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# INTRODUCTION

Dear Client.

Thank you for having chosen our autoclave, we know how to exchange your fidelity, with maximum attention and service definitely corresponding to your expectations.

Before using this autoclave, we invite you to read with maximum attention the user's manual and then keep it in a place accessible to all operators in charge of STERILIZATION.

Sterilise means adopting a specific working methodology and adhering to precise operational protocols:

<u>DISINFECTION</u> obligatory phase, to ensure operator safety, to be done with immersion in chemical liquids or thermo-disinfection;

<u>CLEANSING</u> the most important phase that ensures the removal of all types chemical and organic residues. The most suitable instruments are ultrasound baths;

<u>DRYING</u> essential phase, which prevents corrosion of the instruments and interference of the STERILIZATION cycle;

ENVELOPING essential phase for sterility maintenance over time;

STERILIZATION final step steam STERILIZATION.

#### The autoclave is the key point of this methodology.

We remind you that failure to carry out all the phases of the STERILIZATION process may invalidate the final result.

For installation, maintenance and assistance ask <u>exclusively</u> for a technician authorized. We invite you to use and ask for <u>exclusively</u> original spare parts.



# 02 USE AND DESTINATION OF USE OF THE AUTOCLAVE

The autoclave is able to sterilize the three types of load provided for by the standard EN13060, especially:

	ONYX-B 5.0	ONYX-B 8.0
METAL OR SOLID MATERIALS Instruments with no cavities and no obstacles to the penetration of steam	max kg. 5	max kg. 8
POROUS OBJECTS Simple or composite materials that can absorb fluids (fabrics, gowns, surgical gauzes, dressings, etc)	max kg. 1,5	max kg. 2
HOLLOW OBJECTS  Materials or devices with cavities, obstructions, etc. These are subdivided into two types, classified according to the length and diameter of the cavity.  Approximately:  TYPE B: cannulas, tubes or devices with large passages.	max kg. 5	max kg. 8
TYPE A: turbines, hand pieces and devices with blind or small holes		

The charges (Kg) change depending to the type of cycle which is performed. Watch Fig.B.

\*Only for European Countries



The autoclave shall only have to be used for the sterilization of tools and materials being compatible with the steam sterilization system. Always make sure that the loads that need to undergo sterilization can stand the temperatures scheduled for the selected cycle.

03 SAFETY

## 3.1 Safety marking



HAZARDOUS VOLTAGE



ATTENZIONE ATTENTION ATTENTION ACHTUNG

ALTA TEMPERATURA HIGH TEMPERATURES TEMPERATURES ELEVEES HOHE TEMPERATUR HIGH TEMPERATURE



# **ATTENZIONE**

TOGLIERE TENSIONE PRIMA DI RIMUOVERE IL COPERCHIO

# WARNING DISCONNECT THE MAINS SUPPLY BEFORE REMOVING THIS COVER

DISCONNECT THE POWER BEFORE REMOVING THE LID



EARTH CONNECTION

# 3.2 Safety devices

The following safety devices are installed:

- 1. Safety valve set at 2.4 bar 0/+10%
- 2. Electromagnetic lock to prevent the door from opening while the cycle is running
- **3.** Resistance over temperature thermostats

#### 3.3 Safety notes

- **1.** The manufacturer is liable for the marketed product in accordance with current regulations. The **manufacturer's liability will expire** when operations are carried out on the device, or a part of it, by unskilled personnel or using non-original spare parts.
- **2.** There should be no potential risk of explosion and/or fire in the room where the autoclave is installed.
- **3.** The autoclave should be installed in a special well-ventilated room.

#### 3.4 Disposal



Refer to annex Cod. 0Z00H0004





# TECHNICAL DATA

		ONYX 5.0	ONYX 8.0	
	Working temperature	+5°C ÷ +40°C		
	Maximum altitude	2.00	00 m	
⋖	Max relative humidity at 30°C	80%		
DAT	Max relative humidity at 40°C	50%		
MECHANICAL DATA	Dimensions of space occupied (L x H x P)	474 x 497 x 650	474 x 497 x 795	
N Y	Space occupied with open door	495 mm		
Ë	Weight (empty tanks)	60kg.	66kg.	
Σ	Weight (full tanks + room full)	70kg.	76kg.	
	Weight of area of support	2058	N/m <sup>2</sup>	
	Potential sound level	< 70	db A	
	Power voltage	230 V a.c. +/-10	% single phase	
AL.	MAX power	1,5 kW	2,2 kW	
ELECTRICAL	Frequency	50 / 6	60 Hz	
ECT	Power cord	2 + 1 x	1mm <sup>2</sup>	
EL	Fuses	5x20 10A	6.3x35 F12A	
	Heat transmitted	3.6 E <sup>6</sup> J / hour		
~	MAX working pressure	2.4 bar (relative)		
CHAMBER	MAX empty	- 0.9 bar (relative)		
Ψ	MAX temperature	138 °C		
끙	Material	Inox AISI 304		
	Size (mm)	Ø 245 x 320	Ø 245 x 500	
Z III X	Volume	4,5		
CLEAN WATER TANK	Usable cycles	4	2	
0 \$ -	Material	polyethylene		
	Volume	4,	5 I	
USED WATER TANK	Usable cycles	4	2	
US WA:	Material	polyethylene		
	MAX temperature used water	50°C		
BACTERIO LOGICAL FILTER	Diameter	56 mm		
BAC1 LOG FIL	Filtering capacity	0.3 μm		



# 05 OUTPUTS AND INDICATORS LIST

	00	Spacer
	01	Tap for emptying used water tank
	02	Tap for emptying clean water tank – (tap filling up trought osmosis)
	03	Exceeding full for used water tank
	04	Pipe fitting for emptying used water tank (back)
	05	Feeding socie with fuses
	06	RS232 serial port
	07	Socket for connection of osmosis system
	80	Bacterial filter
	09	Pipe fitting for manual willing up of clean water
8	10	Main switch
rig.	11	SD CARD Slot
LIST (Fig.A)	12	Display
	13	Pipe fitting for discharging used water (front)
AND INDICATORS	14	121°C Cycle
ATC	15	134°C Cycle
)   	16	134°C Fast Cycle
Z	17	134°C Flash Cycle
	18	134°C Safety Cycle
	19	134°C Prion Cycle
UTPUTS	20	134°C Prion Fast Cycle
OUT	21	Helix / Bowie&Dick Test
0	22	Vacuum Test
	23	MAX level used water tank
	24	MAX level clean water tank
	25	MIN level clean water tank
	B-M1	Multifunction push button 1
	B-M2	Multifunction push button 2
	B-M3	Multifunction push button 3
	PUMP WATER	Push button for filling up of water
	SELECT CYCLE	Push button for selection of cycle



# **UNPACKAGING**

The autoclave is shipped in a suitable package to be transported and moved easily and to protect its contents.

The packaging must not be subject to impact, must be handled with care and avoid dropping it or roll it.

In case autonomous handling means are not available handle the packaged autoclave always in two persons.

Autoclave is placed on wooden pallet and packed with corrugated cardboard internal and external application.

For remove the autoclave to its pack please remove first the corrugated cardboard. For lift the autoclave please use the belts.



The autoclave shall have to be handled by at least two people and by using belts only.



Do not lift the autoclave from the inferior part of the door or command panel, this incorrect operation can create problems of a mechanical nature.

## ATTENTION: Always conserve original packaging.

All'interno the package you will find the following documents:

- USER'S MANUAL: to be read with attention and kept in a place available to all operators assigned to sterilization.
- CERTIFICATION: which must be conserved.
- INSTALLATION REPORT TESTING AND GUARANTEE CONDITIONS: must be completed upon installation of the machine following the instructions indicated on the form.
- QUICK USE GUIDE: should be kept in the vicinity of the machine.
- CERTIFICATION OF SAFETY WALVE.



# 07 ACCESSORIES

DUAL TRAY HOLDER				
	ONYX 5.0	ONYX 8.0		
Material	Alluminium anodized			
Size (L x H x P)	192 x 165 x 280 192 x 165 x 460			
Picture	Fig.1			
Envelope standard	1			
Code	SXBA349 2ZXZA0073			

TRAY				
	ONYX 5.0	ONYX 8.0		
Material	Alluminium	n anodized		
Size (L x H x P)	183 x 17 x 284	185 x 17 x 460		
Picture	••••	9.2		
Envelope standard	4			
Code	DANA049 DXLA349			

# TRAY EXTRACTION AND DOOR ADJUSTMENT WRENCH

Use for extract the trays and for door adjustement (par. 15)



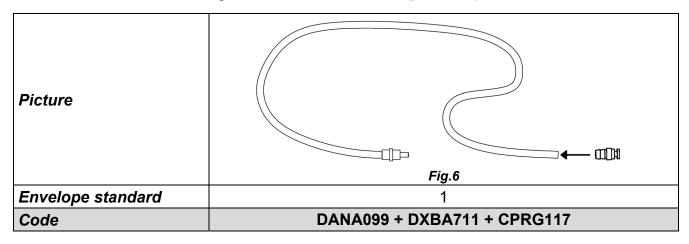
# CHAMBER AND DOOR GASKET CLEARING SPONGE

Use to clean sterilization chamber and door gasket (par. 15)

Picture	Fig.5
Envelope standar	1
Code	CPMG004

## WATER FILLING PIPE WITH FILTER AND PIPE FITTING

Use for manual water loading on the front of autoclave (par. 10.2)



# WATER DISCHARGE PIPE

Use to drain the water used from the faucet on the front of the autoclave (Fig.A–pos. 13) - (par. 10.8)

Picture	Fig.7
Envelope standard	1
Code	DANA130



#### BLACK PLASTIC SPACER PIN

Put the spacer in the autoclave's back panel (Fig.A–pos. 0). It's necessary for guarantee a good ventilation if you place the autoclave near a wall.

Picture	Fig.8
Envelope standard	1
Code	CPAP014

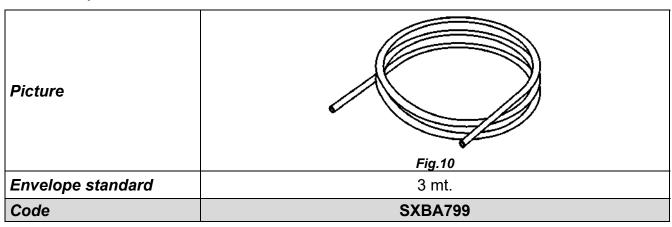
# FITTING FOR REAR TAPS DISCHARGE

Tighten the loading faucet (Fig.A-pos. 2) to empty the loading tank and tighten the drain faucet (Fig.A-pos. 4) to empty the drain tank.

Picture	Fig.9
Envelope standard	1
Code	CPRG096

# PIPE FOR DISCHARGE UTILITIES

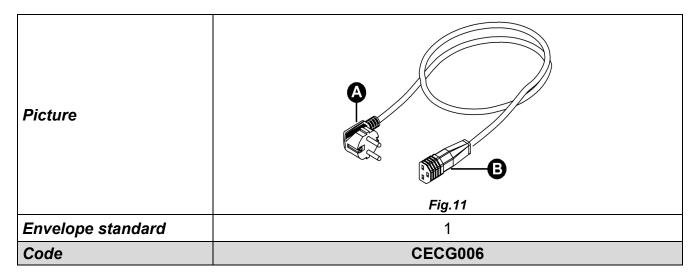
- 1 Clean water overflow hose
- 2 Used water overflow hose
- **1-** Connect one end of the hose to the clean water overflow hose fitting (Fig.A-pos. **1**), and the other in a water recovery container.
- **2-** Connect one end of the hose to the fitting (Fig. A–pos. **3**), and the other to a used water recovery container.





# **POWER SUPPLY CORD**

Take the power supply cord provided (pos. **B**) and insert the female plug (Fig.A-pos. **5**) in the socket of the back panel of the autoclave then insert the male plug (pos. **A**) in the electric plug of the system.



#### **MEMORY CARD**

To be used to memorize the autoclave cycles (for the best compatibility with the device, it is advisable to always use the original memory card).

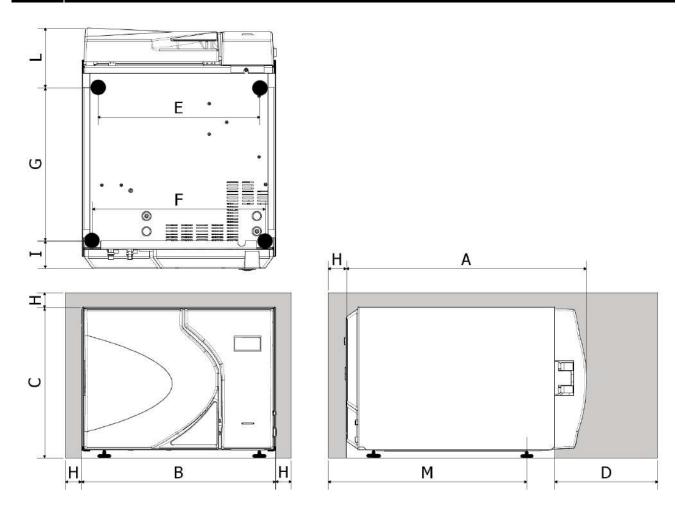
<u>WARNING: The card contains the software reading log cycle - Carry out the rescue</u> and installed on the PC before the commissioning of the autoclave (see par.12)

Picture	Fig.12
Envelope standard	1
Code	CEGS001

#### **IMPORTANT**

Ask for and use only and exclusively original accessories.

# 08 INSTALLATION



	ONYX 5.0 ONYX 8.0		
Α	650 mm	795 mm	
В	474	mm	
С	497	mm	
D Max. hatch	495 mm		
E	425 mm		
F	425 mm		
G	402 mm 435 mm		
Н	min. 50 mm		
	74 mm		
L	170 mm 275 mm		
M	525 mm 575 mm		

- 1. Install the autoclave in environments suitable to sterilization.
- 2. The premises have to be suitably lit and ventilated, in compliance with regulations in force.
- **3.** Install the autoclave away from heat sources and water splashes.
- **4.** Position the autoclave on a surface, suitable to support the weight (80 Kgs.) and with adequate dimensions.
- **5.** Place the autoclave at a height allowing easy intervention by the operator for inspection and clearing of the whole sterilization chamber.
- **6.** Open the door of the autoclave and remove all packages containing the single accessories from inside the sterilization chamber.
- **7.** Leave inside the sterilization chamber only the tray carrier with the trays. All other accessories should be positioned in a separate space available to operators.
- 8. Don't put anything on the autoclave.
- 9. Do not lean on the door.
- **10.**Leave a space of at least 5 cm in the rear of the autoclave, using the spacer (Fig.A–pos. **0** / Fig.8) and in the sides of the unit to ensure the ventilation required.
- **11.** Make connections of supplied pipes in the back (chapter 7).
- **12.** Always make sure the electrical system to which the autoclave is to be connected is in conformity with the legislation in force and sized to suit the specifications of the said device.
- **13.**Connect the power supply cord to the socket on the rear panel of the autoclave (Fig.A–pos. **5**).
- **14.** Connect the electrical plug to the system ensuring that it is adequate to the supply of the machine.

**NOTE:** Do not use extensions, reducers or adapters for connection as this could cause micro interruptions with consequent generation of alarm signals.

**15.** Turn the autoclave on by pressing the mains switch (Fig.A-pos. **10**) and open the hatch of the autoclave itself. Wait a few seconds, there will be two acoustic signals to inform you of the acquisition of the parameters for the automatic barometric alignment, at the same time the text <u>DOOR OPEN</u> will appear on the display.

NOTE:

Never select a command before hearing the two sound signals, the autoclave will not accept the chosen programming.



# PROGRAMMING DISPLAY

From the first page press **Setup** to enter the autoclave setup menu.

# LANGUAGE



Press the central button to change the language of menus and vocal messages.



Press the arrow to shift to the next item

#### DATE AND TIME



Press the central button to enter the date/time setup.

<u>0</u>0:00 00/00/1900



00:00

00/00/<u>1900</u>



When the box flashes press the arrows to select the desired value.

Press once more the central button to move among boxes and the arrows to select a value.

Go on until the last value is selected.

Press the central button for the last time to display the final selection page.

~

Press to confirm selected values and go back to the setup menu

Pres

Press to restart the procedure

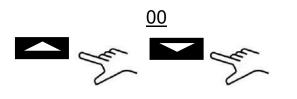
**X** 

Press to cancel selected values and go back to the setup menu

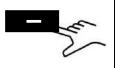


# **EXTERNAL PRINTER**

After the printer installation *(optional accessory, following the instructions inside)*, is possible to print the traceability adhesive labels to be stuck on the wrap before starting sterilization is entered.



When the box flashes press the arrows to select the number of labels to be printed.



Press the central button to move to the next selection.



When the box flashes press the arrows to select the number of months before expiry.

Press the central button for the last time to display the final selection page.

# **SETUP OSMOSIS SYSTEM**

- USE OSMOSI'S SYSTEM : On / Off with the button the supply system with osmosis device (optional). When the system is activated the charge pump is disconnected.
- CYCLES SINCE CHG: Cycles from the last change of filters are visualized.
- RESET OSMOSI COUNTER: It allows you to reset the counter when you replace the filters.

#### **BACTERIOLOGIC FILTER**

- CYCLES PERFORMED: Cycles from the last change of filter are visualized.
- RESET COUNTER: It allows you to reset the counter when you replace the filter.



# **ACCOUNT MANAGER**

- SHOW USERS: It allows you to see the already registered users.
- NEW USERS: It allos to register a new user.
- DELETE: It allows you to delete already registered users.
- LOAD CHECK: on/off (par. 10.6).

#### **NEW USERS:**



Press the central button to enter a new user.



ENTER NAME: When the box is flashing, press the arrow keys to scroll the characters until the desired user name, confirming each box with the button

ENTER PASSWORD: choose the desired password using the same procedure the "enter name".

# **SERVICE MODE**

Access to the service menu (after password entry). This mode is reserved exclusively for the setup by an <u>authorised personal</u>. The manufacturer shall not be held responsible for any tampering with or injury to unauthorised staff.



# **USE INSTRUCTION**

After installing the autoclave proceed with preparation and use.

## 10.1 Turn on the autoclave and barometric alignment

Press the main switch (Fig.A–pos. 10). After the display of the logo, the autoclave checks the memory and the connections. Once checks are over the autoclave shifts to the operating setup.



Open the door and wait for some seconds until an acoustic signal informs that the automatic barometric alignment values have been acquired; at the same time the display shows the message <u>DOOR OPEN</u>.

# THE AUTOCLAVE IS READY FOR USE

# ATTENTION:

Selecting any cycle, excluding vacuum cycle, will activate the preheating mode of the autoclave.

Be careful, do not touch the surfaces of the boiler because they are hot.

# 10.2 Clean water tank filling

Connect the hose supplied (Fig. 6) to the front fitting of the autoclave (Fig. A-pos. 9).

Put the other end of the hose with the filter inside the demineralised or distilled water container.

At this point, press the **PUMP WATER** button to operate the water loading pump and keep it pressed until the countdown appears.

The pump loads the clean water tank inside the autoclave. If the maximum level is not achieved within 180 seconds the pump stops automatically and it will be necessary to press button **B-PUMP**.

The pump stops automatically when the maximum level is achieved.



#### 10.3 Characterisstics of the water to be used

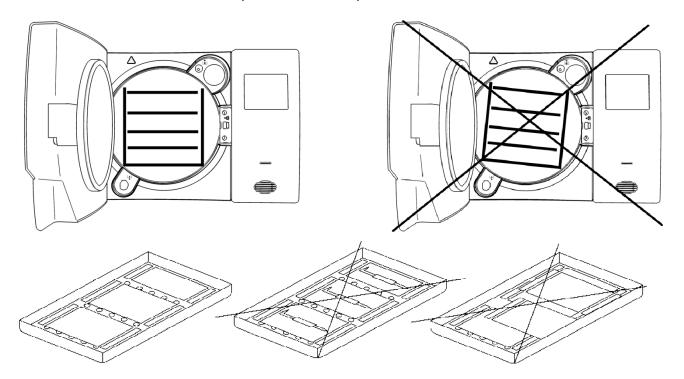
#### TABLE SHOWING THE QUALITY LEVELS LAID BY THE EN13060

CEN STANDARD EN13060			
Evaporation residue	<b>S</b>	10	mg/l
Silicon oxide	<b>≤</b>	1	mg/l
Iron	<b>S</b>	0.2	mg/l
Cadmium	<u>≤</u>	0.005	mg/l
Lead	<b>S</b>	0.05	mg/l
Remains of heavy metals apart from iron, cadmium,	<u> </u>	0.1	mg/l
lead		0.1	1119/1
Chloride (Cl')	<b>S</b>	2	mg/l
Phosphate (P20s)	<b>S</b>	0.5	mg/l
Conductivity (at 20°C)	<b>S</b>	15	μs/cm
Ph value (acidity level)	5 ÷ 7,5		
Appearance	Transparent, clear, without deposits		
Hardness (and alkaline earth ions)	≤ <b>0.02</b> mmol/l		

# 10.4 Loading of the materials in the autoclave

Arranging the materials to be sterilized on the provided trays, as follows:

- Do not superpose the materials
- Arrange the wrapped materials with the paper side facing upwards
- Never bring the materials into contact with the sterilization chamber or the autoclave door
- Put scissors and dental forceps with blades open



After loading the materials, close the door of the autoclave. The display will show the icon and the message *DOOR CLOSED*.



# 10.5 Starting the sterilization cycle

After the steps listed above, choose the most suitable STERILISATION program for the prepared load, by pressing the **SELECT CYCLE** button.

After choosing the program, start the cycle by pressing the button. The door will lock automatically, and the cycle will begin.

During the cycle the display shows all parameters and information related to the cycle in progress. In this setup the display shows: the type of cycle, the cycle status, the time remaining before the end of cycle (for the Vacuum Test it identifies the whole cycle, while for all the other cycles it identifies the sterilization phase plus that of drying), the number of cycles done by the machine and the button allowing access to the list of working parameters.



## 10.6 End of cycle

An acoustic signal will inform the operators about the finished STERILISATION cycle and the display will show the *END CYCLE* icon and message.

Unlock the door by pressing the button displayed on the display by one of the three multi-function buttons. Should there be pressure present inside the chamber, the button will not trigger the unlocking. Wait for the complete depressurization of the chamber and repeat the operation. With the door unlocked, pull the door handle and open.

Now, if the CHARGE CONTROL (<u>SETUP</u> → <u>ACCOUNT MANAGEMENT</u>) is "ON", is asked to validate the charge by the user. If the charge is validated, give consent specifying USER and USER PASSWORD, afterwards will be given the confirmation of <u>VALIDATED</u> <u>CHARGE</u>. If the charge doesn't result validated you have to give negative result to end the operation in **NOT VALIDATED CHARGE**.

# 10.7 Unloading the sterilized materials

Wear personal protective equipment in compliance with regulations on safety and hygiene at work. Extract the trays by using the spanner provided (Fig.3/4), let rest the instruments and store them in environments which are not exposed to contamination.

# 10.8 Discharge used water

When the used water level LED (Fig. A-pos. 23) lights up, the used water collection tank must be emptied.

# If nothing is done, the operation of the autoclave is blocked.

Take the hose supplied (Fig.7), and insert it into the used water drain fitting located on the front of the autoclave (Fig.A-pos. 13). Put the other end of the hose in a container and unscrew the ring nut, turning it anticlockwise, the water will fall into the container, emptying the tank.

#### **IMPORTANT:**

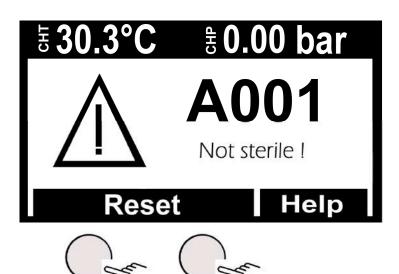
- **A** The hose located in the receiving container must never touch or be immersed in the discharged water, otherwise sucking up will occur.
- **B** Always wait until the discharge water has been completely drained. The used water maximum level LED turns off when some water still remains into the tank, consequently do not considered it as a reference for this operation.

When drained, screw in the ring nut and remove the hose.

# 10.9 Interruption of a sterilization cycle

A sterilization cycle can be voluntarily interrupted by pressing the button **Stop** for at least 2 seconds.

The autoclave will send out a beep and the display will show the alarm message A001.



For reset the alarm, <u>press at the same time</u>, the multifunction push buttons on the <u>Reset</u> <u>bar up to the cancelling of the same</u>.



# **STERILIZATION CYCLES**

## 11.1 Descriptions cycles

The autoclave has three series of cycles:

A – operation cycles

B - night cycles

C – test cycles

# 11.2 Operation cycles

All operating cycles, have the fractional vacuum system and can sterilize hollow, porous and solid materials, however, are differentiated according to user priority and to characteristics of the materials for the sterilization. The sterilization temperatures possible are 121°C and 134°C.

- <u>Cycle 121°C Standard</u>: it is used for thermolabile materials, load capacity up to 5 Kg (Onyx5.0) / 8 Kg (Onyx8.0) with a normal cycle time.
- <u>Cycle 134°C Standard</u>: it is used for not thermolabile materials, load capacity up to 5 Kg (Onyx5.0) / 8 Kg (Onyx8.0) with a normal cycle time.
- Cycle 134°C Fast: keeps the use of 134°C Standard but it is created for low loads (up to 1,5 Kg (Onyx5.0) / 2 Kg (Onyx8.0)), consequently also the time of the cycle is shorter.
- <u>Cycle 134°C Safety</u>: created for immediate needs of the instrumentation, has a shorter cycle time, load capacity up to 5 Kg (Onyx5.0) / 8 Kg (Onyx8.0). Not suitable for wrapped loads.
- <u>Cycle 134°C Flash</u>: how to Safety cycle has been created for immediate need of the instrumentation but with a load capacity up to 1,5 Kg (Onyx5.0) / 2 Kg (Onyx8.0). Not suitable for wrapped loads.
- <u>Cycle 134°C Prion</u>: created for Creutzfeldt-Jakob disease (mad cow syndrome), load capacity up to 5 Kg (Onyx5.0) / 8 Kg (Onyx8.0), the cycle time is higher than 134°C Standard.
- Cycle 134°C Prion Fast: created for need to perform a Prion Cycle with lower load (up to 1,5 Kg (Onyx5.0) / 2 Kg (Onyx8.0)) in a shorter time.

Please refer Fig.B for a detailed summary.

# 11.3 Night cycles

The autoclave is equipped with a economizer special device. It is possible to perform all cycles mentioned without operator. At the end of the cycle, if the door isn't opened, the autoclave automatically turns off, remains turn on the main switch only (Fig.A-pos. 10). Upon arrival of the operators, simply press any button to turn on the autoclave and read to display the outcome of the cycle.

## 11.4 Test cycles

Available test cycle:

- Bowie&Dick test par. 13.3
- Helix test par. 13.4
- Vacuum test par. 13.5

# 11.5 Cycle diagram

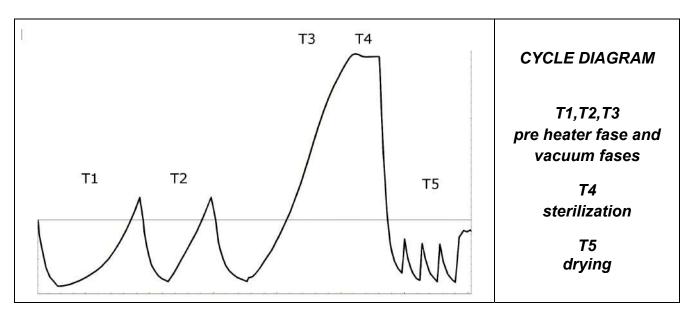


TABLE OF TESTS TYPE AS RULE EN13060	
Type test	Operative cycle
Dynamic sterilizer chambre pressure	X
Air Leakage	X
Empty chamber	X
Solid load	X
Small porous items	X
Small porous loads	X
Full porous load	X
Hollow load B	X
Hollow load A	X
Multiple wrapping	X
Dryness, solid load	X
Dryness, porous load	X

TECNO-GAZ is at your service to provide sterilization tests for the management of your sterilization routine



# **SOFTWARE VISUALIZATION CYCLES**

#### 12.1 Installation

Enter the SD memory card in your computer.

The LogViewer folder is located at: <SD Card>:\

Access the SD memory card and copy the LogViewer folder on your computer.

Open the folder *LogViewer* and run the LogViewer program by double click link, recognizable by the magnifying glass icon (**Figure1**).

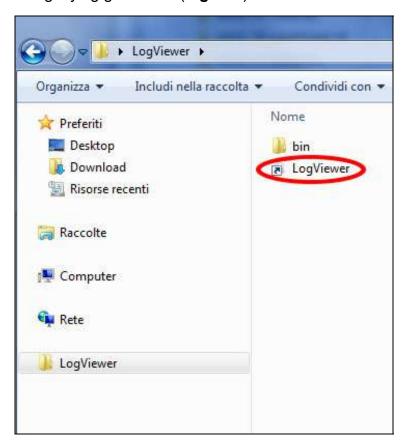


Figure 1: LogViewer folder. Double click on logviewer to run it

If the program doesn't start by link, open bin folder and run program *log\_viewer*, recognizable by the magnifying glass icon.



WARNING: Please check that Microsoft .NET Framework is installed on your PC. If it is not, open the folder Microsoft.NET available on SD card and install the executable file contained inside.

#### 12.2 Language setting

The default language at first run of *LogViewer* is English. It is possible to change the language by the dropdown menu on right of window. Languages available are English, Italian, German, French e Spanish. The program saves the selected language and to next run loads the user interface in that language.

# 12.3 | Single log file viewing

Select by dropdown menu  $File \rightarrow Open$  (**Figure 2**) to view the cycle details of a particular log file. The program will show a dialog box for the file selection that you want open.

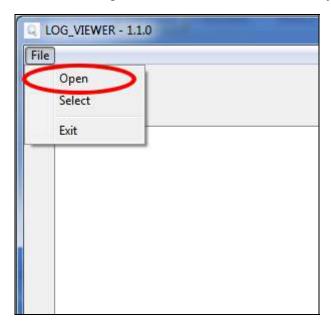


Figure 2: Logviewer window, Open item

The program shows the cycle log as showed in **Figure 3**. In the window are showed different kind of data:

- Step of the sterilization cycle;
- Date and time of data recording;
- Time to end of cycle;
- Chamber temperatures and pressure (values returned by probes T1, T2 e P1);
- Mains voltage;
- Cycle outcome, readable on last line.

The kind of cycle related to log is returned in the box in center position.

During the log viewing, Options item is present in menu bar and allows access to two functions: *Make Report and Make Log PDF*.

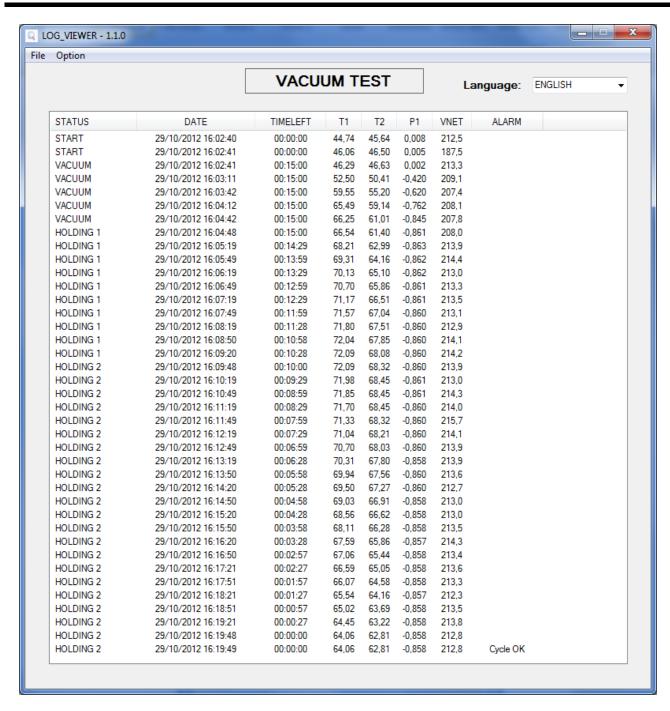


Figure 3: log viewing mode of Vacuum cycle

# 12.4 Open directory

Select by dropdown menu  $File \rightarrow Select$  (**Figure 4**) to browse the log files in a particular folder. The program will show a dialog box to specify the path to browse.

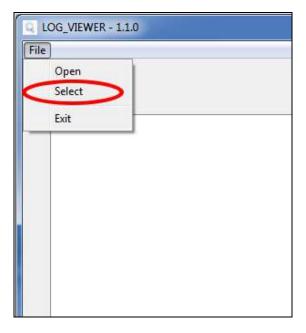


Figure 4: item Select, for browsing folder

The program display only \*.log files with valid content in the selected folder, and shows a list as in **Figure 5**.

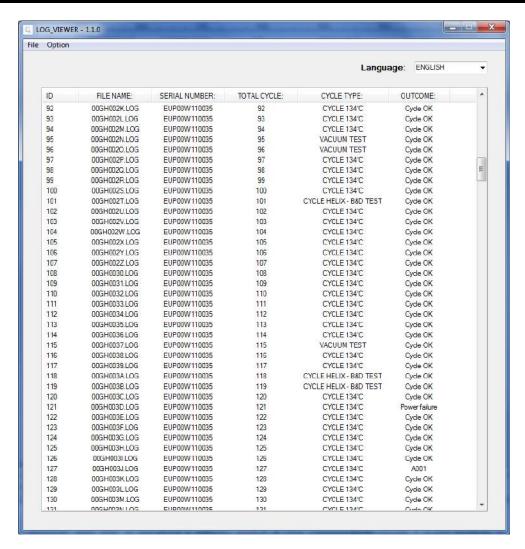


Figure 5: browsing folder

Log files are showed as a list that provides a preview with serial number of sterilizer, cycle number, kind of cycle and the outcome. By single-click on a list item, the detailed report of corresponding log is displayed, as showed in **Figure 3**.

In this case, on the left of the box that shows the kind of cycle, is displayed the *Back* button to come back to browsing window.

During the folder browsing, Options item is present in menu bar and allows access to two functions: *Make Report and Make Log PDF*.

# 12.5 Make Report

During log viewing, by selecting from menu  $Options \rightarrow Make \ Report$ , the program returns a table with all cycle data and show them in a new window (**Figure 6**).

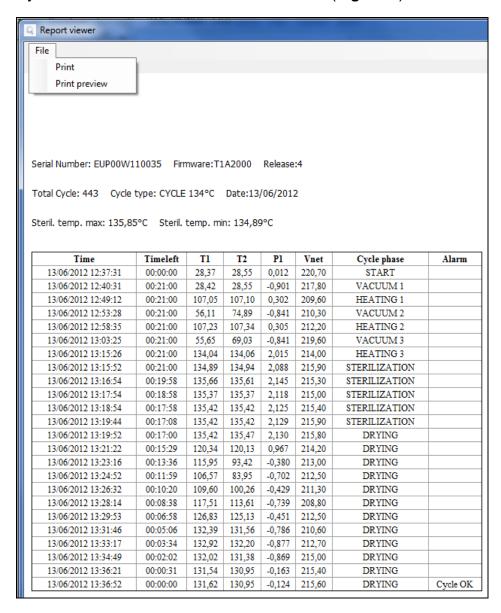


Figure 6: report window

From this window is possible display a print preview ( $File \rightarrow Print \ preview$ ) or print ( $File \rightarrow Print$ ).



#### 12.6 Make PDF

During the viewing of a log, by selecting from menu  $Options \rightarrow Make\ PDF$ , Logviewer make a PDF file which contains the cycle details (**Figure 7**).

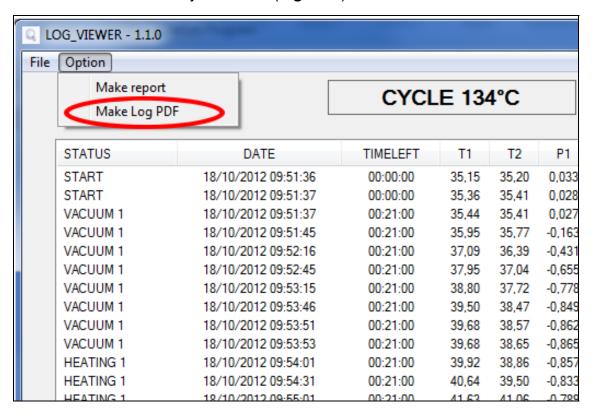


Figure 7: menu Options, the item Make PDF

The PDF file will be created in the same folder where \*.log file is located, in sub-folder Report, accessible by File Manager tool in Windows. If Report folder doesn't exist, it will be created. At the end of the process, the program open the destination folder by a window of File Manager in Windows.

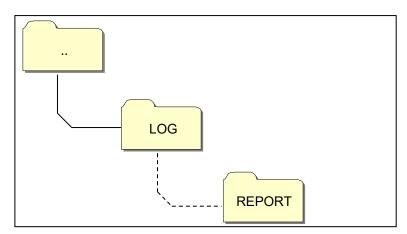


Figure 8: when PDF file is created, the program saves the file Report folder, inside the log file origin folder

The created file name is compound by serialnumber-cyclenumber.pdf.

#### 12.7 Make folder PDF

In browsing folder mode is available the Make folder PDF function in Options item of menu bar.

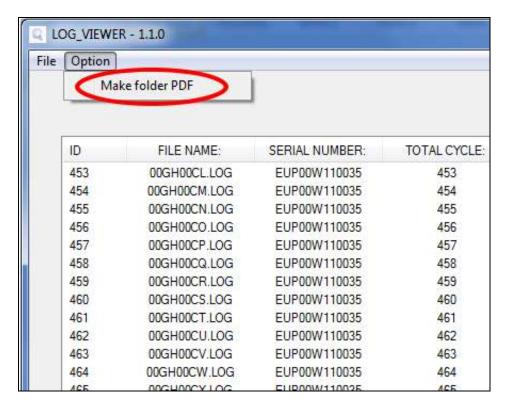


Figure 9: Make folder PDF function, visible in browsing folder mode

On mouse click, a loading bar that indicates the progress of the process is displayed. The PDF files will be created within the browsed folder, in subfolder *Report*, accessible by *File Manager* tool of Windows. If the folder *Report* doesn't exist, it will be created.

At the end of the process, the program opens the destination folder by a window of *File Manager* in Windows.

The created file name is compound by *serialnumber-cyclenumber.pdf*.

ile Option						
				Lang	uage: ENGL	
ID	FILE NAME:	SERIAL NUMBER:	TOTAL CYCLE:	CYCLE TYPE:	OUTCOME	
1	00GH00A0.LOG	EUP00W110035	360	CYCLE 134°C	Cycle OK	
2	00GH00A1.LOG	EUP00W110035	361	CYCLE 134°C	Cycle OK	
3	00GH00A2.LOG	EUP00W110035	362	CYCLE 134°C	Cycle OK	
4	00GH00A3.LOG	EUP00W110035	363	CYCLE 134°C	Cycle OK	
5	00GH00A4.LOG	EUP00W110035	364	CYCLE 134°C	Cycle Ok	
6	00GH00A5.LOG	EUP00W110035	365	CYCLE 134°C	Cycle OK	
7	00GH00A6.LOG	EUP00W110035	366	CYCLE 134°C	Cycle OK	
8	00GH00A7.LOG	EUP00W110035	367	VACUUM TEST	Cycle OK	
9	00GH00A8.LOG	EUP00W110035	368	CYCLE 134°C	Cycle OK	
10	00GH00A9.LOG	EUP00W110035	369	CYCLE 134°C	Cycle OK	
11	00GH00AA.LOG	EUP00W110035	370	CYCLE 134°C	Cycle OK	
12	00GH00AB.LOG	EUP00W110035	371	CYCLE 134°C	Cycle OK	
13	00GH00AC.LOG	EUP00W110035	372	CYCLE 134°C	Cycle OK	
14	00GH00AD.LOG	EUP00W110035	373	CYCLE 134°C	Cycle OK	
15	00GH00AE.LOG	EUP00W110035	374	CYCLE 134°C	Cycle OK	
16	00GH00AF.LOG	EUP00W110035	375	CYCLE 134°C	Cycle OK	
17	00GH00AG.LOG	EUP00W110035	376	CYCLE 134°C	Cycle OK	
18	00GH00AH.LOG	EUP00W110035	377	CYCLE 134°C	Cycle OK	
19	00GH00AI.LOG	EUP00W110035	378	CYCLE 134°C	Cycle OK	
20	00GH00AJ.LOG	EUP00W110035	379	CYCLE 134°C	A101	
21	00GH00AK.LOG	EUP00W110035	380	CYCLE 134°C	Cycle OK	
22	00GH00AL.LOG	EUP00W110035	381	CYCLE 134°C	Cycle OK	
23	00GH00AM.LOG	EUP00W110035	382	VACUUM TEST	Cycle OK	
24	00GH00AN.LOG	EUP00W110035	383	VACUUM TEST	Cycle OK	
25	00GH00AO.LOG	EUP00W110035	384	VACUUM TEST	A001	
26	00GH00AP.LOG	EUP00W110035	385	CYCLE 134°C	Cycle OK	
27	00GH00AQ.LOG	EUP00W110035	386	CYCLE 134°C	Cycle OK	
28	00GH00AR.LOG	EUP00W110035	387	CYCLE 134°C	A001	
29	00GH00AS.LOG	EUP00W110035	388	CYCLE 134°C	Cycle OK	
30	00GH00AT.LOG	EUP00W110035	389	CYCLE 134°C	Cycle OK	
31	00GH00AU.LOG	EUP00W110035	390	CYCLE 134°C	Cycle OK	
32	00GH00AV.LOG	EUP00W110035	391	CYCLE 134°C	Cycle OK	

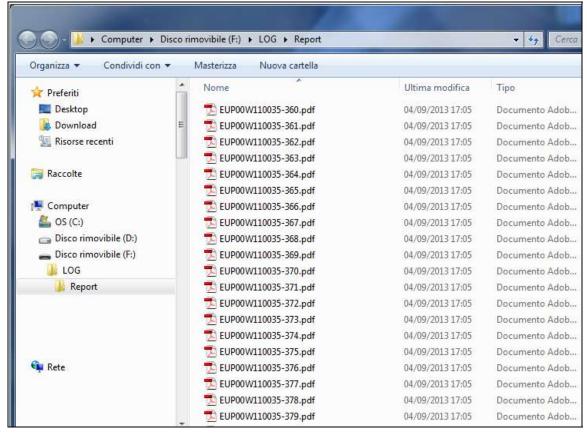


Figure 10: Browsed folder with LogViewer and destination folder of made files.



# **INSTALLATION OSMOSIS SYSTEM**

#### **Setting osmosis system**

The autoclave is also designed for loading demineralised water through an external osmosi demineralisation system *(optional accessory)*.

The operator before installing the system, must schedule the autoclave following the instructions below:

Turn the autoclave on by pressing the mains switch (Fig. A-pos. 10).

When the autoclave is brought up on the operating screen, press **Setup** and select the menu setup osmosis system.

Activate by setting the USE OSMOSI'S SYSTEM item to ON.

Exit the menu and return to the operating screen.

NOTE

Connected by a demineraliser, if the maximum water level has not been reached, the operation of the autoclave will be blocked.

#### **WARNING:**

The number on the osmosi management screen indicates how many STERILISATION cycles have been performed since changing filters.

When you reach the maximum number of cycles, a message on the display will inform the user. It's necessary to remember to reset the cycles counter when you change the filter on the osmosis system selecting **RESET OSMOSI COUNTER** in the SETUP OSMOSIS SYSTEM submenu.

#### Connection of the demineralizer

Here as follows the detail of the specific connection to the autoclave of the water supply hose and electrical plug connection:

- Turn off the autoclave, if ON (Fig.A–pos. 10).
- Close the cock upstream the demineralizer;
- Install the demineralizer as indicated in its manual;
- Wrap the male thread of the hose coupler with teflon or another component ensuring water tightness;
- Screw the hose coupler on the female thread of the clean water discharge (FIG.A–pos. 2);
- Insert the hose from the demineralizer into the hose coupler and screw it to the autoclave;
- Insert the feeding coupler of the demineralizer into the port (FIG.A–pos. 7) on the rear panel of the autoclave;
- Open the valve upstream the demineralizer;
- Be sure there is no water leakage;



- Switch on the autoclave;
- Carry out one or several sterilization cycles to check for the correct connection and mainly to be sure of the absence of any leak.

Ţ	At the end of every day always close the cock upstream the demineralizer
<b>∱</b>	Connect the demineralizers exclusively to suitable autoclaves
NOTE	For the connection of the demineralizers to the autoclaves, see also the demineralizer manual.
NOTE	The first filling can take a longer time. Afterwards the autoclave will automatically fill during cycles

# **MAINTENANCE**

Correct maintenance of the autoclave assures correct funcioning of it and a secure saving in terms of time and costs for assistance and maintenance. The following operations are compulsory feasible by operators.

#### Cleaning of chamber

Every 20 cycles or one a week

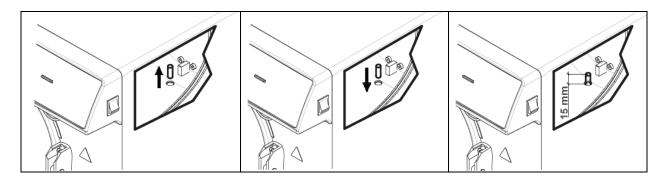
Clean periodically the chamber, remove eventual deposits or debris, thus avoiding the introduction in the discharging circuit of material which can cause obstructions. For correct cleaning use only deminerlized water and the abrasive sponge provided *(non abrasive side* – Fig. 5).

<u>To execute absolutely with cold chamber to avoid burns – Never use solvents, detergents, chemical solutions, descaling agents or other similar products.</u>

# Cleaning of chamber filter

Every 20 cycles or once a week

Pull up the filter (spare code DXBA091), paying attention not to damage it, wash with demineralized water and dry with cloth. Then replace in the seat, making sure that protrudes about 15 mm.



#### Cleaning of tray and tray holder

Every 20 cycles or once a week

Clean with sponge supplied (non abrasive side) and demineralized water.

## Change of the bacteriological filter

Every 200 cycles or when it assumes a dark colour

Substiture the bacteriological filter (Fig.A–pos. 9) turning it counterclockwise to unscrew and clockwise to screw. <u>Use only original filter (spare code DAVA101)</u>. It's necessary to remember to reset the cycles counter when you change the filter selecting **RESET COUNTER** in the BACTERIOLOGIC FILTER submenu.

#### Cleaning of the door gasket

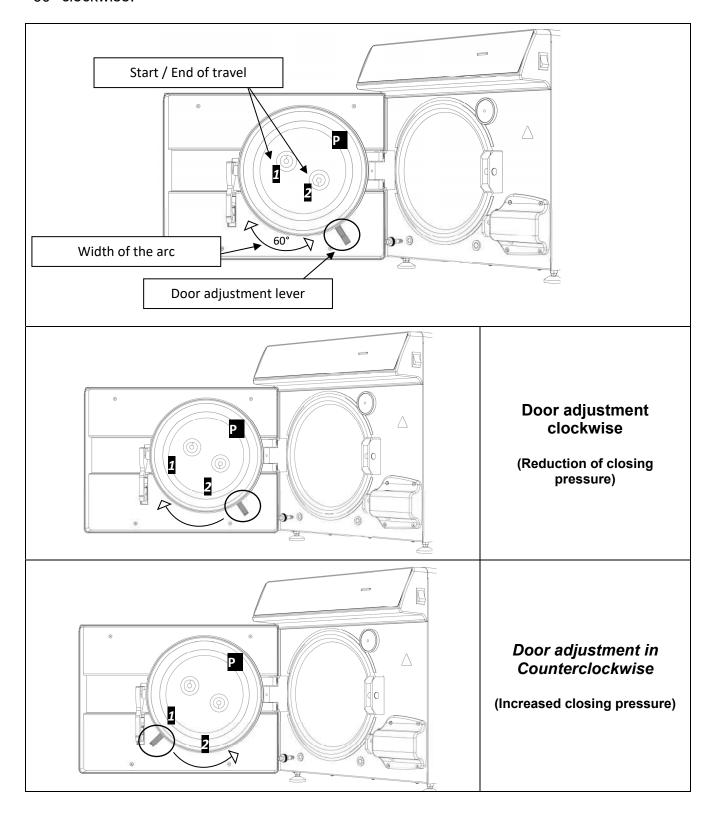
Every 20 cycles or once a week

Periodically remove eventual residuals which are deposited on the circumference of the seal (spare code DANA038) using water and the sponge provided (non abrasive side), or else a moistened cloth

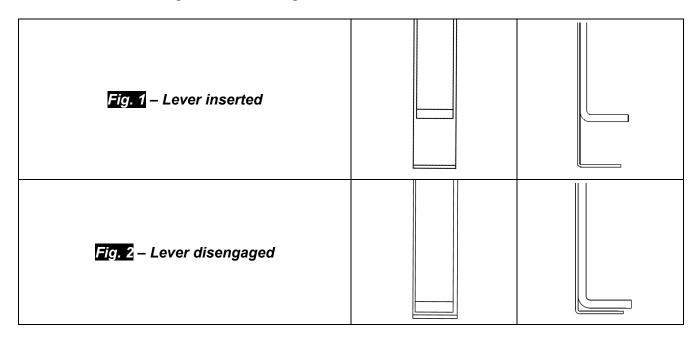


# **Door regulation** Every 2 mouths

To preserve the functional integrity of the machine, the closing pressure of the door P must be adjusted by acting on the door regulator. Use the lever and rotate 60° anticlockwise to increase the closing pressure; if instead you want to decrease the closing pressure, turn 60° clockwise.



To execute a wider arc, it is necessary to disengage the levers by keeping them together as in Fig. 2 and bring them to the start of stroke 1 or 2 (If you want to rotate the lever to decrease the closing pressure, start of stroke 2. If you want to rotate the lever to increase the closing pressure, start of travel 1) After having brought the levers to the start of travel, release them as in Fig. 1 and rotate again in the desired direction.





# 14.1 Authorized technicians ordinary maintenance

	Clean the chamber				
	Clean the metal filter in the chamber				
	Replace the seal of the chamber door (DANA038)				
	Lubricate the closing system of the chamber door				
	Adjust the closing system of the chamber door				
	Replace the bacteriological filter (DAVA101)				
	Replace the water loading filter (DARA054)				
	Clean the Y brass filter downstream of the radiator				
	Clean the water loading solenoid valve or replace it if necessary				
EVERY TWO	Clean the tanks				
YEAR /	Check the tank level probes				
EVERY 1000 CYCLES	Clean the radiator and cooling fans				
	Check the condition of the electrical/pneumatic circuit				
	Check that there are no traces of disinfectant in the pneumatic circuit.				
	Please note: ignoring traces of disinfectant may result in the need for				
	supplementary maintenance of the equipment				
	Check the safety valve				
	Check the efficiency of the vacuum pump				
	Perform validation in compliance with the local standards and on the basis				
	defined by the local standards				
	Perform the electrical safety tests in compliance with the local standards				
	and on the basis defined by the local standards				
	Measure the conductivity of waterμS/cm				
	Replace the valves and o-rings of the vacuum pump – Clean/check the				
AFTER 2000	condition of the Knf membranes (CPGM025 x4 – CPGM043 x2) -				
CYCLES	Thomas (CPGM050 x4 – CPGM051 x4 – CPGM052 x2)				
0.0220	Check the three N/C solenoid valves				
	Check the heating part				
AFTER 3000	Replace the three N/C solenoid valves (CEECG021 x3)				
CYCLES	Replace the heating part (DXBA835 or DHYA035)				
	Clean/check the condition of the membranes of the vacuum pump				

# **MESSAGES OF ERRORS**

Messages of error are emphasized through an Alfa-numerical code, consisting in a letter and three numbers.



If an alarm message is diplayed (code "A") the cycle <u>is to be considered</u> <u>aborted</u>: it will be necessary to repeat all the preparation and sterilization operations.

To reset alarms and errors hold down at the same time the buttons under the bar indicated with **Reset**.

ERROR	CAUSE	SOLUTION
A 001	Cycle interrupted by the user	Reset and restart the system
A 101	Vacuum not archieved in 10 min.	<ul><li>Check the gasket</li><li>Check the door adjustment</li><li>Reset and restart the system</li></ul>
A 111	Vacuum not maintained on the first phase of VACUUM TEST	<ul><li>Check the gasket</li><li>Check the door adjustment</li><li>Reset and restart the system</li></ul>
A 121	Vacuum not maintained on the second phase of VACUUM TEST	<ul><li>Check the gasket</li><li>Check the door adjustment</li><li>Reset and restart the system</li></ul>
A131	During preheating phase the autoclave did not load right water amount	Reset and restart the system
A132	Error in the flow-meter operation	Reset and restart the system
A133	Pressure above the allowable limit during the water recall for the warmup phases	Reset and restart the system
A 200	Error in the control of the EV operation	Reset and restart the system
A 400 A 401 A 403 A 405	Error in the locking operation	Reset and restart the system
A 551	Pressure out of limit	<ul><li>Let cool the room</li><li>Reset and restart the system</li></ul>
A 637	Error in the access to the memory card	<ul> <li>Check that the SD card is correctly inserted</li> <li>Chech SD card: lever might have moved on "lock" position</li> <li>Reset and restart the system</li> </ul>
A 651	Reading of the T1 probe during sterilization above the maximum limit	<ul><li>Let cool the room</li><li>Reset and restart the system</li></ul>



A 653	Reading of the T2 probe during sterilization above the maximum limit	<ul><li>Let cool the room</li><li>Reset and restart the system</li></ul>
A 661	Error in the probe reading	Reset and restart the system
A 662	Error in the probe reading	Reset and restart the system
A 701	Error for failed pressure achievement during the first two phases of the warm-up	Reset and restart the system
A 711	Error for failed pressure achievement during the third phase of the warm-up	Reset and restart the system
A 751	Reading of the T1 probe during sterilization below the minumum limit	Reset and restart the system
A 753	Reading of the T2 probe during sterilization below the minumum limit	Reset and restart the system
A 781	Temperature of the 121°C cycle out o the maximum limit	<ul><li>Let cool the room</li><li>Reset and restart the system</li></ul>
A 782	Temperature of the 134°C cycle out o the maximum limit	<ul><li>Let cool the room</li><li>Reset and restart the system</li></ul>
A 801	Errors of out of maximum time during the first phases of discharge	<ul><li>Clean the filter in the room</li><li>Reset and restart the system</li></ul>
A 811	Errors of out of maximum time during the last phase of discharge	<ul><li>Clean the filter in the room</li><li>Reset and restart the system</li></ul>
A 901	Cycle interrupted due to power supply failure	<ul> <li>Check the power supply system of the machine and of the room.</li> <li>Reset and restart the system</li> </ul>

It's need to make a SD CARD periodic backup.

In the event of one of the alarms persisting after some time, consult technical assistance.



# 16 SOLUTION TO OPERATING PROBLEMS

In most cases alarms or errors are caused by lack of attention or lack of familiarity with some technical and operational aspects. You will find below the list of some anomalies with associated solutions.

# 16.1 The autoclave does not dry materials correctly

- Replace the bacteriological filter with a new original one.
- Non original trays, without holes or with different holes made of different material have been used.
  - It is advisable to use original trays only.
- Instruments have not been arranged correctly. Carefully comply with instructions of par. 10.4

#### 16.2 The autoclave chamber has turned white

- Change immediately the type of water used, use exclusively demineralized or distilled water, as indicated in the previous chapters and then clean the chamber.
- The whitish colour may be a consequence of the evaporation of organic materials from the instruments. Instruments should undergo a more suitable and deeper cleaning.
- Check the demineralizer installed.

## 16.3 The autoclave chamber hass bluish-green stains

• Instruments have not been cleaned correctly after the cleaning, rinse more carefully, if the stains remain apply to the phone technical service.

# 16.4 The sterilization cycle interrupts without any patent reason

 Check whether the autoclave is connected to the power mains through extensions, reducers or adapters, if so remove such accessories and connect the autoclave directly to the power socket.

#### 16.5 The autoclave does not receive controls

- I The autoclave is carrying out the automatic barometric alignment, wait for the double acoustic signal after the door opening, then set functions.
- The demineralized water tank is empty, the Led indicating the minimum level is ON, fill the tank with pure water.
- The used water tank is full, the Led indicating the maximum level is ON, discharge used water.

#### 16.6 Stains on instruments

- Instruments get yellow due to the deposit of residual chemical fluid which has fixed on the instruments due to heating. The rinsing was not suitable.
- The sterilization chamber has yellow stains. Some instruments with traces of chemical fluid have been loaded into the chamber, such fluid has fixed due to heating. The rinsing was not adequate.
- Instruments have whitish stains, the rinsing has been done with very limy water and the
  instruments have not been carefully dried. For the final rinsing we suggest the use of
  demineralized water and a careful drying of the instruments
- Instruments have blackened since the material they are made of contain a high percentage of carbon.



# 17 PROCEDURE FOR SERVICE AND ASSISTANCE

In case of failure, review, validation, contact the service centers **TECNO-GAZ S.p.A**.

# See annex for Authorized Service Centers Cod. 0Z00H0002



Assistance will assess the return at headquarters or with the intervention of a technician, and having viewed the machine in order to draw up a cost estimate, which will be forwarded to the distributor customer who will forward it to the final customer, for acknowledgement and signing.

After receiving prior written acceptance of the cost estimate, the autoclave will be serviced and reshipped according to times indicated on the cost estimate.

In case the autoclave must be shipped for repairs, controls, reactivation, revisions, validations follow the obligatory indications below:

- **1.** Use the original packaging; if this is no longer in your possession, use adequate packaging. The merchandise travels at risk to the sender.
- 2. Ship the autoclave only (do not include any component contained in the accessories kit).
- **3.** Carefully clean the sterilization chamber and autoclave in general before shipping. In case it arrives dirty or with residual the autoclave with be returned without being repaired, or it will be put through a cleansing action and disinfection.
- **4.** Always empty the clean water tank through the attachment located on the back of the autoclave (Fig.A–pos. **2**).
- **5.** Always empty the used water tank through the attachment located on the back of the autoclave (Fig.A–pos. 4).
- **6.** Indicate by letter and insert in the package a document which indicates precisely the irregularity or service desired.
- 7. Ship at your expense, otherwise you will be billed for shipping.

All non original packaging which arrives will be disposed of.

Autoclave will be returned with new and original packing to insure maximum protection for your autoclave during shipping. <u>Cost of packaging will be charged to client</u>.

# A CONSUMABLE SPARE PARTS SUMMARY

	PORTATRAY STANDARD			TRAY	
	ONYX 5.0	ONYX 8.0		ONYX 5.0	ONYX 8.0
	SXBA349	2ZXZA0073		DANA049	DXLA349
	TRAY EXTRACTION			POWER SUPPLY CORD	
4	DA	NA008		CECG006	
	SP	ACER		BACTERIAL FILTER	
	CP.	AP014		DAVA101	
	FILTER	CHAMBER		DOOR GASKET	
	DXBA091			DANA038	
	PIPE FOR CHARGING WATER			PIPE FOR DISCHARGING USED WATER	
	DANA099 + DXBA711 + CPRG117			DANA130	
	PIPE FITTING FOR DISCHARGING USED WATER CPRG096			PIPES FOR DISCHARGE UTILITIES	
				SXBA799	
	SPONGE				
	CPMG004				
CHEMICAL INTEGRATOR		200/S o 215-S	BOWIE & DICK TEST	TS001BDT	
BIOLOGICAL INDICATOR		TS002ZBK	HELIX TEST	TS00	1ZHT