## **STEAM STERILIZER**

# **Extrema Plus**



## **OPERATING MANUAL**





Edition: 2 Revision: 2 Date: May 2004



### UPDATING

The following table lists the updating history of the Operating Manual. The field "Description" shortly explains the modifications.

Edit.	Rev.	Date	Description
1	0	09-99	First issue
1	1	11-99	General amendment
1	2	05-01	Pages 3 and 4
1	3	06-01	Pages 11, 12, 14, 62, 66, 68
1	4	08-01	Declaration of Conformity
2	0	11-01	Updating to EPROM release 2
2	1	08-02	New phone number and e-mail address (page 83)
2	2	05-04	A few text changes

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## **FOREWORDS** On thanking for the preference granted, M.O.COM. Ltd. Co. hopes that the performances of this product can result of Your complete satisfaction.

In this manual you will find all the procedures for the correct use and the indications for the complete exploitation of the equipment performances.

We remain at your disposal for any more explanation, as well as suggestions turned to improve the product and the service.

Symbols used through the manual

**APPLICABLE** 

**EUROPEANS** 

DIRECTIVES

PAY PARTICULAR ATTENTION TO THE PARAGRAPHS MARKED BY THE FINGER SYMBOL.

ATTENTION! This symbol points out a potential danger for people. Please OPERATE ACCORDING TO THE SUITABLE PROCEDURES OF THE MANUAL IN ORDER TO PREVENT POSSIBLE DAMAGES TO THE USER AND/OR TO THIRD PARTIES.

**CAUTION!** This symbol points out a potential danger for property. Act according to the suitable procedures of the manual in order to prevent possible damages to material, equipment and/or properties.



I F

CAUTION! This symbol points out a potential danger due to the presence of high temperature.

The product described in this manual is manufactured in accordance with the highest safety standards and doesn't represent any danger for the operator if used according to the following instructions.

The product is in accordance with the following European Directive as applicable:

- **73/23/CEE**, for the approximation to the legislation of the Members States related to low voltage equipment (and following modifications).
- **89/336/CEE**, for the approximation to the legislation of the Members States related to the electromagnetic compatibility (and following modifications);
- 93/42/CEE, concerning the medical devices (and following modifications);

USE IDENTIFICATION The product described in this manual is exclusively intended for the sterilization of re-usable surgical instruments and material.



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THE USE OF THE EQUIPMENT IS STRICTLY LIMITED TO QUALIFIED PERSONEL. NO GROUNDS JUSTIFY THE EQUIPMENT USE OR HANDLING BY UNSKILLED AND/OR UNAUTHORISED PERSONEL.

THE DEVICE MUST NOT BE USED FOR THE STERILIZATION OF FLUIDS, LIQUIDS OR PHARMACEUTICAL PRODUCTS.

Important notes

The information included in this manual are subject to changes without any notice.

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#### 1 - FOREWORDS



#### SCOPE OF THE MANUAL

- The present manual has the scope to supply instructions for:
- general knowledge of the product;
- correct installation and configuration;
- sure and efficient use;
- correct treatment of the material before and after the sterilization.

In the appendix you will find:

- technical characteristics of the product;
- specifications of the sterilization programs;
- maintenance procedures;
- analysis and solution of the problems;
- additional documentation.

#### GENERAL WARNINGS

The product should be used in compliance with the procedures described in the manual and never for purposes differing from the foreseen ones.



THE USER IS RESPONSIBLE FOR THE LEGAL FULFILLMENTS CONCERNING THE INSTALLATION AND USE OF THE PRODUCT.

IF THE PRODUCT IS NOT CORRECTLY INSTALLED AND USED, OR A SUITABLE MAINTENANCE IS NOT OPERATED, THE MANUFACTURER CANNOT BE CONSIDERED RESPONSIBLE OF POSSIBLE BREAKS, MALFUNCTIONS, DAMAGES, LESIONS TO PROPERTY AND/OR PEOPLE.

In order to avoid any danger situations, with possible consequent damages or lesions to property and/or people, the following precautions should be followed:

- Use high quality distilled water only.

The use of <u>water of inadequate quality</u> could seriously damage the equipment. See <u>Appendix A</u>, Technical Characteristics.

- <u>Do not pour</u> any water or liquids over the equipment;
- Do not pour inflammable substances over the equipment;
- <u>Do not operate</u> on the equipment in presence of explosive or inflammable gas;
- Before any maintenance or cleaning action <u>ALWAYS REMOVE</u> the power mains.

If this precaution is impossible or the external mains breaker is far or not visible from the people performing the maintenance, affix the poster **WORKS IN PROGRESS** on the external breaker after having positioned it on OFF.





- Make sure that the electric plant is provided with the earth connection in accordance with the current laws;
- Do not remove any label or plate from the equipment; in case call for new ones.
- Use exclusively original spare parts.



The not observance of what above described makes any responsibility of the Manufacturer to decay .



#### 2 – PACKAGE CONTENT



- Three stainless steel wire trays (Ref. 1);
- One stand stainless steel tray-holders (Ref. 2);
- Operating Manual (Ref. 3);
- Warranty certificate (Ref. 4) (see note).

#### - Box for supplied accessories containing:

- Tray removal tong (Ref. 5);
- Tank of 2 litres provided with fast fitting for manual distilled water filling (Ref. 6);

#### 2 – PACKAGE CONTENT



- Additional bacteriological filter (Ref. 7);
- Draining tank (10 I) (Ref. 8);
- Silicone pipes for sterilizer draining tank connection (Ref. 9);
- External filling tank (10 I) (Ref. 10) and tap (Ref. 11);
- Tube fitting, teflon tape and plastic clips (Ref. 12);
- Special tool for door mechanism unlocking (Ref. 13).
- Hexagonal spanner Ø 14 mm (Ref. 14)

KEEP HOME THE GUARANTEE CERTIFICATE TOGETHER THE INVOICE.

#### LIFTING AND TRANSPORT

The packed product should be handled by using, where possible, suitable mechanic tools (cart elevator, transpallet, etc.) and following the indications printed on the packing. In case of manual handling, the product should be moved by two people and using the proper handles provided on the box.

The sterilizer should be lifted out the box by two people and moved through a cart or similar means.



We recommend to transport and store the equipment at a temperature higher than  $5^{\circ}C.$  A prolonged exposure at lower temperature could cause damages to the product .



Store the <u>original pack</u> that will be used for a possible future transport of the equipment. Use of different pack could cause damages to the product on shipping.



BEFORE MOVING THE STERILIZER IT IS NECESSARY TO EMPTY THE DISTILLED AND RECOVERY WATER TANKS, AFTER THE EQUIPMENT HAS BEEN SWITCHED OFF FOR ABOUT **30** MINUTES FROM THE LAST CYCLE, IN ORDER TO ALLOW THE COOLING OF ALL THE INTERNAL HOT ELEMENTS.



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GENERAL DESCRIPTION	<b>Extrema Plus</b> is the MO.COM. proposal for the new millennium and represents the "state of art" concerning safety and performances as well as the technological frontier in the field of the small steam sterilizers.				
INTRODUCTION	<b>Extrema Plus</b> is a sophisticated equipment but of very friendly use, adaptable to the different demands thanks to the wide possibilities of configuration and choice of the cycles. The equipment is able to treat in fast way every type of load through various patented systems and the operation completely microprocessor controlled.				
	Besides, <b>Extrema Plus</b> allows a better approach by the user, that, rather than to conform himself to the machine characteristics, can "communicate" with it for configuring the performances to the different job requirements.				
	<b>Extrema Plus</b> , thanks to the friendly use, reduced dimensions and agreeable design, represents the ideal partner for the professional requiring the maximum sterilization safety.				
GENERAL FEATURES	<b>Extrema Plus</b> is a completely microprocessored steam sterilizer, with a 17 litres sterilization chamber.				
	It is characterized by an advanced fractionated vacuum system for the complete air removal also from hollow and porous materials as well as by an effective final vacuum drying phase able to eliminate any trace of condensation from the load.				
	An exclusive steam generation system, combined with the electronic management and high accuracy sensors, guarantees an high process speed and high stability of the thermodynamic parameters during the whole sterilization process. All this guarantees a perfect result !				
	<b>Extrema Plus</b> offers 11 sterilization programs (including one program completely programmable), optimized for an effective and fast sterilization of different tools and materials used in medical environment, particularly the dental one.				
	Four programs is directly recalled through a proper selection key on the command panel. Program <b>1</b> is preset and not modifiable (cycle at 134°C for porous material), whereas the programs <b>2</b> , <b>3</b> and <b>4</b> can be modified by the user in order to have at one's disposal those more proper to the needs.				
	Besides the sterilization programs, the sterilizer offers the facility to choice the preheating modes (STAND-BY) according to the frequency usage and the drying modes according to the selected program type and possible problems occurring with some loads or special materials.				
	The print options of the cycle reports, the water filling possibilities and other features can be completely configurable.				
	For more information, refer to Chapter "Setting the equipment".				
	Finally <b>Extrema Plus</b> has the most sophisticated and advanced safety systems in order to guarantee the user against possible operation anomalies, both electric, mechanics, thermal and biologic type.				
	For the description of the safety devices refer to <u>Appendix A</u> (Technical Characteristics).				

#### **3 – GENERAL DESCRIPTION**

#### FRONT DEVICES



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#### **REAR DEVICES**



#### **3 – GENERAL DESCRIPTION**

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#### OPERATING CYCLE EXAMPLE

The sterilization program of Extrema Plus can properly be described by a sequence of phases, each with a well defined activity.

Considering the example of the most complete program (i.e. program 1 at  $134^{\circ}$ C for porous material), after having loaded the material in the chamber, closed the door, selected the program and started the cycle by the START key, with consequent blocking of the door locking mechanism, the following sequence will run:

- 1. Pre-heating of the steam generator and sterilization chamber;
- 2. Chamber air removal and steam penetration inside the load through a series of vacuum (fluid exhaustion from the sterilization chamber) and pressure phases (steam entering into the chamber);
- 3. Pressure increasing, with consequent steam temperature increasing up to the preset sterilization conditions (for the example, **134°C**);
- 4. Stabilization of the pressure and temperature conditions inside the sterilization chamber;
- 5. Run of the sterilization process for the preset time (for the example, 4 minutes);
- 6. Chamber pressure decreasing through steam discharge;
- 7. Vacuum drying phase;
- 8. Venting phase through sterile air;
- 9. Chamber pressure leveling up to atmospheric value.

As reached this last phase the door locking mechanism will be released and the door can be opened to recovery the load from the sterilization chamber paying attention to use proper precautions.

Whereas the phases 1, 3, 4, 6 and 9 are essentially identical for all the cycle types, with little time differences depending on the quantity and consistence of the load and heating conditions, the phases 2, 5, 7 and 8 sharply vary their configuration and duration depending on the selected cycle (and accordingly on the load typology) and on the choices operated by the user.

A standard program can be outlined with the following graph:





FOR DETAILS ABOUT THE AVAILABLE PROGRAMS, REFER TO APPENDIX **B** (**PROGRAMS**)

#### **4 – INSTALLATION**



#### INSTALLATION

INTRODUCTION

For the right operation, features exploitation and life extension of the sterilizer, the <u>first and basic</u> step is the correct and careful installation. Such precaution besides avoids possible malfunctions or damages to the equipment, as well as possible danger situations for property and people.

We suggest to **meticulously** follow the warnings reported on this chapter.

- "Assistenza Clienti" M.O.COM. (see Appendix Z) is at Your disposal for any question or further information.
- The sterilizer is forwarded after having passed a set of programmed controls. Therefore further calibrations for the operation <u>are not necessary any more</u>.

#### **Dimensions and weight**

- Height (total)
   400 mm
- Width (total) 456 mmDepth
- (excluded rear fittings) 515 mm
- Weight (total) about 55 kg



#### **Power supply**

The electric plant to which the sterilizer is connected has to correctly be sized according to the electric characteristics of the equipment. The rating data are reported on the plate on the **rear panel** of the machine.



INSTALL THE EQUIPMENT SO THAT THE PLUG OF THE MAINS CABLE CAN BE EASILY ACCESSIBLE.



VERIFY THE ADEQUACY OF THE ELECTRIC PLANT, PARTICULARLY FOR THE EARTH CONNECTION.

#### DIMENSIONS FOR BUILD MOUNTING

In case the sterilizer has to be set into a piece of furniture it is necessary to provide a suitable space all around the equipment in order to assure an effective ventilation, as well as a free space in the rear in order to allow the passage of the draining pipelines and power supply cord, and to assure an adequate air flow for the cooling of the heating exchanger.

Accordingly it is important that the build for the installation has the **minimum dimensions** as in figure:

Build <u>dimensions smaller</u> than the indicated ones

NT AND <u>NOT GUARANTEE</u> A SUITABLE COOLING, NEQUENT REDUCTION OF THE PERFORMANCES AND/OR POSSIBLE DAMAGES.



IN CASE THE STERILIZER INSTALLATION MAKES THE MAINS BREAKER INACCESSIBLE, USE A MAINS SOCKET INCORPORATING A SWITCH.

DON'T REMOVE THE CARTER NEITHER OTHER EXTERNAL ELEMENTS. ARRANGE INTO THE BUILD THE EQUIPMENT COMPLETE IN EVERY PART.



For the complete technical data refer to appendix A. (Technical Characteristics).





GENERAL INSTALLATION	In order to assure the correct operatio observe the <b>following directions</b> :	n of the equipment and/or avoid situations	s of risk,							
DIRECTIONS	<ul> <li>Install the sterilizer on <u>a plain surface</u>; eventually adjust the rear feet to match possible irregularities.</li> <li>Verify that the plan is called to support the weight of the equipment (abth 55 kg);</li> </ul>									
	verify that the plan is able to support the weight of the equipment (abl. 55 kg);									
	<ul> <li>Allow a <u>suitable space</u> for the ven sterilizer, particularly on the back In case the equipment is set into warnings as above indicated, avo</li> </ul>	initiation (at least 10 cm each side) all arc side. o a piece of furniture, verify the respect iding possible obstruction of the air slot	ct of the ts;							
	<ul> <li><u>Do not install</u> the sterilizer near tubs, sinks or analogous places, avoiding the contact with water or liquid. Otherwise, short circuits and/or situations of potential danger for the operator could occur;</li> </ul>									
	<ul> <li><u>Do not install</u> the sterilizer in environ humidity or in rooms with poor ventile</li> </ul>	nments characterized by the presence of e ation;	xcessive							
	<ul> <li><u>Do not install</u> the sterilizer in environments characterized by the presence of inflammable and explosive <u>gas or vapors</u>;</li> </ul>									
	<ul> <li>Install the equipment in such a way the power supply cable could not be bent or crushed. The cable should run freely to A.C. socket.</li> </ul>									
	<ul> <li>Install the equipment in such a way They should run freely to the external</li> </ul>	n such a way the draining pipelines could not be bent or crushed. to the external draining tank.								
ELECTRICAL CONNECTIONS	The sterilizer should be connected, in compliance with the laws and/or directives in-form to a mains socket of the electric plant with a power rate suitable for the equipmer consumption, and provided with earth connection. The mains socket should be suitably protected through differential switch having for following characteristics:									
	- Rating current L. <b>16 A</b>	Differential switch Mair with	ns socket earth pin							
	- Differential current $I_{\Delta n}$ 0,03 A		0 0							
		Mains switch								
	THE MANUFACTURER IS NOT LIABLE FOR THE DAMAGES CAUSED BY AN INSTALLATION WHERE A NOT SUITABLE ELECTRIC PLANT AND/OR EARTH CONNECTION ARE PROVIDED.									
	In case the mains plug doesn't match the socket, replace the cable plug with a suitable type of same electrical characteristics or anyway suitable for the electrical requirements of the equipment. The plug choice and replacement is on care and responsibility of the user.									
	DIRECTLY CONNECT THE CABLE ADAPTERS OR OTHER ACCESSORIE	E TO THE MAINS SOCKET. <b>DON'T USE</b> EXT ES <b>.</b>	TENSIONS,							

#### **4 – INSTALLATION**

#### CONNECTING THE DRAINING TANK

During the program running, the steam and condensation water is conveyed in a special supplied tank external to the equipment.

CHECK FOR THE CORRECT INSTALLATION OF THE SILENCER ON THE FITTING A OF THE DRAINING TANK

For the <u>correct connection</u> of the tank, proceed as follows:

- Mount the ends of two supplied pipes on the fittings marked A and B, taking care to plug in completely the pipes.
- Lock the pipes on the fittings by using the supplied plastic clips;
- Cut the pipes according to the desired distance and mount the opposite ends on the two fittings of the draining tank, taking care to match the correct connection (A-A and B-B), as shown in the figure;
- Lock the pipes on the fittings by using the supplied plastic clips;
- CHECK THAT THE CONNECTED PIPES ARE RUNNING FREELY FROM THE UNIT TOWARDS THE DRAINING TANK WITHOUT ANY BEND, CRUSH OR OBSTRUCTION.
- Plug the jack of the level probe in the socket mounted on the rear side of the equipment (see figure);



- CP CHECK FOR THE CORRECT MOUNTING OF THE PLUG. IF NOT CONNECTED, THE EQUIPMENT WILL DETECT A FALSE MAX LEVEL IN THE DRAINING TANK, WITH CONSEQUENT LIGHTING OF THE LED ON THE COMMAND PANEL (SEE CHAPTER 5 "FIRST START-UP") AND ALARM SIGNALING GENERATION IF THE START COMMAND IS ENTERED.
- Fill the tank of normal tap water up to the level marked on the tank.
  - PERIODICALLY EMPTY THE TANK HAVING CARE TO LET ALWAYS A MINIMUM OF WATER INSIDE THE TANK CORRESPONDING TO THE MARKED LEVEL, OTHERWISE THE NOISE CAUSED BY THE STEAM DISCHARGE AND THE STEAM EXHAUSTION FROM THE VENT HOLE WILL INCREASE NOTICEABLY.



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NORMALLY HOT WATER AND PRESSURIZED STEAM GOES OUT FROM THE DRAINING FITTINGS. CAREFULLY CONNECT ALL ELEMENTS OF THE DRAINING CIRCUIT IN ORDER TO AVOID DAMAGES AND INJURIES TO PROPERTY AND/OR PEOPLE.



#### CENTRALIZED DRAINING SYSTEM CONNECTION

To avoid the recurrent emptying of the draining tank it is possible to directly connect it to a centralized draining system.

In this case, proceed as follows:

- Remove the pipe fitting from the free venthole, remove the screw plug from the side fitting of the tank and screw it on the previous vent-hole;
- Screw a supplied 1/8" pipe fitting on the side fitting;
- Use teflon ribbon or fitting sealing to get a perfect seal;
- Use one spanner for holding the nut and a second spanner for tightening the pipe fitting.
- Mount on the fitting a pipe of suitable material and sizes (not supplied), taking care to plug in it completely.



- Lock the pipe on the fitting by using the supplied plastic clips.
- Adapt the centralized draining circuit to match this new link (<u>consult a specialized</u> <u>plumber</u>);
- Connect the opposite end of the pipe to the draining plant and verify the sealing.
- Check that the pipe is running freely from the external tank to the centralized draining plant, without any bend, crush or obstruction.

The elements should be arranged according to the following scheme (example):



Stated "x" the ground-fitting point height on the tank, the connection point to the centralized draining system  $\underline{MUST}$  be at a quota < x+30 mm. Higher quotas can jeopardize the correct emptying of the tank.



#### EXTERNAL FILLING TANK CONNECTION (automatic filling feature)

In order to eliminate the recurrent manual distilled water topping up (see **Chapter, First start-up**), it is possible to connect the sterilizer to the supplied external filling tank (10 I) that should be periodically filled by the user.

In this case the filling of the internal reservoir will be automatically controlled by a pump as soon as the water level of the internal reservoir reaches the MIN level.

For the correct connection of the filling tank, proceed as follows:

- Mount the supplied tap on the bottom hole of the filling tank; use the teflon rubber or other sealing to get a perfect seal.
- Mount the supplied silicone pipe on the filling point on the rear of the equipment, taking care to plug in it completely.



- Lock the pipe by using a supplied plastic clip.
- Cut the pipe according to the desired distance and mount the opposite end on the output of the tap of the filling tank.
- Check that the pipe is running freely from the unit towards the filling tank without any bend, crush or obstruction.
- Loosen the top cup to let the water to flow (take care to also remove the possible gasket or under-cup);
- Turn in open position the tap of the filling tank.
- For the setting of the automatic filling refer to Chapter "Setting the equipment"). Please take care to activate this function only <u>After</u> the tank has been filled with distilled water.
- Where available, the external filling tank can directly be fed by a water depuration plant (an inverse osmosis system is recommended) provided with the necessary controls and opportunely connected.

Please contact "Assistenza Clienti" M.O.COM. (see **Appendix Z**) for further in-formations and advice about the connection of different water purification systems to the sterilizer.



CONNECTION TO A PRINTER	To get a control with the most significant data, a standard needle (i.e. IBM Proprinter or Epson 70) or thermal printer equipped with Centronics parallel interface can be connected to the sterilizer printer port. This strip can be filed as tracability report of the carried out sterilization process.					
		IN CASE OF THERMAL PRINTER, STORE THE STRIP IN PLACE ADEQUATE FOR PROTECTING IT FROM LIGHT AND/OR HEAT SOURCES.				
	Connec provideo	t the printer to the sterilizer port through a parallel cable (maximum length = 2m), d one side with DB 25 male connector (sterilizer side).				
	For sett <b>equipm</b>	ing the printer and choice the report characteristics refer to Chapter "Setting the ent".				
		THE EQUIPMENT IS ABLE TO MANAGE ALSO LASER OR INKJET PRINTERS. HOWEVER THESE TYPES OF PRINTERS REQUIRE AT THE END OF EACH PRINTED PAGE A FORM FEED (FF) INSTEAD OF LINE FEED (LF) COMMAND THAT IS NOT MANAGED BY THE STERILIZER. TO GET THE PRINTOUT WILL BE THEREFORE NECESSARY TO ENABLE THE FORM-FEED KEY NORMALLY PROVIDED ON THE PRINTER.				
ACQUIRING THE ENVIRONMENT PRESSURE VALUE	For the acquires operatio	correct operation of internal auxiliary systems, <b>it is necessary</b> that the sterilizer s the environment pressure value of the installation site before starting the first n cycle.				
	The pro <b>selectic</b> Please r	cedure is described in the Chapter "Setting the equipment" (see paragraph <b>Option</b> on in the SETUP program). read <u>carefully</u> the indications supplied.				
		THE EQUIPMENT LEAVES THE FACTORY WITH THE PRESSURE VALUE RELATING THE PRODUCTION ENVIRONMENT STORED INTO THE MEMORY.				
		IF THE PRESSURE ACQUISITION PROCEDURE IS NOT PERFORMED, THE EQUIPMENT WOULD NOT CORRECTLY WORK, WITH DIFFICULT OR IMPOSSIBLE DOOR OPENING AT THE END OF THE PROGRAM .				

#### 5 – FIRST START-UP



Once the sterilizer has correctly been installed, you can proceed to the switching on and FIRST START-UP equipment configuration. SWITCHING ON Switch on the sterilizer through the mains switch mounted on the rear side. T F PERFORM THIS ACTION WITH THE DOOR OF THE STERILIZER IN OPEN POSITION IN ORDER TO ALLOW THE INITIAL CONTROL OF THE SAFETY SYSTEM TO OPERATE CORRECTLY. At the switching on, the equipment turns on in sequence all the front indicators of the **INITIAL SELF-TEST** command panel, allowing a visual check by the user for possible anomalies. The turn on of the signaling is accompanied by an acoustic signal. Ended this check phase the machine performs the automatic test of the safety block of the closing system. On the liquid crystal display (LCD) the following message will appear: PLUS EXTREMA SELFTEST L3 IF THE DOOR WAS CLOSED, THE AUTOMATIC TEST OF THE SAFETY BLOCK CANNOT OCCUR AND THE SELF-TEST IS INTERRUPTED. ON THE LCD DISPLAY THE FOLLOWING MESSAGE APPEARS, ACCOMPANIED BY ACOUSTIC SIGNALS: ΟΡΕΝ тне DOOR CONTINUE то Open the door to allow the test continuation. At the end of self-test the display shows: PLUS EXTREMA SELFTEST PASSED ACQUISITION AND At the switching on, the unit provides for the automatic reading of the environmental pressure value. If the difference between currently read and stored pressure values (see **AUTOMATIC** Chapter "Setting the equipment", par. Setting the option in SETUP mode) is higher **UPDATING OF THE** 

Chapter **"Setting the equipment**", par. Setting the option in SETUP mode) is <u>higher</u> than a preset value, the unit will update automatically the stored value after a short waiting time, otherwise the stored value remains unchanged.

Subsequently, the unit will run the initial self-test (see previous paragraph), and later on the LCD will display the following message accompanied by acoustic signal :

0	bа	r	U	Ρ	D	A 1	ГЕ	D	
€	=	С	0	Ν	Т	I N	U	E	

Pushing key **ESC** <sup>(1)</sup> the unit will enter in STAND-BY mode (see next paragraph).

THE ACQUISITION PROCEDURE (AND POSSIBLE UPDATING) OF THE ENVIRONMENTAL PRESSURE VALUE WILL BE PERFORMED EACH TIME THE UNIT IS SWITCHED ON (THROUGH THE MAINS SWITCH).

**ENVIRONMENTAL** 

PRESSURE VALUE

L<del>I</del>



STAND-BY STATE	Over the self-test procedure the sterilizer goes in <b>STAND-BY</b> state, and the LCD display will show:							
	3 1 / 0 5 / 1 9 9 9 1 1 : 0 5							
	Chtr 00000/00000							
	with the current <b>date</b> and <b>time</b> on the upper line and the <b>cycle counter</b> on the lower line reporting two values: the number of correctly completed cycles on the left and all those that was initiated on the right.							
	THE CYCLE IS CONSIDERED INITIATED AT THE START COMMAND OF THE STERILIZATION CYCLE (FIRST VACUUM PHASE), EXCLUDING THE PREHEATING PHASE. THE CYCLE IS CONSIDERED COMPLETED IF THE END OF THE PROGRAM IS REACHED (SEE CHAPTER "RUNNING THE STERILIZATION PROGRAM").							
	At regular intervals the following message alternates on the display:							
	STANDBY HIGH MANUAL FILLING							
	where the upper line shows the setting of the preheating mode (STAND-BY) and lower line the filling mode of the distilled water reservoir (FILLING).							
	For the date and time setting as well as the choice of the preheating modes (STAND-BY) and reservoir filling (FILLING) refer to Chapter "Setting the equipment".							
	The command panel shows all the LED's turned off (apart the door status and water MIN/MAX level signaling). At the switching on of the equipment the led MIN will normally be turned on.							
	The displays will show:							
	<ul> <li>Temperature display (°C): current sterilization chamber temperature</li> </ul>							
	<ul> <li>Pressure display (bar): current sterilization chamber <u>pressure</u></li> </ul>							
	– Timer display (主):							
	The equipment is frozen waiting for the selection by the user of the desired sterilization program (see Chapter " <b>Selecting the sterilization program</b> ").							
FILLING THE DISTILLED WATER	Before using the sterilizer the first time and all the next times the red indicator MIN of the water level turns on, it is necessary to fill or top up the distilled water reservoir.							
Manual filling	Operate in the following way (with open door) on referring to the figure:							
	1. Hold horizontally the manual filling tank and fill it of distilled water (2 I);							
	2. Connect the fast fitting of the rubber pipe to the inlet mounted on the top right front of the equipment, pushing for a click;							
	3. Position vertically the tank and loosen the cap taking care do not upset water on the machine.							
	4. Now the water will start to flow into the internal reservoir;							
	5. On continuing the filling the MIN level indicator turns off.							
	6. Continue up to dry out the tank;							

#### 5 – FIRST START-UP



- 7. Take the tank and lower it below the connection point, holding it horizontally;
- 8. Push on the metallic clip of the fitting and remove the rubber pipe;
- 9. Fill again the tank (2 I) and repeat once again the steps 2, 3 and 4;
- 10. As the Led <u>MAX</u> turns on (accompanied by an acoustic signal) interrupt the filling and operates as described at the steps 7 and 8.



TO START THE STERILIZATION PROGRAM <u>IS NOT NECESSARY</u> THAT THE LED MAX IS TURNED ON. IT IS SUFFICIENT THAT THE LED MIN IS TURNED OFF.

#### Automatic filling

When the automatic filling system through external tank is installed (see Chapter "Installation"), the filling will occur automatically since the automatic filling option is selected.

Obviously, for the correct operation, the user has to prior fill the external tank.



<u>Only</u> use high quality distilled water. For the indications concerning the water see Appendix A (Technical Characteristics).

For the setting of the automatic filling option refer to Chapter "Setting the equipment"



The automatic filling system never has to work "dryed", a premature usury of the auxiliary water injection pomp might occur. <u>Periodically</u> verify the level of the water into the external tank.

#### DRAINING TANK WATER LEVEL SIGNALING





The max water-level value in the draining tank is properly signaled by the alternate turning on of the red Led MIN and green Led MAX on the command panel of the unit. Provide for the draining of the external tank.

- Do not drain completely the tank, but leave a layer of water corresponding to the sign stamped on the tank. Otherwise, the sound level of the water discharge and the outflow of the steam from the vent-hole will increase considerably.
- IN CASE OF WRONG MAX LEVEL SIGNALING ON THE COMMAND PANEL (THE WATER LEVEL IN THE DRAINING TANK IS LOWER THE MAX LEVEL), CHECK FOR THE CORRECT CONNECTION OF THE PROBE'S PLUG INTO THE REAR SOCKET OF THE UNIT. A FALSE CONNECTION CAUSES THIS WRONG SIGNALING.



## SETTING THE EQUIPMENT

INTRODUCTION

STARTING THE

SETUP PROGRAM

Extrema Plus offers new and wider customization possibilities.

The configuration of the sterilizer can be suited to user's demands, by adapting, for instance, the characteristics of the machine depending on the use frequency and the type of material to be treated.

Through a sophisticated SETUP program a lot of options can be selected by the user through a friendly and easy menu.

Use the SETUP program every time you need. A correct customization of the equipment allows to get the best performances and the maximum satisfaction for the use.

"Assistenza Clienti" M.O.COM. (SEE APPENDIX Z) IS AT DISPOSAL OF THE USERS TO SUPPLY SUGGESTIONS OR ADVICES FOR THE BETTER USE THE OPTIONS AVAILABLE IN THE SETUP PROGRAM.

To enable the SETUP program push for a few seconds on the **SETUP** key (the lowest key on the command panel), up to the liquid crystal display shows:

Е	Х	Т	R	Е	М	Α	Ρ	L	U	S	
			S	6 E	Т	U	Ρ				

The Led closed the key turns on and stays on for all the setup phase to signal this operating status. After a moment the display will show:

PRESS	,
	<b>1 = E S C</b>

Press the key **ENTER** I to enter the SETUP program. Now the display is showing the first level options of the menu (see paragraph **Flowchart of the SETUP program**).

On the contrary, press the key ESC  $\boldsymbol{\Uparrow}$  to exit the SETUP program and return to the normal operation.

THE SETUP PROGRAM CAN ONLY BE RECALLED FROM STAND-BY STATE. DURING THE EXECUTION OF THE PROGRAM THE SETUP MODE <u>CANNOT BE ACCESSED</u>.

FUNCTION OF THE KEYS IN SETUP MODE In the SETUP mode the keys have the function indicated on the right of the key on the background of the command panel and differs from the normal operation as follows:

- Symbol 니 ENTER function, to confirm the data (START/STOP key)
  - Symbol + increment/scrolling up function (program selection key)
  - Symbol decrement/scrolling down function (test selection key)
- Symbol **f ESC** function, to exit the option (SETUP key )

This key configuration remains valid for the SETUP mode.

#### 6 - SETTING THE EQUIPMENT







#### **DESCRIPTION OF** THE MENU **OPTIONS**

On the following the meaning of the main menu and second level options are described.

#### MAIN MENU

The main menu of the SETUP program has 6 options that recall further menus (second level):

BASIC	
ADVANCED	
SPECIAL	
SERVICE	
REVIEW	
EXIT	

(basic options) (advanced options) (special options) (not user available) (review of the selected options) (exit the SETUP mode and return to normal operation. See paragraph Exit the SETUP mode)

L3

THE WAY FOR SETTING THE DIFFERENT OPERATING MODES IS DESCRIBED ON THE PARAGRAPH SETTING THE OPTIONS IN THE SETUP MODE.

#### BASIC Menu

BASIC menu (basic options) is formed by the following options:

LANGUAGE	(current <u>language</u> setting)
DATE	(current <u>date</u> setting);
TIME	(current time setting)
EXIT	(exit the BASIC menu and return to main menu)

#### **ADVANCED** menu

ADVANCED menu (advanced options) is formed by the following options:

PROGRAMS

STAND-BY DRYING OPT. PRINT OPT. FILLING EXIT

(preset sterilization programs selection, as shown on the front panel by LED's 2, 3 and 4) (stand-by mode setting) (dry mode setting) (printer and printing option setting) (reservoir filling mode setting) (exit the ADVANCED menu and return to main menu)

SPECIAL menu **SPECIAL** menu (special options) is formed by the following options:

SET 0 bar DOOR LOCK LCD CONTRAST EXIT

(local pressure acquiring) (door locking mechanism activation) (display contrast adjustment) (exit the SPECIAL menu and return to main menu)

**SERVICE menu** SERVICE menu can be accessed by M.O.COM. Service ONLY.

#### **REVIEW** menu

**REVIEW** menu recall the current settings of the machine, allowing the user to verify the exactness.

The following screens are available (each formed by two lines):

LANGUAGE	language that has been set
XXXXXXX	ENGLISH – (other language)
DATE	date that has been set
dd/mm/yyyy	day/month/year
ТІМЕ	time that has been set

hh:mm

hour:minutes

#### **6 – SETTING THE EQUIPMENT**



2nd PRESET XXXc XXXXXX	preset pro name of t	ogram associated to Led 2 of the front panel the sterilization program
3rd PRESET XXXc XXXXXX	preset pro name of t	ogram associated to Led 3 of the front panel the sterilization program
4th PRESET XXXc XXXXXX	preset pro name of t	ogram associated to Led 3 of the front panel the sterilization program
STAND-BY XXXX	stand-by OFF - LC	mode that has been set )W - HIGH
DRYING OPTIO XXXXX / XXXXX	NS dry type t (LONG / EXTRA /	hat has been set SHORT) - STND ( <i>standard</i> ) - INTEL ( <i>intelligent</i> ) - STND ( <i>standard</i> ) - FAST
PRINT OPTION XXXXX / XX	S printer typ OFF - CF	pe selected / printout number R - CR+LF / number of copies
AUTOFILLING XXXXXX	tank filling ON (auto	g mode that has been set matic) – OFF (manual)
EXIT REVIEW	<u>exit</u> the F	REVIEW menu
For TH SETUP Extrema Plus is	E MEANING OF THE MODE". delivered with the	E ABOVE TERMS SEE PARAGRAPH <b>"Setting the options in</b> following default settings:
For TH SETUP Extrema Plus is DATE: TIME:	E MEANING OF THE MODE". delivered with the	E ABOVE TERMS SEE PARAGRAPH <b>"Setting the options in</b> following default settings: <i>current date</i> <i>current hour</i>
For TH SETUP Extrema Plus is DATE: TIME: PROGRAMS:	E MEANING OF THE MODE". delivered with the Preset 1: Preset 2: Preset 3: Preset 4:	F ABOVE TERMS SEE PARAGRAPH <b>"SETTING THE OPTIONS IN</b> following default settings: <i>current date</i> <i>current hour</i> 134°C POROUS ( <u>not</u> modifiable by the user) 134°C HOLLOW (modifiable by the user) 134°C SOLID (modifiable by the user) 134°C EMERGENCY (modifiable by the user)
For th SETUP Extrema Plus is DATE: TIME: PROGRAMS:	E MEANING OF THE MODE". delivered with the Preset 1: Preset 2: Preset 3: Preset 4: OGRAMS UNDER THATIONS ARE POSSIBL	following default settings: <i>current date</i> <i>current hour</i> 134°C POROUS ( <u>not</u> modifiable by the user) 134°C HOLLOW (modifiable by the user) 134°C SOLID (modifiable by the user) 134°C EMERGENCY (modifiable by the user) 134°C EMERGENCY (modifiable by the user) 134°C FORDIS (MODIFIABLE SETTINGS). OTHER LE FOR DIFFERENT MARKETS.
For th SETUP Extrema Plus is DATE: TIME: PROGRAMS: CF THE PR COMBIN STAND-BY:	E MEANING OF THE MODE". delivered with the Preset 1: Preset 2: Preset 3: Preset 4: OGRAMS UNDER TH ATIONS ARE POSSIBL	following default settings: current date current hour 134°C POROUS ( <u>not</u> modifiable by the user) 134°C HOLLOW (modifiable by the user) 134°C SOLID (modifiable by the user) 134°C EMERGENCY (modifiable by the user) 134°C EMERGENCY (modifiable by the user) HE PRESETS 2, 3 AND 4 ARE PREFERRED SETTINGS. OTHER LE FOR DIFFERENT MARKETS. HIGH
For the setup Extrema Plus is DATE: TIME: PROGRAMS: Combinut STAND-BY: DRYING:	E MEANING OF THE MODE". delivered with the Preset 1: Preset 2: Preset 3: Preset 4: OGRAMS UNDER TH ATIONS ARE POSSIBL	following default settings: <i>current date</i> <i>current hour</i> 134°C POROUS ( <u>not</u> modifiable by the user) 134°C HOLLOW (modifiable by the user) 134°C SOLID (modifiable by the user) 134°C EMERGENCY (modifiable by the user) 134°C EMERGENCY (modifiable by the user) HE PRESETS 2, 3 AND 4 ARE PREFERRED SETTINGS. OTHER LE FOR DIFFERENT MARKETS. HIGH STANDARD STANDARD
For the setup Extrema Plus is DATE: TIME: PROGRAMS: PROGRAMS: STAND-BY: DRYING: PRINT OPT.:	E MEANING OF THE MODE". delivered with the Preset 1: Preset 2: Preset 3: Preset 4: OGRAMS UNDER TH ATIONS ARE POSSIBL Long: Short: Printer: Nr. of copies:	ABOVE TERMS SEE PARAGRAPH <b>"SETTING THE OPTIONS IN</b> following default settings: <i>current date</i> <i>current hour</i> 134°C POROUS ( <u>not</u> modifiable by the user) 134°C HOLLOW (modifiable by the user) 134°C SOLID (modifiable by the user) 134°C EMERGENCY (modifiable by the user) HE PRESETS 2, 3 AND 4 ARE PREFERRED SETTINGS. OTHER LE FOR DIFFERENT MARKETS. HIGH STANDARD STANDARD OFF 1

DEFAULT SETTINGS



#### 6 – SETTING THE EQUIPMENT

We now analyze in detail how to enable the different available options, proceeding with the SETTING THE order as shown in the previous paragraph (Description of the menu options). **OPTIONS IN SETUP** MODE Language option Select the option LANGUAGE with the key , the following screen will be shown: (LANGUAGE option in the BASIC menu) + 1 → E N G L I S H (other language)-↓ Select the desired language. Scroll the list by the key + or – and confirm with the key ↓ to store the choice. With the confirmation command you re-enter in the second level menu. E J FROM NOW ON, THE SETUP MENU WILL BE SHOWN IN THE SELECTED LANGUAGE. **Date option** As selected the option **DATE** through the key  $\downarrow$ , the following screen will be shown: (DATE option in the BASIC menu) dd/mm/yy 1 + - ↓ \_ → Carry out the following operations: Day indication is flashing: adjust for the current date through the keys + and -. Confirm through the key J. Month indication is flashing: adjust for the current month through the keys + and -. Confirm through the key J. Year indication is flashing: adjust for the current year through the keys + and -. Confirm through the key J. With the last confirmation the set date will be stored and the second level of the menu returned. **Time option** As selected the option **TIME** through the key ↓, the following screen will be shown: (TIME option in the BASIC menu) + 1 hh:mm - ↓ ר L Carry out the following operations: Hour indication is flashing: adjust for the current hour through the keys + and -. Confirm through the key J. Minute indication is flashing: adjust for the current minutes through the keys + and -. Confirm through the key J. With the last confirmation the set time will be stored and the second level of the menu returned.

#### 6 - SETTING THE EQUIPMENT



#### Setting the preset sterilization Programs

(PROGRAMS option of the ADVANCED menu)

The selection of the programs and their storing under the preset key of the command panel occurs by performing the following steps through different menu sequence. It is possible to choose both the **preset** programs and the user **configurable** program (CUSTOM).

We will see the two cases.

To select a **PRESET program** operate as follows:

1. As selected the **PROGRAMS** option through the key , the following menu appears:

→ 2 n d	PRESET	+ ↑
3 t h	PRESET	- ↓
4 t h	PRESET	

Choice the position on the command panel (2, 3 or 4) the preset sterilization program has to be associated and select the item through the keys + and -. Confirm by the key  $\downarrow$ .

2. Now the display is showing the list of the available cycles (two lines in turn):

134 c SOLID + 1 ↓ 121c SOLID 134 c WRAPPED WRAPPED 1 21 c 34 c 1 HANDPC HANDPC 1 2 1 C 34 c EMERGN 1 1 21 c POROUS 134c PRION хххс СИЅТОМ

Through the keys + and - scroll the list to find the desired sterilization program.

3. Confirm the choice by the key J. The program will be stored at the selected position.

IF AN IDENTICAL STERILIZATION PROGRAM IS ALREADY PRESENT IN A DIFFERENT PRESET POSITION, THE CHOICE WON'T BE ACCEPTED. ON THE SCREEN THE FOLLOWING WARNING APPEARS, ACCOMPANIED BY ACOUSTIC SIGNALINGS:

тніѕ	PRO	G R A M	IS
ALRE	ADY	PRES	ET!

LF

THE SELECTION CAN BE WHENEVER MODIFIABLE BY PERFORMING AGAIN THE PROCEDURE ABOVE DESCRIBED.

To configure a **<u>CUSTOM</u>** cycle, proceed as follows:

1. As selected the **PROGRAMS** option through the key , the following menu appears:

→	2 n d	PRESET	
	3 t h	PRESET	
	4 t h	PRESET	

Choice the position on the command panel (2, 3 or 4) the CUSTOM sterilization program has to be associated and select the item through the keys + and -. Confirm by the key  $\downarrow$ .

2. Once entered in the available program list, select the item **XXXc CUSTOM** through the keys + and -:



Confirm through the key الـ



3. Now the new menu allowing the choice of the sterilization temperature appears:

<b>&gt;</b>	1	3	4	С	+ ↑
	1	2	1	С	- ↓

Select **121c** for a CUSTOM program with a sterilization process at 121°C, or **134c** for a program at 134°C.

Move on the choice by using the keys + / - and confirm by the key -I.

4. Then the following screen will be shown:

TIME:XX min	+ 1
	- ↓

requiring to choice the duration of the sterilization process.

Use the key + / - to adjust the value, then confirm by the key  $\downarrow$  .

- The sterilization process time ranges between 4 and 30 minutes for the program at 134°C, and between 20 and 30 minutes for the program at 121°C.
- 5. As set the time, appear the menu for selecting the type of the initial vacuum:

$\rightarrow$ F R A C T I O N A T E D	+ ↑
SINGLE	- ↓

Choice **FRACTIONATED** to perform a fractionated vacuum, or **SINGLE** for one prevacuum phase only.

Use the key + / - then confirm by the key J.

6. Now a next menu is shown where the drying modes can be selected:

→LONG DRY	+ ↑
SHORT DRY	- ↓

Choice **LONG** to dry in properly way the porous and/or wrapped instruments or **SHORT** in case of load with unwrapped (or hollow) instruments. Use the key + / - then confirm by the key الم

- 7. Depending on the option selected (LONG or SHORT), two different menus will be prompted:
  - a) Mode LONG

The following options are available:

→ S T A N D A R D	+ ↑
INTELLIGENT	- ↓
EXTRA	

Select STANDARD option for a long preset time drying (about 10 minutes).

WITH BIG LOAD OR SPECIAL MATERIAL, THE **STANDARD** OPTION MIGHT <u>NOT</u> GUARANTEE SOMETIMES A CORRECT RESULT. IN THIS CASE, EXTEND THE DRYING PHASE WITH THE **EXTRA** OPTION.

Select **INTELLIGENT** to enable an automatic drying characterized with a duration (higher or lower the standard one) depending on the load volume, quantity and typology.

WITH COMPLEX LOAD (E.G. WRAPPED INSTRUMENTS IN STERILIZATION "CONTAINER") THE "INTELLIGENT" OPTION MIGHT NOT CORRECTLY OPERATE, WITH RESULTS LOWER THE EXPECTATION. IN THIS CASE USE THE **STANDARD OR EXTRA** OPTIONS AS NECESSARY.

#### 6 - SETTING THE EQUIPMENT



Select **EXTRA** option for extending the drying phase of a selectable time period (e.g. for particularly difficult load).

Enabling this option, the following choice will be prompted:

EXTRA	:XX min	+ ↑
,	<b>↑ = E S C</b>	- ↓

allowing to set the time period of the extra drying. The extended time ranges from **1** to **15** minutes.

#### b) Mode <u>SHORT</u>

The following options are displayed:

→ S T A N D A R D	+ ↑
FAST	- ↓

Select **STANDARD** option for a preset time period drying (about 4 minutes). Select **FAST** option for a very short drying phase but forgoing the complete removal of the residual humidity.

Use the key + / - then confirm by the key .

8. Confirm the choices by the key J. The program is stored at the selected position.

IF THE PROGRAM CUSTOM IS ALREADY PRESENT IN A DIFFERENT PRESET POSITION, THE CHOICE WON'T BE ACCEPTED. ON THE SCREEN THE FOLLOWING WARNING APPEARS, ACCOMPANIED BY ACOUSTIC SIGNALING:

тніѕ	PRO	GRAM	IS
ALRE	ADY	PRES	ЕТ!

- THE SELECTION CAN BE WHENEVER MODIFIABLE BY PERFORMING AGAIN THE PROCEDURE ABOVE DESCRIBED.
- The list of the available programs, their diagrams and the characteristics of the autoclavable material (depending on the programs) can be found in Appendix **B** (**Programs**).

The heating stage in STAND-BY status (pre-heating) can be set according to the high- or low-use of the unit and others possible considerations.

As selected the **STAND-BY** option by the key , the following menu will appears:

→ H I G H	+ ↑
L O W	- ↓
OFF	

Select **HIGH** (<u>high</u> preheating stage) for intensive use and to reduce however the waiting time between one cycle and the other.

Select LOW (low preheating stage) for normal use, maintaining an acceptable waiting time.

Select **OFF** (preheating <u>switched off</u>) for non-continuous use. In this case the waiting time will be longer (10-12 minutes starting from the "cold" start condition).

Use the key + / - then confirm by the key J.



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Setting the STAND-

(STAND-BY option of the

ADVANCED menu)

**BY modes** 

The STAND-BY OPERATING MODE (HIGH OR LOW) IS TIMED IN ORDER TO AVOID HIGH POWER CONSUMPTION OF THE HEATER. SO, AFTER <u>30 MINUTES</u> WITH THE UNIT NOT HANDLED, THE HEATER WILL BE DISABLED (EQUIVALENT TO THE MODE STAND-BY OFF). OPERATING ANY CYCLE KEY (STERILIZATION OR TEST KEY), OR SWITCHING OFF/ON THE UNIT VIA THE MAINS SWITCH, THE ORIGINAL STAND-BY MODE (HIGH OR LOW) WILL BE RESTORED.



#### Setting the Drying Options (DRYING OPTions of the

ADVANCED menu)

To allow the effective drying for the different types of load and in all the conditions, the drying modes must be correctly selected. Operates as follows:

1. Select DRYING OPT. and confirm by the key to access the following menu:

$\rightarrow$ L O N G	+ ↑
SHORT	- ↓

Choice **LONG** (long drying, typical in cycles for WRAPPED and POROUS materials) or **SHORT** (short drying, typical in cycles for SOLID, UNWRAPPED and HOLLOW materials).

Use the key + / - then confirm by the key J.

2. Depending on the choice (LONG or SHORT) two different menus are displayed:

a) LONG option



Select **STANDARD** to enable, for WRAPPED and POROUS cycles, a fixed time drying.

WITH HEAVY LOADS OR PECULIAR MATERIALS THE **STANDARD** OPTION MIGHT SOMETIMES NOT GUARANTEE A PERFECT RESULT. IN THIS CASE EXTEND THE DRYING PHASE BY USING **THE EXTRA** MODE.

Select **INTELLIGENT** to enable an automatic drying characterized with a duration (higher or lower the standard one) depending on the load volume, quantity and typology.

WITH COMPLEX LOAD (E.G. WRAPPED INSTRUMENTS IN STERILIZATION "CONTAINER") THE "INTELLIGENT" OPTION MIGHT NOT CORRECTLY OPERATE, WITH RESULTS LOWER THE EXPECTATION. IN THIS CASE USE THE **STANDARD OR EXTRA** OPTIONS AS NECESSARY.

Select **EXTRA** option for extending the drying phase of a selectable time period (e.g. for particularly difficult load).

Enabling this option, the following choice will be prompted:

EXTRA:XX	min	+ ↑
,J=OK  Î=ES	С	- ↓

where the duration of the extra drying can be set in the range of 1 ÷ 15 minutes.

b) SHORT option

$\rightarrow$ S T A	NDARD	+ ↑
FAS	Т	- ↓

Select STANDARD to enable, for SOLID and HOLLOW cycles, a fixed-time drying.

Select **FAST** to minimize the drying time, forgoing however a perfect removal of the residual humidity.

Scroll the options through the key + / - then confirm by the key J.

#### 6 - SETTING THE EQUIPMENT



## Setting the Printer Options

(PRINT OPTions of the ADVANCED menu)

If the sterilizer is connected to a printer for the recording of the sterilization data, set the necessary parameters in order to guarantee the correct operation.

Proceed as follows:

1. By selecting the item **PRINT OPT.** and confirming it by the key , appear the following menu:

$\rightarrow$ P R I N T E R	+ ↑
REPORT	- ↓

The item **PRINTER** opens a next menu for selecting the line feed mode accordingly with the printer used, whereas the item **REPORT** is used to set the number of the printouts and to enable the reprint of the last performed program.

```
a) PRINTER menu
```

By selecting the item **PRINTER** the following screen is proposed:

 $\begin{array}{c} \rightarrow C R & + \uparrow \\ C R + L F & - \downarrow \\ O F F \end{array}$ 

Choice **CR** if you are using printers that carry out the form feed through a CR command (*Carriage Return*), choice **CR+LF** for printers needing a CR+LF command (*Carriage Return* + *Line Feed*) or **OFF** to disable the data printout.

LOOK UP IN THE PRINTER MANUAL FOR FINDING THE COMMANDS USED (CR OR CR+LF). IF THIS INFORMATION ARE NOT AVAILABLE, CARRY OUT A TEST PRINTOUT WITH BOTH THE OPTIONS TO INDIVIDUALIZE THE CORRECT OPERATING SETTING.

#### b) <u>REPORT</u> menu

By selecting REPORT the following choice is proposed:

→	Ν	R	. со	PIES	+ ↑
	Ρ	R	ΙΝΤ	LAST	- ↓

Select **NR. COPIES** to set the number of the printout copies of the data at the end of the sterilization process (if the printer is connected).

Appears the following screen:

C O P I E S : X	+ ↑
<b>⊣ = О К                                 </b>	- ↓

Use the key + / - to set the desired number of copies (maximum 5). Confirm through the key  $\downarrow$ .

The item **PRINT LAST** allows to reprint the report of the last performed cycle (both correctly terminated or interrupted due to an alarm). The following choice is proposed:

→ N O R M A L	+ ↑
EXTENDED	- ↓

The option **NORMAL** enables a normal printout (that is the reduced one, with the meaningful data of the cycle, and outputted at the end of a cycle correctly performed), whereas the item **EXTENDED** enables the complete printout (that is a report containing all the data, typical for a cycle interrupted by an alarm).



IF THE LAST CYCLE HAS BEEN CORRECTLY COMPLETED (OR INTERRUPTED THROUGH A MA-NUAL STOP) THE REPRINT IN NORMAL OR EXTENDED MODE CAN BE PERFORMED. IF THE LAST CYCLE HAS BEEN INTERRUPTED DUE TO AN OCCURRED ALARM (EXCLUDED A MANUAL STOP) ONLY THE **EXTENDED** MODE WILL BE AVAILABLE.



By entering the reprint command, the display will show the following message:

	Ν	0	N	1	Ρ	R	I	Ν	т	I	Ν	G
I	Ρ	L	Е	Α	S	Е		W	Α	I	Т	

that will remain on until the end of the print.

Use the key + / - to move through the menu and confirm by the key ...

Extrema Plus allows to perform both manually and automatically the topping up of the internal distilled water reservoir; in automatic mode the water will be drawn from an external tank properly connected to the equipment (see **Chapter "Installation"**).

As selected the option FILLING the following choice is proposed:

→	Α	U	Т	0	Μ	Α	Т	I	С	+ 1
	М	Α	Ν	U	Α	L				- ↓

Select the item **AUTOMATIC** to enable the automatic filling. In this operation mode, as the minimum water level of the internal reservoir is reached (red Led MIN turns on), the system will provide to supply the reservoir with water for a preset time. However, if the maximum level is reached (green Led MAX turns on) before the expiration

of the preset time the automatic filling will be disabled in advance.

Activate the automatic filling option only <u>AFTER</u> the external tank has been filled with high quality <u>Distilled Water</u>. Please also remember to <u>OPEN the tap</u> put on the tank.

In **MANUAL** mode the topping up have to be made manually.

Use the key + / - to move through the option and confirm by the key J.

# Acquisition of the environment pressure

(SET 0 bar option of the SPECIAL menu)

At the first set-up and after each new installation of the sterilizer, the user must activate the acquisition of the environment pressure value. This operation **is necessary** for the correct operation of the internal auxiliary systems of the equipment.

By selecting the option SET 0 bar the following screen will show:

SET	VALUE ?	
,	<b>↑ = E S C</b>	

VERIFY THAT THE DOOR OF THE STERILIZER IS COMPLETELY OPEN. ON THE CONTRARY, IF YOU ATTEMPT TO PERFORM THE PRESSURE ACQUISITION WITH THE DOOR CLOSED, THE FOLLOWING MESSAGE WILL BE PRODUCED AND MAINTAINED UNTIL THE DOOR IS NOT OPEN:

ОР	Е	Ν	Т	н	Е		D	0	0	R	
т	0	С	0	Ν	т	I	Ν	U	Е		

Confirm the command by the key I to acquire data. The following message will appear:

сu	RRENT	VALUE
SET	ΙΝΤΟ	MEMORY

followed by an acoustic signal.

To render effective the acquired ambient pressure value it is NECESSARY to EXIT THE SETUP MODE, SWITCH OFF AND THEN ON THE DEVICE BY USING THE MAINS SWITCH.

ADVANCED menu)

Filling mode

Setting the tank

(FILLING option of the

#### 6 - SETTING THE EQUIPMENT





After a few seconds the equipment returns to the **<u>normal operation mode</u>** and in **STAND-BY** state.


PREPARING THE MATERIAL TO BE STERILIZED	The process sterilization can consider effective, reliable and repeatable on condition that the material is first suitably treated and subsequently tidy and correctly arranged into the sterilization chamber.
INTRODUCTION	We notice that the organic residues or deposits of substances used in the medical practice are obviously receptacles of microorganisms and can hamper the contact of the steam with the instrument surfaces, inactivating, at least locally, the lethal process that the sterilization normally guarantees.
	An incorrect arrangement of the load can lead to a difficult and sometimes impossible flowing and/or penetration of the steam on the material, with imaginable consequences. The drying process can strongly be also affected by this factor.
	Therefore we suggest some <b>basic directions</b> concerning this aspects, leaving the user to deepen the problem in the most opportune way.
HANDLING THE MATERIAL BEFORE STERILIZING	<ul> <li>Before everything we remember some precautions that are basic for the handling and moving the contaminated material:</li> <li>Wear rubber gloves of suitable thickness;</li> <li>Wash one's hands, already covered by the gloves, with a germicide detergent;</li> <li>Always use a tray to move the tools;</li> <li>Do never transport them directly picking up by hand;</li> <li>Protect the hands from the contact of possible sharpened or cutting parts in order to avoid the risk of dangerous infections;</li> <li>Immediately separate each item that has not to be sterilized or is not be able to support this process;</li> <li>Wash carefully one's hands covered with the gloves as the handling the not sterile material is over.</li> <li>All the material and/or instruments to be sterilized should be then perfectly cleaned and deprived of whatever kind residues (organic and inorganic deposits, fragments of paper, buffer of cotton or gauze, calcareous residues etc.).</li> <li>Immediately selfer of the CLEANING AND REMOVAL RESIDUE PROCEDURE, BESIDES TO CAUSE PROBLEMS DURING THE STERILIZEN.</li> <li>For an effective cleaning, proceed as follows:</li> <li>Rinse the tools under a throw of running water, immediately after the use;</li> <li>Separate the metallic instruments according to the material type (carbon steel, stainless steel, brass, aluminum, chrome, etc.) in order to avoid electrolyte oxidation;</li> <li>Wash by using an ultrasonic equipment with a mixture of water and germicidal solution, taking care to follow the recommendations of the manufacturer.</li> <li>For the best results use a neutral pH detergent specifically studied for the ultrasonic washing.</li> <li>IF POSSIBLE, USE DEJONIZED OR DISTILLED WATER FOR THE RINSING OPERATION IN ORDER TO PREVENT THE FORMATION OF CALCAREOUS STAINS. IF HIGH HARDNESS TAP WATER IS USED FOR THIS OPERATION IN OF CALCAREOUS STAINS. IF HIGH HARDNESS TAP WATER IS USED FOR THIS OPERATION IN OF CALCAREOUS STAINS. IF HIGH HARDNESS TAP WATER IS USED FOR THIS OPERATION IN OF CALCAREOUS STA</li></ul>
	For the <b>handpieces</b> (turbines, contrangles, etc.), integrate what above described with a treatment in special equipment for the internal cleansing and wiping (sometimes including the lubrication operation).

# 7 – PREPARING THE MATERIAL TO BE STERILIZED





At the end of the sterilization program, remember to lubricate the handpieces internal mechanisms by using the special <u>sterile oil</u>. This precaution guarantees that the useful life of the tool <u>doesn't result in any way reduced</u>.

CONSULT THE INDICATIONS SUPPLIED BY THE MANUFACTURER OF THE INSTRUMENT/MATERIAL TO BE STERILIZED BEFORE TREATING IT INTO THE AUTOCLAVE, VERIFYING POSSIBLE INCOMPATIBILITIES. METICULOUSLY FOLLOW THE USE INSTRUCTIONS OF THE CLEANSING OR DISINFECTANT PRODUCTS AND THE OPERATING MANUAL OF THE WASHING AND/OR LUBRICATION AUTOMATIC EQUIPMENT.

As regards the **textile material** (or in general the porous material), as white uniforms, napkins, caps and other, provides for a <u>careful wash</u> and dry before treating it in autoclave.

DON'T USE DETERGENTS WITH HIGH CONTENT OF CHLORINE AND/OR PHOSPHATES. DON'T BLEACH WITH CHLORINE PRODUCTS. SUCH COMPONENTS COULD DAMAGE THE TRAY-HOLDER, TRAYS AND METALLIC TOOLS ARRANGED INTO THE STERILIZATION CHAMBER.

#### ARRANGEMENT OF THE LOAD





To get the better effectiveness of the sterilization process and to preserve the material in time, follow the indications below reported.

#### General notes for the arrangement of the load on the trays.

- Arrange the tools of different metal (stainless steel, moderate steel, aluminum, etc.) on different trays or however well separate between them.
- In case of **not** stainless steel tools, interpose a sterilization paper napkin or muslin cloth between tray and tool, <u>avoiding direct contacts</u> between the two different materials;
- Arrange however the objects sufficiently outdistanced, in order they maintain the layout for the whole sterilization cycle;
- Verify all the tools are sterilized in open position;
- Arrange the <u>cutting tools</u>, (scissors, lancets, etc.) so they cannot come in contact during the sterilization process; if necessary use a <u>cotton cloth</u> or gauze to isolate and protect them;
- Arrange the containers (glasses, cups, test-tubes, etc.) on one side or inverted position, avoiding possible water stagnation;
- Don't overload the trays over the stated limit (see <u>Appendix</u> <u>A</u>). In a lot of situations, this maximum admitted value might be excessive; in this case always use a bit of common sense.
- Don't stack the trays one above the other or put them in direct contact with the walls of the sterilization chamber. Always use the supplied tray-holder.
- To introduce and extract the trays from the sterilization chamber, always use the supplied special tray removal tong.
- To detect the process result, set a sterilization indicator test per each tray: This precaution avoids from processing once again the same load or, for the worse, from using a not sterilized material. If wrapped material has to be treated, set the indicator test inside one of the wraps.







#### Indications for rubber and plastic pipes

- Always rinse with pyrogen-free water before the use; don't dry them;
- Arrange the pipes on the tray so that the extremities are not obstructed neither crushed.
- Don't provoke pleats neither winds, but leave stretched more linearly as possible.

#### Indications for packets and wrappings

- Arrange the wrappings one close to the other, suitably outdistanced and absolutely not piled up, avoiding that they come to contact with the walls of the chamber.
- In case special objects have to be wrapped, always use a suitable porous material (sterilization paper, napkins of muslin, etc.) closing the wrap with autoclave adhesive ribbon.

#### Indications for wrapped material

- Wrap the tools <u>one by one</u> or, if more tools have to be set in the same wrap, verify that they are of the <u>same metal</u>;
- Seal the wrap with autoclave adhesive ribbon or by a thermal sealer.
- Don't use metallic clips, pins or other, as this jeopardizes the maintenance of the sterility;
- Arrange the envelopes in order to avoid the formation of air pockets that potentially could hamper the correct penetration and removal of the steam.
- Turn the envelopes in order to set the plastic part downward (tray side) and the paper part upward. Verify the correctness of this position, reversing it if necessary.
- If possible, arrange the envelopes on the edge by using a proper stand.
- Never pile up the envelopes.



ALWAYS WRAP THE TOOLS IN CASE OF PROLONGED STORE. SEE ALSO THE CHAPTER "PRESERVING THE STERILIZED MATERIAL".

# **8 – SELECTING THE STERILIZATION PROGRAM**



SELECTING THE	The progra	m choice is fundamental for the success of the sterilization process.
STERILIZATION PROGRAM INTRODUCTION	Since ever is very im physical ch better steril	y tool or material has conformation, consistence and different characteristics, it portant to <b>individualize the more suitable program</b> , both to preserve its paracteristics (avoiding or however limiting any alterations) and to guarantee the lization effectiveness.
	A آھ	GUIDE FOR SELECTING THE PROPER PROGRAM VERSUS THE LOAD IS SHOWN IN THE PPENDIX <b>B (PROGRAMS)</b> .
ABOUT THE	Switch on t	he equipment as described in the Chapter "First start-up".
SELECTION	The displation displation displation displayed by the dis	y doesn't propose any active pre-selection. The equipment is waiting for the election by the user.
CP+	Operate or program (p	the <b>Program Selection</b> key, pressing it one or more times up to the desired preset program 1, 2, 3 or 4, signaled by the turning on of the relative Led).
	The tempe of the select sterilization	rature (°C), pressure (bar) and time ( $^{\bigcirc}$ ) displays will show the set-point values cted cycle, whereas the LCD display is showing the description of the selected program and the active status of the machine, i.e. STAND-BY.
	CI OI LA	N PRESSING THE SELECTION KEY, THE FIRST PROPOSED STERILIZATION PROGRAM IS THE .ST PERFORMED CYCLE.
	For exampl	le, LCD will show the cycle indication:
		134 c POROUS STANDARD
Ept	The second of the cycle Subsequer	d row of the LCD is showing for about 10 seconds the currently set drying mode e. htly, LCD changes to show the operating status of the unit:
		134c POROUS STAND-BY
	To cancel t	his selection press shortly the ESC key ( $f 1$ ) on the command panel.
	Г. Т. W тн (S	HEN YOU ARE SELECTING THE CUSTOM CYCLE, THE LCD WILL SHOW, IN ADDITION TO HE DRYING MODE AS ABOVE, THE INITIAL VACUUM MODE, FRACTIONATED (F) OR SINGLE ):
		134 c CUSTOM F EXTRA (+05)
	T⊦ st	HE SECOND ROW, AFTER ABOUT TEN SECONDS, CHANGES TO SHOW THE OPERATING ATUS OF THE UNIT:
		134 c CUSTOM F STAND-BY
	IF TH TH	NONE SELECTION IS ENTERED THE EQUIPMENT CANNOT START ANYWAY. BY PUSHING ON IE START KEY WITHOUT HAVING SELECTED A PROGRAM, THE LCD DISPLAY WILL SHOW IE FOLLOWING MESSAGE ACCOMPANIED BY AN ACOUSTIC SIGNAL:
		SELECT PROGRAM, PLEASE
	Co FL	DNTEMPORARILY, <u>ALL</u> LED'S RELATING THE STERILIZATION AND TEST PROGRAMS WILL ASH.
		HE USE OF <u>IMPROPER</u> PROGRAM FOR THE TYPE OF MATERIAL TO BE STERILIZED (SEE PPENDIX B) DOESN'T GUARANTEE THE EFFECTIVENESS OF THE STERILIZATION ROCESS.



## 9 – RUNNING THE STERILIZATION PROGRAM

## RUNNING THE STERILIZATION PROGRAM

GENERAL

The sterilization program runs along a cycle characterized by a lot of phases.

The number and the duration of the phases can differ between the programs depending on the air exhausting, sterilization process and drying modes.

The electronic control system monitors the running of the different phases, verifying at the same time if the parameters are correctly respected; if whatever type of anomaly is detected during the cycle, the program will immediately be interrupted and enter in alarm status identified by code and proper message showing the nature of the problem.

With this type of control, the perfect sterilization in every condition will be guaranteed whatever is the sterilization program selected.

STARTING THE STERILIZATION PROGRAM



Now that the load is arranged into the sterilization chamber (with the precautions described on the **Chapter** "**Preparing the material to be sterilized**" and the desired program selected, **close** in right way the door.

The Door Status Led **•** T <u>is flashing</u> (door <u>closed</u>).

Push on the key **START**. The door-locking mechanism is engaged.

The Door Status Led **e** T changes to **ON state** (door <u>locked</u>).

After the START command and for all the sterilization cycle the displays will show the following values:

- Temperature Display (°C): temperature of the sterilization chamber (°C)
- Pressure Display (bar): pressure of the sterilization chamber (bar)
- Timer Display ( <sup>(1)</sup>):
  - ay ( <sup>O</sup>): running time of the sterilization cycle (mm:ss)

The signaling led **e**of the selected program **flashes** for all the cycle.

THE COUNTING OF THE TIME STARTS FROM THE START COMMAND (FIRST VACUUM PHASE), EXCLUDING THE PREHEATING PHASE.

#### SEQUENCE OF PROCESS

As example, we will use the most complete and meaningful cycle, i.e. the cycle relating the

It follows the description of the sterilization cycle, phase by phase.

#### **Preheating**

As entered the START command, the first phase is represented by the preheating phase (**WARMUP**) in order to set the heating resistors on the preset condition foreseen for the start of the cycle.

program 134°C POROUS (preset 1 on the command panel), provided with fractionated

The LCD display is showing:

pre-vacuum.

The process signaling  $\bullet \bigcirc$  is off.

# 9 - RUNNING THE STERILIZATION PROGRAM



First vacuum phase	Reached the stated heating conditions, starts the first vacuum phase (1 VACUUM PULSE) that reduce the pressure into the chamber at the preset value. The following message appears on the screen:
	134c POROUS 1 VACUUM PULSE
	The process signaling
First pressure raising	Reached the preset vacuum value, the steam enters into the chamber and the pressure increases ( <b>1 PRESSURE PULSE</b> ) up to reach the preset value. LCD display shows:
	134 c POROUS 1 PRESSURE PULSE
	The process signaling
Second vacuum phase	At the end of the pressure phase the steam is discharged and starts the second vacuum phase of the sterilization chamber ( <b>2 VACUUM PULSE</b> ). LDC display shows
	134 c POROUS 2 VACUUM PULSE
	The process signaling • remains turned off.
Second pressure raising	The second vacuum phase is followed by a new steam enter into the sterilization chamber, and consequently the pressure raises once again ( <b>2 PRESSURE PULSE</b> ). LCD display shows:
	134 c POROUS 2 PRESSURE PULSE
	The process signaling • remains turned off.
Third vacuum phase	Follows a new discharge of the steam and the start of a third vacuum phase ( <b>3 VACUUM PULSE</b> ). LCD display shows
	134 c POROUS 3 VACUUM PULSE
	The process signaling • remains turned off.
Third pressure raising	This vacuum phase is followed by a last steam enter into the sterilization chamber, and the pressure increases once again ( <b>3 PRESSURE PULSE</b> ) up to the value preset for the sterilization process. On the LCD display appears:
	134 c POROUS 3 PRESSURE PULSE
	The process signaling  remains turned off.



# 9 – RUNNING THE STERILIZATION PROGRAM

<u>Thermodynamic</u> equilibration	On reaching the pressure and temperature values for the selected program, the program waits few seconds to allow the homogenization of the temperature inside the chamber and load (EQUILIBRATION). LCD display is now showing:
	134 c POROUS EQUILIBRATION
	The process signaling • remains turned off.
Sterilization process	On the stabilization of the thermodynamic parameters begins the real sterilization phase of the material ( <b>PROCESS</b> ). Thanks to the continuous monitor of the thermodynamic parameters and the complex management of the hydraulic circuit, the pressure and temperature are maintained constant within the range stated by the program.
	The countdown of the sterilization time starts and the time value is displayed on LCD with the following screen:
	134 c POROUS PROCESS 04:00
	Now the process signaling $\bullet$ $\bigcirc$ <u>is flashing</u> to signal that the sterilization process is in progress.
	As the PROCESS phase is over, the process signaling Led Ochanges to ON steady state to indicate the completion of the sterilization.
	IF, FOR WHATEVER REASON, THE STERILIZATION CYCLE IS INTERRUPTED <u>BEFORE</u> THE COMPLETION OF THE PROCESS PHASE, THE SIGNALING REMAINS <u>FLASHING</u> . IN THIS CASE THE MATERIAL INTO THE STERILIZATION CHAMBER CANNOT BE ANYWAY CONSIDERED STERILE AND MUST NOT ABSOLUTELY BE USED.
<u>Steam discharge</u>	After the sterilization phase follows the steam exhausting from the sterilization chamber ( <b>DEPRESSURIZATION</b> ). The following screen appears:
	134 c POROUS DEPRESSURIZATION
	The process signaling • remains <b>ON</b> .
<u>Vacuum drying</u>	The natural depressurization is followed by a steam forced removal through the vacuum pump action ( <b>VACUUM DRYING</b> ) that generates into the chamber an internal negative pressure to facilitate the steam exhausting. Now the LCD display will show:
	134c POROUS VACUUM DRYING
	The process signaling

# 9 - RUNNING THE STERILIZATION PROGRAM



The vacuum drying phase is then followed by the ventilation phase (VENTILATION) during Ventilation which, on maintaining the vacuum into the chamber, sterile and fresh air is entered to eliminate the condensation and cool the load. On the LCD display appears: 134c POROUS VENTILATION The process signaling • remains **ON**. Ambient pressure Ended the ventilation phase the chamber will be vented by letting the sterile air enter the levelling chamber (LEVELLING) that will reach the atmospheric pressure value, and allow the door opening to recovery the load. LCD display changes to: POROUS 134 c LEVELLING The process signaling  $\blacksquare$  remains **ON**. **Cycle completed** As the pressure into the sterilization chamber reaches the pre-set safety limits, the door locking mechanism will be released. Consequently the door status signaling  $\blacksquare \overline{\mathbb{N}}$  starts to flash and contemporary an acoustic warning signaling is generated. Now the screen will show: 134 c POROUS CYCLE COMPLETE The process signaling  $\blacksquare \bigcirc$  is still **ON**. Open the door and recover the sterilized material by using the supplied tray removal tong. <u>∏</u> ON OPENING THE DOOR, AND IF A PRINTER IS INSTALLED, A REPORT OF THE STERILIZATION CYCLE WILL BE PRINTOUT. CHECK THIS REPORT, SIGN ON THE PROPER LINE AND FILE IT IN A SURE PLACE. REFER TO THE REPORT EXAMPLES IN APPENDIX B, PROGRAMS. ON OPENING THE DOOR, THE EQUIPMENT GOES IN THE STAND-BY STATE. REPEAT THE PROCEDURES DESCRIBED IN THE CHAPTER "SELECTING THE STERILIZATION PROGRAM" IF A NEW STERILIZATION CYCLE HAS TO BE PERFORMED. COMPLETED THE PROGRAM, AND UNTIL THE DOOR IS NOT OPENED, THE HEATING RESISTORS ARE DISABLED. ACCORDINGLY THE EQUIPMENT, WHATEVER IS THE CURRENT STAND-BY MODE, COOLS DOWN SLOWLY. Now the equipment is ready to perform a new cycle. L F COMPLETED THE PROGRAM, WHENEVER THE DOOR IS NOT OPENED, THE VACUUM PUMP IS PERIODICALLY ACTIVATED TO REMOVE ANY TRACE OF CONDENSATE FROM THE STERILIZATION CHAMBER. ON THE LCD IT APPEARS: ACTIVE SUCTION Î то S T O P PUMP



#### MANUAL INTERRUPTION OF THE PROGRAM









This command is detected by the equipment as an <u>alarm</u>, for the program is not correctly completed.

Accordingly and until the safety conditions are not reached the LCD display is showing:

whereas the timer display ( $\oplus$ ) is showing the error code **E999** and an acoustic signaling sounds.

Reached the safety conditions, the machine activates a <u>special procedure</u> asking for a manual door unlocking by the user:

Ρ	R	Е	S	s	↑	то	U	Ν	L	ο	С	κ	
				т	ΗE	DO	0	R					

Push on the key **1** to release the locking mechanism. The message changes to:

	М	Α	Ν	UAL	<b>S T O P</b>
0	Ρ	Е	Ν	ТНЕ	DOOR

Finally, on opening the door it is asked for resetting the equipment:

MANUA	LSTOP
RESET	SYSTEM

The system **RESET** is performed <u>by holding pressed for 3 seconds and more the key</u> **PROGRAM SELECTION** until a confirmation acoustical signal.

On opening the door, and if a printer is installed, the report of the performed sterilization cycle will be printout, containing the error signaling (**E999**). Check this report, sign and file it in a sure place.

Refer to the report examples in Appendix B, Programs.

After the RESET the equipment enters in STAND-BY state and now will be ready to perform a new program.



FOR THE COMPLETE DESCRIPTION OF THE ALARMS SEE APPENDIX E (ALARM INDICATIONS).



AFTER A MANUAL INTERRUPTION OF THE PROGRAM (MANUAL STOP) ALWAYS VERIFY THE STATE OF THE LED PROCESS BEFORE USING THE TREATED MATERIAL OF THE STERILIZATION CHAMBER.

IF THE SIGNALING IS **STEADY ON** THE LOAD CAN BE CONSIDERED **STERILE** AND CONSEQUENTLY USED. WE RECOMMEND ITS IMMEDIATE USE.

ON THE CONTRARY, IF THE LED IS OFF, THE MATERIAL CONTAINED INTO THE STERILIZATION CHAMBER CANNOT BE CONSIDERED STERILE AND MUST NOT ABSOLUTELY BE USED.

# 9 - RUNNING THE STERILIZATION PROGRAM



RESULT OF THE PROGRAM	After the completion of the cycle we recommend to verify the result of the sterilization If the cycle is over (indication <b>CYCLE COMPLETE</b> ) without interruption caused by whatever alarms, the complete asepsis of the material will be guaranteed.
	A further verification tool is represented by the printout of the sterilization parameters.
PRINTING THE DATA OF THE	It is a good rule, if a printer is connected to the sterilizer, to verify that the data printed on the report issued at the end of the sterilization program have a positive checking.
CYCLE	The print of the meaningful data relating the thermodynamic parameters, pressure and temperature (bar and °C), and time (minutes) of the sterilization cycle, with special care on the sterilization phase, will be automatically performed at the end of every cycle simply by opening the door.
	Check the values on the report and the possible additional information to have further confirmation of the quality of the performed sterilization process.
	Sign on the proper line and file the document for a possible future use. Copies of the document can be eventually used for identifying the load (or parts of it) with sterilization date/hour and details relative to the type of the performed cycle.
	To choice the number of copies refer to the <b>Chapter "Setting up the equipment"</b> .
Ph h	ON REQUEST BY THE OPERATOR IT IS POSSIBLE TO GET THE EXTENDED REPORT OF THE STERILIZATION PROCESS DATA, INCLUDING THE VALUES OF ALL THE SENSORS INSTALLED ON THE EQUIPMENT. TO START THIS PRINTING OPTION HOLD DOWN THE KEY <b>ESC</b> 1 <b>ON THE COMMAND</b> PANEL WHILE OPENING THE DOOR.
	For the details concerning the printing options, refer to the report examples in <b>Appendix B</b> , <b>Programs</b> .



PRESERVING THE STERILIZED	The sterilized material has to adequately be handled and preserved to maintain own sterility in time until its use.
MATERIAL	An improper maintenance can provoke its fast recontamination.
GENERAL	However this provokes an hazardous situation, as the alternative is to use the contaminated material (unconsciously in many cases) with risk for both operator and patient, or to perform a new sterilization process with inevitable waste of time and resources.
	Therefore we retain useful to give some basic advice, letting the operator make further carefully investigations.
HANDLING	By assuming that the sterilizer is arranged in a clean place, without dust and damp, pay attention to the following indications when handling and moving the sterile material:
	<ol> <li>Remove the load from the sterilization chamber by wearing cleaned, or better, sterile <u>gloves and white uniform</u>. For greater precaution put a protective mask on the face;</li> </ol>
	<ol> <li>Place the trays on a dry table, suitably cleaned and disinfected. Pay attention to <u>outdistance</u> or however <u>separate</u> the sterile material from the area of the contaminated material to be sterilized;</li> </ol>
	3. Touch the material and/or the tools as less is possible, paying very much attention <u>do</u> <u>not lacerate or damage the wraps;</u>
	4. Let the tools cool before transporting (and storing). If necessary, use dry, clean and disinfected containers to move the material. The containers must be closed or, if open type, covered with clean cloths.
STORING	The sterile material, on waiting for the use, must be stored by taking opportune measures in order to slow as possible the contamination process:
	<ol> <li>Preserve the material and/or tools inside the protective wraps used for the sterilization. <u>Don't wrap</u> the tools after the sterilization as such practice, besides to be useless, is completely without meaning;</li> </ol>
	<ol> <li>Store the material in a <u>dry place</u>, suitably <u>clean and disinfected</u>, away from areas where the infected material transits. If possible, prefer the closed areas provided with ultraviolet illumination;</li> </ol>
	3. <u>Identify</u> the sterile material by affixing the sterilization date (use a copy of the printed report or an adhesive labels);
	4. In the first place use the material stored for longer time (by using a FIFO criteria, "first in first out"). This allows to have <u>homogeneously stored</u> material, avoiding too long storing periods with consequent risks.
	5. <u>Don't store</u> for long time the material. Do not neglect that, even if the above indications have been followed, the material tends however to degrade, with a new contamination within a certain time.
	CF CHECK ON THE SPECIFICATIONS SUPPLIED BY THE MANUFACTURER OF THE PACKING MATERIAL FOR THE MAXIMUM STORING TIME ADMITTED.

## **11 – TEST PROGRAMS**



## TEST PROGRAMS

**OVERVIEW** 

For protecting both operator and patient safety, the functionality and effectiveness of an important process as the sterilization of medical devices must be periodically verified.

For this reason, **Extrema Plus** offers the possibility to perform in simple and automatic way two different test programs:

- Helix Test (HT)
- Vacuum Test (VT)

**Helix Test** (HT) allows to perform a cycle at  $134^{\circ}$ C characterized by a special time of the sterilization phase (3.5 min.); the cycle is provided with fractionated vacuum like the POROUS and HOLLOW programs.

Through a proper device it is possible to value the correct penetration of the steam inside the porous loads (see next paragraph).

Such cycle is also proper to measure the penetration of the steam inside the porous loads (standard **Bowie & Dicks** test packet).

**Vacuum Test** (VT) allows to verify the perfect watertight of the hydraulic circuit of the sterilizer.

By measuring the vacuum offset within a stated time and comparing it with preset limit values, it is possible to determine the quality of the sterilization chamber and connecting pipelines watertight.

#### HELIX TEST (HT)



For selecting the HT program press one or two times the **TEST SELECTION** key until the relative signaling turns on. LCD display visualizes:

HELIX TEST STAND-BY

-	Temperature display (°C) shows the nominal value:	134
_	Pressure display ( <b>bar</b> ) shows the nominal value:	2,10

Timer display (<sup>(b)</sup>) shows the foreseen time of the process:
 **3.30** (mm:ss)

The test device is a PTFE pipe, long 1.5 m and of internal diameter of 2 mm, with a small watertight screw capsule mounted on one end containing an opportune chemical indicator. The other end of the pipe is free to allow the penetration of the steam.

For performing the test, insert the chemical indicator, consisting of a paper strip with a special reacting inch, inside the capsule of the device (that must be always perfectly dried). Close the capsule in such a way no leakage through the gasket is possible.

The device and the chemical indicators for the Helix Test (HT) are not supplied with the equipment. For more information contact "Assistenza Clienti" M.O.COM. (see Appendix Z)

Set the device on the middle tray of the equipment, approximately in the center. **Don't introduce** other material inside the chamber.

Close the door and start the program through the key **START**. The program Led (**HT**) will flash for all through the program.



ALL THE INDICATIONS DISPLAYED DURING THE CYCLE ARE THE SAME AS DESCRIBED ON THE CHAPTER "RUNNING A STERILIZATION PROGRAM".

At the end of the program, recovery the test device from the sterilization chamber, open the capsule and remove the indicator from its place.



If the steam is correctly penetrated, the ink color on the whole length of the strip will be completely turned compared to the start conditions; on the contrary (insufficient penetration) the change will be only partial or missing.

NORMALLY THE TURNING OCCURS FROM A CLEAR COLOR (BEIGE, YELLOW, ETC.) TOWARD A DARK COLOR (BLUE, VIOLET OR BLACK). IN EVERY CASE, METICULOUSLY FOLLOW THE INSTRUCTIONS SUPPLIED BY THE MANUFACTURER ABOUT THE WAY FOR USING AND INTERPRETING THE INDICATOR DEVICE.

The time of the test is about 22 minutes.

If a printer is installed, on opening the door at the end of the program a report of the performed test will be released, including the main data. Affix the chemical indicator in the foreseen area, sign the document and file it.

For more details about the printing reports, refer to the examples in Appendix B, Programs.

VACUUM TEST (VT)



For selecting the VT program press one or more times the SELECTION TEST key until relative signaling turns on. LCD display visualizes:



--.-

- Temperature display (°C) shows:
- Pressure display (**bar**) shows the value of the maximum vacuum reached with the sterilization cycle: -0.90
- Timer display ( <sup>(L)</sup> ) shows: 00.00

The Vacuum Test (VT) program must be carried out with the <u>sterilization chamber</u> <u>unloaded and with trays and tray-holder only</u>.

- CARRY OUT THE VACUUM TEST <u>AS FIRST CYCLE</u> AT THE SWITCHING ON OF THE EQUIPMENT.
- IN ORDER TO AVOID THAT THE HEATING EFFECT <u>INFLUENCES</u> THE VACUUM CHANGE VALUE READ DURING THE VACUUM TEST, THE SYSTEM IS PROGRAMMED TO DISABLE THE TEST IF THE CHAMBER TEMPERATURE SENSOR IS READING A VALUE HIGHER THAN 50° C.

If you are trying to launch the test program with chamber temperature higher than the above preset value, LCD will show the following:



After a few seconds, the unit will automatically return in STAND-BY mode, and will be ready for a new command.

To quickly fall the chamber temperature and allow the Vacuum Test, <u>left open the door</u> until a lower temperature is reached.

Close the door and launch the program through the **START** key. The program Led (VT) will flash for all through the program.

The vacuum phase immediately starts and the LCD display will show:



### **11 – TEST PROGRAMS**



The Temperature display (°C) will visualize ---- -, while the Pressure (bar) and Timer ( $\oplus$ ) displays will show respectively the real-time updated value of the pressure and the total time from the start of the cycle.

As soon as the preset pressure value (-0.90 bar) is reached the vacuum pump is arrested and the pressure stabilization phase (WAITING) activated for 5 minutes LCD display is showing the following message:

VACI	JUM	ТЕЅТ
WAITI	NG	05:00

During this phase an <u>offset of only 10%</u> of the vacuum maximum value is admitted without bearing a test failure. The time is counted down up to the completion of the phase.

Expired this time the effective pressure detection phase (LEAKAGE) starts with a duration of <u>10 minutes</u>.

The LCD display will show:

VACUUM	TEST
LEAKAGE	10:00

During this phase an offset of only  $\pm 0.02$  bar of the start value is admitted. Higher variations lead to the test failure.

The time is counted down up to the completion of the phase.

Expired this time the pressure is returned to the atmospheric value and the LCD display will show:

VACUUM TEST PASSED

An acoustic signaling points out the end of the program.

IF THE PROGRAM IS INTERRUPTED FOR A PRESSURE OFFSETS EXCEEDING THE PRE-SET LIMITS, AN ALARM MESSAGE WILL BE PRODUCED. FOR THE DESCRIPTION OF THE ALARMS SEE APPENDIX E, SOLUTION OF THE PROBLEMS.

The test lasts for about 18 minutes.

If a printer is installed, on opening the door at the end of the program a report of the performed test will be released, including the main data.

For more details about the printing reports, refer to the examples in **Appendix B**, **Programs**.



# **APPENDIX A – TECHNICAL CHARACTERISTICS**

#### **OVERVIEW TABLE**

Equipment	Steam sterilizer	
Model	Extrema Plus	
Туре	B (according to prEN 13060)	
Manufacturer	M.O.COM Via delle Azalee, 1 - 20090 Bl	I. <b>S.r.I.</b> UCCINASCO (MI) - ITALY
Power supply	220/230 V (other voltages on request)	
Mains frequency	50 Hz	
Mains fuses (6,3 x 32 mm)	F 16A 250V	
Power supply board fuses (5 x 20 mm)	F1: T 3,15A 250V (on loads 230V)         F2: T 2A 250V (on primary winding         F3: T 2A 250V (on winding +5V of t         F4: T 2A 250V (on winding +8V of t         F5: T 1A 250V (on winding ±12V of         F6: T 6,3A 250V (on loads 24V)	230V of the mains transformer) the mains transformer) the mains transformer) the mains transformer)
External dimensions (LxDxH)	445 x 425 x 388 mm (rear connections	excluded)
Nominal power	2800 W	
Insulation class	Class I	
Installation category	Cat. II	
Utilization	Internal use	
Environmental operating conditions	Temperature: Relative humidity: Height:	+15°C ÷ +35°C 80% (max) without condensation 3000 m above see-level.
Net weight	about <b>55</b> kg	
Sterilization chamber dimensions (Ø x D)	<b>241</b> x <b>350</b> mm	
Total volume of the sterilization chamber	<b>17 l</b> (0.017 m <sup>3</sup> )	
Utilization volume of the chamber	<b>10 I</b> (0.010 m <sup>3</sup> ) with tray-holder installe	d
Capacity of the distilled water reservoir	about <b>4,6 I</b> (at level <i>MAX</i> ) about <b>0,8 I</b> (at level <i>MIN</i> )	
Sterilization programs	Available: Preset:	<b>11</b> , (see Appendix B) <b>4</b> , (1 fixed + 3 selectable)
Test programs	Helix Test Vacuum Test	
Total sterilizable mass	Solid/hollow unwrapped material:	<b>6</b> kg
(max)	Solid/hollow wrapped material: Porous material:	3 kg 1 kg
Sterilizable mass <u>per tray</u>	Solid/hollow unwrapped material:	<b>2</b> kg
(max)	Porous material:	1 kg <b>0.5</b> kg
Sterilizable mass <u>per each item</u> ( <b>max</b> )	Solid/hollow unwrapped material: Solid/hollow wrapped material: Porous material:	0,5 kg 0,25 kg 0,125 kg
Pre-heating time (from cold)	about 12 min.	
Parallel interface (printer)	DB-25 pin connector (female)	
Serial interface	DB-9 pin connector (female)	
Bacteriologic filter ( <b>PTFE</b> )	Porosity: Connection:	<b>0,2</b> μm 1/8" <b>NPT</b> male connector

# **APPENDIX A – TECHNICAL CHARACTERISTICS**



## SAFETY DEVICES

Extrema Plus is provided with the followings safety devices; a brief description of their function is given on the following:

- Mains fuses (see the data on the overview table)
   Protection of the whole equipment against possible failures of the heating resistors.
   Action: interruption of the electric power supply.
- Protection fuses on electronic circuits (see the data on the overview table)
   Protection against possible failures of the mains transformer primary circuit and low voltage loads.
   <u>Action</u>: interruption of one or more low voltage circuits.
- Thermal cutouts on the mains transformer windings
   Protection against possible vacuum pomp and mains transformer primary winding overheating.
   Action: temporary interruption (up to the cooling) of the winding.
- Safety valve (2,4 bar)
   Protection against possible sterilization chamber over-pressure.
   <u>Action</u>: release of the steam and restoration of the safety pressure.
- Manually resettable thermostat on steam generator (270°C) Protection for possible steam generator overheating.
   <u>Action</u>: interruption of the steam generator power supply.
- Manually resettable thermostat on chamber heating resistors (200°C)
   Protection for possible overheating of the chamber heating resistors.
   <u>Action</u>: interruption of the power supply of the chamber resistors.
- Safety micro-switch for the door status
   Comparison for the correct closing position of the sterilization chamber door.
   <u>Action</u>: signaling of wrong position of the door.
- Door locking mechanism with bistable electromagnet
   Protection against accidental opening of the door (also in case of black-out).
   <u>Action</u>: impediment of the accidental opening of the door during the program.
- Safety micro-switch on the door locking mechanism
   Comparison for the correct closing position of the locking system.
   <u>Action</u>: signaling of the unsuccessful or incorrect operation of the door locking mechanism.
- Self-leveling hydraulic system
   Hydraulic system for the natural pressure leveling in case of manual cycle interruption, alarm or black-out.
   Action: automatic restoration of the atmospheric pressure inside the sterilization chamber.
- On-board system for the sterilization process evaluation
   Continuous monitor of the sterilization process parameters, fully microprocessor managed.
   Action: immediate interruption of the program (in case of anomaly) and generation of alarms.
- Monitoring of the sterilizer operation
   Real time monitoring of all the meaningful equipment parameters.

   Action: generation of alarm messages (in case of anomaly) with possible interruption of the cycle.



## CHARACTERISTICS OF THE FEEDING WATER

DESCRIPTION	VALUES IN THE DISTILLED WATER	VALUES IN THE CONDENSED
DRY RESIDUE	< 10 mg/l	< 1 mg/l
SILICON MONOXIDE SIO <sub>2</sub>	< 1 mg/l	< 0,1 mg/l
IRON	< 0,2 mg/l	< 0,1 mg/l
CADMIUM	< 0,005 mg/l	< 0,005 mg/l
LEAD	< 0,05 mg/l	< 0,05 mg/l
HEAVY METAL RESIDUES (except iron, cadmium and lead)	< 0,1 mg/l	< 0,1 mg/l
CHORIDES	< 2 mg/l	< 0,1 mg/l
PHOSPHATES	< 0,5 mg/l	< 0,1 mg/l
CONDUCTIVITY AT 20°C	< 15 µs/cm	< 3 µs/cm
VALUE of pH	5 - 7	5 - 7
ASPECT	colorless, transparent, without sediments	colorless, transparent, without sediments
HARDNESS	< 0,02 mmol/l	< 0,02 mmol/l



THE USE OF STEAM GENERATED WATER WITH CONTAMINANTS EXCEEDING THE VALUES INDICATED ON THE ABOVE TABLE CAN NOTABLY SHORTEN THE LIFE OF THE STERILIZER. BESIDES THIS CAN PRODUCE AN INCREASE OF THE OXIDATION ON THE MOST SENSITIVE MATERIALS

AND AN INCREASE OF THE CALCAREOUS RESIDUES ON GENERATOR, CHAMBER, INTERNAL SUPPORTS, TRAYS AND TOOLS.

## **APPENDIX B – PROGRAMS**



## **APPENDIX B - PROGRAMS**

#### INTRODUCTION

The steam sterilization is suggested for nearly all the materials and tools on condition that these are able to support without damages a minimum sterilization temperature of **121°C** (on the contrary other sterilization systems at lower temperature should be used).

The material normally autoclavable into a steam sterilizer is as follows:

- Stainless steel surgical instruments;
- Stainless steel generic tools;
- Carbon steel generic tools;
- Dynamic instruments, motorized by air or gears (turbines, contrangles, ablation tools, etc.);
- Glass articles;
- Mineral basis articles;
- Heat-proof plastic articles;
- Heat-proof rubber articles;
- Heat-proof textile articles;
- Treatment material (gauze, tampons, etc.);
- Other autoclavable generic material.
- DEPENDING ON THE CONFORMATION (SOLID, HOLLOW OR POROUS), PACKING (PAPER/PLASTIC WRAPPING, STERILIZATION PAPER, CONTAINER, MUSLIN ETC.) AND HEAT-PROOF CHARACTERISTIC OF THE MATERIAL, THE CORRECT STERILIZATION PROGRAM MUST BE SELECTED BY REFERRING TO THE TABLE OF THE NEXT PAGE.



## OVERVIEW OF THE AVAILABLE PROGRAMS

	N N	IOMINA /ALUE	NL S	MA	AIN DA PRO	TA OF T GRAM	HE		
PROGRAM NAME	Temperature (°C)	Pressure (bar)	Process time (min)	Pre-vacuum (F = fractionated S = single)	Standard drying (E = extended S = short)	Total cycle time (minutes) (medium load + max. load)	Average H2O consumption (1 / cycle)	AUTOCLAVABLE MATERIAL	NOTES
134c POROUS	134	2,10	4	F	E	28÷ 34	0,50	Porous material Wrapped hollow instruments	Fixed on preset nr. <b>1</b> (not changeable)
134c PRION	134	2,10	18	F	L	42÷48	0,50	Porous material Wrapped hollow instruments	
121c POROUS	121	1,10	20	F	E	42÷ 48	0,45	Porous material Wrapped hollow instruments	
134c HOLLOW	134	2,10	4	F	S	23÷26	0,50	Unwrapped hollow instruments	
121c HOLLOW	121	1,10	20	F	S	37÷40	0,45	Unwrapped hollow instruments	
134c WRAPPED	134	2,10	4	S	E	21÷23	0,30	Wrapped solid instruments	
121c WRAPPED	121	1,08	20	S	E	35÷ 37	0,25	Wrapped solid instruments	
134c SOLID	134	2,10	4	S	S	16÷18	0,30	Unwrapped solid instruments	
121c SOLID	121	1,10	20	S	S	30÷32	0,25	Unwrapped solid instruments	
134c EMERGENCY	134	2,10	3	S	FAST	12÷10 (with dry Off)	0,30	MAX LOAD 0,5 kg Unwrapped solid instruments	
134c CUSTOM	134 or 121	2,10 or 1,10	4 > or 20 >	F/S	L/C	n.d.	n.d.	Material and instruments according to the configured cycle	Cycle duration depending on the setting up

HELIX TEST	134	2,10	3,5	F	С	22	500	Test device (without other load)	
VACUUM TEST	-	-0,90	-	-	-	18	-	Empty chamber	



## DIAGRAMS OF THE STERILIZATION PROGRAMS











## **APPENDIX B – PROGRAMS**





Extrema Plus

mocom







## **APPENDIX B – PROGRAMS**





mocom



## DIAGRAM OF THE TEST PROGRAMS







#### **EXAMPLES OF PRINTING REPORTS**

## Normal program report

Model S/N Counter Selection Temperatu Process tin Stand-by Vacuum Pt Drying CYCLE ST	re ne ulses ART	EXTREMA PLUS 99 XP 0000 0007/0015 134 c SOLID 134 c 2.10 bar 4 min LOW SINGLE FAST 23/06/99 12:14 C bar		
		070.4		
00:01 02:02 05:48 06:02 07:02 08:02 09:02 10:02 10:03 10:37 11:41 12:08 13:12	SE DS SPD DE CE	079.4 093.7 135.6 135.9 135.6 135.5 135.5 135.5 135.5 104.1 047.5 047.6 084.6	$\begin{array}{c} +0.00 \\ -0.89 \\ +2.15 \\ +2.17 \\ +2.14 \\ +2.14 \\ +2.14 \\ +2.15 \\ +2.15 \\ +0.00 \\ -0.90 \\ -0.84 \\ -0.04 \end{array}$	
06:02 09:59	MAX MIN	136.0 135.4		
Drying Puls CYCLE EN	ses ID	01 23/06/99 12:27		
STERILIZA	TION:	POSITIVE		
	OPERATO	R		
Model		EVTDEMA		
S/N Counter Selection Temperatu Process tin Stand-by Vacuum Pu Drying	1 re ne ulses	99 XP 0000 0007/0015 34c PORO 134 C 2.10 bar 4 min HIGH FRACTION STANDAR	US IATED	
S/N Counter Selection Temperatu Pressure Process tin Stand-by Vacuum Pu Drying CYCLE ST	1 re ulses ART	99 XP 0000 0007/0015 34c PORO 134 C 2.10 bar 4 min HIGH FRACTION STANDAR 25/06/99 09:52	US IATED	
S/N Counter Selection Temperatu Pressure Process tin Stand-by Vacuum Pu Drying CYCLE ST Time	1 re ulses ART	25/06/99 25/06/99 29 XP 0000 0007/0015 34c PORO 134 C 2.10 bar 4 min HIGH FRACTION STANDAR 25/06/99 09:52 C	US IATED D bar	
S/N Counter Selection Temperatu Process tin Stand-by Vacuum Pt Drying CYCLE ST Time 00:01 01:57 04:53 06:00 07:15 08:22 11:04 11:18 12:18 12:18 12:18 12:18 12:18 15:19 15:53 16:57 22:55 Z4:55 5:BB	1 re ne ulses ART CS 1PV 1PP 2PV 2PV 2PV 2PV 2PV 2PV 2PV 2PV 2PV 2	Def Nelling 34c PORO 134 C 2.10 bar 4 min HIGH FRACTION STANDAR 25/06/99 09:52 C 075.1 047.S 120.5 061.1 135.5 135.4 135.5 135.5 135.4 135.5	bar 	
S/N Counter Selection Temperatu Process tin Stand-by Vacuum Pt Drying CYCLE ST Time 00:01 01:57 04:53 06:00 07:15 08:22 11:04 11:18 12:18 13:18 13:18 14:18 15:53 16:57 22:55 5:BB 11:20 15:11	1 re ne JISES ART CS 1PV 1PP 2PV 2PV 2PV 2PV 2PV 2PV 2PV 2PV SS SS SS SS SS SS SS SS MAX MIN	Def Nelling 34c PORO 134 C 2.10 bar 4 min HIGH FRACTION STANDAR 25/06/99 09:52 C 075.1 047.S 120.5 061.1 120.4 061.1 135.5 135	bar 	
S/N Counter Selection Temperatu Process tin Stand-by Vacuum Pt Drying CYCLE ST Time 00:01 01:57 04:53 06:00 07:15 08:22 11:04 11:18 12:18 13:18 13:18 13:18 13:18 13:18 14:18 15:53 16:57 22:55 24:55 5:8B 11:20 15:11 Drying Puls CYCLE EN	1 re me JISES ART CS 1PV 1PP 2PV 2PP 3PV ET SS SPD ET DS SPD DE CE MAX MIN Ses ID	Def Nelling 34c PORO 134 C 2.10 bar 4 min HIGH FRACTION STANDAR 25/06/99 09:52 C 075.1 047.S 120.5 061.1 120.4 061.1 135.5 135	LUS D US LATED D -0.00 -0.90 +1.00 -0.90 +1.00 -0.90 +2.17 +2.14 +2.15 +2.15 +2.15 +0.90 -0.90 -0.90 -0.90 -0.90 -0.90 +2.17 -2.15 +0.90 -0.90 -0.90 -0.90 -0.90 -0.79 +2.15 -2.15 +0.98 -0.90 -0.90 -0.90 -0.79 +2.15 -2.15 -0.90 -	
S/N Counter Selection Temperatu Process tim Stand-by Vacuum Pt Drying CYCLE ST Time 00:01 01:57 04:53 06:00 07:15 08:22 11:04 11:18 12:18 14:18 15:19 15:53 16:57 22:55 24:55 5:BB 11:20 15:11 Drying Puls CYCLE EN STERILIZA	1 re ne ulses ART CS 1PV 2PV 2PV 2PV 2PV 2PV 2PV 2PV 2PV 2PV 2	Description of the second state of the second	bar 	

#### Extended program report (required by operator)

Model S/N Counte Select Tempe Proces Stand- Vacuu Drying	er ion erature ure ss t ime by m pulse	es	EXT 99 X 0007 1340 2.10 4 mi HIGI FRA STA	REMA P 0000 ~0015 C PORC Bar n H CTION NDARI	PLUS DUS ATED	
CYCL	E STAF	RT	25/0 09:5	6/99 2		
Time		T1	Р	T2	Т3	T4
00:01 00:11 00:21 00:35 00:51 01:01 01: 11 01:21 01:27 01:57	CS 2F 2F E2 E3 4F 4F E4 1PV	075.1 074.9 074.4 074.3 074.3 074.9 074.9 058.5 051.3 047.8 047.8	-0.00 -0.28 -0.46 -0.57 -0.59 -0.62 -0.73 -0.82 -0.83 -0.89 -0.90	130.9 133.3 146.3 152.6 154.2 152.2 146.6 146.8 148.2 149.3 155.3	115.2 114.2 113.2 112.2 111.9 110.4 109.6 108.9 108.2 107.7 105.8	093.4 094.0 094.5 095.0 095.2 095.6 095.7 095.7 095.7 095.7
02:07 02:17	6F 6F	076.5 081.1	-0.57 -0.49	149.9 142.1	105.2 104.6	095.1 094.6
08:15 08:22	9F3 3PV	068.4 061.1	-0.76 -0.79	151.8 153.6	104.7 104.5	102.3 101.7
08:32 08:42	10F 10F	097.4 104.6	+0.01 +0.24	154.7 148.9	104.0 103.7	100.8 101.0
11:04	ET	135.5	+2.15	143.3	111.7	131.7
11:18 11:28	SS 11F	135.9 135.3	+2.17 +2.16	148.5 153.6	113.5 115.9	132.6 133.0
15:19	SE	135.5	+2.15	157.4	126.5	132.5
15:34 15:49 15:53	12F 12F DS	134.4 108.3 104.4	+1.07 +0.25 +0.00	157.0 156.4 156.1	126.8 126.8 126.6	131.2 119.9 116.2
16:04 16:19 16:34 16:49 16:57	12F 12F 12F 12F SPD	094.2 069.2 059.2 053.8 048.4	- 0.50 -0.73 -0.81 -0.87 -0.90	155.1 153.7 152.3 151.2 150.9	125.9 124.5 123.4 122.9 122.7	112.4 112.9 113.5 113.6 113.5
17:04 19:31 19:38	13F 13F 13F	047.1 042.3 042.4	-0.80 -0.89 -0.79	151.0 153.3 153.5	122.5 122.0 122.1	113.5 112.2 112.2
22:55	EPD	094.9	-0.90	153.3	121.7	112.3
23:10 23:25	14F 14F	101.4 105.4	-0.67 -0.57	154.0 153.7	121.7 121.5	112.3 112.3
24:55	DE	112.6	-0.47	149.6	119.1	111.2
25:28 25:33	E15 CE	115.2 115.8	-0.10 -0.04	143.0 147.4	118.4 110.1	110.7 110.7
11:20 15:11	MAX MIN	135.9 135.4				
Drying CYCL	pulses E END		05 25/06/9 10:17	99		
STER	ILIZATI	ON:	POSIT	IVE		
REQU	EXTEI	OPER NDED I BY TH	ATOR REPOF IE OPE	RT ERATO	R	

#### **Report following a Manual Stop**

Model S/N Counter Selection Temperature Pressure Process time Stand-by Vacuum Pulses Drying	EXTREMA PLUS 99 XP 0000 0007/0015 134 c POROUS 134 C 2.10 bar 4 min HIGH FRACTIONATED STANDARD			
CYCLE START	24/06/99 11:13			
Time	C bar			
00:01 CS 01:40 1PV 04:40 1PP 05:40 2PV 07:10 2PP 08:20 3PV 11:20 ET 11:39 SS 12:39 13:39 14:39	$\begin{array}{cccc} 077.6 & +0.01 \\ 088.7 & -0.89 \\ 120.6 & +1.00 \\ 062.9 & -0.79 \\ 135.6 & +1.00 \\ 135.5 & -0.79 \\ 135.4 & +2.15 \\ 135.5 & +2.17 \\ 135.5 & +2.14 \\ 104.1 & +2.15 \\ 047.5 & +2.15 \end{array}$			
STERILIZATION:	NEGATIVE			
OPERATO	)R			
ALARM CODE:	E999			
DESCRIPTION	MANUAL STOP			
Report followin	ng a Black-Out			
Note S/N Counter Selection Temperature Pressure Process time Stand-by Vacuum pulses Drying	99 XP 0000 0006/0012 134c CUSTOM 134 C 2.10 bar 07 min HIGH FRACTIONATED FAST			
CYCLE START	24/06/99			
BLACK OUT	15:31 24/06/99 15:45			
STERILISATION	NEGATIVE			
OPERATO	DR			
ALARM CODF <sup>.</sup>	E000			
DESCRIPTION	BLACK-OUT			



## **APPENDIX B – PROGRAMS**

#### Report following an Alarm

Model			EXT	EXTREMA PLUS				
S/N			99 X	99 XP 0000				
Counter			0007	0007~0015				
Selection			134	134c POROUS				
Temperature			134	134 C				
Pressure			2.10	2.10 Bar				
Process t ime			4 mi	4 min				
Stand-by			HIG	HIGH				
Vacuum pulses			FRA	FRACTIONATED				
Drying			STA	STANDARD				
CYCLI	E STAF	RT	26/0 11:3	6/99 0				
Time		T1	Р	T2	Т3	T4		
00:01 00:11 00:21 00:31 00:35 00:51 01:01 01:11 01:21 01:27 01:57	CS 2F 2F 2F E2 4F 4F 4F E4 1PV	075.1 074.9 074.4 074.3 074.3 074.9 074.9 058.5 051.3 047.8 047.8	-0.00 -0.28 -0.46 -0.57 -0.59 -0.62 -0.73 -0.82 -0.83 -0.89 -0.90	130.9 133.3 146.3 152.6 154.2 152.2 146.6 146.8 148.2 149.3 155.3	115.2 114.2 113.2 112.2 111.9 110.4 109.6 108.9 108.2 107.7 105.8	093.4 094.0 094.5 095.0 095.2 095.6 095.7 095.7 095.7 095.7 095.7		
02:07	6F	076.5	-0.57	149.9	105.2	095.1		
02:17	6F	081.1	-0.49	142.1	104.6	094.6		
08:15	9F3	068.4	-0.76	151.8	104.7	102.3		
08:22	3PV	061.1	-0.79	153.6	104.5	101.7		
08:32	10F	097.4	+0.01	154.7	104.0	100.8	(	
08:42	10F	104.6	+0.24	148.9	103.7	101.0		
11:04	ET	135.5	+2.15	143.3	111.7	131.7	I	
11:18	SS	135.9	+2.17	148.5	113.5	132.6		
11:28	11F	135.3	+2.16	153.6	115.9	133.0		
15:19	SE	135.5	+2.15	157.4	126.5	132.5		
15:34	12F	134.4	+1.07	157.0	126.8	131.2		
15:49	12F	108.3	+0.25	156.4	126.8	119.9		
15:53	DS	104.4	+0.00	156.1	126.6	116.2		
STER	LISATI	ON	NEG	GATIVE				

#### HELIX TEST program report

Model P/N Counter Selection Temperatur Pressure Process tin	re	EXTREMA PLUS 99 XP 0000 0011/0019 ELIX TEST 134 C 2.10 bar 3.5 min		
CYCLE ST	ART	25/06/99 16:38		
Time		С	bar	
00:01 02:06 04:35 05:45 07:02 08:15 11:00 11:14 12:14 13:14 14:14 14:45 15:20 16:34 18:21 19:21 20:06	CS 1PV 2PV 2PPV 3PV ET SS SE DS SPD EPD DE CE	076.4 089.3 120.4 062.5 120.2 061.1 135.6 135.6 135.6 135.6 135.5 135.4 111.5 047.8 059.5 075.4 075.4 075.7	$\begin{array}{c} +0.00 \\ -0.89 \\ +0.99 \\ -0.78 \\ +0.97 \\ -0.79 \\ +2.15 \\ +2.17 \\ +2.15 \\ +2.14 \\ +2.15 \\ +2.14 \\ +0.00 \\ -0.89 \\ -0.86 \\ -0.50 \\ -0.04 \end{array}$	
11:13 14:44	MAX MIN	136.0 135.4		
Drying pulses CYCLE END		01 25/06/99 16:38		
HELIX TES Please attach the indic OPERATC		T COMPLE ator hereur	TE nder	

#### VACUUM TEST program report

Model P/N Counter Selection		EXTREMA PLUS 99 XP 0000 0011/0019 VACUUM TEST		
CYCLE S	TART	29/06/99 11:37		
Time		С	bar	
00:00	CS	035.0	+0.02	
01:39	E1F	037.4	-0.90	
6:39	E2F	038.4	-0.90	
16:39	E3F	042.0	-0.90	
17:54	CE	045.5	-0.10	
CYCLE E	ND	29/06/99 11:41		
VACUUM	TEST:	POSITIVE		
	OPERATO	OR		

CAUTION ! PLEASE REFER TO USER MANUAL

A112

PTC SHORTCIRCUIT

ALARM CODE:

DESCRIPTION



## **APPENDIX C - MAINTENANCE**

#### INTRODUCTION

ORDINARY

SCHEDULED MAINTENANCE In order to guarantee a sure and efficient operation for the whole life of the equipment, a regular maintenance by the user as well as the correct use are necessary.

For a better quality of the maintenance, it is necessary to integrate the ordinary controls with periodic check-up by the Service (refer to appendix Z).

In addition, a **<u>periodic validation of the sterilizer</u>**, i.e. the check of the thermodynamic process parameters comparing them to the reference values measured by tools suitably adjusted, is fundamental.

Refer to the paragraph Validation of the sterilizer, in the following of this appendix.

The ordinary maintenance, as described below, consists of easy manual operations and preventive interventions by the use of simple tools.



IN CASE OF REPLACEMENT OF COMPONENTS OR EQUIPMENT PARTS REQUIRE FOR AND/OR USE ONLY ORIGINAL SPARE PARTS.

The following table reports an overview of the maintenance actions and frequency to be performed on the sterilizer in order to maintain it always efficient.

We suggest to shorten the maintenance interval in case of heavy use:

Cleaning of the gasket and parabola.
Cleaning of the external surfaces
Cleaning of the sterilization chamber and accessories
Desinfection of the external surfaces
Lubrication of the door locking mechanism
Maintenance of the safety valve
Cleaning (or replacement) of the draining filter
Sterilization of the bacteriologic filter
Replacement of the bacteriologic filter
Validation of the sterilizer (see proper paragraph)

Always refer to the **following general directions**:

- <u>Do not wash</u> the sterilizer with direct pressurized or rain throw water. Possible water penetrations on electric and electronic components could jeopardize, also irreparably, the operation of the equipment or internal parts;
- <u>Do not use</u> metal cleaning abrasive cloths, metallic brushes (or other abrasive materials) or both solid and liquid products for cleaning the equipment or the sterilization chamber;
- <u>Do not use</u> chemical products or disinfectant substances for cleaning the sterilization chamber. These products could provoke possible damages, sometimes irremediable, to the sterilization chamber;
- <u>Do not let</u> the calcareous or dirty residues accumulate on the sterilization chamber, door and gasket, but provide for their periodic removal. In the course of the time these residues could cause damages to the elements, and jeopardize the operation of the components installed on the hydraulic circuit.



# **APPENDIX C – MAINTENANCE**

	Image: Construction of the sector of the
MAINTENANCE OPERATIONS	With reference to the previous table, the operations concerning the different maintenance actions are here synthetically described.
Cleaning the gasket and parabola	In order to eliminate the calcareous residues, cleanse the chamber and parabola gasket with a clean cotton cloth soaked with bland water and vinegar solution (or analogous products, verifying in advance the content reported on the label). Dry the surfaces and remove every possible residue before using the equipment.
Cleaning the external surfaces	Clean all the external parts by using a clean cotton cloth dampened with water, eventually added with some neutral detergent. Dry the surfaces and remove every possible residue before using the equipment.
Cleaning the sterilization chamber and accessories	Clean sterilization chamber, tray-holder and trays (and all the internal surfaces) with a clean cotton cloth soaked with water, eventually added with a bland neutral detergent. Rinse carefully with distilled water, paying attention do not let any residue remain on the chamber or accessories.
	STERILIZATION CHAMBER. IN CASE OF EVIDENT RESIDUES, IMMEDIATELY VERIFY THE QUALITY OF THE DISTILLED WATER YOU ARE USING (SEE <u>APPENDIX A</u> ., TECHNICAL CHARACTERISTICS <b>)</b> .
Disinfecting the external surfaces	For the desultory disinfection of the external surfaces both methylated spirit and detergents with a minimum percentage of sodium hypochlorite (or equivalent) can be used. For a good maintenance of the equipment periodically perform the cleaning of all the external parts, by using a cloth dampened with normal neutral cleansers or simply with water.
Lubricating the door locking mechanism	Carefully lubricate the mobile parts and articulations of the door locking mechanism using silicone oil or analogous spray product. Pay attention do not sprinkle the lubricant on sterilization chamber, gasket and the inside part of the parabola.
	Do not use grease or others solid products, as they could produce in the course of the time incrustations and consequent jams of the mechanism.

# **APPENDIX C – MAINTENANCE**



# Maintenance of the safety valve



#### Cleaning (or replacement) the draining filter



Access the safety valve on the back side of the sterilizer. Loosen the grained ferrule with the fingers (or with a proper tool inserted in the two holes of the ferrule) and turn counterclockwise until you get the stop and the idle stroke.

Screw the ferrule again.

Repeat the operation at least for a couple of times.

At the end tighten the ferrule definitively.



THIS OPERATION <u>IS NECESSARY</u> TO GUARANTEE THE CORRECT OPERATION OF THE VALVE IN THE COURSE OF THE TIME .

At the end of the maintenance verify that the ferrule is completely tighten and locked.

During the use, the accumulation of residues within the filter could gradually obstruct the lower draining duct.

For cleaning (or replace) the filter, open the door of the sterilizer and remove the nut **1** with a hexagonal wrench n. 14.

Then remove the water stopper **2** and the relative gasket and, by the same wrench, unscrew the fitting **3** for accessing the filter **4**.

Remove the filter from the support and carefully clean it under a throw of running water, using if necessary a pointed tool to remove possible extraneous bodies of greater dimensions.

If the filter cannot be recovered provide for the replacement with a new one. Plug the filter in the support blocking it with a drop of pipe-fitting sealing (if available).

Reassemble all the parts following in opposite order the procedure, paying attention to let the draining holes **5** remain at the level of the chamber wall.

Sterilization of the bacteriological filter

Periodically eliminate the bacterial charge of the bacteriological filter by means of a sterilization process at 121°C for porous material (program 121c POROUS). At the end of the program screw it completely on the support.

THE PROCESS STERILIZATION DOESN'T REMOVE THE OBSTRUCTION OF THE FILTER, NEITHER PROLONGS IN ANY WAY ITS LIFE. THEREFORE PLEASE FOLLOW THE <u>REPLACEMENT</u> <u>INTERVALS</u> AS REPORTED ON THE SCHEDULED MAINTENANCE TABLE.

Replacement of the bacteriological filter

At the expiration of the stated interval or whenever a visible obstruction of the filter is noticed (signaled by a color markedly tending towards the grey) unscrew the bacteriologic filter from the support, replace it with a new one that must be screwed completely on the fitting.



A SPARE BACTERIOLOGICAL FILTER IS SUPPLIED WITH THE EQUIPMENT. TO REQUIRE ADDITIONAL FILTERS REFER TO THE <u>APPENDIX Z</u>, SERVICE.





#### PERIODIC VALIDATION OF THE STERILIZER

As for every equipment, a decadence of the performances and components during the life, depending on the utilization type and frequency, is inevitable.

In order to guarantee a constant process safety it is necessary to verify, at periodic expiration (possibly yearly), the **process thermodynamic parameters** (pressure and temperature), checking if these are remaining within admitted limits or not.

The performance validation of the sterilizer is at care and responsibility of the user.

The reference European standards **EN 554** (*Sterilization of the medical devices - Method for the validation and systematic control of the steam sterilization*) and **EN 556** (*Sterilization of the medical devices – Requirements for the medical devices marked with "STERILE" indication*) supply an effective guide tool for carrying out the verifications on the steam sterilizers.

Since these controls require, besides a specific experience and knowledge, the use of a special tools (high accuracy sensors and probes, data logger, dedicated software, etc.), properly verified and adjusted, it is necessary to address to **companies specialized** in this activity.

"Assistenza Clienti" M.O.COM. (see Appendix Z) is at your disposal to supply every possible information concerning the periodic validation of the sterilizers.



## **APPENDIX D - GENERAL PROBLEMS**

#### **OVERVIEW**

If during the equipment use a problem or an alarm signaling occurs, it is not the case to immediately worry. This could not be caused by a breakdown, but more probably by an abnormal situation, often only transitory (for instance a black-out), or by an incorrect use.

In any case, it is important to individualize beforehand the cause of the anomaly and to carry out the opportune corrective actions autonomously or by calling the Customer Service.

To this purpose, the indications for the diagnosis and resolution of the general problems, as well as an accurate description of the alarm codes, their meaning and the consequent actions for their solution are supplied in the following.

#### ANALYSIS AND RESOLUTION OF THE PROBLEMS

If Your sterilizer doesn't work correctly, please perform the followings verifications before contacting the Customer Service:

PROBLEM	POSSIBLE CAUSE	PROPOSED SOLUTION
The sterilizer doesn't switch on.	The plug of the power supply cable is not correctly plugged in the socket.	Plug in correctly the power supply cable.
	Voltage lack at the output socket.	Verify the cause of the voltage lacking and try to recovery it.
	The mains switch and/or the automatic circuit breaker are in OFF state.	Set the switch in ON position.
	The mains fuses are burned.	Replace the fuses with others of the same type and value.
		(See <u>Appendix A</u> , <b>Technical characteristics</b> ).
After the <b>START</b> command, the sterilization cycle <b>doesn't start</b> .	The equipment is performing the pre-heating phase ( <i>WARMUP</i> ).	Wait for the sterilizer reaches the correct thermal conditions for the start of the sterilization cycle.
		<b>NOTE:</b> Under normal operating conditions, the preheating average time is about 12 minutes.
The <b>red Led MIN</b> turns on.	The distilled water level of the internal reservoir is lower the minimum level.	Topping up the reservoir with distilled water until the lighting of the green Led MAX (or at least the turning off of the red Led MIN).
The <b>red Led Alarm</b> turns on.	An alarm signaling has been generated with a proper code (see <i>TIMER display</i> ) and message (see <i>LCD display</i> ).	Verify the alarm code and operate consequently.
		(See following paragraphs, <i>Alarm signaling</i> , <i>Alarm codes</i> and <i>Troubleshooting</i> ).
The safety valve intervenes.	Anomalous over-pressure inside the chamber.	Verify the correct top ferrule locking of the safety valve.
		<b>NOTE:</b> Let the equipment cool or use gloves to avoid from burning oneself when you are touching the valve.



PROBLEM	POSSIBLE CAUSE	PROPOSED SOLUTION
At the end of the program ( <b>CYCLE</b> <b>COMPLETE</b> ) it is impossible to open the door.	Residual pressure inside the chamber.	Wait for some minutes until the pressure return to the 0.00 bar, and <u>retry</u> to open the door.
	NOTE: LCD displays the message: NOW LEVELLING PLEASE WAIT	verify that the bacteriologic filter is not obstructed and, if necessary, replace it.
		The procedure for storing the environment pressure value (function SET 0 bar) has not been correctly performed. Call for the Customer Service (see <u>Appendix Z</u> ).
	The safety friction of the handle is loosen.	Push on the handle (pay attention to not damage it) against the equipment until to set it in the position parallel with the door. Retry to open the door.
	The door-locking system is remained engaged at the end of the cycle.	After having reset the alarm ( <i>code E021</i> ), verify that the handle is in the correct closing position.
		Call the <b>SETUP</b> program and the <b>DOOR LOCK</b> option in the menu <b>SPECIAL</b> for the manual command of the mechanism. (see <u>Chapter</u> "Setting the equipment").
		<b><u>NOTE</u></b> : In case of unsuccessful, carry out the manual unlocking through the supplied tool. ( <u>see note</u> at the end of this appendix).
Presence of water on the table of the sterilizer.	Fittings or draining pipelines not correctly connected.	Verify the locking of the fittings; if necessary perform the assembly with greater attention to the sealing (see <b>Chapter - Installation</b> )
		Check that the pipelines towards the draining tank are completely fitted; verify that the proper clamps are positioned on the pipes.
	Feeding water pipe coming from the external reservoir not correctly connected.	Verify the locking of the pipe; if necessary perform the assembly with greater attention to the sealing (see <b>Chapter - Installation</b> ).
		Check that the pipelines coming from the external tank is completely fitted; verify that the proper clamp is positioned on the pipe.
	Steam leakage from the gasket.	At the end of the cycle clean with a dampened cloth the gasket and the parabola of the chamber. Check for possible damages on the gasket.
		Carry out a new cycle and verify the condition.
Presence of water around the draining tank.	Draining pipes not correctly connected to the tank.	Check that the pipelines towards the draining tank is completely fitted; verify that the proper clamps are positioned on the pipes.
	Lack of the closing tap of the tank.	Arrange the plastic screw tap on the tank, in order to avoid accidental water escape.
Difficulty for reaching the correct vacuum in the chamber (problems of drying, presence of water in the sterilization chamber at the end of the cycle, etc.).	Sterilization chamber draining filter obstructed.	Provide for the cleaning or replacement of the draining filter.
		(see <u>Appendix C</u> " Maintenance").
	Draining circuit obstructed or draining pipes obstructed.	Verify the draining pipes (and the fittings on which they are fitted) are without obstructions and runs freely from the equipment to the condensation recovery tank.
	Air slots on the sides and/or on the rear obstructed or heat exchanger insufficiently aired.	Remove every possible obstruction from the air slots and from the heat exchanger.
		Verify the equipment is not on direct contact with walls or surfaces (see <b>Chapter</b> " <b>Installation</b> ").

# **APPENDIX D – GENERAL PROBLEMS**



PROBLEM	POSSIBLE CAUSE	PROPOSED SOLUTION
Excessive damp on the material and/or the tools at the end of the program.	Excess of material inside the chamber.	Verify the quantity of sterilized material and make sure do not overcome the maximum admitted quantities, according to the typology of the load.
		(See overview table in <u>Appendix A</u> , " <b>Technical</b> characteristics").
	Load not correctly arranged.	Arrange the load, particularly the wrapped one, according to the indications.
		(See <u>Chapter</u> "Preparing the material to be sterilized ").
	Wrong selection of the sterilization program	Choose the proper sterilization program for the type of material to be sterilized.
		(See <i>Table</i> in <u>Appendix B</u> , " <b>Programs</b> ").
	Obstruction on the sterilization chamber draining filter.	Provide for cleaning or replacing the draining filter.
		(See <u>Appendix C</u> , <i>"Maintenance"</i> ).
Oxidation traces or spots on the tools	Poor quality of the tools.	Check the quality of the tools showing the problem, make sure that the material of the tools is autoclavable.
	Poor quality of the distilled water.	Empty the reservoir and fill it with high quality distilled water (possibly obtained by inverse osmosis).
		(See Characteristics of the feeding water in <u>Appendix</u> <u>A</u> , " <b>Technical characteristics"</b> ).
	Organic or inorganic residues on the tools	Carefully clean the material before the sterilization cycle.
		(See <u>Chapter</u> "Preparing the material to be sterilized ").
	Contact among tools of different metal.	Separate the tools of different metal with proper expedients.
		(See <u>Chapter</u> "Preparing the material to be sterilized ").
	Presence of calcareous residues on the wall of the sterilization chamber and/or accessories.	Perform the cleaning of the equipment and parts as indicated.
		(See <u>Appendix C</u> , <i>"Maintenance"</i> ).
Bluing or blackening of the materials.	Wrong selection of the sterilization program.	Verify the adequacy of the temperature of the sterilization program selected according to the material to be treated.
		(See <i>Table</i> in <u>Appendix B</u> , " <b>Programs"</b> ).
The printer (if installed) doesn't print the report.	Printer not switched on.	Switch on the printer.
	Parallel cable not correctly connected or wrong model.	Verify that the cable used is suitable for the printer and correctly connected.
	Sterilizer not correctly configured for the use of the printer.	Provide for setting the equipment according to the used printer.
		(See <u>Chapter</u> "Setting the equipment").

IF THE PROBLEM PERSISTS, CALL FOR THE CUSTOMER SERVICE (SEE APPENDIX Z) BY COMMUNICATING THE <u>MODEL</u> AND THE <u>SERIES NUMBER OF THE STERILIZER</u>. THESE DATA MAY BE FOUND ON THE MANUFACTURING PLATE ON THE REAR SIDE OF THE EQUIPMENT AND ON THE GUARANTEE CERTIFICATE.





### MANUAL RELEASE OF THE DOOR LOCKING MECHANISM

In case of failure of the door safety lock it is possible to release it manually, through the supplied tool. Operate as follows:

- 1. Move forward the sterilizer, putting it out the support plane of some centimeter in order to access the hole corresponding to the mechanism movement axle;
- 2. Firmly hold the equipment, pay attention do not fall it down avoiding damages or injuries to property and/or people;
- 3. Insert the special supplied tool (Ref. 15 see page 3) into the hole below the frame;
- 4. Screw the tool on threaded shaft of the electromagnet without tightening;
- 5. Pull downward the tool until the mechanism is unlocked;
- 6. Unscrew the tool and remove it;
- 7. Arrange the equipment on the support plane;
- 8. Open the door and recover the load.





# **APPENDIX E - ALARM SIGNALING**

OVERVIEW	Each time an <b>anomalous condition</b> occurs during the sterilizer operation an alarm signaling with a <u>specific code</u> (formed by one letter and three figures) will be generated.		
	The alarm codes are divided in <b>three categories</b> :		
	• E = <u>ERROR</u> Wrong action and/or use, or external equipment cause. Problem generally recoverable by the user. Code format: <u>Exxx</u> (xxx = identification number 000 ÷ 999)		
	• A = <u>ALARM</u> Failure of <u>first level</u> , not concerning the safety. Problem generally recoverable on site by a specialized technician. Code format: Axxx (xxx = identification number 000 ÷ 999)		
	• H = <u>HAZARD</u> Failure of <u>second level</u> , involving the safety. Problem generally recoverable by the Customer Service. Code format: Hxxx (xxx = identification number 000 ÷ 999)		
ALARM PROCEDURE	The intervention of the alarm procedure causes the <b>interruption of the program</b> (or the normal operation), associated with the <b>alarm code</b> displaying, a <b>message</b> on LCD display (see table below), an <b>acoustic signaling</b> and the lighting of the <b>alarm red led</b> (steady or intermittent).		
	DURING THE ALARM PROCEDURE THE TEMPERATURE (°C) AND PRESSURE (BAR) DISPLAYS WILL SHOW <u>ALWAYS</u> THE CURRENT VALUES OF THE STERILIZATION CHAMBER. The alarm procedure is designed in order <u>to avoid</u> the user from any possible <u>confusion</u> between an anomalous cycle and a cycle correctly completed, and consequently from <u>unintentionally using of the not sterile material</u> .		
	The performing of the alarm procedure <u>differs</u> according to whether it occurs during or out the program execution, and is structured for driving the user until the final <u><b>RESET</b></u> of the sterilizer.		
Alarm occurring	If the alarm occurs <u>during the sterilization or test program</u> the LCD will show:		
during the sterilization cycle	Alarmmessage LEVELLING		
	Reached the safety conditions, the equipment enables a <u>special procedure</u> , on the asking the user for manually unlocking the door with the following message:		
	PRESS Î TO UNLOCK THE DOOR		
All	Press the key ft to unlock the door locking mechanism. The following message appears:		
	Alarm message OPEN THE DOOR		
	Opened the door, the user is required to reset the equipment:		
	Alarm message RESET SYSTEM		


or, according to the preset RESET modes:

IF A PRINTER IS INSTALLED, ON OPENING THE DOOR AT THE END OF THE CYCLE THE REPORT (NORMAL OR EXTENDED ACCORDING TO THE TYPE OF THE OCCURRED ALARM) RELATIVE TO THE STERILIZATION PROGRAM JUST PERFORMED, AND INCLUDING THE ERROR SIGNALING WILL BE PRINTED. VERIFY THE PRINTOUT, SIGN IT ON THE SPECIAL SPACE AND FILE IT IN A PROPER PLACE. REFER TO THE PRINTOUT EXAMPLES IN **APPENDIX B "PROGRAMS"**.

If the alarm occurs **out the sterilization or test program** the following message will be shown:

Alarm message ALARM!

or, according to the foreseen RESET modes,

which will automatically change with the message:

Alarm message RESET SYSTEM

THE ALARMS OCCURRED OUT OF THE PROGRAM WILL NOT PRODUCE ANY REPORT.

RESET OF THE SYSTEM

Alarm occurring

cycle

out the sterilization





The RESET of the system can be performed in two alternative ways, according to the type of alarm occurred (see table of the **paragraph** "List of the alarm codes" following this appendix):

- By pressing for about 3 seconds the PROGRAM SELECTION key. An acoustic signal will be generated as RESET confirmation;
- <u>By switching off and on the equipment</u> through the mains switch.
   On turning on the sterilizer the normal initial autotest will be performed.

IF THE EQUIPMENT HAS SWITCHED OFF (MAINS SWITCH IN OFF) BEFORE THE RESET THROUGH THE PROPER KEY WILL CAUSE A FURTHER ALARM (BLACK-OUT, CODE E000) AT THE NEXT SWITCHING ON. IN FACT, THE ALARM PROCEDURE WILL BE CONSIDERED NOT COMPLETED IF MISSED THE CORRECT AND COMPLETE RESTORATION.

After the RESET, and the possible technical service, the equipment will go in STAND-BY status, ready to perform a new program.

IF THE CYCLE INTERRUPTION OCCURS DURING PARTICULAR PHASES, A CLEANING PROCEDURE OF THE HYDRAULIC CIRCUIT WILL START ON THE NEXT CYCLE, WITH THE FOLLOWING MESSAGE ON LCD:

134 c	POROUS
CIRCUIT	CLEANING

Over the cleaning procedure, the sterilization cycle selected will start automatically.



#### LIST OF THE ALARM CODES

The alarm codes, LCD messages and consequent RESET modes are listed in the following.:

CODE	ALARM DESCRIPTION	LCD MESSAGE	RESET MODE		
	ERRORS (category E)				
E000	Black-out	BLACK-OUT			
E010	Door open	DOOR OPEN			
E020	Door unlocked	DOOR UNLOCKED			
E021	Door locked	DOOR LOCKED			
E030	Minimum water level in the filling tank (MIN)	WATER MIN			
E031	Maximum water level in the filling tank (MAX)	EXHAUST MAX			
E041	Too much frequent filling up of the tank ( <i>automatic filling</i> )	FILLING PROBLEM	PROGRAM SELECTION key		
E900	Unsuccessful Vacuum Test ( <i>during the LEAKAGE phase</i> )	TEST FAILED			
E901	Unsuccessful Vacuum Test ( <i>during the WAITING phase</i> )	TEST FAILED			
E902	Unsuccessful Vacuum Test ( <i>timeout vacuum pulses exceeded</i> )	TEST FAILED			
E999	Manual interruption of the cycle	MANUAL STOP			
	ALARMS (ca	tegory A)			
A022	Problem of the door locking mechanism	LOCKING PROBLEM			
A032	Problem of the level probes	LEVEL PROBLEM			
A040	Unsuccessful reservoir filling (automatic filling)	FILLING PROBLEM	1		
A101	Failure of the thermo-resistor PT1 (sterilization chamber)	PTC BROKEN			
A102	Failure of the thermo-resistor PT2 (steam generator)	PTC BROKEN			
A103	Failure of the thermo-resistor PT3 (heating resistor)	PTC BROKEN			
A104	Failure of the thermo-resistor PT4 (on the wall of the sterilization chamber)	PTC BROKEN	Switching off the equipment		
A111	Short-circuit of the thermo-resistor PT1 (sterilization chamber)	PTC SHORTCIRCUIT	(OFF)		
A112	Short-circuit of the thermo-resistor PT2 (steam generator)	PTC SHORTCIRCUIT			
A113	Short-circuit of the thermo-resistor PT3 (heating resistor)	PTC SHORTCIRCUIT			
A114	Short-circuit of the thermo-resistor PT4 (on the wall of the sterilization chamber)	PTC SHORTCIRCUIT	]		
A121	Instability of the thermo-resistor PT1 (sterilization chamber)	PTC FLICKERING	]		
A200	Pre-heating not performed within the timeout (heating resistor problem).	HEATING PROBLEM	]		
A250	1° vacuum pulse not performed within the timeout	PV1 TIMEOUT	PROGRAM SELECTION		
A251	1° raising towards the atmospheric pressure not performed within the timeout	ATM1 TIMEOUT	key		



CODE	ALARM DESCRIPTION	LCD MESSAGE	RESET MODE
A252	1° vacuum pulse not performed within the timeout	PP1 TIMEOUT	
A253	2° vacuum pulse not performed within the timeout	PV2 TIMEOUT	
A254	2° raising towards the atmospheric pressure not performed within the timeout	ATM2 TIMEOUT	
A255	2° vacuum pulse not performed within the timeout	PP2 TIMEOUT	PROGRAM SELECTION
A256	3° vacuum pulse not performed within the timeout	PV3 TIMEOUT	- Key
A257	3° raising towards the atmospheric pressure not performed within the timeout	ATM3 TIMEOUT	
A258	3° vacuum pulse not performed within the timeout	PPP TIMEOUT	
A259	PROCESS phase not started within the timeout	PROCESS TIMEOUT	
	HAZARDS (ca	ategory H)	
H150	Failure of the pressure probe MPX	MPX BROKEN	
H160	Short-circuit/disconnection of the pressure probe MPX	MPX SHORTCIRCUIT	Switching off the equipment (OFF)
H170	Instability of the pressure probe MPX	MPX FLICKERING	
H400	Ratio P <sub>conv</sub> /T unbalanced (P <sub>conv</sub> >T) ( <b>PROCESS</b> phase)	P/T PROBLEM	
H401	Ratio T/P <sub>conv</sub> unbalanced (T>P <sub>conv</sub> ) ( <b>PROCESS</b> phase)	T/P PROBLEM	
H402	Temperature over the MAX limit ( <i>PROCESS phase</i> )	T OVER LIMIT	
H403	Temperature under MIN limit ( <b>PROCESS</b> phase)	T UNDER LIMIT	
H404	Temperature fluctuating over the limit ( <i>PROCESS phase</i> )	PT1 FLUCTUATING	
H405	Pressure over the MAX limit ( <i>PROCESS phase</i> )	P OVER LIMIT	PROGRAM SELECTION key
H406	Pressure under the MIN limit ( <b>PROCESS</b> phase)	P UNDER LIMIT	
H990	Over-pressure (sterilization chamber, MPX)	OVERPRESSURE	
H991	Over-heating (sterilization chamber, PT1)	OVERHEATING PT1	]
H992	Over-heating (steam generator, PT2)	OVERHEATING PT2	
H993	Over-heating (band heating resistor, PT3)	OVERHEATING PT3	



#### ANALYSIS AND RESOLUTION OF THE PROBLEMS

Depending on the occurred alarm type, the indications to find the possible causes and restore the correct operation are listed on the following table:

CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION	
	ERRORS (category E)		
E000	Sudden interruption of the electric power supply ( <b>black-out</b> ).	Wait for the return of the electric power supply and perform the <b>RESET</b> according to the instructions.	
		Verify the <b>correct sterilization</b> of the load before using the treated material.	
	Accidental switching off of the main switch and/or disconnection of the	Reconnect the plug and/or switch on the equipment, and perform the <b>RESET</b> according to the instructions.	
	plug from the a.c. socket.	Verify the <b>correct sterilization</b> of the load before using the treated material.	
	Mains fuses burned.	Replace the fuses of same type and value (see <i>Table in <u>Appendix A</u></i> , " <i>Technical characteristics"</i> ).	
		Switch on the equipment and perform the <b>RESET</b> according to the instructions.	
		Verify the <b>correct sterilization</b> of the load before using the treated material.	
E010	Door open (or <u>not</u> correctly close)	Perform the <b>RESET</b> according to the instructions.	
	on the start of the cycle ( <b>START</b> ).	Correctly close the door and restart the cycle.	
	Failure of the door micro-switch.	Call for the Customer Service (see <u>Appendix Z</u> ).	
E020	Door locking mechanism <u>not</u> correctly activated on the start of the cycle ( <i>START</i> ).	Perform the <b>RESET</b> according to the instructions.	
		<u>Correctly</u> close the door, pushing completely the handle, and try to restart again the program	
	Failure of the door locking mechanism.	Call for the Customer Service (see <u>Appendix Z</u> ).	
E021	Door locking system <u>not</u> released at the end of the cycle ( <b>CYCLE</b> <b>COMPLETE</b> ).	Perform the <b>RESET</b> according to the instructions.	
		Call the <b>SETUP</b> program and select the <b>DOOR LOCK</b> option in the menu <b>SPECIAL</b> in order to operate manually the mechanism. (see <u>Chapter</u> "Setting the equipment").	
		<b><u>NOTE</u></b> : In case of <b>unsuccessful</b> result, manually perform the releasing of the mechanism through the supplied tool.	
	Failure of the door locking mechanism.	Call for the Customer Service (see <u>Appendix Z</u> ).	
E030	Internal reservoir water level under	Perform the <b>RESET</b> according to the instructions.	
	the minimum (MIN).	Provide for filling up the water until the turning on of the Led MAX (or turning off at least of the Led MIN).	
	Failure of the MIN level signaling.	Call for the Customer Service (see <u>Appendix Z</u> ).	
E031	Draining tank water level over the	Perform the <b>RESET</b> according to the instructions.	
		Provide for draining the tank, letting a minimum level of water as marked to remain.	
	Cable of the draining tank level	Perform the <b>RESET</b> according to the instructions.	
	equipment.	Connect the jack of the level signaling cable to the inlet on the back of the sterilizer.	
	Failure of the MAX level signaling.	Call for the Customer Service (see <u>Appendix Z</u> ).	





CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
E041	Connecting pipe between external tank and sterilizer <b><u>not</u></b> correctly connected.	Perform the <b>RESET</b> according to the instructions. Verify the connection of the water filling pipe, tighten both ends on the fitting through the supplied plastic clips. Eliminate possible obstructions on the pipe route.
	Failure of the water pump.	Call for the Customer Service (see <u>Appendix Z</u> ).
	Problem on the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).
E900	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions. Carefully clean the gasket with a clean cloth of cotton dampened with
		water. Restart the program.
	Sterilization chamber too much	Perform the <b>RESET</b> according to the instructions.
	warm.	Carry out the test with the sterilization chamber at moderate temperature (for instance in the morning, at the first switching on of the equipment).
	Problem on the hydraulic circuit.	Call for the Customer Service ( <i>see <u>Appendix Z</u></i> ).
E901	Excess of damp inside the	Perform the <b>RESET</b> according to the instructions.
		Carefully dry the sterilization chamber and restart the program.
	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions.
		Carefully clean the gasket with a clean cloth of cotton dampened with water.
		Restart the program.
	Problem on the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).
E902	Excess of damp in the sterilization	Perform the <b>RESET</b> according to the instructions.
	chamber.	Carefully dry the inside of the sterilization chamber and again restart the program.
	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions. Carefully clean the gasket with a clean cloth of cotton dampened with water. Restart the program.
	Failure of the vacuum pump.	Call for the Customer Service (see <u>Appendix Z</u> ).
	Problem on the hydraulic circuit.	
E999	Manual interruption of the	Perform the <b>RESET</b> according to the instructions.
	sterilization or test program. (see also <u>Chapter</u> "Running the sterilization program")	Verify the <b>correct load sterilization</b> before using the treated material.
		ALARMS (category A)
A022	Door not completely open during the initial automatic self-test.	Open completely the door, verifying the closing hook doesn't prevent the activation of the mechanism.
		Switch off ( <b>RESET</b> ) and switch on again the equipment.
	Failure of the door locking mechanism	Call for the Customer Service (see <u>Appendix Z</u> ).
	Door locking mechanism released	Perform the <b>RESET</b> according to the instructions.
		Call for the Customer Service (see <u>Appendix Z</u> ).
A032	Water level signaling connector not plugged in.	Call for the Customer Service (see <u>Appendix Z</u> ).
	Failure of the level signaling(s)	



CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION	
A040	Lacking of water in the external tank	Perform the <b>RESET</b> according to the instructions.	
	(automatic ming).	Fill the tank with sufficient distilled water, <b>and remember to periodically verify the level</b> .	
	Connecting pipe between the	Perform the <b>RESET</b> according to the instructions.	
	correctly connected.	Verify the connection of the water filling pipe, tighten both ends on the fitting through the supplied plastic clips.	
		Eliminate possible obstructions on the pipe route.	
	Failure of water pump.	Call for the Customer Service ( <i>see <u>Appendix Z</u></i> ).	
A101	Failure of the temperature probe of the sterilization chamber (PT1).		
A102	Failure of the temperature probe of the steam generator (PT2).		
A103	Failure of the temperature probe of the heating resistor (PT3).		
A104	Failure of the temperature probe of the chamber wall (PT4).		
A111	<b>Wrong</b> connection of the temperature probe (sterilization chamber) to the pcb connector.		
	Short-circuit of the temperature probe (sterilization chamber).		
A112	<b>Wrong</b> connection of the temperature probe (steam generator) to the pcb connector.	Call for the Customer Service (see <u>Appendix Z</u> ).	
	Short-circuit of the temperature probe (steam generator).		
A113	<b>Wrong</b> connection of the temperature probe (heating resistor) to the pcb connector.		
	Short-circuit of the temperature probe (heating resistor).		
A114	Wrong connection of the temperature probe (chamber wall) to the pcb connector.		
	Short-circuit of the temperature probe (chamber wall).		
A121	Instable operation of the temperature probe (sterilization chamber).		
A200	Release of the steam generator safety thermostat.	Provide for the manual reset of the thermostat installed on the rear side of the equipment (see <u>Chapter</u> "Product description").	
		Unscrew the protection plastic cap, push on the <u>red button</u> for a click and replace the cap.	
		Switch off ( <b>RESET</b> ) and switch on again the equipment.	
	Release of the heating resistor safety thermostat.	Call for the Customer Service (see Appendix 7)	
	Wrong operation of the steam generator or heating resistor.		



CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION	
A250	Presence of water or condensation inside the sterilization chamber.	Perform the <b>RESET</b> according to the instructions. Carefully dry the sterilization chamber and restart the program. <u>Do not</u> introduce material soaked by water or liquid into the chamber.	
	Obstruction on the sterilization chamber draining filter.	Provide for cleaning or replacing the draining filter. (See <i>Appendix C</i> , <i>"Maintenance"</i> ).	
	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions. Carefully clean the gasket with a clean cloth of cotton dampened with water. Restart the program.	
	Failure of the vacuum pump.	Only families (see from the first second sec	
	Problem on the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).	
A251	Wrong operation of the water pump.		
	Problem on the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).	
	Release of the steam generator safety thermostat.	Provide for the manual reset of the thermostat on the rear side of the equipment (see <u>Chapter</u> " <i>Product description"</i> ). Unscrew the protection plastic cap, push on the <u>red button</u> until a click and replace the cap.	
		Switch off ( <b>RESET</b> ) and switch on the equipment.	
	Release of the heating resistor safety thermostat. Wrong operation of the steam generator or heating resistor.	Call for the Customer Service (see <u>Appendix Z</u> ).	
A252	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions. Carefully clean the gasket with a clean cloth of cotton dampened with water. Restart the program.	
	Too much load.	Perform the <b>RESET</b> according to the instructions. Verify the quantity of material into the sterilization chamber and pay attention to not exceed the maximum admitted quantity according to the load typology. (see <i>Table in <u>Appendix A</u></i> , <i>Technical characteristics</i> ).	
	Problem of the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).	
	Release of the steam generator safety thermostat.	Provide for the manual reset of the thermostat on the rear side of the equipment (see <u>Chapter</u> " <b>Product description</b> ").	
		Unscrew the protection plastic cap, push on the <u>red button</u> until a click and replace the cap. Switch off ( <b>RESET</b> ) and switch on again the equipment	
	Release of the heating resistor safety thermostat. Wrong operation of the steam generator or heating resistor.	Call for the Customer Service (see <u>Appendix Z</u> ).	



CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
A253	Presence of water or condensation	Perform the <b>RESET</b> according to the instructions.
	into the sterilization chamber.	Carefully dry the sterilization chamber and restart the program.
		<b><u>Do not</u></b> introduce material soaked with water or liquid into the chamber.
	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions.
		Carefully clean the gasket with a clean cloth of cotton dampened with water. Restart the program.
	Failure of the vacuum pump.	Call for the Customer Service (see Annondix 7)
	Problem on the hydraulic circuit.	Call for the Customer Service (See <u>Appendix 2</u> ).
A254	Wrong operation of the water pump.	
	Problem on the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).
	Release of the steam generator safety thermostat.	Provide for the manual reset of the thermostat on the rear side of the equipment (see <u>Chapter</u> "Product description").
		Unscrew the protection plastic cap, push on the <u>red button</u> until a click and replace the cap.
		Switch off ( <b>RESET</b> ) and switch on again the equipment.
	Release of the heating resistor safety thermostat.	Call for the Customer Service (see Annendix 7)
	Wrong operation of the steam generator or heating resistor.	
A255	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions.
		Carefully clean the gasket with a clean cloth of cotton dampened with
		Restart the program.
	Excess of load.	Perform the <b>RESET</b> according to the instructions.
		Verify the quantity of material in the sterilization chamber and pay attention to not exceed the maximum admitted quantity according to the load typology. (see <i>Table in <u>Appendix A</u></i> , <i>Technical</i>
		characteristics).
	Problem of the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).
	Release of the steam generator safety thermostat.	Provide for the manual reset of the thermostat on the rear side of the equipment (see <u>Chapter</u> "Product description").
		Unscrew the protection plastic cap, push on the <b><u>red button</u></b> until a click and replace the cap.
		Switch off ( <b>RESET</b> ) and switch on again the equipment.
	Release of the heating resistor safety thermostat.	Call for the Customer Service (see Annondix 7)
	Wrong operation of the steam generator or heating resistor.	our for the oustomer ourvice (see <u>Appendix E</u> ).
A256	Presence of water or condensation in the sterilization chamber.	Perform the <b>RESET</b> according to the instructions. Carefully dry the sterilization chamber and restart the program. <u><b>Do not</b></u> introduce material soaked with water or liquid into the chamber.
	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions.
		Carefully clean the gasket with a clean cloth of cotton dampened with water.Start again the program.
	Failure of the vacuum pump.	Call for the Quetomor Service (and America 7)
	Problem on the hydraulic circuit.	Can for the Customer Service (see <u>Appendix Z</u> ).



CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
A257	Wrong operation of the water pump. Problem on the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).
	Release of the steam generator safety thermostat.	Provide for the manual reset of the thermostat on the rear side of the equipment (see <u>Chapter</u> "Product description").
		Unscrew the protection plastic cap, push on the <u>red button</u> until a click and replace the cap.
		Switch off ( <b>RESET</b> ) and switch on again the equipment.
	Release of the heating resistor safety thermostat.	Call for the Customer Service (see Annendix 7)
	Wrong operation of the steam generator or heating resistor.	Gan for the Gustomer Gervice (See <u>Appendix 2</u> ).
A258	Air leakage on the gasket	Perform the <b>RESET</b> according to the instructions. Carefully clean the gasket with a clean cloth of cotton dampened with water.
		Restart the program.
	Excess of load.	Perform the <b>RESET</b> according to the instructions.
		Verify the quantity of material in the sterilization chamber and pay attention to not exceed the maximum admitted quantity according to the load typology. (see <i>Table in <u>Appendix A</u></i> , <i>Technical characteristics</i> ).
	Problem on the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).
	Release of the steam generator safety thermostat.	Provide for the manual reset of the thermostat on the rear side of the equipment (see <u>Chapter</u> "Product description").
		Unscrew the protection plastic cap, push on the <u>red button</u> until a click and replace the cap.
		Switch off ( <b>RESET</b> ) and switch on again the equipment.
	Release of the heating resistor safety thermostat.	Call for the Customer Service (see Annendix 7)
	Wrong operation of the steam generator or heating resistor.	our for the oustomer bervice (See <u>Appendix 2</u> ).
A259	Excess of load.	Perform the <b>RESET</b> according to the instructions.
		Verify the quantity of material in the sterilization chamber and pay attention to not exceed the maximum admitted quantity according to the load typology. (see <i>Table in <u>Appendix A</u></i> , <i>Technical characteristics</i> ).
	Air leakage from the gasket	Perform the <b>RESET</b> according to the instructions.
		Carefully clean the gasket with a clean cloth of cotton dampened with water.
		Restart the program.
	Problem on the hydraulic circuit.	Call for the Customer Service (see <u>Appendix Z</u> ).



CODE	POSSIBLE CAUSE	SUGGESTED SOLUTION
HAZARDS (category H)		
H150	Break of the pressure probe (MPX).	
H160	Wrong connection of the pressure probe cable (MPX) to the p.c.b. connector.	
	Short-circuit of the pressure probe (MPX).	
H170	Instable operation of the temperature probe (sterilization chamber).	
H400	Problem of the hydraulic circuit.	
H401	Problem of the hydraulic circuit.	
H402	Wrong operation of the steam generator.	
	Problem of the hydraulic circuit.	
H403	Wrong operation of the steam generator.	Call for the Customer Service (see Appendix Z).
	Problem of the hydraulic circuit.	,
H404	Wrong operation of the steam generator.	
	Problem of the hydraulic circuit.	
H405	Wrong operation of the steam generator.	
	Problem of the hydraulic circuit.	
H406	Wrong operation of the steam generator.	
	Problem of the hydraulic circuit.	
H990	General operation problem.	
H991	General operation problem.	
H992	General operation problem.	
H993	General operation problem.	



#### **APPENDIX F – DRAWINGS**



## **APPENDIX F – DRAWINGS**



### HYDRAULIC DRAWING





# **APPENDIX G – DECLARATION OF CONFORMITY**

Sistemi innovativi di sterilizzazione	<b>DECLARATION OF CONFORMITY</b> Application of the EEC Directives 93/42 - 89/336 - 73/23		
Name of the Manufacturer:	M.O.COM. S.r.I Manifattura Odontoiatrica Complementare		
Address of the Manufacturer:	Via delle Azalee, 1 - 20090 Buccinasco (MI) - ITALY		
Product description:	Steam sterilizer		
Model:	EXTREMA PLUS		
Made in:	ITALY		
The undersigned hereby declares that the above mentioned goods entirely <b>conform</b>			
Reference standards:	EN 61010-1 EN 61010-1-A2 EN 61010-2-041 CEI EN 50081-1 CEI EN 50082-1		
	EN 55014 EN 55022 EN 60555-2 (CEI 77-3) EN 60555-3 (CEI 77-4) EN 61000-4-2 EN 61000-4-3 EN 61000-4-4 ASME VIII Div. 1 (Add. 1999) DIN 58946 T5 TRD 421 TRD 511		
	t. Our		
01/01/2000	à		
Date	Signature		
	Alfio VILLA Name and Surname		
	Legal Agent Function		





# **APPENDIX H – OPERATOR'S NOTES**




#### **APPENDIX Z – CUSTOMER SERVICE**

#### FOR ANY SERVICE INTERVENTION BOTH DURING AND OUT THE PRODUCT WARRANTY PERIOD PLEASE CALL DIRECTLY

# THE CUSTOMER SERVICE

#### OF THE AGENT OR RETAILER THAT SUPPLIED THE EQUIPMENT

M.O.COM. Ltd. Co. is at complete disposal of the Customers for any technical additional information concerning the product, as well as for any suggestions on the steam sterilization procedures.

Please contact at the following address:

M.O.COM. Srl Assistenza Clienti Via delle Azalee, 1 20090 Buccinasco (MI) ITALY

 Tel.
 (+39) 02-45701505

 Fax
 (+39) 02-45701258

 e-mail
 at@mocom.it

To help us in product quality and service improving, please send Your comments and/or suggestions to the followings **e-mail** addresses:

uc@mocom.it

(marketing and sales)

Besides, You can send comments and/or suggestions by letter or fax to the above indicated address.

Thanks in advance for the valuable assistance that you would supply to us.