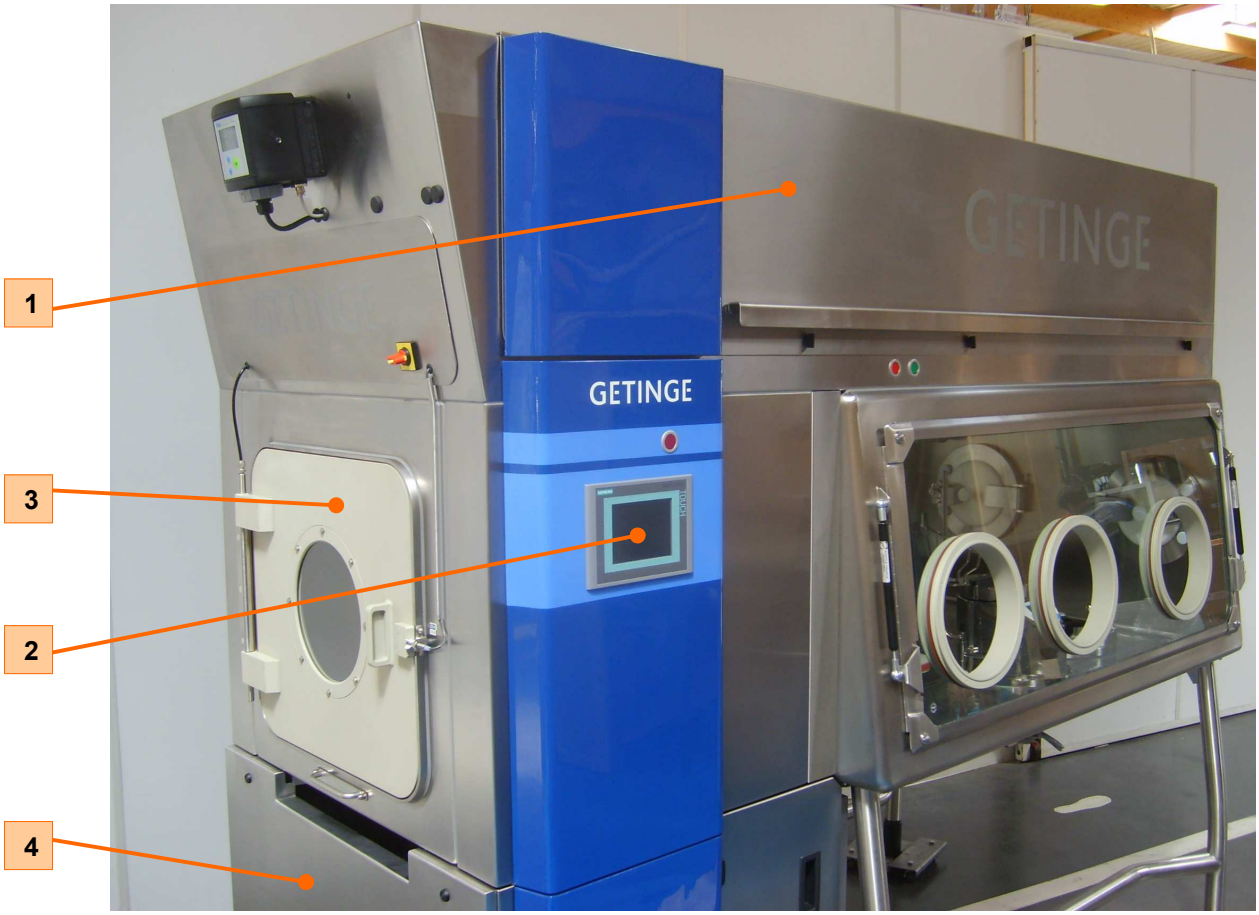
- Set the master switch to position **1**.
- Check that the operator panel switches on. The welcome view appears automatically:

7. EQUIPMENT DESCRIPTION

7.1. OVERVIEW

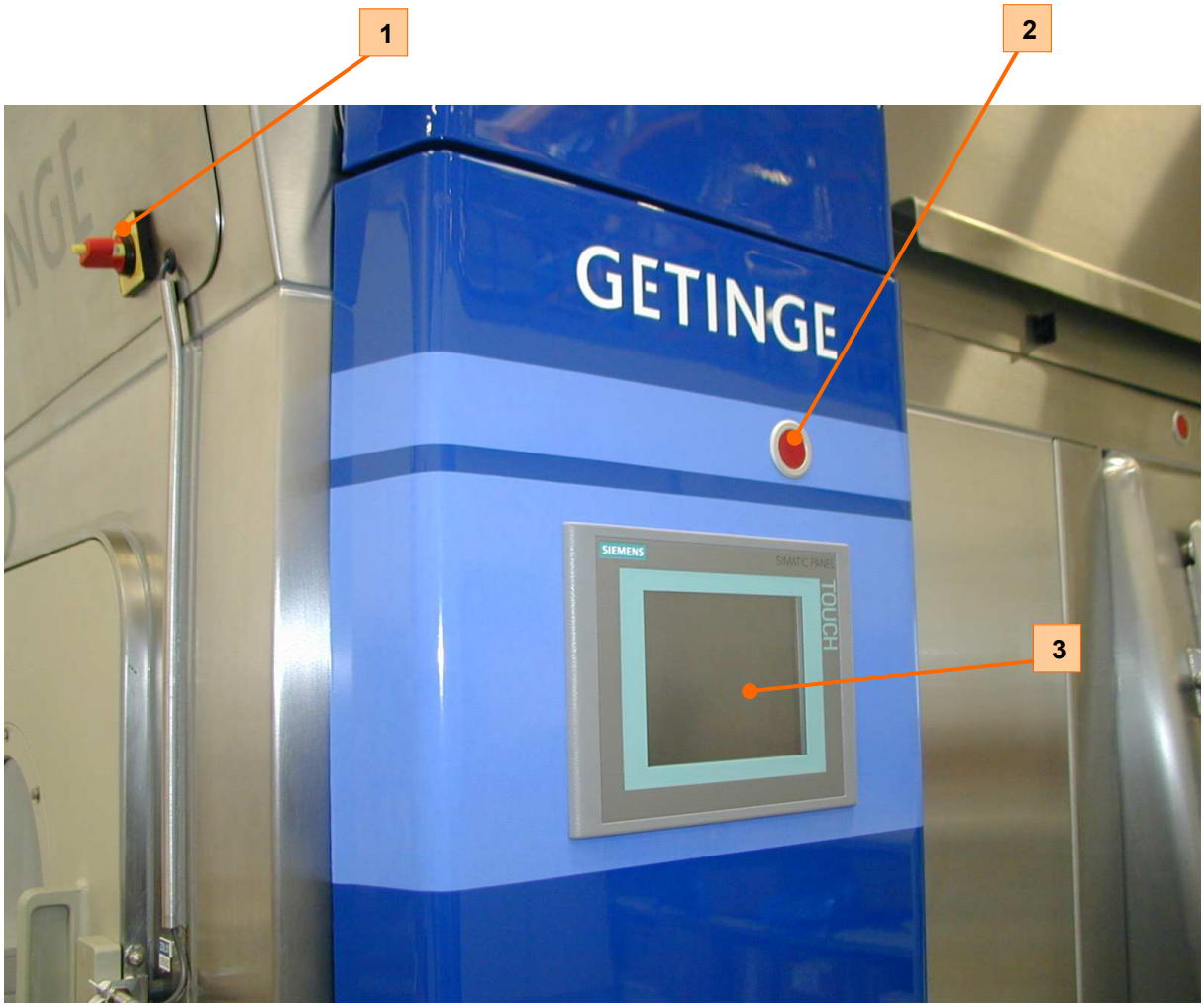


Number	Designation
1	Work station
2	Sleeves and gloves
3	Quick biodecontamination airlock
4	H_2O_2 container
5	Red/green LEDs for door opening authorisation
6	Touch-sensitive operator interface



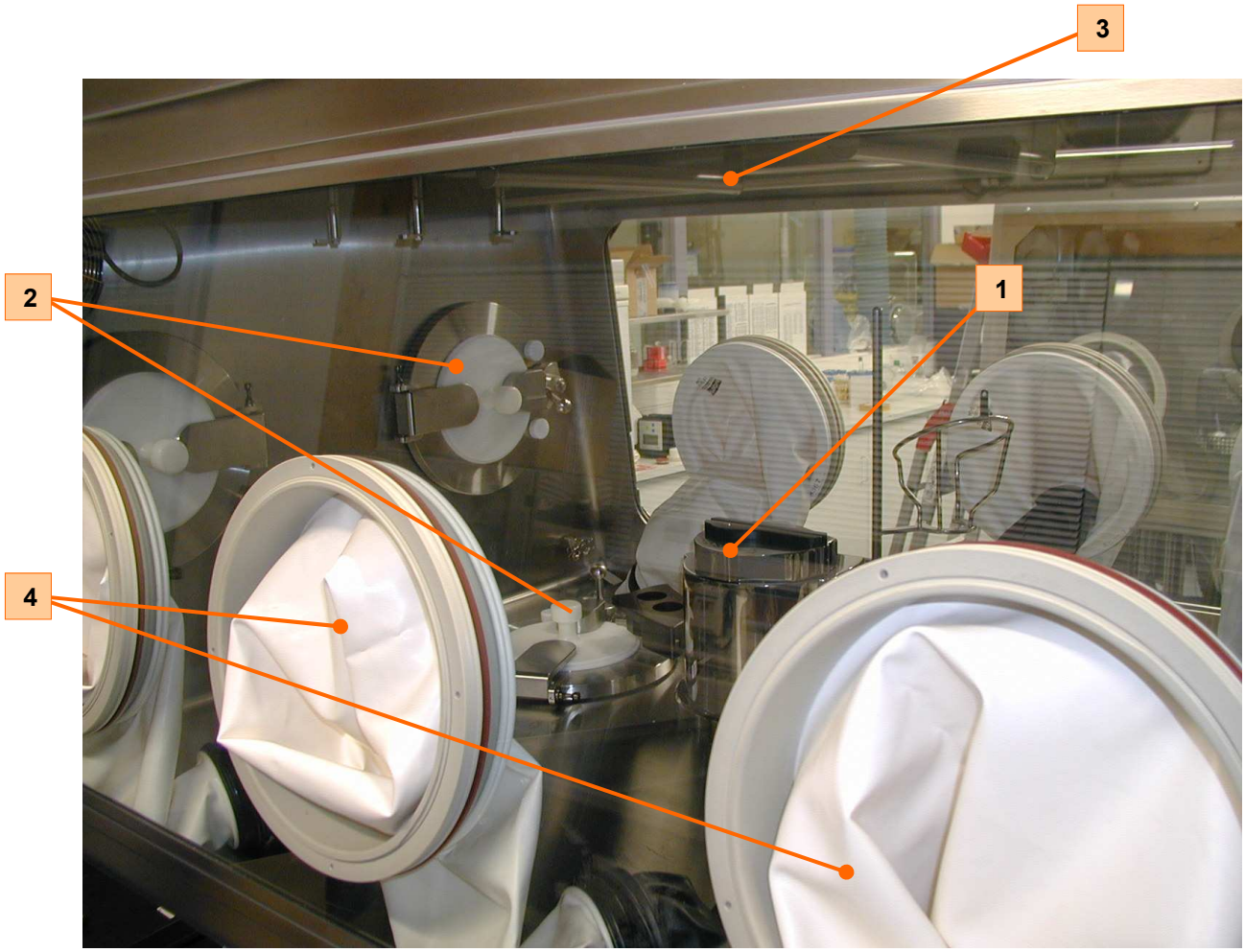
Number	Designation
1	Ventilation / Filtration
2	Control-command
3	Biodecontamination airlock
4	Built-in STERITRACE II hydrogen peroxide sterilizer

7.2. OPERATOR INTERFACE



Number	Designation
1	Master power switch
2	**EMERGENCY AERATION** push-button
3	Touch screen

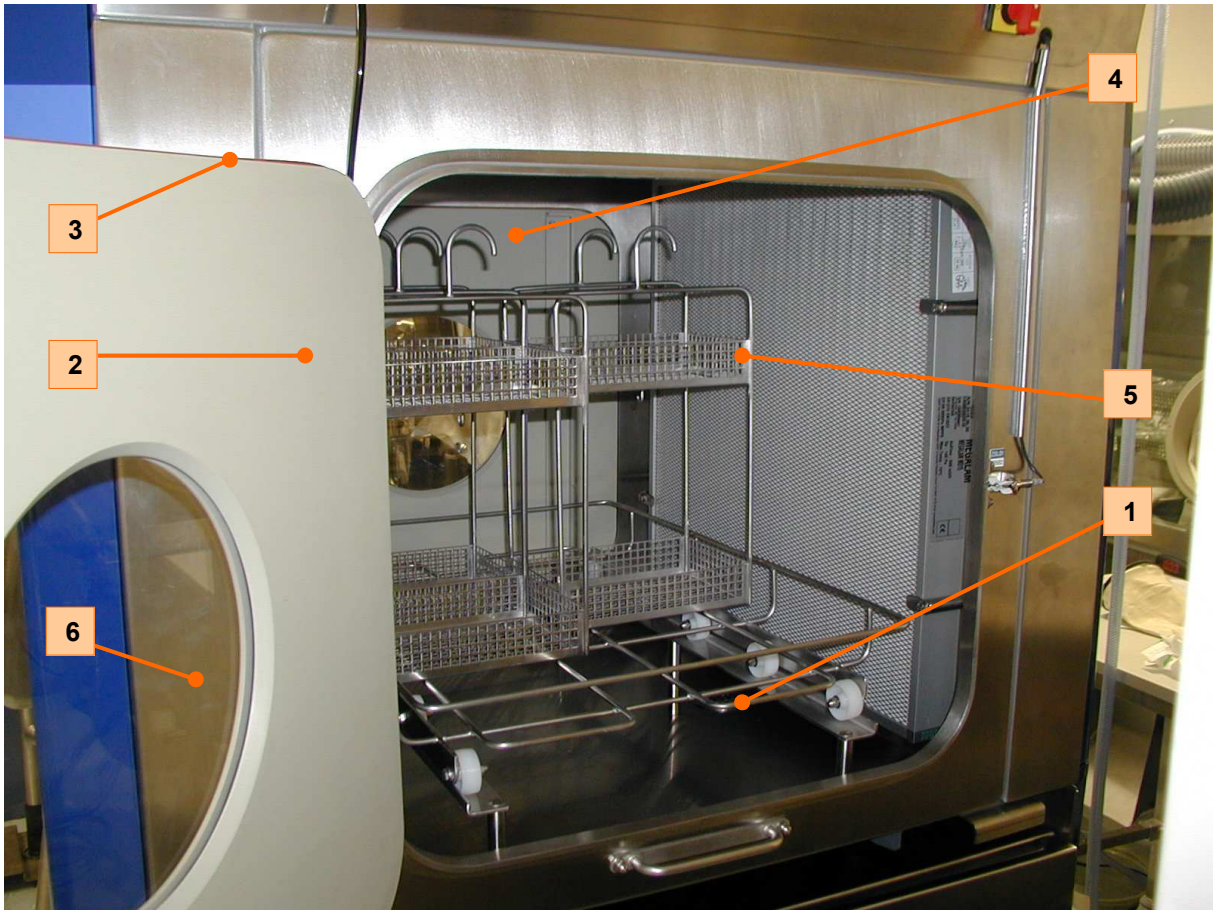
7.3. WORK STATION



Number	Designation
1	Steritest pump
2	DPTE® S transfer system
3	Basket hanging bars
4	Sleeve and glove

DANGER	Special precautions must be taken when opening the inner door. Consult chapter 5 – Information and Safety.

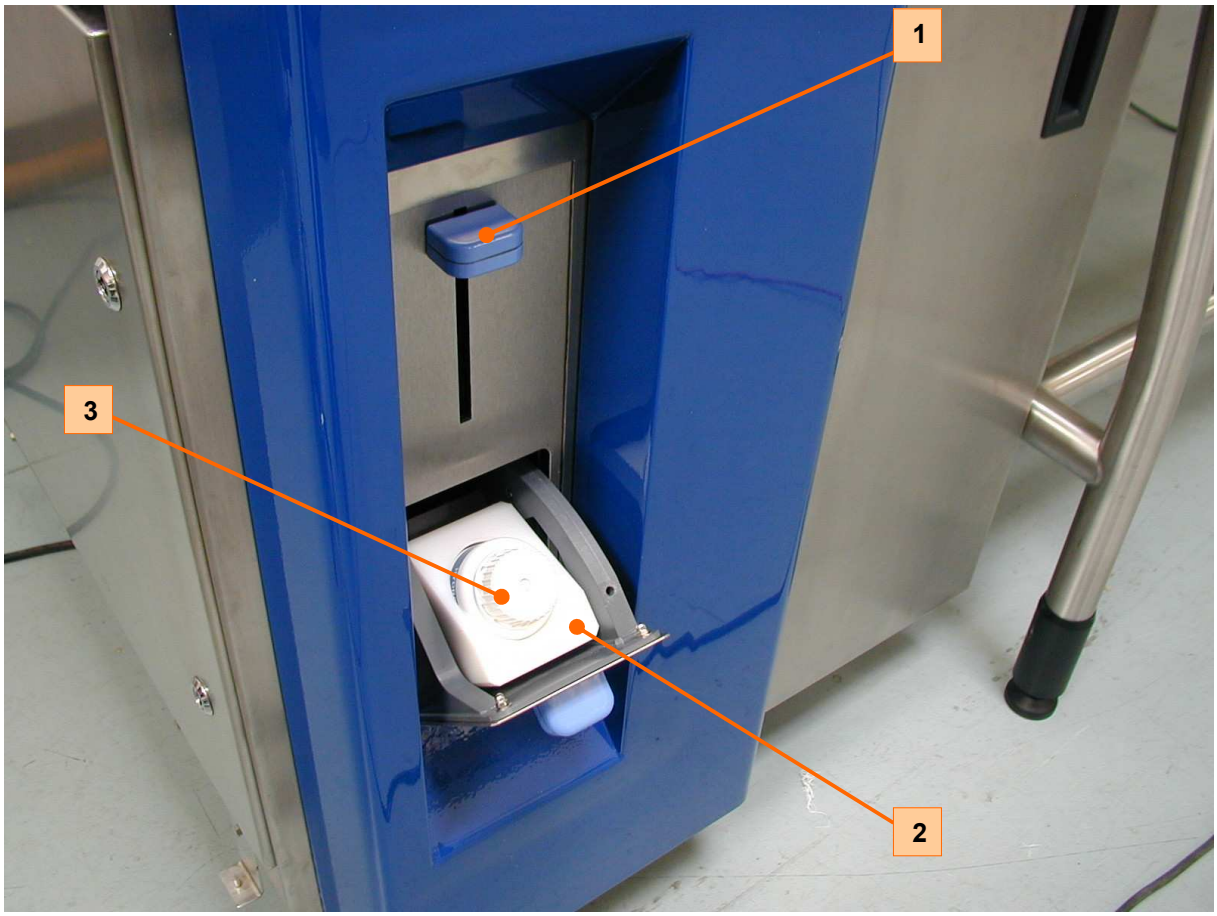
7.4. BIODECONTAMINATION AIRLOCK



Number	Designation
1	Transfer trolley
2	Biodecontamination airlock door
3	Sealing gaskets
4	Inner door
5	Basket
6	Inspection window

IMPORTANT	To help when loading the baskets in the transfer trolley, a preparation trolley can be placed in front of the airlock.

7.5. STERITRACE II STERILIZER INTERFACE



Number	Designation
1	Needle-positioning lever (*perforation of the cap of the vial*)
2	Vial container
3	Hydrogen peroxide vial

7.6. HANDLING

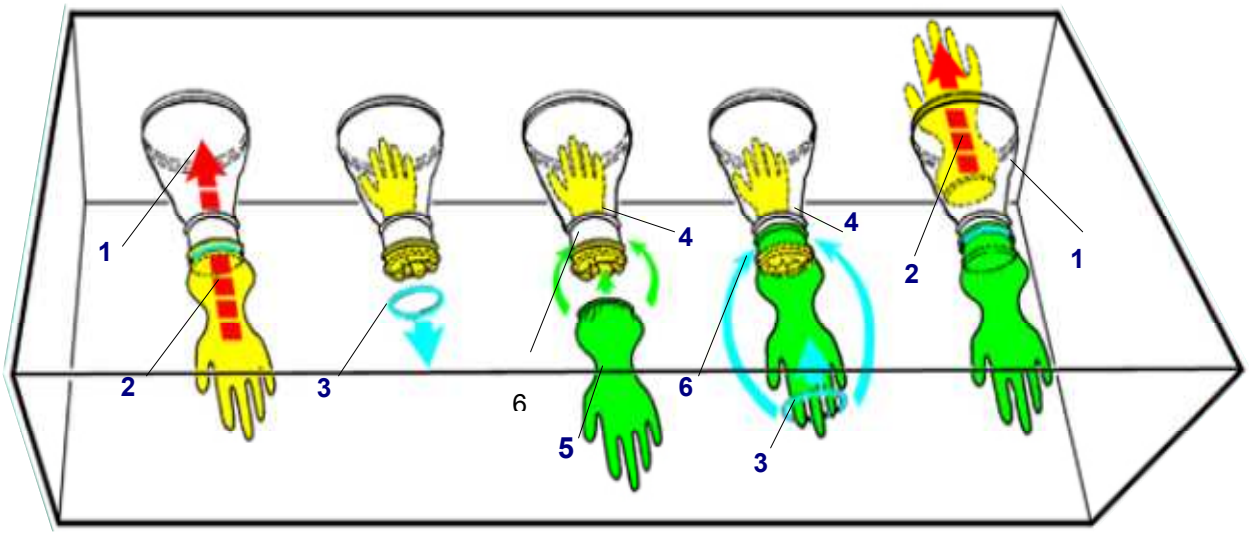
Before each sterilization cycle, Getinge-La Calhène recommends checking the integrity of the isolator gloves. The method consists of:

- conducting a test by raising the oxygen level to assess glove performance (*GLT testing device – operator manual NT 3020/1*)

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 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.

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.

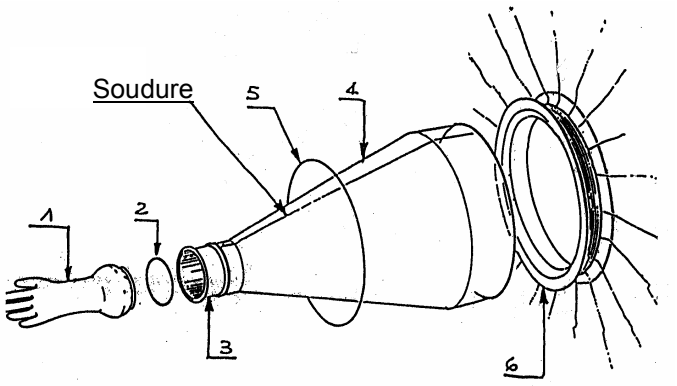
Disinfection must be performed using a method and products that will not damage the materials (*isopropyl alcohol or another disinfectant product*).

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

Note: ***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.***
Glove replacement frequency will be determined according to their use and the frequency with which the isolator is sterilized.

Manipulation inside the isolator is done through glove-sleeve assemblies. The neoprene gloves are available in different sizes. The sleeves are made from Hypalon® or PVC / PVC-coated polyester.

CAUTION	Before starting operations, it is compulsory to remove any objects that might damage the glove: watch, rings, etc. Getinge-La Calhène also recommends wearing under-gloves (*for hygiene*) and over-gloves, which must be replaced frequently (*to reduce cross-contamination*).



Number	Designation
1	Gloves
2	R48 O-ring
3	Equipped cuff ring
4	Sleeve
5	R77 O-ring
6	Shoulder ring

PVC / Divetex sleeve
Neoprene glove

Hypalon® sleeve
Hypalon® glove

8. OPERATION

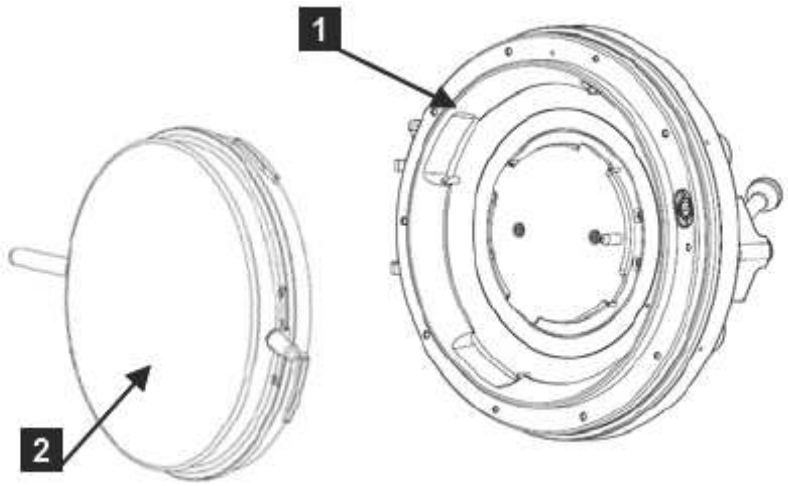
8.1. TRANSFER SYSTEM

The unit is equipped with two DPTE® ALPHA 190 transfer systems, one of which is fixed to the work top of the work station allowing the connection of a DPTE-DispoBagTM transfer system to ensure safe evacuation of liquid/solid waste. The other one is fixed to the vertical wall for connecting the Tubing system for evacuating tests.

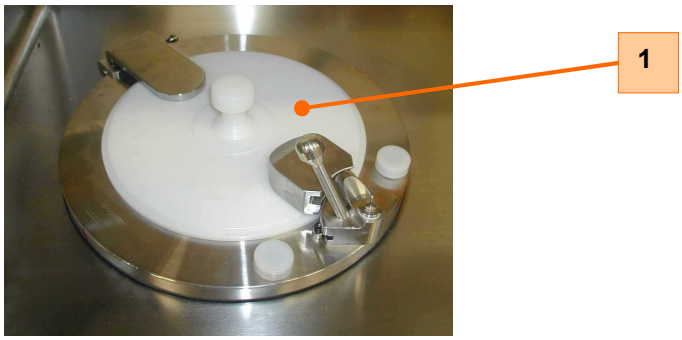
Once the Beta part or parts are connected, the double door or doors can be opened by turning the lever.

Each one of the two work stations *(facing each other)* can be equipped with these DPTE® transfer systems.

It consists of two parts:



Number	Designation
1	DPTE-S® 190 (*Alpha part*)
2	Dummy container (*Beta part*) – (*optional*)



The following is provided for the connection of a Beta part: DPTE-DispoBag™ or DPTE-Tubing™.

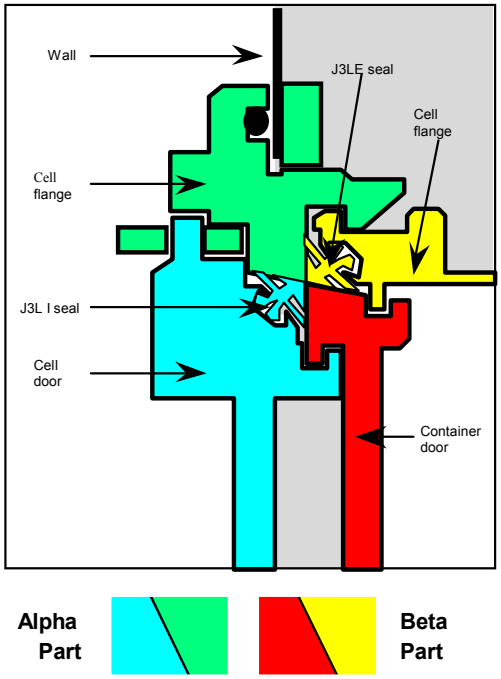
This system is completely interlocked. It allows completely safe connection / disconnection of the Alpha and Beta parts. The door can only be opened using the lever when a Beta part is connected to the Alpha part and, likewise, the Beta part can only be disconnected if the door is closed.

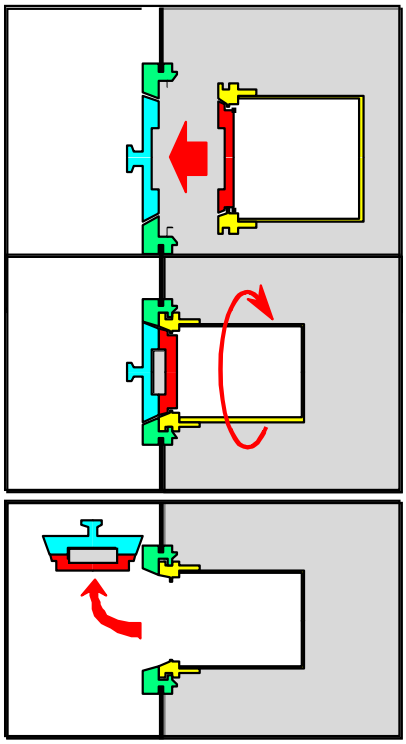
The dummy container is used to facilitate biodecontamination of the seal surface. It can be replaced with a multipurpose container (*supplied as standard*).

Operating principle of the DPTE® system

Description of principle

- 2 Alpha and Beta parts
- 2 opposing lip seals
- 4 overlapping components, interlocked by rotation of the Beta part





1. Moving the container forwards

2 . Locking by rotation

3 . Opening of the double door

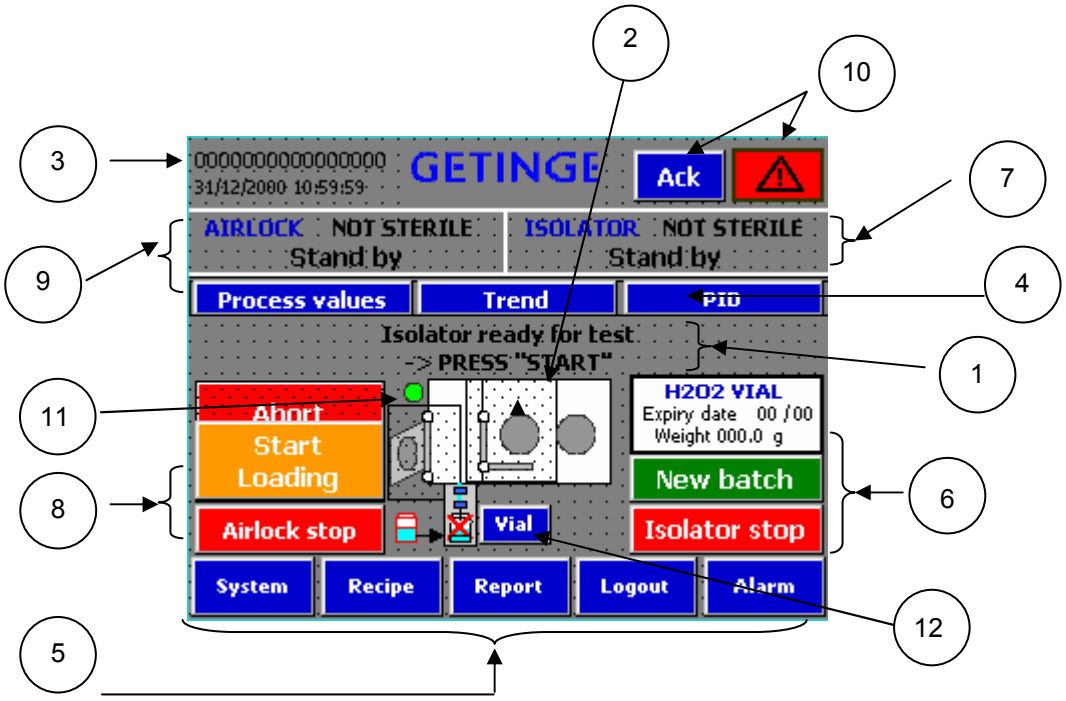
8.2. PROCESS

After a power failure or when a user logs off, the following view appears:

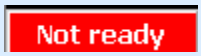
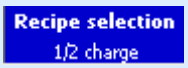
To access the user view, press the screen.

User view

To start a complete cycle, the operator must follow the instructions on the panel with the help of the block diagram.



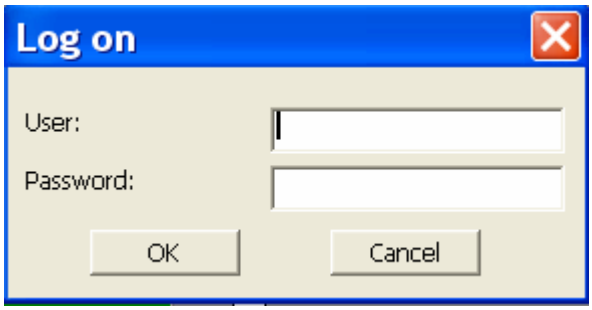
Number	Designation
1	Operator instructions
2	Block diagram of a cross-section of the machine
3	User logged in
4	Alarm in progress (*appears when an alarm is active*) OR Process values | Trend | PID providing access to the process values or the curves or the PID.
5	Buttons to access the various menus. System — Provides access to the system configuration menu (*access level >= Maintenance*). Recipe — Provides access to the recipes (*access level >= Validation*). Report — Provides access to the reports (*access level >= Operator*). Logout — Allows the operator to log out from the system. Alarm — Displays the alarm window (*access level >= Operator*).

Number	Designation
6	Isolator control buttons.  Halts an isolator cycle in progress (*in the case of a biodecontamination, the airlock automatically launches the emergency phase*).  Launches the isolator cycle.  Launches a new batch *(in production or waiting production phase).*  Pressing this button displays the locking conditions.
7	Isolator operation status.
8	Airlock control buttons.  Halts an isolator cycle in progress (*in the case of a biodecontamination, the airlock automatically launches the emergency phase*).  Launches the airlock cycle.  Pressing this button displays the locking conditions.  Allows the user to select a recipe for biodecontamination.  Allows to start the loading phase if the automatic transition “Loading → Unloading” is not selected
9	Biodecontamination airlock operation status.
10	Appears if an alarm is active. The  button acknowledges the alarms.
11	Door status LED (*red = locked; green = unlocked*)
12	Displays the weight and the expiry data of the H_2O_2 vial.

CAUTION	The administrator customer is responsible for defining the users and their passwords and for deleting the default users in the following table (*see technical manual*).

8.2.1. User password

- Operator mode requires the entry of a user password.
- When any of the buttons are pressed, the following screen appears:



- Enter the username (*default "Oper"*) followed by the password (*default "101"*).
- Confirm your entry by pressing the "OK" button.
- The logged-in user can then be seen in the following view:

Default password table

Access level		User	Password
0	Visitor	N/A	N/A
1	Operator	Oper	101
2	Validation	Valid	201
3	Maintenance	Maint	301
9	Administrator	Admin	100

8.2.2. Cycle progress

"The goal of steps 1 to 4 is to prepare the isolator during initial commissioning or after a cleaning or maintenance operation with breach of containment (*operation recommended once per month*). The isolator is not sterile at the start of this phase, and is sterile at the end. Steps 5 to 14 describe the sequence of phases during routine production.

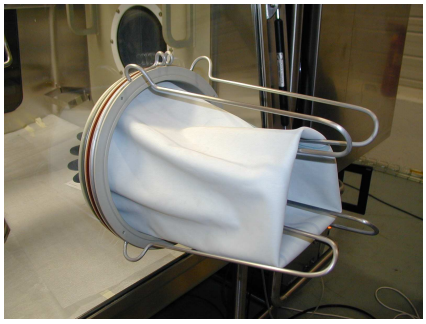
Step 1:

– Preparing the isolator for biodecontamination.

The operations are as follows:

- Make sure that the inside of the isolator is clean and free from objects (*stainless-steel baskets, vials, equipment, etc.*). Tools designed to remain inside the isolator (*scales, etc.*) can remain there. Objects that are left inside the isolator may risk compromising the quality of the biodecontamination, since the biodecontamination cycle parameters have been validated with the isolator empty.
- Make sure that the gloves and sleeves are installed correctly.
- Take a sleeve support and position it in the sleeve and on the RGI 300 by "separating" the spring-mounted ring.

- "Slip" the cuff ring onto the sleeve support until it comes to a stop against the bead.
- "Hitch" the sleeve up as far as possible to uncover all its surfaces.

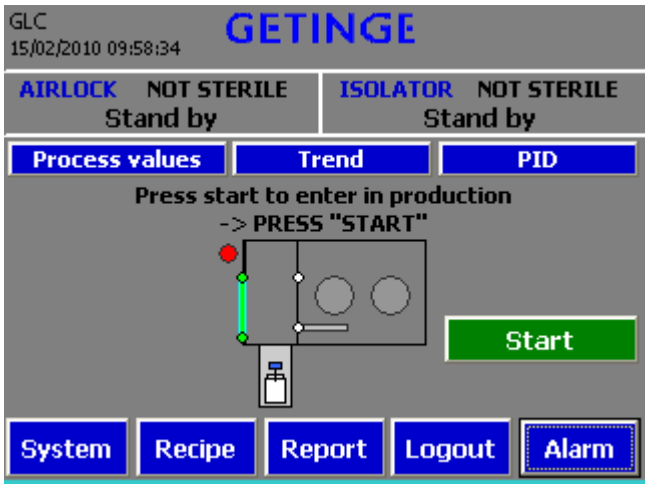


- Do the same for the other sleeve supports.
- Perform these steps in the opposite order to remove the sleeve supports.
- Make sure a dummy container or a multipurpose container is properly connected to each DPTE® system and that the doors of all the DPTE® systems are open.
- Make sure the outer door of the biodecontamination airlock is closed.

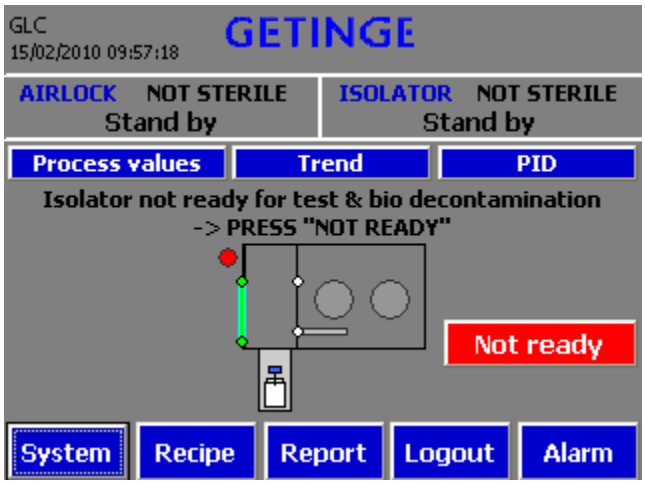
- Make sure the inner door of the biodecontamination airlock is open.
- Make sure a vial of HYDROCYDE is inserted in the container of the Steritrace II sterilizer and that the needle-positioning lever is in the bottom position.

Step 2:

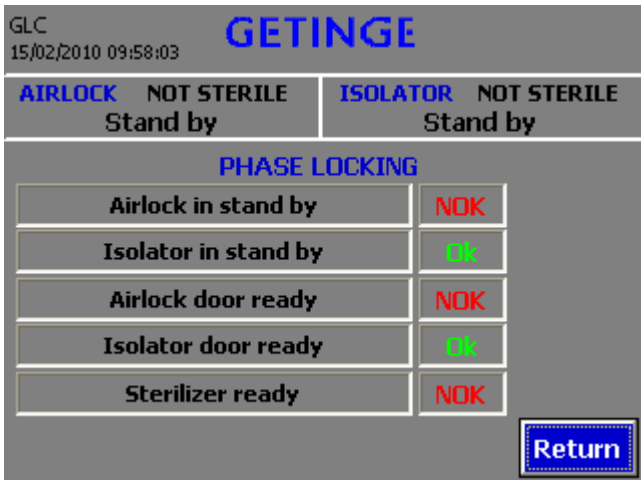
– If the "Start" button is displayed, all the conditions are in place to begin a cycle. Press this button to move on to step 2.



– If the "Not ready" button is displayed, one or more conditions are missing to begin a cycle.



– Press the "Not ready" button and the following window appears.



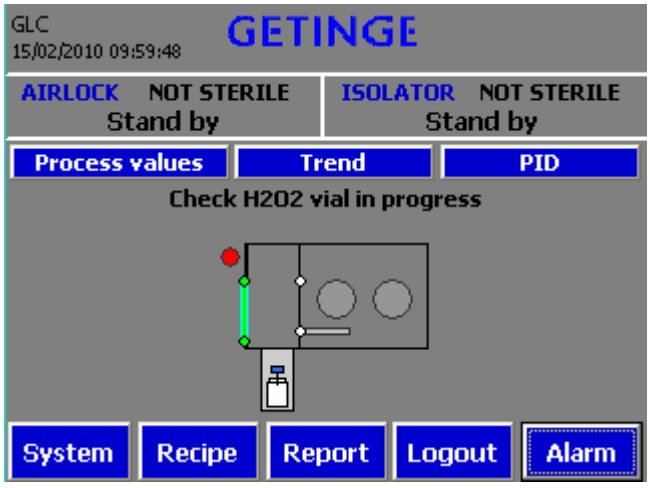
– All the locking parameters must be set to "YES" in order to begin the cycle.

Yes -> Condition met
No -> Condition missing

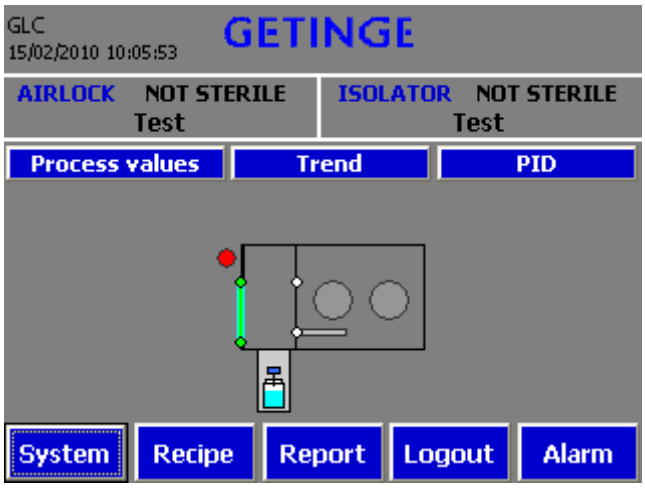
– Press the enter key to return to the user view.

Note: Correct the missing condition and then restart the process from step 1.

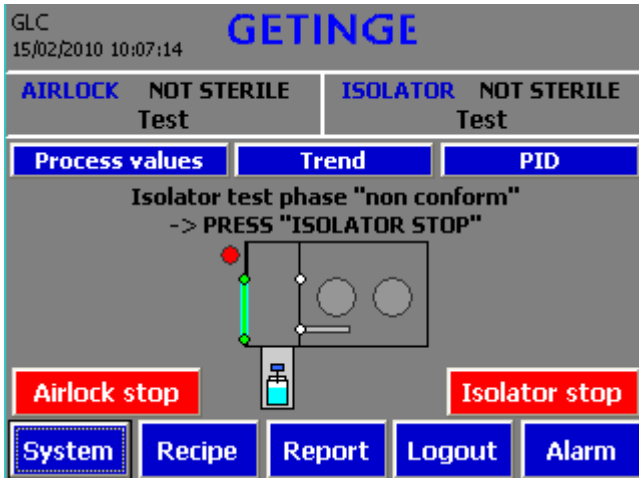
Step 3: – The cycle starts in test phase



– If the verification of the H_2O_2 bottle is correct, the following window appears. The following phases then succeed one another automatically (*see steps 3 and 4*).

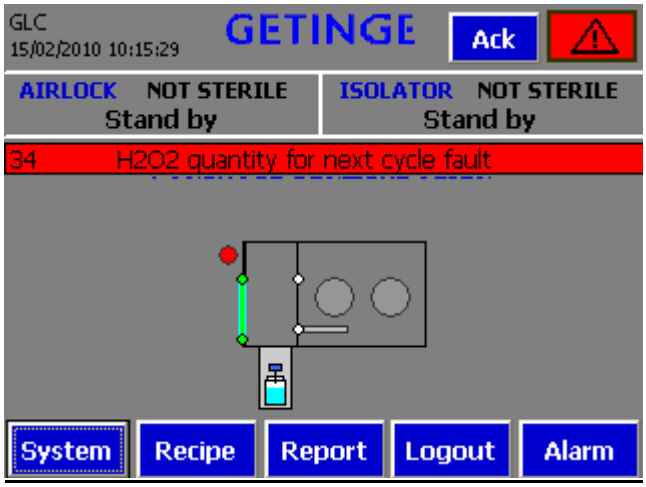


– If the cycle takes place without any faults and if the test is declared non-compliant, the following window appears:



– Press "Isolator stop" and return to step 1.

– If the verification of the bottle is not correct, the following window appears.



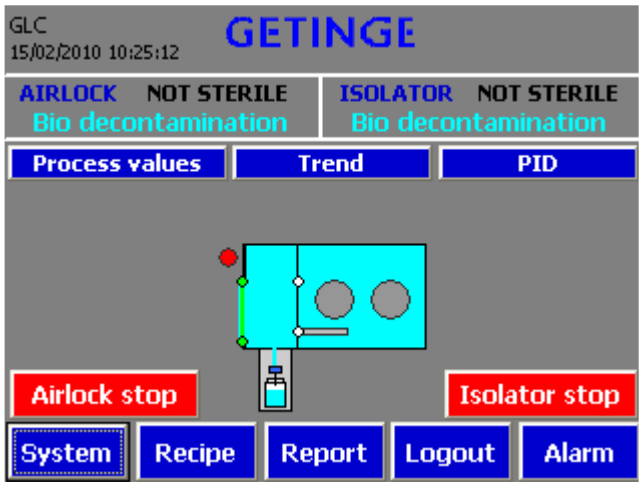
***Note*: Correct the missing condition and then restart the process from step 1.**

– Three possible alarms:
- H_2O_2 quantity for next cycle fault,
- H_2O_2 vial expiry date fault,
- H_2O_2 vial presence fault,

– Replace the H_2O_2 vial and acknowledge the alarm. A new verification takes place.

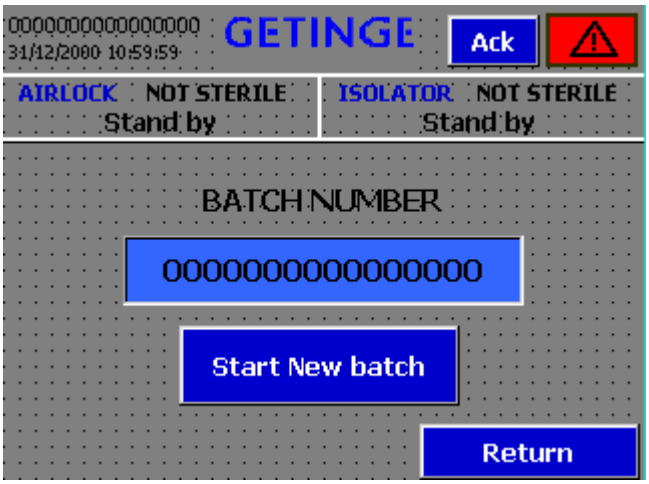
Step 4: – The test phase is correct.

If the test phase is correct, the biodecontamination cycle starts automatically and the following animation appears:



Step 5: – If the biodecontamination phase is completed with no errors, the isolator automatically enters the waiting production phase and the airlock enters the unloading phase.

Step 6: – To start a production phase, press [New batch] button – the following windows appears:

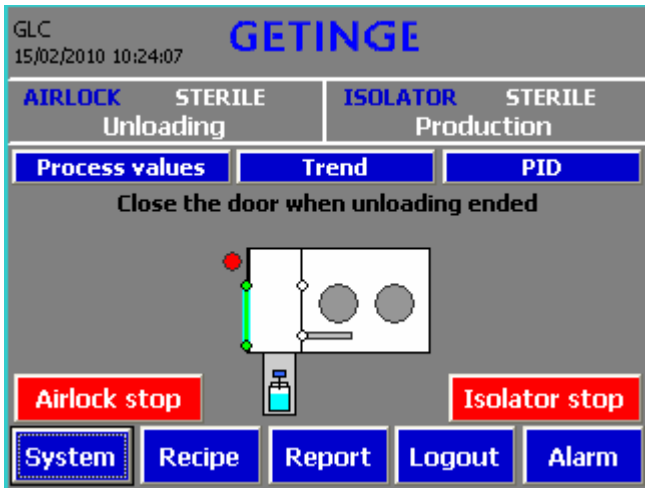


Step 7: – Enter a batch number and press “Start new batch” button – the production phase starts automatically.

Perform the following operations:

- Close all the doors of the DPTE®.
- Disconnect the multipurpose containers (*or dummy containers*).
- Connect instead the necessary accessories (*according to the chosen option*): DPTE-Tubing™ or DPTE-DispoBag™.
- Open the door of the airlock. Note that it will remain open for all the remaining steps of the process.

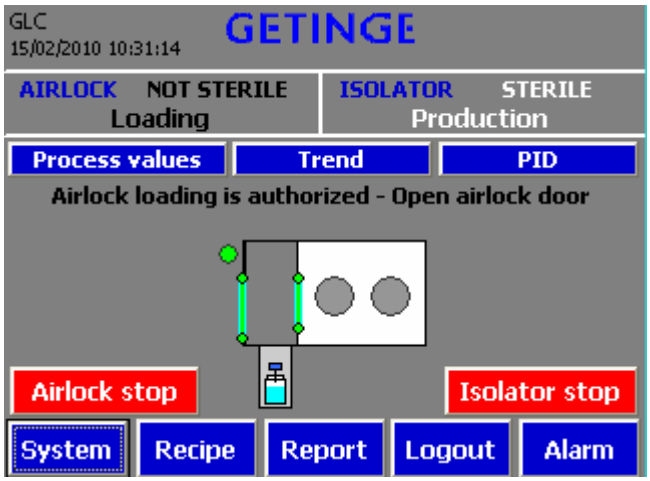
The following animation appears:



The operator can transfer the load (*in the presence of a load*) into the isolator and then close the door.

Step 8: – The isolator door is closed. The airlock is in loading phase.

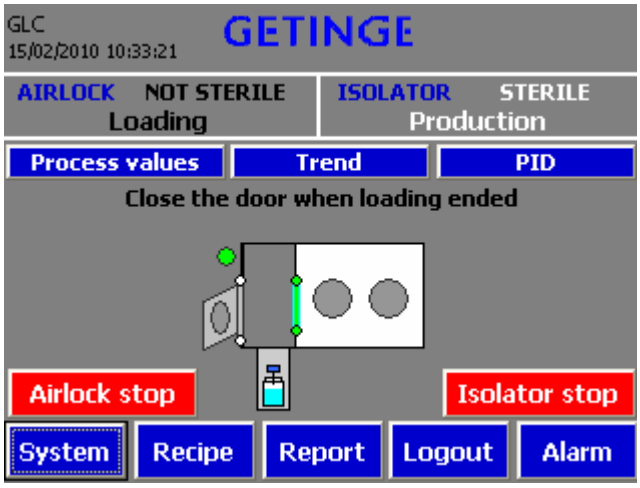
The airlock is not sterile; the door of the airlock can be opened.
The following animation appears:



After opening the door of the airlock, the operator can insert the load.

Step 9: – The airlock door is closed. The airlock is in loading phase.

The airlock is not sterile.
The following animation appears:

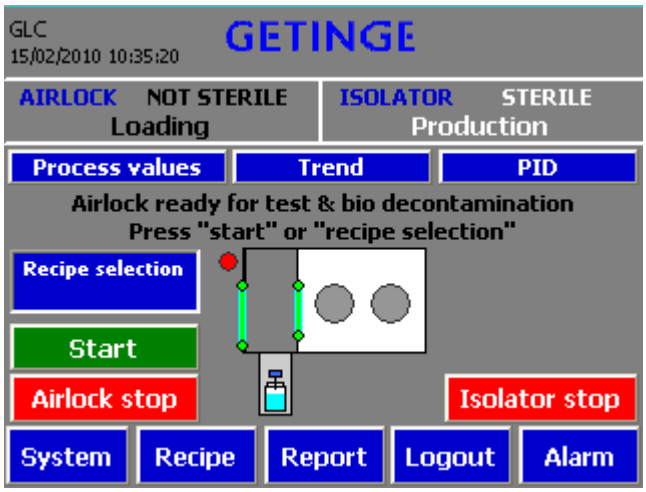


When the load is inserted, the operator can close the airlock door.

Step 10: – The airlock door is closed. The airlock is in loading phase.

The airlock is not sterile. The operator can still open the airlock door (*if opened, the animation in step 6 is displayed*).

The following animation appears (*if there is a transition before starting biodecontamination in manual mode; in the case of "auto" selection, biodecontamination starts automatically after closing the door*):



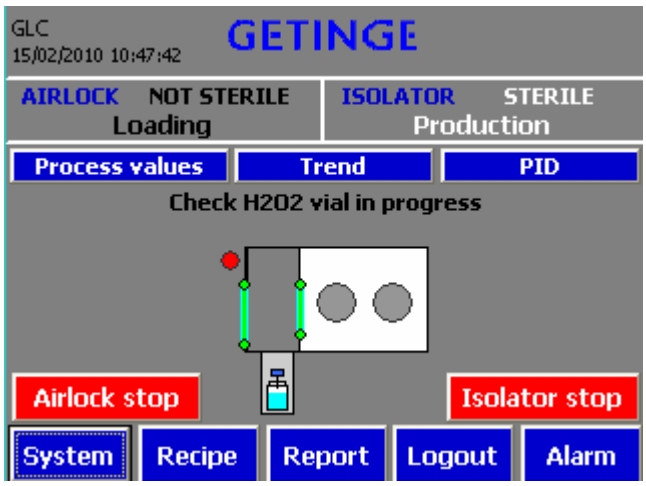
– The "Start" button is displayed.
All the conditions required for beginning a cycle are met. Press this button to move on to step 9.

– The operator wants to select another recipe for the biodecontamination phase.
Press the "Recipe selection" button and the following view appears:

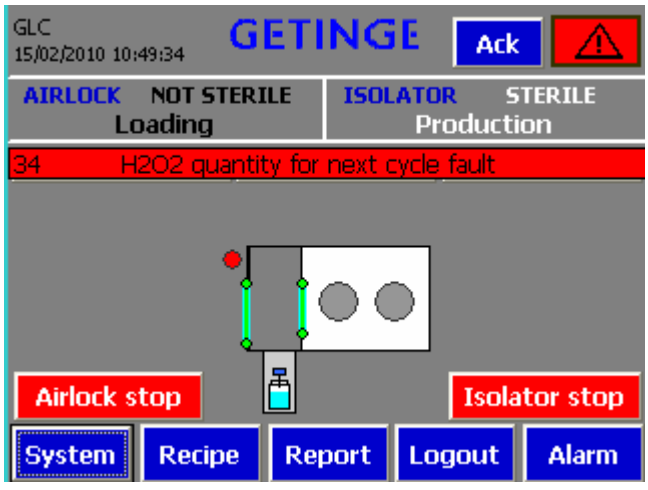
– Select a recipe and then confirm. The following animation appears:

The "Start" button and the selected recipe are displayed. All the conditions required for beginning a cycle are met. Press this button to move on to step 9.

Step 11: – The airlock begins to check the H_2O_2 bottle.



– If the verification of the sensor is not correct, the following window appears.

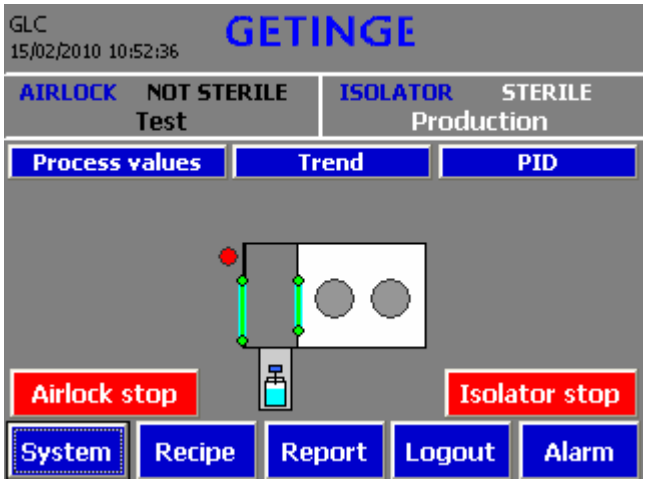


***Note*: Correct the missing condition and then restart the process from step 7.**

– Three possible alarms:
- H_2O_2 quantity for next cycle fault,
- H_2O_2 vial expiry date fault,
- H_2O_2 vial presence fault.

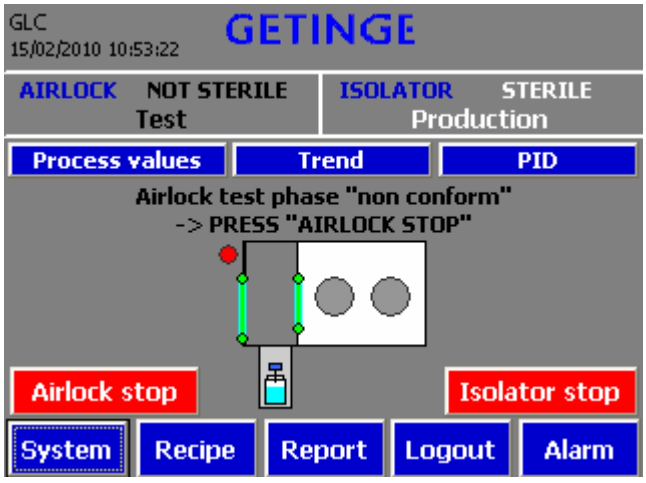
– Replace the H_2O_2 vial and acknowledge the alarm. A new verification takes place.

– If the verification of the bottle is correct, the following window appears. The test phase starts.



– If the test phase is correct, the following phases then succeed one another automatically (*see steps 10 and 11*).

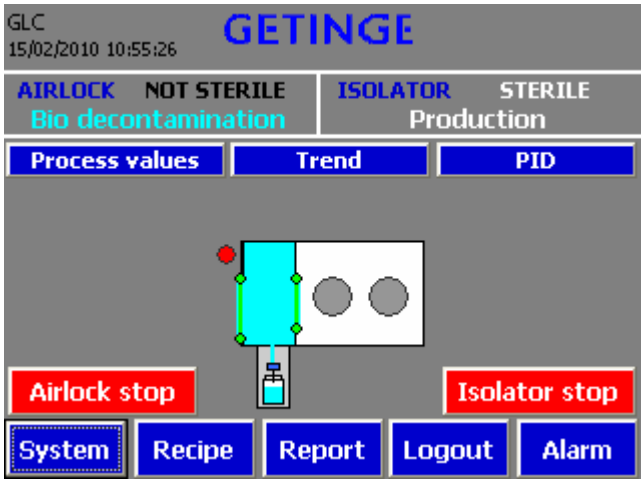
– If the cycle takes place without any faults and the test is declared non-compliant, the following window appears:



– Check the tightening of the clamps, cable glands and hose attachments.
– Press "stop airlock" and return to step 7.
– If the fault continues, consult the Getinge After-Sales Service Centre for your region.

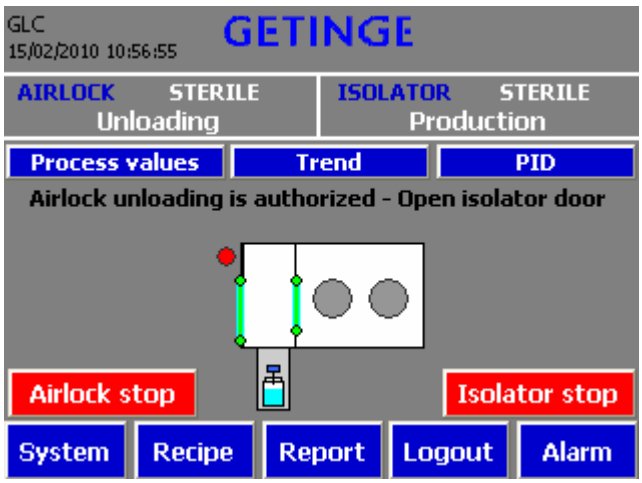
Step 12:

- The test phase is correct.
- If the leak test phase is correct, the biodecontamination cycle starts and the following animation appears:

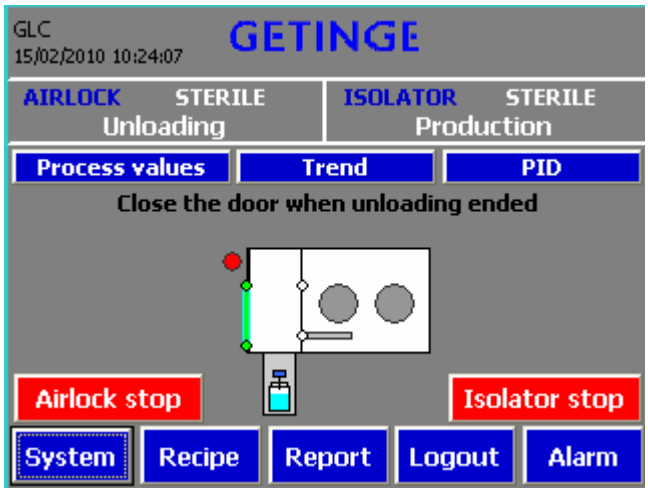


Step 13:

- If the biodecontamination phase is completed with no errors, the airlock enters the unloading phase.
  The airlock is now sterile.
  The following animation appears:



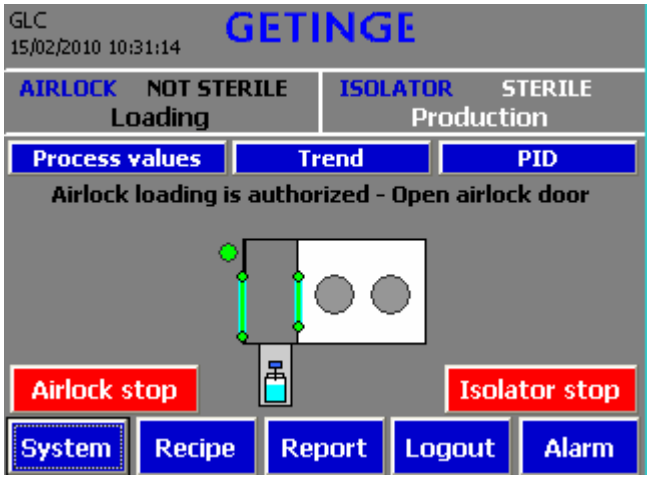
– The operator can transfer the load to the isolator.



– After transferring the load to the isolator, the operator can close the door again.

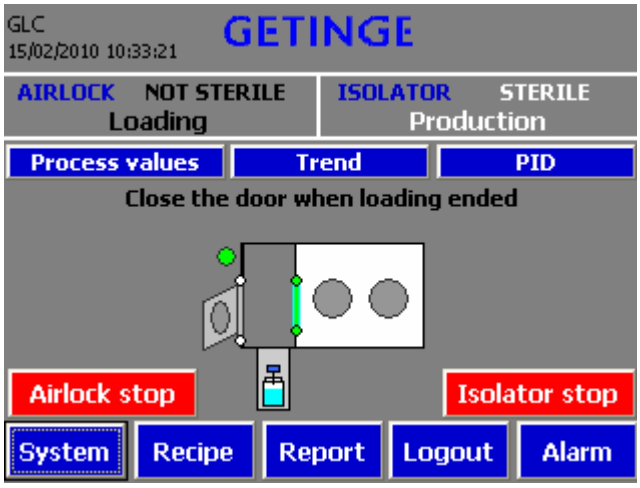
Step 14:

– The isolator door is closed. The airlock is in loading phase.
The airlock is not sterile; the door of the airlock can be opened.
The following animation appears:



– After opening the door of the airlock, the operator can insert the load.

Step 15: – The airlock door is closed. The airlock is in loading phase.
The airlock is not sterile.
The following animation appears:

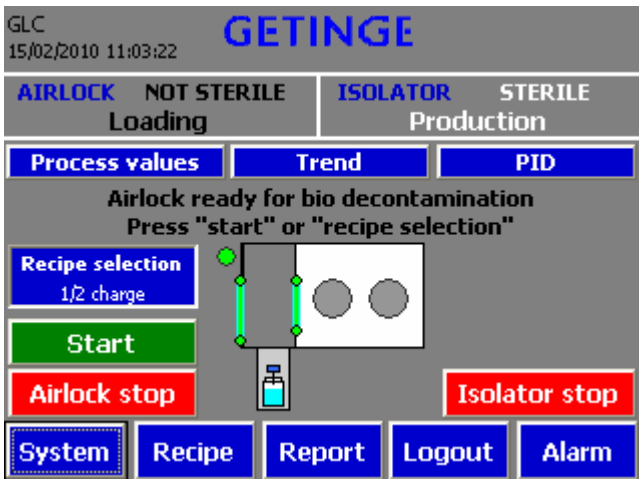


When the load is inserted, the operator can close the airlock door.

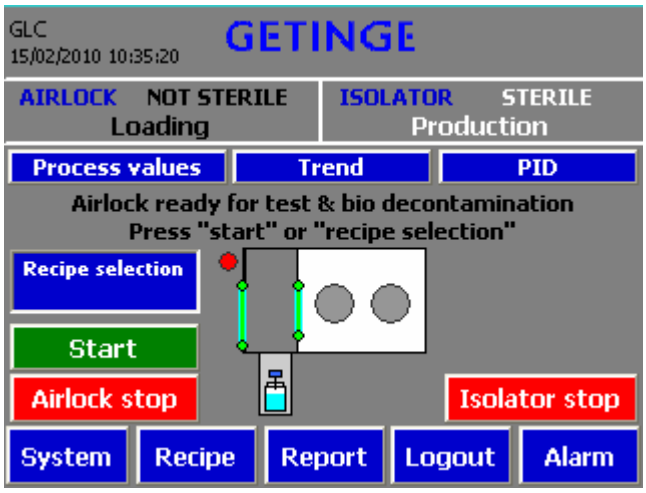
Step 16: – The airlock door is closed. The airlock is in loading phase.

The airlock is not sterile. The operator can still open the airlock door (*if opened, the animation in step 12 is displayed*).

– If the test phase is still valid, the following animation appears:



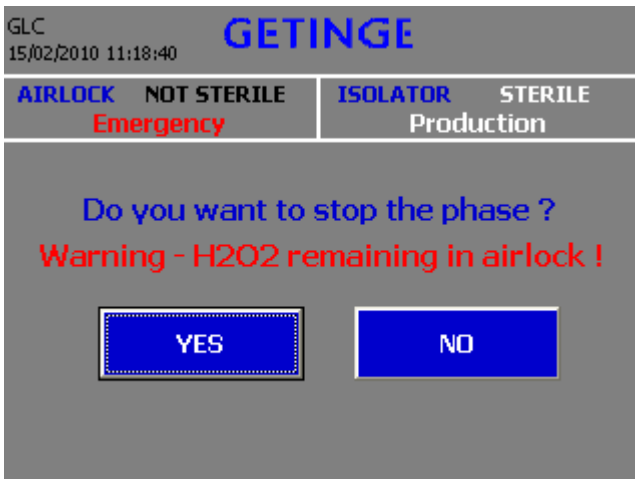
– If the test phase is not valid, the following animation appears:



– Perform the same steps for subsequent cycles.

8.3. STOPPING A CYCLE BY THE USER

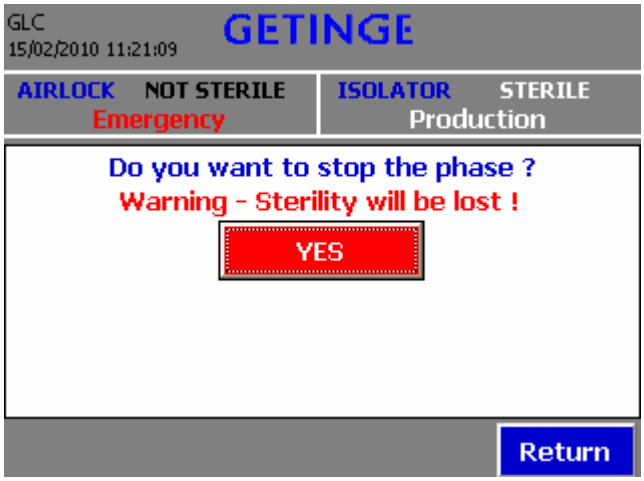
– The operator can halt a cycle by pressing the isolator or airlock "stop" button.
– The following view appears:



– If the "YES" button is pressed, the cycle is halted.

DANGER	Premature halting of the aeration process will allow the outer door to be opened with a residual level of H_2O_2 in the machine which is higher than the minimum level defined for normal operation. This therefore represents a risk of inhalation for the operator when opening the outer door of the biodecontamination airlock.

- If the "NO" button is pressed, the cycle continues.
- The following view appears during production:



- If the "YES" button is pressed, the cycle is halted and the isolator is no longer sterile.
- If the "NO" button is pressed, the cycle continues.

8.4. EMERGENCY AERATION

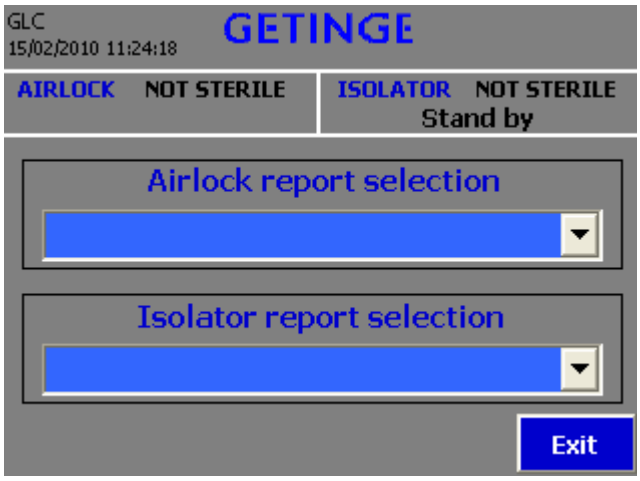
In the event of a problem during the biodecontamination phase, the operator can launch emergency aeration by pressing the red button next to the "EMERGENCY AERATION" touch screen.

8.5. PRINTING

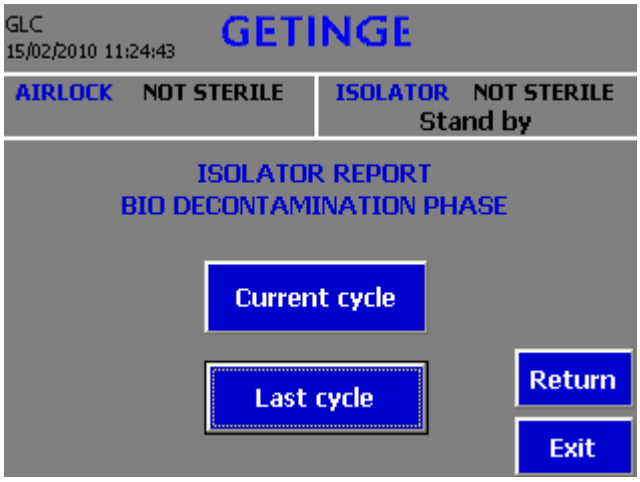
If the printing option is selected, a report is automatically generated at the end of each phase.
The data from the preceding cycle are always stored in the memory and can then be printed from the user screen. This is particularly useful for reprinting in the event of a printer error (*no paper, empty ink cartridge, paper jam, etc.*).

Procedure for printing a phase report

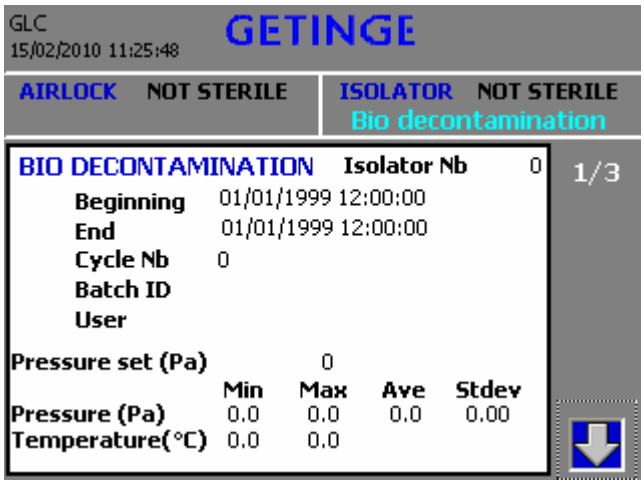
– In the user view, press the "report" button and the following view appears:



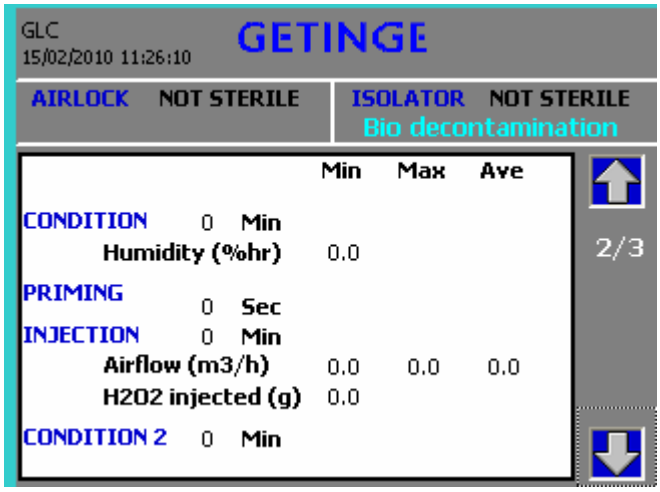
– Select the phase to print (*isolator or airlock*).



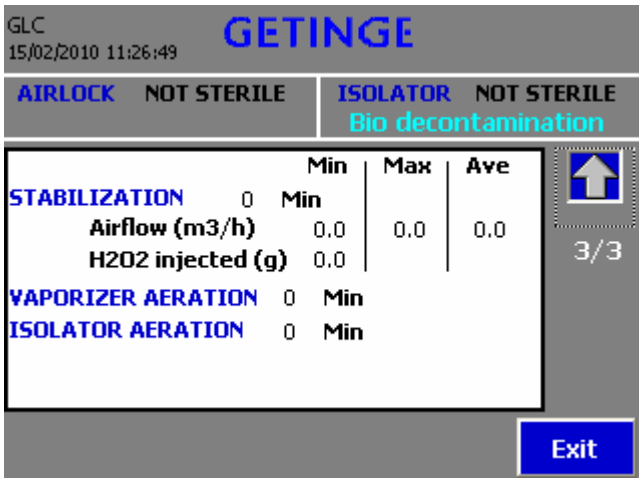
– Select "current cycle" or "last cycle"



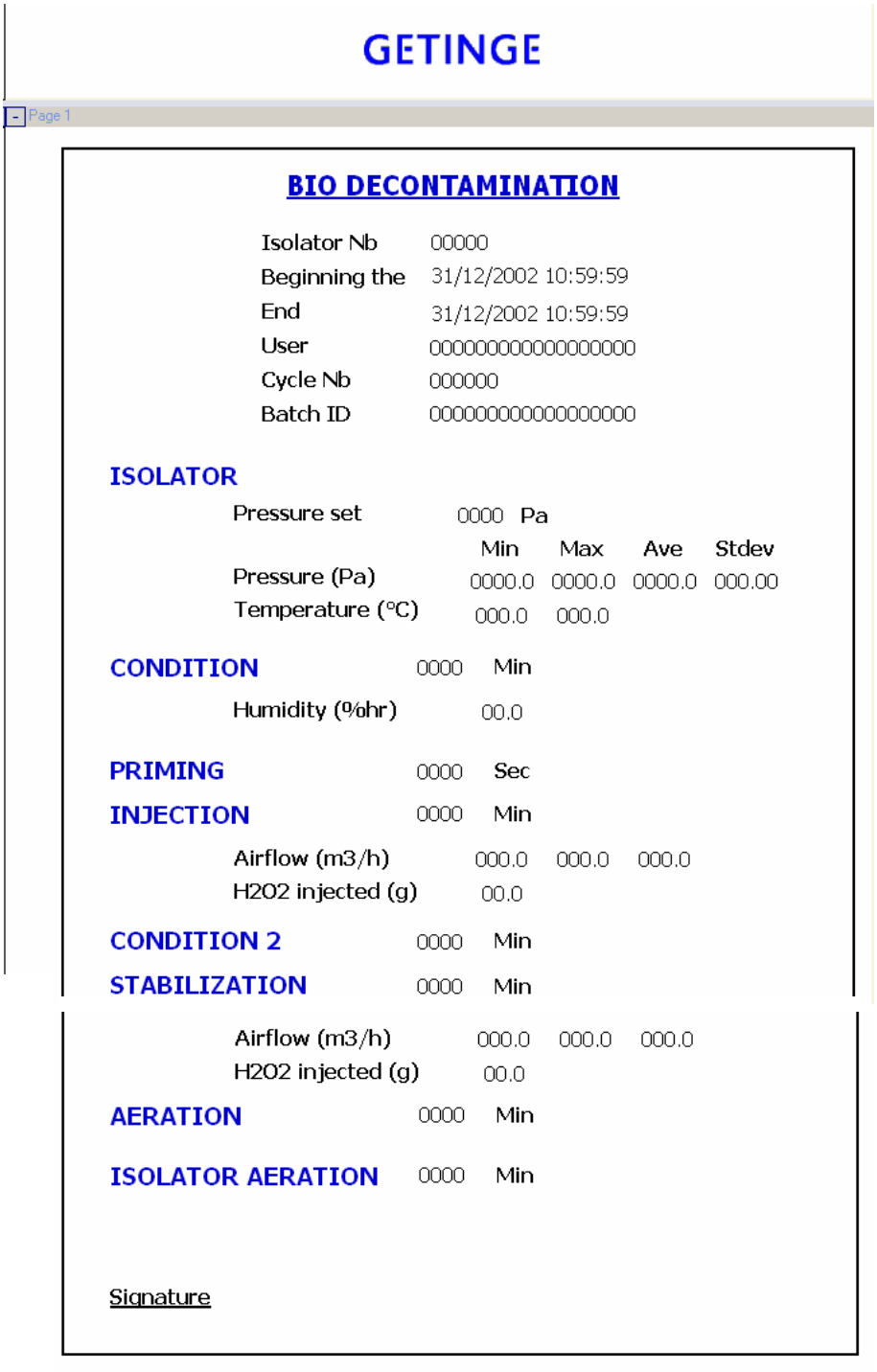
– Press the  button to scroll down the menu until the following window appears:



– Press the  button to scroll down the menu until the following window appears:



– Press the  button to print the report.



GETINGE

Page 1

BIO DECONTAMINATION

Isolator Nb	00000
Beginning the	31/12/2002 10:59:59
End	31/12/2002 10:59:59
User	0000000000000000000
Cycle Nb	000000
Batch ID	0000000000000000000

ISOLATOR

Pressure set 0000 Pa

	Min	Max	Ave	Stdev
Pressure (Pa)	0000.0	0000.0	0000.0	000.00
Temperature (°C)	000.0	000.0		

CONDITION 0000 Min

Humidity (%hr) 00.0

PRIMING 0000 Sec

INJECTION 0000 Min

Airflow (m3/h)	000.0	000.0	000.0
H2O2 injected (g)	00.0		

CONDITION 2 0000 Min

STABILIZATION 0000 Min

Airflow (m3/h)	000.0	000.0	000.0
H2O2 injected (g)	00.0		

AERATION 0000 Min

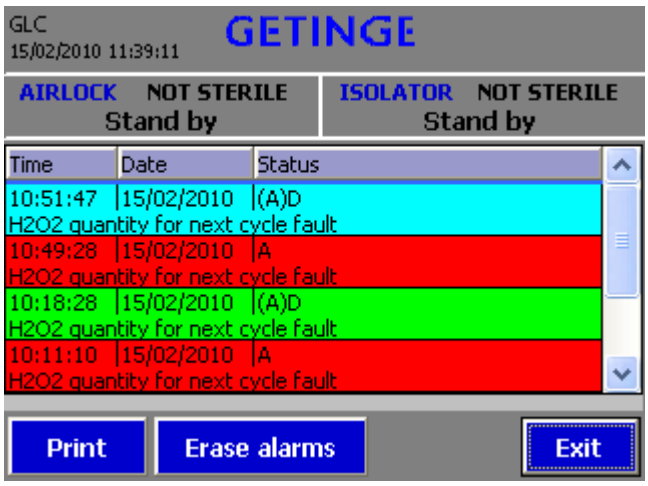
ISOLATOR AERATION 0000 Min

Signature

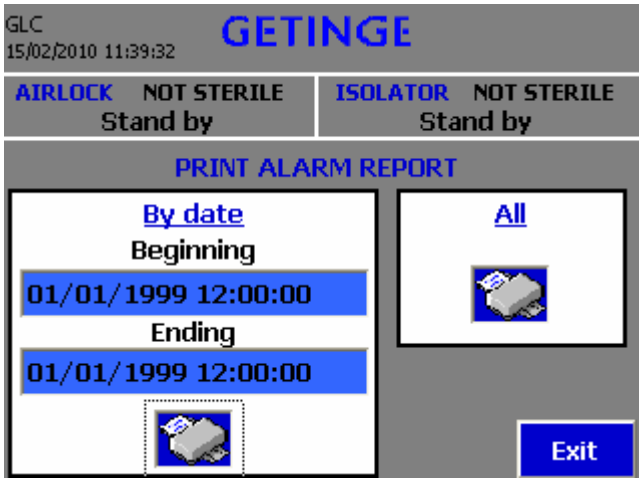
Perform the same steps for all the subsequent phases.

Procedure for printing the alarm log

– In the user view, press the "alarm" button and the following view appears:

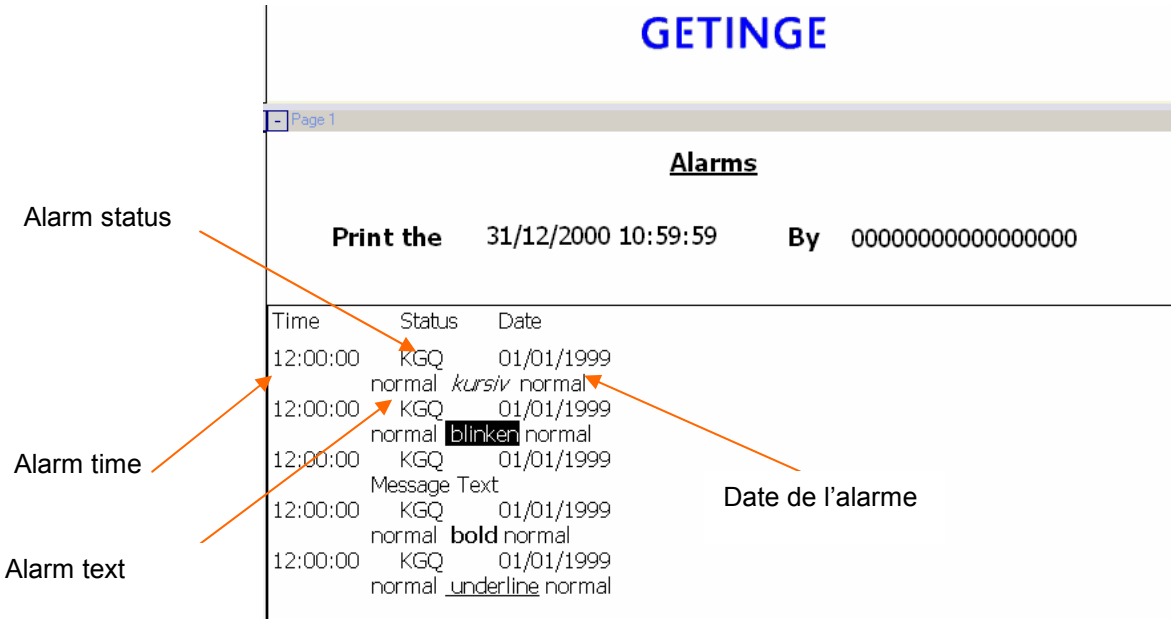


– Press the "print" button.



– There are two options for printing the alarm log:
  - All: Prints all the alarms in the memory.
  - By date: Prints the alarms comprised between the start date and the end date.

– Alarm log

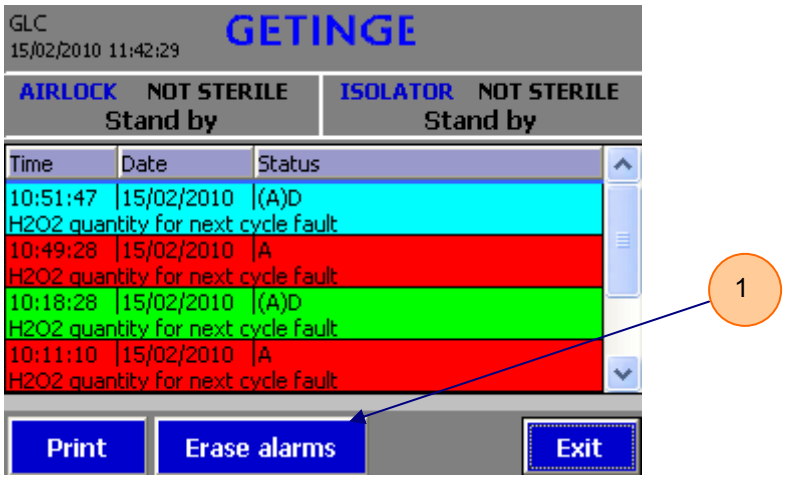


Alarm status:

– A alarm appearing.
– (A) D alarm disappearing and acknowledged.

8.6. 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*).

1 Deletes all the alarms in the memory (*access level* >= *Maintenance*).

Note: Please consult the technical manual for the list of alarms and corrective actions.

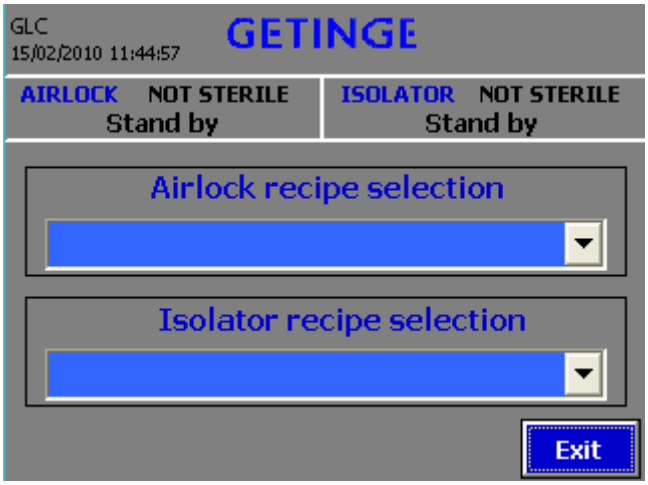
8.7. RECIPE

The parameters are defined and validated by Getinge-La Calhène. Any modification may cause a change in the cycle.
The "recipe menu" can be accessed from the main view with at least "validation" access level.

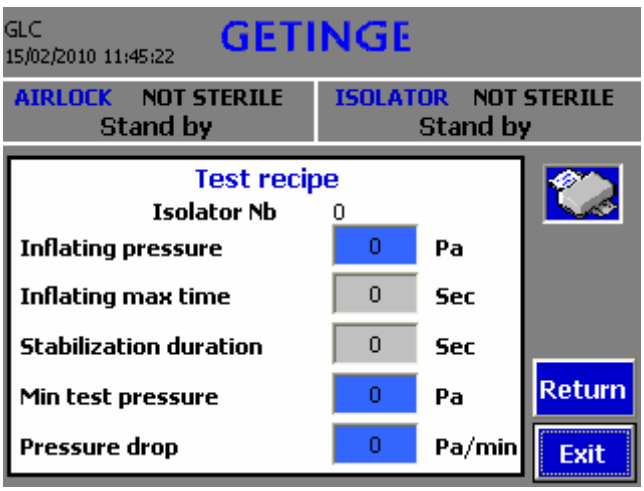
WARNING	Do not modify the parameters of the "Isolator biodecontamination", "Airlock biodecontamination", "Isolator emergency" and "Emergency" recipes without first checking the effectiveness of the aeration phase – See technical manual (*calibration and verification chapter*).

Procedure for modifying recipe parameters

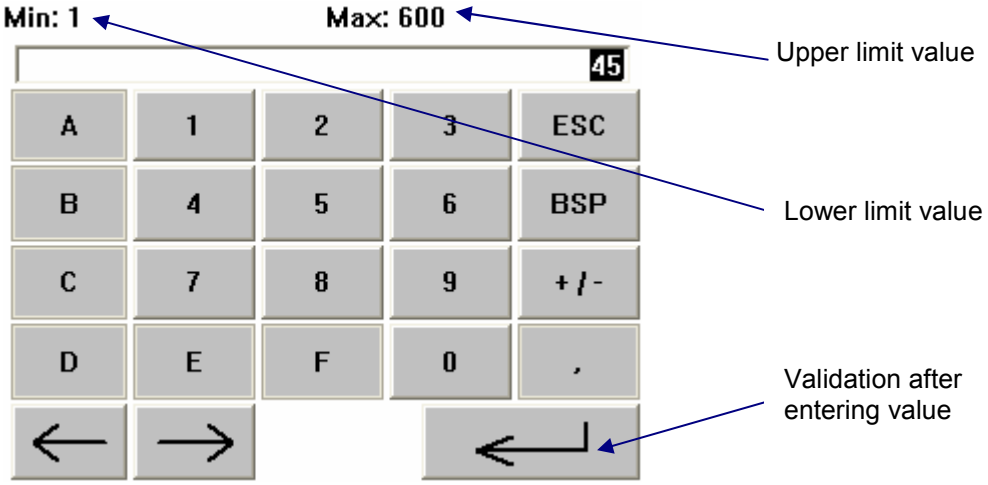
– In the user view, press the "recipe" button and the following view appears:



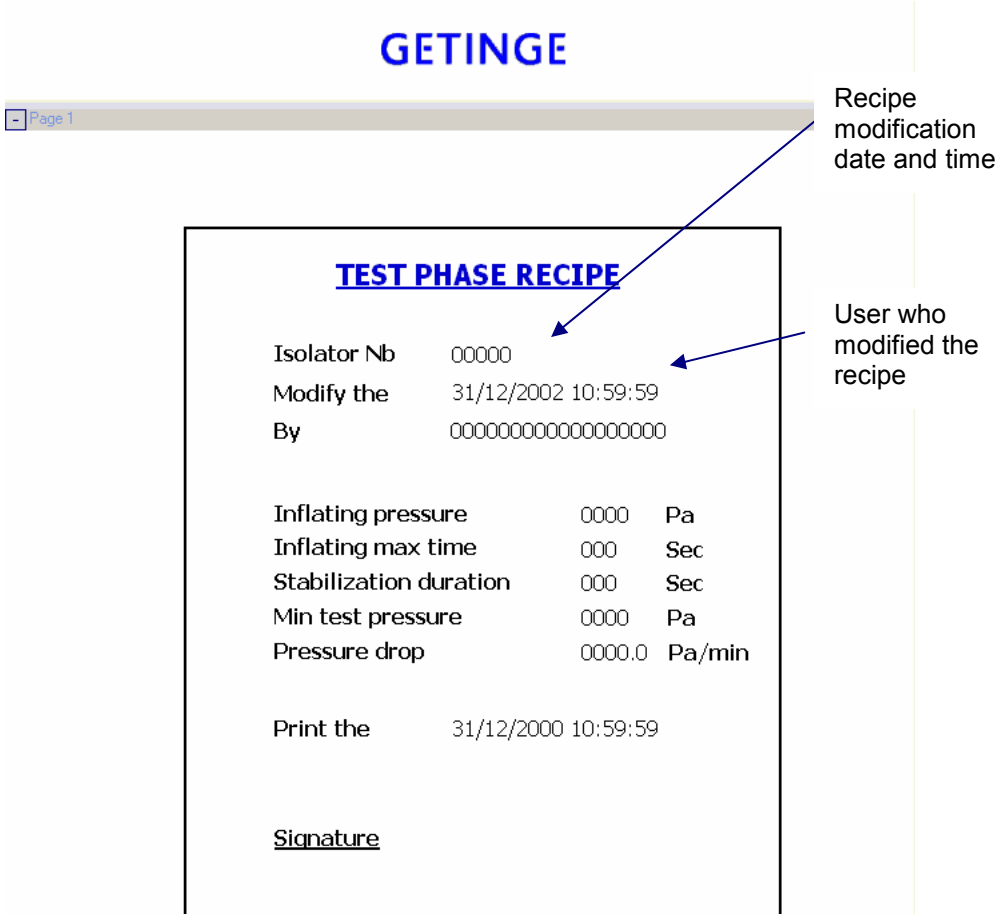
– Select the recipe to be modified.



– Press the value to be modified. The following window opens:



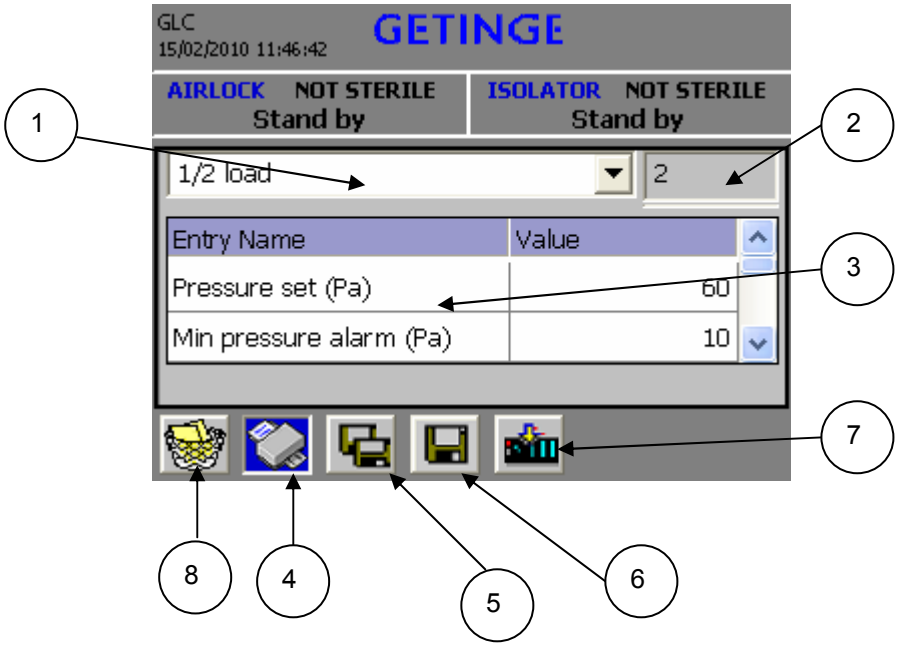
– Press the  button to print the recipe.



– Perform the same steps for the recipes of the isolator biodecontamination, production, unloading, loading and emergency phases.

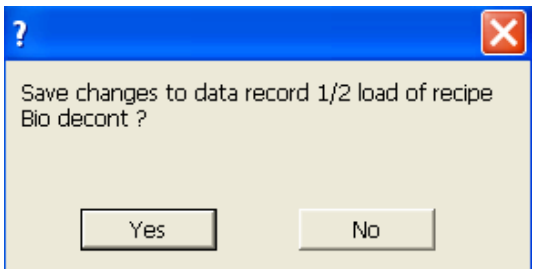
Airlock biodecontamination recipe modification

– Select the airlock biodecontamination recipe. The following view appears:



Number	Designation
1	Allows the user to select a recipe
2	Number of the selected recipe
3	Name of the parameter to be changed
4	Prints the selected recipe
5	Saves the selected recipe with a new name
6	Saves the modifications to the selected recipe
7	Directly transfers the parameters of the selected recipe to the PLC
8	Deletes the selected recipe

– A confirmation pop-up window appears when saving a recipe.



8.8. CLEANING

It is advisable prior to any cleaning operation on the isolator, to consult the leaflet NT 3015/12.

CAUTION	Before beginning to use any other cleaning products, it is essential to check their chemical compatibility with the sterilant, the materials used to manufacture the isolator and its various accessories.

9. INSTRUCTIONS FOR THE TOOLS AND ACCESSORIES

9.1. DPTE-BETA BAG™

Safe waste disposal with DPTE-BetaBag™.
The DPTE® 190 beta is fixed to a mixed bag (*20-litre liquid – 100-litre solid*). The overall system has been 100 % tested for leaks.
It is available, ready for use and gamma sterilized.
Like all the DPTE® systems, they provide transversal airtight protection between the operator and the environment.

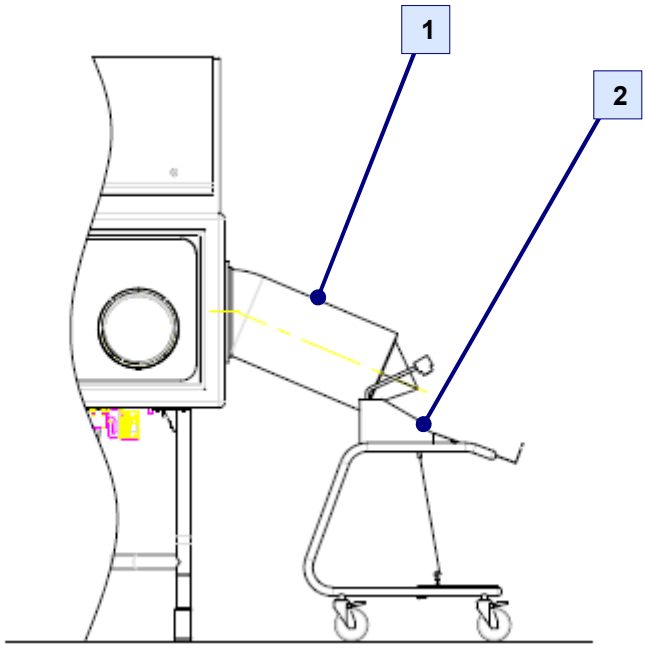
9.2. TUBING SYSTEM

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.

The outlet tube uses the DPTE® system and the operating mode is the same as for a standard container.

The tube and DPTE® assembly is sterilized by radiation.

– It consists of two parts:



Number	Designation
1	Tube
2	Welding machine

9.2.1. Basket

- The baskets are made of 316 L stainless steel.
- Dimensions *(mm)*: 240 x 160 x 370
- Max. admissible load: 2 kg

9.2.2. Basket *(½ campaign)*

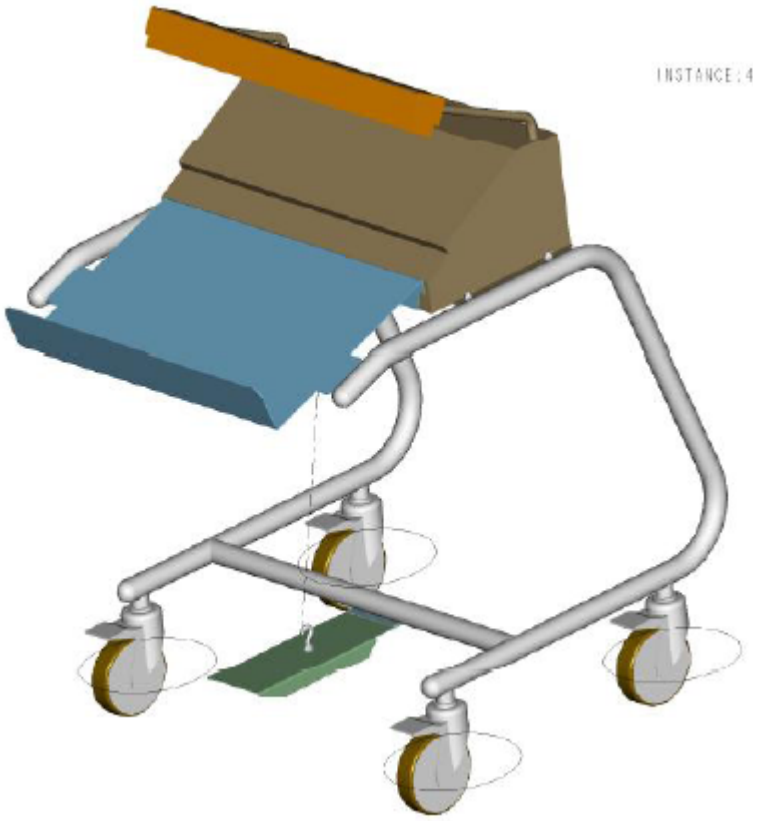
- The basket is made of 316 L stainless steel.
- Dimensions *(mm)*: 240 x 160 x 370
- Max. admissible load: 5 kg

9.2.3. Welding machine

The welding machine and its frame are made of 316L stainless steel. The welding machine consists of a double welding line and a cutting system.

This machine makes it possible to isolate the product to be transferred while keeping the containment in the isolator.

The sleeve is cut with precision between the two weld lines.



10. OPTION LIST

10.1. CONTROL SYSTEM

☐	PLC server traceability
☐	Printer *(with PLC system)*
☐	Printer *(without PLC system)*

10.2. ACCESSORIES

☐	Trolley for mixed waste
☐	4 stainless-steel baskets
☐	H_2O_2 metering system for the operator room
☐	2 ergonomic seats
☐	1 welding machine *(Tubing™ system only as an option)*
☐	2 welding machines *(Tubing™ system only as an option)*

10.3. CONSUMABLES

☐	DPTE-Beta Bag® 190, mixed waste
☐	Tube *(Tubing system™ only as an option)*
☐	10 neoprene gloves, 3/10, Size 7 - Sterile
☐	6 Hypalon sleeves
☐	12 vials of hydrogen peroxide with RFID chips
☐	Cleaning kit

11. 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® (*for example a container*).
DPTE-BetaBag™	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.

APPENDICES

(2 appendices)

GETINGE

HYDROCYDE – Hydrogen Peroxide 35%

Specifications

	Minimum	*Maximum*
Hydrogen peroxide, %	35.0	35.7
pH, Apparent	2.4	3.8
Color, APHA		10
Appearance	**Clear**	

Properties

	Minimum	*Maximum*
Active Oxygen, %	16.4	23.5
Specific gravity at 20°C, g/mL	9.45	9.98
Boiling point at 760 mm Hg, °C	1.132	1.195
Freezing point, °C	-32	-51
Vapor Pressure at 30°C, mm Hg	18	23
Appearance	Clear liquid with a slightly pungent odor	

Miscellaneous

CAS No.: 7722-84-1

HYDROCYDE 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 H2SO4:	< 0.03%
IRON:	< 0.5 ppm
TIN:	< 10 ppm

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.

1. IDENTIFICATION DE LA SUBSTANCE/PRÉPARATION ET DE LA SOCIÉTÉ/ENTREPRISE

Fiche de Données de Sécurité générique

Identification de la préparation	:	PEROXYDE D'HYDROGENE - 20% <= CONCENTRATION < 40%
Grades	:	Albone 30, Albone 35S, Albone 35W, Peroxal 30PG, Peroxal 35DS, Peroxal 35PG, Valsterane 25AL1, Valsterane 35AL1, Valsterane 35AL2, Valsterane 35AL3, Valsterane 35AL3 S, Valsterane 35AL4, Valsterane 35 S
Utilisation recommandée	:	Agent de blanchiment Agent d'oxydation Générateur d'oxygène Industrie des parfums Cosmétiques Usage médical
Fournisseur	:	ARKEMA – France OXYGENES 420 rue d'Estienne d'Orves 92705 Colombes Cedex France Téléphone : +33 (0)1 49 00 80 80 Télécopie : +33 (0)1 49 00 83 96 http://www.arkema.com Email address : pars-drp-fds@arkema.com
Numéro de téléphone d'appel d'urgence	:	+33 1 49 00 77 77 - ORFILA : 01 45 42 59 59

2. IDENTIFICATION DES DANGERS

Dangers les plus importants:

Effets possibles sur la santé	:	Provoque des brûlures. Nocif en cas d'ingestion. Irritant pour les yeux et la peau. Irritant pour les voies respiratoires.
Effets sur l'environnement	:	Nocif pour les poissons. Toxique pour la daphnie Toxique pour la flore aquatique
Dangers physico-chimiques	:	Oxydants Risque de décomposition par contact avec des matériaux incompatibles Danger d'explosion sous l'action de la chaleur. Favorise l'inflammation des matières combustibles. Risque d'inflammation ou d'explosion en mélange avec des matières organiques (au dessus d'une certaine concentration)
Dangers spécifiques / CE	:	NOCIF

Nocif en cas d'ingestion.
Irritant pour les voies respiratoires et la peau.
Risque de lésions oculaires graves.

3. COMPOSITION/INFORMATIONS SUR LES COMPOSANTS

Composants

Nom Chimique *)	No.-CE	No.-CAS	Concentration	Classification
peroxyde d'hydrogene	231-765-0	7722-84-1	20 - 40 %	R 5 O; R 8 C; R35 Xn; R20/22

(en solution aqueuse)

*) Voir chapitre 14 pour le nom approprié de l'expédition

Pour le texte complet des phrases R mentionnées dans cet article, voir chapitre 16.

4. PREMIERS SECOURS

Conseils généraux : Sous la douche
Enlever immédiatement tout vêtement souillé ou éclaboussé y compris les chaussures

Inhalation : Amener la victime à l'air libre.
Oxygène ou respiration artificielle si nécessaire.
Mettre sous surveillance médicale
En cas de troubles :
Hospitaliser

Contact avec la peau : Laver immédiatement et abondamment à l'eau.
Consulter un médecin.
En cas de brûlures étendues, hospitaliser

Contact avec les yeux : Lavage immédiat et abondant à l'eau en écartant bien les paupières pendant au moins 15 minutes
Consulter d'urgence un ophtalmologiste

Ingestion : Ne pas tenter de faire vomir, rincer abondamment la bouche et les lèvres à l'eau si le sujet est conscient, puis hospitaliser d'urgence

Protection pour les secouristes : Vêtement de protection

5. MESURES DE LUTTE CONTRE L'INCENDIE

Moyen d'extinction approprié : En cas d'incendie impliquant le produit :
Eau pulvérisée

Moyens d'extinction non-appropriés : Tout autre moyen d'extinction

Dangers spécifiques : Favorise l'inflammation des matières combustibles.
Décomposition thermique en :
Oxygène, susceptible d'activer les foyers de combustion

danger de surpression dans les bouteilles exposées à la chaleur : risque d'explosion

Méthodes particulières d'intervention : Se tenir du côté d'où vient le vent et opérer à distance de sécurité
Prévoir un système d'évacuation rapide des conteneurs
En cas d'incendie, éloigner les conteneurs exposés au feu
Refroidir les récipients/réservoirs par pulvérisation d'eau.

Équipement de protection spécial pour le personnel préposé à la lutte contre le feu : Porter un appareil de protection respiratoire autonome et des vêtements de protection.

6. MESURES À PRENDRE EN CAS DE REJET ACCIDENTEL

Précautions individuelles : Evacuer le personnel non nécessaire ou non équipé de protection individuelle
Prohiber le contact avec la peau, les yeux et l'inhalation des vapeurs.
Prohiber toute source d'étincelles et d'ignition - Ne pas fumer.
Si les conditions de sécurité le permettent, colmater la fuite
Eliminer tous les matériaux incompatibles

Précautions pour la protection de l'environnement : Endiguer avec du sable ou de la terre (ne pas utiliser de produits combustibles)
Ne rejeter à l'égout ou en milieu naturel qu'après forte dilution à l'eau

Récupération : Enlever avec un absorbant inerte.
Ne jamais réintroduire le produit répandu dans un autre conteneur: Risque de décomposition.

Neutralisation : Diluer dans de l'eau.

Elimination : Évacuer l'eau de rinçage comme les eaux usées.

7. MANIPULATION ET STOCKAGE

Manipulation

Mesures techniques/Précautions : Consignes de stockage et de manipulation applicables aux produits:
Liquides
Nocifs
Irritants
voire
Corrosifs
Prévoir une ventilation et une évacuation appropriée au niveau des équipements.
Prévoir douches, fontaines oculaires.
Prévoir poste d'eau à proximité.

Précautions pour la manipulation sans danger : Veillez à ne pas laisser se développer des surpressions
Ne pas laisser le produit confiné entre deux vannes
Manipuler en évitant les projections

Stockage

Mesures techniques/Conditions de stockage : Stocker à l'écart des matières combustibles ou oxydables
N'utiliser que des conteneurs et du matériel très propres exempts de traces d'impuretés

Ne jamais retourner du produit non utilisé dans le récipient de stockage.
Les conteneurs ne seront utilisés que pour ce produit
Protéger de la lumière.
Protéger de toute contamination
Protéger de la chaleur
Contrôler régulièrement la température
Inspecter régulièrement les stockages en notant les signes anormaux (corrosion, gonflement, élévation de température)
Prévoir des évents munis de filtres sur les réservoirs pour éviter les entrées d'impuretés
Prévoir une cuvette de rétention
Consulter ARKEMA avant réalisation des stockages

Produits incompatibles : Matières combustibles
Agents réducteurs
Matières organiques
Métaux
Oxydes métalliques
Bases
Acétone

Matériel d'emballage

Recommandé : Acier inoxydable
Aluminium
décapés et passivés
Polyéthylène
Verre au Bore
joints en Polytétrafluoroéthylène PTFE recommandés

Matières à éviter : Tout autre matériau

8. CONTRÔLE DE L'EXPOSITION/PROTECTION INDIVIDUELLE

Mesures générales de protection : Prévoir un renouvellement d'air et/ou une aspiration suffisante dans les ateliers

Paramètres de contrôle

Valeurs limites d'exposition

peroxyde d'hydrogene

Source	Date	Type de valeur	Valeur (ppm)	Valeur (mg/m3)	Remarques
INRS (FR)	06 2006	VME	1	1,5	-
ACGIH	2007	TWA	1	–	–

Équipement de protection individuelle

Protection respiratoire : En cas de ventilation insuffisante, porter un appareil respiratoire approprié.
En cas de déversement, porter un masque

Protection des mains	:	Gants en néoprène Ne pas porter des gants de cuir.
Protection des yeux	:	Lunettes de sécurité
Protection de la peau et du corps	:	Vêtements de protection (à proscrire : textile, cuir) Bottes en caoutchouc ou en plastique
Mesures d'hygiène	:	Prohiber le contact avec la peau, les yeux et l'inhalation des vapeurs. En cas de projection, retirer les vêtements imprégnés et les plonger aussitôt dans l'eau

9. PROPRIÉTÉS PHYSIQUES ET CHIMIQUES

État physique (20°C)	:	liquide
Couleur	:	incolore
Odeur	:	piquante
pH	:	< 3
Point/intervalle d'ébullition	:	(Concentration : 30%) 106 °C
Point/intervalle de fusion	:	(Concentration : 30%) -26 °C
Pression de vapeur	:	(Concentration : 30%) 18 hPa (20 °C)
Masse volumique	:	(Concentration : 30%) 1.110 kg/m3 (20 °C)
Solubilité		
Hydrosolubilité	:	(20 °C) complètement soluble
Constante de Henry	:	PEROXYDE D'HYDROGENE: Constante de Henry: (Concentration : 50%) 10,0E-03 $Pa.m^3/mol$

10. STABILITÉ ET RÉACTIVITÉ

Conditions à éviter	:	Protéger de la lumière Protéger de la chaleur
Matières à éviter	:	Matières combustibles Matières organiques Risque(s) de : Réaction explosive Métaux Oxydes métalliques Bases Agents réducteurs Poussières

(risque de décomposition exothermique autoaccélérée)
Acétone
(formation de mélanges explosifs)

Autres informations : Produit stable dans les conditions normales de stockage et de manipulation
Présence d'un stabilisant

11. INFORMATIONS TOXICOLOGIQUES

Toxicité aiguë

Inhalation :
• Chez l'homme :
A fortes concentrations de vapeurs/brouillards
Risque d'oedème pulmonaire
Effets retardés possibles

• Chez l'animal:
A fortes concentrations de vapeurs/brouillards
Pas de mortalité/4 h/rat(170 mg/m3)

Ingestion :
• Chez l'homme :
Risque de brûlures de la bouche, de l'oesophage et de l'estomac
Par libération rapide d'oxygène :
Risque de dilatation de l'estomac et d'hémoragie, pouvant entraîner des lésions graves
Risque mortel
Expérimentalement, chez l'animal
(en solution aqueuse)
Nocif en cas d'ingestion.
DL50/rat: 1.200 mg/kg
(35 %)

Dermale :
• Chez l'animal:
(en solution aqueuse)
Peu ou pas nocif par contact avec la peau
Pas de mortalité/lapin: 2.000 mg/kg
(35 %)

Effets locaux

Inhalation :
• Chez l'homme :
A fortes concentrations de vapeurs/brouillards
Irritant pour les voies respiratoires.

Contact avec la peau :
• Chez l'homme :
Les effets de contacts avec la peau peuvent inclure:
Erythème
Oedème
Décoloration
Expérimentalement, chez l'animal
Irritant pour la peau.
Nécrose superficielle
(35 %)
Durée d'exposition: 4 h
(lapin)
(Après contact semi-occlusif)

Contact avec les yeux : • Chez l'homme :
Peut provoquer des lésions oculaires irréversibles.
Expérimentalement, chez l'animal
Irritation sévère des yeux
(en solution dans eau, 35 %)
(lapin)

Sensibilisation

Contact avec la peau : PEROXYDE D'HYDROGENE :
Expérimentalement, chez l'animal
Non sensibilisant cutané
cobaye

Toxicité par administration répétée : PEROXYDE D'HYDROGENE :
• Chez l'animal:
eau de boisson: 3 moisrat
Irritation de la muqueuse gastrique
Dose sans effet toxique observable (NOAEL): 26 mg/kg/d

Effets spécifiques

Génotoxicité
In vitro : PEROXYDE D'HYDROGENE :
Génotoxique

In vivo : PEROXYDE D'HYDROGENE :
Non génotoxique

Carcinogénicité : PEROXYDE D'HYDROGENE :
A la suite de gavages répétés avec le produit, des tumeurs stomacales sont observées chez le rongeur par effet irritant local sur la muqueuse gastrique
Les effets expérimentaux ont été observés chez l'animal à des doses très supérieures à celles avec lesquelles l'homme est en contact dans les conditions usuelles d'emploi

12. INFORMATIONS ÉCOLOGIQUES

Mobilité : PEROXYDE D'HYDROGENE:
Constante de Henry: (Concentration : 50%) 10,0E-03 Pa.m^3/mol

Persistance et dégradabilité
Dans l'eau : PEROXYDE D'HYDROGENE :
Décomposition : quelques minutes à 24h
Dépend de la teneur en composés minéraux et en micro-organismes

dans l'air : PEROXYDE D'HYDROGENE :
Dégradation dans la troposphère :
Temps global de demi-vie: 10 - 20 h

Dégradable dans l'atmosphère
Photolyse
réaction avec radicaux OH
Subit également un dépôt par lessivage (eau atmosphérique) et par voie séche (dépôt au sol)
Temps global de demi-vie: 20 h

Bioaccumulation : PEROXYDE D'HYDROGENE :
Se décompose : non bioaccumulable

Écotoxicité : De par sa composition :
Nocif pour les poissons.
Toxique pour la daphnie

Toxicité aquatique

Toxicité aiguë
poisson : PEROXYDE D'HYDROGENE :
Nocif pour les poissons.
CL50, 96 h (poisson) : 16,4 - 37,4 mg/l

Invertébrés aquatiques : PEROXYDE D'HYDROGENE :
Toxique pour la daphnie
CE(I)50, 48 h (Daphnia magna) : 2,4 mg/l

Plantes aquatiques : PEROXYDE D'HYDROGENE :
Toxique pour les algues.
CE50, 72 h (Algues) : 1,6 - 5 mg/l

micro-organismes : PEROXYDE D'HYDROGENE :
CE50 (Boues activées) : 466 mg/l
(OCDE Ligne directrice 209)

13. CONSIDÉRATIONS RELATIVES À L'ÉLIMINATION

Elimination du produit : Diluer dans de l'eau.

Elimination des emballages : Nettoyer le récipient avec de l'eau.
Recycler ou incinérer
En accord avec les réglementations locales et nationales.

14. INFORMATIONS RELATIVES AU TRANSPORT

ADR
UN Numéro : 2014
Nom d'expédition : PEROXYDE D'HYDROGÈNE EN SOLUTION AQUEUSE
Classe : 5.1

Groupe d'emballage	:	II
Code de classification	:	OC1
Numéro de danger	:	58
Etiquette	:	5.1 (8)

ADNR

UN Numéro	:	2014
Nom d'expédition	:	PEROXYDE D'HYDROGÈNE EN SOLUTION AQUEUSE
Classe	:	5.1
Groupe d'emballage	:	II
Code de classification	:	OC1
Numéro de danger	:	58
Etiquette	:	5.1 (8)

RID

UN Numéro	:	2014
Nom d'expédition	:	PEROXYDE D'HYDROGÈNE EN SOLUTION AQUEUSE
Classe	:	5.1
Groupe d'emballage	:	II
Code de classification	:	OC1
Numéro de danger	:	58
Etiquette	:	5.1 (8)

IATA Cargo

UN Numéro	:	2014
Nom d'expédition	:	Hydrogen peroxide, aqueous solution
Classe	:	5.1
Groupe d'emballage	:	II
Etiquette	:	5.1 (8)

IATA Passenger

UN Numéro	:	2014
Nom d'expédition	:	Hydrogen peroxide, aqueous solution
Classe	:	5.1
Groupe d'emballage	:	II
Etiquette	:	5.1 (8)

IMDG

UN Numéro	:	2014
Nom d'expédition	:	HYDROGEN PEROXIDE, AQUEOUS SOLUTION
Classe	:	5.1
Groupe d'emballage	:	II
Etiquette	:	5.1 (8)
No EMS Numéro	:	F-H, S-Q
Polluant marin	:	non

15. INFORMATIONS RÉGLEMENTAIRES

DIRECTIVE CEE

Fiches de données de sécurité	:	conformément au Règlement (CE) No. 1907/2006
Classement / étiquetage CE		
PREPARATIONS DANGEREUSES	:	D. 1999/45/CE modifiée par D. 2001/60/CE
Symbole(s)		

Xn	Nocif

Phrase(s) R

R22	Nocif en cas d'ingestion.
R37/38	Irritant pour les voies respiratoires et la peau.
R41	Risque de lésions oculaires graves.

Phrase(s) de sûreté

S 3	Conserver dans un endroit frais.
S17	Tenir à l'écart des matières combustibles.
S26	En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
S28	Après contact avec la peau, se laver immédiatement et abondamment avec de l'eau.
S36/37/39	Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux/du visage.

Composants dangereux qui doivent être listés sur l'étiquette:
peroxyde d'hydrogene

REGLEMENTATION FRANCAISE

Fiches de données de sécurité	:	Arrêté du 5.1.93 modifié par arrêté du 9.11.2004
PREPARATIONS DANGEREUSES	:	Arrêté du 9.11.2004 modifié par arrêté du 07.02.2007
Maladies à caractère professionnel Sécurité au travail	:	Code de la Sécurité sociale : articles L461-6 et D.461-1 Code du travail art. R 232-5 à 5-14. Captation des vapeurs, aérosols et particules solides à la source d'émission. Assainissement
Installations classées	:	Loi n° 76-663 du 19.7.76 et circulaire du 17-7-78
Déchet	:	Loi n°75-633 du 15.7.75 - Instruction technique du 22.1.80 sur les déchets industriels– Arrêté du 02.02.1998, modifié par l'arrêté du 29.05.2000 et par l'arrêté du 03.08.2001, relatif aux prélèvements et à la consommation d'eau, ainsi qu'aux émissions de toute nature des installations classées pour la protection de l'environnement soumises à autorisation
Inventaires	:	EINECS: Conforme TSCA: Conforme AICS: Conforme DSL: Tous les composants de ce produit sont sur la liste Canadienne DSL. ENCS (JP): Conforme KECI (KR): Conforme PICCS (PH): Conforme IECSC (CN): Conforme

16. AUTRES DONNÉES

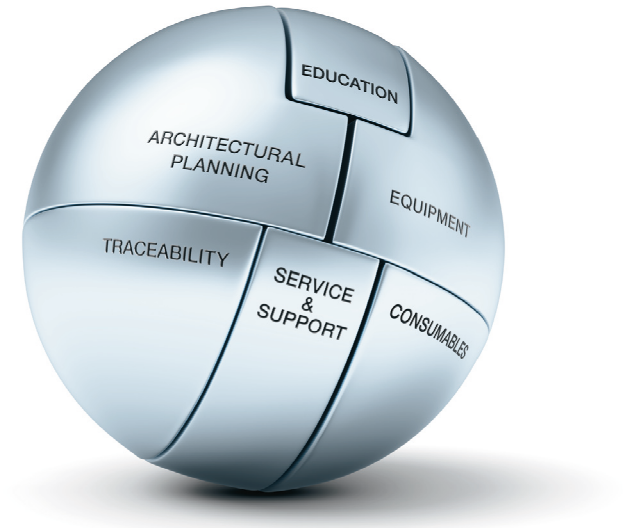
Texte intégral des phrases R mentionnées sous les Chapitres 2 et 3

R 5	Danger d'explosion sous l'action de la chaleur.
R 8	Favorise l'inflammation des matières combustibles.
R20/22	Nocif par inhalation et par ingestion.
R22	Nocif en cas d'ingestion.
R35	Provoque de graves brûlures.
R37/38	Irritant pour les voies respiratoires et la peau.
R41	Risque de lésions oculaires graves.

Bibliographie : Fiche toxicologique INRS : N° 123 - Peroxyde d'hydrogène et solutions aqueuses

Autres informations : En cas d'emploi dans des formulations, nous contacter pour l'étiquetage

Ce document s'applique au produit EN L'ETAT, conforme aux spécifications fournies par ARKEMA
En cas de combinaisons ou de mélanges, s'assurer qu'aucun danger nouveau ne puisse apparaître
Les renseignements contenus dans cette fiche sont donnés de bonne foi et basés sur nos dernières connaissances relatives au produit concerné, à la date d'édition.
L'attention des utilisateurs est attirée sur les risques éventuellement encourus lorsqu'un produit est utilisé à d'autres usages que ceux pour lesquels il est destiné. Cette fiche ne doit être utilisée et reproduite qu'à des fins de prévention et de sécurité.
L'énumération des textes législatifs, réglementaires et administratifs ne peut être considérée comme exhaustive.
Il appartient au destinataire du produit de se reporter à l'ensemble des textes officiels concernant l'utilisation, la détention et la manipulation du produit pour lesquelles il est seul responsable.
L'utilisateur du produit doit également porter à la connaissance des personnes qui peuvent entrer en contact avec le produit (emploi, stockage, nettoyage des conteneurs, interventions diverses) toutes les informations nécessaires à la sécurité du travail, à la protection de la santé et de l'environnement, en leur transmettant cette fiche de données de sécurité.



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Getinge is the world's leading provider of solutions for effective cleaning, disinfection and sterilization in the healthcare and life science sectors. We are dedicated to helping our customers provide maximum productivity in the most cost-efficient way. We do this by offering well thought through and customized solutions. This means that we are with our customers all theway from architectural planning and education to traceability and support – with complete solutions, long-term commitment and global presence. Getinge – Always with you.

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GETINGE GROUP is a leading global provider of equipment and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, GETINGE and MAQUET. **Arjohuntleigh** focuses on patient handling and hygiene, disinfection, DVT prevention, medical beds, therapeutic surfaces and diagnostics. **GETINGE** provides solutions for infection control and prevention within healthcare and life sciences. **MAQUET** specializes in therapeutic applications, products, solutions and services for OR and ICU