

Medical Waste Treatment

TRUSTER SERIES

USER'S AND MAINTENANCE MANUAL

SMI MEDICAL SRL
VIA RINCHIOSA, 20/C
54033 MARINA DI CARRARA (MS) – ITALIA



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WIRING DIAGRAM

PIPING DIAGRAM

PNEUMATIC DIAGRAM

REVISION INDEX

Revision	Date	Description
1.0	20/05/2021	First emission

SAFETY WARNINGS

The warnings listed below are given for the purpose of reducing risks for personnel and to avoid making the equipment unsafe insecure due to poor maintenance. Thus both operators and maintenance personnel must carry out the instructions given in this manual for the operation and maintenance of this sterilizer.



There is a shredder inside the machine. Pay the **MAXIMUM ATTENTION** in case of accidental starting of the shredder with doors open (this condition can occur during maintenance). Risk of very serious damage or death



Care must be taken with the components, assemblies or points which bear the warning “GENERAL HAZARD”.



Care must be taken when opening the electrical panel and junction boxes marked with the warning “DANGER – LIVE ELECTRICAL EQUIPMENT”

ATTENTION ! For the use or maintenance of this equipment it is necessary to wear personal protective equipment such as:

- Disposable, non-sterile latex glove, CE Marking, compliant with European Standard EN 374 1-2-3 – EN 388-3
- Safety boot with high resistance PVC upper. Puncture-proof steel toe cap and interlamina, CE Marking in compliance with European Standard EN 20345 S5 II category
- 4-layer filter facepiece in hypoallergenic material, one of which is made up of activated carbon. Protection from welding fumes, organic vapours, nauseating odours, medium toxicity 0.002 micron dusts, CE marking in compliance with European Standard EN 149:2001+A1 : 2009 Class FFP2D -III category
- Cut Protection Gloves, Material, polyurethane Internal finish, seamless textile support in HDPE fibers. External finish: ventilated back CE marking in compliance with European standard EN 388 (Mechanical Risks)
- Glasses. Single lens with wraparound structure. Integrated dipstick. Colorless anti-scratch and anti-fog polycarbonate lens CE marking in compliance with European standard EN 166 3-1 .2 1F
- Protective suit. The tayvek protective coverall offers a high protective barrier. Complies with European Directive 89 /686 / EEC



WARNING! The standard cycles set for the equipment have been validated, therefore any modification of the cycles requires validation by authorized personnel prior to use.



WARNING! The user cycle is programmed as a fabric cycle, therefore any changes require validation by authorized personnel before use.



WARNING! The calibration procedure must be carried out by qualified personnel. Improper use of this function can result in damage to the sterilization process and cause injury to the personnel.



WARNING! Do not tamper with safety devices: safety valves, mechanical door lock devices, limit switches, pressure switches and the safety thermostat. Such actions could result in incorrect operation of the equipment and compromise the safety of the operator. Any work done on these devices must be carried out only by qualified or authorized technicians.



WARNING! If the cycle is not carried out properly, the material must be considered not sterile. Be careful of biological risks.



The operators who use the TrustEr must be qualified for this type of activity.



The maintenance and repair of the TrustEr must be done by qualified and authorized service personnel.



The TrustEr loading area of the must be kept clean in order to avoid hazardous conditions due to a slippery floor.



The inner carts must be handled wearing special gloves to avoid burns at the end of the sterilization cycle.



Protective gloves must be worn whenever one is in contact with the hot sterilization chamber.



Care must be taken with all the internal parts of the TrustEr that are not protected, as they can cause burns during maintenance or repair when the TrustEr is hot.



Protective gloves must be worn when checking the functioning of the safety valve.



Electrical power must be locked out before starting any repair or maintenance work on the TrustEr.



All of the TrustEr safety devices must not be modified or tampered with for any reason whatsoever.



The front panel of the TrustEr must be kept clean using a soft cloth and mild solutions for stainless steel.



The chamber must be kept clean using a soft cloth and mild solutions for stainless steel.



Sharp or pointed tools must not be used to insert or remove the chamber seal from its seat.

NOTES ON THE USE OF THIS MANUAL

This manual is designed for all users of TrustEr series sterilization systems.

The descriptions that follow, ***unless otherwise specified***, are valid for any TrustEr series medical waste treatment system.

INTENDED USE

TRUSTER SERIES

Medical waste treatment equipment are used for the sterilization of all kind of “Bio-Hazard” medical waste; the system is able to shred and sterile the bio-infectious medical waste and it's able to transform the contaminated waste into “domestic” waste. Not suitable for inactivation of medicine chemical toxic residual, X-ray liquid waste or radioactive components.

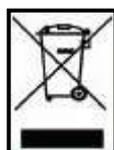
This apparatus is manufactured according to Directive 97/23 EC (PED)

INFORMATION FOR THE USERS

Art. 13 of European Legislative Decree 151/2005, provides the following information concerning:

The user has the obligation not to dispose of waste electrical and electronic equipment (WEEE) as unsorted municipal waste and to carry out separate collection;

WEEE collection systems are available to the user, as well as the possibility of returning the equipment to the distributor at the time of purchasing new equipment. Users who do not comply with the WEEE disposal obligation contribute to harming the environment and human health due to the presence of hazardous substances in the equipment or to improper use of them or of parts of them.



The crossed bin symbol on the equipment or on its packaging indicates that at the end of its life this product must be collected separately from other waste.

The separate collection of this equipment at end of life is organized and managed by the manufacturer. The user who wishes to dispose of this equipment should contact the manufacturer and follow the system that it has adopted to allow the separate collection of the equipment at end of life.

Separate collection for the subsequent recycling, treatment and environmentally compatible disposal helps to prevent possible negative effects on the environment and on health and promotes the reuse and/or recycling of the materials making up the equipment.

Illegal dumping of the product by the owner involves the application of the penalties provided for by law.

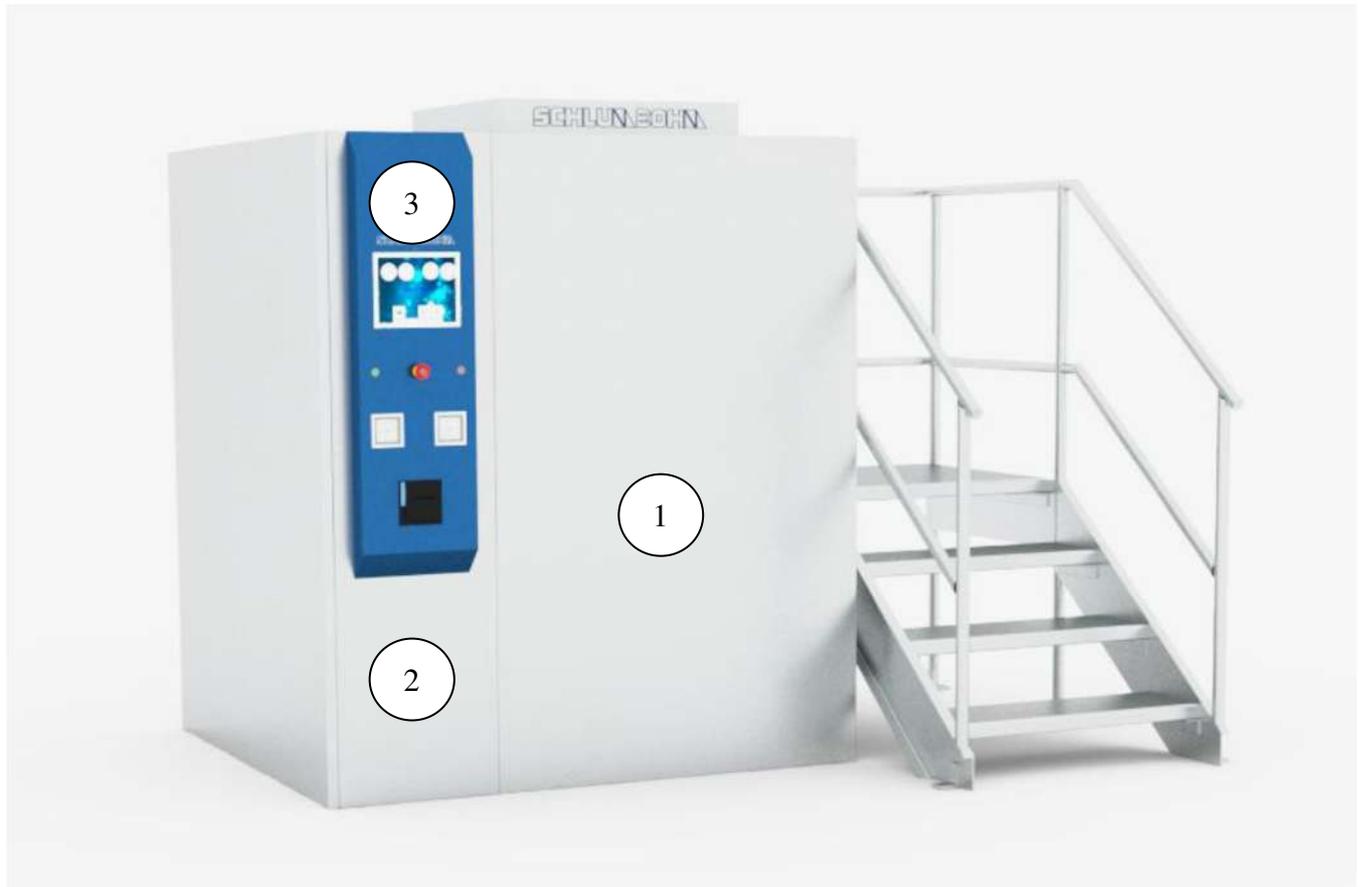
For the proper procedure for disposing of the equipment at end of life we suggest that you contact the “ecoR’it” collection center.

Contacts:



www.ecorit.it

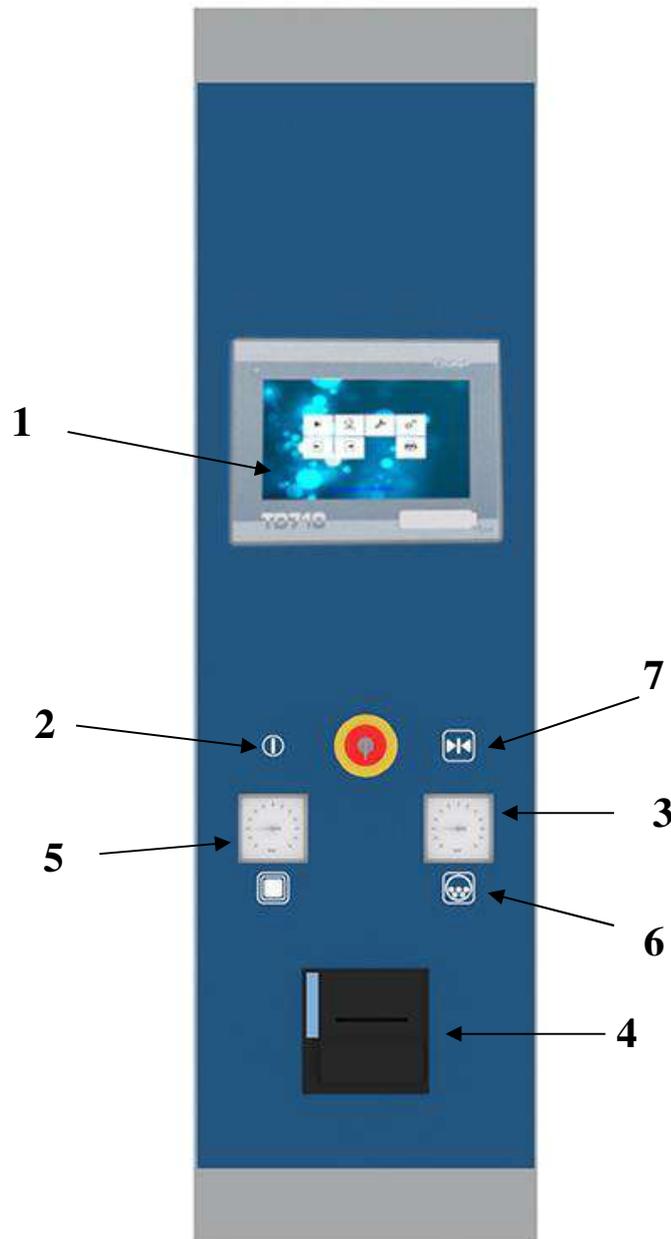


TRUSTER SERIES, MEDICAL WASTE TREATMENT EQUIPMENT**Fig. 1****FRONT VIEW**

- 1** Sterilization chamber
- 2** Technical Compartment / Module
- 3** Loading side control panel

The feature represents the main parts of a sterilizer. The door can slide by horizontal moving. The technical module can be at the right site of the chamber or at the left site of the chamber

SYMBOLS – LOADING SIDE CONTROL PANEL



- 1 Touch screen (Display)
- 2 ON/OFF button
- 3 Emergency stop button
- 4 Printer

- 5 Generator vacuum manometer
- 6 Jacket vacuum manometer
- 7 Close button

Fig. 2

1.0 GENERAL INFORMATION

1.1 - Warranty

To be defined with SMI Medical and local distributor;

1.2 – Other conditions

Other conditions are to be agreed upon with SMI Medical

1.3 – Types of cycles

The sterilizer has a series of programmed and tested cycles, as shown in the table.

Material	Cycle	°C	min	Packaging type
Waste material, plastic, glass, paper, wood, organic tissue, needles.		134°C	5	Sterilizable bags, plastic container, bottle.
No material allowed in chamber. Internal filter sterilization (if fitted)		121°C	20	Empty chamber
No material allowed in chamber. Preheating cycle		134°C	5	Empty chamber
Vacuum leak test			10	Empty chamber



WARNING!

Do not introduce in chamber metallic waste except low quantity of needles. Can made severe injuries to the rotating blades.

Once the sterilizer is loaded and has reached temperature, the sterilization cycle can be started by choosing the cycle on the touch screen. Parameters and the stages can be checked during the cycle on the screen and with the printer.

At the end of the cycle, run completely and properly, the sterilizer can be opened from the opposite side for unloading the sterilized material. Unload the materials and close the unloading side door of the sterilizer.

1.4 – Guidelines for medical waste.

Waste classification :

Waste is divided into two large families based on its origin:

Municipal waste

- domestic waste, even bulky, from premises and inhabited places for residential use;
- non-hazardous waste from rooms and places used for uses other than those mentioned above, assimilated to urban waste in terms of quality and quantity, following the issue of the appropriate municipal regulation;
- waste from street sweeping;
- waste of any nature or origin, lying on public roads and areas or on private roads and areas in any case subject to public use or on seashores and lakes and on the banks of watercourses;
- vegetable waste from green areas, such as gardens, parks and cemetery areas;
- waste from exhumations and exhumations, as well as other waste from cemetery activities

Special waste

- waste from agricultural and agro-industrial activities;
- waste deriving from demolition and construction activities, as well as hazardous waste deriving from excavation activities;
- waste from industrial processes;
- waste from craftsmanship;
- waste from commercial activities;
- waste from service activities;
- waste deriving from waste recovery and disposal activities, sludge produced by drinking water purification and other water treatments and waste water purification and fume abatement;
- Waste deriving from healthcare activities;

-
- deteriorated and obsolete machinery and equipment;
 - disused motor vehicles, trailers and the like and their parts.

The European Community has held that for a waste to be considered dangerous, it must contain at least one substance that possesses one (or more) dangerous characteristics indicated in Annex III of Directive 91/689/EEC.

The dangerous characteristics are:

H9 "Infectious":

Substances containing viable microorganisms or their toxins, known or reasonably believed to cause disease in humans or other living organisms

Sanitary waste

Typologies

- Non-hazardous medical waste
 - Public and private, medical / veterinary facilities (diagnosis, treatment, prevention)
- Sanitary waste assimilated to urban waste
 - Canteens of health facilities
 - Catering activities of the hospital wards, excluding the infectious ones
 - Glass, paper, cardboard, plastic, packaging
 - Garbage
 - Waste consisting of disposable clothing
 - Orthopedic plasters, sanitary towels, pediatric or geriatric diapers
 - Biological samples (faeces, urine and blood) after sterilization
- Hazardous medical waste not at risk of infection
 - Basic-acid reagents and solutions
 - Fixing and developing liquids
 - Fluorescent lamps
 - Batteries, cells
 - Filter earths for chromatography
 - Waste oils from vacuum pumps

- Hazardous medical waste with an infectious risk
- Waste from infectious isolation environments (airborne transmission, class IV biological agents)
- Waste contaminated by:
 - blood, or other biological fluids visibly contaminated with blood
 - potentially infectious faecal material or urine
 - biological fluids (semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, etc.)
- Waste from veterinary activity:
 - contaminated by human or animal pathogens
 - come into contact with any body or fluid excreted or secreted potentially pathogenic

(example list of types of medical waste)

Composition	Typology	Legal regime
Research activity and bacteriological diagnostics	Plates, culture media, etc.	Dangerous infectious risk
Sharp	Needles, syringes, blades, glasses, disposable scalpels, lancets	Dangerous infectious risk
Anatomical	Tissues, organs.	Dangerous infectious risk
Pharmaceuticals	Experimental guinea pigs	Specials

Packaging

Containers differentiated by labelling, type, size and destination:

- Rigid container (in cardboard or plastic), containing a polyethylene bag.
The container (40 L) must be equipped with a closure system, marked with the waste symbol (black R on a yellow field), the waste designation ("dangerous medical waste with infectious risk") and the European Waste Code (CER)
- Autoclavable pouches (20-30 L).

Validation

The validation of the sterilizer can be done through biological tests according to the UNI 10384 standard and Pharmacopoeia Ninth Edition. The biological test according to the pharmacopoeia must be "Bacillus stearothermophilus spores ATCC7953, population $> 1 \times 10^5$, value D at $121^\circ = 1.5 \text{ min}$ "

The spores should be placed inside the transport trolley protected from contact with the material (e.g., placed on the bottom with an inverted steel mesh basket on top). At the end of the sterilization cycle they must be recovered and incubated according to the specifications described by the manufacturer.

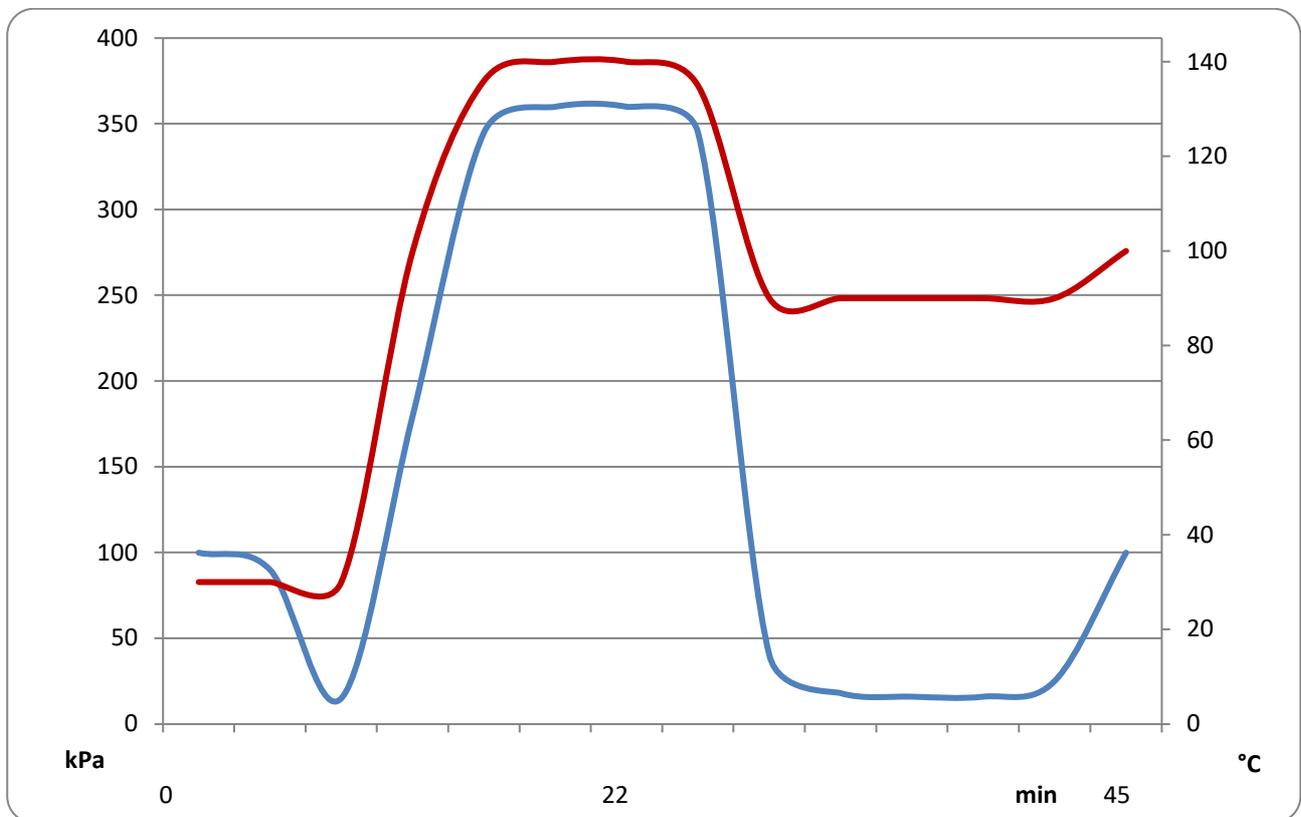
1.5 – Sterilization cycles

The following illustrations show the pressure – temperature – time diagrams of the cycles programmed.

Some parameters of cycles in the “L” versions may be changed during the testing of the machine in order to be best adapted to the conditions of use.



STANDARD STERILIZATION CYCLE – 134°C, 10 minutes



Description of stages

		Vacuum Test	Conditioning	Heating	Sterilization	Chamber draining	Washing	Drying
Enablement	On/Off	OFF	ON	ON	ON	OFF	OFF	ON
Max Leak	mBar	-	-	-	-	-	-	-
Vacuum	kPa	-	30.0	-	-	-	-	30.0
Pressure	kPa	-	180.0	-	-	-	-	-
Heating	°C	-	134.0	134.0	134.0	-	-	134.0
Stage time	min	-	-	-	10	-	-	10
Max time	min	-	10	20	-	-	-	10
Vacuum time	min	-	5	-	-	-	-	-
Pulses	nr.	-	1	-	-	-	-	-
Ramp	°C/min	-	-	-	-	-	-	-
Ramp	kPa/min	-	-	-	-	-	-	-
Stop at set point		-	-	-	-	-	-	OFF

Sterilization cycle at 134°C

Includes the following stages:

- steam in the jacket
- vacuum up to a preset
- introduction of steam into the chamber up to 134°C
- sterilization for a time of 10 minutes
- removal of steam from the chamber camera
- final vacuum in the chamber up to a preset value and steam in the jacket for drying the material
- restoring of pressure conditions in the chamber with the introduction of sterile air
- end of cycle

**USER CYCLE – 110-144°C, 1-9999 minutes**

With the user cycle the sterilization cycle parameters and stages can be changed. The stages are:

- **VACUUM TEST**
- **CONDITIONING**
- **HEATING**
- **STERILIZATION**
- **CHAMBER DRAINING**
- **WASHING**
- **DRYING**
- **AERATION**

For these stages, the following can be modified:

VACUUM TEST

- Stage enablement (ON/OFF)
- The acceptable loss expressed in millibar (mbar) during the test time interval
- The vacuum set point to be reached to start the stabilization (kPa)
- The heating temperature of the jacket (°C)
- The test time (min)
- The maximum time for reaching the vacuum set point (min)

CONDITIONING

- Stage enablement (ON/OFF)
- Vacuum set point (kPa)
- Pressure set point (kPa)
- The heating temperature of the jacket (°C)

NB: The jacket temperature must be adequate to allow the reaching of the pressure set point in the chamber. If the pressure corresponding to the temperature selected is less than the set pressure, the maximum time alarm will be activated.

Example: setting a pressure set point of 200 kPa, the jacket temperature must be set at least 123°C (See temperature/pressure table, Fig. 9)

- The number of vacuum/pressure repetitions
- First vacuum time (min)
- The activation of the control function of the pressure in respect of the liquid temperature means that the vacuum set is calculated with an mayor approximation of the Mollier curve

HEATING

- Stage enablement (ON/OFF)

NB: disabling this stage will automatically disable also the sterilization stage.

- Heating set point (°C)
- Ramp-up expressed in °C per minute
- Maximum time for reaching the set point

NB: setting a ramp-up of 1°C per minute, for example, to reach a set point of 134°C from a temperature of 100°C will require $134-100 = 34^\circ\text{C}$, or 34 minutes. Consider this time before setting a maximum time.

- Pressure ramp-up kPa/sec. When this option is selected, the degree of pressure increase will be applied to the entire cycle.

STERILIZATION

- Stage enablement (ON/OFF)

NB: Enabling this stage will automatically enable also the heating stage.

- Sterilization time (min), (this unit is expressed in seconds only for the B&D cycle)
- Sterilization temperature (°C)
- Enabling of the F0 (F zero)

This function allows you to use real time as the time basis, if the F0 is disabled or the time calculated with respect to temperature if the F0 function is enabled. Please see other publications for further knowledge about the F0 function.

CHAMBER DRAINING

- Stage enablement (ON/OFF)
- Pressure ramp-down in mBar per minute until reaching atmospheric pressure, approx. 105 kPa

WASHING

- Stage enablement (ON/OFF)
- Vacuum set point 1 (kPa)
- Aeration set point 2 (kPa)

NB: the aeration set point must be higher than the vacuum set point

- The number of vacuum/aeration repetitions
- The maximum time for reaching the vacuum set point (min)
- The jacket heating temperature (°C)

DRYING

- Stage enablement (ON/OFF)
- Vacuum set point (kPa)
- Hold time under vacuum (min)
- Jacket heating temperature (°C)
- The maximum time for reaching the vacuum set point (min)
- Stop at set point. This function stops the pressure value when the set point is reached. With this option disabled the vacuum continues even after reaching the set point.

AERATION

The set point for this stage cannot be modified

There are 20 User cycles, identified by a number. User cycle number 1 will be printed with this name. Given below is the table for the steam temperature/pressure ratio:

°C	mBar	°C	mBar
100	1014	121	2051
101	1051	122	2116
102	1089	123	2183
103	1128	124	2252
104	1168	125	2323
105	1209	126	2395
106	1252	127	2469
107	1295	128	2545
108	1340	129	2623
109	1387	130	2703
110	1434	131	2785
111	1483	132	2869
112	1533	133	2954
113	1585	134	3042
114	1638	135	3132
115	1692	136	3224
116	1748	137	3319
117	1806	138	3415
118	1865	139	3514
119	1925	140	3615
120	1987		

Fig. 3

1.6 – Safety systems

The machine is equipped with the following safety devices, which make it extremely reliable:

Device for temperature fault during the sterilization cycles.

Uses two temperature sensors, at a threshold of -0°C with respect to the sterilization set point.

Maximum pressure protection device.

Spring-loaded safety valve certified in accordance with PED 97/23 installed directly on the body of the steam generator.

Device against the introduction of steam in the chamber if the door is open or not securely closed.

Limit switch for the correct positioning of the loading door(s).

Device that prevents the simultaneous opening of doors (two-door model).

Limit switch for the correct positioning of the loading door(s).

Safety device on the door seal

Checks the pressure in the seal by means of a pressure switch.

Heating element maximum temperature safety device

Thermostat inserted in the body of the generator in contact with the heating elements.

Circuit breakers for motor protection

Fuse and electrical protection on the electrical system auxiliaries

Low voltage power packs with SELV (Safety Extreme Low Voltage) output

Emergency stop button for all machine functions (reset in standby with key and restart the running of the cycle with new start command)

Differential protection on the steam production circuit board (heating elements)

Accident prevention devices

Releasing microswitches on the electrical power panel.

Dual buttons (two hands required) for closing the door.

Emergency button on the control panel for stopping immediately the operation of the sterilizer and cutting off the mains electrical power. This button is tested for resistance to accidental contact.



The pipes through which the steam passes and which therefore reach high temperatures are insulated with heat-resistant material. These pipes have pneumatic valves that also reach relatively high temperatures, but due to their form and function, they cannot be insulated. Therefore special caution is required when working near these valves.

1.7 – Safety systems and functions set points

The tables below show the safety and function components and their respective settings.

Safety

Component	Set point
Generator safety valve SS3 <i>See piping diagram in the appendixes</i>	3.5 Bar
Seals pressure switch SP10 <i>See piping diagram in the appendixes</i>	0.5 Bar
Heating element thermostat TC3 <i>See piping diagram in the appendixes</i>	150°C

Functions

Component	Set point
Drain thermostat TC20 <i>See piping diagram in the appendixes</i>	60°C
Pressure regulator FRM <i>See piping diagram in the appendixes</i>	6.0 Bar
Generator pressure switch SP4 <i>See piping diagram in the appendixes</i>	3.0 Bar

1.8 – Operator codes

The operation of the machine provides for twenty operators, with a recognition code entered for each operator. The following functions have been defined, which can be associated to the operators in order to meet the department needs:

1	Start standard cycles
2	Start B&D / vacuum test
3	Start user cycles
4	Edit user cycles
5	Edit standard cycles
6	Change date and time
7	Change heating type
8	Change maintenance and forcing outputs
9	Change general parameters
10	Change printing parameters
11	Reset alarms
12	Manual cycle advance
13	Calibration

These codes and their functions can be changed according to need, so as to define maintenance functions (e.g.: change maintenance and forcing outputs, calibration). Operator 1 has all the functions enabled (supervisor) and cannot be changed. When first activated, the machine will have the following configuration:

Operator no.	Code	Name
1	1001	OPERATOR 1
2	1002	OPERATOR 2
3	1003	OPERATOR 3
4	1004	OPERATOR 4
5	1005	OPERATOR 5
6	1006	OPERATOR 6
7	1007	OPERATOR 7
8	1008	OPERATOR 8
9	1009	OPERATOR 9
10	1010	OPERATOR 10
11	1011	OPERATOR 11
12	1012	OPERATOR 12
13	1013	OPERATOR 13
14	1014	OPERATOR 14
15	1015	OPERATOR 15
16	1016	OPERATOR 16
17	1017	OPERATOR 17
18	1018	OPERATOR 18
19	1019	OPERATOR 19
20	1020	OPERATOR 20

At the start of a cycle the operator name for the code entered will be printed. The operator code will be requested each time that the need arises, such as to reset an alarm or use the calibration function.

Operator	Start standard cycles	Start B&D / vacuum	Start user cycles	Edit user cycles	Edit standard cycles	Change date and time	Change heating type	Change maintenance and forcing outputs	Change general parameters	Change printing parameters	Reset alarms	Manual cycle advance	Calibration
1	x	x	x	x	x	x	x	x	x	x	x	x	x
2	x	x	x			x					x		
3	x	x				x					x		
4	x					x					x		
5	x										x		
6	x												
7	x												
8	x												
9	x												
10	x												
11	x												
12	x												
13	x												
14	x												
15	x												
16	x												
17	x												
18	x												
19	x												
20	x												

Fig. 4

x = Function enabled.

(1) Function enabled with additional code.

1.9 - Alarms

The alarms that may occur during the running of the cycle will be displayed and printed. The display will show the stage and the type of alarm, and they can be reset only by code (see 1.7). For some types of alarm action is required by the technical personnel before restoring the conditions of use. The following table indicates the type of alarm:

TYPE OF ALARM	LEVEL 1	LEVEL 2	LEVEL 3	TECHNICAL ACTION
Cycle cancelled			●	
Thermal protection devices			●	●
No water			●	●
Minimum temperature			●	●
Maximum temperature			●	●
Emergency temperature			●	●
Maximum stage time	●			●
Chamber transducer failure			●	●
Chamber Pt100 failure			●	●
Jacket transducer failure			●	●
Loading side door open			●	●
Sterile side door open			●	●
Maximum pressure			●	●
PLC low battery	●			●
Temperature calibration	●			●
Pressure calibration	●			●
Seal minimum pressure			●	●
Emergency stop button			●	
Manual stop			●	
Faulty safety lock	●			●
No power supply				●
Max drain temperature	●			●
Vacuum test fail		●		●
Shredder blocked			●	●

The alarms described in the table are the following:

Cycle cancelled

This alarm occurs when the cycle is canceled using the procedure described on the touch screen.

Thermal protection devices

This alarm occurs when a thermal protection device is activated. This happens when there are problems in the motors of the vacuum pump or the water pump or the electrical network.

No water

This alarm occurs when a maximum time limit has been reached for filling the generator with water.

Minimum temperature

This alarm occurs during the sterilization stage, when the chamber temperature falls below the set threshold (sterilization temperature).

Maximum temperature

This alarm occurs during the sterilization phase, when the chamber temperature rises above the set threshold (sterilization temperature +3°C).

Emergency temperature

This alarm occurs when the chamber temperature exceeds 140°C.

Maximum stage time

This alarm occurs when the time of the stage in progress exceeds the set point for that stage.

Chamber transducer failure

This alarm occurs when an error is detected in the pressure transducer signal.

Chamber Pt100 failure

This alarm occurs when an error is detected in the signal of the chamber PT100 resistance thermometer.

Jacket transducer failure

This alarm occurs when an error is detected in the signal of the jacket pressure transducer.

Loading Side/Sterile Side door open

This alarm occurs when the door limit switch does not send the signal that the door is closed properly during a cycle.

Maximum pressure

This alarm occurs when the maximum pressure threshold is exceeded in the chamber (+3.0 bar, 400 kPa).

Temperature Calibration

This alarm occurs when a difference of more than two degrees Celsius is detected between the temperature regulation sensors.

Pressure Calibration

This alarm occurs when a difference of more than 50 mBar is detected between the two pressure transducers.

Maximum drain temperature

This alarm occurs when the drain temperature remains high (>60°C) for more than five minutes.

Vacuum test fail

This alarm occurs when the vacuum test does not fall within the specified range (1.3 mbar/min).

Maximum degree of unsaturation/overheating (%) of the steam in the chamber

This alarm occurs when the degree of unsaturation or overheating, expressed as a percentage, calculated from the pressure and the temperature, is greater than $\pm 10\%$.

Seal minimum pressure

This alarm is activated when a drop in pressure in the door seals is detected.

Emergency stop button

This alarm is displayed after resetting the emergency stop button. (no. 4, Figs. 7 and 8)

PLC Battery

This alarm occurs when the battery of one or both PLCs must be replaced.

Manual Stop

This alarm occurs when the cycle is canceled by using the stop button on the control panel (no. 3, Figs. 7 and 8).

Faulty safety lock

This alarm occurs when an error is detected in the door safety lock circuit.

No power supply

This alarm occurs when there is an electrical power outage.

(Note: This alarm occurs even if the machine is turned off using the button on the control panel (no. 4 Fig. 7).

Shredder blocked

This alarm occurs when ampere of shredder motor rise to maximum level. When append the motor was stopped and restart in reverse direction for 10 seconds. This procedure try to unblock the blade form heavy part of material. This procedure is repeat for five times. If the alarm occur again after this five time the shredder was stopped and manual intervention needed for remove the block.

There is a level for each type of alarm:

- LEVEL 1

is an alarm that is only displayed and does not change the sequence of the cycle

- LEVEL 2

is an alarm that terminates the cycle after a pressure balancing stage

- LEVEL 3

is an alarm that terminates the cycle after executing a procedure for draining the steam and restoring the chamber atmosphere consisting of vacuum and aeration. In case of a cycle with habilitate cooling this function is on.

In the case of an electrical power failure at any stage of the cycle, when the power returns to the machine the alarm level 3 procedure is started (sect. 2.18).

2.0 STERILIZER OPERATION

2.1 – PRELIMINARY OPERATIONS

To be carried out when starting or resuming activity after downtime:



The operators who use the sterilizer must be qualified for this type of activity.



The maintenance and repair of the sterilizer must be done by qualified service personnel.

- Make sure that the WATER INLET (piping diagram in the appendixes), STEAM INLET (if the sterilizer is fed directly from the network) and AIR INLET valves placed inside the sterilizer are open.



A Fabrics warm up cycle MUST BE run before starting the day's activities.

The following must be done each time a cycle is started:

- Check that the door seal is securely in its seat before closing the door.
- Check that the door seal is clean.



Sharp or pointed tools must not be used to insert or remove the chamber seal from its seat.

- Check that there is paper in the printer..
(A red line on the paper means that the roll is about to run out.)



Do not pull on the paper when the printer is operating!

- Check the operation of the ink ribbon.

THE STERILE DOOR CANNOT BE OPENED AFTER A TEST CYCLE!

2.2 – STARTING THE STERILIZER

Check that the emergency stop button (no.4, Figs. 7 and 8) is not activated.
Turn on the sterilizer by pushing the ON-OFF button (no.2, Fig. 7)

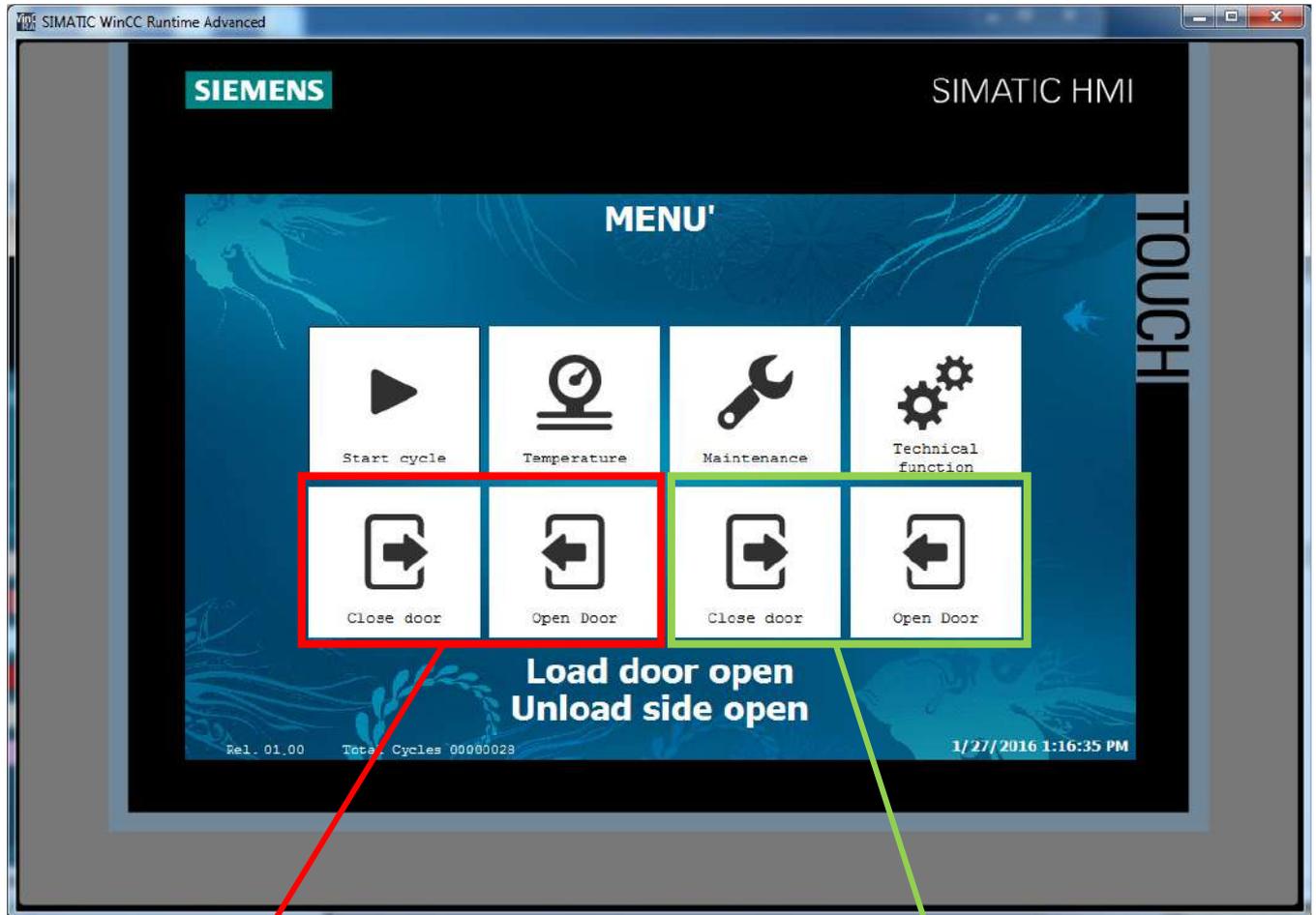
The display will show:



This page shows the software version, the sterilizer model and the number of cycles performed.

Touch any part of the screen to go to the next page.

2.3 – MAIN MENU



Load trolley door

Waste up load door

Open the trolley door by pressing the button



and keep pressing it until the door is fully opened. Load the empty trolley.

Close the door by pressing at the same time the



button on the screen and the close button on the control panel (7, Fig.7).



Open the waste up door by pressing the button  and check the open door message “Load door open”. Load the upper chamber with the waste material to be sterilize.



Close the waste up door by pressing the  button and wait until the message “Load door open” was cancelled.

From the main menu you can access the different functions of the machine:



START A CYCLE: regards the management of the cycles (sect. 2.4 to sect. 2.10)



TEMPERATURE : regards the machine operating status (sect. 2.11)



MAINTENANCE: regards the scheduled maintenance for the machine (sect. 4.0)



TECHNICAL FUNCTIONS: regards the management of the technical parameters (sect. 3.0)

The presence of an alarm is indicated by a red background. To cancel an alarm in progress, see paragraph 2.18.

2.4 - PROCEDURES FOR STARTING THE CYCLE

The cycle is started with the selection of some of the settings briefly summarized below:

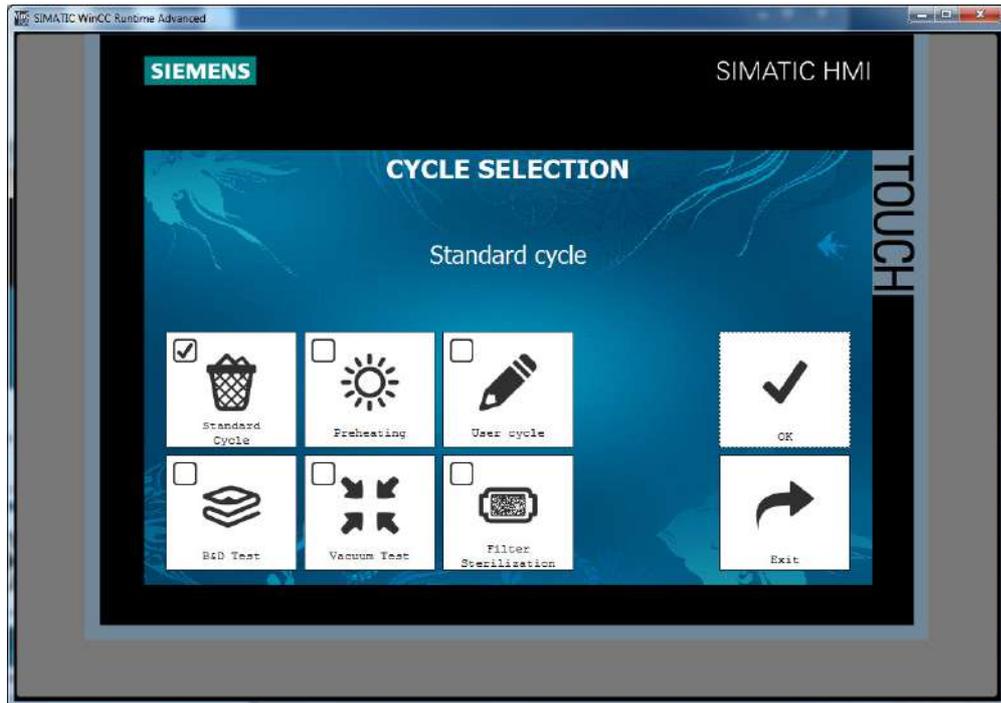
- Select the type of cycle
- Enter the operator code (if requested or enabled)
- Confirm the data

Thus the first operation will be:



Press from the main menu (sect. 2.3)

The display will show the cycles available depending on the sterilizer model:



SELECTING THE CYCLE ACCORDING TO THE MATERIAL

Select the cycle according to the type of material to be sterilized (see sect.1.4). The machine is set up with the following basic cycles:



- STANDARD CYCLE at 134°C.

EXPOSURE TIME 10 min. This cycle is for sterilizing waste material



- INTERNAL FILTER STERILIZATION at 121°C (If fitted).

EXPOSURE TIME 20 min. . This cycle is for sterilizing the internal filter

**- PREHEATING CYCLE at 134°C.**

EXPOSURE TIME 5 min. This cycle is for preheat the machine at the beginning of working day

**- VACUUM LEAK TEST**

HOLD TIME 10 min. MAXIMUM LEAKAGE 13MBAR (1.3MBAR/MINUTE)

**- USER CYCLE.**

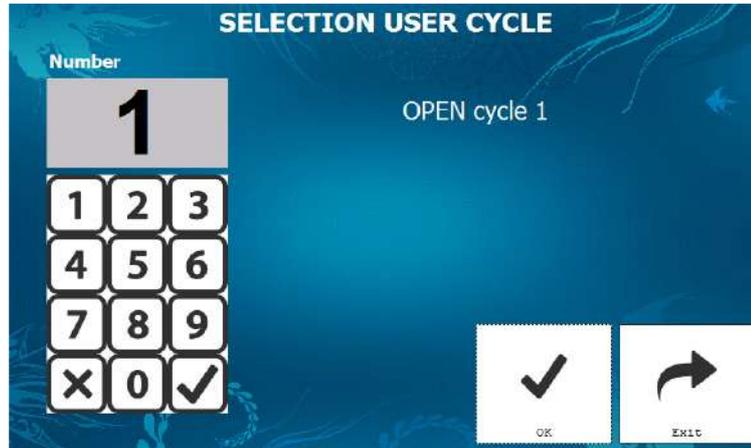
Pressing this button opens the user cycles library

Press  to exit and return to the main menu

Press  to start the cycle.

If the user cycle is selected

The screen will show:



Select the user cycle number and enter a value between 1 and 20.

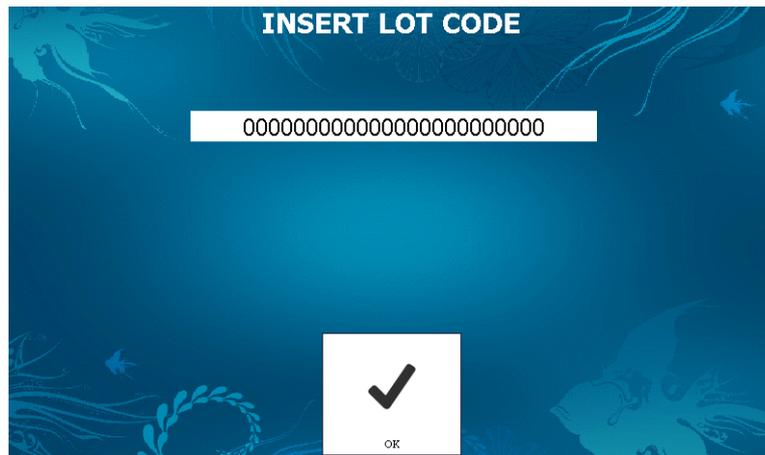
Press  to exit from the page without selecting.

Press  to confirm and return to the cycle selection page.

2.6 – ENTERING THE LOT CODE

This function can be enabled or disabled according to the internal procedure of the sterilized material management system.

The screen will show :



Select to enter the lot code;

At this point the alphanumeric keyboard described in sect. 3.1.1 will be displayed.

Press



to confirm.

2.7 – ENTERING THE OPERATOR CODE

This function can be enabled or disabled according to the sterilized material management system.

The operator code is always requested for tests (B&D or Vacuum Test)

The screen will show:



Enter the operator code.

Press  to confirm

Press  to cancel.

2.8 - CONFIRM CYCLE START

Before starting the cycle the data entered must be confirmed. The screen will show:



Press  to cancel the procedure and return to the Select Cycle page, or press



to confirm and start the cycle.

This page:



draws the operator's attention, reminding them that one of the machine components has reached the predetermined number of work cycles. This message does not affect, however, the execution of the cycle. To see which component it concerns, go to the main menu to enter in the "Maintenance" section and, if necessary, request the maintenance personnel to carry out the required maintenance.

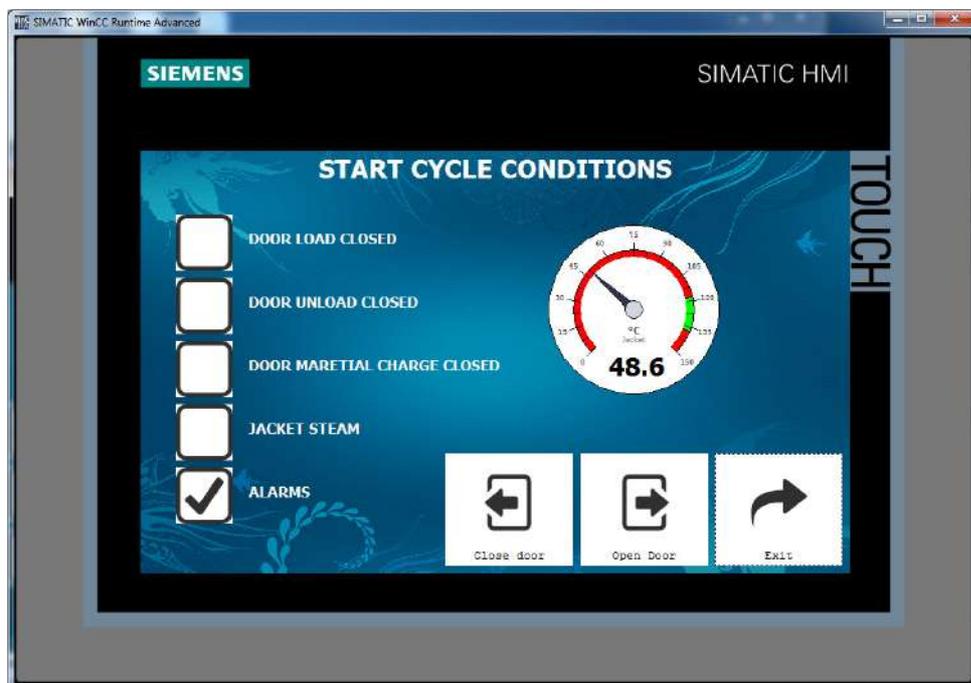
2.9 - AUTOMATIC DRAINING OF THE GENERATOR

For sterilizers that have a built-in steam generator, an automatic emptying is programmed by the amount of water in the generator.

2.10 - CHECK CONDITIONS FOR PROCEEDING TO THE START OF THE CYCLE

Before starting the selected cycle, the device checks the conditions of the systems.

The screen will show:



- **Door(s) closed**

If the door is not closed, close it following the procedure given in sect. 2.2

- **Jacket Steam**

When turned on, the sterilizer takes about 20 minutes to reach the set point. The jacket (sect. 2.11) must reach the appropriate pressure for the cycle selected.

- **Alarms**

Check for any active alarms. Before starting the cycle, any alarms in progress must be reset (sect. 2.18).

After checking the condition of the systems, their icons light up, after which the cycle begins.



Press  to cancel the cycle start procedure and to return to the Select Cycle page (sect.2.4). Then repeat the procedure following the steps given in the preceding pages.

2.11 - STAGE IN PROGRESS

This page is displayed when the cycle starts and shows the main parameters of the sterilizer :



The following parameters are displayed in real time:

- Chamber pressure and temperature
- Jacket temperature
- Drain temperature
- Filter temperature
- Shredder motor current
- Total cycle "F0"
- Steam saturation percentage
- Cycle number
- Remaining time



Press to access a selection submenu (sect. 2.14).



Press to cancel the cycle in progress (sect. 2.13).

2.13 - CYCLE CANCELLATION



As described in section 2.11, by pressing it possible to cancel the cycle in progress.
The screen will show:

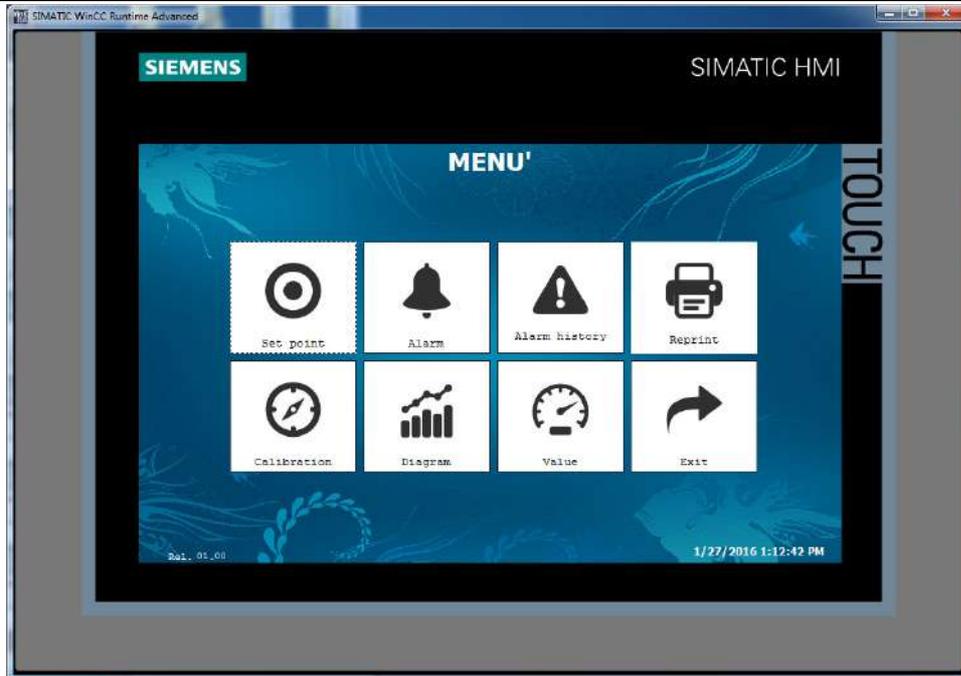


Press to continue running the cycle in progress.
The screen will return to displaying the stage in progress.



Press to begin the procedure for cancelling the cycle in progress.

2.14 - SELECTION MENU



Allows you to compare the set point value of the current stage with the programmed set point value (sect. 2.15)



Allows you to view the alarms in progress (sect. 2.18).



Allows you to view the alarms history (sect.2.18.1).



Allows you to view the process values in the chamber and in the jacket (sect. 2.16).



Allows you to view in real time the changes in temperature and pressure (sect. 2.17).



Allows entering in the calibration menu (sect. 3.13).

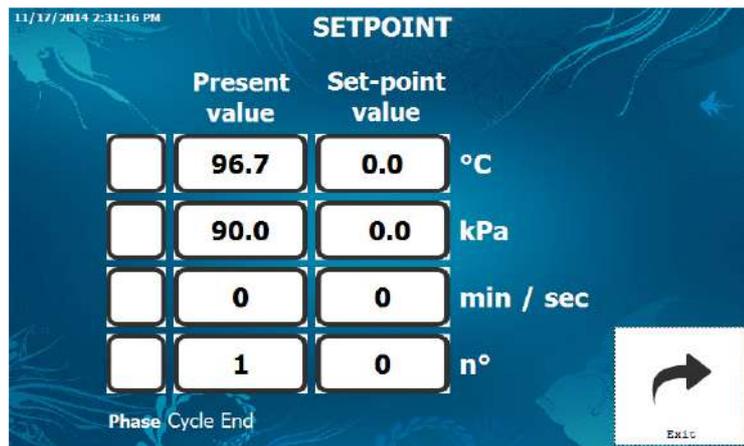


Reprint the last cycle.



Press to return to the display of the page menu. (sect. 2.14)

2.15 - SET POINT PAGE



The following are displayed:

- chamber temperature in °C;
- chamber pressure in kPa;
- stage time in minutes;
- number of vacuum/pressure pulses;
- time;
- date.

The icon indicates the parameter in comparison, according to the stages. During the B & D cycle, in the sterilization phase, the stage time will be expressed in seconds.



Press to return to the display of the page menu (sect. 2.14).

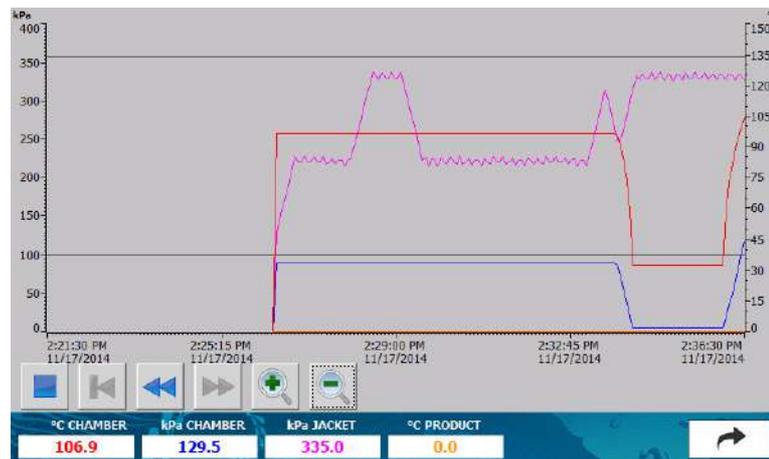
2.16 - SYNOPTIC

The synoptic page shows the status of the actuators in the sterilizer and all process variables (temperature/pressure). This is a technical function only for maintenance purpose for the diagnosis of malfunctions.

2.17 - DIAGRAM PAGE



From the menu page press  to display the chamber temperature and pressure graph as a function of time.



The following are displayed:

- chamber temperature in °C;
- product temperature in °C (LAB-STM)
- chamber pressure in kPa;
- jacket pressure kPa.



With these tools it is possible to move and zoom the plot area.

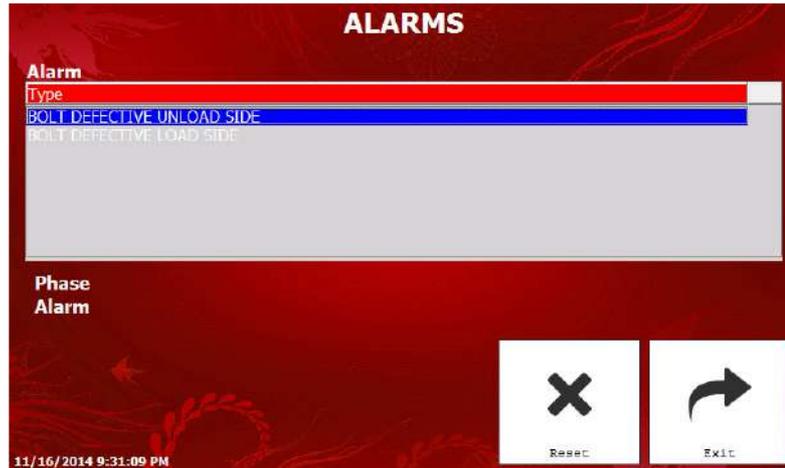


Press  to return to the display of the page menu (sect. 2.14).

2.18 - ALARMS PAGE



Press  from the menu in section 2.14 to display the alarms still in progress. This page is displayed automatically every time that an alarm occurs. The screen will show:



Pressing  you will be prompted for the operator code (sect. 2.7) to turn off the alarm. (See table, section 1.7)

After entering the operator code, with the corresponding function enabled, if the cycle is running the display will return to the selection menu, or to the main menu if the alarm occurred at the end of the cycle.

After resetting the alarm during the cycle, at the end this page will be displayed again



to remind the operator that an alarm occurred. Press  to return to the main menu.

2.18.1 - ALARM HISTORY PAGE

The page displays all the alarms that have occurred over time. The list shows the date and time of the alarm.

ALARM HISTORY

Time	Date	Text
2:38:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:37:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:36:34 PM	11/17/2014	BOLT DEFECTIVE UNLOAD SIDE
2:36:34 PM	11/17/2014	BOLT DEFECTIVE LOAD SIDE
2:36:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:35:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:34:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:33:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:32:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:31:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:30:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:29:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.
2:29:17 PM	11/17/2014	TRANSD.CHAMBER FAIL
2:29:17 PM	11/17/2014	WATER SHORTAGE
2:29:17 PM	11/17/2014	TRANSD. JACKET FAIL
2:29:17 PM	11/17/2014	PROBE CHAMBER FAIL
2:29:17 PM	11/17/2014	BOLT DEFECTIVE UNLOAD SIDE
2:29:17 PM	11/17/2014	BOLT DEFECTIVE LOAD SIDE
2:29:17 PM	11/17/2014	TRANSD.CHAMBER FAIL 2
2:29:17 PM	11/17/2014	PROBE CHAMBER FAIL 2
2:28:20 PM	11/17/2014	Date/time could not be set, error code: 1314,1.

Exit

Press to return to the selection menu.

2.19 - CYCLE END

At the end of the cycle, the sterile side door can be opened (for two door sterilizers) only if there are no alarms. In all other cases (single door sterilizer, the end of a test or of a cycle with an alarm) the loading door can be opened.

If the cycle is finished with no alarms, this page will be displayed:



In the case of a two door sterilizer, open the sterile side door with button 11 in Fig. 8, remove the trolley and close the door with buttons 7 in Fig. 8. If the sterilizer has only one door, press anywhere on the screen to return to the main menu. Open the door



by pressing and holding the button until the door is fully opened, and then



remove the trolley. Close the door pressing at the same time the button on the screen and the close button on the control panel (7, Fig. 7)

The doors in pass-through sterilizers are interlocked, which means that you cannot open a door if the other door is open. The door on the unloading side may be opened only at the end of a correctly run sterilization cycle, and it can continue to be opened and closed until the door on the loading side is opened.



THE DOORS ARE INTERLOCKED. A DOOR CANNOT BE OPENED IF THE DOOR ON THE OPPOSITE SIDE IS ALREADY OPEN.

If the cycle that has just ended is a test (B & D or vacuum test), the sterile side door cannot be opened (in two door sterilizers) and the display shows:



Press any point on the screen to return to the main menu (sect. 2.3) and start the door opening and closing procedure as described above.

In the case of the end of cycle with an alarm the screen will show:



Press any point on the screen to return to the main menu (sect. 2.3) and start the door opening and closing procedure as described above.



WARNING! If the cycle is not carried out properly, the material must be considered not sterile. Be careful of biological risks.

2.20 – PRINTING

A printout is produced in real time for each cycle started. Given below is an example of a printout of a cycle run.

```

=====
+   AIC-SCHLUMBOHM   +
=====
TRUSTER.50      Rel.01.00   Sterilizer model
ID-LS00000                               Serial number
Operator:                               Operator name
Operatore 1                               Lot code (if enabled, sect. 3.9)
Standard cycle                               Type of cycle
Steriliz.      T=140.0°C   Sterilization parameters
                t=0020min   Number of pulses
=====                               Type of heating
Start cycle     14:05:13
                22/09/15   Date and time of cycle start
Progressive n.  00000028   sequential number
=====
14:05  103.6°C  100.0kPa   Indication of the time, chamber temperature and
CONDITIONING                               chamber pressure at the time of the changing of the
14:05  103.6°C  090.6kPa
Vacuum N.01    030.0
14:12  102.2°C  022.6kPa
HEATING        140.0 °C
14:22  140.6°C  370.2kPa
STERILIZATION  0020 min
Time  T. Cham.  P. Cham.
14:23  140.6°C  371.8kPa
14:23  140.7°C  370.9kPa
14:24  140.7°C  372.6kPa
14:24  140.7°C  374.3kPa
14:36  140.6°C  387.7kPa
.
.
.
14:36  140.6°C  386.7kPa
14:37  140.5°C  385.0kPa
14:37  140.6°C  386.0kPa
14:38  140.6°C  386.4kPa
14:38  140.6°C  385.5kPa
14:39  140.6°C  384.7kPa
14:39  140.6°C  385.3kPa
14:40  140.6°C  387.4kPa
14:40  140.6°C  385.8kPa
14:41  140.6°C  386.3kPa
14:41  140.7°C  385.0kPa
14:42  140.6°C  384.6kPa
14:42  140.6°C  383.7kPa
DRYING        030.0 kPa
14:55  103.3°C  029.9kPa
DRYING        0010 min
15:05  104.8°C  017.1kPa
AERATION
=====
15:06  106.1°C  092.8kPa   Indication of the cycle run regularly
CYCLE ENDED VALID                               Maximum and minimum temperature reached during
Temper. Max    140.8 °C   sterilization.
Temper. Min    140.5 °C   Total cycle time
Total time     0059 min
=====

```

2.21 - STERILIZER CHARGING / DECHARGING OPERATIONS

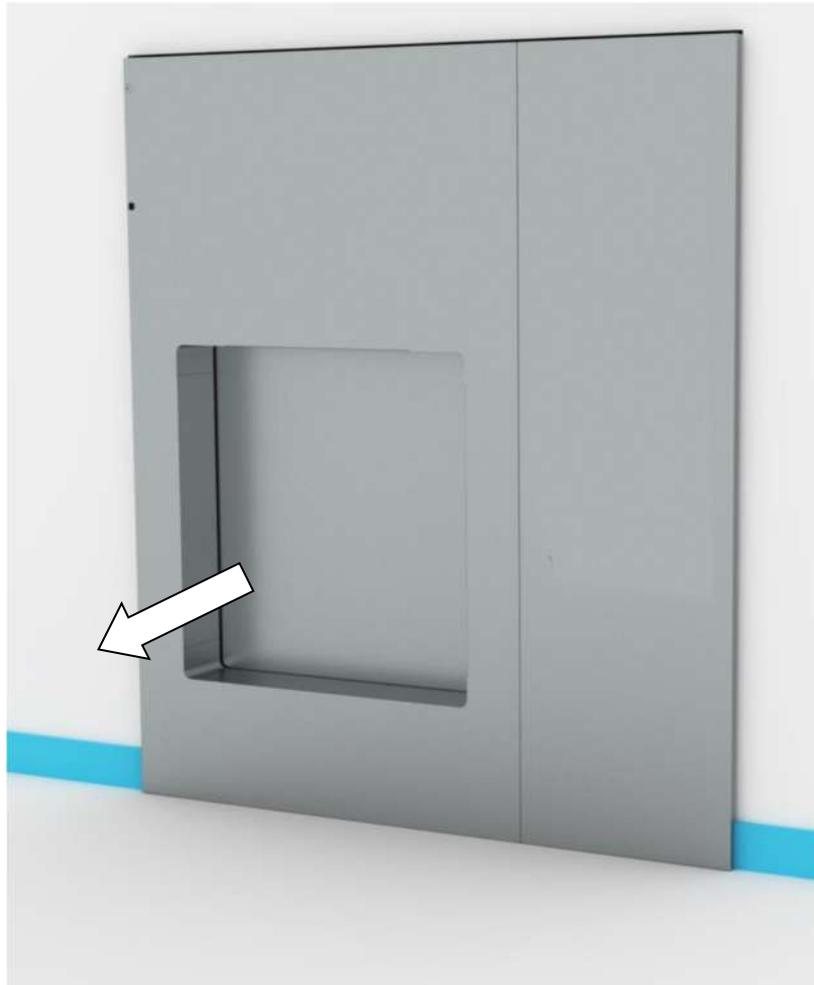
The operation must be done in the follow step:

- 1- Open the upper TrustEr load door and charge the waste material into the chamber then close the upper waste load door.



- 2- Select and start the cycle

- 3- At the end of the cycle, open the discharge side door, remove the FILLED trolley and close the door.



WARNING! At the end of the cycle the trolley is extremely hot. Wear the protection glove before move it

3.0 TECHNICAL FUNCTIONS

3.1 - ENTERING DATA

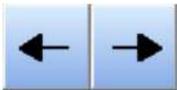
Whenever you need to enter codes consisting of digits and characters, an alphanumeric keyboard will be displayed, such as for entering the lot code. Its different functions are described below.

3.1.1 – Entering alphanumeric data.

To change an alphanumeric value, if the keyboard is not already displayed, touch the field of the value that you wish to change, and the following keyboard will appear:



Press  for capital letters and special characters.

Use  to scroll through the line.

Press  to exit from the keyboard.

Press  to access the numeric keypad.



Press  again to return to the alphanumeric keyboard.

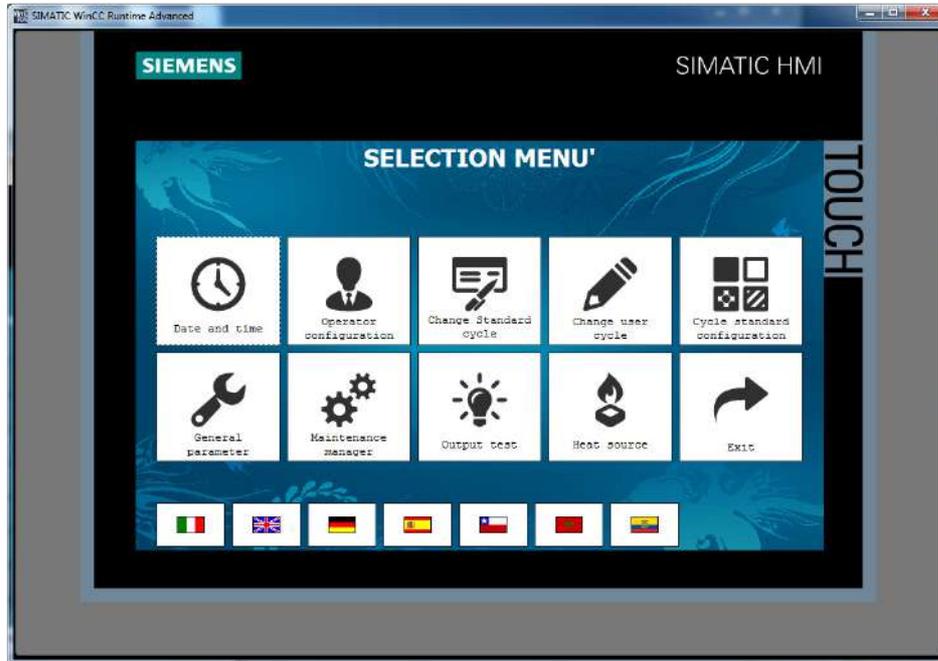
3.2 – PROCEDURE FOR THE MANAGEMENT OF TECHNICAL PARAMETERS



Press  from the main menu (sect. 2.3)
 Enter your operator code (sect. 2.7) and press OK.
 Depending on the functions matched with the operator code, some functions may or may not be enabled.

3.3 - ACCESS TO THE MENUS

When the operator code has been entered, the following menu will be displayed:



Allows you to change the date and the current time (sect. 3.4)



Allows you to configure the operators (sect. 3.9)



Allows you to change the parameters of the standard cycles (sect. 3.11)



Allows you to change the parameters of the user cycles (sect. 3.6)



Allows you to enable/disable the selectable cycles (sect. 3.11.1)



Allows you to change the parameters for sterilizer management (sect. 3.10).



Allows you to change the maintenance parameters (sect. 3.8)



Allows you to activate outputs manually (sect. 3.13)



Allows you to change the type of heating (sect. 3.5)

In the aforementioned menu you can also select the desired language.

Touch the flag to select the language of the touch screen, e.g.  for Italian or  for English.

Press  to exit.

3.4 – CHANGE DATE AND TIME



Press  from the selection menu (sect.3.3).

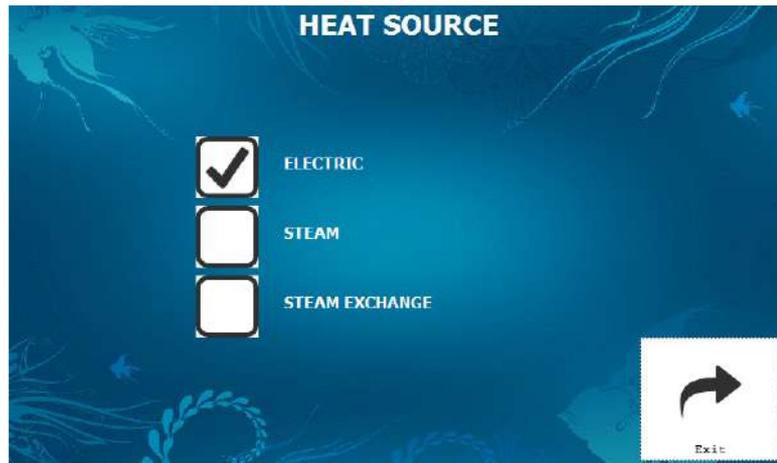
Select the various fields to edit and enter the desired number using the numeric keypad.

Press  to memorize the changes

Press  to exit.

3.5 - CHANGING THE HEATING SYSTEM

Press  from the selection menu (sect.3.3).



Choose the type of heating by selecting the button.

Press  to exit.

3.6 - CHANGING THE PARAMETERS IN THE USER CYCLES



WARNING! The user cycle is programmed as a fabric cycle, thus any changes require validation according to applicable regulations by specialized and authorized personnel before use.

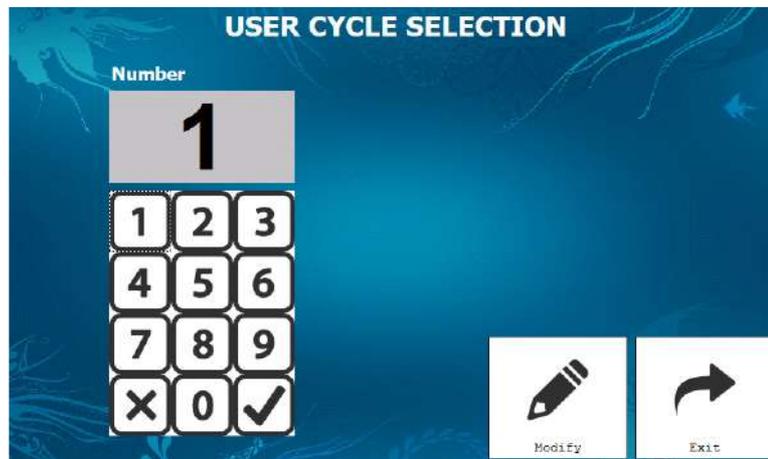
Press  from the selection menu (sect.3.3).

The screen will show:



Press  to continue.

The screen will show:



Enter the number of the cycle you wish to edit using the numeric keypad.

Press  to exit.

Press  to confirm.

At this point, the screen will show the parameters to be changed of the different stages. Proceed as described for changing parameters (sect.3.7).

3.7 - CHANGING THE CYCLE PARAMETERS

All the parameters can be changed using the keypad shown below.



The icon  or  indicates the enablement of the stage shown on the page.

Use the arrow keys  and  to select the stage to be edited.

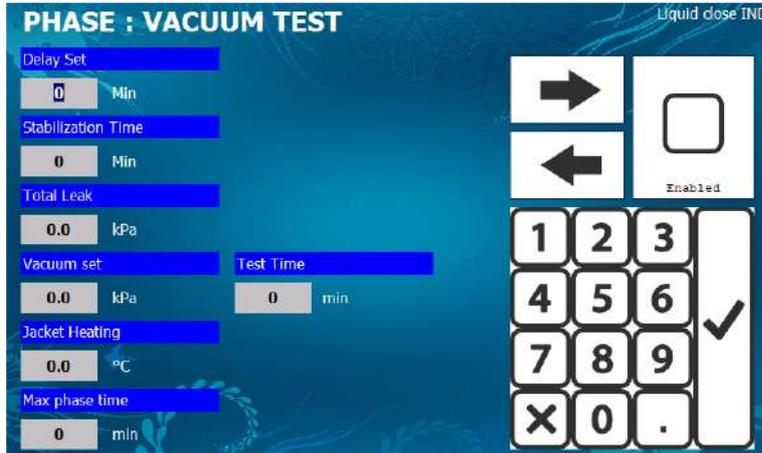
As soon as an open cycle or a standard cycle to be edited is selected, the parameters for the stages making up the cycle will be displayed. The stages are:

- VACUUM TEST**
- CONDITIONING**
- HEATING**
- STERILIZATION**
- CHAMBER DRAINING**
- WASHING**
- DRYING**

The first stage that will be displayed for editing will there for be the **VACUUM TEST** stage.

PHASE – VACUUM TEST

This stage makes it possible to run a vacuum leak test as according to current regulations.

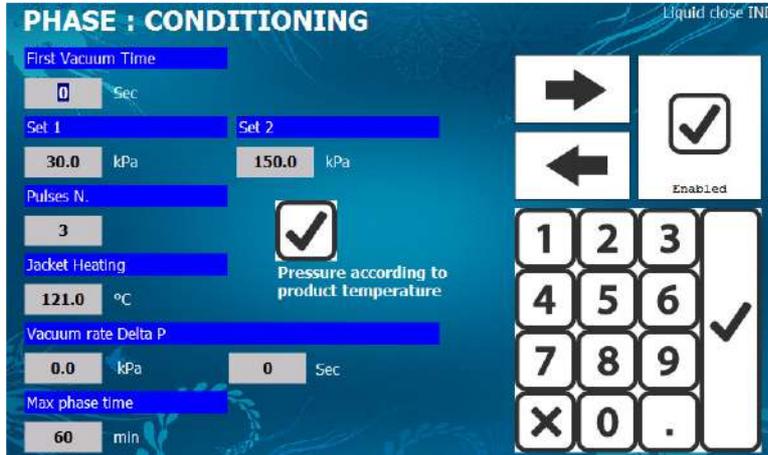


The following parameters can be modified:

Delay to set point	delay time in reaching the vacuum set point
Stabilization time	hold time without active vacuum
Total leakage:	value in mbar of the total loss over the time established
Vacuum set point:	minimum set point that must be reached by the pressure in the chamber
Test time:	duration of the test
Jacket heating:	jacket regulating temperature
Maximum stage time:	maximum time for reaching the set point.

PHASE – CONDITIONING

This stage makes it possible to carry out alternating vacuum and steam pulses to allow the heating of the load and the removal of air from the sterilization chamber.

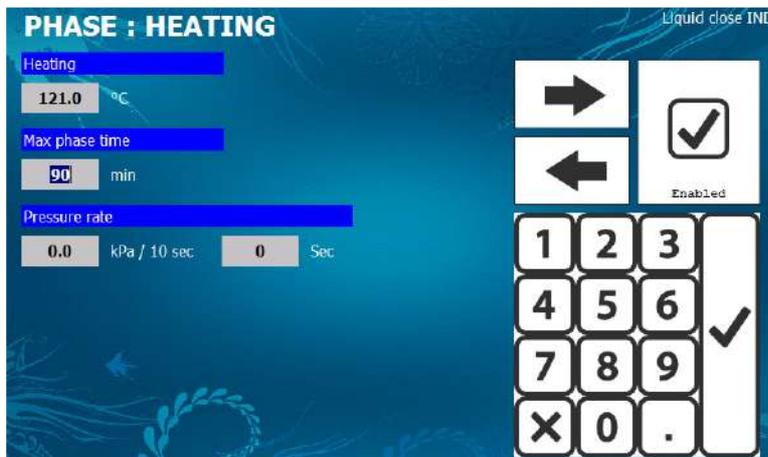


The following parameters can be modified:

- | | |
|---|--------------------------------------|
| First vacuum time | first vacuum hold time at set point |
| Set point 1 and Set point 2 | minimum/maximum pressure value |
| No. pulses | number of vacuum repetitions |
| Jacket temperature | jacket regulation temperature |
| Stage maximum time | maximum time to reach the set point. |
| Vacuum increase | ramp down value in kPa/sec |
| Pressure in function of the product temperature, habilitation of calculation of vacuum set in function of the measured temperature of the product under process | |

PHASE – HEATING

This stage is for heating the sterilization up to the sterilization temperature.

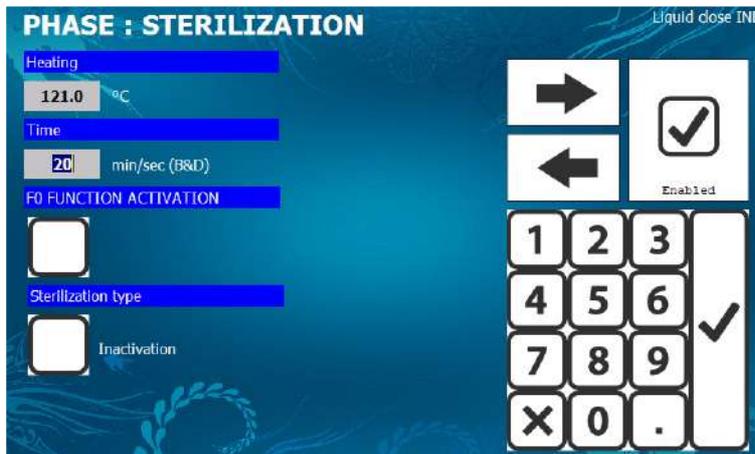


The following parameters can be modified:

Heating	chamber and jacket regulation temperature
Stage maximum time	maximum time to reach the set point.
Pressure rate:	It's possible to manage the up-curve of the pressure in Kpa/sec

PHASE 5 – STERILIZATION

This stage maintains the sterilization temperature for the preset time.



The following parameters can be modified:

Heating	chamber regulation temperature
Time:	stage time. For the Bowie & Dick test the sterilization time is expressed in seconds

F0 function habilitation

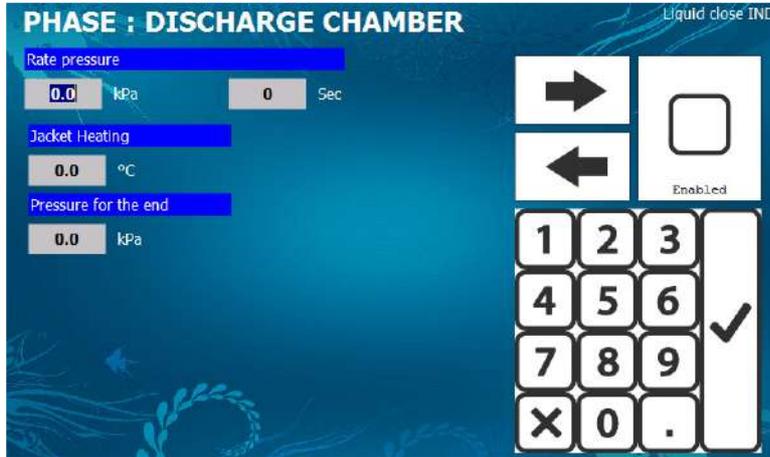
The icon or indicates the enablement of the F0 function

Sterilization type

The icon or means the habilitation of the inactivation function. This function allows the sterilization of the condensate inside the sterilizer, it's used for high pathogen material

PHASE – CHAMBER DRAINING

This stage allows the gradual draining of the pressure.

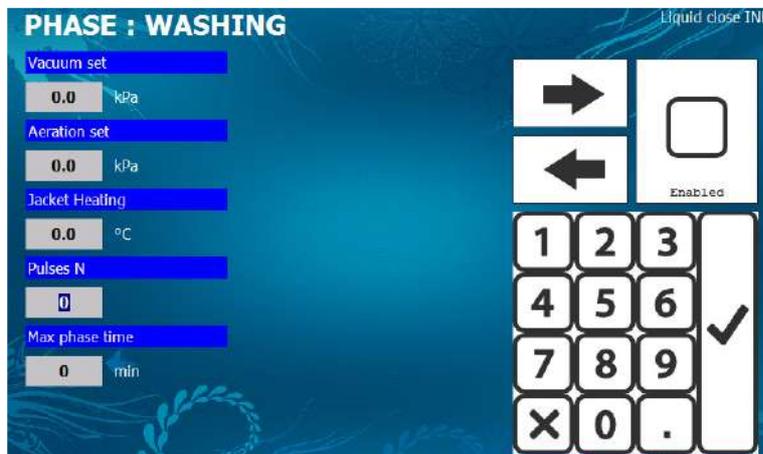


The following parameters can be modified:

- Pressure ramp / Time indicates the ramp down of the pressure in the chamber down to the set point in kPa/sec
- Final pressure indicates the pressure to be reached

PHASE - WASHING

This stage makes it possible to carry out alternating vacuum/air pulses to increase the drying efficiency of the load after sterilization



The following parameters can be modified:

- Vacuum and aeration set points chamber vacuum/aeration value

Jacket heating	jacket regulation temperature
No. pulses	number of vacuum repetitions
Stage maximum time	maximum time to reach the set point

PHASE – DRYING

This step allows the drying of the load after sterilization remaining under a vacuum



The following parameters can be modified:

Vacuum set point	vacuum value that the pressure in the chamber must reach
Jacket heating	jacket regulation temperature
Time	duration of the time remaining under vacuum
Stage maximum time	maximum time to reach the set.

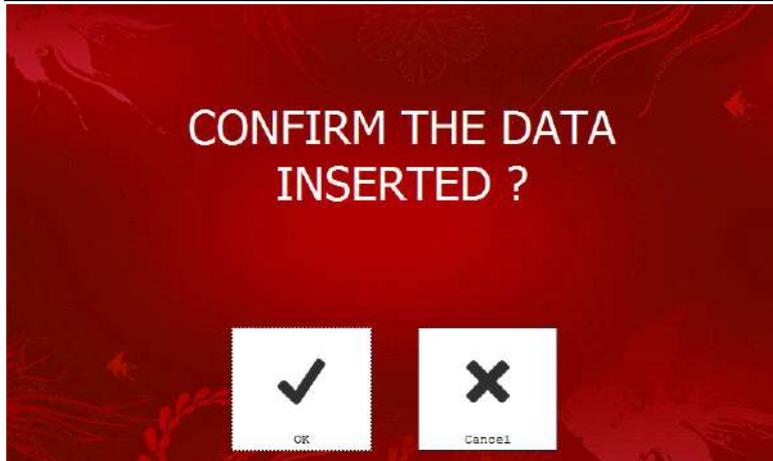


The icon  or  indicates the enablement of the Set Point Stop function, the vacuum is stopped at the pressure value indicated.



Pressing  accesses the confirmation of the data.

The screen will show:



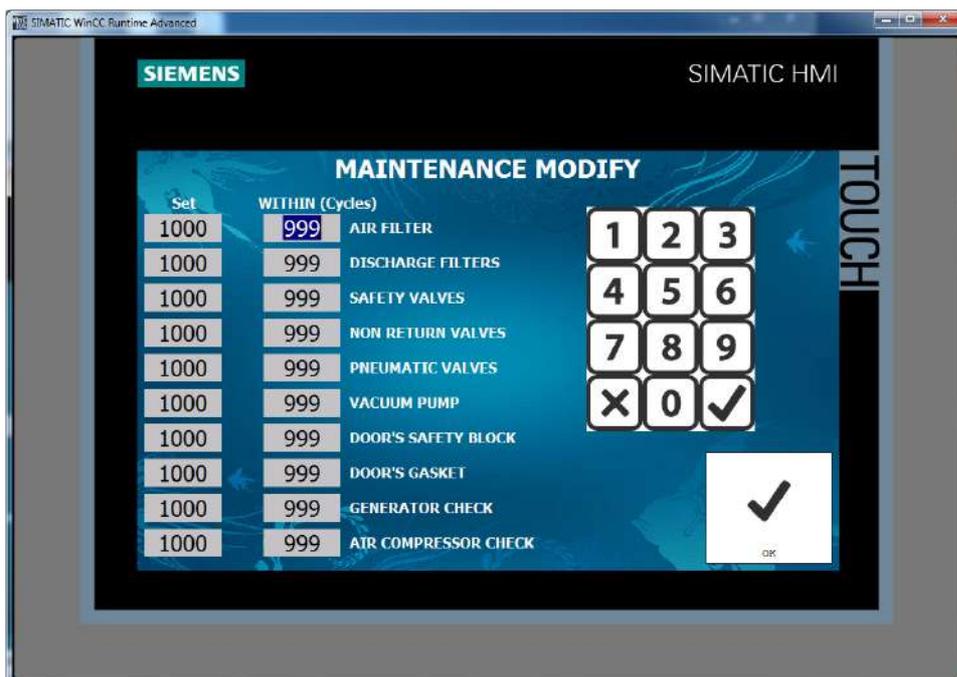
Press  to confirm the data entered.

Press  to cancel

after the selection the screen will return to the selection menu (sect.3.3).

3.8 - CHANGING THE MAINTENANCE PARAMETERS

The screen will show:



select the component and enter the value of the starting cycles. This value will be decremented each time you start a sterilization cycle. When zero is reached, the need to carry out maintenance in the cycle start page will be indicated.



Press to confirm.

3.9 - OPERATOR CONFIGURATION

This function makes possible the configuration of the operators with the possibility of assigning them a code, a name and a set of operational functions.



To change the data for an operator, enter the operator number and press . The code, name and authorizations associated with the operator will be displayed. At this point you need only select the "code" field to change the password and authorizations required. Press the "?" to get a reminder of the functions:

1	Start standard cycles
2	Start B&D / vacuum test
3	Start user cycles
4	Edit user cycles
5	Edit standard cycles
6	Change date and time
7	Change heating type
8	Change maintenance and forcing outputs
9	Change general parameters
10	Change printing parameters
11	Reset alarms
12	Manual cycle advance
13	Calibration



To change the operator name select and in the page



Touch the “name” field and enter the name of the operator .

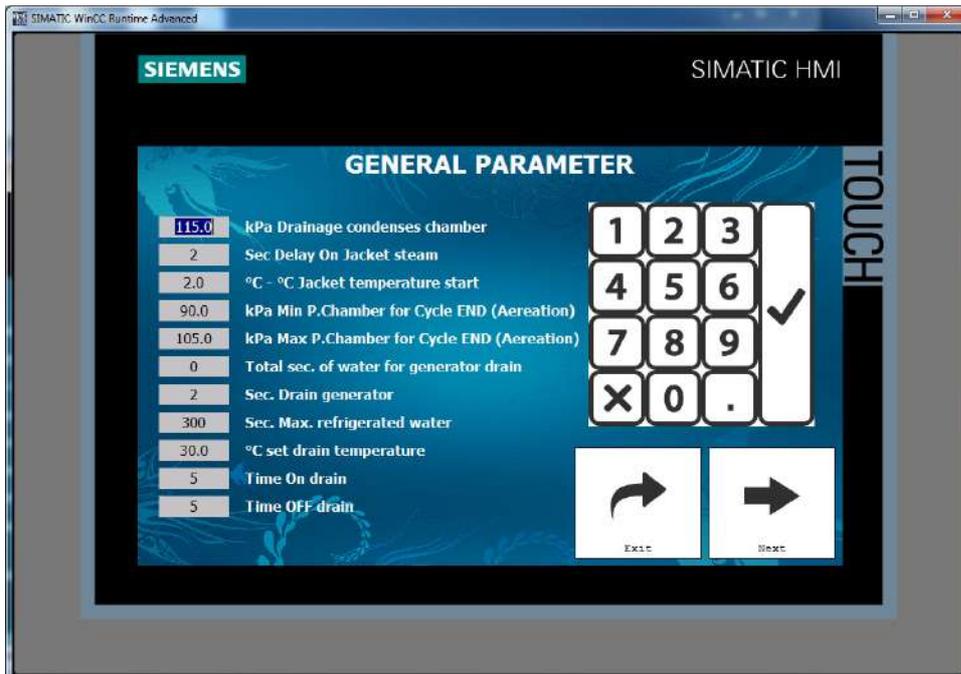
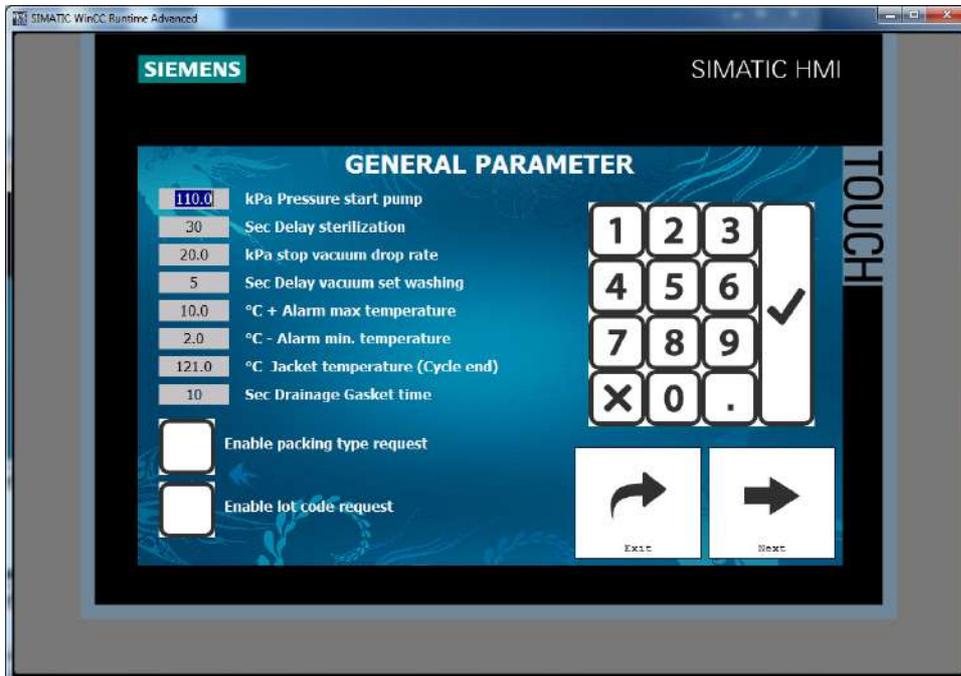
press  to return to the preceding menu.

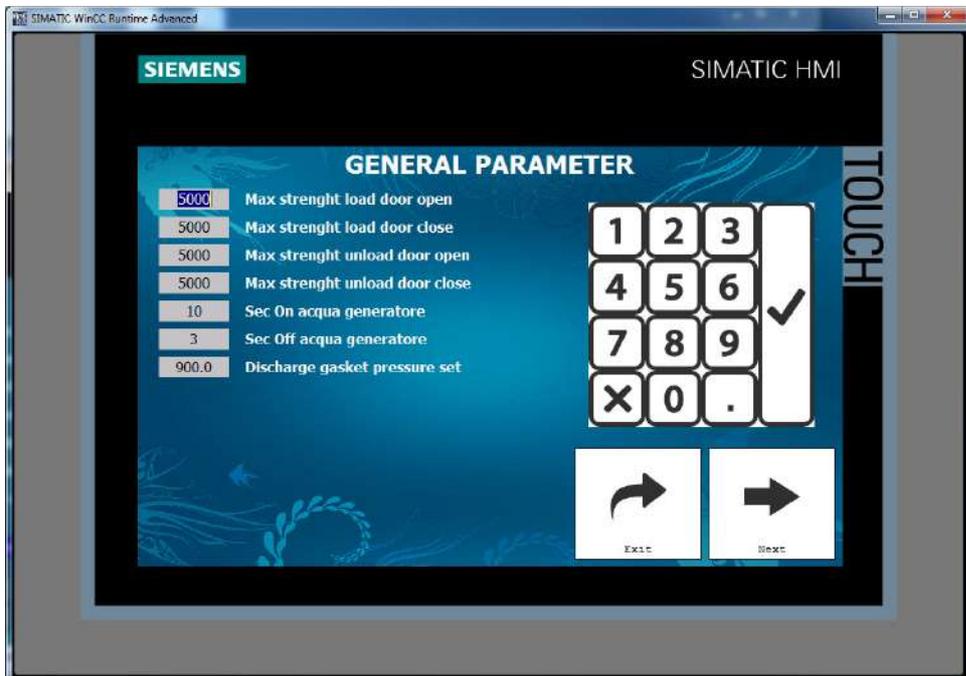
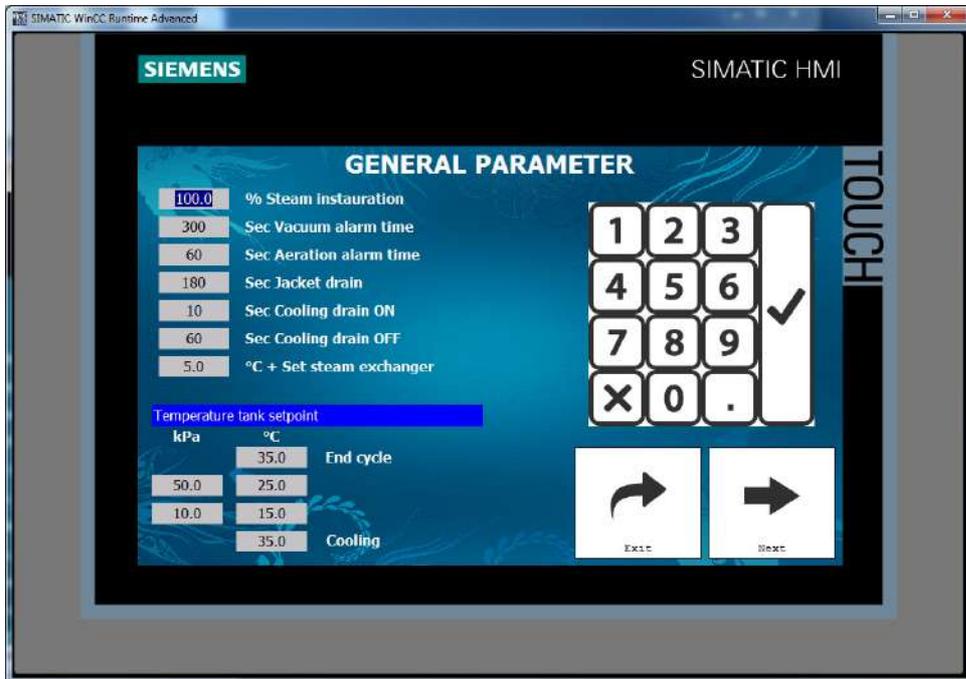
3.10 - GENERAL PARAMETERS MENU

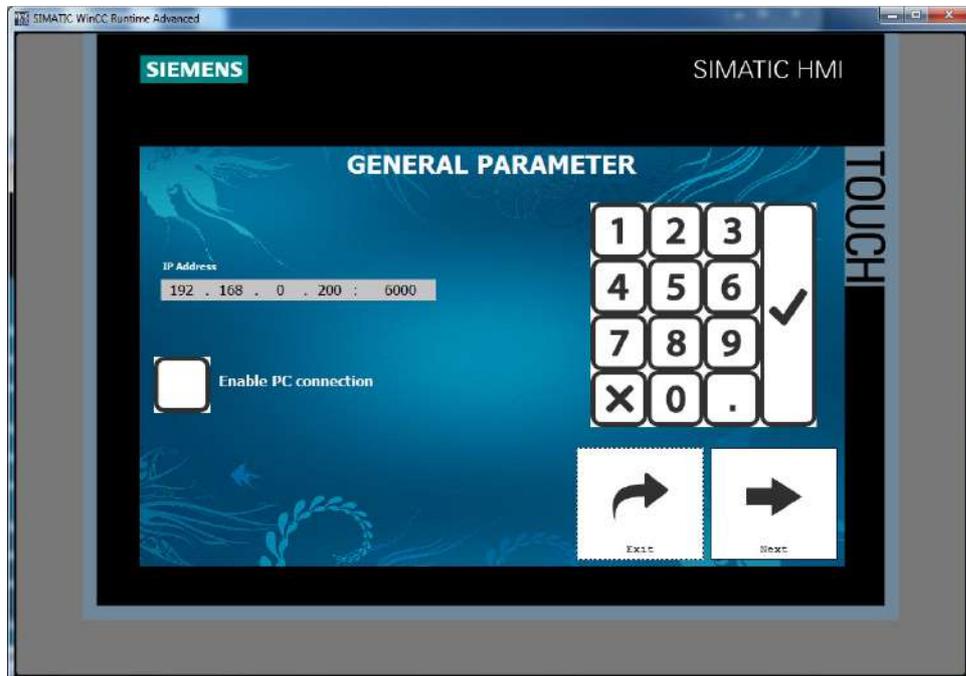
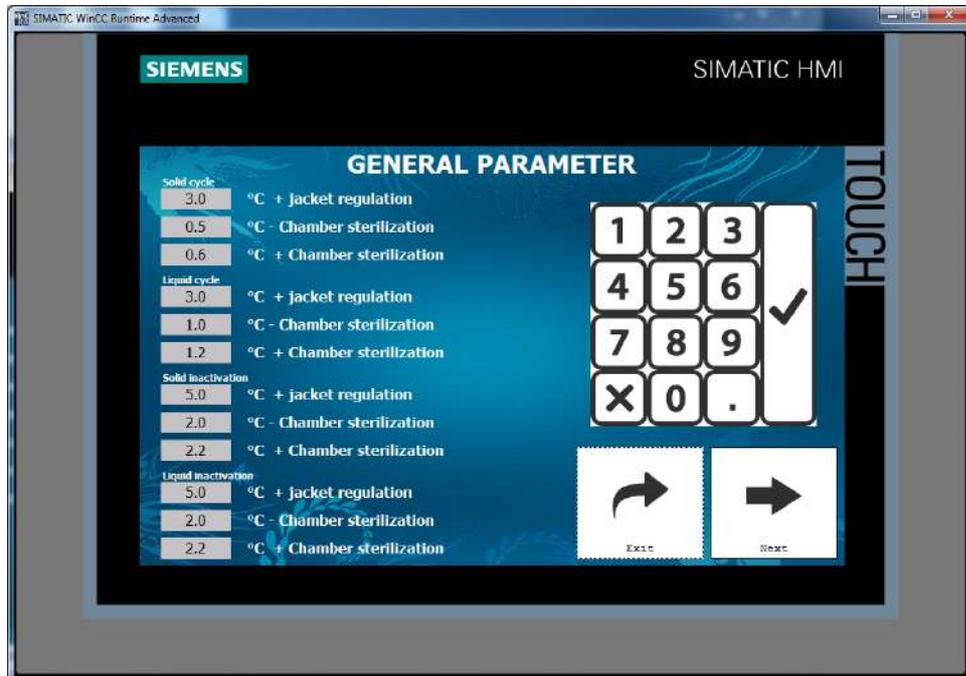
This function allows the changing of the sterilizer's operating parameters.



WARNING! The changing of the operating parameters must be done by qualified personnel. Improper use of this function can result in damage to the sterilization process and cause injury to personnel.







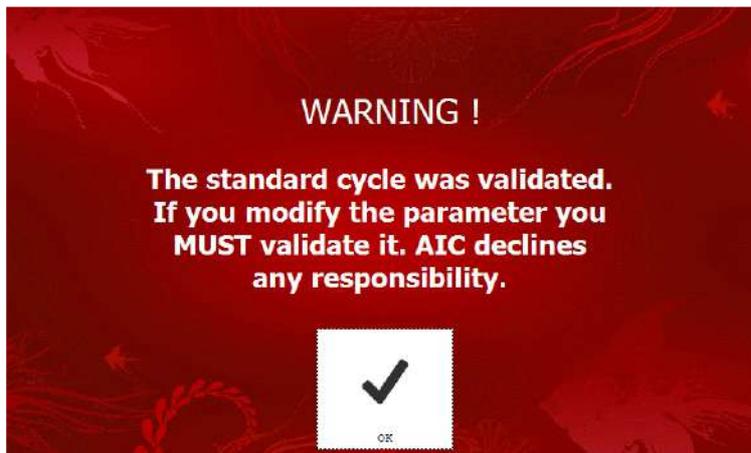
to change the parameters, selected the desired field and enter the value using the numeric keypad.

Use the arrows  and  to select the parameters page and press  to return to the preceding menu.

3.11 - CHANGING THE STANDARD CYCLES

Press  from the selection menu (sect.3.3).

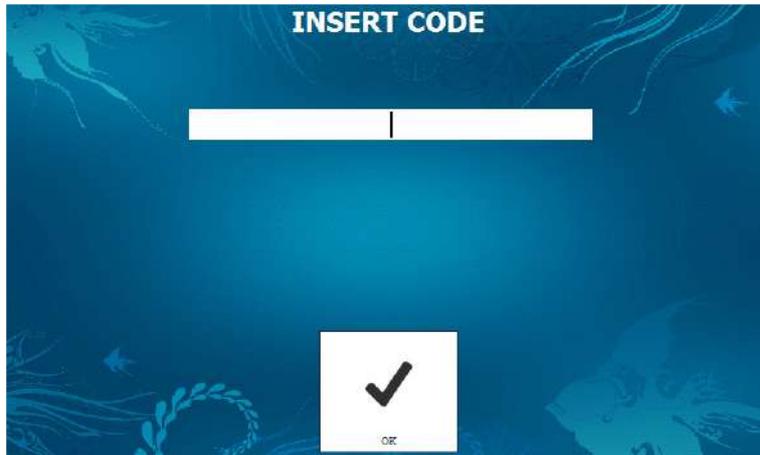
The screen will show:



This message is a reminder that making changes to the standard cycle requires validation for compliance with the regulations in force.

Press  to continue.

The screen will show:



Enter the code for changing the standard cycles using the alphanumeric keyboard as described in sect. 3.1.1.

This code is issued upon request made to SMI Medical specifying the ID number that appears on the printout (ES: ID1309001)

The screen will show:



Select the standard cycle you wish to modify, press  and proceed as specified for the changing of parameters. (Sect. 3.7).

3.12 – CONFIGURATION OF STANDARD CYCLES



Press from the selection menu (sect.3.3).

The screen will show:



Touch the screen to select the cycle to enable/disable from the “select cycle” menu.

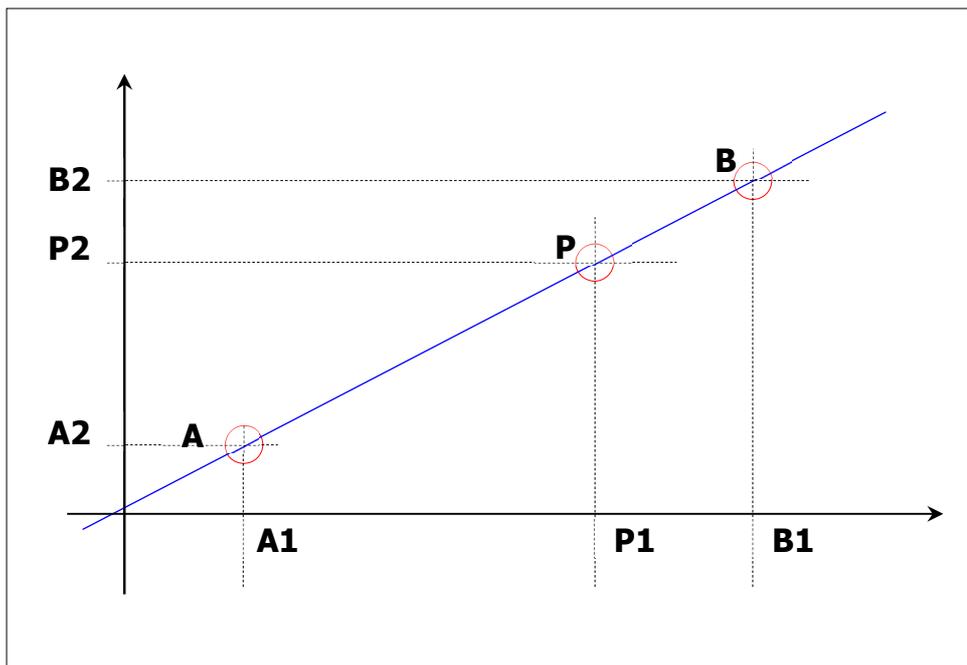
3.13 - CALIBRATION



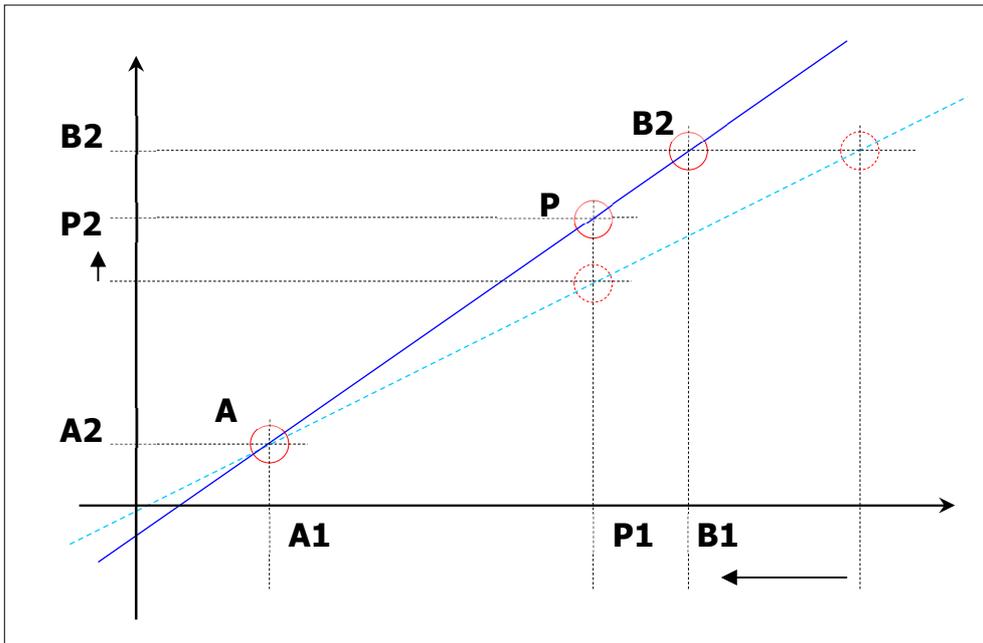
WARNING! The calibration procedure must be carried out by qualified personnel. Improper use of this function can result in damage to the sterilization process and cause injury to the personnel.

NOTE: This function requires certified reference instrumentation (e.g. temperature well, sample pressure gauge, etc.)

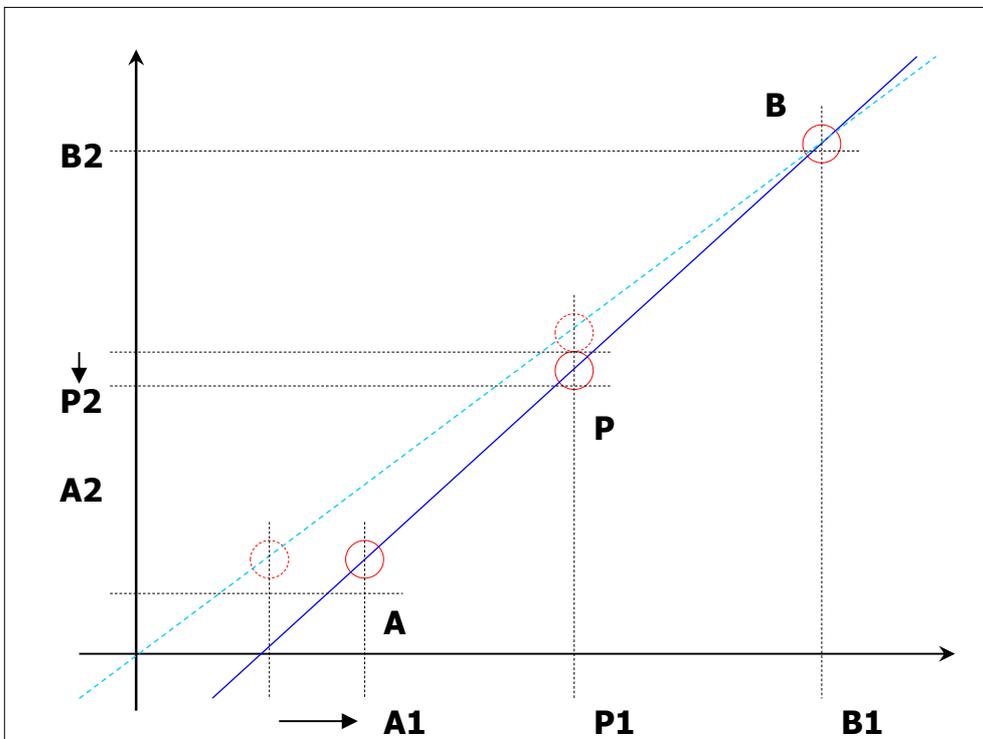
The calibration function acts on the analog temperature and pressure values that are detected by the sterilizer. These analog values are converted with a linearization function as in the following diagram:



where points A2 and B2 are the extremes of the input value to be converted and A1 and B1 are the corresponding output extremes. Taking an input value P2, its corresponding output value P1 is the projection of point P2 on the axis generated by A1-A2, B1-B2 at points A and B. Thus a change in the abscissa of points A1 and B1 will change the A1-A2, B1-B2 axis and the resulting projection of P2 on point P.



This is the axis that results from changing point B1. To get the same point P1 on the abscissa, the value of P2 must approach point B2 on the ordinate.



This is the axis that results from changing point A1. To get the same point P1 on the abscissa, the value of P2 must approach point A2 on the ordinate.

The temperature scale is from 0 to 155.0°C, expressed in tenths of a degree.

Considering a possible negative error in the conversion of the input signal, the value of A1 (zero) can be negative. The values for the temperature of A1 and B1 will therefore be:

A1 = 0.0
B1 = 155.0

The pressure scale is 0 – 600 kPa , expressed in tenths of kPa.
As with temperature, A1 can be negative. The pressure values of A1 and B1 will therefore be:

A1 = 0.0
B1 = 600.0

The procedure for changing values A1 and B1 is given below.



Press  to enter in the calibration function from the selection menu (sect. 2.14). You will be prompted for the operator code (sect. 2.7), and if the function is enabled for the operator (Table, sect. 1.7) the screen will show a warning message:



Press  to continue,

The screen will show:



Select the component to be calibrated from among the following:



Chamber pressures, Jacket and air check.



Chamber temperature, product, air-check, water tank, vacuum filter, heat exchanger, condensate



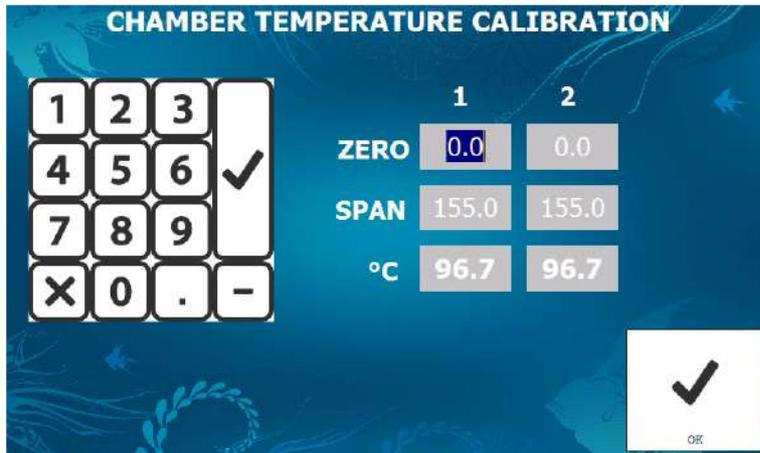
Press to exit

The procedure to calibrate temperature and pressure are the same for all indicated measures. It follows the detail for chamber and jacket

CALIBRATION OF THE CHAMBER TEMPERATURE.

There are two chamber temperature sensors, both positioned in the drain, thus it is necessary to remove them from their position and put them in a reference temperature system.

Wait for them to stabilize and then proceed with the calibration:



The display shows the values for ZERO (A1) and SPAN (B1) of the first sensor on the left and the second on the right. Change the ZERO and SPAN values, checking the result obtained P1 by selecting the parameter and entering from the numeric keypad.

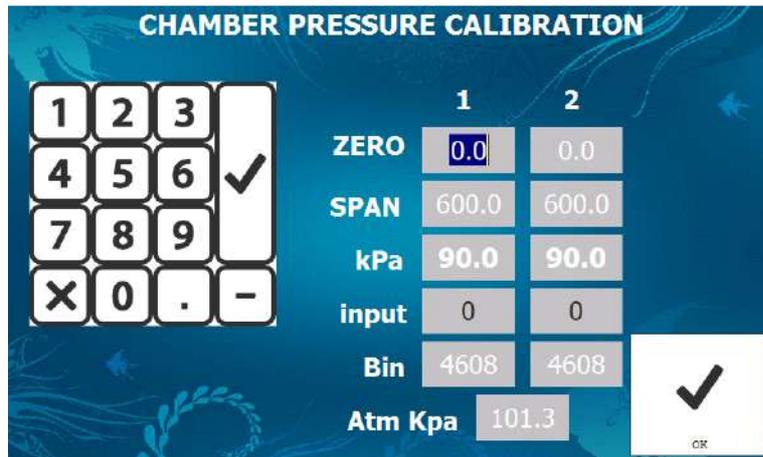
NB: The changes applied to sensor values A1 and B1 are immediate

To determine the values of A1 and B1 several points of reference must be checked, such as:

- 0°C
- 121°C
- 134°C
- 150°C

CALIBRATION OF THE CHAMBER PRESSURE.

As with temperature, the pressure is also detected by two sensors. It will therefore be necessary to connect a pressure measuring instrument to the chamber for comparison, or to apply a reference pressure directly to the sensors.



The display shows the values for ZERO (A1) and SPAN (B1) of the first sensor on the left and the second on the right. Change the ZERO and SPAN values, checking the result obtained P1 by selecting the parameter and entering from the numeric keypad.

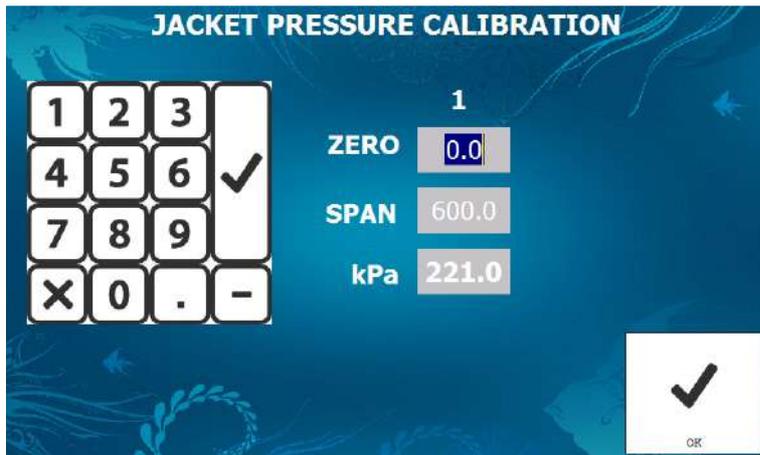
NB: The changes applied to sensor values A1 and B1 are immediate

To determine the values of A1 and B1 several points of reference must be checked, such as:

- 0 kPa (-1.0 bar)
- 100 kPa (0.0 bar) atmospheric pressure
- 200 kPa (1.0 bar)
- 300 kPa (2.0 bar)
- 450 kPa (3.5 bar)

CALIBRATION OF THE JACKET PRESSURE

The jacket pressure is also detected by a sensor. In this case also it will be necessary to connect a pressure measuring instrument for comparison, or to apply a reference pressure directly to the sensor.



The display shows the values for ZERO (A1) and SPAN (B1) for the sensor. Change the ZERO and SPAN values, checking the result obtained P1 by selecting the parameter and entering from the numeric keypad.

NB: The changes applied to sensor values A1 and B1 are immediate

To determine the values of A1 and B1 several points of reference must be checked, such as:

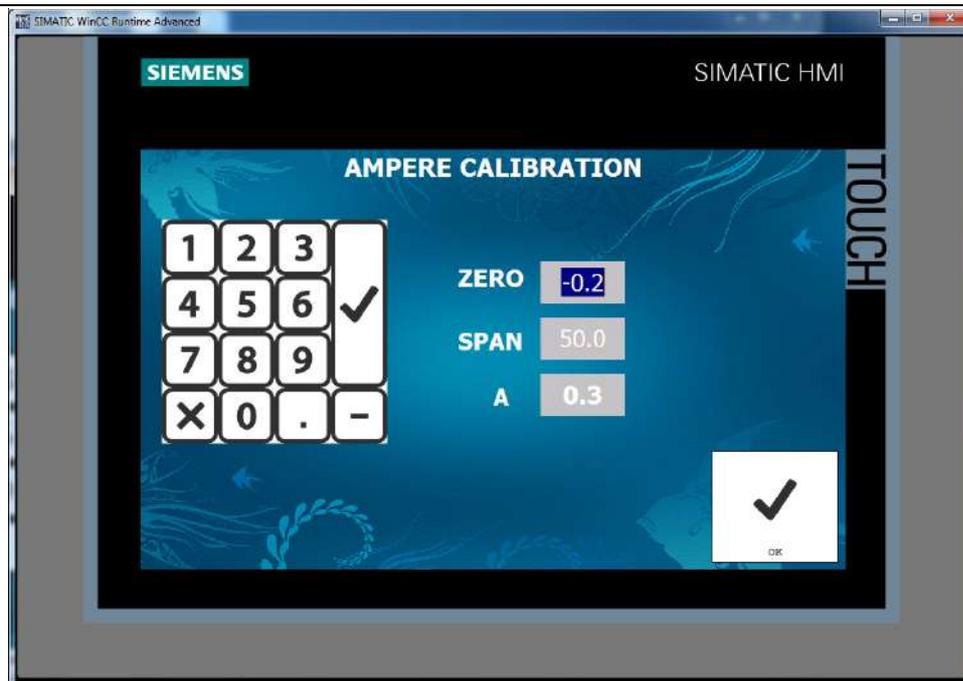
- 0 kPa (-1.0 bar)
- 100 kPa (0.0 bar) atmospheric pressure
- 200 kPa (1.0 bar)
- 300 kPa (2.0 bar)
- 450 kPa (3.5 bar)



Pressing the  key returns you to the selection menu.

CALIBRATION OF THE SHREDDER MOTOR AMPERE

The shredder motor ampere is check by ampere shunt. In this case, also it will be necessary to connect an ampere clamp instrument for comparison.



The display shows the values for ZERO (A1) and SPAN (B1) for the sensor. Change the ZERO and SPAN values, checking the result obtained P1 by selecting the parameter and entering from the numeric keypad.

NB: The changes applied to sensor values A1 and B1 are immediate

To determine the values of A1 and B1 several points of reference must be checked, such as:

- 0 A
- 5 A
- 10 A
- 15 A
- 25 A

Pressing the



key returns you to the selection menu.

3.14 - MANUAL ACTIVATION OF THE OUTPUTS



WARNING! The forcing outputs procedure must be carried out with maximum caution by qualified personnel. Improper use of this function can result in damage to the sterilization process and cause injury to the personnel.



This function must be used solely for maintenance purposes and only by qualified technical personnel.

NB: This function cannot be accessed during the running of a cycle!

The procedure of forcing the outputs acts directly on the internal functions of the PLC, temporarily allowing the operator to manually activate the output bits through the touch screen user interface.



Pressing

the screen will show the following warning:



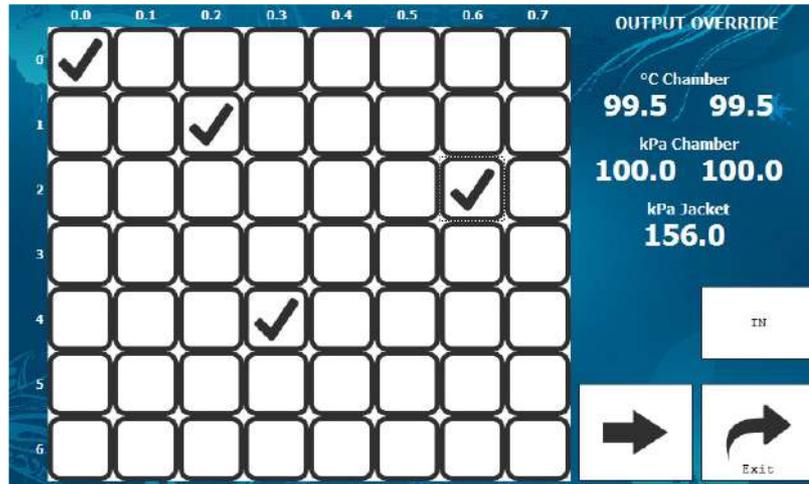
Press



to enter the outputs activation page.

All the outputs will be set at their default value (OFF)

The screen will show:



It is possible to activate each single bit of channels 0,1,2,3,4 and 5; each bit has its own function inside the machine system, and refers to the wiring diagram given in the appendix.

Locate the output to be activated/deactivated in the grid and enter it.



The icon  or  indicates the activation of the output.



Press  to return to the main page.

4.0 MAINTENANCE

4.1 - GENERAL MAINTENANCE INFORMATION

All information provided in this chapter is provided for qualified personnel who have had suitable training regarding electrical and piping systems for doing repair and maintenance work in the event of various types of breakdowns and failures.



WARNING! The door is a moving mechanical part that is very heavy. Use extreme caution when servicing.



WARNING! The sterilizer does not have a master switch. Cut off power before the sterilizer before performing electrical maintenance.



WARNING! Some internal parts of the sterilizer (pipes, valves, various surfaces) are at high temperatures.



WARNING! Wear individual protection against burning or contact with infected fluids or materials.



WARNING! Switch off the electricity power from the main switch before start any maintenance or repair. Be sure that anyone cannot switch on the device during the maintenance or repair procedure.

4.2 - SCHEDULED MAINTENANCE

Data on preventive maintenance can be accessed from the main menu (sect. 2.3). This function makes it possible to check the correct operation of the components and alerts you to the limits of operation of the components under control.



Press  from the main menu (Sect. 2.3).

The screen will show how many cycles are left before replacing or checking the various components.



Press to return to the main menu.

To access any machine component the maintenance person must be provided with the key for opening the module and the tools to remove the side panels of the machine, after taking all the necessary safety measures in order to avoid being in direct contact with the elements that are live, moving or at high temperature. After checking the actual status of the component, the maintenance person can enter, from the main menu, the “technical functions” chapter and reset the reference values for the next maintenance (see sect. 3.8).

4.3 - ADDITIONAL USEFUL MAINTENANCE TIPS

In addition to that indicated by the touch screen, it is recommended that the following preventive maintenance operations be carried out periodically:

CHECK Ad ogni avvio del ciclo verificare che la griglia non sia occlusa da materiale. Eventualmente pulirla con l’ausilio di una spazzola a maglie metalliche.

CHECK Ad ogni avvio del ciclo verificare che le guarnizioni di tenuta siano perfettamente pulite. Nel caso pulire le guarnizioni con un panno morbido ed acqua calda. Nel caso di sporco eccessivo utilizzare anche un sapone neutro.

CHECK the perfect functioning of the control components such as: pressure gauges, vacuum manometers, recorders, printers, thermostats, pressure switches, vacuum switches, automatism, etc., with any necessary adjustments or fine-tuning.

CHECK the piping system, checking seals and the elimination of any leaks.

CHECK and clean filters.

CHECK the electrical system and connections.

CHECK the safety systems, safety valves, door piston seals, clean the seats of the door seals.

CHECK and replace, if necessary, tap and valve gaskets.

CHECK sensors and resistance thermometers.

CHECK and lubricate if necessary the moving mechanical parts.

CHECK the air compressor and top up the oil level.

CHECK pilot valves and replace ring seals.

4.4 - CLEANING THE STERILIZER

CLEANING THE STERILIZATION CHAMBER: to be done in the following manner:

- When the chamber is in normal conditions, wash with warm water and neutral shampoo; do not use sharp or pointed utensils; rinse.
- When the chamber has accumulations of surface deposits, wash with warm water and non-corrosive or neutral detergents. Do not use sharp or pointed utensils. Rinse.
- When the chamber is heavily encrusted with deposits, wash as in the first case and apply a passivating paste found on the market, following the manufacturer's instructions. Leave the paste in contact with the surface to be cleaned depending on the intensity of the action required, and then remove it thoroughly with water, especially from the corners. Do not use sharp or pointed utensils. Repeat the washings.

CLEANING THE PANELS: use a soft cloth and a mild solution for stainless steel.



WARNING! It is recommended that the seats of the door seals be cleaned periodically for longer life

4.5 - DOOR SEAL CLEANING OR REPLACEMENT

For proper sterilizer operation, the door seals should be periodically cleaned and replaced.

To do this, proceed as follows:

- 1- remove the seal from its seat using utensils that are not sharp or pointed
- 2- clean the seal with hot water and neutral soap.
- 3- clean the seal seat with a cloth wetted with hot water and a blunt utensil.
- 4- reinsert the seal manually.

4.6 - BACTERIOLOGICAL AIR FILTER REPLACEMENT

To replace the bacteriological air filter, proceed as follows:

- 1- Start a Sterilization Filter cycle
- 2- open the module panel using the key
- 4- open the front panel of the sterilization chamber
- 5- open the housing of the bacteriological air filter using suitable tools
- 6- insert the new filter
- 7- close the housing and close the sterilizer, working in reverse order

4.7 - STEAM FILTER REPLACEMENT (Only a steam heating sterilizer)



WARNING! Close the steam inlet before proceeding with the replacement of the component.

- 1- turn off the sterilizer using button 4, Fig.5
- 2- open the sterilization chamber door on the loading side
- 3- open the module panel using the key
- 4- remove the locking screw on the side of the front panel
- 5- open the front panel of the sterilization chamber
- 6- close the steam inlet valve
- 7- loosen the 12 screws on the filter housing flange.
- 8- unscrew the 12 screws on the filter housing flange
- 9- remove the cartridge and replace it or if possible clean it with compressed air or descaling solutions
- 10- refit the screws into the flange
- 11- reopen the steam valve and check the tightness of the flange
- 12- close the sterilizer, working in reverse order



WARNING! When the steam inlet valve is closed the section of pipe up to the pneumatic valve remains under pressure. If you proceed immediately with the replacement of the filter by loosening the screws, wait until the steam is released from the pipe through the flange, thus using the necessary caution. If you wait for the filter to cool before replacing it, the part of the pipe which was under pressure may be under a vacuum due to condensation, thus even after removing the screws it will not be possible to move the flange. Open the steam inlet valve slowly to compensate for the pressure loss in the pipe.

4.10 – FUSE REPLACEMENT



WARNING! The sterilizer does not have a master switch. Cut off power before the sterilizer before performing electrical maintenance.

The fuses in the electrical panel are located in the fuse block. Replace fuses following this procedure:

Turn off the sterilizer.

Open the module panel using the key

Open the electrical panel with its key

Locate the fuse to be replaced. The amperage is described in the wiring diagram.

Open the fuse block pushing the tab "A" downward.
Remove the bad fuse and insert the new one.
Close the fuse block pushing the tab "A" upward.
Close the electrical panel
Close the module panel

4.11 – RESTORING THE THERMAL PROTECTION DEVICES



WARNING! The sterilizer does not have a master switch. Cut off power before the sterilizer before performing electrical maintenance.

The motor thermal protection devices in the electrical panel can be restored by following the procedure described below:

Turn off the sterilizer.

Open the module panel using the key

Open the electrical panel with its key

Locate the thermal protection device to be restored

Close the electrical panel

Close the module panel

4.12 - PRINTER

4.12.1 - PAPER ROLL REPLACEMENT (FIG.18)

To change the paper roll, proceed as follows:

1. open the printer door and insert the paper roll, in the proper direction of rotation
2. insert the end into the mouth of the printing mechanism
3. Press the FEED button and allow a few centimeters of paper to come out from the printer
4. insert the end into the slot in the printer door and close the door.

4.12.2 - CHANGING THE INK RIBBON

To replace the ink ribbon, proceed as follows:

1. open the printer door and remove the used cartridge, pressing on the spot marked PUSH
2. insert the new ribbon, making sure that it is positioned properly
3. tighten the ribbon by turning the knurled knob and close the printer door.

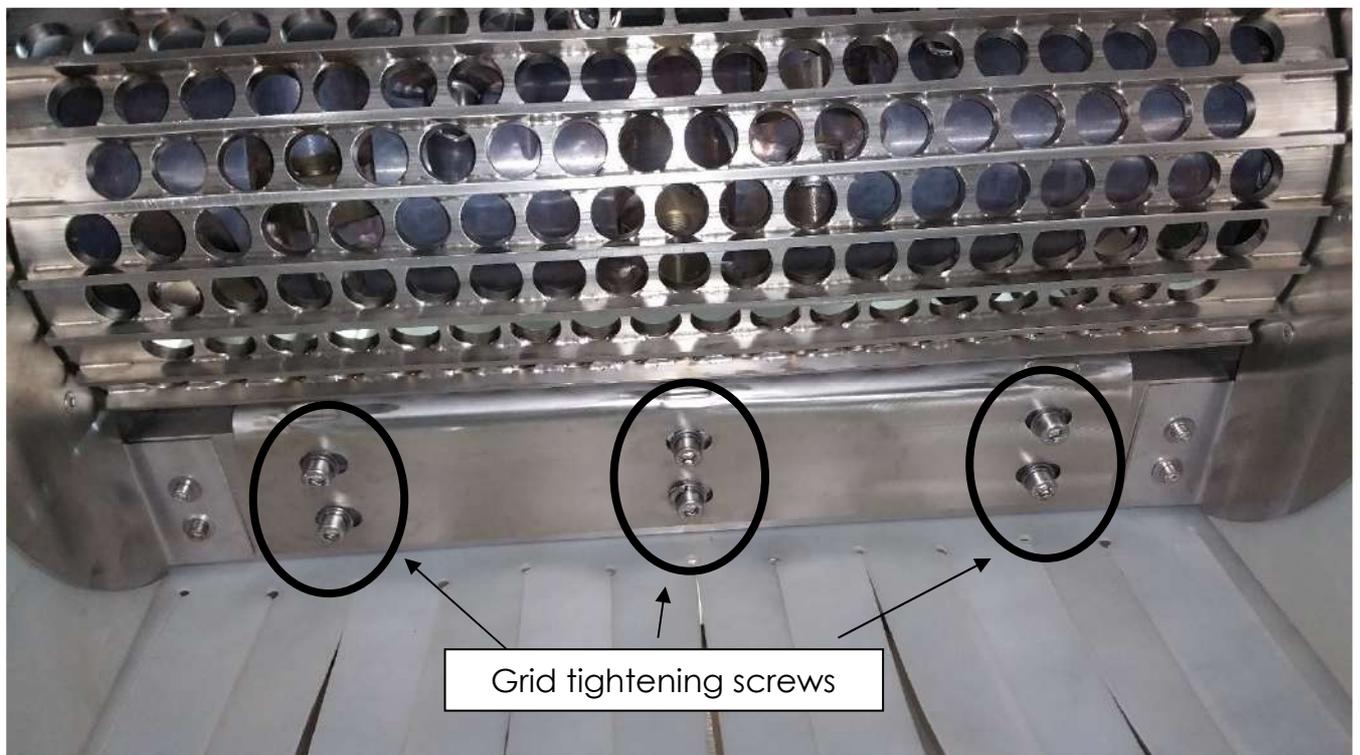
4.13 EXTRAORDINARY MAINTENANCE AND REPAIRS

Extraordinary maintenance and repairs must be carried out by technical personnel that is qualified or authorized by SMI Medical.

If components are replaced with parts not authorized by the manufacturer of the equipment, the SMI Medical company declines any liability upon the occurrence of any problems.

Grid cleaning.

The grid is fixed to the lower part of the shredder cylinder using the screws shown in the photo:



WARNING! Make sure the device is turned off

Remove the screws from both sides and remove the grid.

Proceed with cleaning by brushing with neutral detergents.

To reassemble, reinsert the grille and fix it with the screws, proceeding with cross-tightening.

To keep the grate clean it is necessary to insert about ten hardwood blocks of about 20x20cm into the shredding chamber. Start the cleaning cycle and wait until the shredding is complete. If necessary, repeat the procedure.

Replacing the strips (if present)



WARNING! Make sure the device is turned off

The lateral silicone conveyor strips are fixed using the screws shown in the photo:



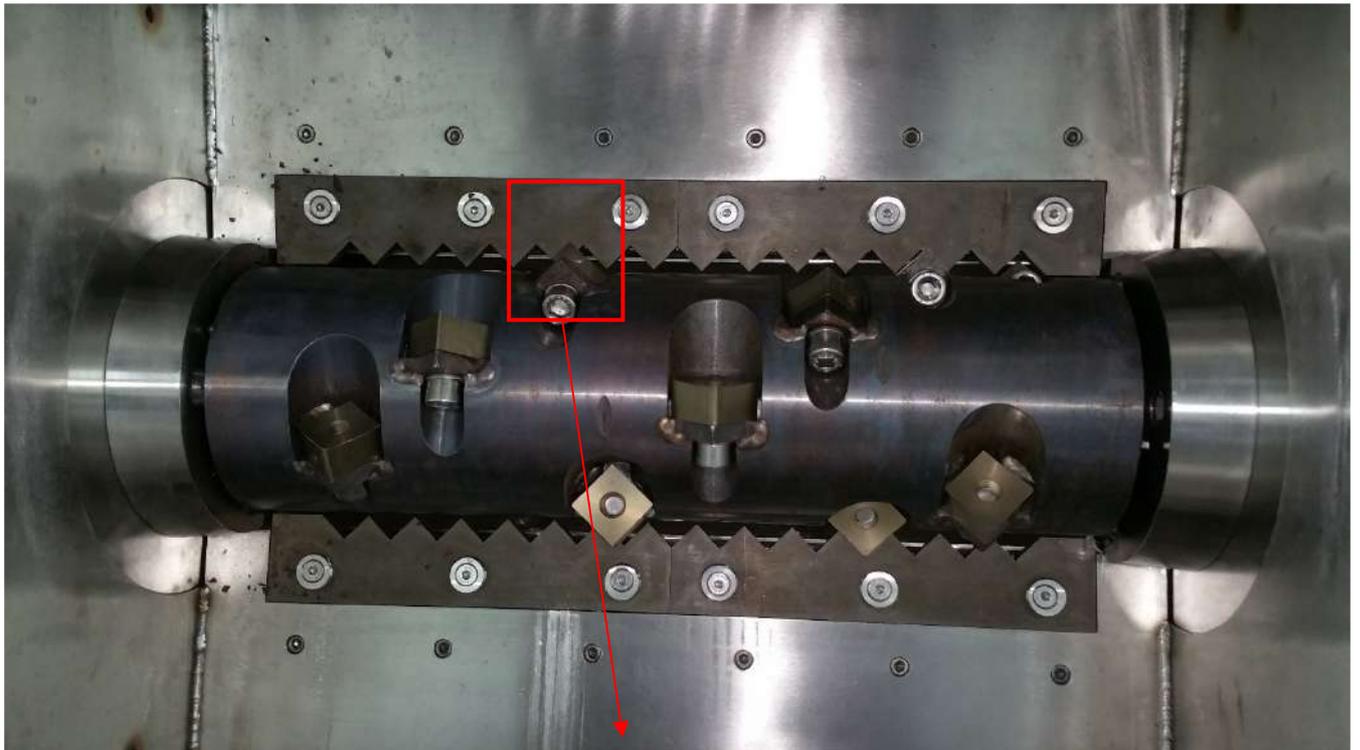
Shredder teeth replacement



WARNING! Make sure the device is turned off

The tines can be accessed from the top (shredding chamber) or from the bottom after removing the grate. Act on the tightening bolts shown in the photo.

The shredder teeth can be used twice by rotating them 180° before replacing them.



Check shredder transmission oil

The shredder shaft is connected to the motor via a mechanical reduction gear. This reducer has gears in an oil bath which must be checked using the sight glass shown in the photo:



4.14 - TROUBLESHOOTING TABLE

PROBLEM	PROBABLE CAUSE	REMEDY	
Jacket does not pressurize	No electrical power	Check arrival of power to the contactor and the contacts, the fuses in the electrical panel, the minimum water level device (if water is missing, the heating elements turn off)	
	No compressed air	Check arrival of air from the network or compressor	
Insufficient vacuum	Vacuum pneumatic valve leak	Clean the seat or replace the valve	
	Air pneumatic valve leak	Check pilot electrovalve; if necessary replace the coil	
	Aeration check valve leak	As above	
	Steam pneumatic valve leak	As above	
	Vacuum pump motor seized	Check the pump.	
	Seal for door(s)	Check the condition of the seal and if necessary clean and reinsert in its seat.	
Low steam pressure in chamber	Insufficient pressure from the external steam network (for steam operation)	Check the pressure in the network	
	No water in the generator**	Check the water level in the generator	
	Generator** heating element burnt out	Check and/or replace	
	Chamber steam inlet valve	Check and if necessary adjust the opening, slowly turning the valve handle	
	Drain pneumatic valve leak	Check and if necessary replace the seal (or valve)	
	Faulty temperature sensor	Check the cable for wear; replace	
	Steam leaking from door	Check the seal; replace if worn	
	Chamber condensate trap clogged	Check and if necessary unclog	
	Vacuum pump does not start	Pump thermal protection device	Check the vacuum pump motor; check that there is no resistance to rotation, if necessary, press the button on the thermal protection device inside the electric panel, restoring the contacts.
		Water loading pump does not start	Investigate the cause of the fault; restore contacts by pressing the button on the thermal protection device inside the electric panel; or replace the fuse.
Shredder motor blocked	Motor thermal protection device; motor burned out; gear blocked by material.	Investigate the cause of the fault; remove the material that block the gear; restore contacts by pressing the button on the thermal protection device inside the electric panel.	

5.0 ACCESSORIES

5.1 - MAGNETIC WATER SOFTENER

The use of this accessory is recommended for the treatment of the water supply that feeds the sterilizer.

It prevents the formation of scale in the water circuit in new installations, and in installations already in operation, it aids the progressive dissolution of existing scale incrustations.

It also eliminates the necessary periodic maintenance operations for the elimination of scale and protects the inside of the pipes from rusting.

The best performance of the device is obtained under the following conditions:

- max. pressure: 20 Atm
- max. temperature: 250°C
- water pH: 7 – 9
- optimal velocity: 1 – 2 m/sec.
- capacity: there are no limits

Technical information

The softener has to be periodically subjected to an inspection that consists exclusively of cleaning the inner core, which over time may have become covered with a patina or metal particles that make it function less effectively.

For cleaning, wire brushes **MUST NOT** be used, as this would immediately make the device unusable. Instead solutions must be used that can be obtained from the supplier or, alternatively, wet a cloth with lemon juice or vinegar and run it over the inner core. This action will remove the plaque as well as any ferrous deposits that will be accumulated over time.

For any other operations beyond the above, please contact the supplier's support service, which will send a technician.

5.2 - SOUNDPROOFED ELECTRIC COMPRESSOR

The electric compressor is necessary if there is no compressed air network, for supplying the pneumatic system. It has 0.5 HP motor, and it is installed inside the sterilizer cabinet.

Suggestions for best performance

- a)** Expel periodically (every weekend if possible) the condensate that stagnates in the tank.
- b)** To do this, pressurize the tank, remove the plug from the electrical outlet, move the compressor to an area where the release of water will not damage the floor, tilt the compressor slightly forward and unscrew the valve on the bottom on the tank.
- c)** Periodic checks (every week) of the oil level can be easily done with the level indicator (if necessary, add oil).
- d)** The compressor is equipped with a motor protector that stops it automatically in case of overload or when the temperature of the compressor reaches 100–110°C. If this occurs during normal use, turn the switch to "OFF" and let it cool for about ½ hour.

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- e) The motor protector will automatically reactivate the contact when the temperature reaches about 60–70°C.
 - f) Turn the switch back to "ON" and check that everything functions properly.
 - g) Always work with the compressor on a flat surface.
 - h) Do not inspect or repair the compressor when it is connected to the electrical power outlet.

To top up the oil

- Remove the rubber cap on the intake pipe, remove the suction filter and nozzle from the nylon bag, and screw the nozzle onto the bottle of oil supplied.
- Proceed with the introducing of the oil through the suction pipe, until the optimum level is reached, as shown on the plate. Keep the oil that remains in the bottle for topping up in the future.
- Then, by simply pressing on the pipe, insert the suction filter; after filling with oil the compressor must not be turned upside down or tilted excessively, to prevent oil from spilling out.
- Recover the oil in the filter every month by opening the valve, with the compressor running, for about 1 minute.

NEVER USE ANY OIL OTHER THAN THAT RECOMMENDED BY THE MANUFACTURER.

5.4 - DRAIN COOLING DEVICE

The device allows the control of the sterilizer drainage temperatures; in fact all the fluids being drained (condensate and water) pass through this container, in which they are mixed with cold water before being discharged. The drainage temperature can be set by the pressure control switch in the junction box. The sterilizer is shipped with the drainage temperature set at 60°C.

REQUALIFICATION

TABLE - FREQUENCY OF PERIODIC REQUALIFICATION OF PRESSURE EQUIPMENT
 MANUFACTURED IN COMPLIANCE WITH DIRECTIVE PED 97/23
 (Article 10, paragraphs 3 and 5)

D.Lgs. no. 329 of 01-12-2004

EQUIPMENT/ASSEMBLIES CONTAINING FLUIDS IN GROUP 2 (D.Lgs. 93/2000 Art. 3)	
<i>Vessels/assemblies containing compressed, liquefied and dissolved gases or vapors other than water vapor classified in category III and IV and vessels of superheated water vapor belonging to categories I to IV</i>	<i>Frequency of inspections:</i> <ul style="list-style-type: none"> - every 3 years: operation check - every 10 years: integrity check
<i>Steam generators</i>	<i>Frequency of inspections:</i> <ul style="list-style-type: none"> - every 2 years: operation check and internal visit - every 10 years: integrity check

After 10 years of service a structural/integrity check of the machine is necessary.