

STEAM STERILIZER



OPERATING MANUAL



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Quality System certified by











REVISIONS

The following table lists subsequent editions/revisions of the manual. The "Description" field brief explains the subject of the latest revision.

| Ed. | Rev. | Date | Description |
|-----|------|---------|--|
| 1 | 0 | 06-2006 | First issue |
| 1 | 1 | 11-2006 | Page 50 and 60 (cycle time updated, disposal instructions added) |
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| | | | |
| | | | |

TABLE OF CONTENTS

| 1 - IN | ITRODUCTION | |
|--------|---|----|
| | APPLICABLE EUROPEAN DIRECTIVES | |
| | INTENDED USE | |
| | PURPOSE OF THE MANUAL | |
| | GENERAL WARNINGS | |
| 2 - C(| ONTENTS OF THE PACKAGE | |
| | DIMENSIONS AND WEIGHT | |
| | DESCRIPTION OF THE CONTENTS | |
| | HANDLING THE PRODUCT | 4 |
| 3 - PF | RODUCT INTRODUCTION | 5 |
| | INTRODUCTION | 5 |
| | GENERAL CHARACTERISTICS | 5 |
| | FRONT | 6 |
| | REAR | 7 |
| | CONTROL PANEL | 8 |
| | LCD DISPLAY | 8 |
| | OPERATING CYCLE EXAMPLE | 9 |
| 4 - IN | ISTALLATION | 10 |
| | INTRODUCTION | |
| | COMPARTMENT DIMENSIONS FOR BUILT-IN INSTALLATIONS | 10 |
| | GENERAL INSTALLATION PRECAUTIONS | 11 |
| | ELECTRICAL CONNECTIONS | 11 |
| | CONNECTING THE DATA RECORDING MILLFLASH | |
| | CONNECTING AN EXTERNAL WATER FILLING TANK | |
| | CONNECTING THE MILLDROP | 12 |
| | DIRECT CONNECTION TO A CENTRALIZED DRAINING POINT | |



| 5- FIRST START-UP | 14 |
|---|--|
| TURNING ON THE EQUIPMENT | |
| INITIAL AUTOMATIC TEST | |
| ACQUISITION AND UPDATING OF THE AMBIENT PRESSURE VALUES | |
| STAND-BY MODE | |
| FILLING DISTILLED WATER | |
| Manual filling | |
| Automatic filling (option) MAX LEVEL OF USED WATER | |
| | |
| 6 - CONFIGURATION | |
| | |
| STARTING AND ENTERING THE SETUP MODE | |
| MEANING OF THE KEYS IN SETUP MODE | |
| DESCRIPTION OF THE MENU ITEMS | |
| DEFAULTS SETTINGS | |
| ACTIVATING CONFIGURATION OPTIONS | |
| Setting the language Setting the date | |
| Setting the time | |
| Setting the password | |
| Setting the sterilization programs | |
| Setting the STAND-BY mode Setting the printing mode | |
| Setting the tank filling mode | |
| Acquisition of the ambient pressure | |
| Adjusting the contrast of the liquid crystal display EXIT THE CONFIGURATION MODE | |
| | |
| 7 - PREPARING THE MATERIAL | |
| 7 - PREPARING THE MATERIAL | |
| INTRODUCTION | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION PROCEDURE 9 - RUNNING THE CYCLE INTRODUCTION | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION PROCEDURE 9 - RUNNING THE CYCLE | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION PROCEDURE 9 - RUNNING THE CYCLE INTRODUCTION STARTING THE CYCLE PROGRAM EXECUTION | 31 31 32 34 34 34 34 34 36 36 37 |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION PROCEDURE 9 - RUNNING THE CYCLE INTRODUCTION STARTING THE CYCLE PROGRAM EXECUTION RESULT OF THE CYCLE | |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION PROCEDURE 9 - RUNNING THE CYCLE INTRODUCTION STARTING THE CYCLE PROGRAM EXECUTION RESULT OF THE CYCLE CHECK OF THE CYCLE DATA REPORT (OPTION) | 31 31 32 34 34 34 34 36 36 36 37 40 41 |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION PROCEDURE 9 - RUNNING THE CYCLE INTRODUCTION STARTING THE CYCLE PROGRAM EXECUTION RESULT OF THE CYCLE | 31 31 32 34 34 34 34 36 36 36 37 40 41 |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION PROCEDURE 9 - RUNNING THE CYCLE INTRODUCTION STARTING THE CYCLE PROGRAM EXECUTION RESULT OF THE CYCLE CHECK OF THE CYCLE DATA REPORT (OPTION) | 31 31 32 34 34 34 34 36 36 36 36 37 40 41 42 |
| INTRODUCTION TREATING THE MATERIAL BEFORE STERILIZATION ARRANGING THE LOAD 8 - PROGRAM SELECTION INTRODUCTION PROCEDURE 9 - RUNNING THE CYCLE INTRODUCTION STARTING THE CYCLE PROGRAM EXECUTION RESULT OF THE CYCLE CHECK OF THE CYCLE DATA REPORT (OPTION) MANUAL CYCLE INTERRUPTION | 31 31 32 34 34 34 36 36 36 37 40 41 41 42 43 |
| INTRODUCTION | 31 31 32 34 34 34 36 36 36 37 40 41 42 43 |
| INTRODUCTION | 31 31 32 34 34 34 36 36 36 36 36 37 40 41 41 42 43 43 |
| INTRODUCTION | 31 31 32 34 34 34 34 36 36 36 36 36 36 36 36 36 36 36 36 36 |
| INTRODUCTION | 31 31 32 34 34 34 34 36 36 36 36 36 36 36 36 37 40 41 41 42 42 43 43 43 43 43 43 |



| APPENDIX A – TECHNICAL CHARACTERISTICS | |
|---|----|
| SUMMARY TABLE | |
| SAFETY DEVICES | |
| WATER SUPPLY CHARACTERISTICS | |
| APPENDIX B – PROGRAMS | |
| INTRODUCTION | |
| PROGRAM SUMMARY TABLE | |
| STERILIZATION PROGRAM DIAGRAMS | 51 |
| TEST PROGRAM DIAGRAM | |
| EXAMPLES OF PRINTED REPORTS | 55 |
| APPENDIX C – MAINTENANCE | |
| INTRODUCTION | |
| ORDINARY MAINTENANCE PROGRAM | |
| MAINTENANCE DESCRIPTION | |
| Clean gasket and porthole | |
| Clean external surfaces | |
| Clean sterilization chamber and accessories Disinfect external surfaces | |
| Clean internal distilled water tank | |
| Safety valve maintenance | |
| Clean/replace the drain filter | |
| Replace bacteriological filter Replacing the paper in the printer (option) | |
| PERIODIC STERILIZER VALIDATION | |
| RECYCLING / DISPOSAL INSTRUCTIONS | |
| APPENDIX D – GENERAL PROBLEMS | 61 |
| INTRODUCTION | 61 |
| ANALYSIS AND RESOLUTION OF PROBLEMS | 61 |
| APPENDIX E – ALARMS | 64 |
| INTRODUCTION | |
| ALARM INTERVENTION | |
| Alarm during a cycle | 64 |
| Alarm outside the cycle | |
| RESETTING THE SYSTEM | |
| ALARM CODES | |
| ANALYSIS AND RESOLUTION OF PROBLEMS | |
| APPENDIX F – DIAGRAMS | |
| ELECTRICAL DIAGRAM (BOARD TYPE "T") | |
| PLUMBING DIAGRAM | |
| APPENDIX G – DECLARATION OF CONFORMITY | 75 |
| APPENDIX H – NOTES PER THE OPERATOR | 76 |
| APPENDIX Z – TECHNICAL SUPPORT | 77 |



INTRODUCTION

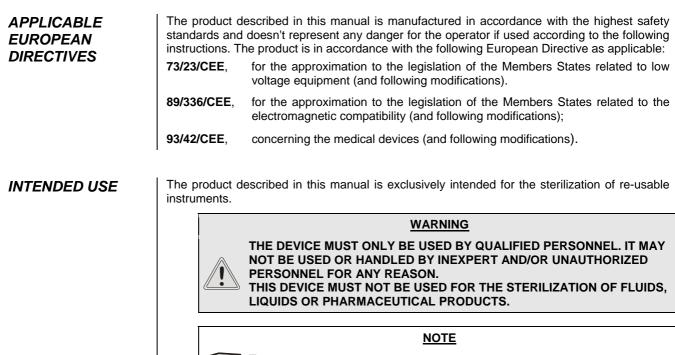
Dear Customer

Thank you for choosing a product from M.O.COM. Srl. We hope that you will find it completely satisfactory.

This manual describes all procedures for the correct use of the device and instructions for deriving the full benefit from its features.

In any case, we will be available to provide explanations and to receive any suggestions you may have for improving our products or services.

NOTE PAY SPECIAL ATTENTION TO PARAGRAPHS INDICATED BY THE POINTING FINGER. WARNING WARNING WARNING WARNING THIS SYMBOL INDICATES A POTENTIAL DANGER OF INJURY. FOLLOW THE PROCEDURES DESCRIBED IN THE MANUAL TO AVOID INJURING THE USER AND/OR OTHERS. DANGER DANGER THIS SYMBOL INDICATES A POTENTIAL DANGER OF PROPERTY DAMAGE. FOLLOWS THE INSTRUCTIONS IN THE MANUAL TO PREVENT POTENTIAL DAMAGE TO MATERIALS, EQUIPMENT OR OTHER PROPERTY. DANGER THIS SYMBOL INDICATES A POTENTIAL DANGER DUE TO HIGH TEMPERATURE. DANGER THE MATERIA



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Symbols used in the manual



PURPOSE OF THE MANUAL

The purpose of this manual is to provide instructions for:

- becoming generally familiar with the product;
- its correct installation and configuration;
- its safe, efficient use;
- handling materials before and after sterilization.
- Its appendices also provide:
- the product's general technical specifications;
- sterilization program specifications;
- maintenance;
- troubleshooting;
- a variety of other documentation.

GENERAL WARNINGS

When using this product, <u>always</u> follow the instructions in the manual and never use for anything other than its intended purpose.



THE USER IS RESPONSIBLE FOR ALL LEGAL REQUIREMENTS RELATED TO THE INSTALLATION AND USE OF THIS PRODUCT. THE MANUFACTURER WILL NOT BE RESPONSIBLE FOR ANY BREAKAGE, MALFUNCTIONS, PROPERTY DAMAGE OR INJURY IN THE EVENT THAT THE PRODUCT IS NOT INSTALLED OR USED CORRECTLY.

Please observe the following precautions in order to avoid injury or property damage:

- Use ONLY distilled water of high quality.

WARNING



THE USE OF WATER OF INADEQUATE QUALITY CAN SEVERELY DAMAGE THE DEVICE. SEE APPENDIX A, TECHNICAL CHARACTERISTICS IN THIS REGARD.

- Do not pour water or other liquids on the device;
- <u>Do not</u> pour inflammable substances on the device;
- Do not use the device in the presence of gas or explosive or inflammable vapors;
- Before performing any maintenance or cleaning, ALWAYS DISCONNECT the electricity.

DANGER

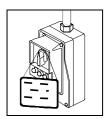
WHENEVER IT IS NOT POSSIBLE TO DISCONNECT THE ELECTRICITY TO THE DEVICE, OR IF THE EXTERNAL POWER GRID SWITCH IS FAR AWAY OR, AT ANY RATE, NOT VISIBLE TO THE MAINTAINER, PLACE A WORK IN PROGRESS SIGN ON THE EXTERNAL POWER GRID SWITCH AFTER TURNING IT OFF

- Make sure the electrical system is grounded conforming to current laws and/or standards;
- **Do not** remove any label or nameplate from the device; request new ones, if necessary.
- Use <u>only</u> original replacement parts.

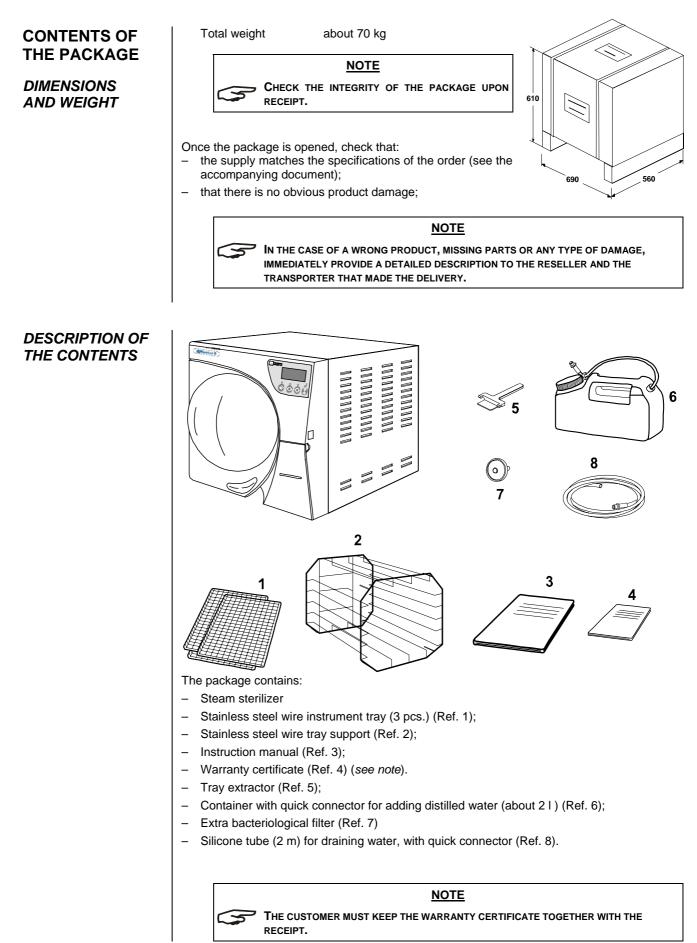


WARNING

THE FAILURE TO OBSERVE THE ABOVE, RELEASES THE MANUFACTURER FROM ALL LIABILITY.







C -5

}}}



HANDLING THE PRODUCT

Where possible, the packaged product must be handled using suitable mechanical means (forklift truck, transpallet, etc.) and following the instructions shown on the package. In the case of manual handling, the product must be lifted by two persons using the handles cut in the side of the box.

Once removed from the box, the sterilizer must be lifted by two persons and transported on a cart or other similar device.

<u>WARNING</u>

WE RECOMMEND THAT THE DEVICE BE TRANSPORTED AND STORED AT A TEMPERATURE NO LOWER THAN 5 °C. PROLONGED EXPOSURE TO LOW TEMPERATURE AN DAMAGE THE PRODUCT.

NOTE

***** KEEP THE ORIGINAL PACKAGING AND USE IT WHENEVER THE DEVICE IS TO BE TRANSPORTED. THE USE OF DIFFERENT PACKAGING COULD DAMAGE THE PRODUCT DURING SHIPMENT.

DANGER

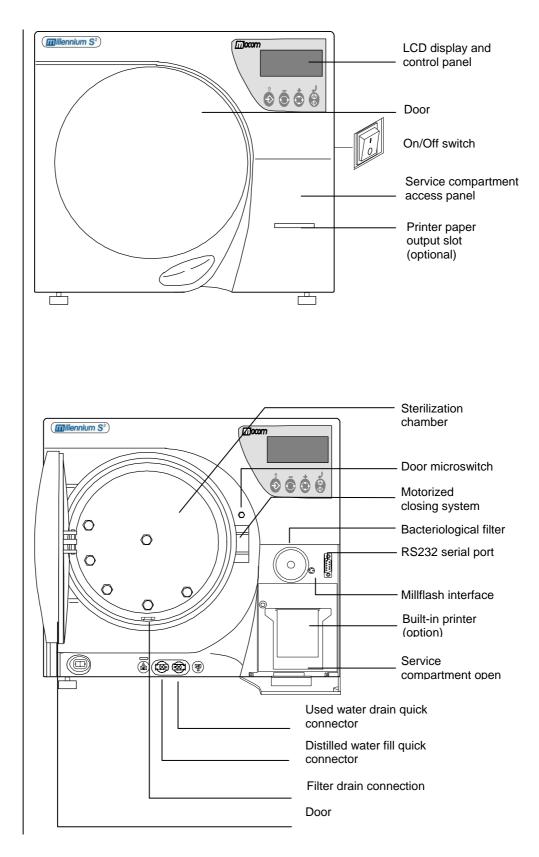
BEFORE TRANSPORT, LEAVE THE DEVICE TURNED-OFF FOR ABOUT 30 MINUTES AFTER THE LAST PROGRAM FINISHES AND DRAIN THE DISTILLED WATER AND USED WATER TANKS SO THAT THE ALL THE HOT INTERNAL PARTS WILL HAVE TIME TO COOL.



| PRODUCT INTRODUCTION | Millennium S ² is MO.COM.'s revolutionary type S (EN 13060) small steam sterilizer and a new de facto standard for safety, performance, flexibility and ease of use. | | |
|----------------------------|---|--|--|
| INTRODUCTION | It is a sophisticated but, at the same time, easy to use device that, thanks to its wide range of configuration options and patented operating devices, satisfies every need for sterilizing medical devices, guaranteeing the maximum performance under all conditions. | | |
| | It also features a better way of relating to users who, rather than having to adapt to the machine and its characteristics, are able to "converse" with it and configure it to meet their own needs. | | |
| | Thanks to its remarkable ease of use, small size and pleasant appearance, it is the ideal partner for all professional who demand the maximum sterilization safety. | | |
| GENERAL CHARACTERISTICS | Millennium S ² is a completely microprocessor-controlled steam sterilizer with a large (21-liter) sterilization chamber made of stamped stainless steel. | | |
| | It is characterized by an advanced single vacuum system for the complete removal of air, even from wrapped materials, and an effective final vacuum drying phase capable of eliminating all traces of humidity from the load. | | |
| | Its exclusive steam generation system, effective plumbing circuit and electronic management (supplemented by high-precision sensors) guarantees high process execution speeds and excellent thermodynamic parameter stability. Moreover, its Process Evaluation System constantly monitors all the machine's "vital" parameters in real-time, guaranteeing absolute safety and a perfect result. | | |
| | It offers users 6 sterilization programs, all equipped with customizable, optimized drying for the fast, effective sterilization of the various types of loads (instruments and materials) used in a medical environment. Four of these can be selected directly from the control panel, which has a new simplified, design. | | |
| | And then, there are interesting options for configuring the preheating mode (based on the sterilizer's use rate, and the automatic filling of the internal distilled water tank via an external tank or Milldrop equipment (optional feature). | | |
| | Please refer to the chapters "Installation" and "Configuration" for more details. | | |
| | Finally, Millennium S ² has one of the most complete, sophisticated and advanced safety systems available today to protect users in the case of any electrical, mechanical, thermal or biological operating anomaly. | | |
| | NOTE | | |
| | PLEASE REFER TO APPENDIX A (TECHNICAL CHARACTERISTICS) FOR A DESCRIPTION OF THE SAFETY DEVICES. | | |
| | | | |

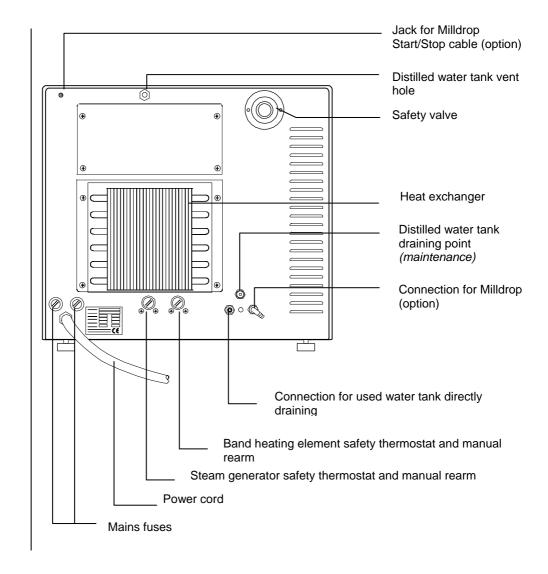


FRONT

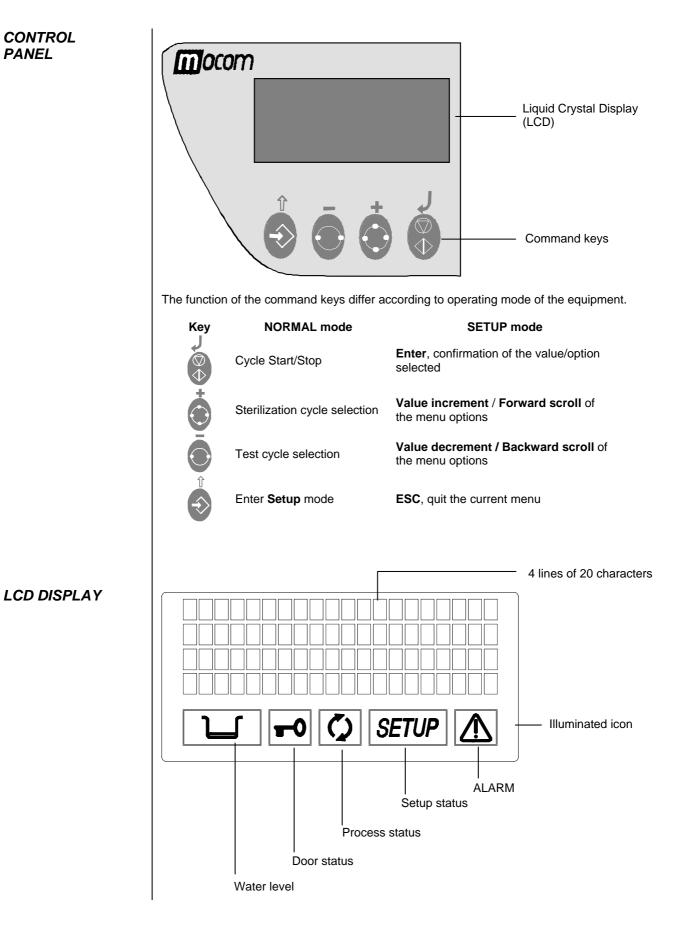




REAR









OPERATING CYCLE EXAMPLE

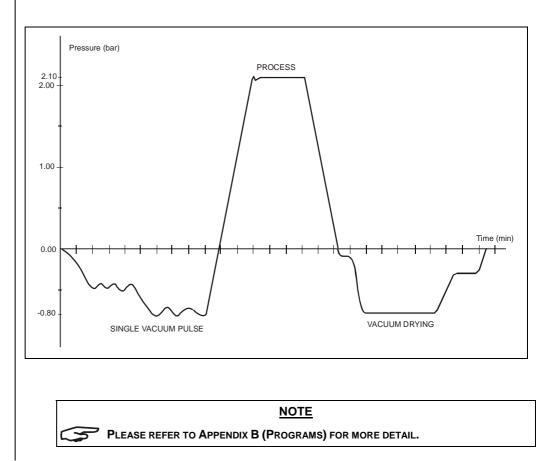
The Millennium S^2 sterilization program can be described as a succession of phases, each with a specific purpose.

For example, the standard program (for wrapped materials, 134 $^{\circ}$ C - 4'), after loading the material in the chamber, closing the door, selecting the program and starting the cycle (and the consequent locking of the door opening mechanism), offers the following sequence (see chart, below):

- 1. preheating the generator and sterilization chamber;
- 2. removing the air through a single vacuum phase (extraction of the fluid from the sterilization chamber);
- 3. raising the pressure, with the consequent increase in the temperature of the steam, until reaching the conditions required for sterilization (in the example, **134** °C);
- 4. stabilizing the pressure and temperature;
- 5. sterilizing for the required time (in the example, 4 minutes);
- 6. depressurizing the sterilization chamber;
- 7. vacuum-drying phase;
- 8. ventilating the load with sterile air;
- 9. bringing the pressure of the sterilization chamber back to the atmospheric level.

After reaching atmospheric pressure, the door is automatically unlocked and it can be opened to remove the load from the sterilization chamber.

It should be emphasized that phases 1, 2, 3, 4, 6 and 9 are identical in all cycles, with slight variations of duration that are solely dependent on the quantity and consistency of the load and the heating conditions of the sterilizer while phases 5, 7 and 8 clearly vary their configuration and/or duration on the basis of the cycle selected (and, as a consequence, the type of load) and the choices made by the user.





The first and fundamental step in achieving good sterilizer operation, long life and complete INSTALLATION use of its features is a correct, careful installation. Moreover, this precaution will avoid the danger of physical injury or property damage, not to mention malfunctions and damage to the INTRODUCTION machine. So, please follow the instructions in this chapter scrupulously. NOTE ' M.O.COM. CUSTOMER SUPPORT (SEE APPENDIX Z) WILL ANSWER YOUR QUESTIONS AND PROVIDE ADDITIONAL INFORMATION. THE STERILIZER HAS PASSED ALL REQUIRED INSPECTIONS BEFORE BEING PLACED ON THE MARKET. IT DOES NOT REQUIRE ANY ADDITIONAL CALIBRATION BEFORE BEING PLACED IN SERVICE. **Dimensions and weight** Height (total) 420 mm Width (total) 480 mm Depth (excluding rear connections) 660 mm Total weight 58 kg Electricity The electrical system to which the sterilizer will be connected must be suitably dimensioned based on the electrical characteristics of the device. This information is shown on the back of the machine. When installing the sterilizer inside a cabinet, you COMPARTMENT must provide adequate space all around the device DIMENSIONS FOR (> 10cm, specially on the rear side) to provide **BUILT-IN** effective ventilation as well as a large enough **INSTALLATIONS** opening in the back that, in addition to allowing the passage of the power cord will also provide an adequate air flow and the consequent optimum cooling of the heat exchanger. It is indispensable that the built-in compartment have the following minimum dimensions shown in the figure. WARNING COMPARTMENT DIMENSIONS LESS THAN THOSE SHOWN MAY COMPROMISE THE CORRECT CIRCULATION OF AIR AROUND THE DEVICE AND MAY NOT PROVIDE ADEQUATE COOLING. WITH THE CONSEQUENT DETERIORATION OF PERFORMANCE AND/OR POSSIBLE DAMAGE. NOTE IF THE MAIN SWITCH IS INACCESSIBLE WHEN INSTALLED IN THE COMPARTMENT, USE AN ELECTRIC PLUG THAT INCORPORATES AN ON/OFF SWITCH. DO NOT REMOVE THE UPPER COVER OR ANY OTHER EXTERNAL PART. WHEN INSTALLED IN THE COMPARTMENT, THE DEVICE MUST BE COMPLETE WITH ALL ITS PARTS.

PLEASE REFER TO APPENDIX A (TECHNICAL CHARACTERISTICS) FOR COMPLETE TECHNICAL DATA.

660 670 550

500

millennium S²

1

420

480



| GENERAL INSTALLATION PRECAUTIONS | Obey the following warnings for the correct operation of the device and/or to avoid <u>risky</u> <u>situations</u> : | | |
|--|--|--|--|
| | Install the sterilizer on a <u>flat surface</u>; if necessary, adjust the leveling feet to compensate for an irregular surface. Make sure that the support surface is <u>strong enough</u> to support the weight of the fully equipped and loaded device (about 66 kg); | | |
| | Leave <u>adequate space for ventilation (at least 10 cm on each side)</u> all around the sterilizer, especially in back. If the device is built-in to a cabinet, be sure to respect the warnings in the preceding paragraph, avoiding an obstructions to the air intake; | | |
| | Do not install the sterilizer near tubs, sinks or similar places, to <u>avoid contact with water or liquids</u>. This could cause short circuits and/or potentially dangerous situations for the operator; | | |
| | Do not install the sterilizer in a place that is <u>excessively humid</u> or <u>poorly ventilated</u>; | | |
| | Do not install the machine were there is <u>gas</u> or inflammable and/or explosive <u>vapors</u>; Install the device so that the power cord is <u>not bent</u> or <u>crushed</u>. It must run freely all the way to the socket. Install the device that any external pipe is <u>not bent</u> or <u>crushed</u>. | | |
| | | | |
| | | | |
| ELECTRICAL CONNECTIONS | The sterilizer's must be connected to a socket of the electrical system of adequate capacity for | | |
| CONNECTIONS | the device's absorption and ground provided, in conformity with current laws and/or standards. The socket must be suitably protected by a breaker having the following characteristics: | | |
| CONNECTIONS | | | |
| CONNECTIONS | The socket must be suitably protected by a breaker having the following characteristics: | | |
| CONNECTIONS | The socket must be suitably protected by a breaker having the following characteristics: Nominal current In 16 A | | |
| CONNECTIONS | The socket must be suitably protected by a breaker having the following characteristics: Nominal current I_n 16 A Differential current I_{Δn} 0.03 A | | |
| CONNECTIONS | The socket must be suitably protected by a breaker having the following characteristics: - Nominal current In 16 A - Differential current I _{∆n} 0.03 A WARNING THE MANUFACTURER WILL NOT BE LIABLE FOR DAMAGES CAUSED BY INSTALLING THE STERILIZER ON AN INADEQUATE ELECTRICAL | | |
| CONNECTIONS | The socket must be suitably protected by a breaker having the following characteristics: - Nominal current In 16 A - Differential current I∆n 0.03 A WARNING WARNING THE MANUFACTURER WILL NOT BE LIABLE FOR DAMAGES CAUSED BY INSTALLING THE STERILIZER ON AN INADEQUATE ELECTRICAL SYSTEM AND/OR NOT EQUIPPED WITH A GROUND. If it is necessary to replace the plug on the power cord, use one with equal characteristics or, at any rate, adequate to the device's electrical characteristics. The user is entirely responsible | | |
| CONNECTIONS | The socket must be suitably protected by a breaker having the following characteristics: - Nominal current I_n 16 A - Differential current $I_{\Delta n}$ 0.03 A $\frac{WARNING}{INSTALLING THE STERILIZER ON AN INADEQUATE ELECTRICAL SYSTEM AND/OR NOT EQUIPPED WITH A GROUND.}$ If it is necessary to replace the plug on the power cord, use one with equal characteristics or, at any rate, adequate to the device's electrical characteristics. The user is entirely responsible for the selection and replacement of the plug. | | |

CONNECTING THE DATA RECORDING MILLFLASH

The sterilizer can be connected to MILLFLASH allowing the recording of the cycle data in .txt format file and $% \mathcal{A}$ its management by PC.

The connectors of the service box are used for interfacing; refer to MILLFLASH Operating Manual for the installation instructions.



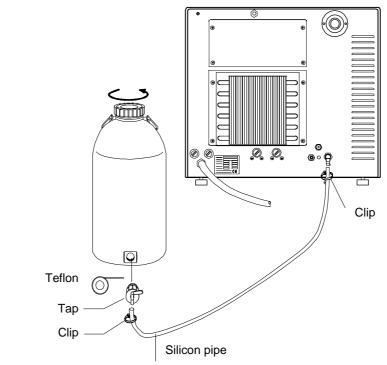
CONNECTING AN EXTERNAL WATER FILLING TANK (OPTIONAL, automatic filling function)

To avoid having to periodically fill the water tank (see **Chapter 5**, "**First Start-Up**"), it is possible, where this feature is provided, to connect the sterilizer to an external filling tank (supplied as an option), that the user will periodically fill, or to a commercially-available, reverse-osmosis water purification system with accumulation tank.

In that case, when the internal water tank reaches the MIN level, the autoclave activates a pump that automatically fills the internal tank.

Follow the instructions below for the correct connection of the external tank:

 Install the tap provided on the filling tank; use Teflon tape or connector sealant for a perfect seal.

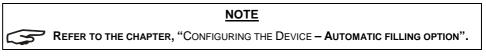


- Use the filling tanks silicone tube (or other suitable tube, length 2m) and insert it on the filling connector taking care to push it completely on.
- Lock the tube to connector with the plastic tie provided.
- Insert the other end of the tube on the tap of the filling tank.
- Make sure that the tube runs freely from the device to the filling tank, without being bent, crushed or obstructed in any way.
- Loosen the upper plug to facilitate the flow of water (also remove any gasket or underplug);
- Open the tap on the filling tank.

NOTE

REFER TO THE CHAPTER, "CONFIGURING THE DEVICE - AUTOMATIC FILLING OPTION".

CONNECTING THE MILLDROP (OPTIONAL, automatic filling function) If provided, this feature allows the sterilizer to be connected to MILLDROP (water treatment system by reverse osmosis) warranting the automatic reservoir filling with high quality demineralized water. Refer to MILLDROP operating manual for the installation instructions.



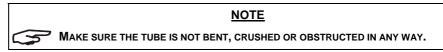
For additional information and advice about the correct connection of the sterilizer to the various water purification systems, contact M.O.COM. customer support (see **Appendix Z**).



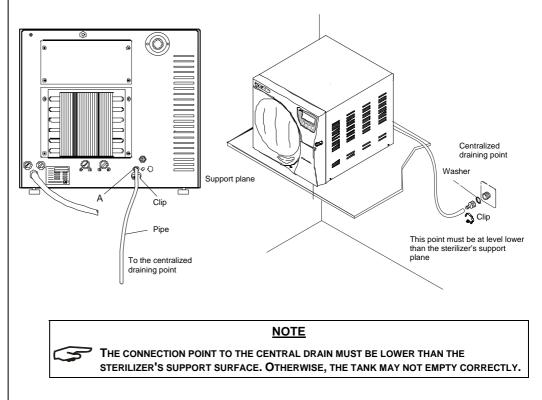
DIRECT CONNECTION TO A CENTRALIZED DRAINING POINT

To avoid having to periodically empty the internal used water tank, it is possible to connect it directly to a central drain.

- Insert the silicone tube (provided) or other suitable plastic tube on hose union A; push the tube all the way on and lock with the plastic tie or other means;
- Cut the tube to measure, push the free end on the connection provided on the centralized draining point and lock with the plastic tie or other means;



The following diagram provides an indicative arrangement of the components:



FIRST START-UP

Once the sterilizer has been correctly installed, it may be turned on and prepared for use.

Turn on the equipment by the main (luminous) switch located on the right side of the machine.

NOTE

TURNING ON THE EQUIPMENT

INITIAL

TEST

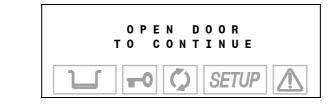
AUTOMATIC

Do this with the sterilizer's door <u>open</u>.

When turned on, the control panel lights up and beeps so you can visually check its correct operation. The panel then displays this message:



NOTE IF THE DOOR IS CLOSED, THE TEST IS INTERRUPTED. THE PANEL THEN BEEPS AND DISPLAYS THE FOLLOWING MESSAGE.



Open the door to allow the test to continue. At the end of the test you will see:



ACQUISITION AND UPDATING OF THE AMBIENT PRESSURE VALUES The sterilizer measures the <u>ambient pressure</u> for the correct operation of several auxiliary devices. Whenever the difference between the value read and that previously stored (see the Chapter, **"Configuring the Device - Acquisition the ambient pressure**) is <u>higher</u> than a set value, the system <u>automatically</u> updates the stored value after a brief delay. <u>Otherwise</u>, the data remains <u>unchanged</u> without updating.

After updating, the device performs the initial automatic test procedure (see the preceding paragraph). At the end, the display shows the following **notice** (accompanied by a beep):

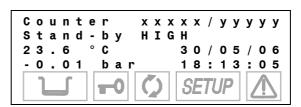


When \downarrow is pressed, the device goes to STAND-BY mode (see the following paragraph).



STAND-BY MODE

After the initial test, the sterilizer goes to STAND-BY mode and the display shows:



The upper line is the **cycle counter** for sterilizations performed, with the number of correctly completed cycles on the <u>left</u> and the total number started on the <u>right</u>. The line below shows the Stand-by status and the preheating mode (High-Low-Off). The two lower lines show the temperature and pressure of the sterilization chamber on the left and current **date** and **time** on the right.



A CYCLE BEGINS WITH THE START OF THE STERILIZATION CYCLE (FIRST VACUUM PHASE), EXCLUDING THE PREHEATING PHASE. A CYCLE ENDS AT THE END OF THE PROGRAM (SEE THE CHAPTER, "PROGRAM EXECUTION").

TO SET THE DATE AND TIME AS WELL AS THE PREHEATING MODE AND DATA PRINTOUT, PLEASE REFER TO THE CHAPTER, "CONFIGURATION".

At regular intervals, the first two lines on the display alternate with the modes set for printing (OFF/ON) and filling (Manual):



The icons in the lower part of the LCD screen remain off with the exception of the door status and/or water level indicators, which light-up if the door is closed and/or the level in the filling tank reaches its MIN or MAX values (or the MAX value in the drain tank).

During the first start-up, the MIN water level icon in the filing tank is normally on.

The device waits for the selection of the desired sterilization program (see the Chapter, "Program Selection").





WHEN THE DOOR IS OPEN IN STAND-BY MODE, A BEEP INDICATES THAT THE SURFACES INSIDE THE DEVICE ARE HOT. TO AVOID BURNS, TAKE CARE NOT TO TOUCH THE STERILIZATION CHAMBER, THE SUPPORTS PROVIDED OR THE INSIDE OF THE DOOR WITH YOUR BARE HANDS.



RESERVOR EMP

199999999999

FILLING DISTILLED WATER

Manual filling

The first time the sterilizer is used, and later when the MIN water level indicator comes on, you will have to fill, or top-off, the internal distilled water tank.

With reference to the figure (and with the door open), proceed as follows:

- 1. Fill the manual container (2 I) with distilled water, keeping it horizontal;
- 2. Connect the tube's quick connector to the corresponding female connector under the chamber entrance (marked $(\overrightarrow{Hz0})$), pushing until you hear a

click;

- 3. Place the container in a vertical position, at the same time, loosening the plug and taking care <u>not</u> to spill water on the machine.
- 4. The water will begin to flow into the tank;
- 5. Continue filling until the MIN level indicator turns off.
- 6. Continue until the water is drained from the container;
- 7. At this point, lower the connector below the connection point, keeping it horizontal;
- 8. While pinching the tube with your fingers, press the metal lever located on the side of the connector and detach the quick connector;
- 9. Refill the container (2 I) and repeat the operations described in points 2, 3 and 4 a second time;
- 10. When the <u>MAX level</u> icon comes on (accompanied by a beep), stop filling and detach the quick connector as described in points 7 and 8.

NOTE



The icon MAX does <u>not</u> have to be on in order to start a sterilization program. The icon MIN indicator off is sufficient.

In the event of installation for automatic filling from an external tank or demineralizer Milldrop (see the Chapter, "Installation"), the filling will occur automatically after the automatic filling option has been selected.

Obviously, for the correct operation, the user must<u>fill the external tank or switch on the Mildrop</u> in advance.



NOTE

⁷ USE ONLY HIGH QUALITY DISTILLED WATER. FOR THE SPECIFICATIONS OF THE WATER SUPPLY, SEE APPENDIX A (TECHNICAL CHARACTERISTICS).

To set the automatic filling option, please refer to the Chapter, "Configuring the Device".

WARNING

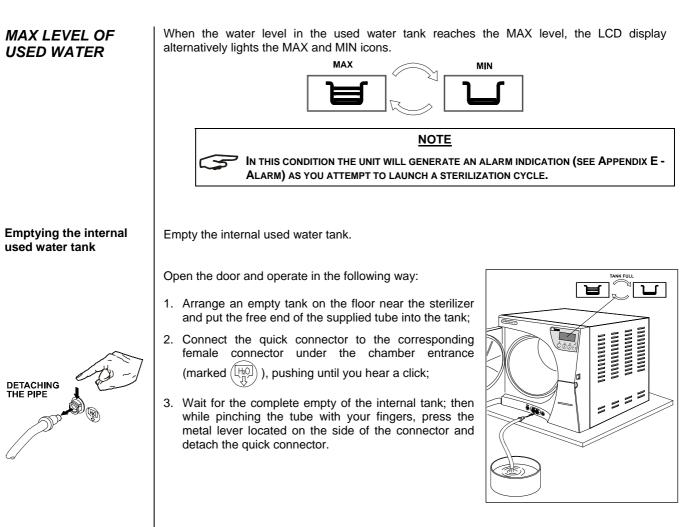
THE AUTOMATICALLY FILLING SYSTEM MUST <u>NEVER</u> RUN DRY; THIS CAUSES PREMATURE WEAR TO THE AUXILIARY WATER-INJECTION PUMP. <u>PERIODICALLY</u> CHECK THE WATER LEVEL IN THE EXTERNAL TANK.



Automatic filling (option)







mocom

CONFIGURATION

INTRODUCTION

Millennium S² offers personalization options never previously seen on any steam sterilizer. Users may configure the device to meet their own needs. For example, the device's performance may be adapted on the basis of the type of activity, the type of material to be sterilized or its frequency of use.

The SETUP program allows selecting from numerous options that users activate through an intuitive, easy-to-use menu.

<u>NOTE</u>

Use the SETUP PROGRAM WHENEVER NECESSARY. A CORRECTLY PERSONALIZED DEVICE PROVIDES THE BEST PERFORMANCE AND THE MOST SATISFACTORY USE. M.O.COM. CUSTOMER SUPPORT (SEE APPENDIX Z) IS AVAILABLE TO HELP USERS BY PROVIDING SUGGESTIONS OR ADVICE ON THE BEST WAY TO USES THE OPTIONS IN THE SETUP PROGRAM

STARTING AND ENTERING THE SETUP MODE



To start the **SETUP** program, hold down the \uparrow key on the control panel for several seconds, until the display shows:





ICON SETUP ON THE DISPLAY LIGHTS-UP AND STAYS ON OR THE ENTIRE CONFIGURATION PHASE.

When you press the \downarrow key, you enter the SETUP mode. The screen shows the first-level menu items (see the paragraph, **SETUP flowchart**).

Pressing the **ESC** key \hfill quits the SETUP program and takes you back to normal operation (stand-by mode).



Key

NOTE THE SETUP PROGRAM CAN ONLY BE STARTED IN STAND-BY MODE. IT IS NOT ACCESSIBLE DURING STERILIZATION OR TEST CYCLES.

In SETUP mode the control panel keys have different functions than in normal mode.

KEYS IN SETUP MODE

MEANING OF THE

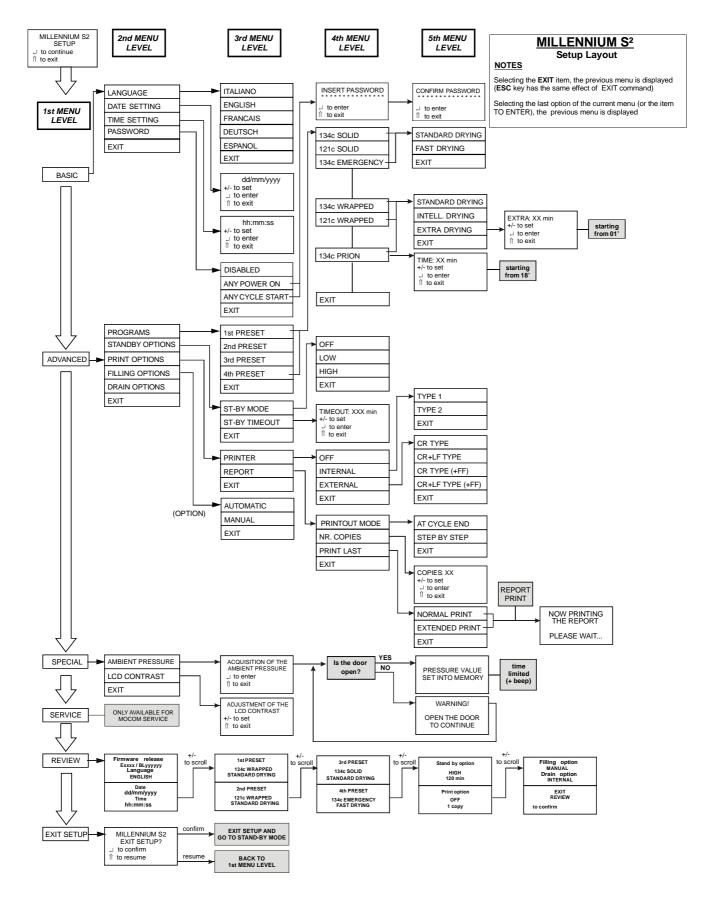
SETUP mode

function ENTER, confirm the selected option or value

- Increase the value /scroll down
- **Decrease the value /scroll up** the menu items
- $\hat{\mathbb{T}}$ **ESC**, exit the selected menu option



6. CONFIGURATION





DESCRIPTION OF THE MENU ITEMS

Now, we describe the meaning of the various main menu and second-level menu items.

MAIN MENU

The main menu has 6 entries that open additional (second-level) menus:

| BASIC |
|-------------|
| ADVANCED |
| SPECIAL |
| SERVICE |
| DATA REVIEW |
| EXIT SETUP |
| |

(basic <u>options</u>) (advanced <u>options</u>) (special <u>options</u>) (menu not accessible to users) (<u>summary</u> of options selected) (<u>exit</u> the SETUP program and return to normal operation. In this regard, see the paragraph, Exiting the SETUP program)



THE METHODS FOR CHANGING THE VARIOUS ITEM SETTINGS ARE FOUND IN THE PARAGRAPH, ACTIVATING CONFIGURATION OPTIONS.

BASIC Menu

5

The Basic menu (basic options) consists of the items:

| LANGUAGE | |
|--------------|--|
| DATE SETTING | |
| TIME SETTING | |
| PASSWORD | |
| EXIT | |

(language <u>setting</u>) (setting the current <u>date</u>); (setting the current <u>time</u>) (setting the **password**) (<u>exit</u> the BASIC menu and return to the main menu)

ADVANCED Menu

The Advanced menu (advanced options) consists of the items:

| PROGRAMMES | (setting preselected <u>sterilization programs</u> , shown on the LCD display) |
|------------------|--|
| STAND-BY OPTIONS | (<u>stand-by</u> mode settings) |
| PRINT OPTIONS | (setting <u>printer</u> and <u>printing options</u>) |
| FILLING OPTIONS | (available on request) |
| DRAIN OPTIONS | (not available) |
| EXIT | (<u>exit</u> the ADVANCED menu and return to the main menu) |

SPECIAL Menu

The Special menu (special options) consists of the following items:

| AMBIENT PRESSURE | (acquisition of the ambient pressure) |
|------------------|---|
| LCD CONTRAST | (adjusting the <u>contrast</u> of the Liquid Crystal Display) |
| EXIT | (exit the SPECIAL menu and return to the main menu) |

SERVICE Menu

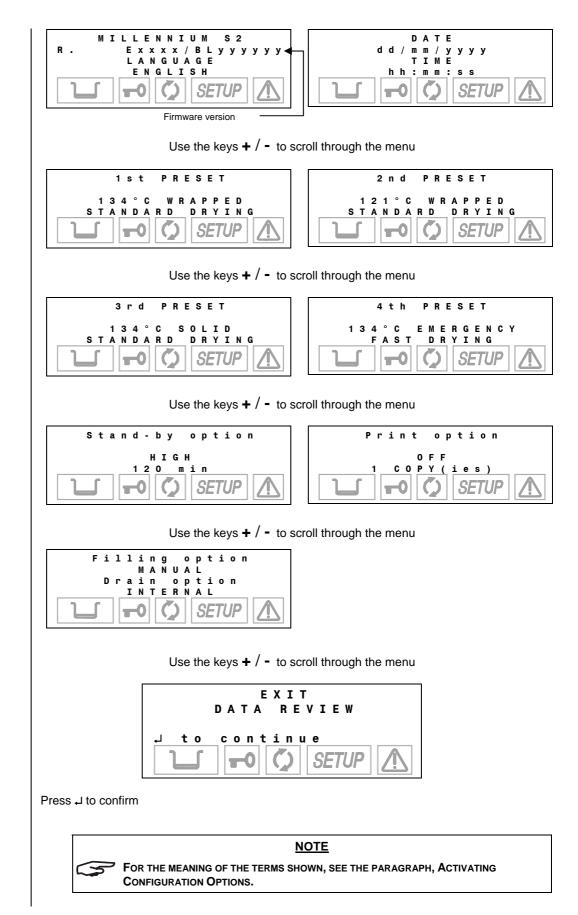
The Service menu can **ONLY** be accessed by the Service department.

DATA REVIEW Menu

The Data Review displays a summary of the device's <u>current settings</u>, allowing users to verify their correctness.

It has the following screens (shown by way of example):







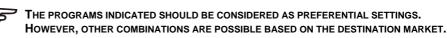
DEFAULTS SETTINGS

The sterilizer leaves the factory with the following settings:

| DATE: | | <i>current date</i> | |
|-----------|-----------|---------------------------------|--|
| TIME: | | current time | |
| PROGRAMS: | Preset 1: | 134°C WRAPPED (standard drying) | |

121°C WRAPPED (standard drying) Preset 2: Preset 3: 134°C SOLID (standard drying) 134°C EMERGENCY Preset 4:

NOTE



| ST-BY MODE: | HIGH (preheating) |
|------------------|-------------------|
| PRINT OPTIONS: | OFF 1 copy |
| FILLING OPTIONS: | MANUAL |
| DRAIN OPTIONS: | INTERNAL |

ACTIVATING CONFIGURATION

Setting the language (LANGUAGE on the BASIC Menu)

Setting the date

BASIC Menu)

(DATE SETTING on the

Now, we provide a detailed explanation of how to select the various available options, proceeding in the shown in the previous paragraph.

Select LANGUAGE using the , key. The following screen will appear:



Select the desired language. Move using the + or - keys and confirm using the \downarrow key to store the selection. After the data is confirmed, you return to the second-level menu.



AS SOON AS THE SELECTION IS CONFIRMED, ALL THE MENUS OF THE SETUP PROGRAM WILL BE DISPLAYED IN THE LANGUAGE SET.

When DATE SETTING is selected with the , key, you will see:



Proceed as follows:

- The day flashes: set the current date with the + and keys. Confirm with J.
- The month flashes: set the current month with the + and keys. Confirm with J.
- The year flashes: set the current year with the + and keys. Confirm with J.

The date is stored. Once the last confirmation is given, you return to the second-level menu.

OPTIONS



Setting the time (TIME SETTING on the BASIC menu) When TIME SETTING is selected with the , key, you will see:



Proceed as follows:

- The hours flash: set the current hour with the + and - keys. Confirm with J.

- The minutes flash: set the current value with the + and - keys. Confirm with J.

The time is stored. Once the last confirmation is given, you return to the second-level menu.

When PASSWORD is selected with the , key, you will see this menu:

Setting the password (PASSWORD on the BASIC menu)

| → | A | N | Y Y | P | 0 | W | E | | 0 N S T A R T | + ↑ ↓ |
|----------|---|---|--------|-------|---|---|---|---|------------------|-------------|
| | | ſ | | | 0 | | Ç |) | SETUP | |

Select **DISABLED** to use the device freely, without any limitation on operator access.

Select **ANY POWER-ON** to protect the machine with a password at the time it is turned-on (power-on from the main switch).

This makes sure that the machine can only be powered-on by authorized personnel, but afterwards it can be used by others without limitation.

Select **ANY CYCLE START** to protect the autoclave with a password to be entered both at power-on and at the start of every sterilization program. Only authorized personnel will be able to use it.



ENTERING A PASSWORD PROVIDES MORE CONTROLLED USE OF THE PRODUCT BUT, AT THE SAME TIME, INEVITABLY MAKES IT MORE CUMBERSOME. SO AS NOT TO OVERLY COMPLICATE USING THE DEVICE, WE RECOMMEND ONLY ACTIVATING THIS OPTION WHEN IT IS REALLY NEEDED.

When the **ANY POWER-ON** or **ANY CYCLE START** options are selected, the following screen is displayed:



Enter the password with the + and - keys (fixed length, **8 characters**). Confirm with the \downarrow key. Then, the following message will appear:



Enter the password again using the + and - keys. Confirm with the \downarrow key.



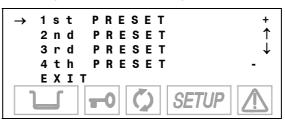


To change the password, first select the DISABLE option, which cancels the previous password, and then select the ANY POWER-ON or ANY CYCLE START option, entering the new password as described above.

Setting the sterilization programs (PROGRAMS on the ADVANCED menu) The program setting and their storing on four pre-set positions is achieved in various steps using several menus in sequence.

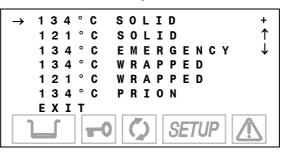
To associate **a cycle** and define several of its parameters, proceed as follows:

1. Select **PROGRAMS** using the J key; the following menu appears:



Define the position (1, 2, 3 or 4) to which the sterilization program will be associated using the + and - keys. Confirm with the \downarrow key.

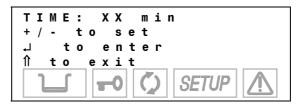
2. From here, you enter the list of available cycles:



Using the + and - keys, scroll the list until you identify the sterilization program desired.

3. Confirm the selection with the \downarrow key.

When the **PRION** program is selected, you will go to a screen for selecting the sterilization time.



A value can be set, starting from 18 to 30 minutes.

As a function of the choices made, you will go to one of two alternative menus that allow selecting the type of drying to associate to the selected program.



a) Programs with short drying (SOLID, EMERGENCY): STANDARD DRYING + DRYING ↑ FAST EXIT SETUP 1 It is possible to select STANDARD mode (the default setting) or FAST (reduced drying, recommended for light loads). Move using the + and - keys and confirm with the , key. NOTE ⁷ THE EMERGENCY PROGRAM PROVIDES ONLY FAST DRYING. **C**3 b) Programs with long drying (WRAPPED, PRION): STANDARD DRYING + INTELL. DRYING 1 EXTRA DRYING T EXIT Setup -0 It is possible to select STANDARD (default setting), INTELLIGENT (automatic drying that adjusts its duration longer or shorter than standard drying on the basis of the volume and/or quantity and type of load) or EXTRA (drying extended by a selectable value, recommended for critical loads). Move using the + and - keys and confirm with the , key. NOTE WITH LARGE LOADS OR SPECIAL MATERIALS, THE STANDARD OPTION MAY NOT 5 PROVIDE A PERFECT RESULT. IN THIS CASE, EXTEND THE DRYING PHASE BY USING THE EXTRA MODE. When the EXTRA option is activated, the following screen appears: EXTRA: ХХ min + / t o set t o enter î tо exit SETUP 0 which permits setting the duration of extra drying from between 1 and 15 minutes (time to be added to the STANDARD DRYING time). Set the value and confirm the selection with the J kev. NOTE THE SELECTION CAN BE CHANGED AT ANY TIME BY FOLLOWING THE PROCEDURE DESCRIBED ABOVE. WHENEVER AN IDENTICAL STERILIZATION PROGRAM IS ALREADY PRESENT IN ANOTHER POSITION, THE SELECTION IS NOT ACCEPTED. THE FOLLOWING WARNING APPEARS ON THE DISPLAY, ALONG WITH A BEEP: THIS PROGRAM IS ALREADY PRESET Setup NOTE

THE LIST OF AVAILABLE PROGRAMS, THEIR SCREENS AND THE CHARACTERISTICS OF STERILIZABLE MATERIALS (IN RELATION TO THE PROGRAMS) ARE CONTAINED IN

APPENDIX B (PROGRAMS).



Setting the STAND-BY mode (STAND-BY OPTIONS on the ADVANCED menu) Based on the equipment's frequency of use, or other considerations, it is possible to select the heating level during the STAND-BY (preheating) phase and the time beyond which STAND-BY is deactivated.

When you select **STAND-BY OPTIONS** with the \downarrow key, you access the following menu:



When you select **STAND-BY MODE**, an additional menu appears where you can set the heating level:



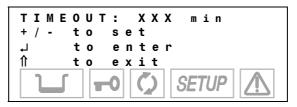
Select **HIGH** (<u>high</u> preheating level) for intense use or, at any rate, to reduce the wait time between one cycle and the next to a minimum.

Select LOW (low preheating) for normal use, since the wait time will be relatively shorter, in any case.

Select **OFF** (<u>deactivate</u> preheating) for occasional use. In this case, the wait time will be longer (up to about 10-12 minutes for a "cold start"). Move using the + and - keys; confirm with the , J key.

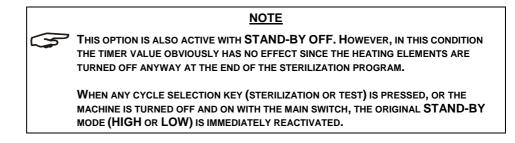
On the other hand, when the **ST-BY TIME-OUT** option is selected, it is possible to set the time for deactivating STAND-BY, i.e., how many minutes after the last cycle the heating elements are turned off.

The following screen appears:



It is possible to set a value between **0** and **300** minutes (in 30-minute increments), after which the heating elements are turned off (a condition analogous to STAND-BY OFF), avoiding the useless consumption of electricity.

Set using the + and - keys; confirm with the \downarrow key.





Setting the printing

mode (PRINT OPTIONS on the ADVANCED menu) When the sterilizer is equipped with a printer (option) for recording sterilization program data, it is necessary to set the parameters required for its proper operation.

1. Select **PRINT OPTIONS** using the J key and the following menu appears:



Select **PRINTER** to select the settings for the printer used, or **REPORT** to set the number of copies to print and to reprint data from the last program executed.

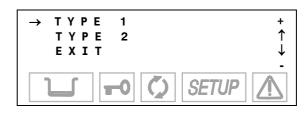
a) Item **PRINTER**

The following screen appears:



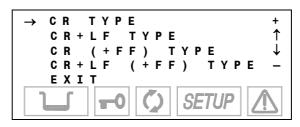
Select OFF to deactivate the printing of data at the end of a sterilization (or test) cycle.

Select **INTERNAL** to enable the thermal printer set (option) inside the front of the sterilizer. In this case, another menu opens:

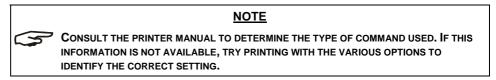


Select Type 1 for the model 1 of the printer installed. Select Type 2 for the model 2 of the printer installed.

If, on the other hand, you choose **EXTERNAL**, the data will be printed on an external peripheral. Following this selection, another menu opens:



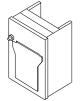
Activate **CR** to use printers that advance the paper only on the CR (*Carriage Return*) command, or **CR+LF** for that require the CR+LF (*Carriage Return* + *Line Feed*) commands, or with **+FF** (Form-Feed) for printers that require the addition of this command.



Printer model 1



Printer model 2





b) Item REPORT

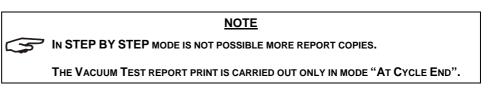
The following screen appears:



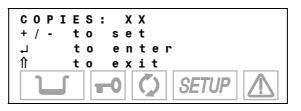
Select item PRINTOUT MODE to chose the mode the data are printed: The following options appear:



Select **AT CYCLE END** to print the report al the end of the cycle. Select **STEP BY STEP** to print the data at each phase of the cycle, as result in the normal printout (see Examples of printed report in Appendix B).



Activate **NR. COPIES** to set the number of copies of the cycle report to print at the end of the program. The following text appears:



Set the number of copies desired (up to a $\underline{maximum}$ of 5). Confirm with the \downarrow key.

On the other hand, the selection **PRINT LAST** reprints the report for the last cycle executed (whether it terminated correctly or was interrupted by an alarm). The following screen appears:



The **NORMAL PRINT** command activates normal printing (that with salient cycle data produced at the end of a correctly executed cycle), while **EXTENDED PRINT** activates complete printing (including all the data typical of a cycle interrupted by an alarm).



NOTE IF THE LAST CYCLE COMPLETED CORRECTLY (OR WAS INTERRUPTED BY MANUAL STOP) IT WILL BE POSSIBLE TO REPRINT IT IN EITHER NORMAL OR EXTENDED MODE. IF THE LAST CYCLE WAS INTERRUPTED BY AN ALARM (MANUAL STOP EXCLUDED) IT ONLY THE **EXTENDED** MODE WILL BE AVAILABLE.

Following the reprint command, this message will be displayed:



which will remain on the screen until printing is finished.

The internal tank can be filled either manually or automatically (option), in the latter case, drawing water from an external device (tank or demineralizer Milldrop connected to the device (see Chapter "Installation").

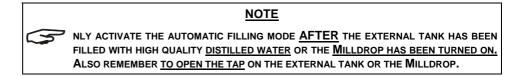
After **FILL OPTIONS** is selected, the following menu appears:



When AUTOMATIC FILL is selected, automatic filling is activated.

In this case, as reached the minimum water level (icon MIN on) in the internal tank, the equipment enable the auxiliary water feeding pump for a pre-set time or a time needed to reach the maximum level (icon MAX on).

When the maximum level (MAX signal) is reached, the automatic system is deactivated.



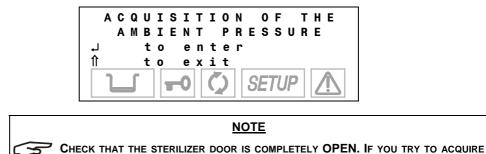
THE PRESSURE WITH THE DOOR <u>CLOSED</u> THE FOLLOWING MESSAGE WILL BE DISPLAYED:

When MANUAL FILL is selected, the internal tank must be filled manually (see the Chapter, "First Start-Up").

Scroll through the items with the + and - keys; confirm with the , key.

The first time the sterilizer is used and after any reinstallation, the sterilizer must acquire the ambient pressure. This operation is necessary or the correct operation of several of the device's auxiliary systems

When AMBIENT PRESSURE is activated, the following screen appears:



Setting the tank filling mode (FILLING OPTIONS on

the ADVANCED menu)

Acquisition of the ambient pressure (AMBIENT PRESSURE on the SPECIAL menu)





which remains until the door is opened.

Confirm the acquisition of the data by pressing the \downarrow key. This message appears:

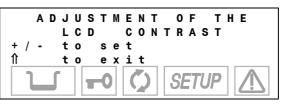


accompanied by a beep. The ambient data pressure has been acquired.

On the other hand, press the ft key to cancel the operation.

The LCD contrast adjustment allow to obtain the screen reading as clear as possible, compensating different sterilizer positioning or ambient brightness.

When LCD CONTRAST is activated, this screen appears:



Press the + key increases the contrast while the - key decreases it.

Place yourself in your usual working position and adjust the contrast until the display is as clear and readable as possible.

Completed the sterilizer configuration, proceed as follows to return in normal mode:

CONFIGURATION MODE

EXIT THE

Adjusting the

crystal display

SPECIAL menu)

contrast of the liquid

(LCD CONTRAST on the

NOTE **S**

? To return to the first level from any current menu level, just select item EXIT OF THE CURRENT MENU AND CONFIRM BY → KEY. ALTERNATIVELY, YOU CAN PRESS ((ESC) KEY ONE OR MORE TIMES.

Select **EXIT** and confirm with the \downarrow key. _ This text appears on the display:

Go to the first-level menu

(see the SETUP layout).



After several seconds, the device returns to normal operation in STAND-BY mode.



The sterilization process can be considered effective, reliable and repeatable so long as the PREPARING THE material is suitably treated first and then correctly arranged in the sterilization chamber in an MATERIAL orderly manner. INTRODUCTION In fact, it should be emphasized that organic residues or deposits of substances used in medical practice are the inevitable receptacles of microorganisms and may obstruct contact between the steam and the walls of the instrument, deactivating, at least locally, the lethal process that sterilization normally provides. On the other hand, an incorrect arrangement of the load can make the circulation and/or penetration of the steam into the material difficult and sometimes impossible with the imaginable consequences. Even the drying process can be strongly influenced by this factor. For this reason, below we provide some basic suggestions regarding these aspects, leaving the user to study the subject further in the most suitable way. TREATING THE First of all, it should be recalled that, when handling and managing contaminated material, it is a good idea to take the following precautions: MATERIAL Wear rubber gloves of adequate thickness; **BEFORE** STERILIZATION Clean your gloved hands with a germicide detergent; Always carry the instruments on a tray. _ Never carry them in your hands; Protect your hands from contact with any sharp points or edges; this will avoid the risk of contracting a dangerous infection; Immediately remove any article that does not need to be sterilized or that is not capable of withstanding the process; Carefully wash your still gloved hands when done handling non-sterile material. All materials and/or instruments to be sterilized must be perfectly clean, without any type of residue (deposits of organic/inorganic material, fragments of paper, cotton/guaze pads, lime, etc.). NOTE IN ADDITION TO CAUSING PROBLEMS DURING STERILIZATION, THE FAILURE TO CLEAN AND REMOVE RESIDUE CAN DAMAGE THE INSTRUMENTS AND/OR THE STERILIZER, ITSELF. An effective cleaning consists of the following: 1. Rinse the instruments under running water immediately after use; 2. Separate metal instruments by type of material (carbon steel, stainless steel, brass, aluminum, chromium, etc.), to avoid electrolytic oxidation-reduction; 3. Wash in an ultrasound cleaner using a mixture of water and germicidal solution, carefully following the manufacturer's recommendations. 4. For best results, use a detergent specifically designed for ultrasound washing, with a neutral pH. NOTE SOLUTIONS CONTAINING PHENOLS OR QUATERNARY AMMONIA COMPOUNDS CAN CAUSE CORROSION ON INSTRUMENTS AND THE METAL PARTS OF ULTRASOUND DEVICES. 5. After washing, carefully rinse the instruments and make sure that residues have been completely eliminated; if necessary, repeat the washing cycle or clean manually. NOTE TO AVOID THE FORMATION OF LIME SPOTS, RINSE WITH DEIONIZED OR DISTILLED WATER, IF POSSIBLE. WHENEVER VERY HARD TAP WATER IS USED, WE RECOMMEND ALWAYS

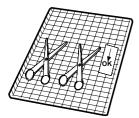
DRYING THE INSTRUMENTS.

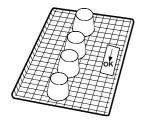


WARNING

CONSULT THE INSTRUCTIONS PROVIDED BY THE MANUFACTURER OF THE INSTRUMENT/MATERIAL TO BE STERILIZED <u>BEFORE</u> SUBJECTING IT TO AUTOCLAVE TREATMENT, CHECKING FOR ANY INCOMPATIBILITIES. SCRUPULOUSLY FOLLOW THE METHODS OF USING DETERGENTS OR DISINFECTANTS AND THE USAGE INSTRUCTIONS OF THE AUTOMATIC DEVICES FOR WASHING AND/OR LUBRICATING THEM.

ARRANGING THE LOAD





Follow the instructions below for the most efficient sterilization process, preserve the material and increase its useful life.

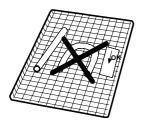
General notes for positioning on trays.

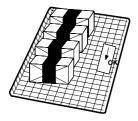
- Arrange instruments made of <u>different</u> metals (stainless steel, tempered steel, aluminum, etc.) on <u>different trays</u> or well <u>separated</u> from each other.
- In the case of instruments <u>not</u> made of stainless steel, place a paper sterilization napkin or a muslin cloth between the tray and the tool, <u>avoiding direct contact</u> between the two different materials;
- In any case, arrange the objects <u>sufficiently distant from each other</u> that they will remain so for the entire sterilization cycle;
- Make sure that all instruments are sterilized in an open position;
- Position <u>cutting instruments</u>, (scissors, scalpels, etc.) so they can <u>not</u> <u>come into contact</u> with each other during sterilization; if necessary, use a cotton or gauze cloth to isolate and protect them;
- Arrange recipients (glasses, cups, test tubes, etc.) resting on their side, or upended, so avoid pooling water;
- <u>Do not</u> load trays beyond their indicated limit (see <u>Appendix A</u>).
- Since this value is understood to be the <u>maximum allowed limit</u>, it can be <u>excessive</u> in some cases, so always use <u>common sense</u>.
- Do not stack trays or put them in direct contact with the walls of the sterilization chamber.
- <u>Always</u> use the tray support provided.
- To insert and extract trays from the sterilization chamber, always use the extractor provided.

<u>NOTE</u>

PLACE A CHEMICAL STERILIZATION INDICATOR ON EVERY TRAY TO INDICATE THAT THE PROCESS HAS OCCURRED: THIS AVOIDS USELESSLY REPROCESSING THE SAME LOAD OR, WORSE, USING <u>NON-STERILIZED MATERIAL</u>. IF PROCESSING <u>WRAPPED MATERIAL</u>, PLACE THE INDICATOR <u>INSIDE</u> ONE OF THE WRAPPINGS.







Notes for rubber and plastic tubing

- Always rinse before use with pyrogen-free water; do not dry them;
- Arrange the tubing on the tray so that their ends are not obstructed or crushed.
- Do not bend or wind them, but allow them to lie as straight as possible.

Notes for packets and packages

- Arrange packages side-by-side, suitably spaced and absolutely <u>not</u> piled, to avoid their coming in contact with the walls of the chamber.
- Whenever it is necessary to wrap particular objects, <u>always</u> use suitably porous material (sterilization paper, muslin napkins, etc.), closing the wrapping with autoclave adhesive tape.

Notes for wrapped material

- Wrap instruments <u>individually</u> or, when more than one instrument are placed in the same wrapping, make sure that they are made of the <u>same metal</u>;
- Seal the wrapping with adhesive tape for autoclaves or heat-sealing machines.
- Do not use staples, pins or other fasteners since they can compromise the maintenance of sterility;
- Arrange the envelopes so as to avoid forming air pockets that obstruct the correct penetration and removal of the steam.
- Orient the envelopes so as to leave the plastic side up and the paper side down (tray side).
- In any case, check that they are correctly positioned, turning them over, if necessary.
- If possible, place the envelopes <u>edgewise</u> to the tray, with a suitable support.
- Never superimpose envelopes on top of each other.

WARNING

WHENEVER YOU ANTICIPATE PROLONGED STORAGE, <u>ALWAYS WRAP</u> THE INSTRUMENTS. SEE THE <u>CHAPTER</u>, "PRESERVING STERILIZED MATERIAL".



INTRODUCTION

PROCEDURE

Program selection is <u>fundamental</u> for a successful sterilization process.

Since each instrument, or material in general, has different shape, consistency and properties, it is important <u>to identify the most suitable program for it</u>, both for preserving its physical characteristics (avoiding or, at any rate, limiting alterations) as well to guarantee the most effective sterilization.

A guide to selecting the most suitable program for the load is provided in <u>Appendix B</u> (Programs)

Power-on the equipment.

NOTE IF A PASSWORD HAS BEEN ENABLED (SEE THE CHAPTER CONFIGURATION - SETTING THE PASSWORD), YOU WILL BE ASKED TO ENTER THE ACCESS CODE:



Enter the password using the + and – keys. Confirm with the J key.

The display does not offer any active preselection. The device is waiting for the user to select a program.

Press the **PROGRAM SELECTION** key one or more times until you reach the desired program (1, 2, 3 or 4, also shown on the upper left of the display).

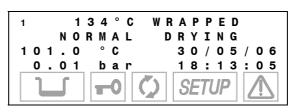


<u>NOTE</u> WHEN THE SELECTION KEY IS PRESSED, THE <u>FIRST STERILIZATION PROGRAM</u> <u>PROPOSED</u> IS THE ONE USED FOR THE <u>LAST CYCLE EXECUTED.</u>

In the two lines above the description, the display shows the <u>description</u> of the selected program and the type of drying set and, below, the set-point values for the temperature (°C), pressure (**bar**) and time (**mm:ss**) of the cycle selected. By way of example, the display shows:

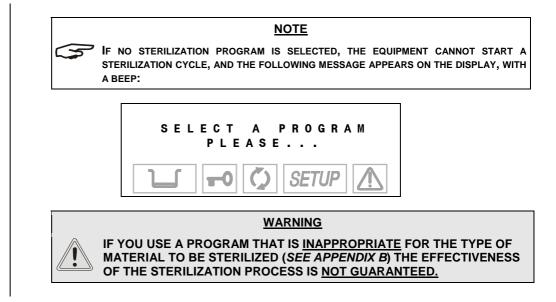


After a brief interval, the display changes and shows the temperature and pressure values of the chamber, with the current date and time.

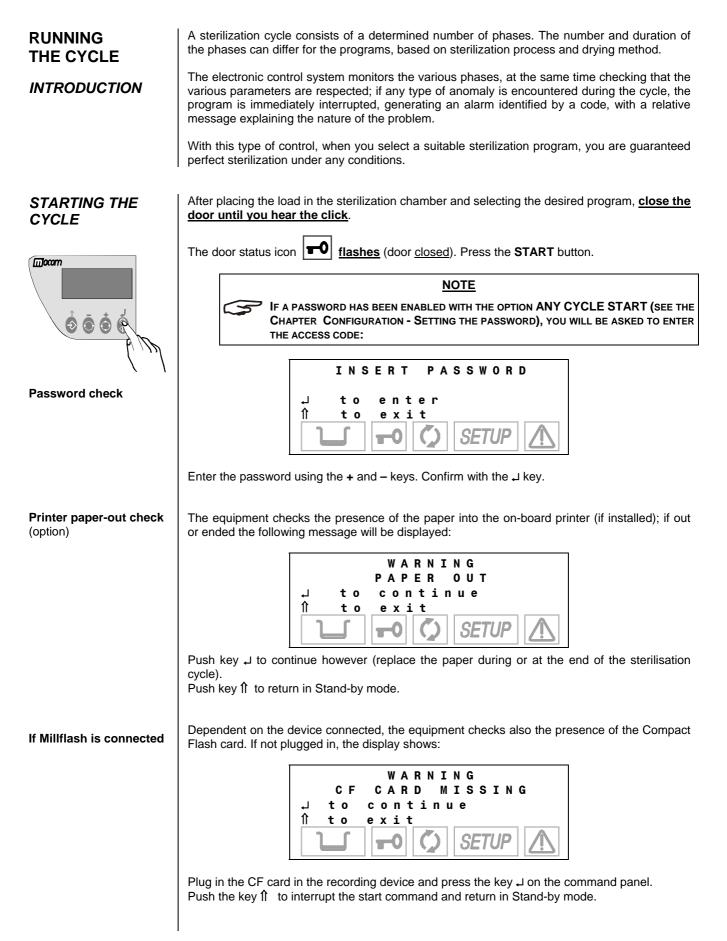


To cancel the selection, press ESC 1 on the control panel.











In case of the card memory full or insufficient to store the new cycle data, the following message will be displayed: WARNING CF CARD FULL continue t o . 1 € t o exit Setup or WARNING MEMORY FULL ontinue t o € exit t o -0 SETU 1 Push key L to continue without recording the cycle data. Push key 1 to interrupt the start command; download the files on PC and delete the memory content according to the instructions of the Millflash Operating Manual. Repeat the Start command. The equipment locks the door. **Door locking** The door status icon remains steady on (door locked). When START is pushed, and for the entire sterilization cycle, the lower lines of the display will show the following parameters: Pressure of the sterilization chamber (bar) Temperature of the sterilization chamber (°C) Progressive time of the sterilization cycle (mm:ss) 134°C WRAPPED 1 WARMUP o 101.9 С 0.01 bar 00:00 The time is counted from the start of the sterilization cycle (first vacuum phase), excluding the preheating phase. PROGRAM Now, we will analyze the execution of a sterilization cycle, phase by phase. **EXECUTION** For our example, let's take the most complete and important cycle, i.e., the program 134 °C WRAPPED. When the START button is pressed, the first phase is PREHEATING, which brings the Preheating chamber to temperature required for starting the cycle. The display shows the following: °C WRAPPED 134 WARMUP o 23.9 С 0.01 00:00 bar SET 1 The icon that shows the status of the sterilization process is off.



Vacuum phase

<u>Rise in</u> pressure

Thermodynamic

equilibrium

When the pre-set vacuum value is reached, steam is injected and the pressure begins to rise, until the established value is reached.

When the optimum temperature is reached, the vacuum phase (VACUUM PULSE) is started

WRAPPED

PULSE

01:25

and brings the chamber pressure down to the established value. The display shows:

134°C

VACUUM

°C

bar

1

84.1



When the pressure and temperature values for the selected program have been reached, the sterilizer waits a moment to allow the temperature in the chamber and the load to stabilize (EQUILIBRATION). The liquid crystal display shows:



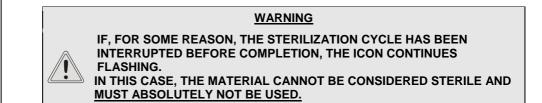
When the thermodynamic parameters are balanced, the actual sterilization phase of the materials begins (HOLDING TIME).

Thanks to continuous monitoring of the thermodynamic parameters and sophisticated management of the plumbing circuit, the pressure and temperature are maintained **<u>constant</u>** within the limits required by the program. The display shows the following:



The icon **<u>flashes</u>** to indicate that the treatment of the load is in progress.

At the end of the sterilization phase, the icon **O** remains <u>steady on</u> to indicate the complete sterilization of the material in the sterilization chamber.



time

Sterilization



Steam discharge

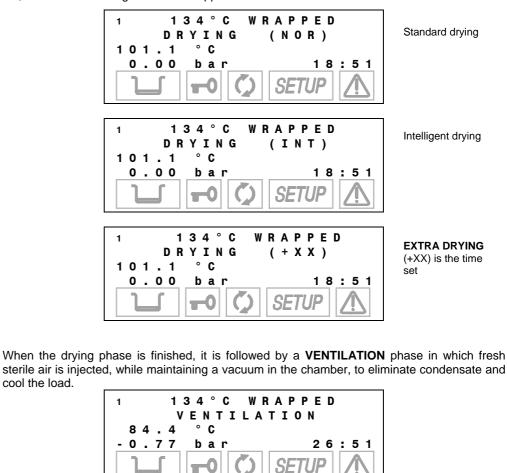
At the end of the sterilization phase, the steam is released from the sterilization chamber (**STEAM DISCHARGE**). The liquid crystal display shows:



The icon for the sterilization process status [1] is steady on.

Drying

After the steam under pressure is released, its forced removal begins with the vacuum pump (**DRYING**): for this purpose, low pressure is created in the sterilization chamber to facilitate the evaporation of the steam and its consequent elimination. As a function of the type of drying set, one of the following screens will appear:

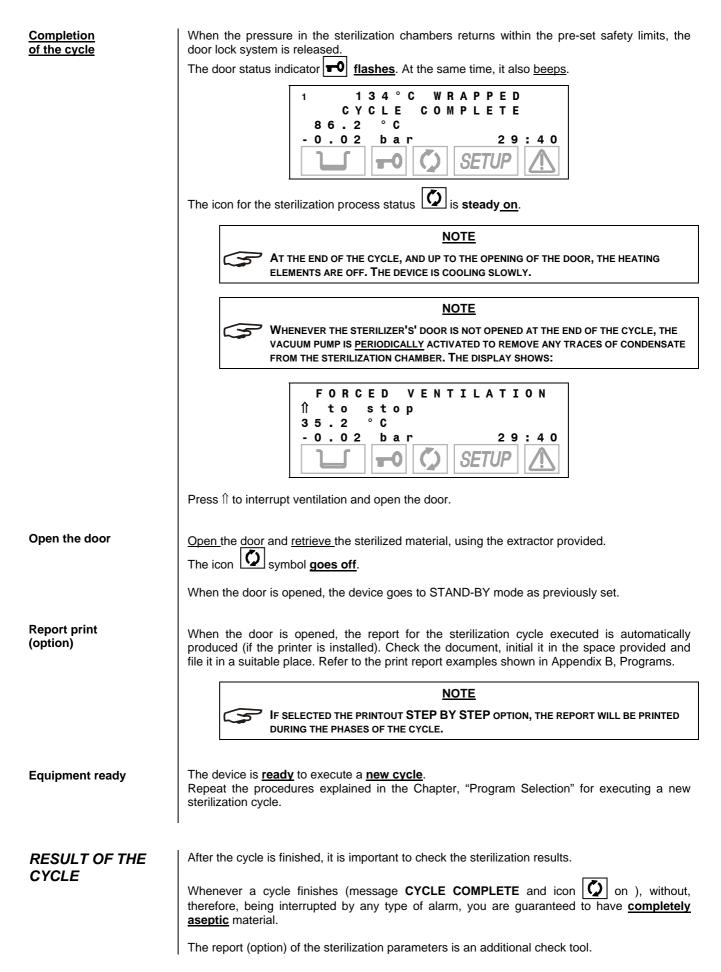


Ventilation

Leveling to the atmospheric pressure

At the end of the ventilation phase, the chamber is brought back to atmospheric pressure (**LEVELLING**) by injecting sterile outside air to allow the opening of the door and the retrieval of the load.







CHECK OF THE CYCLE DATA REPORT (OPTION)

However, it is a good practice to check that the print report issued at the end of the sterilization program, also specifies a positive outcome.

At the end of the cycle, the salient data for the thermodynamic parameters (temperature, pressure and time) of the sterilization cycle, with particular attention to the sterilization phase true and proper, is printed by simply opening the door.

So, check the values on the print report and any additional indications for a further confirmation of the good outcome of the sterilization process.

The operator should sign in the space provided and file the document for possible future use. If necessary, copies of the document can be used to identify the load (or parts of it) with the date/time of sterilization and details of the type of cycle performed.

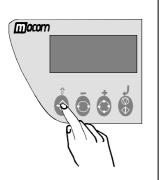


To select the number of copies to print, consult <u>Chapter 6</u>, Configuration - Setting the printing mode.

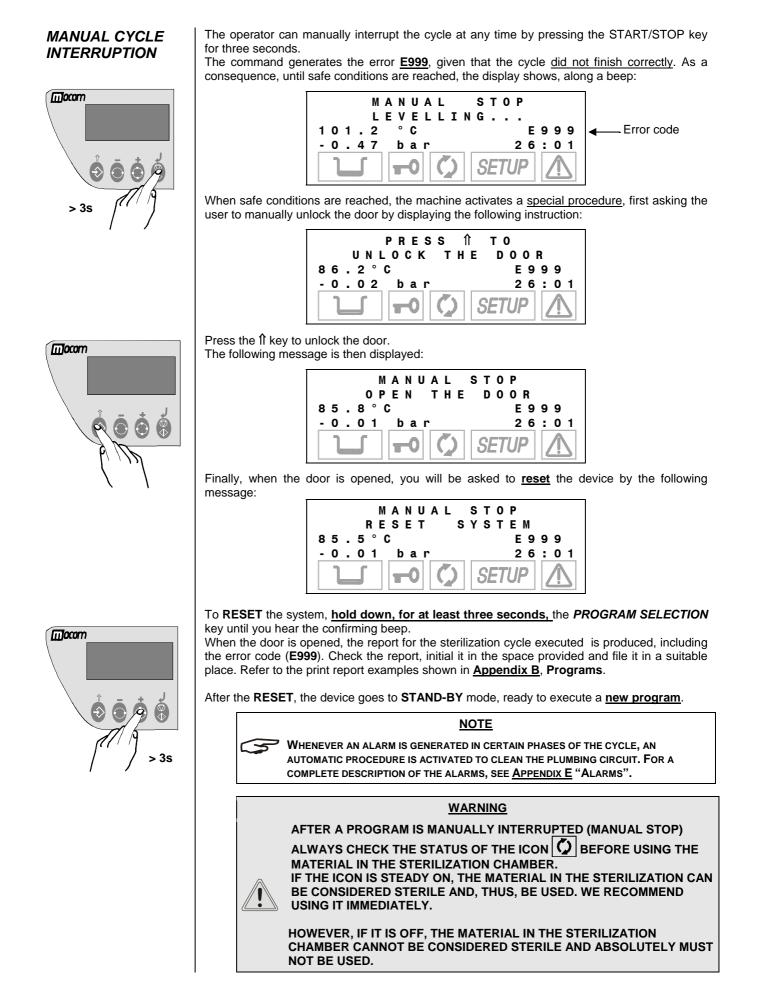
<u>NOTE</u>

Y TO START THIS PRINT FUNCTION, HOLD DOWN THE ÎT (ESC) KEY ON THE CONTROL PANEL WHILE OPENING THE DOOR. THE OPERATOR CAN ALSO REQUEST AN EXTENDED PRINTOUT OF THE STERILIZATION PROCESS DATA, INCLUDING THE RECORDED VALUES OF ALL THE SENSORS INSTALLED ON THE MACHINE.

For complete details about printing the summary, please refer to the report examples shown in <u>Appendix B</u>, Programs.







| $\square O$ | com |
|-------------|-----|
|-------------|-----|

| STORING STERILIZED | The sterilized material must be <u>adequately treated and stored</u> to maintain its sterility over time, until its use. |
|-----------------------|--|
| MATERIALS | Inadequate storage <u>can</u> cause <u>rapid recontamination</u> . |
| INTRODUCTION | This leads to problems regardless of what you do since you will either be using recontaminated material (most of the time unconsciously), placing the user and patient at risk, or you will have to run the sterilization cycle again, with an inevitable waste of time and resources. |
| | For this reason, we think it will be useful to provide several basic suggestions, leaving the operator the task of further study of specific texts. |
| HANDLING | Assuming that the sterilizer is located in a clean place, free of dust and not too damp, the following precautions should be taken when <u>handling</u> and/or <u>carrying</u> sterile material: |
| | 1. Remove the load from the sterilization chamber wearing <u>gloves</u> and a clean, or even better, sterilized <u>smock</u> . As an additional precaution, wear a protective mask on your face; |
| | 2. Rest the tray on a <u>dry</u> , suitably <u>clean</u> and <u>disinfected</u> surface. Take care to <u>distance</u> or, at any rate, <u>separate</u> the sterile material from the area where contaminated material is kept waiting to be sterilized; |
| | Touch the material and/or instruments as little as possible, taking extreme care <u>not</u> to <u>cut</u> or <u>damage</u> the wrappings; |
| | 4. Let the instruments <u>cool</u> before any transport (and subsequent storage). If necessary for transport, transfer the material using dry, clean and disinfected containers. The containers must be <u>closed</u> or, if open, <u>covered</u> with clean cloths. |
| STORAGE | Sterile material waiting for used must be stored using the appropriate techniques. These will significantly <u>slow</u> recontamination: |
| | Store the material and/or instruments in the protective wrappings that were used during sterilization. <u>Do not</u> wrap the instruments <u>after</u> sterilization since, in addition to being useless and completely senseless, is also potentially damaging; |
| | 2. Store the material in a <u>dry</u> , suitably <u>clean</u> and <u>disinfected</u> place, <u>far</u> from the area where infected material passes. If possible, use closed compartments equipped with ultraviolet light; |
| | 3. <u>Identify</u> the sterile material by attaching the sterilization data (attaching a copy of the printed report or an adhesive label); |
| | 4. First use the material that has been stored the longest (FIFO, "First In First Out"). This results in material that is <u>homogeneously stored</u> , avoiding storing for too long, with the consequent risks. |
| | 5. <u>Never</u> store material for <u>too long</u> . In fact, do not overlook the fact that materials will tend to degrade and be recontaminated in a finite time, even when the above instructions are followed. |
| | NOTE |
| | CONSULT THE SPECIFICATIONS PROVIDED BY THE MANUFACTURER OF THE PACKAGING MATERIAL RELATIVE TO THE MAXIMUM ALLOWED STORAGE TIME. |
| | 1 |



TEST PROGRAMS

INTRODUCTION

Millennium \boldsymbol{S}^{2} offers the possibility of, simply and automatically, executing the test program:

Vacuum Test

The **Vacuum Test** program allows checking the perfect seal of the sterilizer's entire plumbing system.

By measuring the variation in the degree of vacuum in a certain span of time and comparing it with pre-set limit values, it is possible to determine the effectiveness of the seal of the sterilization chamber, the various tubes and the cut-off devices.

VACUUM TEST



To select the **VACUUM TEST** program, press the **Test Selection** key one or two times until the display reads:



The Vacuum Test program is run with the **<u>sterilization chamber empty</u>**, and only the trays and their supports.

NOTE

Run the Vacuum Test as the first cycle after powering-on the equipment.

To avoid the heating of the sterilization chamber influencing the variation of the vacuum value measured during the Vacuum Test, the system is programmed to prevent its execution when the temperature sensors of the sterilization chamber shows a value higher than 50° C.

If you try to start the program with a higher temperature than indicated above, the liquid crystal display will read:



After a short time, the device will automatically return to STAND-BY mode, ready for use.

Close the door and start the program with the START key.

NOTE

⁷ IF A PASSWORD HAS BEEN SET WITH THE ANY CYCLE START OPTION (SEE THE CHAPTER, CONFIGURATION, SETTING THE PASSWORD), YOU WILL BE ASKED TO ENTER THE ACCESS CODE. IN ADDITION, THE EQUIPMENT CHECKS THE PRINTER PAPER PRESENCE AND, IF MILLFLASH IS CONNECTED, THE PRESENCE OF THE COMPACT FLASH CARD AND ITS MEMORY CAPACITY.

THE POSSIBLE WARNING MESSAGES, AND THE CONSEQUENT ACTIONS TO CARRY OUT, ARE THE SAME AS DESCRIBED FOR A STANDARD STERILIZATION CYCLE.

The vacuum phase begins <u>immediately</u> and the display shows the pressure (**bar**), and the total time from the start of the program.:





When the pre-set pressure is reached (-0.80 bar) the pump stops and the pressure stabilization phase begins (WAITING PERIOD), which lasts <u>5 minutes</u> (shown on the display as a scalar value):



During this phase, a variation of the maximum low pressure is allowed of <u>not more than 10%</u>, without this causing the test to fail.

When the wait phase ends, the pressure <u>verification</u> phase, true and proper, begins (**LEAKAGE PERIOD**), with a duration of <u>10 minutes</u>:



In this phase, a variation of <u>up to ± 0.02 bar</u> is allowed, compared to the initial phase value. Higher variations cause the test to fail.

When this phase is also completed, the pressure is brought back to atmospheric pressure.



When the program finishes is signaled with a beep, the display will read:





F THE PRESSURE CHANGE EXCEEDS THE PRE-SET LIMIT, THE PROGRAM IS INTERRUPTED AND ALARM MESSAGE IS GENERATED. SEE A COMPLETE DESCRIPTION OF THE ALARMS IN <u>APPENDIX E</u>.

The duration of the test is about 23 minutes.

When the door is opened at the end of the program, a report of the test cycle is printed (if the printer is installed) with all the salient data.

For complete details about printed reports, please refer to the examples shown in <u>Appendix</u> <u>B</u>, Programs.



SUMMARY TABLE

| Device | Steam Sterilizer |
|---|--|
| Classification (as per 93/42/CEE) | 11 |
| Model | millennium S ² |
| Manufacturer | M.O.COM. S.r.I. Via delle Azalee, 1 20090 BUCCINASCO (MI) - ITALY |
| Power supply voltage | 220V – 240 V~ |
| Frequency | 50/60 Hz |
| Mains fuses (6.3 x 32 mm) | F 16A 250V |
| On-board fuses (board type "T") <i>(5 x 20 mm)</i> | F1: T 6,3A 250V(trafo secondary winding)F2: T 3.15A 250V(trafo primary winding)F1 PTR: T 3.15A 250V(printer protection) - option |
| External dimensions (LxDxH) | 480 x 660x 420 mm (excluding rear connections) |
| Nominal power | 2300 W (10A) |
| Insulation class | Class I |
| Installation category | Cat. II |
| Environment of use | Internal use |
| Noise level | <60 db(A) |
| Environmental operating conditions | Temperature:+15 °C ÷ +40 °CRelative humidity:max 80%, non-condensingAltitude:max 3000 m (a.s.l.) |
| Net weight | about 58 kg(empty with trays and support)about 62 kg(empty, with trays and supports and water at MAX level |
| Sterilization chamber dimensions (<i>D x D</i>) | 250 x 450 mm |
| Sterilization chamber total volume | about 21 I (0.021 m ³) |
| Sterilization chamber useful volume (with tray supports inserted) | about 13 I (0.013 m ³) |
| Distilled water tank capacity (supply) | about4.6 I(water at MAX level)about0.8 I(water at MIN level) |
| Sterilization programs | Available:6 (see Appendix B)Pre-sets:4 (direct selection by user) |
| Test programs | Vacuum Test |
| Preheating time (from cold) | about 10 minutes |
| Serial connection | DB-9 pin (female) connector |
| Bacteriological filter (PTFE filtering element) | Porosity: 0.2 μm Connection: male 1/8" NPT connector |



SAFETY DEVICES

The sterilizer is equipped with the following safety devices for which we provide a brief description of their function:

- Mains fuses (see summary table data) Protection inside the device against a fault in the heating elements. Action: cuts the electricity.
- Fuses protecting the electronic circuits (see summary table data) Protection against a fault in the primary transformer circuit and low voltage uses. Action: cuts power to one or more low-voltage circuits.
- Thermal circuit breakers on the mains voltage windings Protection against overheating of the vacuum pump motor and the primary transformer windings. Action: temporary cut-off (until cooling) of the winding.
- Safety valve Protection against overpressure in the sterilization chamber. Action: release of the steam and restoration of the safety pressure.
- Steam generator manual rearm safety thermostat Protection against steam generator overheating. Action: cut-off of the electricity to the steam generator.
- Heating element manual rearm safety thermostat Protection against overheating of the heating elements of the container under pressure. Action: cut-off of the electricity to the chamber heating element.
- Door position safety microswitch Confirmation of the correct closing position of the door of the container under pressure. Action: signals wrong door position.
- Mechanized door lock mechanism with electromechanical protection (pressure switch) Protection against accidental opening of the door (even in a blackout). Action: prevents accidental opening of the door during a program.
- Door lock mechanism safety microswitch Confirmation of the correct closing of the door lock. Action: signaling the failure or incorrect operation of the door lock mechanism.
- Self-leveling plumbing system

Plumbing system structure for the spontaneous leveling of the pressure in the case of a manual interruption of the cycle, alarm or blackout.

Action: automatic restoration of atmospheric pressure in the sterilization chamber.

Integrated system for evaluating the sterilization process Continuous verification of the sterilization process parameters entirely managed by microprocessor. Action: immediate interruption of the program (in case of anomaly) and generation of alarms.

Monitoring of the sterilizer's operation Real-time oversight of all significant parameters when the machine is powered. Action: generation of alarm messages (in the case of anomaly) with possible interruption of the cycle.



WATER SUPPLY CHARACTERISTICS

| DESCRIPTION | WATER SUPPLY VALUES | VALUES IN CONDENSATE |
|---|--|--|
| DRY RESIDUE | < 10 mg/l | < 1 mg/l |
| SILICON OXIDE SIO ₂ | < 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 |
| CHLORINES | < 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 |
| pH VALUE | 5 - 7 | 5 - 7 |
| APPEARANCE | colorless, transparent, without sediments | colorless, transparent, without sediments |
| HARDNESS | < 0.02 mmol/l | < 0.02 mmol/l |

<u>NOTE</u>

WHEN PURCHASING DISTILLED WATER, ALWAYS CHECK THAT THE QUALITY AND CHARACTERISTICS DECLARED BY THE PRODUCER ARE COMPATIBLE WITH THOSE SHOWN IN THE TABLE.

WARNING

THE USE OF WATER FOR GENERATING STEAM CONTAINING CONTAMINANTS IN LEVELS EXCEEDING THOSE SHOWN IN THE TABLE WILL SIGNIFICANTLY SHORTEN THE STERILIZER'S LIFE.

IN ADDITION, THIS MAY INCREASE THE OXIDATION OF MORE SENSITIVE MATERIALS AND INCREASE LIME RESIDUES ON THE GENERATOR, BOILER, INTERNAL SUPPORTS AND INSTRUMENTS.

5



INTRODUCTION

The steam sterilizer is appropriate for almost all materials and instruments, so long as they are able to tolerate, <u>without</u> <u>damage</u>, a **minimum temperature of 121** °C (otherwise, you will need to use other low-temperature sterilization systems).

The following material can <u>normally</u> be sterilized with steam:

- Stainless steel surgical/generic instruments;
- Carbon steel surgical/generic instruments;
- Rotating and/or vibrating instruments driven by compressed air (turbines) or mechanical transmission (counter-angles, tooth scalers);
- Glass articles:
- Mineral-based articles;
- Articles made of heat-resistant plastic;
- Articles made of heat-resistant rubber;
- Heat-resistant textiles;
- Medication materials (gauze, pads, etc.);
- Other generic material suitable for autoclave treatment.

NOTE

DEPENDING ON THE CONFORMATION OF THE MATERIAL, ANY PACKAGING (PAPER/PLASTIC ENVELOPE, STERILIZATION PAPER, MUSLIN NAPKIN, ETC.) AND ITS HEAT-RESISTANCE, IT IS INDISPENSABLE THAT YOU CHOOSE THE APPROPRIATE PROGRAM BY REFERRING TO THE TABLE SHOWN ON THE NEXT PAGE.



WARNING

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



PROGRAM SUMMARY TABLE

| | NO | MINAL | VAL | UES | BASIC PROGRAM PARAMETERS | | | STERILIZABLE MATERIAL | | | | | | |
|------------------------|---------------------|-------------------|-----------------------|--------------------------|--|--------------------------------------|---|--|---|--|------------------------|---------------------------|------------------------------|---|
| PROGRAM DESCRIPTION | Temperature (°C) | Pressure (bar) | Holding time (min) | Cycle type (EN 13060: | Pre-vacuum (F=fractionated; S=single) | Standard drying (L=long; S=short) | Total cycle time (average load ÷ max load) | Average consumption H ₂ O (ml/cycle) | Average energy consumption (kWh/cycle) | ТҮРЕ | MAX TOTAL MASS (kg) | MAX MASS PER TRAY (kg) | MAX MASS PER ARTICLE (kg) | NOTES |
| 134 °C PRION | 134 | 2,10 | >18 | s | S | L | 54÷57 | 410 | 0,7 | Solid instruments in single package | 4,00 | 1,25 | 0,25 | |
| 134 °C WRAPPED | 134 | 2,10 | 4 | s | S | L | 41÷44 | 375 | 0,6 | Solid instruments in single package | 4,00 | 1,25 | 0,25 | We recommend using the 3-tray configuration |
| 121 °C WRAPPED | 121 | 1,10 | 20 | s | S | L | 53÷56 | 400 | 0,6 | Solid instruments in single package | 4,00 | 1,25 | 0,25 | |
| 134 °C SOLID | 134 | 2,10 | 4 | N | S | S | 28÷31 | 375 | 0,5 | Unpackaged solid instruments | 7,50 | 1,50 | 0,50 | |
| 121 °C SOLID | 121 | 1,10 | 20 | Ν | S | S | 41÷44 | 400 | 0,5 | Unpackaged solid instruments | 7,50 | 1,50 | 0,50 | |
| 134 °C EMERGENCY | 134 | 2,10 | 3 | Ν | S | Fast | 18÷21 | 375 | 0,45 | Unpackaged solid instruments | 0,50 | 0,50 | 0,50 | |
| VACUUM TEST | - | -0,80 | - | - | - | - | 23 | - | - | Empty chamber | - | - | - | |

(5 1)

.

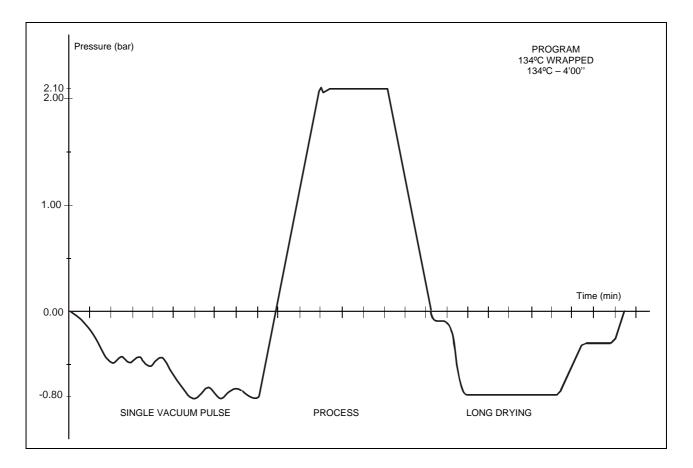
NOTES

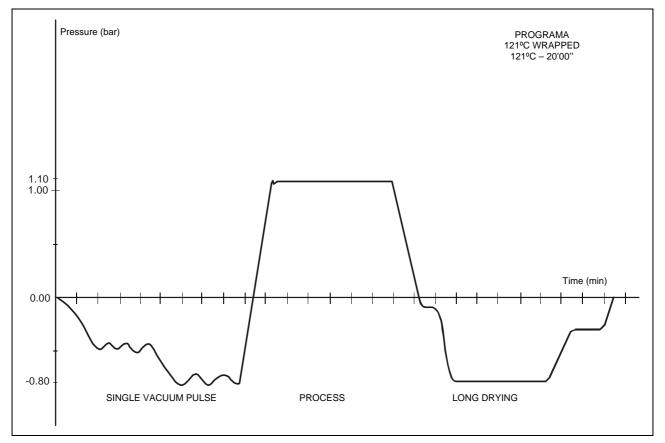
SINGLE = PRE-VACUUM WITH SINGLE VACUUM PULSE (SEE FIGURES IN THE FOLLOWING PAGES)

2) LONG = 14 MINUTES VACUUM DRYING (TYPICAL OF WRAPPED CYCLES) SHORT = 4 MINUTES VACUUM DRYING (TYPICAL OF SOLID CYCLES)

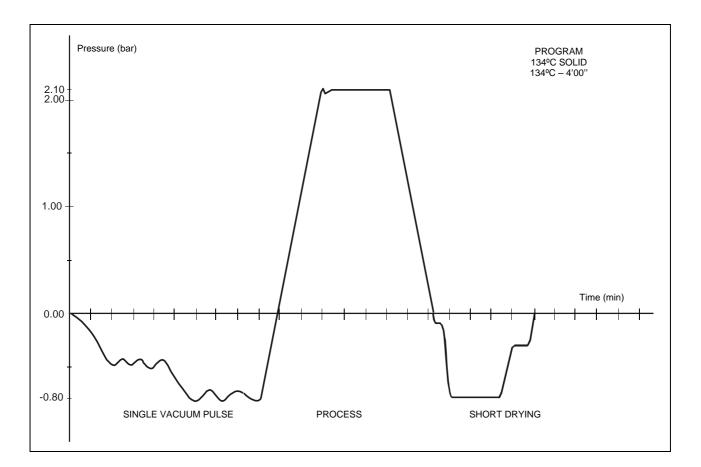


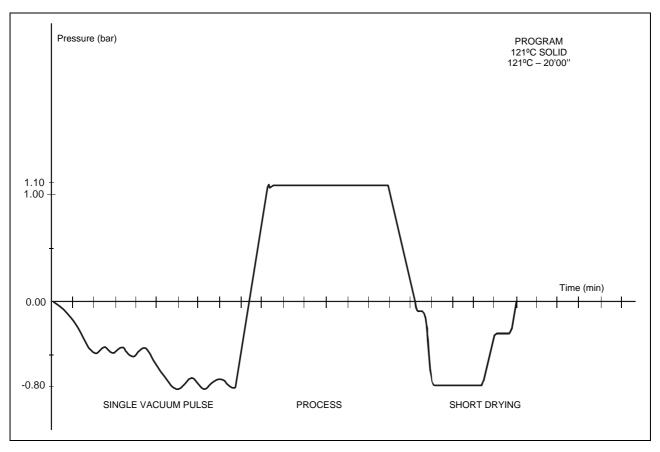
STERILIZATION PROGRAM DIAGRAMS



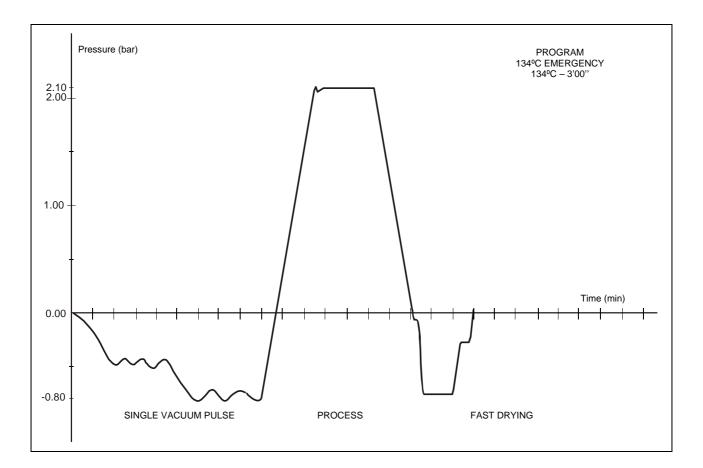


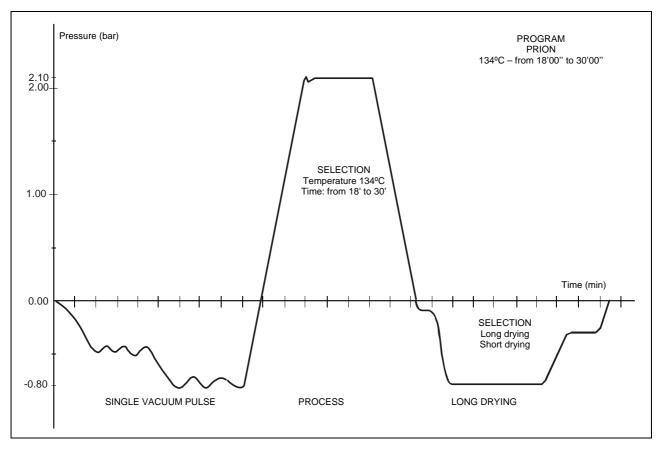






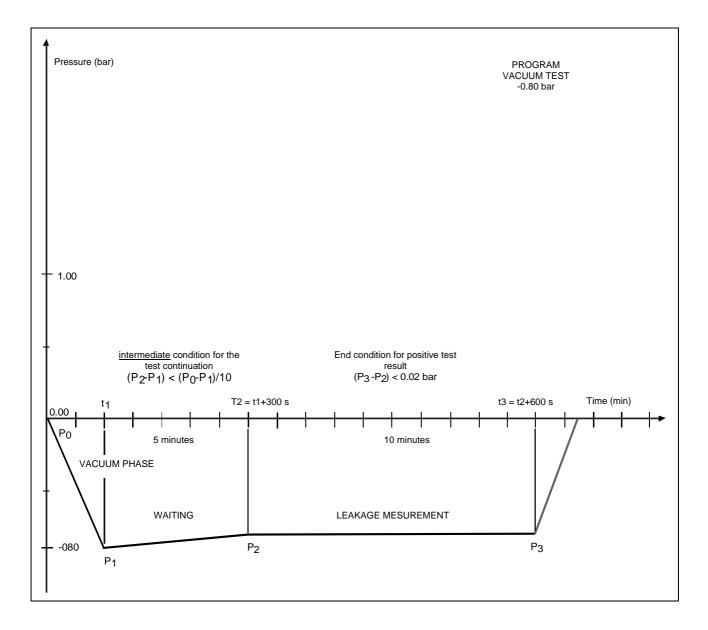








TEST PROGRAM DIAGRAM





EXAMPLES OF PRINTED REPORTS

Cycle Report (normal)

| | - | - | • | - | | | |
|---|--|---|---|--|--|--|--|
| Model S/N Ver. SW Counter Selection Temperatuu Pressure Process tim Stand-by Pre-vacuun Drying | ie | 06 B E100 0009 134° 134° 2.10 4 mir HIGH SINO | MILLENNIUM S2 06 BL 0239 E1002/BL000012 00099/00101 134°C WRAPPED 134°C 2.10 bar 4 min HIGH SINGLE STANDARD | | | | |
| CYCLE ST. | ART | | 09/05/2006 16:48 | | | | |
| Time | | °C | | bar | | | |
| 00:00 05:38 10:19 10:34 11:34 12:34 13:34 14:34 15:33 17:33 30:33 31:33 31:33 | CSV 1PV ET SS SE DS SPD EPD DE CE | 073. 076.0 135.9 135.4 135.4 135.4 135.7 135.7 105.3 085.9 088. 093.0 093.2 | 0 5 3 3 3 7 7 7 3 9 1 6 | -0.02 -0.83 +2.14 +2.13 +2.13 +2.13 +2.14 +2.14 +2.14 +2.14 +2.13 +0.00 -0.07 -0.62 -0.07 -0.03 | | | |
| 10:34 11:42 | MAX MIN | | 135.8 135.6 | | | | |
| Drying Puls CYCLE EN | | | 14 09/05/2006 17:20 | | | | |
| STERILIZA | TION: | POS | POSITIVE | | | | |
| | OPERAT | | | | | | |
| C | ycle Re the ope | port (| exter | nded) | | | |
| Model S/N Ver. SW Counter Selection Temperatuu Pressure Process t ir Stand-by Pre-vacuun Drying | ne | 06 B E100 0009 134° 134° 2.10 4 mir HIGH SINO | Bar า 1 | 0012 1 | | | |
| CYCLE ST. | ART | 09/09 16:48 | 5/2006 3 | | | | |
| Time | PT1 | Р | PT2 | PT3 | | | |
| 00:00 CS 00:10 03 00:20 03 00:30 03 00:40 03 00:50 03 01:20 03 01:50 03 01:20 03 01:52 04 | 0 073.2 0 073.1 0 073.1 0 073.0 0 073.0 0 073.0 0 072.9 0 072.8 | -0.02 -0.09 -0.15 -0.20 -0.25 -0.29 -0.33 -0.41 -0.30 | 161.0 163.2 166.2 169.8 173.3 175.7 177.1 177.9 172.1 | 166.2 165.4 164.6 163.7 162.8 162.0 161.1 159.8 158.9 | | | |

PT4

044.8 045.1 045.4

045.7 046.0 046.3

046.6 047.1

048.1

048.6 049.0

049.4

095.3

097.1 098.7

100.3

118.5

111.8

109.6

172.5 175.1 179.2

144.6 144.8 145.0

145.4

...... 121.7 +0.75 167.2 132.8

109.2 +0.18 167.3 132.3 105.3 +0.00 167.0 132.4

074.6 -0.36 074.9 -0.41 075.0 -0.44

121.0 +1.01 122.5 +1.11 123.9 +1.21 125.3 +1.31

.....

159.0 159.3 159.5

146.3

144.6 142.9

141.3

| 19:13 | 140 | 077.3 | -0.60 | 157.9 | 168.1 | 090.9 |
|---|-----------------------------------|---|--|--|--|---|
| 19:33 19:49 19:59 | 140 140 140 | 073.3 071.3 070.3 | -0.60 | 157.0 156.4 156.0 | 167.2 166.4 165.9 | 089.8 089.0 088.6 |
| 20:09 20:19 20:32 20:42 | 140 140 140 140 140 | 069.5 068.2 067.9 066.6 065.8 | -0.60 -0.63 | 155.6 155.2 154.7 154.3 | 165.3 164.7 163.8 163.3 162.7 | 088.1 087.7 087.1 086.7 086.2 |
| 20:52 21:02 23:29 | 140 140 140 | 065.0 080.8 | -0.68 | 153.9 153.5 148.2 | 162.7 162.3 162.8 | 085.9 080.6 |
| | | | | | | |
| 26:57 | 140 | 085.9 | -0.65 | 141.5 | 163.2 | 075.6 |
| 27:17 27:32 | 140 140 | 085.5 086.9 | -0.60 | 140.8 140.3 | 162.9 162.9 | 075.2 074.9 |
| 29:16 | 140 | 086.2 | | 137.3 | 163.0 | 073.3 |
| 29:36 29:46 | 140 140 | 087.6 087.3 | -0.62 -0.64 | 136.7 136.4 | 162.9 163.1 | 073.0 072.9 |
| 10:34 11:42 | MAX MIN | 135.8 135.6 | | | | |
| Drying CYCLE | | | 14 09/05/2 17:20 | 2006 | | |
| STERIL | IZATIO | N: | POSIT | IVE | | |
| | | OPER | | | | |
| Model S/N Ver. SV Counte Selectio Tempe Pressu Proces Stand-t | r on rature re s time | IVIAI | 06 B E100 0010 | -ENNIUM 2 0239 02/BL000 05/00111 2C WRAF 2C bar n | 012 | |
| Pre-vac Drying | | | SINC STA | GLE NDARD | | |
| CYCLE | START | - | 11/0 09:0 | 5/2006 7 | | |
| Time | | | °C | | bar | |
| 00:00 05:10 08:31 08:46 09:46 10:46 11:46 | | | 079. 085. 135. 135. 135. 135. 135. | 3 5 7 7 8 | -0.02 -0.85 +2.14 +2.14 +2.13 +2.13 +2.14 +2.14 | |
| STERIL | IZATIO | N: | NEG | ATIVE | | |
| ALARM CODE: DESCRIPTION | | | E999 MAN | 9 IUAL STO | OP | |
| DATE TIME | | | 11/0 09:1 | 5/2006 9 | | |
| Please | | AUTION the user | | I | | |
| | | PERATO | | | | |

Report following a Blackout

| S/N Ver. SW Counter Selection Temperati Pressure Process ti Stand-by Pre-vacuu Drying | me | 03 BL 000 Exxxx/BL 0006/001 134c PRI0 134 °C 2.10 bar 18 min HIGH SINGLE FAST | уууууу 2 | | |
|--|-----------------------------|--|-------------------|--|--|
| CYCLE S | TART | 19/05/06 | | | |
| BLACK O | UT | 15:31 19/05/06 | | | |
| STERILIZ | ATION | 15:45 NEGATIV | Έ | | |
| | OPERAT | | | | |
| | | | | | |
| ALARM C DESCRIP | ODE: TION | E000 BLACK-O | UT | | |
| | | | | | |
| Model S/N Ver. SW Counter Selection | | MILLENN 03 BL 000 Exxxx/BL 0011/001 VACUUM |)1 УУУУУУ Э | | |
| CYCLE S | TART | 19/05/06 11:37 | | | |
| Time | | С | bar | | |
| 00:00 | CS | 035.0 | +0.00 | | |
| 01:39 | E1F | 037.4 | -0.80 | | |
| 6:39 | E2F | 038.4 | -0.79 | | |
| 16:39 | E3F | 042.0 | -0.79 | | |
| 17:54 | CE | 045.5 | -0.01 | | |
| CYCLE E | CYCLE END 19/05/06 11:41 | | | | |
| VACUUM TEST: POSITIVE | | | | | |
| | OPERATOR | | | | |

02:02 040 02:12 040 02:22 040

08:16 110 08:26 110

15:04 130

15:24 130

15:33 DS

110

08:26 08:36

08:46 110



In addition to correct use, the user needs to perform ordinary maintenance in order to guarantee safe, efficient operation over the device's entire life.

INTRODUCTION

For better quality maintenance, supplement ordinary checks with regular periodic examinations by the service department (see Appendix Z).

It is also fundamental to perform a <u>periodic sterilizer validation</u>, i.e., a check of the thermodynamic parameters of the process, comparing them with the reference values provided with suitably calibrated instruments. In this regard, see the paragraph, "Periodic Sterilizer's Validation", further below in this Appendix.

The ordinary maintenance described below consists in easy manual operations and preventive interventions involving simple instruments.

<u>WARNING</u>

IN THE EVENT OF THE REPLACEMENT OF THE DEVICE'S COMPONENTS OR PARTS, REQUEST AND/OR USE ORIGINAL REPLACEMENT PARTS

ORDINARY MAINTENANCE PROGRAM

<u>ONLY.</u>

| The table summarizes the | maintenance required to keep the sterilizer operating at peak |
|----------------------------|---|
| efficiency. In the case of | very intense use, we recommend shortening maintenance |
| intervals: | |
| | |

| DAILY | Clean the gasket on the porthole Clean external surfaces |
|--|--|
| WEEKLY | Clean the sterilization chamber and relative accessories Disinfect external surfaces |
| MONTHLY | Clean the internal distilled water tank Safety valve maintenance Clean (or replace) the drain filter |
| EVERY 3-6 MONTHS (depending on frequency of use) | Replace bacteriological filter |
| ANNUALLY | Validate sterilizer (see dedicated paragraph) |

Keep the following general warnings in mind:

- <u>Do not</u> wash the sterilizer with direct jets of water, either under pressure or sprinkled. Seepage into electrical and electronic components could damage the functioning of the device or its internal parts, even irreparably;
- <u>Do not</u> use <u>abrasive cloths</u>, metal <u>brushes</u> (or other aggressive materials) or <u>metal-</u> <u>cleaning products</u>, whether solids or liquids, to clean the device or sterilization chamber;
- <u>Do not</u> use <u>chemical products</u> or <u>disinfectants</u> to clean the sterilization chamber. In fact, these products can damage the sterilization chamber, even irreparably;
- <u>Do not</u> allow <u>lime residue</u> or <u>other substances</u> to accumulate in the sterilization chamber or on the door and its gasket, but periodically remove them. In fact, they can <u>damage</u> these parts over time in addition to <u>compromising</u> the operation of the components installed along the <u>plumbing circuit</u>.

NOTE

THE FORMATION OF WHITE SPOTS ON THE BASE OF THE INTERNAL WALLS OF THE STERILIZATION CHAMBER MEANS THAT YOU ARE USING LOW-QUALITY DEMINERALIZED WATER.



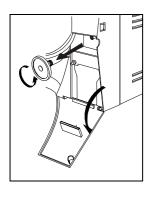
| | DANGER |
|---|--|
| | <u>BEFORE</u> PERFORMING ORDINARY MAINTENANCE, MAKE SURE THAT THE POWER SUPPLY CORD IS REMOVED FROM THE MAINS SOCKET. |
| | WHENEVER IT IS NOT POSSIBLE, PUT IN OFF THE EXTERNAL BREAKER OF THE EQUIPMENT POWER SUPPLY LINE. |
| | IF THE EXTERNAL BREAKER IS <u>FAR AWAY</u> OR, AT ANY RATE, <u>NOT</u> <u>VISIBLE</u> TO THE MAINTAINER, PLACE A WORK IN PROGRESS SIGN ON THE EXTERNAL BREAKER <u>AFTER</u> TURNING IT OFF. |
| | |
| MAINTENANCE DESCRIPTION | With reference to the preceding table, let's take a summary look at the various maintenance to be performed. |
| Clean gasket and porthole | To remove traces of lime, clean the gasket of the container under pressure and the porthole with a clean, cotton cloth soaked in a weak solution of water and vinegar (or similar product, after first checking its contents on the label). |
| | Dry the surfaces and remove any residue before using the device. |
| Clean external surfaces | Clean all the external parts using a clean cotton cloth dampened with water and, possibly, the addition of a neutral detergent. Dry the surfaces and remove any residue before using the device. |
| Clean sterilization chamber and accessories | Clean the sterilization chamber, support and trays (and internal surfaces in general) with a clean cotton cloth soaked in water and, possibly, the addition of a small amount of neutral detergent. Carefully rinse with distilled water, taking care not to leave any type of residue in the chamber or on accessories. |
| | NOTE |
| | DO NOT USE SHARP OR POINTED INSTRUMENTS TO REMOVE LIME ENCRUSTATION FROM THE STERILIZATION CHAMBER. WHENEVER THERE ARE VISIBLE DEPOSITS, IMMEDIATELY CHECK THE QUALITY OF THE DISTILLED WATER USED (SEE <u>APPENDIX A</u> ,). |
| Disinfect external surfaces | For the occasional disinfection of the external surfaces, you can use either denatured alcohol or detergents with a minimum percentage of sodium hypochlorite (or equivalent). |



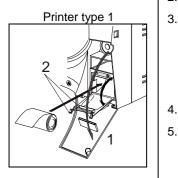
| Clean internal distilled water tank | Arrange an empty container on the floor near the sterilizer and put the free end of a tube into it. Unscrew the plug (1) from the rear draining point and plug-in the other end of the tube. Wait until the internal tank is completely drained; close the draining point with the plug. Prepare 4 liter of distilled water mixed with 10% of pure alcohol and fill the supplied standard container Now fill completely the internal tank with this solution (see chapter "<i>Filling distilled water</i>" for the procedure) and allow the solution to sit for 30 minutes. <u>WARNING</u> DO NOT RUN ANY CYCLE DURING THIS PERIOD. Drain again the internal tank and discard the solution. Close the draining point with the plug. | | | | | |
|-------------------------------------|--|--|--|--|--|--|
| Safety valve maintenance | Access the safety valve located on the rear of the machine. Loosen the knurled locking ring with your fingers (or a suitable tool inserted in the two holes in the ring itself), turning counter-clockwise until it reaches the end and turns loosely. Retighten the locking ring and repeat the operation a couple of times. <u>Definitively</u> tighten the locking ring <u>all the way down</u>. | | | | | |
| | WARNING WARNING THIS OPERATION IS <u>NECESSARY</u> TO GUARANTEE THE CORRECT FUNCTIONING OF THE VALVE OVER TIME. AT THE END OF MAINTENANCE, MAKE SURE THAT THE LOCKING RING IS COMPLETELY SCREWED ON AND TIGHTENED. | | | | | |
| Clean/replace the drain filter | With use, various residues will probably tend to accumulate inside the filter, obstructing the lower drain tube over time. | | | | | |
| | 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 fitting (2) and the filter (3). 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 material of greater dimensions. | | | | | |
| 2 | If the filter cannot be reused, replace it with a new one. | | | | | |
| 3 4 | Plug the filter in the support, block it with a drop of sealing (if available), having care to not obstruct the holes | | | | | |
| | Reassemble all parts following reversely the above procedure, paying attention on screwing down the fitting (2) so as to let the draining holes (4) at level of the chamber wall. | | | | | |



Replace bacteriological filter



Replacing the paper in the printer (option)



When it is due to be changed, or when you notice visible clogging of the filter (indicated by a color markedly tending towards gray) unscrew the bacteriological filter from its support and replace it with a new one by screwing it all the way down on the connector on the front of the machine.

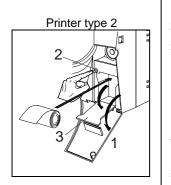


NOTE A REPLACEMENT BACTERIOLOGICAL FILTER IS <u>SUPPLIED</u> WITH THE DEVICE. TO REQUEST OTHERS, PLEASE REFER TO <u>APPENDIX Z</u>, TECHNICAL SUPPORT.

- 1. Open the door of the service compartment to access the printer,
- 2. Push the tongues to open the printer door and access the paper compartment,
- Remove the empty roll and place a new roll of thermal paper so that the paper unrolls 3. off the top;
 - the roll must have the following dimensions:
 - width 57 mm
 - diameter max 45 mm
 - Unroll about 15 cm of paper and close the compartment door,
 - Thread the paper in the slot of door of the service compartment and reclose.
- 1. Open the door of the service compartment to access the printer,
- Push the button on the left to open the printer door and access the paper compartment, 2.
- Remove the empty roll and place a new roll of thermal paper so that the paper unrolls 3. off the top;

the roll must have the following dimensions:

- width 57 mm
- diameter max 45 mm
- 4. Unroll about 15 cm of paper and close the compartment door (the paper will automatically advance outside the window for several centimeters),
- 5. Thread the paper in the slot of door of the service compartment and reclose.





| PERIODIC STERILIZER VALIDATION | As happens with all equipment, it is possible, and sometimes inevitable, to have a decrease in performance and the effectiveness of components along its lifespan, in a period of time dependent on its frequency of use. |
|--------------------------------------|--|
| | To guarantee the safety of the process over time, it is periodically (possibly annually) necessary to <u>verify</u> the <u>thermodynamic process parameters</u> (pressure and temperature), to check if they continue to remain within allowed limits or not. |
| | The requalification of the sterilizer's performance is the responsibility of the user of the product. |
| | The reference European standards EN 554 (<i>Sterilization of the medical devices - Method for the validation and systematic control of the steam sterilization</i>) and EN 556 (<i>Sterilization of the medical devices – Requirements for the medical devices marked with "STERILE" indication</i>) supply an effective guide tool for carrying out the verifications on the steam sterilizers. |
| | Since, in addition to specific experience and training, these controls require the use of special equipment (high-precision sensors and probes, data loggers, dedicated software, etc.) suitably verified and calibrated, it is necessary to contact a <u>company specializing</u> in these activities. |
| | The M.O.COM. Srl customer support department (see Appendix Z) is available to provide any information relative to the periodic validation of steam sterilizers. |
| RECYCLING / DISPOSAL | Millennium S2 is mainly built from fiber-reinforced polymers, metals and electronic components. |
| INSTRUCTIONS | In case of disposal: |
| | - Separate the various components according to the materials they are made of. |
| | - Drop the sterilizer with a company specialized on recycling these products. |
| | - Do not abandon the sterilizer in unsecured places. |

- Always refer to current/applicable laws in the country of use.



INTRODUCTION

If you run into a problem or alarm while using the device, you should <u>not</u> be immediately concerned. It may not, in fact, be related to a breakdown but, more probably to an anomalous situation, often merely transitory (such as a blackout), or incorrect use.

In any case, it is important to first identify the cause of the anomaly and then take suitable corrective action, either autonomously or with the help of the **Technical Support Department (see Appendix Z)**.

For this purpose, below, we provide instructions for diagnosing and resolving general problems, in addition to a precise description of the alarm codes, their meaning and their solution.

ANALYSIS AND RESOLUTION OF PROBLEMS

If your sterilizer is not working correctly, please make the following checks before calling the Technical Support Department:

| PROBLEM | POSSIBLE CAUSE | PROPOSED SOLUTION |
|--|--|---|
| | The power cord is not plugged-in. | Plug it in. |
| | There is no voltage at the socket. | Check the cause of the lack of voltage at and socket and fix it. |
| The sterilizer does <u>not</u> power-on. | The main switch and/or differential switch are OFF. | Turn the switch ON. |
| | | Replace with good fuses of equal nominal value. |
| | The mains fuses are blown. | (See the Summary Table in <u>Appendix A</u> , Technical Characteristics). |
| After pressing START , the sterilization cycle | The device is preheating. | Wait for the sterilizer to reach the proper operating conditions for starting the program. |
| does <u>not</u> start. | The device is preneating. | NOTE: Under normal conditions, the average preheating time is about 10-15 minutes. |
| The MIN water level icon is lit. | The distilled water level inside the tank is below the minimum level. | Fill the distilled water tank until the MAX level indicator comes on (<i>or, at any rate, until the MIN</i> level signal turns off). |
| The alarm icon is lit. | An alarm was triggered, with the generation of the relative code and message (see <i>LCD</i>). | Check the alarm code and take the appropriate action. (See the <i>following paragraphs</i> , <i>Alarms</i> , <i>Alarm Codes</i> and <i>Troubleshooting</i>). |
| The safety valve has intervened. Locking ring loosened. Presence of anomalous overpressure in the chamber. | | Check that the knurled locking ring is correctly tightened on the upper part of the safety valve. |
| At the end of the program (CYCLE COMPLETE), I'm not able to open the door. | There is residual pressure in the sterilization chamber at the end of the cycle. <u>NOTE</u> : the display shows: NOW LEVELLING PLEASE WAIT | Wait several minutes, until the pressure returns to 0.00 bar, and <u>try</u> to open the door again. Check if the bacteriological filter is clogged and, if necessary, replace it with a new one. The procedure for storing the ambient temperature (SET 0 bar function) was not executed correctly. Contact the Technical Support Department (see Appendix Z) |
| | At the end of the cycle, the safety door lock remains on. | Contact the Technical Support Department (see Appendix Z). |



| PROBLEM | POSSIBLE CAUSE | PROPOSED SOLUTION |
|---|---|---|
| | Drain connectors or tubing (option) | Check the tightness of the fittings; if necessary, reassemble, paying more attention to sealing. |
| | not correctly connected to the device. | Check that the tubes to the drain tank are completely pushed onto the connectors; make sure that the plastic ties have been applied. |
| There is water on the support surface of the | The tube for the automatic water | Check the tightness of the connector; if necessary, reassemble, paying greater attention to sealing (see the <i>Chapter, "Installation"</i>). |
| sterilizer. | supply (option) not correctly connected. | Check that the tube coming from the external tank/Milldrop is completely pushed onto the connector; make sure that the plastic tie has been applied. |
| | Steam leaks from the door gasket. | At the end of the cycle, clean the gasket and porthole of the container under pressure. Check if the gasket is damaged. Run another cycle and check the situation. |
| | Drain filter of the sterilization | Clean or replace the drain filter |
| The sterilizer has problems creating a | chamber obstructed. | (See <u>Appendix C</u> "Maintenance"). |
| vacuum in the chamber (drying problems, | Drain circuit obstructed or drain tubes choked (option). | Check that the drain tubes (and the connectors they are pushed onto) are not obstructed and run freely. |
| presence of water in the sterilization chamber at the end of the cycle, | The air intake on the frame and/or the cover are obstructed or the heat | Remove all possible obstructions from the air intake and heat exchanger. |
| etc.). | exchanger is not sufficiently ventilated. | Check that the device is not in direct contact with walls or surfaces (see the <u>Chapter,</u> "Installation"). |
| | Excessive quantity of material inside the sterilization chamber. | Check the quantity of material sterilized and make sure that it does not exceed the maximum allowed quantity, depending on the type of load. |
| | | (See the <i>Summary Table</i> in <u>Appendix A</u> , Technical Characteristics"). |
| Excessive humidity on | Material <u>not</u> correctly positioned. | Position the material, and especially wrapped material, according to the instructions. |
| the material and/or instruments at the end | | (See the <u>Chapter,</u> "Preparing the Material"). |
| of the program. | Wrong sterilization program | Select the appropriate sterilization program for the type of material to be treated. |
| | selection | (See the <i>Summary Table</i> in <u>Appendix B</u> , " Programs "). |
| | Drain filter of the sterilization | Clean or replace the drain filter |
| | chamber obstructed. | (See <u>Appendix C</u> "Maintenance"). |
| | Quality of the instruments is <u>not</u> adequate. | Check the quality of the instruments with the problem, checking whether the material they are made of can tolerate steam sterilization. |
| Traces of oxidation or | Quality of the distilled water not | Empty the tank and fill it with high-quality distilled water. |
| spots on instruments | adequate. | (See the Water Supply Characteristics in <u>Appendix A</u> , "Technical Characteristics"). |
| | Organic or inorganic residues on the instruments | Carefully clean the material before subjecting it to the sterilization cycle. |
| | | (See the <u>Chapter,</u> "Preparing the Material"). |



| PROBLEM | POSSIBLE CAUSE | PROPOSED SOLUTION |
|--|---|--|
| | Contact between instruments made | Separate instruments made of different metals. |
| Traces of oxidation or | of different metals. | (See the <u>Chapter,</u> "Preparing the Material"). |
| spots on instruments (continue) | Lime residue on the wall of the sterilization chamber and/or accessories. | Clean the device and its parts, as required. (See <i>Appendix C</i> " <i>Maintenance</i> "). |
| Blackening of the instruments or damage | Wrong sterilization program | Check the adequacy of the sterilization temperature of the selected program in relation to the material to be treated. |
| to the material. | | (See the <i>Summary Table</i> in <u>Appendix B</u> , " Programs"). |
| | Wrong printer configuration. | Configure the sterilizer for the type of printer used (Configuration program). |
| | | (see the <u>Chapter,</u> "Configuring the Device"). |
| The printer (option) is <u>not</u> printing the | Paper used-up. | Insert a new roll of paper. |
| summary report | | (See <u>Appendix C</u> , "Replacing the Paper"). |
| | Paper jammed. | Clear the jam. Check the dimensions of the roll of paper. (See <u>Appendix C</u> , <i>"Replacing the Paper"</i>). |

<u>NOTE</u>

Should the problem persist, contact the Customer Service (see <u>Appendix Z</u>) providing the <u>model</u> of the sterilizer and the <u>serial number</u>. This information is found on the serial number plate on the rear of the device and on the

WARRANTY CERTIFICATE.



| INTRODUCTION | Every time an anomalous condition occurs during the operation of the sterilizer, an alarm is generated, identified by a specific code (consisting of a letter followed by a 3-digit number). | |
|-----------------------|--|--|
| | Alarm codes are divided into <u>three categories</u> : | |
| | E = <u>ERROR</u> Wrong maneuver and/or use, or a cause external to the device. A problem that can generally be fixed by the user. Code format: Exxx (xxx = identifying number from 000 ÷ 999) A = <u>ALARM</u> <u>First-level</u> fault, <u>not linked</u> to safety. A problem that normally is fixed by a specialized technician on-site. | |
| | Code format: Axxx (xxx = identifying number from 000 ÷ 999) H = <u>HAZARD</u> Second-level fault, <u>linked</u> to safety. A problem generally fixed by the Technical Support Center. Code format: Hxxx (xxx = identifying number from 000 ÷ 999) | |
| ALARM INTERVENTION | NOTE | |
| MILKVLNNON | IN THE CASE OF AN ALARM, PLEASE ONLY REMOVE VOLTAGE FROM THE DEVICE AFTER EXECUTING A RESET (SEE THE PARAGRAPH, "RESETTING THE SYSTEM"). | |
| | The intervention of the <u>alarm</u> causes the interruption of the cycle (or the normal equipment | |
| | operation) with the relative appearance of an alarm code and a message on the display, accompanied by a beep and the lit alarm icon (intermittent). | |
| | NOTE | |
| | DURING THE ALARM PROCEDURE, THE DISPLAY <u>ALWAYS</u> SHOWS THE CURRENT TEMPERATURE AND PRESSURE IN THE STERILIZATION CHAMBER. | |
| | This procedure is designed so as <u>not</u> to allow the user to <u>mistake</u> an anomalous cycle for a correctly completed cycle and, as a consequence, <u>involuntarily using non-sterile material</u> . | |
| | The alarm procedure is <u>differentiated</u> depending on whether it occurs <u>during</u> the execution of the program or <u>outside</u> , and is structured to guide the user to the <u>necessary RESET</u> of the sterilizer. | |
| Alarm during a cycle | If the alarm intervenes during a program, the display will show the message: | |
| | (Alarm Message) LEVELLING 114.6°C XXXX 0.70 bar 11:30 III:50 SETUP | |
| | Whenever an alarm is generated in certain phases of the cycle, an automatic procedure is activated to clean the internal water circuit. The display will contain the notice: | |
| | (Alarm Message) CIRCUIT CLEANING 100.6°C XXXX 0.70 bar 11:40 SETUP (Alarm Code | |

Millennium S²



At the end of what has been described and having reached safe conditions, the machine activates a <u>special procedure</u>, that asks the user to manually unlock the door:



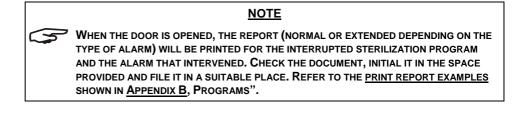
Press the 1 key to unlock the door lock mechanism; the following message appears:

| (Alarm OPEN T | • | , |
|---------------------|---|--------------------|
| 100.8°C 0.01 bar | 1 | X X X X 1 : 4 2 |

Once the door is open, the user is finally asked to reset the system:



Perform a **RESET** (described below) and then turn-off the equipment and check the error or make the repair.



If the alarm intervenes outside the sterilization or test program the display will show:



Turn-off the equipment and check the alarm.

Or, depending on the type of alarm:



Perform a RESET (described below) and then turn-off the device and check the alarm.



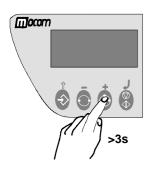
NOTE

ALARMS THAT INTERVENE OUTSIDE OF A PROGRAM <u>DO NOT PRODUCE</u> A PRINTED REPORT.

Alarm outside the cycle



RESETTING THE SYSTEM





The system is **RESET** in <u>two alternative</u> ways, depending on the alarm that occurred (see the **Alarm Code List** *further below in this appendix*):

1. <u>Press the</u> *PROGRAM SELECTION* key for about 3 seconds. *A beep confirms the RESET;*

WARNING



2. <u>Turn-off the device</u> and then power-on using the main switch. Upon power-up, the sterilizer will perform its normal initial test.

After RESET, and any technical intervention necessary to eliminate the fault, the device will go to STAND-BY mode, ready to execute a new program.



ALARM CODES

The list of alarm codes and, consequently, the messages displayed on the LCD and relative RESET mode, is as follows:

| CODE | ALARM DESCRIPTION | LCD INDICATION | RESET MODE |
|-----------------------|--|------------------|-----------------------|
| | ERRORS (cate | egory E) | |
| E 000 | Blackout | BLACK-OUT | |
| E 010 | Door open | DOOR OPEN | _ |
| E 020 | Exceeded timeout for activating door lock system (closing) | DOOR UNLOCKED | |
| E 021 | Exceeded timeout for activating door lock system (opening) | DOOR LOCKED | |
| E 030 | Water in the fill tank at minimum (MIN) level | WATER MIN | |
| E 031 | Water in the drain tank at maximum (MAX) level | EXHAUST MAX | Press key |
| E 041 (option) | Filling the tank too frequently (automatic filling) | FILLING PROBLEM | (> 3 seconds) |
| E 900 | Vacuum Test failed (<i>during the LEAKAGE PHASE</i>) | TEST FAILED | |
| E 901 | Vacuum Test failed (<i>during the WAITING PHASE</i>) | TEST FAILED | |
| E 902 | Vacuum Test failed (vacuum pulse timeout exceeded) | TEST FAILED | |
| E 999 | Manual cycle interruption | MANUAL STOP | |
| | ALARMS (cate | egory A) | |
| A 022 | 2 System door lock microswitches failed (OFF- OFF) LOCKING PROBLEM | | |
| A 023 | System door lock microswitches failed (ON-ON) | LOCKING PROBLEM | |
| A 024 | System door lock microswitches failed (ON-OFF) | LOCKING PROBLEM | |
| A 032 | Sensor-level problem | LEVEL PROBLEM | |
| A 040 | Failure to fill the tank (automatic filling) | FILLING PROBLEM | _ |
| A 101 | PT1 broken (sterilization chamber) | PTC BROKEN | |
| A 102 | PT2 broken (steam generator) | PTC BROKEN | |
| A 103 | PT3 broken (<i>heating element</i>) | PTC BROKEN | Turning-off device |
| A 104 | PT4 broken (sterilization chamber wall) | PTC BROKEN | |
| A 111 | PT1 short-circuited (sterilization chamber) | PTC SHORTCIRCUIT | |
| A 112 | PT2 short-circuited (steam generator) | PTC SHORTCIRCUIT | |
| A 113 | PT3 short-circuited (<i>heating element</i>) | PTC SHORTCIRCUIT | |
| A 114 | PT4 short-circuited (sterilization chamber wall) | PTC SHORTCIRCUIT | |
| A200 | Pre-heating not performed within the timeout (heating resistor problem). | HEATING PROBLEM | |



| CODE | ALARM DESCRIPTION | LCD INDICATION | RESET MODE | |
|-------|---|------------------|-------------------------|--|
| A 250 | 1st vacuum pulse not reached within timeout | PV1 TIMEOUT | | |
| A 251 | 1st rise to atmospheric pressure not reached within timeout | ATM1 TIMEOUT | Press key | |
| A 258 | 3rd pressure pulse not reached within timeout | PPP TIMEOUT | | |
| A 259 | Phase of PROCESS not started within timeout | PROCESS TIMEOUT | (> 3 seconds) | |
| A 260 | Chamber depressurization not completed within timeout | | | |
| | HAZARDS (ca | tegory H) | | |
| H 150 | MPX pressure sensor broken | MPX BROKEN | Turning of t | |
| H 160 | MPX pressure sensor short-circuited/not connected | MPX SHORTCIRCUIT | – Turning-off device | |
| H 400 | Ratio P _{conv} /T not balanced (P _{conv} >T) (<i>Phase PROCESS</i>) | P/T PROBLEM | | |
| H 401 | Ratio T/P _{conv} not balanced (T>P _{conv}) (<i>Phase PROCESS</i>) | T/P PROBLEM | | |
| H 402 | Temperature above MAX limit (<i>Phase PROCESS</i>) | T OVER LIMIT | | |
| H 403 | Temperature below MIN limit (<i>Phase PROCESS</i>) | T UNDER LIMIT | | |
| H 404 | Temperature fluctuating over the limit (<i>Phase PROCESS</i>) | PT1 FLUCTUATING | | |
| H 405 | Pressure above MAX limit (<i>Phase PROCESS</i>) | P OVER LIMIT | Press key | |
| H 406 | Pressure below MIN limit (<i>Phase PROCESS</i>) | P UNDER LIMIT | (> 3 seconds) | |
| H 410 | Wrong maintenance time (Phase PROCESS) | TIMING PROBLEM | | |
| H 990 | Excessive pressure (sterilization chamber, MPX) | OVERPRESSURE | | |
| H 991 | Overheating (sterilization chamber, PT1) | OVERHEATING PT1 | | |
| H 992 | Overheating (steam generator, PT2) | OVERHEATING PT2 | | |
| H 993 | Overheating (band heating element, PT3) | OVERHEATING PT3 | | |



ANALYSIS AND RESOLUTION OF PROBLEMS

Based on the <u>type of alarm</u>, below we provide instructions for identifying the possible causes and restoring correct operation:

| CODE | POSSIBLE CAUSE | PROPOSED SOLUTION |
|--------------------------|---|---|
| | | ERRORS (category E) |
| E 000 | Sudden power failure <i>(blackout)</i> . | Wait for electricity to return and perform RESET following the instructions. |
| | Accidentally turning-off the main switch and/or pulling the plug out of the socket. | Reconnect the plug and/or power-on the device and perform RESET following the instructions. |
| | Mains fuses blown. | Replace with good fuses of equal nominal value. (See the <i>Summary Table</i> in <u>Appendix A</u> , Technical Characteristics "). Turn-on the device and perform RESET following the instructions. |
| E 010 | Door open (or <u>not</u> properly closed) at the start of the program (<i>START</i>). | Perform RESET following the instructions. Close the door <u>properly</u> and restart the program. |
| 2010 | Door position microswitch broken. | Contact the Technical Support Department (see <u>Appendix Z</u>). |
| E 020 | Limit microswitch (<i>CLOSED</i> position) of the door lock mechanism broken. | Perform RESET following the instructions. Try to start the program a second time. |
| | Door lock system gear motor broken. | If the problem persists contact the Technical Support Department (see <u>Appendix Z</u>). |
| E 021 | Limit microswitch (OPEN position) of the door lock mechanism broken. | Perform RESET following the instructions. |
| E 021 | Door lock system gear motor broken. | Contact the Technical Support Department (see <u>Appendix Z</u>). |
| E 030 | Water level in the fill tank below minimum (MIN) level. | Perform RESET following the instructions. Top-off the water until the MAX level indicator comes on (or at least until MIN indicator goes off). |
| | MIN water level indicator broken. | Contact the Technical Support Department (see <u>Appendix Z</u>). |
| E 031 | Level in the used water tank over the MAX. | Perform RESET following the instructions and empty the tank. |
| E 041 (option) | Connection tube between the sterilizer and a possible external filling device not correctly installed. | Perform RESET following the instructions. Check that the water supply tube is correctly and solidly connected to the relative connectors. Eliminate all possible obstructions along the path of the tube. |
| () | Water filling pump broken. | Contact the Technical Support Department |
| | Problem in the plumbing circuit. | (see <u>Appendix Z</u>). |
| E 900 | Air leaking through the gasket | Perform RESET following the instructions. Carefully clean the gasket with a clean cotton cloth dampened with water. |
| | Problem in the plumbing circuit. | Start the program again. Contact the Technical Support Department (see <u>Appendix Z</u>). |



| CODE | POSSIBLE CAUSE | PROPOSED SOLUTION |
|-------|--|--|
| | | Perform RESET following the instructions. |
| | Excessive humidity in the sterilization chamber. | Carefully dry the inside of the sterilization chamber and start the program again. |
| E 901 | | Perform RESET following the instructions. |
| | Air leaking through the gasket | Carefully clean the gasket with a clean cotton cloth dampened with water. |
| | | Start the program again. |
| | Problem in the plumbing circuit. | Contact the Technical Support Department (see <u>Appendix Z</u>). |
| | Excessive humidity in the | Perform RESET following the instructions. |
| | sterilization chamber. | Carefully dry the inside of the sterilization chamber and start the program again. |
| | | Perform RESET following the instructions. |
| E 902 | Air leaking through the gasket | Carefully clean the gasket with a clean cotton cloth dampened with water. |
| | | Start the program again. |
| | Vacuum pump broken. | Contact the Technical Support Department |
| | Problem in the plumbing circuit. | (see <u>Appendix Z</u>). |
| | Manual interruption of sterilization or test program. | Perform RESET following the instructions. |
| E 999 | (Also see the <u>Chapter</u> , "Running | Check that the load has been correctly sterilized (see LCD indicators) |
| | the Program") | before using the material. |
| | | ALARMS (category A) |
| A 022 | Limit microswitch(es) on the door lock mechanism broken. | Contact the Technical Support Department (see <u>Appendix Z</u>). |
| A 023 | Limit microswitch(es) on the door lock mechanism broken. | |
| A 024 | Limit microswitch(es) on the door lock mechanism broken. | |
| A 032 | Connector of the water level indicators not connected. | |
| | Level indicator(s) broken. | |
| A 101 | Chamber temperature sensor (PT1) broken. | |
| A 102 | Steam generator temperature sensor (PT2) broken. | |
| A 103 | Heating element temperature sensor (PT3) broken. | |
| A 104 | Chamber wall temperature sensor (PT4) broken. | |
| A 111 | Incorrect connection of the temperature sensor (sterilization chamber) to the connector. | |
| | Temperature sensor short circuit (sterilization chamber). | |
| A 112 | Incorrect connection of the temperature sensor (steam generator) to the connector. | |
| | Temperature sensor short circuit | |
| | (steam generator). | |



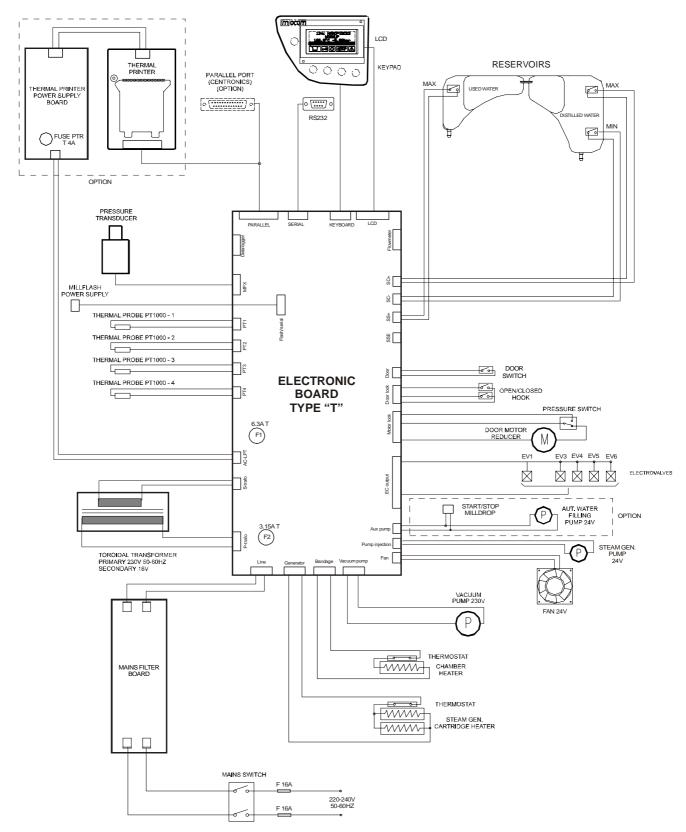
| A 113 | Incorrect connection of the temperature sensor (heating element) to the connector. Temperature sensor short circuit (heating element). | |
|-------|---|--|
| A 114 | Incorrect connection of the temperature sensor (chamber wall) to the connector. | |
| | Temperature sensor short circuit (chamber wall). | |
| | Intervention of the steam generator safety thermostat. | <u>Manually rearm</u> the thermostat(s) located on the back of the device (see the <u>Chapter,</u> "Product Introduction"). |
| A 200 | Intervention of the heating element safety thermostat. | Unscrew the black plastic protection cap, press the <u>red button</u> until you hear a click and replace the cap. |
| | Heating or steam generator heating element malfunction. | Turn-off (RESET) and then turn-on the device. If the problem persists contact the Technical Support Department (see <u>Appendix Z</u>). |
| | Presence of water or condensate in the sterilization chamber. | Perform RESET following the instructions. Carefully dry the inside of the sterilization chamber and start the program again. <u>Do not</u> put material impregnated with water, or liquids in general, in the chamber. |
| A 250 | Drain filter of the sterilization chamber obstructed. | <u>Clean</u> or <u>replace</u> the drain filter (See <u>Appendix C</u> "Maintenance"). |
| | Air leaking through the gasket. | Perform RESET following the instructions. Carefully clean the gasket with a clean cotton cloth dampened with water. Start the program again. |
| | Vacuum pump broken. | |
| | Problem in the plumbing circuit. | Contact the Technical Support Department (see <u>Appendix Z</u>). |
| | Water injection pump malfunction. | Contact the Technical Support Department (and Annondia 2) |
| | Problem in the plumbing circuit. | Contact the Technical Support Department (see <u>Appendix Z</u>). |
| A 251 | Intervention of the steam generator safety thermostat. | |
| | Heating element safety thermostat intervened. | See A 200. Contact the Technical Support Department (see <u>Appendix Z</u>). |
| | Heating or steam generator heating element malfunction. | |
| | Steam leaking through the gasket. | Perform RESET following the instructions. Carefully clean the gasket with a clean cotton cloth dampened with water and start the program again. |
| | | Perform RESET following the instructions. |
| A 258 | Excessive load. | Check the quantity of the material in the sterilization chamber and make sure that it does not exceed the maximum allowed. |
| | | (See the Summary Table in <u>Appendix A</u> , Technical Characteristics). |
| | Problem in the plumbing circuit. | Contact the <u>Technical Support Department</u> (see <u>Appendix Z</u>). |



| CODE | POSSIBLE CAUSE | PROPOSED SOLUTION |
|--------|---|--|
| | | Perform RESET following the instructions. |
| | Excessive load. | Check the quantity of the material in the sterilization chamber and make sure that it does not exceed the maximum allowed. |
| A 259 | | (See the Summary Table in <u>Appendix A</u> , Technical Characteristics). |
| A 233 | | Perform RESET following the instructions. |
| | Steam leaking through the gasket. | Carefully clean the gasket with a clean cotton cloth dampened with water and start the program again. |
| | Problem in the plumbing circuit. | Contact the Technical Support Department |
| A 260 | Problem in the plumbing circuit. | (see <u>Appendix Z</u>). |
| | | HAZARDS (category H) |
| H 150 | Pressure sensor (MPX) broken. | |
| H 160 | Incorrect connection of the pressure sensor (MPX) to the connector. | |
| | Pressure sensor (MPX) short circuit. | |
| H 400 | Problem in the plumbing circuit. | |
| H 401 | Problem in the plumbing circuit. | |
| H 402 | Steam generator malfunction. | |
| | Problem in the plumbing circuit. | |
| H 403 | Steam generator malfunction. | |
| 11 400 | Problem in the plumbing circuit. | Contact the Technical Support Department |
| H 404 | Problem in the plumbing circuit. | (see <u>Appendix Z</u>). |
| 11 404 | Steam generator malfunction. | |
| H 405 | Problem in the plumbing circuit. | |
| | Steam generator malfunction. | |
| H 406 | Problem in the plumbing circuit. | |
| | Steam generator malfunction. | |
| H 410 | Timer problem | |
| H 990 | General operating problem. | |
| H 991 | General operating problem. | |
| H 992 | General operating problem. | |
| H 993 | General operating problem. | |

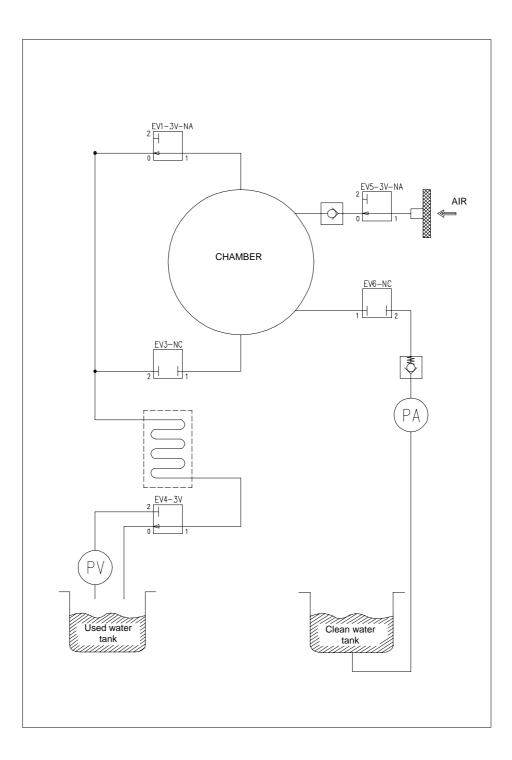


ELECTRICAL DIAGRAM (BOARD TYPE "T")





PLUMBING DIAGRAM





| Sistemi innovativi di sterilizzazione | DECLARATION OF CONFORMITY Application of Directives 93/42/CEE - 89/336/CEE - 73/23/CEE | |
|---------------------------------------|---|--|
| Manufacturer's Name: | M.O.COM. S.r.I Manufacture of Dental Accessories | |
| Manufacturer's Address: | Via delle Azalee, 1 - 20090 Buccinasco (MI) - ITALY | |
| Product description: | Steam sterilizer | |
| Model: | millennium S ² | |
| Constructed in: | ITALY | |
| | The undersigned declares that the above material | |
| | conforms | |
| to the | EEC Directives 93/42 - 89/336 - 73/23 (and following updates). | |
| 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 EN 60555-3 EN 61000-4-2 EN 61000-4-3 EN 61000-4-4 EN 61000-4-5 EN 61000-4-6 EN 61000-4-8 EN 61000-4-11 ENV 50204 EN 13060 | |
| 31/05/2006 | t. Qua | |
| 51/05/2000 | / | |
| Date | Signature | |
| | Signature <u>Alfio VILLA</u> Name and Surname | |



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FOR ANY REQUEST FOR TECHNICAL SERVICE FOR THE PRODUCT, WHETHER IN OR OUT OF WARRANTY, DIRECTLY CONTACT THE

TECHNICAL SUPPORT DEPARTMENT

OF THE DEALER OR RESELLER THAT SUPPLIED THE PRODUCT.

M.O.COM. Srl is completely available to customers to provide any technical information about the product as well as to offer suggestions and advice on steam sterilization procedures.

In this regard, please refer to the following address:

M.O.COM. Srl Customer Support Via delle Azalee, 1 20090 Buccinasco (MI) ITALY Tel. (+39) 02-45701505 Fax (+39) 02-45701258 e-mail <u>at@mocom.it</u> website <u>www.mocom.it</u>

To help us in the indispensable work of <u>improving</u> the quality of our products and service, please send your comments and/or suggestions to the following **e-mail** address:

uc@mocom.it

(Commercial / Sales Department)

Or, you can send a letter or fax to the above address.

Thank you in advance for your valuable assistance.