TRADE Raypa®

R.ESPINAR, S.L.

QMS-Quality Management Systems
REGISTERED FIRM
ISO 9001
EN ISO 9001
Nº Reg.: ESP 2429

INSTRUCTION MANUAL

AUTOCLAVE FOR STERILIZATION

"CLINOCLAV"

Model: AH-21 B PLUS

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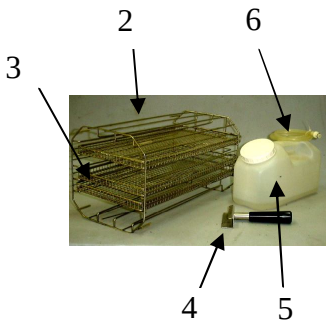
This manual has been written for safety reasons, read the instructions carefully before installing and /or using this apparatus.
If this apparatus should be sold or transferred, ensure that this manual is given to the new owner, for the correct use and installation.
This manual should be kept near the apparatus for cases of doubt in its use and for maintenance reasons.

INDEX

1 PACKING LIST AND ACCESSORIES

1.1 Included elements

- 1 Water steam Sterilizer AH-21 B PLUS (1).
- 1 Tray support (2).
- 3 Trays for instrumental (3).
- 1 Trays holder (4).
- 1 Container with quick connection to fill the distilled water reservoir (5).
- 1 silicon tube with quick connection to unload water (6).
- 1 Instructions manual (7)



1.2 Optional accessories

- Table top printer
  Power supply: 230 V
  Connection RS-232
  It uses standard paper Ø50x57mm
  Ref. ITS

- Built in printer
  This accessory must be installed at our facilities.
  It uses thermal paper of Ø50x57mm
  Ref. IT

- Kit of cords and control software
  Ref. SOFT-RS232

2 SAFETY

This sterilizer has been built in accordance to actual technology and respecting the safety regulations. In spite of this, the device can cause damages:

- If it is used to unforeseen.
- If it is manipulated by unskilled people or without the adequate training.

2.1 Symbols

They identify dangerous situations and precautions that have to be taken.

NOTICE

Information of a risk that can be dangerous for the health or damage the device. Proceed following the indicated procedure.

ELECTRIC RISK

Risk of electrical accident if accessing to the zones indicated by this symbol, or during operations indicated in this manual

BURN RISK BY CONTACT WITH HIGH TEMPERATURE ZONES

IMPORTANT INFORMATION

To obtain good results or for an optimal functioning of the device.

2.2 Staff qualification

The device has to be manipulated only by personal able to evaluate the risk of using this machine.

All personal without the adequate training or in learning phase need a careful initiation. The present user's instructions may be a suitable base for it.

2.3 Intended use

This sterilizer has been developped to be used at the Laboratory to sterilize solids, porous and with cavities, wrapped or unwrapped

2.4 Improper use

Any different use from the one mentioned or any other no corresponding to the technical data is considered as improper use.

For any damages caused by this kind of uses, the unique responsible will be the user.

The following uses are specially considered as improper:

- The use of this device in locals or dependences requiring anti-deflagration devices.
- The use of this device to **sterilize liquids.**

2.5 Modifications

All modifications made in the instrument, in its functioning and in its accessories or spare parts, can expose the operator to some risks unforeseen in this manual.

Any modifications need the written consent of R. Espinar, S.L.

2.6 Safety measures

This equipment is provided with safety features to assure a suitable operation:

- Safety valve protecting against over pressure in the sterilization chamber.
- Safety Thermostat with manual rearm.
- Steam generator: Protection against over-heating.
- Safety thermostat with manual rearm against overheating of the heater in chamber.
- Safety switch for a defective door closure avoids starting a sterilization cycle with an open door.
- Blocking hydraulic device to avoid opening the door in the case of existing positive pressure inside the chamber.
- Process evaluation integrated system: continuous verification of sterilization parameters In the case of any anomaly, it aborts program and generates the corresponding warning message.

2.7 Operator submitted risks

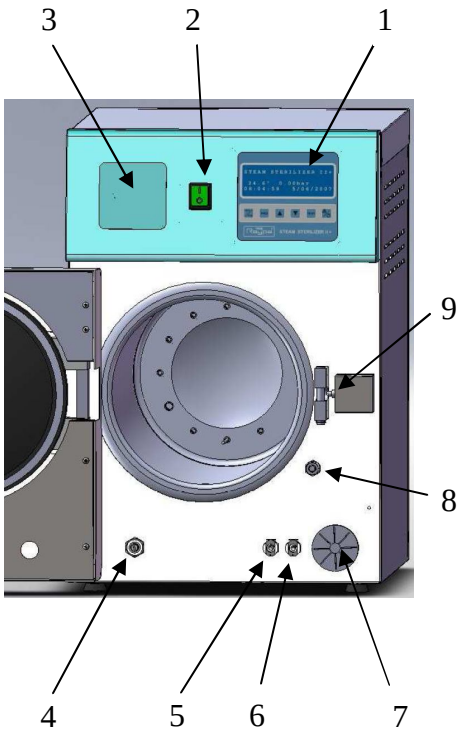
An autoclave operates with pressure, temperature and electricity. For this reason, safety rules have to be followed to avoid any dangerous risk for the operator.

Due to the possibility of contact with parts at temperatures higher than 60ºC, there is a potential risk of burns

There is a risk of being exposed to steams

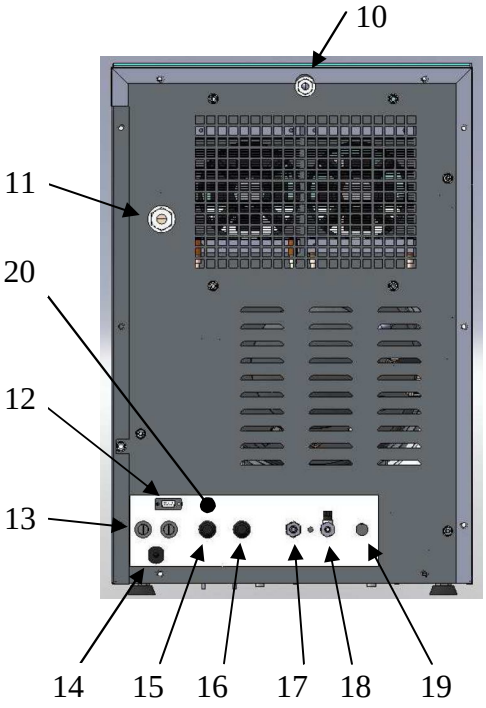
There is an electric shock hazard.

3 DESCRIPTION OF THE EQUIPMENT



(FRONT)

1) Microprocessor with LCD screen having 4 rows of 20 characters.
2) Main switch.
   Position ***I*** switches all circuits and gets lighted on.
3) Printer (Optional).
4) Cap and water unloading filter.
5) Quick connection to load the distilled water reservoir.
6) Quick connection to unload the used water reservoir.
7) Bacteriologic filter.
8) Hydraulic device.
   It avoids opening the autoclave with any positive pressure inside.
9) Safety switch.
   Avoids starting a cycle with the door open or not properly closed.



(BACK)

10) Reservoir air vent.
11) Safety valve outlet.
12) Connection RS-232 port.
13) Fuses.
14) Power cord.
15) Heater safety thermostat with manual rearm.
16) Steam generator safety valve with manual rearm.
17) Connection for automatic loading of distilled water reservoir.

NOTE:
Two connections for outlets 10 and 11 are supplied. They will enable you to connect a flexible tube to these outlets and to drainpipe.

18) Connection for direct unloading of used water.
19) Connection for direct unloading of distilled water reservoir.
20) Selector “PC-Printer” (units with printer “IT”)

4 INSTALLATION

Once unpacked, check that all components are in good conditions. It is important just in case of having any damage to be claimed to the forwarder, distributor, etc.

4.1 Location

The instrument will be placed in a suitable horizontal surface. Due to safety reasons, the distance between the instrument and the wall has to be no less than 6 cm. A distance of 10 cm. has to left to both sides of the machine

Do not block the ventilation grille in the back of the instrument to assure a suitable cooling of the heat exchanger.

4.2 Connection to the mains

A characteristics plate situated in the rear of the equipment shows voltage, power, etc. Check that the supply has compatibility with the equipment.

The electrical connection has to be necessarily grounded.

It is forbidden to interrupt the ground wire, to avoid any risk due to internal defects.

5 CONTROL/MICROPROCESSOR DESCRIPTION

The autoclave includes a controller according to EN-13060 rules.

The sterilization control is done by a microprocessor capable of a continuous evaluation of thermodynamic variables of the process.

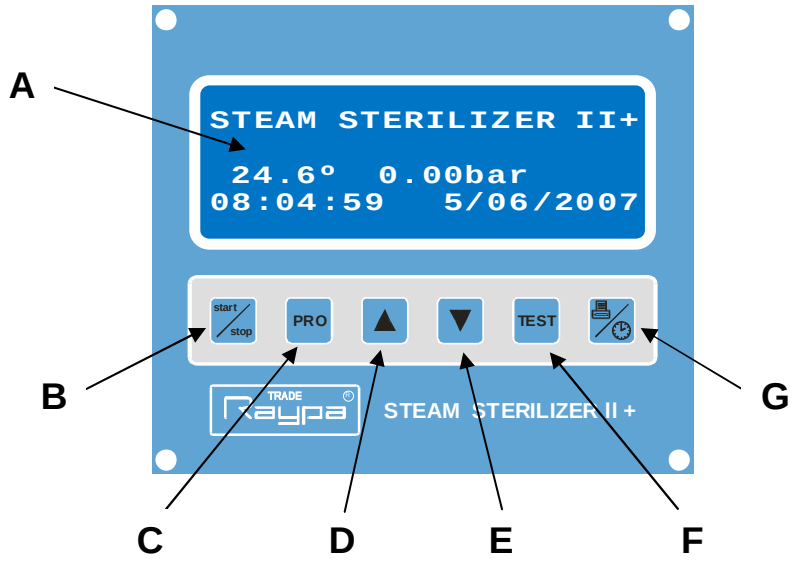
This microprocessor has 10 pre-defined sterilization programs and 4 user-free.

Among the functions of the microprocessor, we can emphasize the folllowing ones:

- Pre-heating of the sterilization chamber out of any cycle (stand-by: ON), to get a quicker sterilization cycle.
- Automatic distilled water re-filling.
- Automatic tests of:
  - Vacuum: To verify that the hydraulic circuit is hermetic with no pressure loss.
  - Helix / BD test: This test allows a cycle at 134ºC during 3,5 minutes and fractionated vacuum. To evaluate penetration of the steam in objects with hollows.

    BOWIE&DICK test allows the evaluation of the steam penetration in porous objects to be sterilized.
- Automatic recovery of ambient atmospheric pressure
- Forced ventilation cycle, in the case of keeping the lid closed alter ending a cycle. It avoids condensations along the cooling process of the autoclave.

5.1 Description of the microprocessor



A) Display LCD

LCD screen with a blue background with four lines of 20 characters.

B) Start/Stop key 

To start or stop the current selected program.

To stop a sterilization cycle, press the key during 2 seconds.

C) Programming 

By pressing the key, the selected program is displayed. By using the increase/decrease keys, all existing programs can be displayed

By keeping pressed more than 5 seconds, configuration mode is enabled..

D/E) Increment key  and decrease 

In programming mode, you can use them to increase/decrease the value of the edited parameters or to change the menu. Out of programming can be used to select the program or test.

F) Tests key 

To select the Vacuum test or the Helix / BD test. When

programming can be used to escape from editions.

G) Printer/clock key 

It is used to print out sterilization/tests reports. It can be used to access to clock/date configuration (press during 2 seconds).

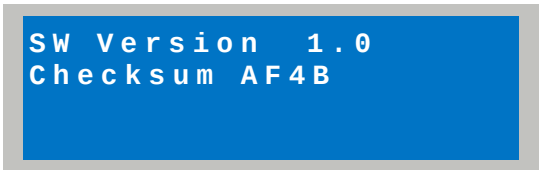
6 STARTING SCREENS

Once the autoclave has been connected to the mains, press main switch (2); it will get lighted on.

The display (A) from the microprocessor will show the following screens:

Welcome message:

In the case of maintaining pressed any key during the connection to the mains, the version of the software and control checksum is displayed.

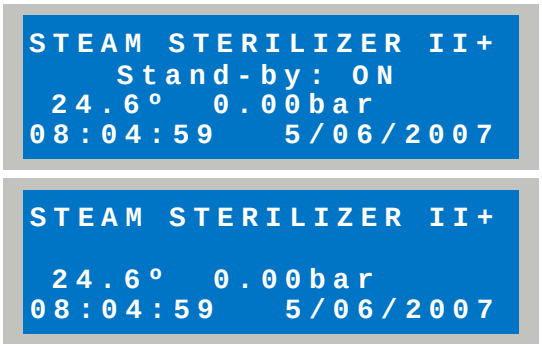


Afterwards, two beeps are heard and all pixels are displayed. There is a self control, to check any potential anomaly. **The user is asked** to open the door (if closed) to automatically acquire ambient pressure data.

The user should open the door, and after a few seconds, the system checks that pressure do not differs more than 0,01 bar from the stored one. In the case of a difference bigger than 0,01 the systems enters the new detected value. This pressure is called:

ambient pressure.

Afterwards, it is displayed the following screen



The line: “Stand-by: ON” (out of cycle heating) it will not be shown, unless a standby time has been programmed or this time has been elapsed already.

7 USER CONFIGURATIONS

To enter into the configuration screen is done by pressing the key PRO for 5 seconds, until ”CONFIGURATION” is shown.

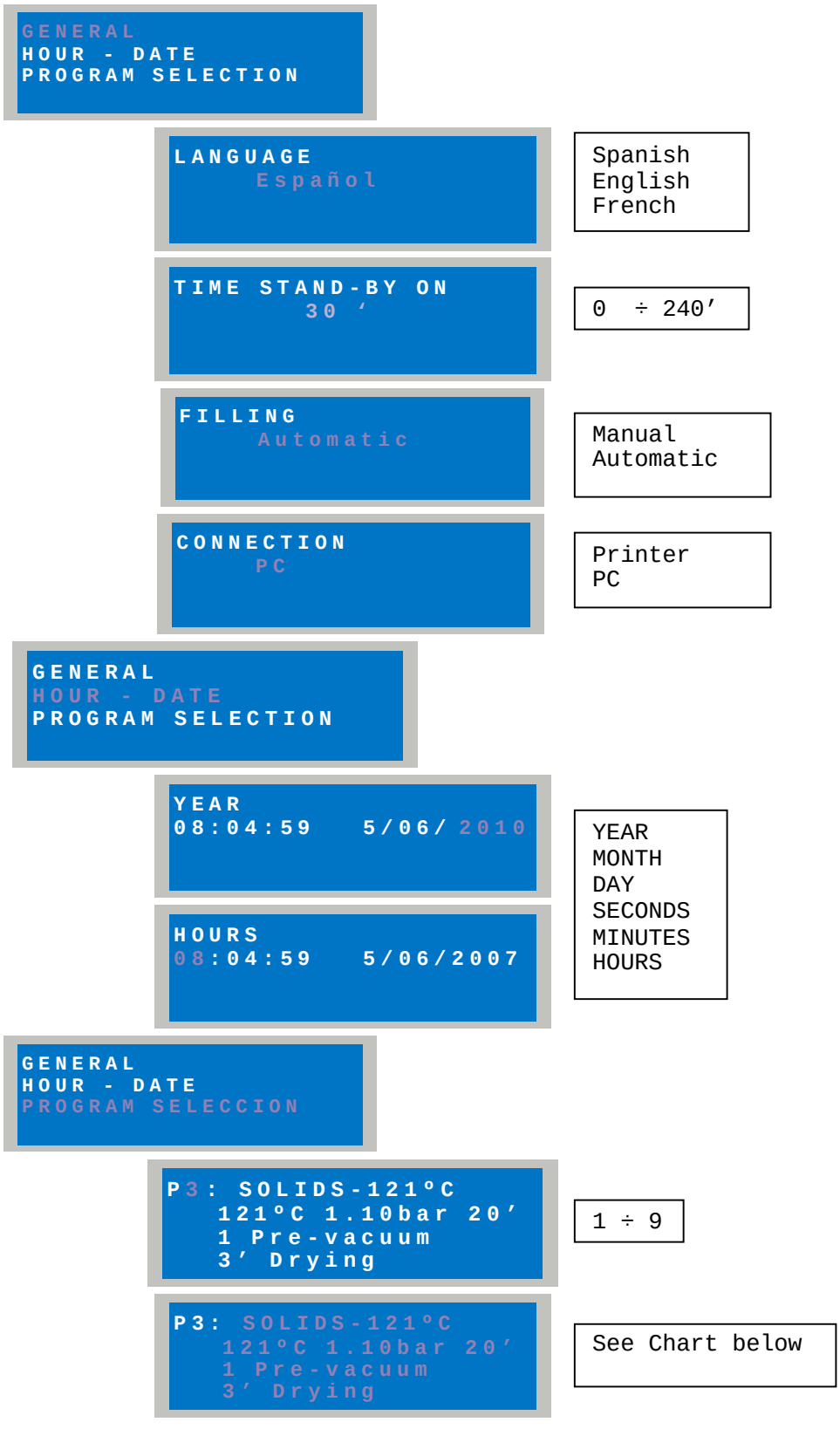
Keep in mind that after 2 seconds might appear the menu to modify programs (first line: “PROGRAM”), in this case, keep on pressing until “CONFIGURATION” is shown in the first line.

By pressing again the key PRO we will enter into the main configuration menu. Notice that the first line is blinking.

It indicates that first line is the selected option to continue by pressing again the key PRO. With keys ▲ ▼ we are able to select another line from the menu. To exit, press the key TEST.

7.1 Configuration tree

See below the complete configuration tree:



7.2 Chart of Programs

Name	Pre-vacuum	Temp. / Pres. Sterilization	Sterilization time	Drying time	Type of cycle EN 13060	Material Esterilizable
POROUS-134ºC	3	134ºC 2.1 bar.	4’	10’	B	Non wrapped porous objects. Porous objects in one package. Porous objects in a double package. Solids and hollow objects in one package. Solid and hollow Instrument in a double package
PRION-134ºC			18’		B	Porous objects non wrapped. Porous objects in one package. Porous objects in a double package. Hollow instrumental in one package. Solid and hollow Instrument in a double package
POROUS-121ºC		121ºC 1.1 bar.	20’		B	Porous objects non wrapped. Porous objects in one package Porous objects in a double package. Hollow instrumental in one package. Solid and hollow Instrument in a double package
HOLLOW-134ºC		134ºC 2.1 bar.	4’	5’	S	Non wrapped hollow instrumental
HOLLOW-121ºC		121ºC 1.1 bar.	20’		S	Non wrapped hollow instrumental
WRAPPED-134ºC	1	134ºC 2.1 bar.	4’	10’	S	Solid Instrumental in one package
WRAPPED-121ºC		121ºC 1.1 bar.	20’		S	Solid Instrumental in one package
SÓLIDS-134ºC		134ºC 2.1 bar.	4’	5’	N	Solid instrumental non wrapped
SÓLIDS-121ºC		121ºC 1.1 bar.	20’		N	Solid instrumental non wrapped
FLASH-134ºC		134ºC 2.1 bar.	3’	1’	N	Solid instrumental non wrapped
USER 1-xxxºc	1 ó 3	121ºC 1.1 bar. o 134ºC 2.1 bar.	3’ ÷ 40’	0’ ÷ 20’	x	
USER 2-xxxºc					x	
USER 3-xxxºc					x	
USER 4-xxxºc					x	

7.3 Selecting a program from the menu

When you enter into the menu “Program Selection”, you can define the programs you are going to work with and enable them to let them as usable ones.

In the previous chart (see 7.2), 10 pre-defined programs and 4 user free can be enabled to a maximum of 9 working programs (P1 a P9).

7.4 Defining and enabling a program

From P1 to P9, you can assign a pre-defined or user-free program.

To do this, proceed as follows:

Enter in “User configuration” (see section 7).

Using keys ▲ ▼ select line: “Program Selection”, and press PRO to enter in a specific program with its pre-defined program.

The nº of the program blinks. With keys ▲ ▼ enter the number of program you want (e.g. P1).

In the case of assigning a different program to this position P1, press PRO and the program configuration will start to blink. By pressing ▲ ▼ you will see all pre-defined programs. To validate any of them, press TEST, thus, the position P1 will store the wanted program.

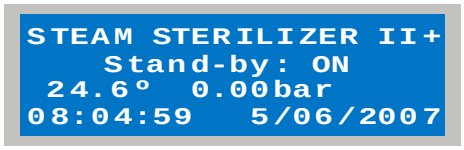
To define and assign more programs, proceed in the same manner.

In the case of assigning 4 programs (P1 to P4), proceed to cancel programs P5 to P9, if having programs already.

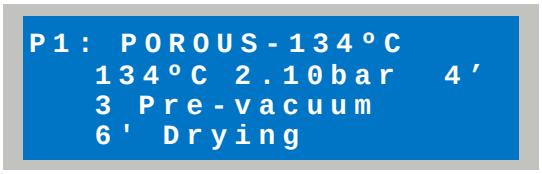
Proceed as previously, accessing through menu “Erase” with keys ▲ ▼

7.5 Programming/Modifying a program “USER1 xxx ºC”

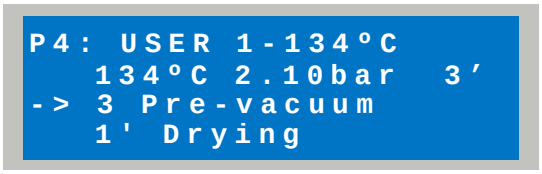
In the case of assigning a user free program, you must have it configured. To do this, go to first screen:



Press key PRO and the screen will show a program.

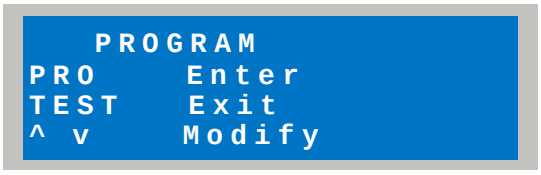


Using keys ▲ ▼ look for the position having the user free program.

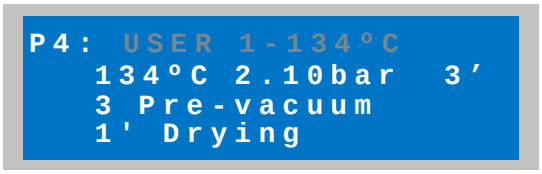


A program can be modified by the user when in the third line appears the symbol of an arrow pointing right.

To edit the program, keep on pressing key PRO for 2 seconds, until edition screen is shown.



To edit the program press again PRO and the selected will be displayed (name of the involved program blinks).



Using the key PRO you will be able to select the different parameters (they blink when selected) and eventually modify the values by using the keys ▲ ▼.

Using the keys ▲ ▼ with the name of the program selected, leads to the corresponding edition of the name, where you will see the first letter blinking.

With the key PRO the next letter will be edited and with keys ▲ ▼ you will be able to modify the character. To exit the editor, press TEST.

The different values for the programmable parameters are:

- Sterilization temperature = 121ºC to 134ºC
- Sterilization time = 3' ÷ 40'
- 1 o 3 pre-vacuum
- Drying time = 0' ÷ 20'

8 STERILIZATION CYCLE

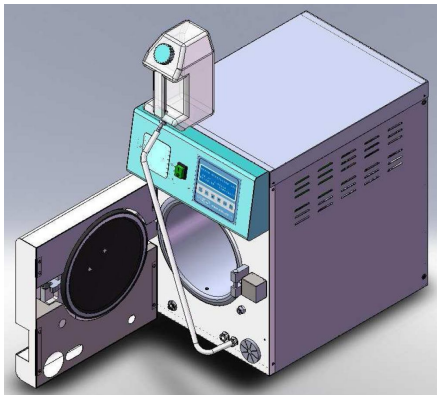
8.1 Filling with water the reservoir

When using the autoclave for the first time, or when the water level from the reservoir is LOW the following message is displayed:

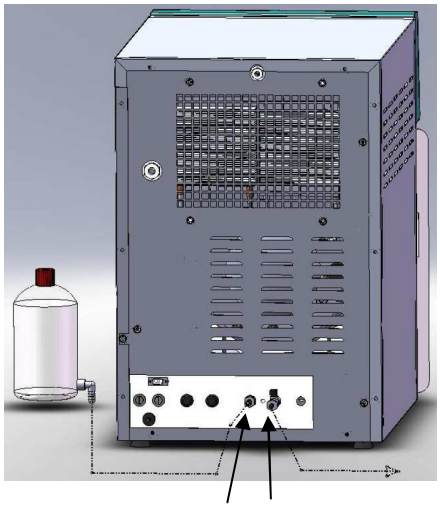
This situation is maintained until the water level reaches the maximum. Then a boozer advises.

The filling can be done in two ways; MANUAL or AUTOMATICALLY. The autoclave has been configured for a MANUAL filling.

8.1.1. MANUAL filling



- Fill the container for the manual load (2 L) with distilled water, maintaining a horizontal position.
- Connect the tube with the quick connection system into the female provided in the autoclave (5), pushing it until a “click” sounds.
- Place the container in vertical position (see figure) on top the autoclave loosing the cap a little bit without spilling the contents.
- The water will flow into the loading reservoir.
- Continue to empty totally the container or until to hear the beep meaning that the reservoir is full (warning message disappears).
- Stop the process and place the container under connection height, in horizontal position.
- Pressing the tube with the fingers, remove it from (5) by pressing the provided lever.



8.1.2 AUTOMATIC filling

To avoid manual fillings a bigger container can be used to feed distilled water automatically.

To do this, install a 25 L container. Connect to the provided back connection (17) using a suitable tubing and clamps to assure a tight connection. Loose the cap to allow a good flow.

To avoid emptying the used water reservoir, you can connect (18) to the drainage by installing a tube with clamps.

Drainage should be under the autoclave base. The tube cannot be left submerged or bended.

Fill the container with good quality distilled water.

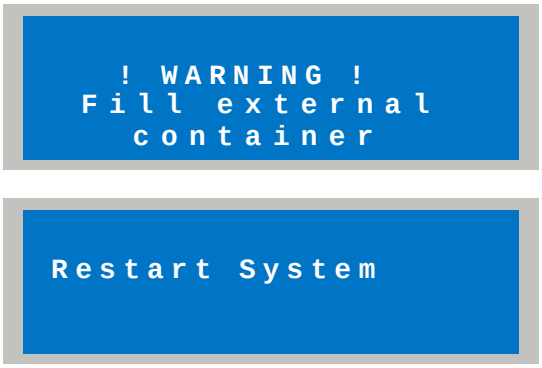
Program the option of automatic filling at General Menu USER CONFIGURATION (see section 7).

Do not program this option before having the container connected and filled up with distilled water.

When the water level is low, a filling pump will provide water from the external container. It will automatically stop when the reservoir is full. Meanwhile, the screen shows the following message

In the case of not reaching the maximum level in 5 minutes, the following message

is displayed:



The loading pump will remain disabled until a restart will be made. Afterwards, the pump will start normally.

In the case of re-filling of the external container while the warning is displayed, when the maximum level is reached, the warning disappears and a beep is heard.

To use water exceeding contaminants as indicated in the below chart, can lead to a shorter autoclave lifetime.

Also, it can increase the oxidation process in sensible parts of the autoclave, as well as salt deposits in the sterilization chamber and internal supports.

SUGGESTED MAX. LEVEL OF CONTAMINANTS IN DISTILLED WATER AND WATER PROPERTIES OF WATER TO BE USED FOR STEAM STERILIZATION

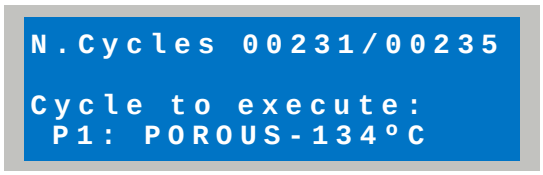
	Feeding water values	***Values in condensated***
Evaporation residues	= 10 mg/l	= 1,0 mg/kg
Silica, Si O2	= 1 mg/l	= 0,1 mg/kg
Iron	= 0,m2 mg/l	= 0,1 mg/kg
Cadmium	= 0,005 mg/l	= 0,005 mg/kg
Lead	= 0,05 mg/l	= 0,05 mg/kg
Traces of heavy metals except: iron, cadmium, lead	= 0,1 mg/l	= 0,1 mg/kg
Chloride	= 0,2 mg/l	= 0,1 mg/kg
Phosphate	= 0,5 mg/l	= 0,1 mg/kg
Conductivity (at 20 ºC)	= 15 µs/cm	= 3 µs/cm
pH	5 a 7	5 a 7
Aspect	Clean, No sediment	Clean, No sediment
Hardness	= 0,02 mmol/l	= 0,02 mmol/l

Try to purchase water compatible with indicated properties in the chart.

8.2 Starting a sterilization cycle

To run any cycle, press start/stop and select the needed program with the keys ▲ ▼ if necessary. Two counters are shown in the screen:

- Number of cycles already done and finished OK
- Number of started cycles.

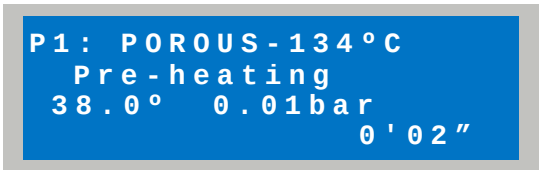


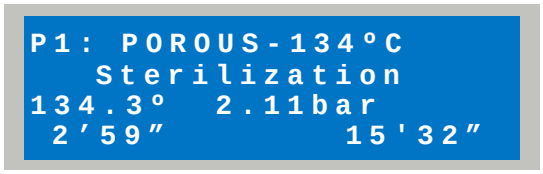
To start the sterilization cycle, press again start/stop. If the door is not closed, the following message is displayed during 5 seconds:

If during these 5 seconds, the door is closed by the user, the sterilization cycle will start automatically.

While the cycle is running, the following information is displayed:

- Number and name of the program.
- Phase of the cycle.
- Temperature and pressure in the chamber.
- Cycle elapsed time, right bottom in the screen
- Partial phase elapsed time, left bottom in the screen.





A sterilization cycle includes the following steps:

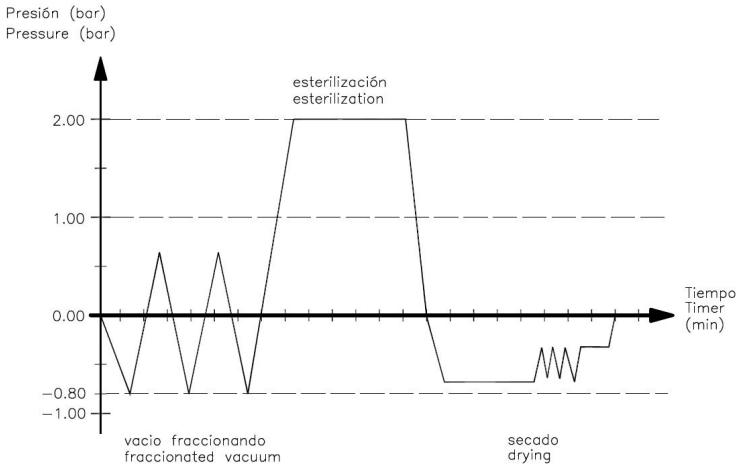
- Pre-heating

- Vacuum pulse 1
- Pressure pulse 1
- Unloading 1
- Vacuum pulse 2
- Pressure pulse 2
- Unloading 2
- Vacuum pulse 3
- Pressure pulse 3
- Stabilization (it starts when 121.0ºC or 134.0ºC are reached)
- Sterilization (it starts when 121.8ºC or 134.8ºC are reached)
- Unloading
- Drying
- Cooling
- Levelling
- Cycle completed

Total elapsed time starts at pre-heating step and finishes at cycle completed step Sterilization cycle will end with a beep and asking for opening the door. Once opened, a sterilization report is printed showing in the screen:

Afterwards, it shows the next message confirming a right sterilization cycle.

If for any reason, and during the cycle, an anomaly is detected, the control will pass to a FORCED STOP, displaying “STERILIZATION NEGATIVE” asking for a restart of the system, consisting in a switch off-switch on of the autoclave.



CICLO DE ESTERILIZACIÓN
STERILIZATION CYCLE

9 TEST PROGRAMS

The autoclave is provided with automatic test programs to verify sterilization processes:

- Vacuum test
- Helix / Bowie Dick Test

9.1 How it works the Vacuum test

To run the test, press TEST, to select the Vacuum test.

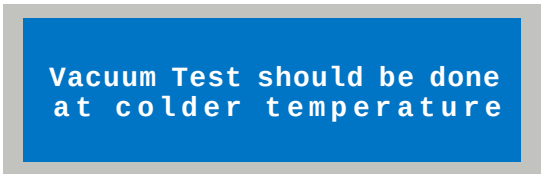
The screen shows two counters:

- Number of completed Vacuum tests.
- Number of initiated Vacuum tests.

To start the test, press start/stop.

Temperature in the chamber should be lower than 45ºC. Otherwise, the screen will

show:



During the test, the screen will show:

- The name of the step of the test.
- The temperature and pressure inside the chamber.
- Total test elapsed time, right bottom in the screen .
- Partial step remaining time, left bottom in the screen

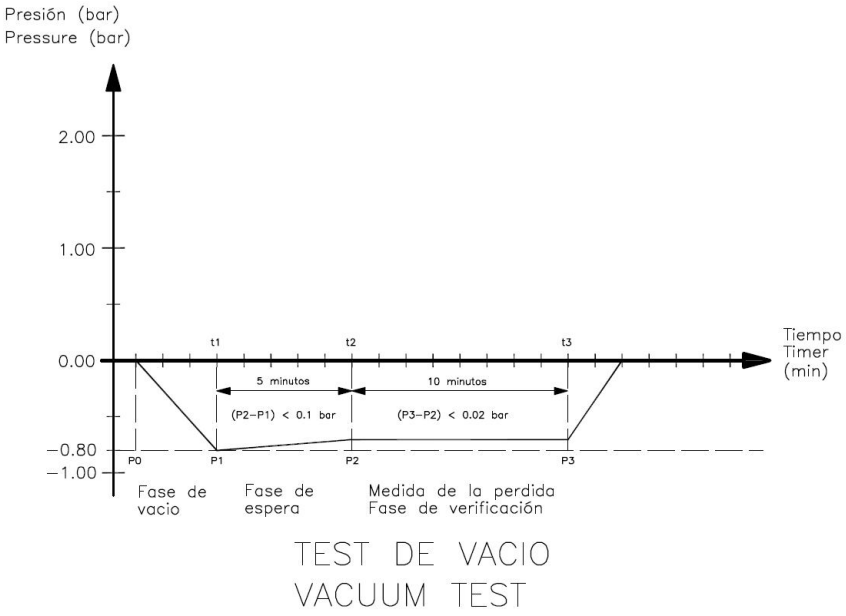
Each Vacuum test includes the following steps:

- Vacuum pulse
- Waiting time (5')
- Verification (10')
- Levelling
- TEST END

Ending steps **Waiting time** and **Verification,** pressures and temperatures are checked to make sure that the test has been carried out without problems. Otherwise, a warning message is displayed (see Section 15 “Alarms and warning messages”).

The test ends with a beep and asking for opening the door. Once opened, a report is printed and the following message is displayed:

If for any reason, and during the cycle, an anomaly, the control will pass to a FORCED STOP, displaying “VACUUM TEST NEGATIVE” asking for a restart of the system, consisting in a switch off-switch on of the autoclave.



TEST DE VACIO
VACUUM TEST

9.2 Helix – BD Test

Helix – BD test involves a sterilization cycle with special programming:

- Sterilization temperature = 134ºC
- Sterilization time = 3’ 30”
- 3 pre-vacuums
- Drying time = 4’

To run the test, press TWICE key TEST, to select Helix –BD. Two counters are displayed in the screen:

- Number of Helix-BD test already done.
- Number of Helix-BD test – BD started.

To start the test, press key start/stop.

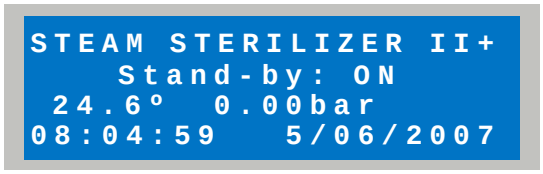
In the case of Helix test use device according to the rule EN 867-5 and place it in the sterilizing chamber (centre of intermediate tray).

In the case of Bowie Dick test use a standard test package and place it in the sterilizing chamber (centre of intermediate tray).

10 USE OF STAND-BY FUNCTION

The function Stand-by offers a sterilization chamber pre-heating to save time during the sterilization cycles.

When pre-heating, the message “Stand-by: ON” is shown:



The parameter TIME STAND-BY ON from GENERAL menu should be programmed in the case of need. Value = ‘0’ means no pre-heating.

Pre-heating operates with the door open or closed

Pre-heating operates:

- Alter switching on the autoclave.
- Alter ending a cycle or test, and open the door.

If Pre-heating ends, message “Stand-by: ON” will disappear:

- At the end of the programmed time, a beep sounds.
- After solving a faulty status.
- In the case of a not started Vacuum test due to the remaining heat in the autoclave.

11 FORCED VENTILATION

It is intended to avoid condensations while the autoclave cools to ambient temperature with the lid closed. It starts after ending a sterilization process or a Helix-DB test and 8 minutes without opening the door.

This ventilation is avoided in the case of a temperature lower than 45ºC.
Once completed the process, the autoclave beeps. After 8 minutes the forced ventilation is repeated. The display shows:

Levelling phase:

If for any reason, and during the process, the door is opened, forced ventilation will finish, and the autoclave will pass to “Stanby-ON” status.

12 FORCED STOP

It takes place when a test or a sterilization cycle has been interrupted due to a **failure** or to an **alarm**. Among the **alarms,** the stop of the system due to a shutdown can be one of them.
The forced stop is displayed in the screen:

A restart should be made.

13 PREPARING THE PRODUCTS TO BE STERILIZED

Ton assure the efficiency of the sterilization process, the products to be sterilized should be handled in a proper way and distributed in some order inside the chamber.

TREATMENT OF THE PRODUCTS PRIOR TO STERILIZE

To manipulate and to carry **contaminated** material, it is advised to follow the instructions below:

- Use rubber gloves of a suitable thickness
- Use a tray to carry the material
- Avoid to carry any product directly in your hands
- Protect your hands against sharp objects
- Wash thoroughly your hands (even with gloves) once finished the manipulation

Next proceed to clean the products removing any remaining residues.

To guarantee a convenient cleaning proceed as follows:

- Rinse the instruments under tap water, alter using them.
- Divide the metallic instruments according to the composition (carbon steel, stainless steel, aluminium, brass, etc.) to avoid an electrolytic oxidation-reduction phenomenon.
- Carry out a washing, using an ultrasonic bath or manually, with a solution of water and a germicidal. For best results, use a dedicated detergent for ultrasonic bath with a neutral pH.

After washing, rinse and check. If necessary, repeat the process.

To avoid chalk stains, last rinse should be made with distilled/demineralised water. If you use tap water, you should to dry the material.

14 LOADING THE AUTOCLAVE

For a correct sterilization distribute the objects as described below:

- Instruments with different composition (stainless steel, carbon steel, brass, aluminium, etc.) should be placed in different trays, or with space between them.
- When the instruments are made of stainless steel, you should place an hydrophobic paper between the object and the tray to avoid direct contact.
- In any case, objects to be sterilized should be placed separately.
- Always place the objects to sterilize in open position.
- Place the vessels, graduated cylinders, etc leaning on a side, to avoid water accumulation.
- Do not overload the trays
- Do not stack the trays nor in direct contact with the wall. Always use the trays support.

PLASTIC AND RUBBER TUBES

- Rinse before use. They should be clean, washed and rinsed.
- Place the tubes on the tray avoiding obstructions and bending.
- Leave them as linear as possible.

PACKAGES AND WRAPPED PRODUCTS

- Place the packages not stacked and separately avoiding contact with the wall.
- When wrapping an objet, use a suitable paper (sterilization paper, paper towels, etc.) closing with an autoclave indicator tape.

ENVELOPED OBJECTS

- Wrap the instruments separately, or with the same composition together.
- Seal the envelopes with an autoclave indicator tape.or using a thermo sealer.
- Do not use metallic staples, pins or similar.
- Place the envelopes on the tray with the plastic sheet side down
- Do not stack the envelopes between them.

15 WARNING MESSAGES AND ALARMS

In the case of a failure or alarm, the corresponding message is displayed.

Failures have a code number.

Alarms are situations potentially due to a failure or not. For this reason, you will see ¡WARNING!. Among them, the stop of a cycle by the user or due to a shutdown as well as warnings to fill / empty reservoirs

FAILURES		
Number	**Message**	**Possible cause**
1	Chamber probe Pt-1	Breakage of probe PT100.
2	Steam probe Pt-2	
3	Heating probe Pt-3	
4	Wall probe Pt-4	
6	Pressure probe Ma	Breakage of probe mA.
19	Ambient pressure	Wrong pressure in chamber when switching the instrument, and capturing **Ambient pressure**. Out of range: – 0,47 bar. < P < 0,05 bar. (possible variations of atmospheric pressure, due atmospheric conditions and up to 4000 meters). The failure (message and beep) will disappear after 5 sec. , failure 20 “Incorrect pressure” will be checked.. Autoclave should be re-started with the door open.
20	Incorrect pressure	Wrong pressure in chamber out of any cycle-test, where pressure should be practically equal to **ambient pressure.** Out of range: **Ambient pressure** – 0,05 bar. < P < **Ambient pressure** + 0,10 bar. Autoclave should be re-started with the door open
21	Presostat activated	Presostato de seguridad activado fuera de un ciclo de esterilización.
22	Pressostat deactivated.	Safety pressostat deactivates when chamber pressure > **Ambient pressure** + 0,45 bar.
23	Door open	Open door detector indicates door open during a cycle – test .
29	Sterilization temp.	Stabilisation temperature lasts more than 10’
		During Sterilisation, temperature is out of range: 121.0 ºC ≤ T ≤ 124.9 ºC o 134.0 ºC ≤ T ≤ 137.9 ºC, for more than 10 sec.
30	Sterilisation press.	During Sterilisation, pressure is out of range: 1.03 bar. ≤ P ≤ 1.30 bar. o 2.02 bar. ≤ P ≤ 2.39 bar. , for more than 10 sec..
31	Preheating time	Preheating lasts more than 60’.
32	Pulse Vacuum time	Any of the vacuum pulses lasts more than 15’.
33	Pulse Pressure time	Any of the pressure pulses lasts more than 120’.
34	Unloading time	Any of the unloading steps lasts more than 10’.
35	Levelling time	Any of the Levelling steps lasts more than 10’.
36	Loading tank levels	Anomalous detection of level. It detects max. Level but not low level.
37	Sterili.Press.-Temp.	During the sterilisation phase, the ratio pressure and its theoretical value is out of range: Theoretical Pres. - 0.05

		bar < Pressure < Theoretical Pres. + 0.25 bar, for more than 10 sec..

ALARMS	
Message	**Possible cause**
Shutdown	There has been a shutdown during a sterilisation cycle or test
Manual stop	The user has aborted the cycle- test.
P2 - P1 >= 0.1 Bar	Vacuum Test: Ending phase “Wait (5')”, condition “P2 - P1 < 0.1 bar.” is not valid to continue the test.
T3 - T2 >= +- 3ºC	Vacuum test: Ending phase de “Verification (10')”, condition “Temp3 – Temp2 < 3ºC” is not valid to validate the test.
P3 - P2 > 0.013 Bar	Vacuum test: Ending the phase “Verification (10')”, condition “P3 - P2 < 0.02 Bar.” Is not valid to validate the test.
Empty internal tank	Warning of empty condensates reservoir (full).
Empty external tank	Warning of full condensates reservoir.
Fill loading tank	If FILLING = Manual, warning of low level in internal reservoir. User has to refill to the maximum level.
Fill external tank	If FILLING = Automatic, warning of an uncomplete filling in 5’. Loading pump will remain turned off. After a re-start of the autoclave, the pump will turn to work normally.
Check battery/clock	Wrong Date-hour. Check the value and the battery

16 DATA PRINT OUT

In the case of the autoclave includes a printer (accessory IT) or a table top printer /accessory ITS) connected through the port RS-232, data from sterilizations or tests can be printed.

Reports about sterilization cycles and tests are printed automatically when door is open after ending the cycle/test. These reports are stored in memory, and the last one can be re-printed at any time.

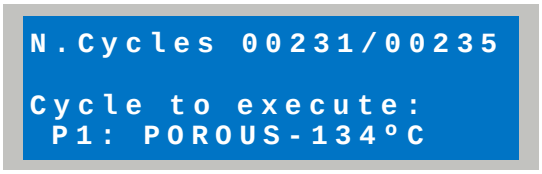
During the printing, the screen shows:

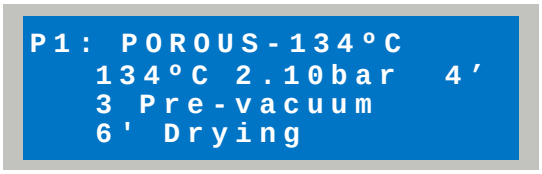
Pressing the key  the last report is printed again.

Memory stores not only the last cycle-test completed. It has last cycle, last vacuum test and the last Helix-BD. To print one of

them, you should press  and select the one needed :.

To print the last cycle :





To print the last vacuum test:

To print the last Helix-BD:

Print out is not available while a test or a cycle is running. Reports include all data according EN-13060/2002.

Normal print out includes chamber pressure and temperature. Data from other probes are printed in the case of a failure, or eventually, by pressing the key  and  at the same time..

Examples of a positive sterilization cycle report and a negative one (failure):

```
STEAM STERILIZER II+
S/N 03415
SW Version  1.0
N.Cycles 00016/00018


P1: POROUS-134ºC
   134ºC 2.10bar  4'
   3 Pre-vacuum
   6' Drying

08:47:57  10/06/2007
                    ºC          bar
                  ------------------
CS        00:00      30.2       -0.01
1PV       09:22      75.6       -0.80
1PP       09:27      76.5        0.40
2PV       09:38      77.9       -0.80
2PP       09:45      78.3        0.40
3PV       10:14      78.6       -0.80
SS        11:50     134.6        2.11
 1'       12:50     134.5        2.11
 2'       13:50     134.2        2.10
 3'       14:50     134.3        2.10
SE        15:50     134.3        2.11
SPD       16:29      98.4        0.09
EPD       22:29      95.0       -0.70
CE        25:08      86.1       -0.02

MAX       11:52     134.8
MIN       13:48     134.2

09:13:06  10/06/2007


    Sterilization   POSITIVE


OPERATOR :


.................................
```

```
STEAM STERILIZER II+
S/N 03415
SW Version  1.0
N.Ciclos 00016/00019


P1: POROUS-134ºC
   134ºC 2.10bar  4'
   3 Pre-vacuum
   6' Drying

09:37:46  10/06/2007
           PT1    P    PT2   PT3   PT4
          ----------------------------
CS  00:00  47.2 -0.01  45.0  43.6  44.3


    00:10  47.2  0.00  45.1  43.5  44.3
09:37:56  10/06/2007

    Sterilization   NEGATIVE

    FAILURE:27   Blocking door

        ¡WARNING!
    SEE USER MANUAL


OPERATOR :


.................................
```

An extended report (all probes) differs in including temperature readings from all probes.

```
          |
          |
           PT1    P    PT2   PT3   PT4
          ----------------------------
CS  00:00  30.2 -0.01  31.3  30.5  30.4
1PV 09:22  75.6 -0.80 181.2 147.8  60.3
1PP 09:27  76.5  0.40 180.6 147.9  62.7
          |
          |
```

A report from a Helix-BD test differs in the following informations::

```
|
N.Tests  00007/00007


TEST HELIX / BD

|
|

Test Helix / BD  COMPLETE
Please, stick here indicator paper control
```

Explanation of printed codes in reports:

" CS "	Cycle Start
" 1PV "	1ª Pulsation Vacuum
" 1PP "	1ª Pulsation Pressure
" 2PV "	2ª Pulsation Vacuum
" 2PP "	2ª Pulsation Pressure
" 3PV "	3ª Pulsation Vacuum
" SS "	Stabilization Start
" SE "	Sterilization End
" SPD "	Start Process Dry
" EPD "	End Process Dry
" CE "	Cycle End

Max. and min. temperature values during sterilization are displayed as: " MAX " y " MIN ".

Vacuum test report with positive result:

```
STEAM STERILIZER II+
S/N 03415
SW Version  1.0
N.Tests  00018/00019


VACUUM TEST


10:21:41  10/06/2007
                    ºC          bar
                  ------------------
CS       00:00      28.3      -0.01
E1P      01:25      28.3      -0.80
E2P      06:25      28.7      -0.79
E3P      16:25      28.7      -0.79
CE       17:08      28.4      -0.01

10:38:49  10/06/2007


    Vacuum Test   POSITIVE


OPERATOR :


.....................................
```

Explanation of printed codes in a Vacuum test

" CS " Cycle Start
" E1P " End 1 Phase
" E2P " End 2 Phase
" E3P " End 3 Phase
" CE " Cycle End

16.1 Connection RS-232

This autoclave has a 9 pins connector (12) in the back side, to be able to connect a table top printer or a PC.
You should select if a printer or a PC (see section 7) will be connected to the RS-232. In option "connection" select "PC" or "printer"

Printer has to be able to print 40 rows as minimum and it should have interface RS-2321 at 9.600 bps. 8 bits, no parity, 1 stop bit, and a buffer of 150 characters minimum..

Connection cord to printer should be: "Cable Null-modem" with 9 pins connector. Connection cord for a PC should be a standard one for serial port of 9 pins.

The instrument has specific software for PC connection (optional). In the case of not having in the PC a connection RS-232, a RS232-USB adapter should be used.
The installation CD has an Instruction manual to help the user.
Requirements:
Operative System Windows 98SE, XP, Vista
Screen resolution: 1024 x 768 pixels.

IMPORTANT: If the autoclave has a installed printer (ref. IT), you should select the switch (20) in position “PC” to connect to a computer and “PRINTER” to connect to the printer.
To use the printer (ref. IT) after the PC, move to “PRINTER” position and remove the communications cord .

17 MAINTENANCE

To assure a safe and efficient use along the autoclave lifetime, it is advisable to run regularly some maintenance operations
It is important to carry out periodically an **autoclave validation**, to verify all thermodynamic parameters compared to reference values from suitable calibrated devices.

☛ SEE SECTION “**AUTOCLAVE VALIDATION”**

The regular maintenance described further on, are easy manual operations or preventive operations.
IN THE CASE OF A COMPONENT REPLACEMENT, ASK OR USE ORIGINAL SPARE PARTS.

17.1 Standard maintenance

See below a chart with the routine operations to have it in good working conditions.
In the case of a **very intense use** of the autoclave it is recommended to **strengthen** the maintenance intervals

DAILY	Clean the gasket and inner side of the door Clean external surfaces
WEEKLY	Clean the sterilization chamber and accessories Disinfection of external surfaces
MONTHLY	Clean or replace the unloading filter Bacteriologic filter sterilization
EVERY 3/6 MONTHS (upon use)	Replace bacteriologic filter
EVERY 6/12 MONTHS (upon use))	Safety valve maintenance (see specific section)
YEARLY	Autoclave validation (see specific section)

Keep always in mind the following **general advices:**

- **Do** not clean the autoclave using direct water jet. Potencial infiltrations in electric and electronic components may affect, even in a irreversible way the normal work of the instrument.
- **Do** not use abrasives, metallic brushes or products for metal cleaning (solids and liquids) to clean the autoclave or the sterilization chamber
- **Do** not use chemicals or disinfectant substances to clean the sterilization chamber. These products can lead to damages in the chamber.
- **Do** not use acid cleaning agents, chloride solvents or salt solutions for cleaning purposes.
- **Do** not let to accumulate chalk residues in the sterilization chamber, door and gasket, remove them periodically

  With time all these residues can damage in parts of the

instrument as well as affect to the normal work of components in the piping circuit.

BEFORE STARTING ANY REGULAR MAINTENANCE OPERATION, CHECK THAT GENERAL SWITCH IS IN POSITION 0 (SWITCHED OFF) .

17.2 Description of maintenance operations

17.2.1 Cleaning the gasket and inner part of the door

To remove chalk traces from the gasket and inner pert of the door, a cotton cloth embedded in a weak solution of water and acetic acid (or vinegar)

Dry the surfaces and remove any residue left after using it.

17.2.2 Cleaning external surfaces

Clean all external surfaces using a cotton cloth slightly moistened in water; some neutral detergent can be used if necessary. Dry the surfaces before using the autoclave again.

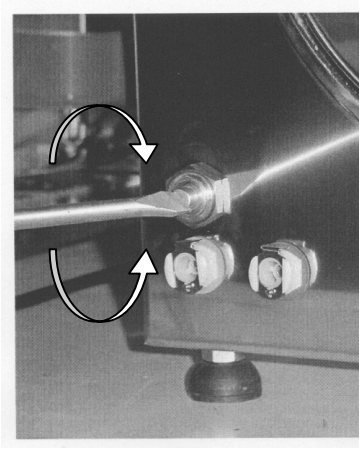
17.2.3 Cleaning sterilization chamber and accessories

Clean the sterilization chamber, protecting tray and baskets, using a cotton cloth moistened in water. If necessary, some neutral could be added to the water. Rinse thoroughly with distilled water, paying attention to any residue could be left.

☛ DO NOT USE SHARP INSTRUMENTS TO REMOVE CHALKY STAINS IN THE STERILIZATION CHAMBER. QUALITY OF DISTILLED WATER USED SHOULD BE CHECKED .

17.2.4 DIsinfection of external surfaces

Use denatured alcohol.



17.2.5 Cleaning / replacement of unloading filter

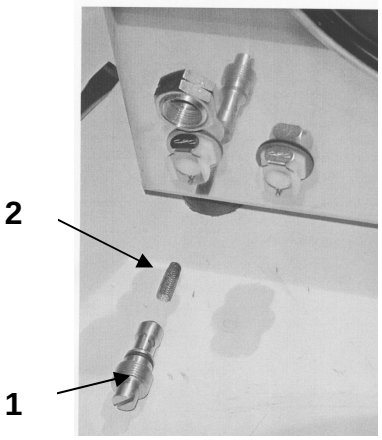
With the normal use different type of residues can remain in the filter and eventually obstruct the inner unloading tube.

To clean or replace the filter, open the door and with screwdriver unscrew the filter support (1).

Remove the filter (2) from the support (1) and clean it carefully under a hot water jet. If necessary, a sharp instrument can be used to remove incrustations.

If the filter appears to be useless, replace it by a new one.

Place the filter in its support and screw the assembly into the autoclave.



17.2.6 Bacteriologic filter sterilization

Remove periodically the bacterial load sterilizing at 121 ºC. At the end of the program screw it tightly in its support.

☛ THE STERILIZATION PROCESS DOES NOT REMOVE OBSTRUCTIONS IN THE FILTER NOR EXTEND ITS LIFETIME. IT IS EMPHASIZED TO FOLLOW THE INTERVALS FOR ITS REPLACEMENT DESCRIBED IN THE MAINTENANCE TABLE.

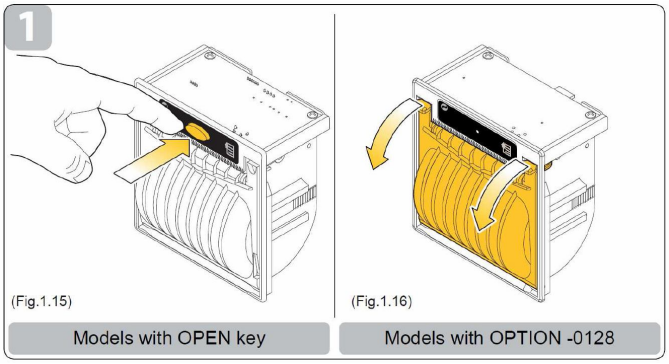
17.2.7 Bacterlologic filter replacement

After the recommended time of use or if evident deterioration or obstruction has been detected (most of the times a greyish colour

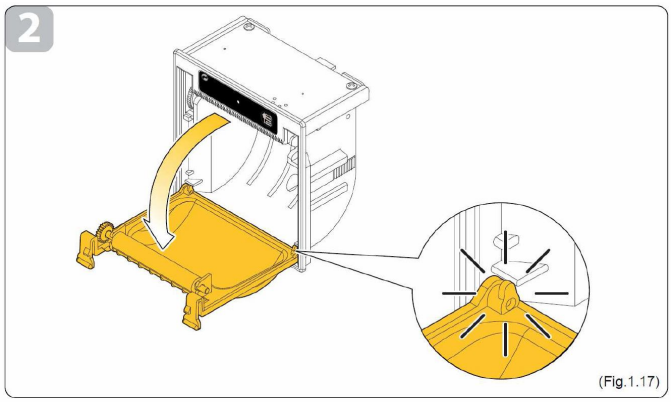
appearance), unscrew the filter from the support and replace it with a new one

17.2.8 Loading a new paper roll in the printer

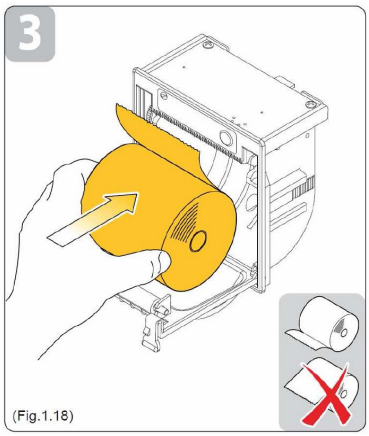
To replace the paper roll proceed as follows:

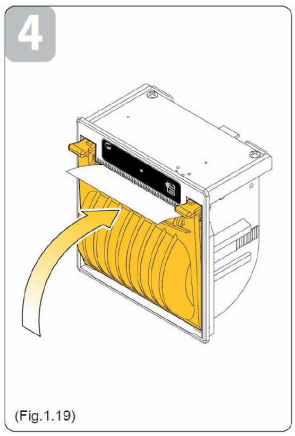


1) Open the lid by pressing the open button (fig. 1.15) or using the grooves (fig. 1.16) depending upon model.



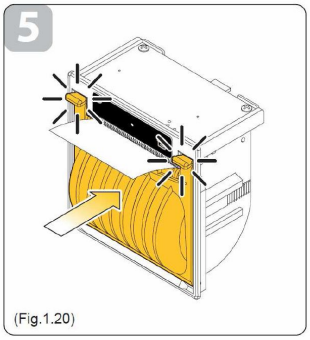
2) Move down the lid (fig. 1.17).



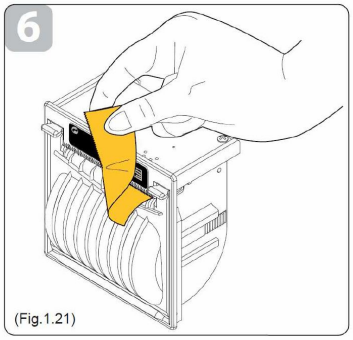


3) Place the paper roll making sure that it has been left in the right position (fig. 1.18).

4) Take out the paper end and close the lid (fig. 1.19).



(Fig.1.20)



(Fig.1.21)

5) Press the lid (fig. 1.20).

6) Remove the excess of paper as in the figure (fig. 1.21).

7.2.9 Safety valve maintenance

This operation is needed to guarantee the correct work of the valve.

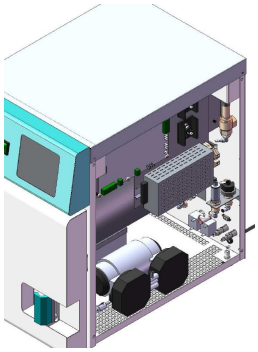


Fig.1

Notice:

- *Carry out this operation with the autoclave at ambient temperature and without pressure.*
- *Make sure that the autoclave is completely* ***switched off***

Access to the safety valve mounted in the back side by unscrewing the plate (fig. 1).

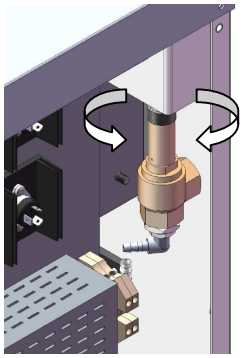


Fig.2

Loose the knurled shell counter clockwise (fig. 2) until you hear a “click” and the consequent movement.

Screw clockwise and repeat this operation a couple of times.

Tighten the shell.

Verify that the shell has been properly screwed and tightened.

17.2.10 Autoclave validation

to guarantee a constant process safety along the time, it is necessary **verify** periodically (at least once per year) **the thermodinamic parameters of the process** (pressure and temperature), checking that they are within the admitted minimal limits.

The re-qualification of the autoclave is under **user total responsibility**.

Current European normative **EN 554** (*Sterilization of medical devices. Validation and routine control of sterilization by moist heat*) y **EN 556** *(Sterilization of medical devices. Requirements for medical devices to be designated "STERILE"),* provide an efficient tool to carry out these verifications in water steam sterilizers.

Given that such controls require some qualification and experience, the use of specific tools or devices (sensors and high precision probes, data logger devices, specific software, etc.) properly controlled and calibrated, it is emphasized to address to **specialised Companies** for this activity.

18 REPAIRS AND SPARE PARTS

Only original spare parts from RAYPA can guarantee a correct functioning and safety of the instrument.

Code	Description
78042	Door gasket
79013	Bacteriologic filter
41000	Unloading filter
69024	Steam generator pump
	Automatic filling pump
69022	Vacuum pump
66090	Steam generator heater
66086	Tank belt heater
68041	Probe Pt100 sterilization tank (Pt.1)
68012	Probe Pt100 Tank belt heater (Pt.3)
68013	Probe Pt100 steam generator (Pt.2)
	Probe Pt100 tank wall (Pt.4)
69023	Cooling fan
68042	Safety thermostat steam generator
	Safety thermostat tank belt heater
68047	Safety presostat
61025	Electrovalve EV2 24V CC
61015	Electrovalve EV6 230V CA
61023	Electrovalve EV1 24V CC
	Electrovalve EV4 24V CC
	Electrovalve EV5 24V CC

61024	Electrovalve EV3 24V CC
61027	Pressure transducer 0/4 bar – 4/20 mA

Before any intervention in the instrument, switch it off.

Contact your Distributor in the case of any fault.

NOTICE: In the case of returning goods for repairing, make sure of cleaning and decontaminating them before.

19 WARRANTY

This instrument has one year warranty against any manufacturing defect. This warranty is not applicable in the case of an improper use or alien reasons to R. Espinar.

Any manipulation of the instrument without previous agreement with R. Espinar, SL will cancel the warranty.

20 APPENDIX

20.1 Technical data

- Tank dimensions: Ø250 x 430 mm.
- External dimensions (height x wide x deep: 630x420x630 mm.
- Capacity: 21 litros
- Weight: 30 kg.
- Power supply: 230V 50/60Hz
- Power: 2300 W.
- Amperage: 10 A.
- Fuses: 16 A - 6,3x32 mm.
- Class of insulation: Class I
- Class of installation: Class II
- Noise level: 60 dB(A) max.
- Total mass to sterilize:

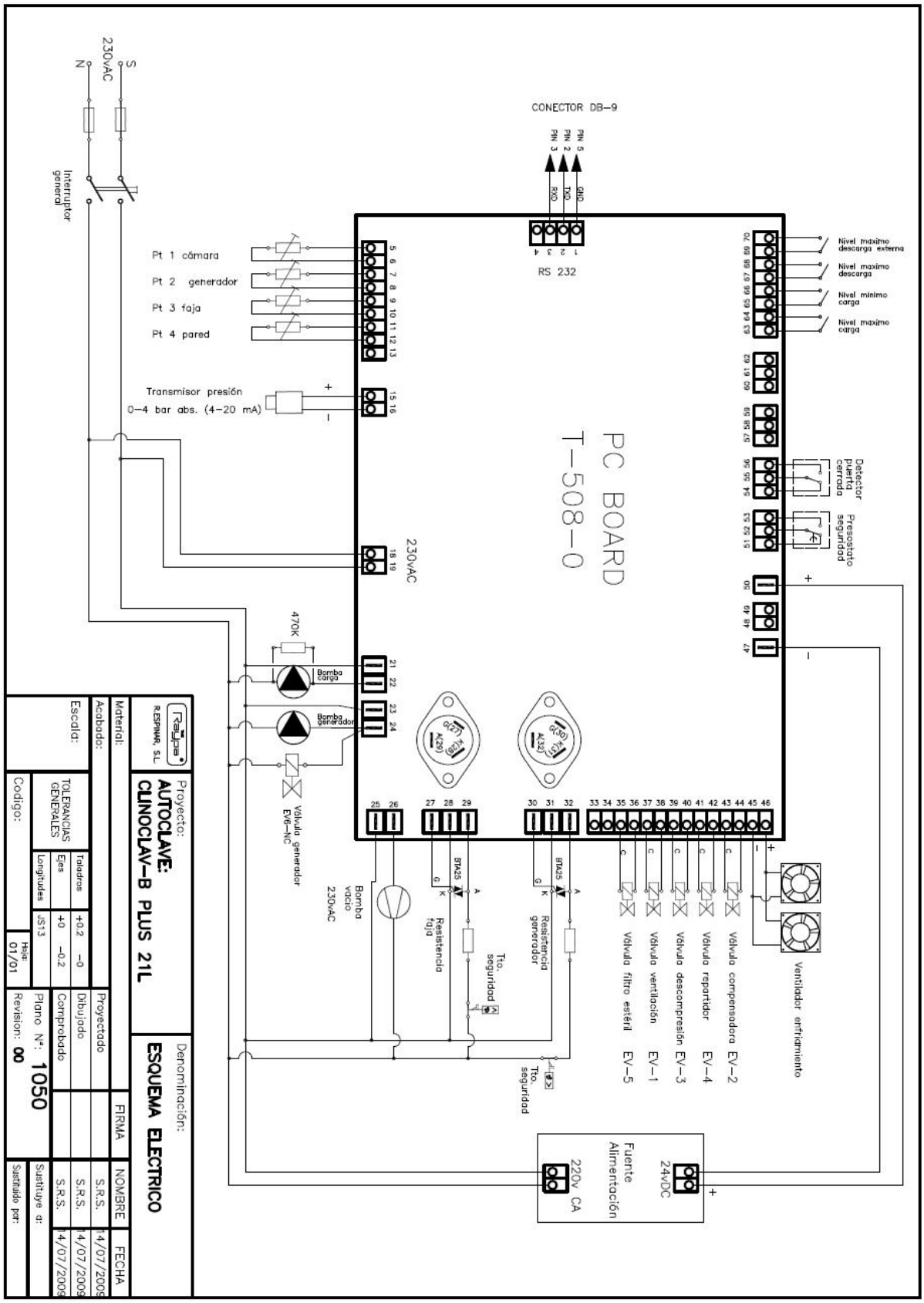
  Porous material: 1,3 kg

  Solid material and/or hollow non wrapped: 6,3 kg

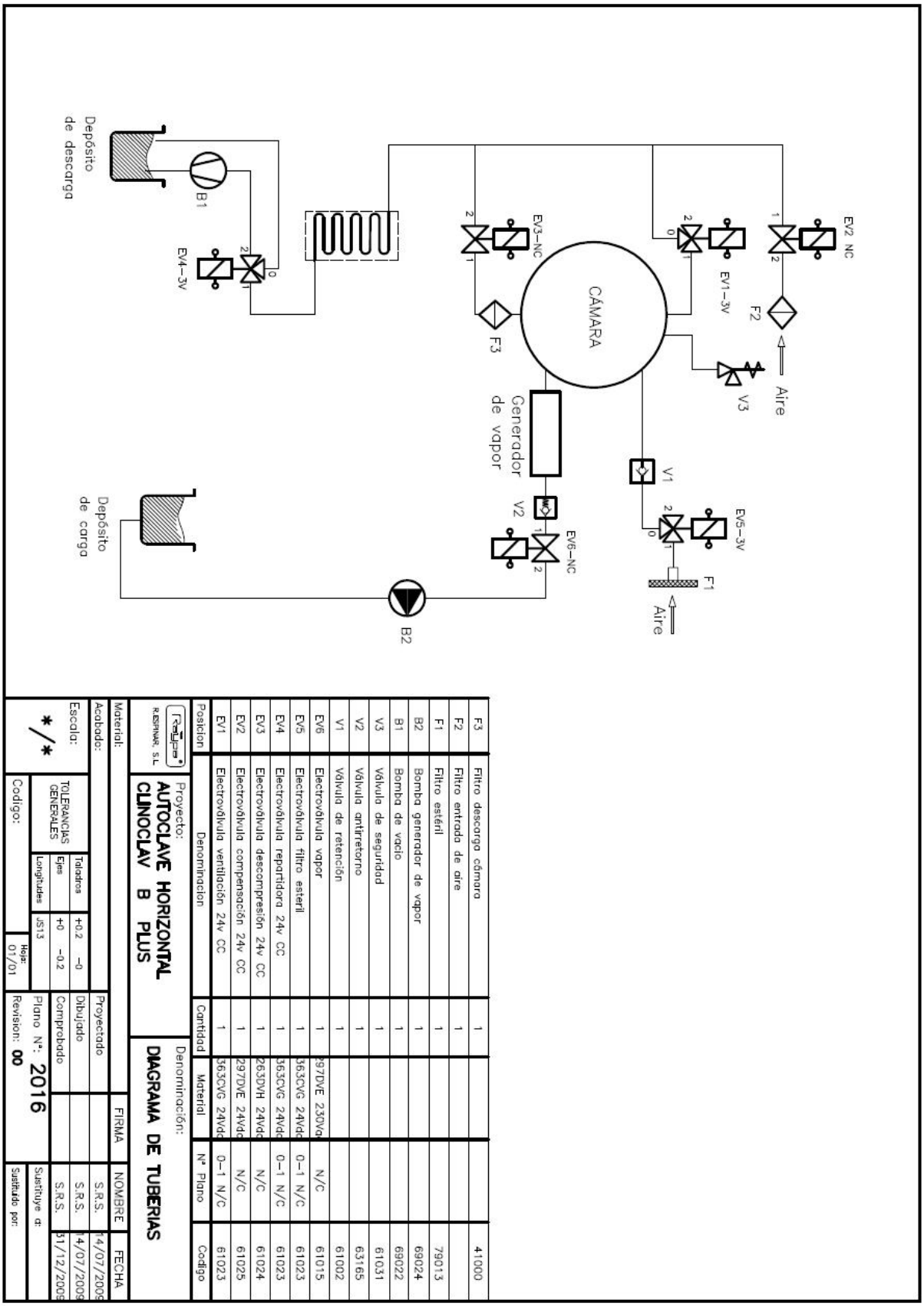
  Solid material and/or hollow wrapped: 3,8 kg
- Ambient conditions: +5º C +30º C max 80% HR

- Languages: Spanish, English, French

16.3 Electric diagram



16.4 Piping diagram



Posicion	Denominacion	Cantidad	Material	Nº Plano	Codigo
F3	Filtro descarga cámara	1			41000
F2	Filtro entrada de aire	1			
F1	Filtro estéril	1			79013
B2	Bomba generador de vapor	1			69024
B1	Bomba de vacio	1			69022
V3	Válvula de seguridad	1			61031
V2	Válvula antiretorno	1			63165
V1	Válvula de retención	1			61002
EV6	Electroválvula vapor	1	297DVE 230Vca	N/C	61015
EV5	Electroválvula filtro esteril	1	363CVG 24Vdc	0-1 N/C	61023
EV4	Electroválvula repartidora 24v CC	1	363CVG 24Vdc	0-1 N/C	61023
EV3	Electroválvula descompresión 24v CC	1	263DVH 24Vdc	N/C	61024
EV2	Electroválvula compensación 24v CC	1	297DVE 24Vdc	N/C	61025
EV1	Electroválvula ventilación 24v CC	1	363CVG 24Vdc	0-1 N/C	61023

Proyecto: AUTOCLAVE HORIZONTAL CLINOCLAV B PLUS

Denominación: DIAGRAMA DE TUBERIAS

R.ESPINAR, S.L.

Material:

Acabado:

Escala: */*

Codigo:

Hoja: 01/01

		FIRMA	NOMBRE	FECHA
Proyectado			S.R.S.	14/07/2009
Dibujado			S.R.S.	14/07/2009
Comprobado			S.R.S.	31/12/2009

TOLERANCIAS GENERALES: Taladros +0.2 −0; Ejes +0 −0.2; Longitudes JS13

Plano Nº: 2016

Revision: 00

Sustituye a:

Sustituido por:

16.5 Declaration of conformity

DECLARACIÓN DE CONFORMIDAD
DECLARATION OF CONFORMITY

El fabricante: **R.ESPINAR S.L.**
The manufacturer::
Avda. del Vallés 322, 08227 TERRASSA (Barcelona) ESPAÑA

declaramos bajo nuestra exclusiva responsabilidad que el producto(s):
declare in our sole responsibility, that the following product(s):

AUTOCLAVES DE ESTERILIZACIÓN "AHS"
STERILIZATION AUTOCLAVES "AHS"

"AH-21 N2" / "AH-21 S2 DRY" / "AH-21 L" / "AH-21 B PLUS"

y que esta declaración se refiere y es conforme a las siguientes Normas Internacionales:
to which this declaration relates to, is in conformity whit the following Standards:

EN-61010-1 Requisitos de seguridad de equipos eléctricos de medida, control y uso en laboratorio. Parte 1: Requisitos generales
Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements

EN-61010-2-040 Parte 2-040: Requisitos particulares para autoclaves de laboratorio
Part 2-040: Particular requirements for laboratory autoclaves

EN-61326 Material eléctrico para medida, control y uso en laboratorio. Requisitos de compatibilidad electromagnetica (CEM)
Electrical equipement for measurement, control and laboratory use. EMC Requirements

AD 2000 Merkblatt Recipientes a presión
Pressure vessels

y que responden a los requisitos esenciales de las directivas:
therefore, it follows the provisions of the directives:

2006/95/CE Baja Tensión
Low Voltage

2004/108/CE Compatibilidad electromagnética
Electromagnetic Compatibility

97/23/CE Equipos a presión
Pressure equipment

R. ESPINAR S.L.

Ramón Espinar Ballet
Director General / *General Manager*

R. ESPINAR, S.L.

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