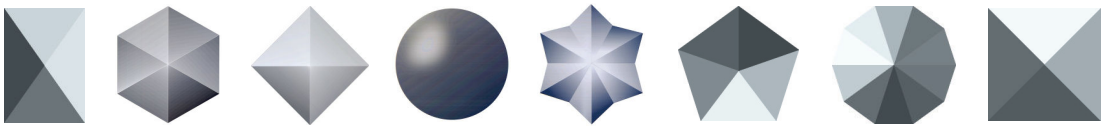
STEAM STERILIZING AUTOCLAVES



SERIES VL

MANUAL OF USE AND MAINTENANCE

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NOTICES FOR SAFETY

The notices following reported have the purpose to reduce the risk for the working staff and to avoid to render unsafe the equipment in consequence of a bad maintenance. Therefore whether the operators or maintenance staff must to execute as indicated in this manual for the use and maintenance of this sterilizer.

Caution must be done to the components, groups or points where it is shown the indication of danger.

Caution must be done to open the electric board and connector block signalled with the indication of " danger – undervoltage"

WARNING the open cycle is programmed as textiles cycle, therefore possible modifications involve a re-validation, from the part skilled staff, before the use.

WARNING the procedure of calibration must be executed by skilled staff. An improper use of this function can cause damages whether to the sterilization process or to the staff.

The operators that use the sterilizer must be skilled for this kind of activity.

The maintenance and repairing of the sterilizer must be executed by technical skilled staff.

The loading area of the sterilizer must be kept cleaned in order to avoid dangerous conditions due to the slippery floor.

Baskets, containers, trays and packing in general and internal trolleys must be handled wearing special gloves to avoid burns at the end of the sterilization cycle.

Protective gloves must be worn whenever you are in contact with the hot sterilization chamber.

Caution must be done for all non protected internal parts of the sterilizer since it can cause burns during the maintenance or repairing of the hot sterilizer.

Protective gloves must be worn to verify the working of the safety valve.

- The electric power must be switch off before to start the repairing or maintenance of the sterilizer.
- For any reason must not be modified or tampered all safety devices of the sterilizer.
- The front panels of the sterilizer must be kept cleaned using a soft cloth and non aggressive solutions for the stainless steel.
- The chamber must be kept cleaned using a soft cloth and non aggressive solutions for the stainless steel.
- Sharp tools must not be used to insert or remove the seal gasket of the chamber from the seat.

IMPORTANT NOTICES FOR LIQUID CYCLE

In case of autoclave with cycle for liquid activated, follows the instructions for a correct execution of the same avoiding risks of explosion of bottles containing hot liquids..

- **DO NOT STERILIZE LIQUIDS CONTAINED IN CONTAINERS ERMETICALLY CLOSED IN THIS KIND OF STERILIZERS.**
- For to sterilize liquids contained in open containers use only the specific cycle.
- Use suitable containers for liquids and temperature.
- To handle carefully the containers wearing protective gloves.

IMPORTANT ADVICE ON THE RIGHT USE OF THIS MANUAL

This manual has been developed to answer to all the user of the CISA Sterilization Units.

In relation to the large range of device we product, and for the different use of each one, to simplify we have created a unique manual book as reference for all the user.

The following description, ***unless it is write in another way***, are useful for each CISA Sterilization Unit.

MEANING OF USE

The CISA Steam Autoclaves are used for the sterilization in Hospital environment for all the temperature-proof material, included textile material, surgical instruments, rubber material with his accessories, as following described in the cycle specification.

CISA steam autoclaves and the full set of attachments are produced also in according with directive 97/23 CEE (PED).

AUTOCLAVES CISA

TECHNICAL DESCRIPTION

AUTOCLAVE SERIE VL

PIC. 1

AUTOCLAVE SERIE CISA VL

FRONT VIEW

1 Sterilization Chamber
2 Touch screen
3 Control panel

1.0 GENERAL INFORMATIONS

1.1 Warranty

GUARANTEE:
12 months from the date of testing but not later than 15 months from the delivery. In guarantee are included only the possible vices and defects of building and the first matters: are excluded all the parts that may deteriorate to cause of carelessness or improper use of equipment.

1.1.1 Other conditions

Other conditions to be agreed with CISA S.p.A

1.2 Choice of cycles, load and packing

In the autoclave are foreseen two programmed and tested cycles suitable to the different kind of materials to sterilize, as listed in the schedule. Furthermore, for to make better the quality of the sterilization the autoclave consents to choose the typology of packing. In this way the cycle will fit to the needs besides, the material to treat, also the type of packing, to avoid inconvenient which condense residuals in the containers, humid or damaged medical paper and bags or tubes exploded.

Cycle	°C	min.	Type of Packing
SOLID	134°C	5	Containers, bags, baskets, paper
LIQUID	121°C	15	Liquids

The loading of the sterilizer must be executed in order that the steam can freely circulate and enter in every package. The load of the autoclave must be distributed in uniform way, and it must not touch the internal parts. All items to sterilize must be shown in such a way that each surface is directly exposed to the sterilizing agent for the temperature and foreseen time. Place the bags and paper packages in the suitable wire baskets in position such to be parallel to the flow of steam and do not press them, the surfaces in polyethylene of the bags must be coupled with them, the small packages must be placed on the top of packages with big dimensions. The instruments must be opened disassembled and with the surface to sterilize free, the contained of the containers and baskets must not be compromise. Particular instruments which containers, tubes, etc. must be placed with the opening toward the bottom to avoid that condensate water collect, and air bubble forms. The tubes must not be closed on sides and folded. The rubber gloves are impermeable to the steam must be put laid and not folded. Once the autoclave is loaded and in temperature can be started to execute the sterilization cycle choosing the same by touch screen. During the execution the parameters and the stages can be checked always on the touch screen. At the end of the cycle, regularly executed, we can open the autoclave on the opposite side for the unload of the material. Discharge the materials avoiding to put them on cold surfaces and close again the door of the autoclave load side. Check that the bags and packages are dried and integral verifying the right color change of the external indicators of process. The steam sterilization can be executed on: surgical instruments, metallic instruments, textile material for medication, non-sensitive rubber material, linen and textiles material for sterile field let alone glassware.

1.3 Washing and packing of the material before the sterilization.

The material before to be submitted to a sterilization process, it must be correctly washed in all of its parts, rinsed with water possibly dematerialized and dried so as to reduce the microbial charge present and remove the presence of dirt, of oily substances and organic material, in that they could interfere on the sterilization process.

The factors that determine a correct operation of cleansing are: chemical (detergent), thermal (temperature of water), time (time of immersion or bath) and mechanical (use of machines or brushes).

The objects to submit to sterilization must have washed using detergent pH neutral.

For instruments of operating theatres must use a detergent product to use according to the instructions pointed out by the manufacturer.

The detergents must be used according the instructions of use especially concerning the dilutions. A product for which is foreseen a dilution at the moment of use must not be used to the pure condition, it is necessary to prepare the preparation in a suitable container following the listed indications.

The cleaning operations must be performed separately from the packing operations to not cause alterations to the packing materials, in practice the material to sterilize must be packed in a room separate from the washing area.

The staff to such operation must be protected during all cleaning operations to avoid that there are wounds, contacts with organic material or detergent products, beside it must pay particular attention towards to sharpened and cutting edge instruments.

The precautions to keep are: remove coarse dirty from the object; immerse the open or disassembled instrument in a container in which the product of treatment or detergent it has been prepared for the fixed time by the manufacturers; friction the object with suitable sponges, brushes or swabs in the internal and external parts do not use metal brushes or abrasive products; rinse with running water possibly dematerialized, to dry, check the efficiency of instruments and in case to lubricate with suitable products pH neutral; after the lubrication the surgical instruments must be sprayed with the compressed air gun to remove the excess of lubricant.

The cleaning by machine must be such to assure that the instruments remaining stop on the instrument-holder eliminating the possibility of mutual impacts and damages.
To avoid the coagulation of albuminous substances in the cleaning stage, the temperature of water could exceed the 45°C only if there is a concentration sufficient high of product of cleaning. The disinfection could be chemothermic or thermal type.
In the use of cleaning products, or cleaning and disinfection combined the instructions of producer must be followed with accuracy (time of action, concentration, temperature).
Only the exact dosing guarantees a perfect result of cleaning and disinfection, with the maximum respect for the materials. A not sufficient dosing of alkaline product (false saving) it allows the risk of corrosion in that it avoids for values of pH higher than 10,5.
In the use of acid cleaning products, could produce corrosion for the presence of chlorine.
This it could avoid only with the use of dematerialized water. The instruments in colored anodized aluminum lose their color with current methods of cleaning by machine and so lose also the coding function. In the case of very dirty surgical instruments, incrusted (blood coagulated, rests of secretion or other material) It could result necessary a further manual or ultrasonic cleaning. In such case it must be examined carefully the instructions for the delicate mechanical treatment of the instruments for microsurgery. In the cleaning by machine must eliminate, during the rinsing stage, all the rests of the cleaning stage, otherwise it could present spots and coloring over the surgical instruments. The use of a neutralization product could help this procedure and improve the result of rinsing. In the practice it is verified that in the treatment of surgical instruments in cleaning and disinfection machines, the best temperature for rinsing (besides for the following drying) is included between 70 and 95°C. At the appear of possible corrosion the rinsing temperature must be limited between 70 and 75°C. Using dematerialized water for rinsing, it could avoid spots and corrosion without limit the temperature. The surgical instruments must be removed from the unit immediately after the end of program must provide at a complete drying. If the instruments before the cleaning by machine are immersed in a cleaning and disinfection solution, for to avoid the formation of foam in the unit it is performed a rinse or it is used a product controlled foam. The instruments with long or narrow cavity as for example metal catheters, metal aspirators, special cannel, etc. they must be rinsed also inside.
The treatment with the machine of instruments for microsurgery and dental instruments as many delicate, it must performed in the automated units only if it is assured a safe fixing of the instruments during the working process. Handles and particular articulated could be treated in the machine if the manufacturer foresee such method and if a safe fixing is assured. As soon as the program of the unit is finished it must to execute a suitable treatment with suitable spray to eliminate possible humidity passed inside of the instruments.
Rotating dental instruments (drills, milling machines and abrasive bodies) are suitable to the treatment in machine only in limited measure. It is preferable the ultrasonic treatment. The same say it for tools for roots. Hand-mirrors covered with rhodium steam, could be treated in machine. Rigid endoscopes have to be disassembled according to the instructions of the manufacturer to may execute the treatment in machine. The gaskets have to be removed. It must to treat in the machine only that particulars of endoscopes expressly shown by manufacturer (excluded for example the optics).
However for the treatment in machine the parts of endoscopes need of a suitable support inside the machine.
It must to assure that also the instruments with internal cavity are cleaned well at their own inside.
The treatment in machine of the flexible endoscopes foresees their cleaning and disinfection in a closed machine. It is not possible to use the usual disinfection and cleaning equipment. For chemothermic processes the temperature must not exceed 60°C. For the endoscopes for which occur a cleaning and disinfection of preparation outside of the unit, it must to use exclusively disinfectants, detergents and detergent additives, that produce a little foam.

Before proceeding to other treatments it must to execute the leak tests described by the manufacturer. In this way it recognizes at the right time drillings and fissures that, following liquids penetrated inside a leak test before or during the execution of cleaning and disinfection program.
A flexible endoscope damaged must be sent immediately to the manufacturer enclosing a description of the cause of the defect. For the treatment by machine it must to use only detergents and disinfectants proper to the particular type of treatment to execute. The flexible endoscope must be placed inside the unit in sure way. Suitable devices must assure a perfect rinsing of all channels and of the external surfaces. In case of treatment by machine, the final rinsing should be executed with sterile dematerialized water. Furthermore it is opportune can arrange of the drying device. For the cleaning in the ultrasonic tank, the surgical instruments must be put in position of opening on suitable sterilization baskets. Attention must be made so that neither the sterilization baskets, neither tools of big surface (lead hands, other baskets) determine zones of shade for the ultrasounds. Warm water without additive does not hand to satisfactory results of cleaning. Is necessary therefore to add an appropriate product for the cleaning. It must respect the prescriptions of the manufacturer about the concentration and the temperature. The temperature of the solutions of cleaning in the ultrasonic tank should be at least 40°C, otherwise the cleaning effect is not assured. A great temperature help the degasification of the cleaning solution and it makes easy the action of the ultrasonic treatment. The appropriate use of a suitable product does not produce coagulation of albuminous substances also to high temperatures. At temperatures between 20 and 25°C it can be used that cleaning and disinfection products that is foreseen for the use at these temperatures only. An excessive concentration of dirt in the ultrasonic tank harms to the cleaning. Therefore the solution must be renewed according to the intervals pointed out by the manufacturer. In the practice it is verified that times of ultrasonic treatment from 3 to 5 minutes and frequencies than at least 35 kHz. it can consider enough (to respect the prescriptions of the manufacturer). The tank of the ultrasonic cleaner must be filled following the instructions of the manufacturer (quantity of water).
To assure a perfect cleaning of instruments they must be completely covered from the cleaning solution. The instruments cleaned by ultrasounds must be submitted then to an accurate rinse by hand or by machine. This rinse must be performed with clean water of quality at least equal to drinkable water. It would be preferable in every case that was demineralized water to avoid the formation of stains. At the end of the rinse the instruments must be immediately and meticulously dried. The micro-instruments must be placed on special supports to avoid the damage of them.
To avoid a damage of the surfaces and the welding of the dental instruments, the ultrasonic bath must not contain acid substances to remove the cement. The handles, the articulated parts and the turbines can not be treated by ultrasounds.
The rotating dental instruments must be treated only with appropriate cleaning and disinfection products. On the special supports is prepared for them foreseen. With this it avoids a damage for mutual contact between the instruments (for example, because of alive edges, diamonds grain, etc.). After a short rinse with water and the immediate drying, the rotating dental instruments must be treated with a product against the corrosion resistant to the sterilization. The flexible endoscopes can not be treated with ultrasounds. The accessories (valves, covers, pliers PE, catheters) can be cleaned by ultrasounds.
The packing of the objects and materials to sterilize has the purpose to preserve the sterility of the treated material up to the moment of the use, it must allow the penetration and the contact of the sterilizing way with the surface of the object, it must to reduce the risk of contamination of the content to the moment of the opening, it must be practical and comfortable.
The objects to sterilize can be manufactured singularly or assembled, in this last case it is correct to follow the orientation of the packing for single necessity (set for medication, for intervention) rather than the packing for quality that offers small hygienic guarantees.

The packing must be of small dimensions and once opened they must be used completely or sterilized again.
Before proceeding to the packing: to check that the material is cleaned, That is entire and that is dry, to get off the assembled parts removing corks and covers, to protect the points of needles and sharp, to place plastics and rubbers in such way to preserve the original form, to roll up the pipes or the very long materials they allow it without creating narrowing.
The packing in containers with filters is suitable for set of surgical instruments, laundry, gauzes and tablets of medication.
Every time it is necessary to check the state of the filters, to replace them periodically following the indications of the supplier, or when they result visibly altered however to follow to the indications of guarantee of the manufacturer.
The contained material in the containers must not be compressed, the laundry should be positioned vertically.
The packing in medical paper for the steam sterilization is suitable for the sets of laundry and surgical instruments, not suitable for the packing of medication, materials of small entity or material disomogeneous among them and deprived of support. The technique of packing must allow the opening of the package without involving the sterility of the objects in it contained, therefore it is necessary to packing the packages in double orthogonal layer using a methodic that allows to guarantee an effective protection an easy opening and an antiseptic extraction of the content.
The double orthogonal layer is necessary in that the medical paper because of the presence of micro-holes can not result an absolute barrier against the microorganisms. The double packing introduce the advantage besides to be able to remove the external layer before the introduction of the package in an area to low microbial charge preventing the entry of dust microscopic that deposited it on the external packing. In the activity of packing do not use pins or clips for the closing.
The packing in bags or tubular of paper Kraft joined polypropylene/polyester is suitable for the steam sterilization and for the single materials or of small and averages dimensions, for the sets of surgical instruments, for laundry and medication.
The formalities of preparation foresee the choice of: a format of bags or tubular suitable considering that the content must not occupy more than 3/4 with its volume. Besides it must be positioned the content in order to guarantee correct maneuvers of opening and extraction to the moment of the use, the hilt of the instruments must present easily accessible, the gauzes and the laundry must maintain intact without opening the moment of the extraction. To check that the pointed or sharp material is protected from supports in plastics and that all the bags are welded to the rims with thermo-welders providing to leave a margin of opening of 5 cm. and what the welding is at least 1 cm. however not less than 6 mm. and not higher than 12 mm. of continuous or multiple type.
For the material that must be used on sterile field it recommends the packing in double bag, both the bags it intended like joined to polyethylene/polyester and Kraft paper must be welded singularly and introduced in the sterilization unit.

1.4 Sterilization cycles

TABLE OF REFEREMENT SATURATED STEAM TEMPERATURE – STEAM PRESSURE

Temperature °C	Pressure kPa
100.0	93.9
101.0	98.2
102.0	102.7
103.0	107.2
104.0	111.8
105.0	116.4
106.0	121.2
107.0	126.0
108.0	131.0
109.0	136.0
110.0	141.1
111.0	146.4
112.0	151.7
113.0	157.1
114.0	162.7
115.0	168.3
116.0	174.1
117.0	180.0
118.0	186.0
119.0	192.1
120.0	198.4
121.0	204.8
122.0	211.3
123.0	218.0
124.0	224.9
125.0	231.8
126.0	239.0
127.0	246.3
128.0	253.8
129.0	261.4
130.0	269.2
131.0	277.2
132.0	285.4
133.0	293.9
134.0	302.5
135.0	311.3
136.0	320.4
137.0	329.7
138.0	339.2
139.0	349.0
140.0	359.1

1.5 Safety systems

The autoclave is equipped of the following safety devices that makes it extremely reliable:

- *Mechanical device against the opening of the door in presence of pressure in chamber with micro of signalling.*
  Piston hydraulically connected to the chamber, that in presence of pressure stops the mouvement of the door. The right working is verified through a magnetic limit switch.
- *Overtemperature device of working during the sterilization phase.*
  Verification by no.1 temperature porbe, on the threshold of +3°C than the sterilization set.
- *Device for the protection of max. pressure.*
  Spring safety valve certified ISPESL directly installed on the body of the steam generator.
- *Device against the letting in of steam in chamber if the door is open or not perfectly closed.*
  Limit switch of righr positioning of the door(s) of load.
- *Safety device of minimum pressure for the opening of the door.*
  Pressure gauge hydraulically connected to the chamber, that consents the drain and the opening of the door at atmospheric pressure in the manual manoeuvre.
- *Safety device on the leak door*
  Verification of the pressure in the gaskets by pressure gauges.
- *Safety device of max. temeprature resistances*
  Thermostat inserted in the body of the generator in contact with the resistances.

⚠ *the pipings crossed by the stean and so reach high temperatures are insulated with thermo-resisting materials. These pipings are stopped by the pneumatic valves that also reach temperatures relatively higher but, seen their form and functionality they cannot be insulated. We advice so a particular attention near of the same.*

1.6 Set-point safety systems and functionality

In the following diagram you have illustrated the components refferring to the security, the functionality and their settings.

Security

Component	*Set-point*
Chamber Safety Valve SS1 *Look at Idraulic scheme in annexes*	**4 Bar**
Gasket Pressostat SP10 *Look at Idraulic scheme in annexes*	**0,5 Bar**
Resistance Termostat TC3 *Look at Idraulic scheme in annexes*	**230°C**

1.7 Operator codes

For the management of the equipment have been foreseen twenty different operators for each of them it has been inserted a reference code. For each operator is available a level that identify the function that change from 1 to 9 and each level has the possibility to execute fixed functions in the unit. From level 1 to level 5 are operator functions, from 6 to 7 maintenance functions and 8 and 9 of supervision. These codes and relatives levels can be changed according to the needs. The unit at its first activation will have the following configuration:

Operator n°	Code	Level	Name
1	0001	9	OPERATOR N.1
2	0002	1	OPERATOR N.2
3	0003	1	OPERATOR N.3
4	0004	1	OPERATOR N.4
5	0005	1	OPERATOR N.5
6	0006	1	OPERATOR N.6
7	0007	1	OPERATOR N.7
8	0008	1	OPERATOR N.8
9	0009	1	OPERATOR N.9
10	0010	1	OPERATOR N.10
11	0011	1	OPERATOR N.11
12	0012	1	OPERATOR N.12
13	0013	1	OPERATOR N.13
14	0014	1	OPERATOR N.14
15	0015	1	OPERATOR N.15
16	0016	1	OPERATOR N.16
17	0017	1	OPERATOR N.17
18	0018	1	OPERATOR N.18
19	0019	1	OPERATOR N.19
20	0020	1	OPERATOR N.20

At the starting of a cycle the name of the operator relative to the inserted code will be printed. The operator code will be required every time that there is the necessity, for example for to reset an alarm, for to do a manual advancing of phase or to use the function of calibration. Such functions will be activated or not according to the level corresponding to the inserted code.

LEVEL	1	2	3	4	5	6	7	8	9
START OF THE CYCLE	*	*	*	*	*	*	*	*	*
CHANGE STANDARD CYCLES									*
CHANGE DATE AND TIME	*	*	*	*	*	*	*	*	*
RESET ALARM	*	*	*	*	*	*	*	*	*
CALIBRATION									*

* Function activated.

1.8 Alarms

The alarms that can intervene during the working of the cycle will be shown and printed.
The alarms described in the list are the following:

- **Thermical switch MV**
  This alarm intervenes when a thermic starts. This happens when there areproblems on the motors of the water pump or the power supply.
- **Cancelled cycle**
  This alarm intervenes when the cycle is cancelled using the procedure described in the touch-screen.
- **Damage Probe chamber**
  This alarm intervenes when there is an anomaly in the signal of the thermoresistance Probe of the chamber.
- **Damage Probe product**
  This alarm intervenes when there is an anomaly in the signal of the thermoresistance Probe of the product.
- **Minimum temperature**
  This alarm intervenes in the sterilization phase, when the temperature of the chamber goes down under the selected threshold (sterilization temperature).
- **Max. temperature**
  This alarm intervenes in the sterilization phase, when the temperature of the chamber rises above the selected threshold (sterilization temperature + 3°C).
- **Door open**
  This alarm intervenes when during a cycle the door limit switch does not signal the right closure.
- **Power fail**
  This alarm intervenes when there is a shortage of power supply.
- **Battery unloads PLC**
  This alarm intervenes when the battery of the PLC must be replaced.
- **Outside time phase**
  This alarm intervenes when the time of phase exceed the selected set for that phase.

2.0 MANAGEMENT OF THE AUTOCLAVE

2.1 PRELIMINARY OPERATIONS

To execute it in starting phase or pick-up again of the activity after the break of the unit:

	The users that use the sterilizer must be skilled for this kind of activity.
	The maintenance and repairing of the sterilizer must be executed by skilled technical staff.

To execute at every start of the cycle:

- ***Check that in the water tanks there are water by the floating placed on the load water tank of the chamber.***

- Check that the gasket is well inserted in the seat before to close the door.

	Sharped tools must not be used for to insert o to remove the seal gasket of the chamber from the seat.

- Check that there is paper in the printing unit.
  (A red bar on the paper indicates the imminent end of the roll).

	Do not pull the paper when the printing unit is running.

- Check the working of the ink tape.

2.2 STARTING OF THE AUTOCLAVE

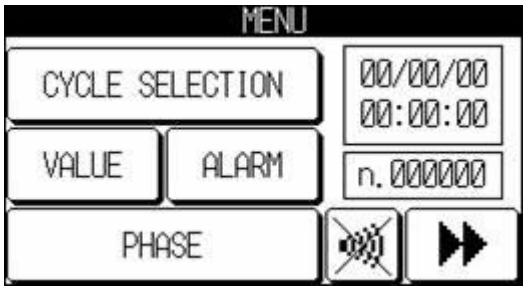
- Check that the emergency push-button is not activated.
- Switch on the autoclave acting on the ON-OFF push-button
- Check that the key selector is in position with the key not inserted.

The display will show :

Push any point of the display to continue.

2.3 MAIN MENU

The display will show :



From the main menu is possible to enter at different functions of the unit:

CYCLE SELECTION relatives at the choice of the cycles

VALUE: relatives at the visualization of the autoclave's value that are the temperature of the two Probes, the error between the two Probes, the pressure in Kpa and the time passed since the start of the cycle.

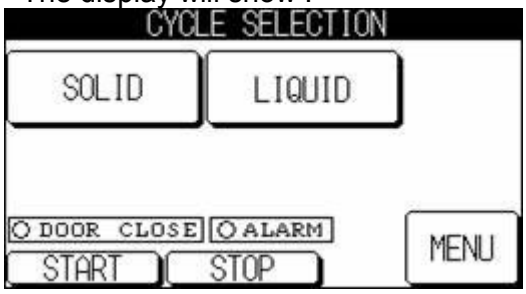
PHASE: relatives at the visualization of the phase in common use that will flash

ALARM: relatives at the storer of the alarms

2.4 PROCEDURES FOR THE STARTING OF A CYCLE

Push **CYCLE SELECTION** from the main menu

The display will show :



2.5 CHOICE OF THE CYCLE AGAINST THE MATERIAL TYPE

Select the cycle that you wish to execute in function of the type of material to sterilize. (see par.1.2)
The cycles foreseen from the unit are the following:

- SOLID at 134°C. EXPOSURE TIME 5'
  This cycle permits to sterilize: solids and anyhow all things that are temperature-proof.

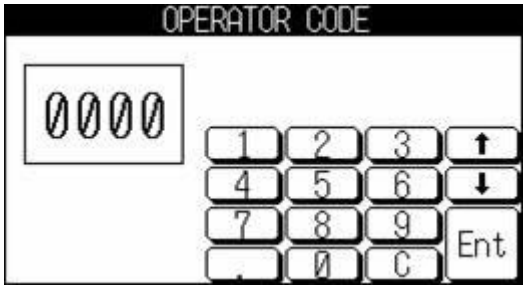
- LIQUID at 121°C. EXPOSURE TIME 15'
  This cycle permits to sterilize: liquids material in open containers, gloves, catheters, rubber materials in general.

Push **MENU** to exit and come back to the main menu

Push **START** to start the choose cycle

2.5.1 INSERTION OPERATOR CODE

The display will show:



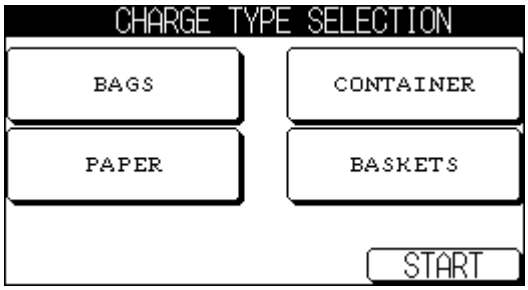
Push the operator code.

Push **ENT** to confirm

Push **C** to delete the inserted numbers.

2.6 CHARGE TYPE SELECTION

After the choose of the cycle and inserted the operator code, the display will show:



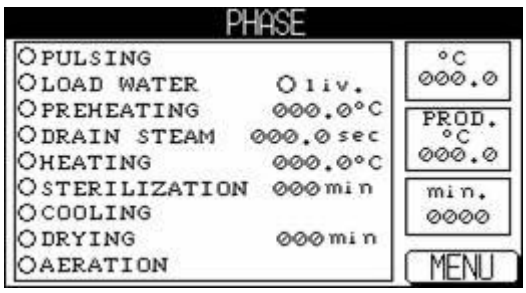
The charge are:
- **BAGS**
- **CONTAINER**
- **PAPER**
- **BASKETS**

Choose the charge to sterilize and push **START.**

2.7 PHASE IN COURSE

This page is shown at the starting of the cycle and it shows the parameters of the autoclave.

The display will show :



The following parameters are visualized in real time:

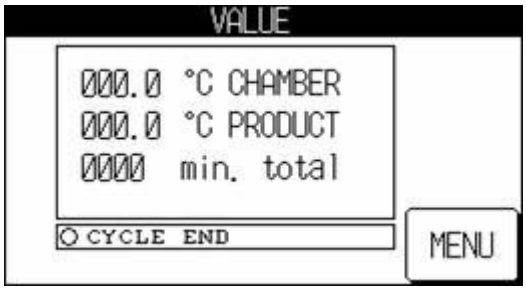
- Temperature chamber
- Temperature of the product
- Time of the cycle

On the display is visualized the cycle in course.

2.8 PAGE VALUES

Push **VALUE** to visualize the process values in the chamber and in the jacket.

The display will show:



There are visualized:
-temperatures chamber in °C;
-temperature in the product;
-total time of the cycle

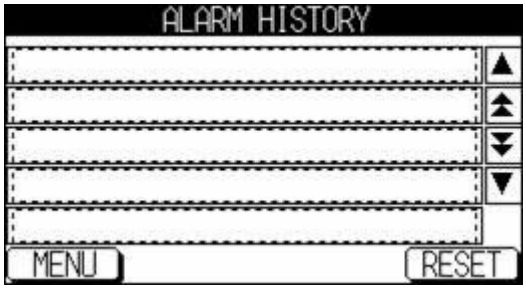
Push **MENU** to come back to the visualization of the page menu

2.9 PAGE ALARMS

Push **ALARMS** to visualize the alarms history already previously resetted.

This page is automatically visualized every time that an alarm intervenes call the operator's attention with an acoustic sound prolonged.

The display will show:



After to have resetted the alarm during the cycle at the end this page will be visualized again for to remember at the operators that an alarm is intervened, push **MENU** to come back to the main menu.

2.10 END OF THE CYCLE

The end of the cycle is shown by a flashing acoustic signal (max. time 5 minutes) and printed.

For to silence the signal push 

The display will show

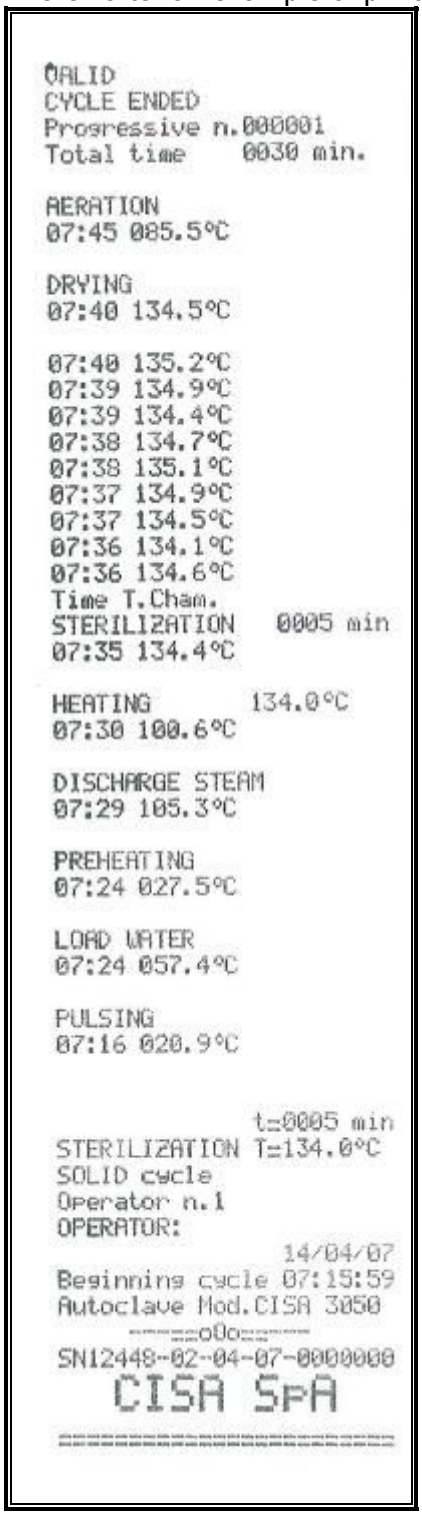
if the cycle just finished is a sterilization cycle, and it will be possible open the door.

Push on the display for to come back to the main menu.

2.11 PRINTS

For each cycle that we start a print in real time is created.

Hereinafter an example of print of an executed cycle:



Progressive number
Total time of the cycle

Immediate value

Indication of the time and temperature of the phase in course.

Phase
Immediate value
Phase
Immediate value

Phase
Immediate value

Phase
Immediate value

Selected cycle with the indication of the temperature and sterilization time.

Operator name
Date and time of start of the cycle

Autoclave model

Serial Number
Heading

Hereinafter an example of print of a cycle executed and non regularly finished:

Progressive number
Total time of the cycle

Alarm

Immediate value

Indication of the time and temperature of the phase in course.

Phase
Immediate value

Phase
Immediate value

Phase
Immediate value

Selected cycle with the indication of the temperature and sterilization time.

Operator name
Date and time of start of the cycle
Autoclave model

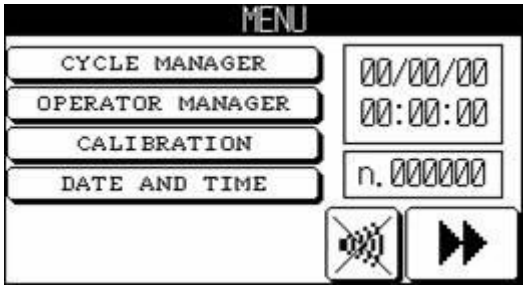
Serial Number
Heading

3.0 TECHNICAL MENU

3.1 – PROCEDURE FOR THE MANAGEMENT OF THE TECHNICAL PARAMETERS

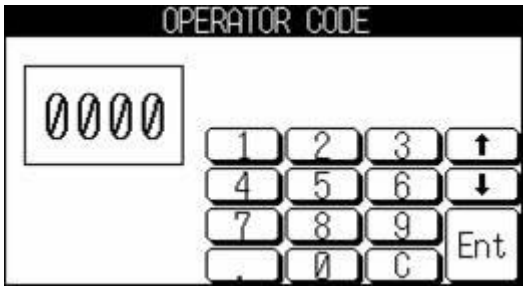
Push  from the main menu

The display will show:



For reach to a submenu it will item an operator code

The display will show:



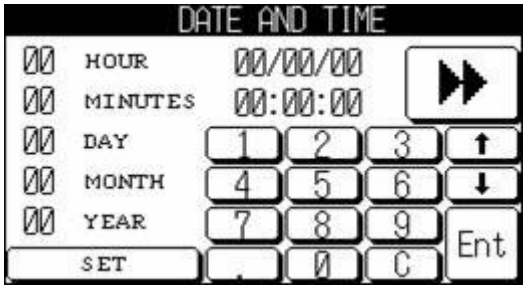
Insert its own operator code.

For reach to the submenu it must be inserted the operator code 1which correspond at level 9.

3.2 CHANGE DATE AND HOUR

Push **DATE AND TIME** from menu of selection.

The display will show:



Shift with arrows on the parameter to modify and select by keyboard the wished values.

Push [▶▶] to exit , Push [Ent] to confirm

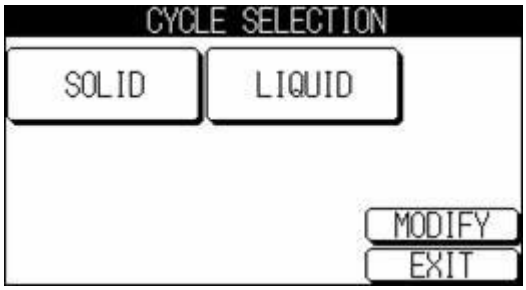
Push [SET] to memorize

For this submenu is not reach the operator code.

3.3 MODIFICATION OF THE STANDARD CYCLES

From the technical menu push **CYCLE MANAGER** to modify the standard cycle.

After insert the operator code the display will show:

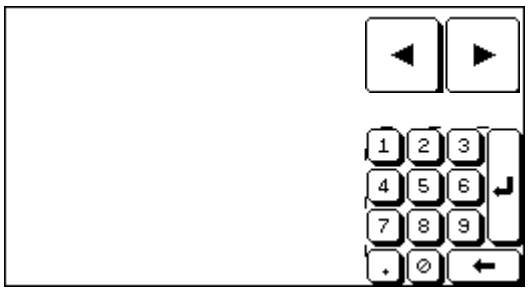


Select the cycle to change and push **MODIFY.**

3.4 MODIFICATION OF THE PARAMETERS OF THE CYCLE

CAUTION the standard cycles selected on the unit have been validated, therefore any modification of the same involve its validation from the part of the skilled staff, before the use.

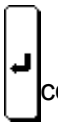
All parameters are modifiable by keyboard below reported.



where:

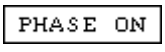
 select the parameter to change

 insertion values

 confirm

 comes back to zero the selected values

 Inserts the decimal values

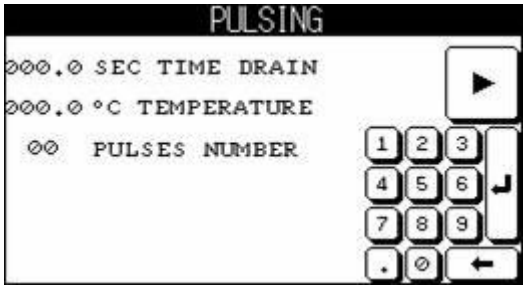
 when it is actives the button is lighted.

As soon as an open cycle or standard cycle to modifies selected the parameters relative to the phases that make the cycle will be visualized. The phases are:

- PULSING
- CHAMBER DRAIN
- HEATING
- STERILIZATION
- COOLING
- DRYING

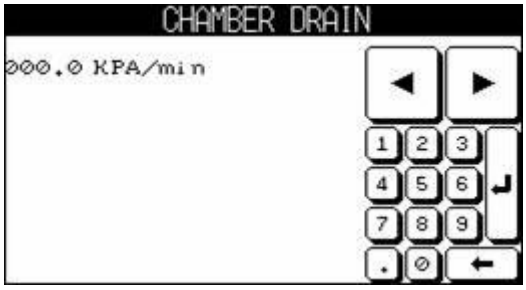
PHASE 1 – PULSING

The display will show



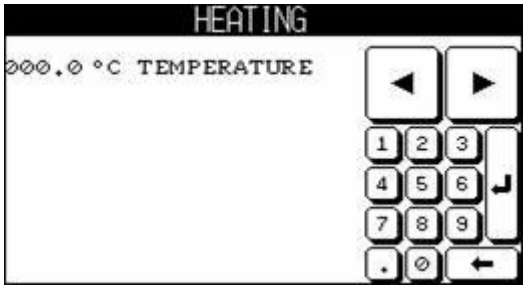
PHASE 2 – CHAMBER DRAIN

The display will show



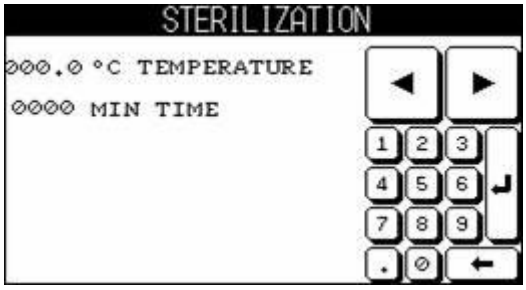
PHASE 3 - HEATING

The display will show



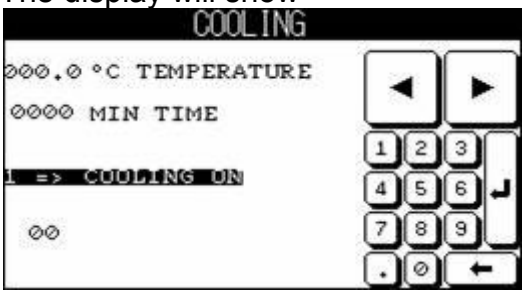
PHASE 4 - STERILIZATION

The display will show



PHASE 5 – COOLING

The display will show



PHASE 6 - DRYING

The display will show:

After the visualization of these pages the display will show:

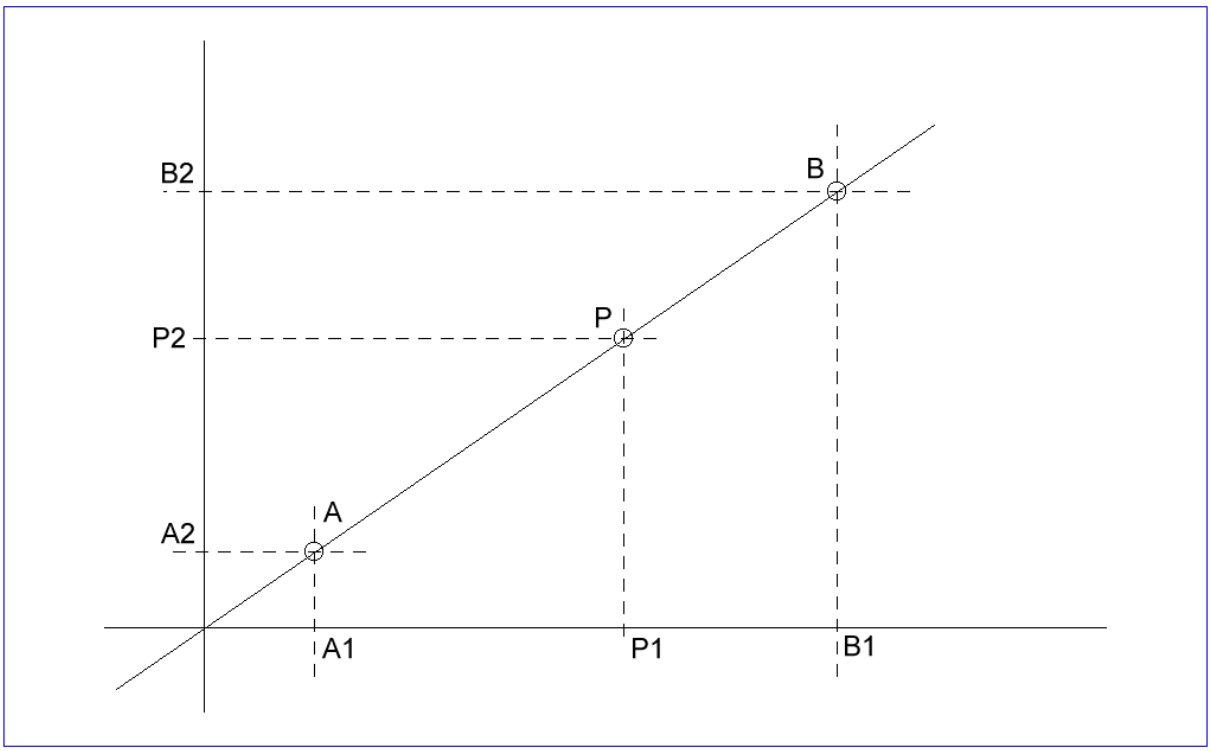
To confirm the modify push yes, instead to not confirm push no.

3.5 CALIBRATION

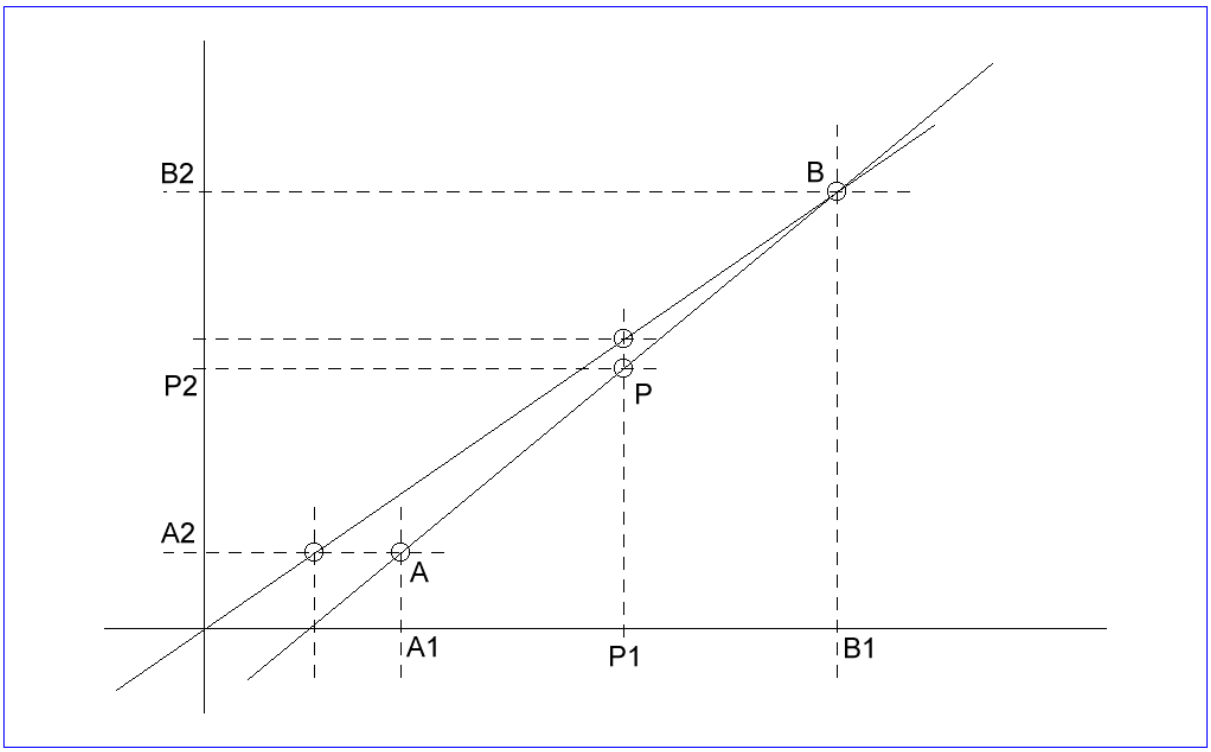
⚠	**The calibration procedure must be executed by skilled staff. An improper use of this function can cause damages whether to the sterilization process or the staff.**

NOTE: For this function is necessary the certified instruments of reference (EX. drain temperature, manometer sample etc.)

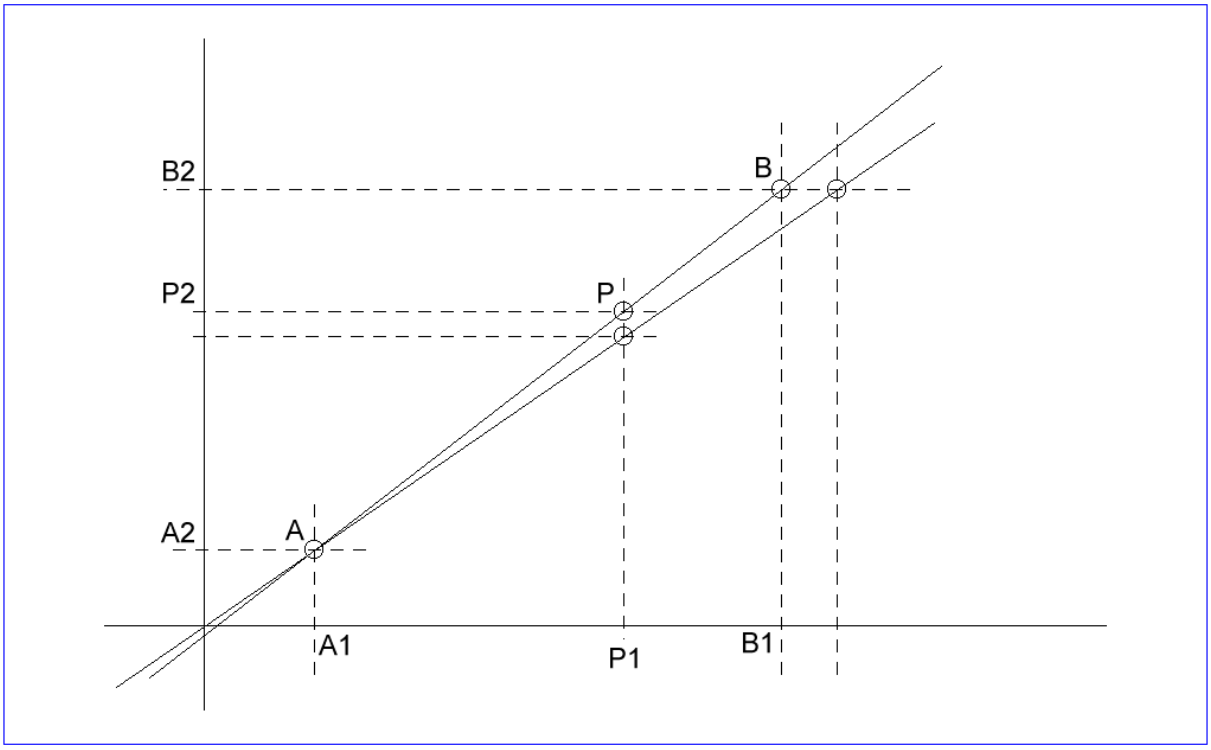
The function of calibration acts on the analogue values of temperature and pressure that are pointed out by the unit. These analogue values are converted with a linear function as from the following diagram:



where points **A2** and **B2** are the extremes of the values to convert in input and **A1** and **B1** are the correspondent extremes in output. Took a value in input **P2** its correspondent value in output **P1** will be the projection of the point **P2** on the axis generated from **A1**-**A2** , **B1**-**B2** in the points **A** and **B**. So a modification on the abscissa of the points **A1** and **B1** will modify the axis **A1**-**A2** , **B1**-**B2** and the consequent projection of **P2** on the point **P**.



This is the resultant axis modifying the point **A1**. For to obtain the same point **P1** on the abscissa , the value of **P2** should get near to the point **A2** on the ordinate.



This is the resultant axis modifying the point **B1** . For to obtain the same point **P1** on the abscissa , the value of **P2** should get near to the point **B2** on the ordinate.

The scale of temperature is 0 – 200,0 °C, expressed in tenth of degree 0 –2000.

Considering a possible negative error in the conversion of the signal in input, the values of **A1** e **B1** are added at a whole value of 1000. After the interpolation for the calculation of **P1** so a such value will be subtracted the initial value of 1000. The values relative to the temperature of **A1** and **B1** so will be:

A1 = 1000

B1 = 3000

The scale of pressure is 0 – 600 kPa , expressed in mill bar 0 – 6000.

As for the temperature the values of **A1** and **B1** are added at a whole of the value of 1000. The values relative to the pressure of **A1** and **B1** so will be:

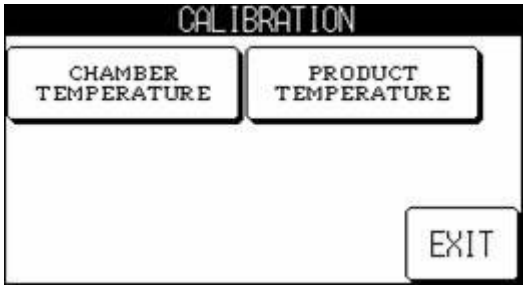
A1 = 1000

B1 = 7000

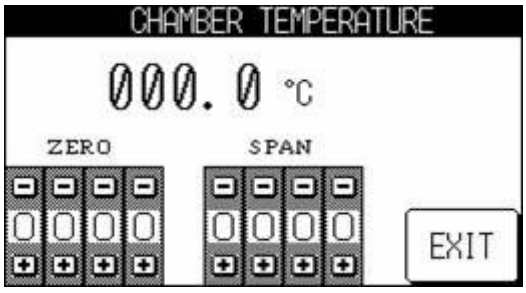
Hereinafter is reported the procedure for the modification of values **A1** and **B1**.

Push **CALIBRATION** from menu of selection

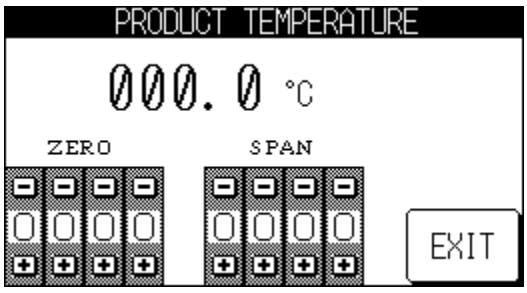
The display will show:



In this section it will modified the following parameters:



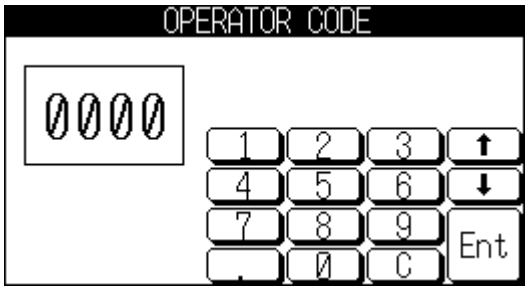
and



On each screen dump push **EXIT** to show the calibration menu.

3.6 OPERATOR CODE

Push **OPERATOR CODE** from menu of selection.



Insert the operator code n°1 and push **Ent**.

The display will show:

Push the operator code to modify.

The display will show:


OPERATOR N.5
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.6
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.7
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.8
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.9
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.10
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.11
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.12
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.13
CODE
0000
LEVEL
0000
EXIT
SPACE
Del


OPERATOR N.14
CODE
0000
LEVEL
0000
EXIT
SPACE
Del

Insert the modify and push  . Push **EXIT** to come back to menu.

4.0 MAINTENANCE

4.1 GENERAL INFORMATIONS ABOUT MAINTENANCE

All information quoted in this chapter are destined to skilled staff that have received suitable electric and hydraulic notions for to intervene in case of failures of different nature.

CAUTION to the chain and the pinion for the lifting of the door.

CAUTION The autoclave has not a general switch. Before to execute electric maintenances switch off the voltage upstream of the same autoclave.

CAUTION Some internal parts of the autoclave (tubes, valves, surfaces) are at high temperatures.

For to enter in any component of the unit the person who make the maintenance, must be provided of the key for opening of the modulo and of the tools for to remove the lateral panels of the unit, after to have adopted all safety measures of the case to avoid to be in direct contact with elements under voltage, in movement or high temperature.

4.2 FURTHER USEFUL MAINTENANCE ADVICES

Further as indicated from the Touch Screen is anyhow, advisable to execute periodically the following preventive maintenance operations:

TO VERIFY	the perfect working of the control and command device like (manometers, manovacuumeters, recorders, printers, thermostats, pressure-gauges, vacuum-gauges, automatism, etc.) with possible setup.
TO CHECK	the hydraulic plant with check of the watertight and elimination of possible leaks.
TO CHECK	and clean the filters.
TO CHECK	the electric plant with relative connections.
TO VERIFY	the safety systems, safety valves, seal piston doors, clean the seat of doors gasket.
TO REPLACE	in case, the gaskets to the cock.
TO CHECK	probes and thermoresistances.
TO CHECK	and in case lubricate the mechanical motion parts.

TO CHECK	the electric steam generator with disassembly of the heating resistances and removal of calcareous deposits.
TO CHECK	air compressor and possible restoration of the oil level.
TO CHECK	pilot valves and replace ring or sealing ring

4.3 CLEANING AUTOCLAVE

CLEANING OF THE STERILIZATION CHAMBER: to execute with the following modalities:

- When the chamber is in normal conditions wash with hot water and neutral shampooing; do not use sharped tools, re-wash.
- When the chamber has superficial store up of deposited wash with hot water and non corrosive or neutral detergents. Do not use sharped tools. Re-wash.
- When the chamber has deposits strongly encrusted as in the first case and apply a pickling agent past present in the market following the instructions of the manufactures. Keep the paste in contact with the surface to clean, according, of the intensity of the action required, so remove it with water meticulously, especially in the corners. Do not use sharped tools. Repeat the washes.

CLEAN PANELS: use a soft cloth a non aggressive solution for stainless steel.

CLEAN GASKETS DOOR: use alcohol and talcum powder.

4.4 REPLACEMENT OR CLEANING OF THE DOOR'S GASKET

For a right working of the sterilizer is opportune to execute periodically the cleaning and replacement of the seal gasket of the doors.
Per questa operazione procedere nel modo seguente:

1- extract the gasket from the seat using non sharped tools
2- clean the gasket with alcohol and strew it with talcum powder
3- clean the seat of the gasket with a cloth imbued of alcohol and a non sharped tool
4- to sprinkle a spray silicone (the same type used for surgical instruments) in the seat for t make the insertion of it.
5- insert again with the hands the gasket.

4.5 – REPLACEMENT OF THE BACTERIOLOGICAL AIR FILTER

For the replacement of the bacteriological filter of the air proceed in the following way:
1-open the door of the sterilization chamber loading side
2- open the panel of the modulo using the key
3- remove the block screw of the frontal panel laterally placed
4- open the frontal panel of the sterilization chamber
5- unscrew the bacteriological filter of the air placed over the sterilization chamber with suitable equipment
6- assemble the new filter
7- close the sterilizer executing the operation on the contrary

4.6 - REPLACEMENT OF THE STEAM FILTER

CAUTION close the steam before to proceed to the replacement

1- switch off the autoclave acting on the push-button n 4 picture 2
1- open the door of the sterilization chamber load side
2- open the panel of the modulo using the key
3- remove the block screw of the frontal panel laterally placed
4- open the frontal panel of the sterilization chamber
5- close the cock steam arrival
6- loosen the 12 screws placed on the flange of the container of the filter.

CAUTION at the moment of the closure of the cock of steam arrival the stretch of tube until the pneumatic valve stays under pressure. If it proceeds immediately at the replacement of the filter loosing the screws await that the steam go out from the tube through the flange, so use due caution. If we await the cooling of the filter before to proceed at the replacement, the part of the tubing that was under pressure can stay under vacuum for the condensation, so also removing the screws of block the flange cannot move. Open <u>slowly</u> the cock of steam arrival to compensate the loss of pressure of the tubing.

7- unscrew the 12 screws placed on the flange of the container of the filter
8- extract the cartridge and replaced it or in case clean it with compressed air or anti incrustation substances
9- assemble again the screws on the flange
10- open again the steam and verify the seal of the flange
11- close the sterilizer executing the operation on the contrary

4.7 - CLEANING OF THE FILTER DRAIN CHAMBER

1- open the door of the sterilization chamber on the load side
2- open the panel of the module using the key
3- open the frontal panel of the sterilization chamber
4- unscrew the cartridge of the filter “Y” placed to the drain chamber under the sterilization chamber. The cartridge is sideways that the cylindrical container.
5- clean the cartridge using compressed air or anti incrustation substances
6- assemble the cartridge on body
7- close the sterilizer executing the operations on the contrary

4.8 - CLEANING OF THE FILTER OF COMPRESSED AIR

CAUTION close the compressed air before to proceed to the cleaning

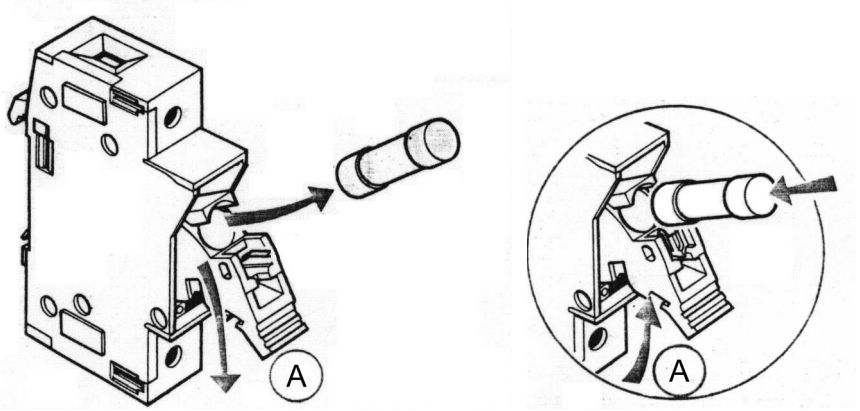
1- open the panel of the modulo using the key
2- disassemble the container of the filter of the compressed air placed in the bottom than to the steam generator
3- clean the filter with the compressed air removing possible deposits
4- put again the cartridge in the container and screw again the same to the body of the filter
5- open again the compressed air
6- close with the key the panel of the modulo

4.9 - REPLACEMENT FUSES

CAUTION The autoclave has not a general switch. Before to execute electric maintenances switch off the voltage upstream of the same autoclave.

The fuses in the electric board are inserted on fuse carriers. Proceed to the replacement following this procedure:

1- Switch off the autoclave.
2- Open the panel of the module using the key
3- Open the electric board with the suitable key
4- Localize the fuse to reset. The amperage is described in the electric diagram.
5- Open the fuse carrier acting on the tab “a” from the top toward the bottom.
6- Remove the failed fuse and insert again the new one.
7- Close the fuse carrier acting on the tab “A” from the bottom toward the top.
8- Close the electric board
9- Close the panel of the module

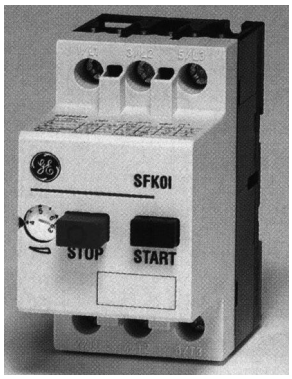


4.10 - RESET THERMICS

CAUTION The autoclave has not a general switch. Before to execute electric maintenances switch off the voltage upstream of the same autoclave.

The thermic protections of the motors in the electric board can be resetted following the procedure below described:

1- Switch off the autoclave.
2- Open the panel of the module using the key
3- Open the electric board with the suitable key
4- Localize the thermic to reset (the red push-button “START” is not pushed)
5- Push the red push-button “START”
6- Close the electric board
7- Close the panel of the module



4.11 REPLACEMENT BATTERIES

The CPU CQM1 inside the autoclave has a battery 3G2A9-BAT08. In normal conditions, the duration is about five years. When the voltage of the battery start to drop it causes an error conditions, visualized from the display.

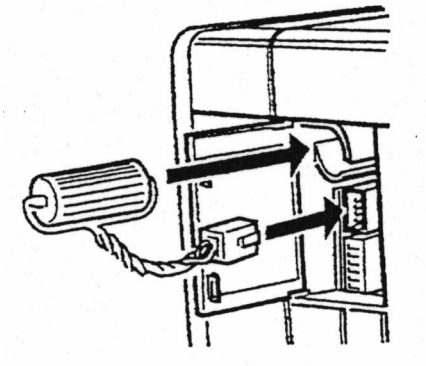
CAUTION replace the battery within one week from the signalling

Use the following procedure to replace the battery. This procedure must be finished within five minutes from the switch off of the autoclave to ensure the backup of the memory.

10- Switch off the autoclave. If the autoclave is switched off, switch it on for at least one minute and than switch it off again.
11- Open the module of the panel using the key
12- Open the electric board with the suitable key
13- Open the compartment in the upper left of the CPU and carefully draw out the battery.
14- Remove the battery connector.
15- Connect the new battery, place it into the compartment and close the cover.
16- Close the electric board and the module of the panel.

WARNING Never short-circuit the battery terminals; never charge the batter; never disassemble the battery and never heat or incinerate the battery. Doing any of these may cause the battery to leak, burn, or rupturing resulting in injury, fire, and possible loss of life or property.

CAUTION The autoclave has not a general switch. Before to execute electric maintenances switch off the voltage upstream of the same autoclave.



4.12 PRINTER

4.12.1 REPLACING THE PAPER ROLL

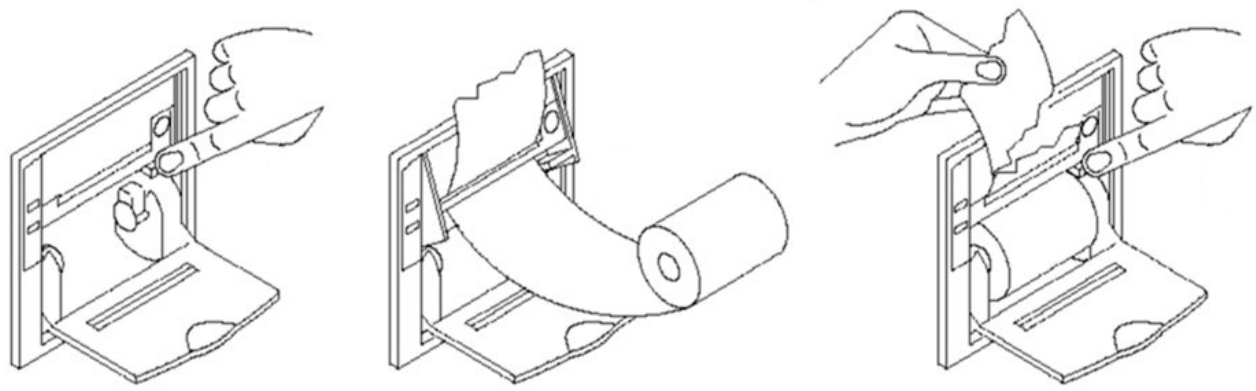
To replace the paper roll follow the instructions before:

1. Open the printer frontal panel and place the paper roll in his right position and sense of rotation.
2. Take the top edge of the paper and insert it in the printing mouth of the printer.
3. push the FEED button on the printer to charge the paper through the printing rolls.
4. Insert the top edge of the paper in the front panel hole and close the printer.

4.12.2 REPLACING THE INKED ROLL

To replace the inked roll of the printer follow the instruction before:

1. Open the frontal panel of the printer and remove the exhausted ink cartridge, by the PUSH button
2. Insert the new inked roll in the same position of the old one
3. Stretch the roll operating on the knurled button and close the panel.



PIC. 2

4.13 EXTRAORDINARY MAINTENANCE

The extraordinary maintenance has to be done from CISA specialized technical people or authorized by CISA.
If some components will be replace with some others not authorized from producer, CISA will not have any responsibility in case of each kind of disadvantage.

4.14 HINTS FOR QUICK REPAIRING LIST

INCONVENIENT	PROBABLE CAUSE	ACTIONS TO TAKE
Jacket does not go in pressure	Power failure	Check the current arrival to remote control switch and the relative contacts, fuses in the electric board, device of water minimum level (if there isn't resistors switch-off)
	Resistors of generator burnt	Check and/or replace
	Shortage of compressed air	Check the arrival from network or compressor
Insufficient vacuum	Water shortage in the network	Check the arrival from network or pump
	Pneumatic valve PV6 is leaking	Clean the seat or replace the valve
	Pneumatic valve PV7 (feeding water pump) is leaking	Check the pilot electro-valve, in case replace the coil
	Non return valve aeration N4 is leaking	As above
	Pneumatic valve PV8 is leaking	As above
	The motor of vacuum pump is tripped	Check the pump.
	Door/s gasket	Check the condition of the gasket and in case clean it and insert it again in the seat.
Low steam pressure in chamber	Shortage of water in the generator **	Check the level
	Cock steam arrival of chamber	Check and in case adjust the opening turning slowly the handle of the cock
	Resistors of the generator burnt **	Check and/or replace
	Pneumatic valve PV20 is leaking	Check and in case replace th gasket (or valve)
	Temperature probe defective	Check the wear and tear of the cable; replace it
	Steam escape from the door	Check the gasket, replace it if it is worn
Condensate residuals in chamber at the end of the cycle	Pneumatic valve PV9 does not open	Clean the seat of the valve; if necessary replace the gasket or the valve
	Cock condensate drain chamber RC9 obstructed	Check and in case clean away deposits
	Other causes: see insufficient vacuum	See: insufficient vacuum
Pump is noisy in the vacuum phase	Cock anticavitation pump RE6 obstructed or out of calibration	Check and in case clean; adjust if necessary the opening
	Water shortage in the network	Check the arrival. **DO NOT USE THE AUTOCLAVE WITHOUT WATER**
The vacuum pump does not start	Thermic of the pump QF1 tripped,	Check the motor of the vacuum pump, verify that there is not resistance to the rotation, if necessary, push the push-button of the thermic, inside of the electric board restorating the contacts.
The pump load water does not start	Thermic QF2 is tripped, motor burnt; pump blocked	Search the cause of the failure, restore the contacts pushing the push-button of the thermic in the electric board, or replace the fuse.
Bowie & Dick Test unsatisfactory	Loss of vacuum	Check the cock condensate drain RC9; this cock must not be tampered. Ensure that the condensate escape and therefore it is not obstructed.