cod. D#0BXAB0000X

mocom®

NOT JUST AN ORDINARY STERILISER

Exacta S

Exacta S²

ISTRUZIONI PER L'USO
OPERATING INSTRUCTION
INSTRUCTION DE SERVICE
GEBRAUCHSANWEISUNG
INSTRUCCIONES DE OPERACIÓN

REVISIONS

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

Code	Ed.	Rev.	Date	Description
D#0BXAB0000X	1	0	08-03-2010	First issue (translation from the original in Italian)
D#0BXAB0000X	1	1	23/03/2010	Application of the EEC Directive 93/42 and subsequent changes.
D#0BXAB0000X	1	2	07/04/2010	Declaration of conformity

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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.

Symbols used in the manual

NOTE

PAY SPECIAL ATTENTION TO PARAGRAPHS INDICATED BY THE POINTING FINGER.

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

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.

THE MATERIAL THE STERILIZER IS COMPOSED OF MUST BE DISPOSED ACCORDING TO THE DIRECTIVE 2002/96/CEE

APPLICABLE EUROPEAN DIRECTIVES

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

2006/95/CE, for the approximation to the legislation of the Members States related to low voltage equipment.

2004/108/CE, for the approximation to the legislation of the Members States related to the electromagnetic compatibility.

93/42/EEC - and subsequent changes, concerning the medical devices.

INTENDED USE

The product described in this manual is exclusively intended for the sterilization of re-usable instruments.

WARNING

THE DEVICE MUST ONLY BE USED BY QUALIFIED PERSONNEL. IT MAY NOT BE USED OR HANDLED BY INEXPERT AND/OR UNAUTHORIZED PERSONNEL FOR ANY REASON.
THIS DEVICE MUST NOT BE USED FOR THE STERILIZATION OF FLUIDS, LIQUIDS OR PHARMACEUTICAL PRODUCTS.

NOTE

THE MANUAL INFORMATION ARE SUBJECT TO CHANGES WITHOUT ANY NOTICE. MO.COM. LTD. CO. WON'T BE RESPONSIBLE FOR DIRECT, INDIRECT, ACCIDENTAL, CONSEQUENT DAMAGES OR OTHER DAMAGES RELATED TO THE SUPPLY OR THE USE OF SUCH INFORMATION.

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, **always** follow the instructions in the manual and never use for anything other than its intended purpose.

WARNING

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.

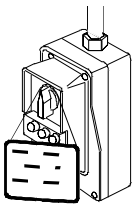
Please observe the following precautions in order to avoid injury or property damage:

– Use **ONLY distilled water** of high quality.

WARNING

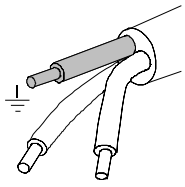
THE USE OF WATER OF INADEQUATE QUALITY CAN SEVERELY DAMAGE THE DEVICE.
SEE APPENDIX A, TECHNICAL CHARACTERISTICS IN THIS REGARD .

– **Do not** pour water or other liquids on the device;
– **Do not** 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 **only original replacement parts**.

WARNING

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

CONTENTS OF THE PACKAGE

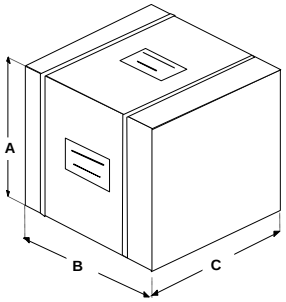
DIMENSIONS AND WEIGHT

NOTE

CHECK THE INTEGRITY OF THE PACKAGE UPON RECEIPT.

Once the package is opened, check that:

- la fornitura corrisponda alle specifiche dell'ordine (vedi documento di accompagnamento);
- non vi siano danni evidenti al prodotto;

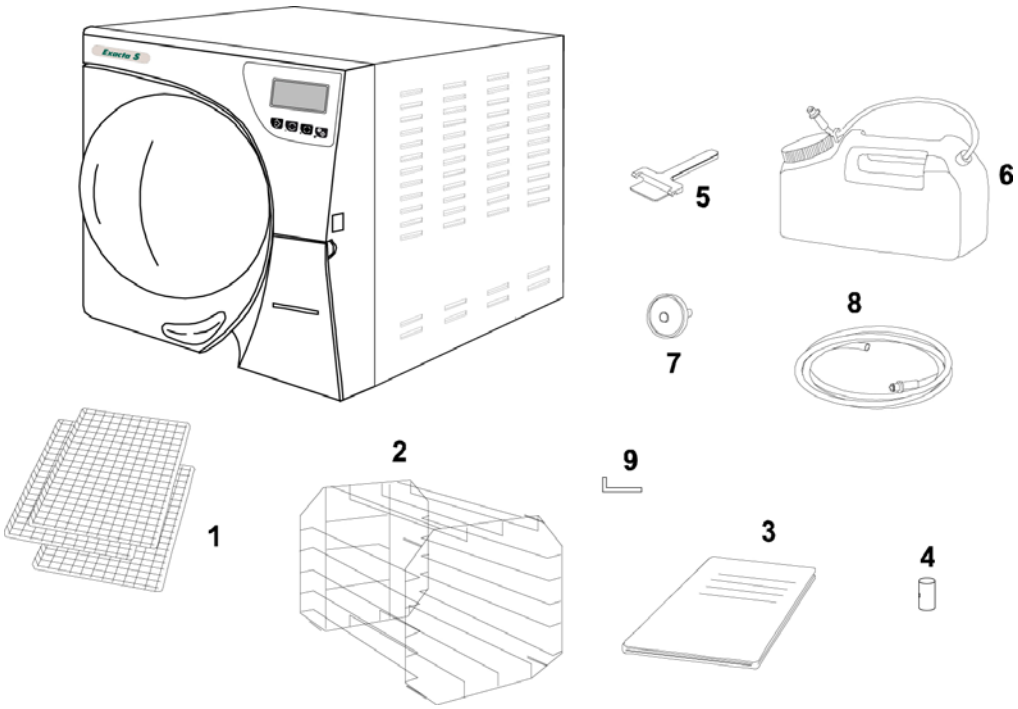


Dimensioni e peso	**S**	**S^2**
A. Height	600 mm	600 mm
B. Width	580 mm	580 mm
C. Depth	700 mm	800 mm
Total weight	62 kg	68 kg

NOTE

IN THE CASE OF A WRONG PRODUCT, MISSING PARTS OR ANY TYPE OF DAMAGE, IMMEDIATELY PROVIDE A DETAILED DESCRIPTION TO THE RESELLER AND THE TRANSPORTER THAT MADE THE DELIVERY.

DESCRIPTION OF THE CONTENTS



The package contains:

1 Stainless steel wire instrument tray (3 pcs.);
2 Stainless steel wire tray support;
3 Operating documentation;
4 Exhaust filter;
5 Tray extractor;
6 Container with quick connector for adding distilled water (about 2 l);
7 Extra bacteriological filter;
8 Silicone tube (2 m) for draining water, with quick connector.
9 Allen key.

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.

WARNING

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

INTRODUCTION

Exacta 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.

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

Exacta is a completely microprocessor-controlled steam sterilizer with a large (17-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 a fast process and excellent stability of the thermodynamic parameters.
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).

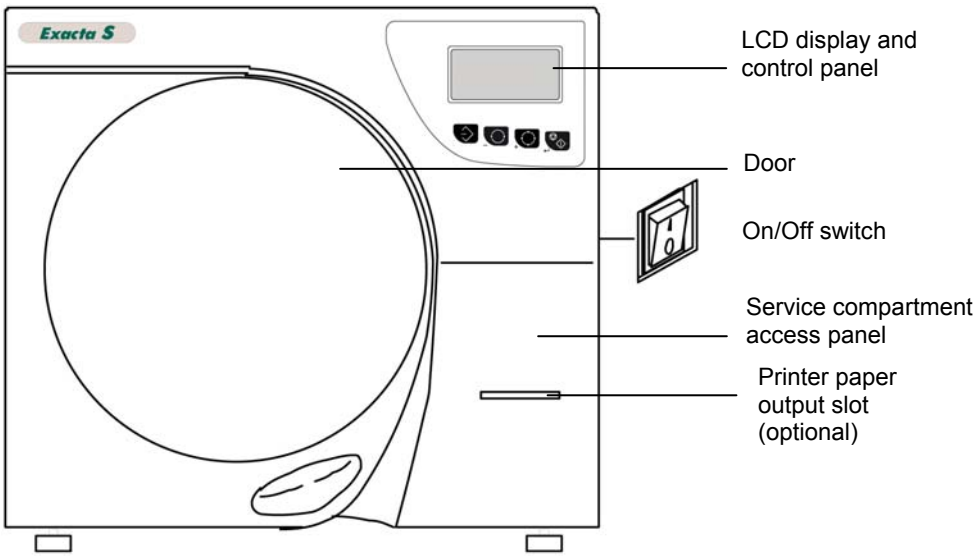
Please refer to the chapters “**Installation**” and “**Configuration”** for more details.

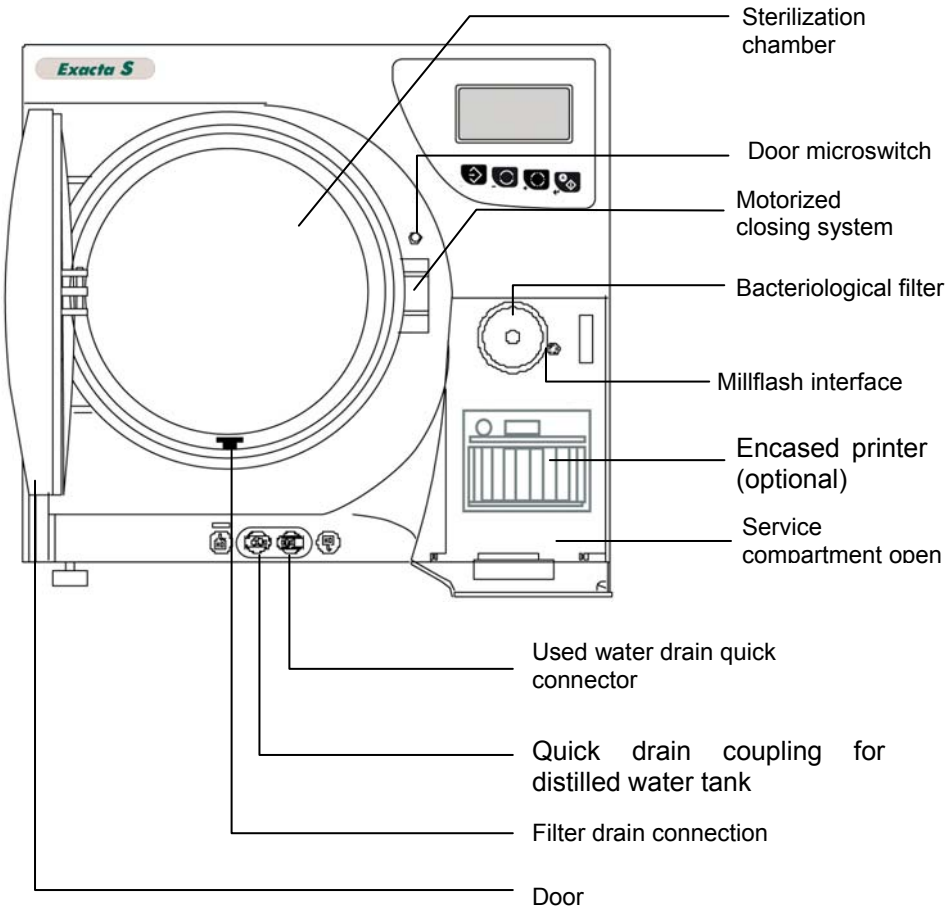
Finally, **Exacta** has one of the most complete, sophisticated and advanced safety systems available today to protect users in the case of any electrical, mechanical, thermal or biological operating anomaly.

NOTE

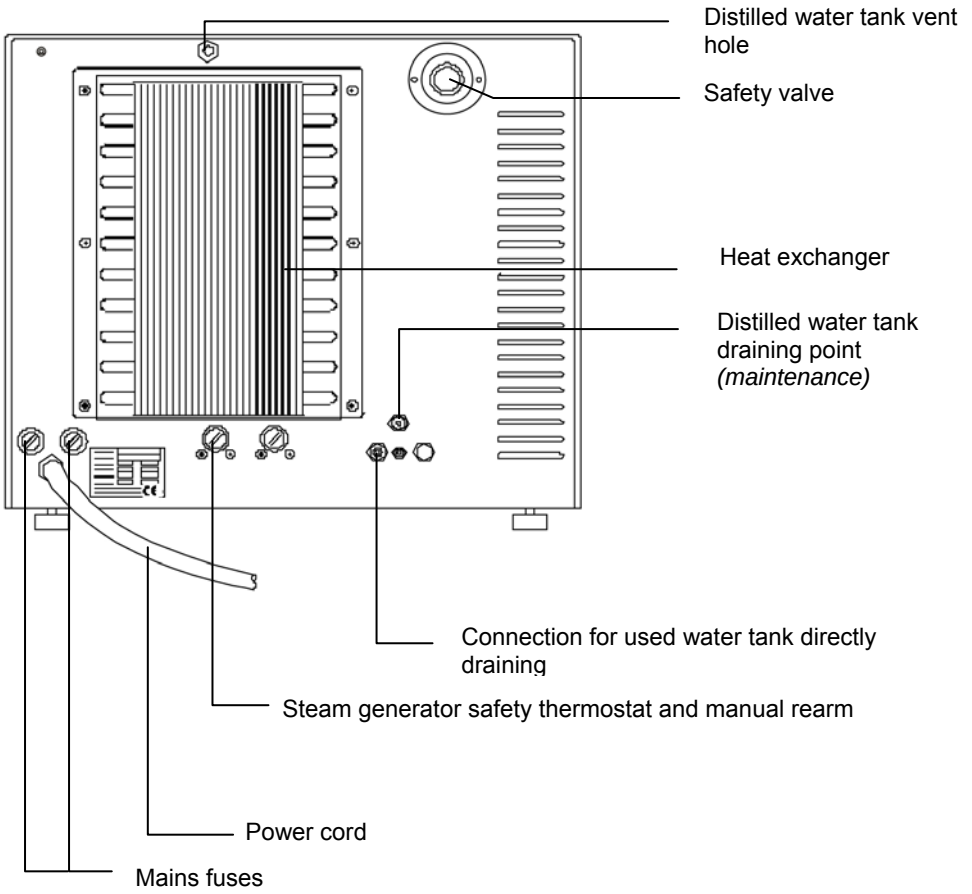
PLEASE REFER TO APPENDIX A (TECHNICAL CHARACTERISTICS) FOR A DESCRIPTION OF THE SAFETY DEVICES.

FRONT

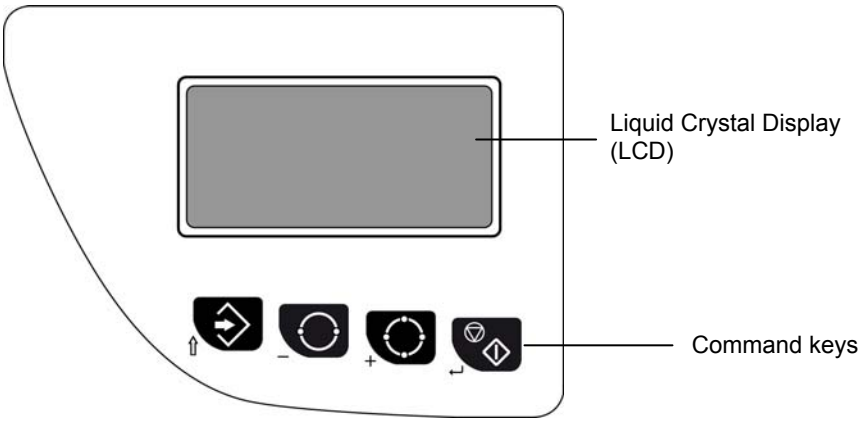

Exacta S
LCD display and control panel
Door
On/Off switch
Service compartment access panel
Printer paper output slot (optional)


Exacta S
Sterilization chamber
Door microswitch
Motorized closing system
Bacteriological filter
Millflash interface
Encased printer (optional)
Service compartment open
Used water drain quick connector
Quick drain coupling for distilled water tank
Filter drain connection
Door

REAR


Distilled water tank vent hole
Safety valve
Heat exchanger
Distilled water tank draining point *(maintenance)*
Connection for used water tank directly draining
Steam generator safety thermostat and manual rearm
Power cord
Mains fuses

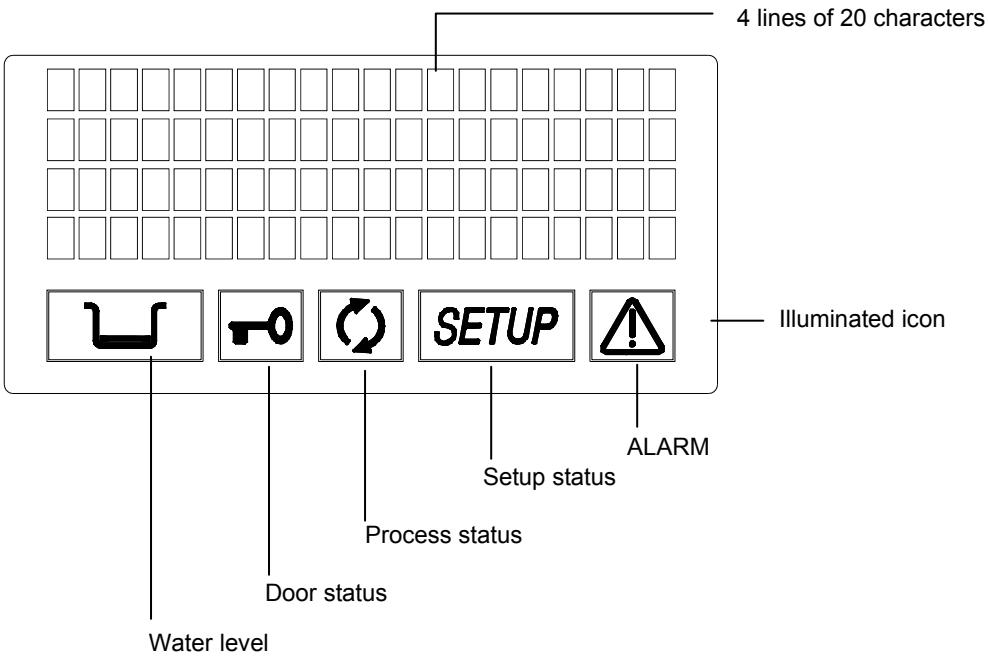
CONTROL PANEL



The function of the command keys differ according to operating mode of the equipment.

Key	NORMAL mode	SETUP mode
	Cycle Start/Stop	**Enter**, confirmation of the value/option selected
	Sterilization cycle selection	**Value increment** / **Forward scroll** of the menu options
	Test cycle selection	**Value decrement / Backward scroll** of the menu options
	Enter **Setup** mode	**ESC**, quit the current menu

LCD DISPLAY



OPERATING CYCLE EXAMPLE

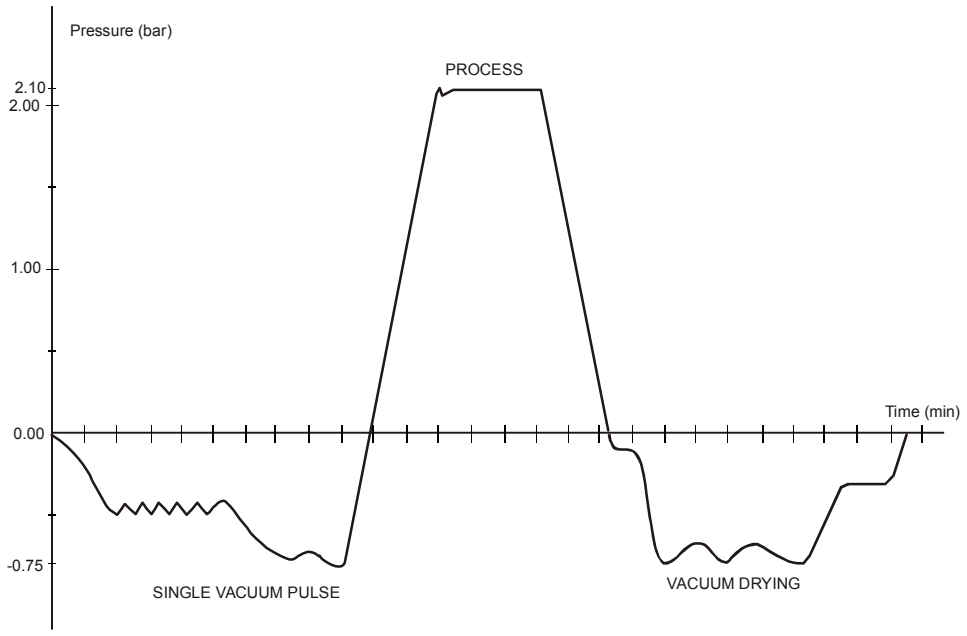
The **Exacta** sterilization program can be described as a succession of phases, each with a specific purpose.

For example, the standard program (for wrapped materials, 134 °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.



NOTE

PLEASE REFER TO APPENDIX B (PROGRAMS) FOR MORE DETAIL.

INSTALLATION

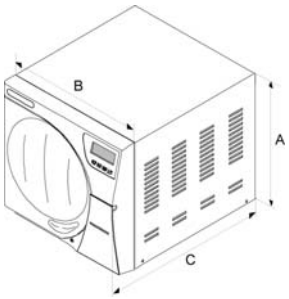
INTRODUCTION

The first and fundamental step in achieving good sterilizer operation, long life and complete 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 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	**S**	**S^2**
A. Height (total)	420 mm	420 mm
B. Width (total)	480 mm	480 mm
C. Depth (excluding rear connections)	560 mm	660 mm
Total weight	53 kg	58 kg

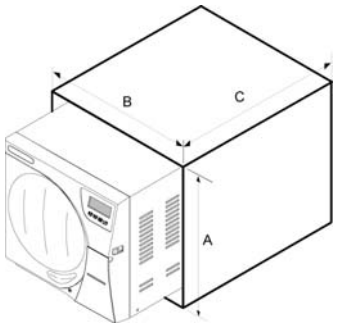


Electricity
The electrical system to which the sterilizer will be connected must be suitably dimensioned based on the electrical characteristics of the device. This information is shown on the **back of the machine.**

COMPARTMENT DIMENSIONS FOR BUILT-IN INSTALLATIONS

When installing the sterilizer inside a cabinet, you must provide adequate space all around the device (> 10cm, specially on the rear side) to provide effective ventilation as well as a large enough 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.

Dimensions and weight	**S**	**S^2**
A. Height	500 mm	500 mm
B. Width	580 mm	580 mm
C. Depth	600 mm	700 mm



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.

GENERAL INSTALLATION PRECAUTIONS

Obey the following warnings for the correct operation of the device and/or to avoid **risky situations**:

- Install the sterilizer on a **flat surface**; adjust the rear leveling feet to compensate for an irregular surface as necessary, and to lower tilt slightly the front side of the machine.
- Make sure that the support surface is strong enough to support the weight of the fully equipped and loaded device (about 60 kg);
- **Leave adequate space for ventilation (at least 10 cm on each side) 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 avoid contact with water or liquids. This could cause short circuits and/or potentially dangerous situations for the operator;
- Do not install the sterilizer in a place that is excessively humid or poorly ventilated;
- Do not install the machine were there is **gas** or inflammable and/or explosive **vapors**;
- Install the device so that the power cord is not bent or crushed. It must run freely all the way to the socket.
- Install the device that any external pipe is not bent or crushed.

ELECTRICAL CONNECTIONS

The sterilizer's must be connected to a socket of the electrical system of adequate capacity for 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:

- Nominal current I_n **16 A**
- Differential current $I_{\Delta n}$ **0.03 A**

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 for the selection and replacement of the plug.

NOTE

ALWAYS CONNECT THE POWER CORD DIRECTLY TO THE SOCKET.
DO NOT USE EXTENSION CORDS, ADAPTERS OR OTHER ACCESSORIES.

CONNECTING THE DATA RECORDING MILLFLASH

The sterilizer can be connected to MILLFLASH allowing the recording of the cycle data in .txt format file and its management by PC.

The connectors of the service box are used for interfacing;
For additional information refer to the Millflash software User's Manual provided with the recording device.

DIRECT CONNECTION TO A CENTRALIZED DRAINING POINT

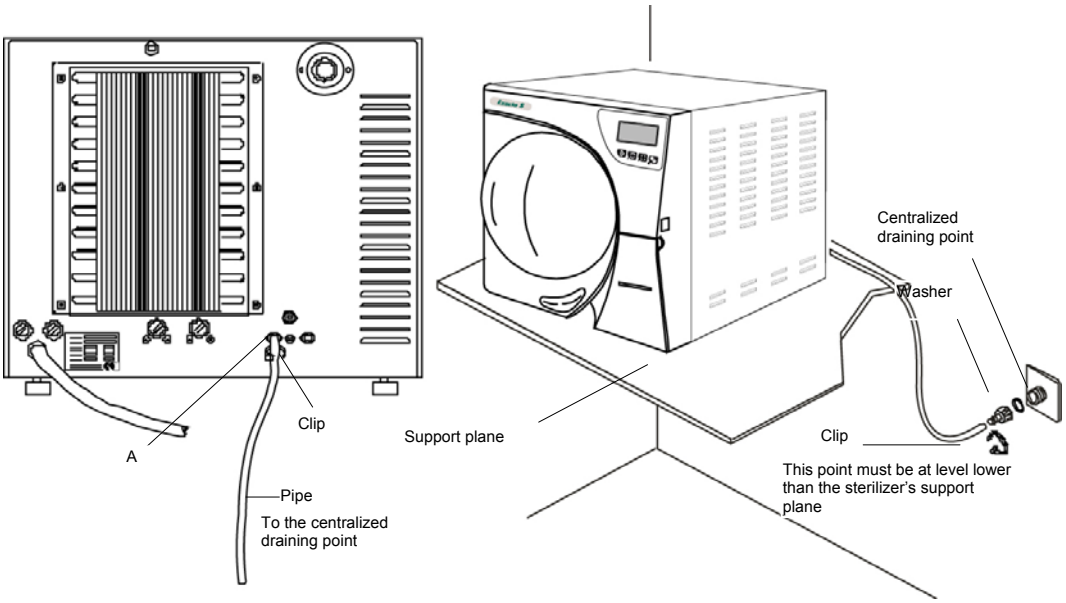
To avoid having to periodically empty the internal used water tank, it is possible to connect it directly to a central drain.

- 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;

NOTE

MAKE SURE THE TUBE IS NOT BENT, CRUSHED OR OBSTRUCTED IN ANY WAY.

The following diagram provides an indicative arrangement of the components:



NOTE

THE CONNECTION POINT TO THE CENTRAL DRAIN MUST BE LOWER THAN THE STERILIZER'S SUPPORT SURFACE. OTHERWISE, THE TANK MAY NOT EMPTY CORRECTLY.

FIRST START-UP

TURNING ON THE EQUIPMENT

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

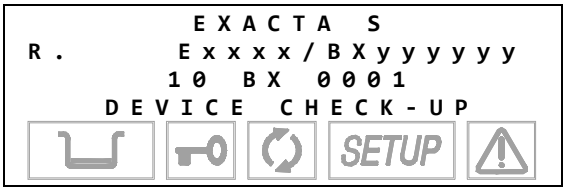
Turn on the equipment by the main (luminous) switch located on the right side of the machine.

NOTE

DO THIS WITH THE STERILIZER'S DOOR OPEN.

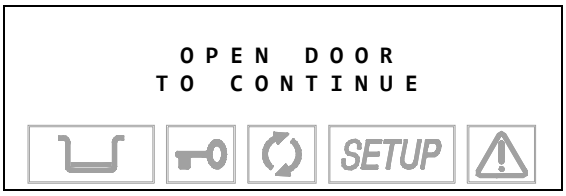
INITIAL AUTOMATIC TEST

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

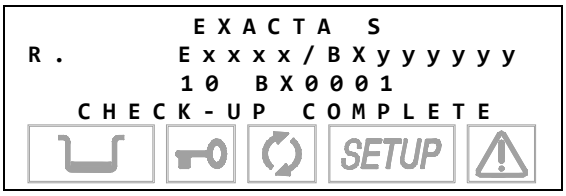


NOTE

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

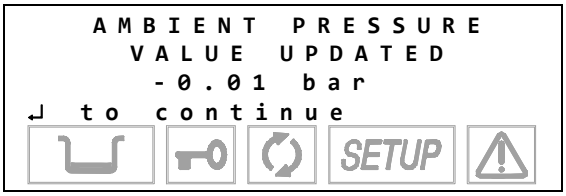


Open the door to allow the test to continue. At the end of the test you will see:



ACQUISITION AND UPDATING OF THE AMBIENT PRESSURE VALUES

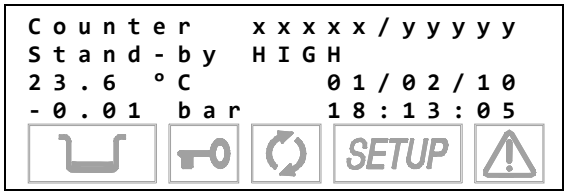
The sterilizer measures the ambient pressure for the correct operation of several auxiliary devices. Whenever the difference between the value read and that previously stored (see the Chapter, **"Configuring the Device - Acquisition the ambient pressure**) is **higher** than a set value, the system **automatically** updates the stored value after a brief delay. Otherwise, the data remains unchanged 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 ↵ 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:



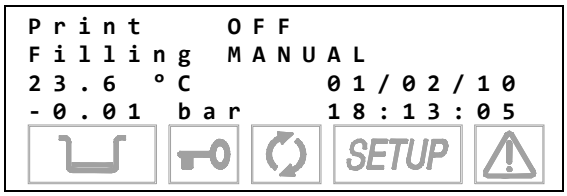
The upper line is the **cycle counter** for sterilizations performed, with the number of correctly completed cycles on the left and the total number started on the right. The line below shows the Stand-by status and the preheating mode (High-Low-Off). The two lower lines show the temperature and pressure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

NOTE

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"**).

DANGER

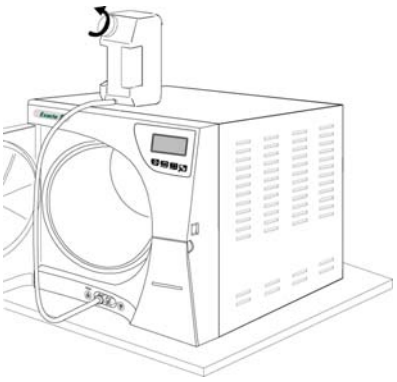
WHEN THE DOOR IS OPEN IN STAND-BY MODE, A BEEP INDICATES THAT THE SURFACES INSIDE THE DEVICE ARE HOT. TO AVOID BURNS, TAKE CARE NOT TO TOUCH THE STERILIZATION CHAMBER, THE SUPPORTS PROVIDED OR THE INSIDE OF THE DOOR WITH YOUR BARE HANDS.

FILLING DISTILLED WATER

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.

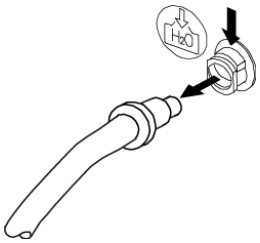
Manual filling

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



1. Fill the manual container (2 l) with distilled water, keeping it horizontal;
2. Connect the tube's quick connector to the corresponding female connector under the chamber entrance (marked H_2O), 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, <u>lower the connector below</u> 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 l) 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.

DETACHING THE PIPE

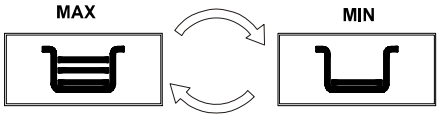


<u>NOTE</u>

THE ICON MAX DOES <u>NOT</u> HAVE TO BE ON IN ORDER TO START A STERILIZATION PROGRAM. THE ICON MIN **INDICATOR <u>OFF</u> IS** SUFFICIENT**.**

MAX LEVEL OF USED WATER

When the water level in the used water tank reaches the MAX level, the LCD display alternatively lights the MAX and MIN icons.



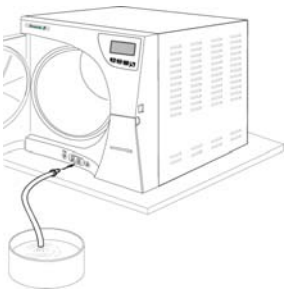
NOTE

IN THIS CONDITION THE UNIT WILL GENERATE AN ALARM INDICATION (SEE APPENDIX E - ALARM) AS YOU ATTEMPT TO LAUNCH A STERILIZATION CYCLE.

Emptying the internal used water tank

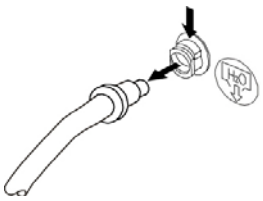
Empty the internal used water tank.

Open the door and operate in the following way:



1. Arrange an empty tank on the floor near the sterilizer and put the free end of the supplied tube into the tank;
2. Connect the quick connector to the corresponding female connector under the chamber entrance (marked H2O), pushing until you hear a click;
3. Wait for the complete empty of the internal tank; then while pinching the tube with your fingers, press the metal lever located on the side of the connector and detach the quick connector.

DETACHING THE PIPE



CONFIGURATION

INTRODUCTION

Exacta 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.

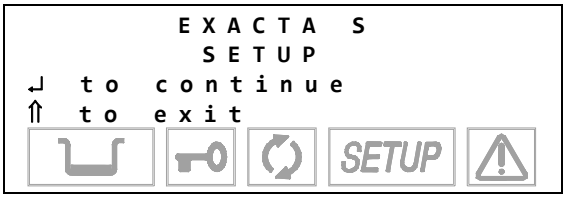
The SETUP program allows selecting from numerous options that users activate through an intuitive, easy-to-use menu.

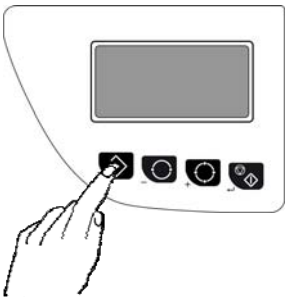
NOTE

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 ⇑ key on the control panel for several seconds, until the display shows:





NOTE

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

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

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

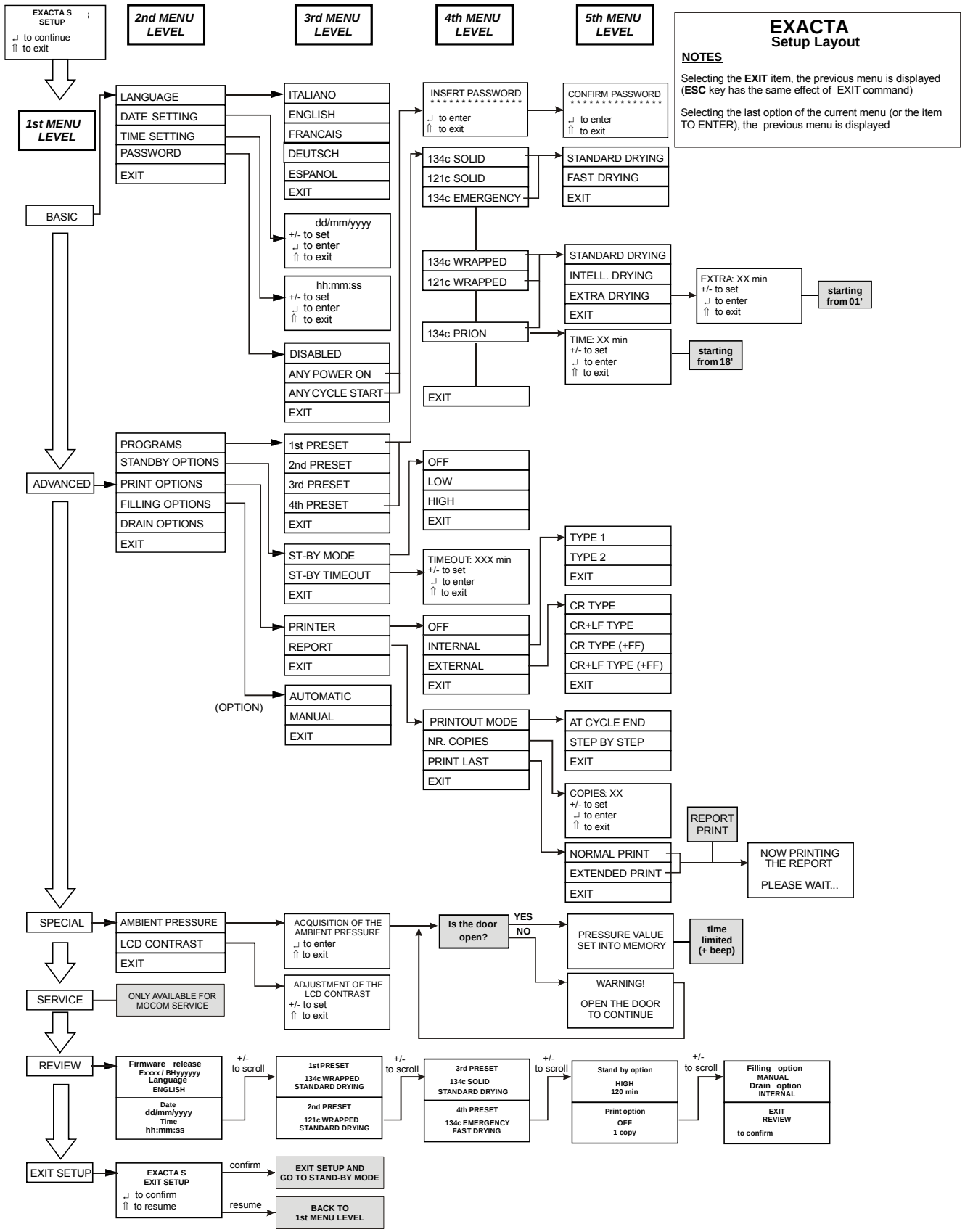
NOTE

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

MEANING OF THE KEYS IN SETUP MODE

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

Key	SETUP mode
↵	function **ENTER**, confirm the selected option or value
	Increase the value /scroll down
	Decrease the value /scroll up the menu items
⇑	**ESC**, exit the selected menu option



EXACTA
Setup Layout

NOTES

Selecting the **EXIT** item, the previous menu is displayed (**ESC** key has the same effect of EXIT command)

Selecting the last option of the current menu (or the item TO ENTER), the previous menu is displayed

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	(basic **options**)
ADVANCED	(advanced **options**)
SPECIAL	(special **options**)
SERVICE	*(menu **not accessible** to users)*
DATA REVIEW	(**summary** of options selected)
EXIT SETUP	(**exit** the SETUP program and return to normal operation. *In this regard, see the paragraph, **Exiting the SETUP program***)

NOTE

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

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

LANGUAGE	(language **setting**)
DATE SETTING	(setting the current **date**);
TIME SETTING	(setting the current **time**)
PASSWORD	(setting the **password**)
EXIT	(**exit** the BASIC menu and return to the main menu)

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

PROGRAMMES	(setting preselected **sterilization programs**, shown on the LCD display)
STAND-BY OPTIONS	(**stand-by** mode settings)
PRINT OPTIONS	(setting **printer** and **printing options**)
FILLING OPTIONS	(not available)
DRAIN OPTIONS	(setting the modes for **emptying** the used water tank)
EXIT	(**exit** the ADVANCED menu and return to the main menu)

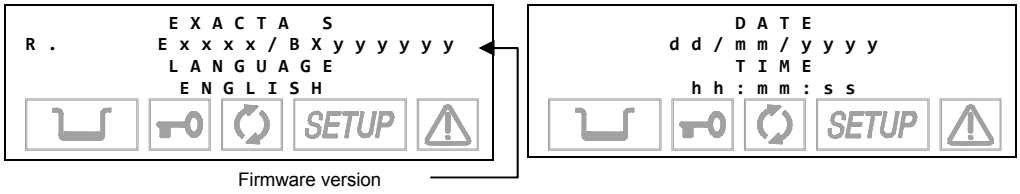
SPECIAL Menu
The Special menu (special options) consists of the following items:

AMBIENT PRESSURE	(acquisition of the **ambient pressure**)
LCD CONTRAST	(adjusting the **contrast** of the Liquid Crystal Display)
EXIT	(**exit** the SPECIAL menu and return to the main menu)

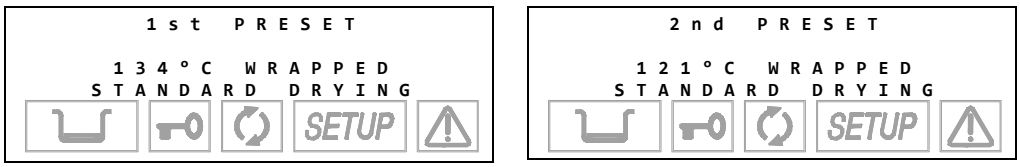
SERVICE Menu
The Service menu can **ONLY** be accessed by the Service department.

DATA REVIEW Menu
The Data Review displays a summary of the device's **current settings**, allowing users to verify their correctness.

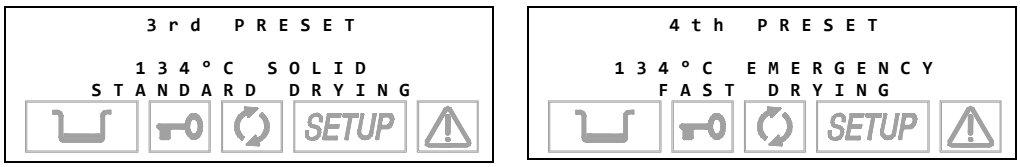
It has the following screens (shown by way of example):



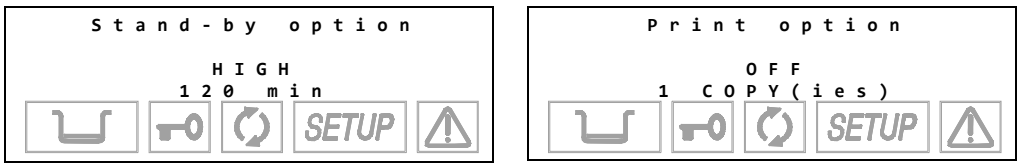
Use the keys **+** / **-** to scroll through the menu



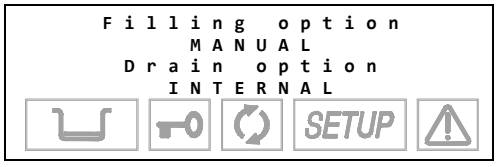
Use the keys **+** / **-** to scroll through the menu



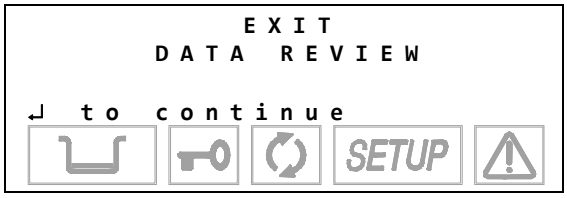
Use the keys **+** / **-** to scroll through the menu



Use the keys **+** / **-** to scroll through the menu



Use the keys **+** / **-** to scroll through the menu



Press ↵ to confirm

NOTE

FOR THE MEANING OF THE TERMS SHOWN, SEE THE PARAGRAPH, ACTIVATING CONFIGURATION OPTIONS.

DEFAULTS SETTINGS

The sterilizer leaves the factory with the following settings:

DATE: ***current date***
TIME: ***current time***

PROGRAMS: Preset **1**: ***134°C WRAPPED*** (***standard*** drying)
Preset **2**: ***121°C WRAPPED*** (***standard*** drying)
Preset **3**: ***134°C SOLID*** (***standard*** drying)
Preset **4**: ***134°C EMERGENCY***

NOTE

THE PROGRAMS INDICATED SHOULD BE CONSIDERED AS PREFERENTIAL SETTINGS. HOWEVER, OTHER COMBINATIONS ARE POSSIBLE BASED ON THE DESTINATION MARKET.

ST-BY MODE: ***HIGH*** (preheating)

PRINT OPTIONS: ***OFF (1 copy with optional printer)***

FILLING OPTIONS: ***MANUAL***

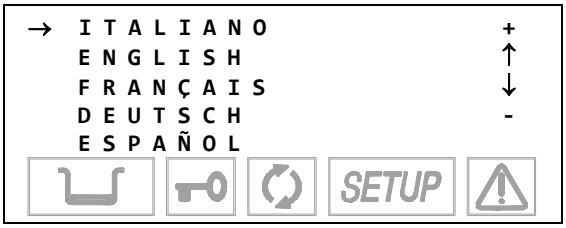
DRAIN OPTIONS: ***INTERNAL***

ACTIVATING CONFIGURATION OPTIONS

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

Setting the language (LANGUAGE on the BASIC Menu)

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



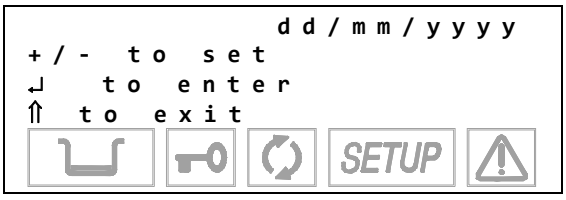
Select the desired language. Move using the **+** or **–** keys and confirm using the ↵ key to store the selection. After the data is confirmed, you return to the second-level menu.

NOTE

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

Setting the date (DATE SETTING on the BASIC Menu)

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



Proceed as follows:

10 The day **flashes**: set the current date with the **+** and **-** keys. Confirm with ↵.

11 The month **flashes**: set the current month with the **+** and **-** keys. Confirm with ↵.

12 The year **flashes**: set the current year with the **+** and **-** keys. Confirm with ↵.

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

Setting the time
(TIME SETTING on the BASIC menu)

When **TIME SETTING** is selected with the ↵ key, you will see:

Proceed as follows:

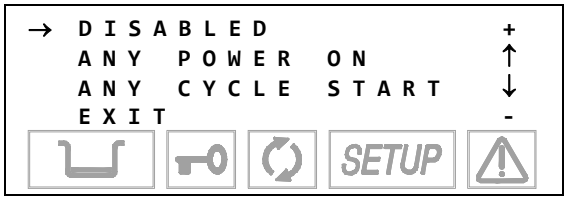
13 The hours **flash**: set the current hour with the **+** and **-** keys. Confirm with ↵.

14 The minutes **flash**: set the current value with the **+** and **-** keys. Confirm with ↵.

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

Setting the password
(PASSWORD on the BASIC menu)

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



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

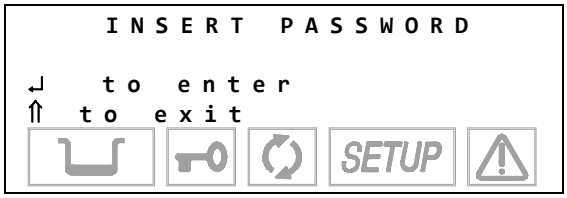
Select **ANY POWER-ON** to protect the machine with a password at the time it is turned-on (power-on from the main switch).
This makes sure that the machine can only be powered-on by authorized personnel, but afterwards it can be used by others without limitation.

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.

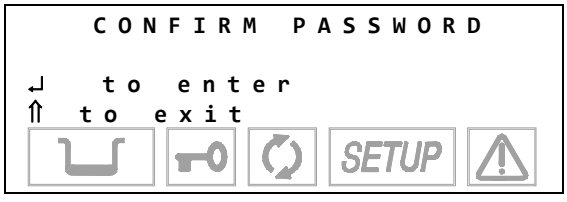
NOTE

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 ↵ key. Then, the following message will appear:



Enter the password again using the **+** and **–** keys.
Confirm with the ↵ key.

NOTE

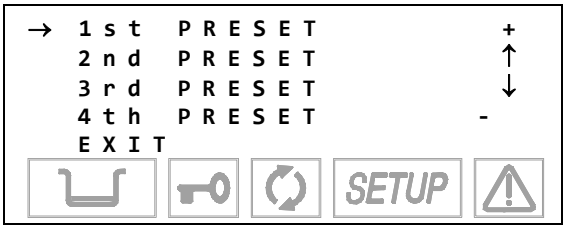
TO CHANGE THE PASSWORD, FIRST SELECT THE DISABLE OPTION, WHICH CANCELS THE PREVIOUS PASSWORD, AND THEN SELECT THE ANY POWER-ON OR ANY CYCLE START OPTION, ENTERING THE NEW PASSWORD AS DESCRIBED ABOVE.

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.

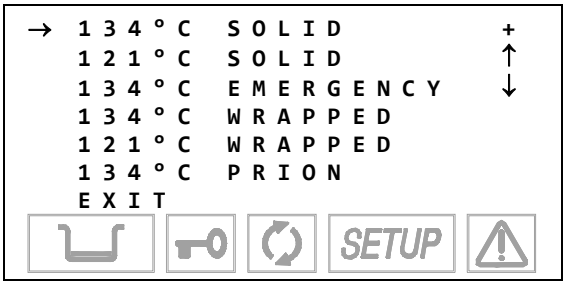
To associate **a cycle** and define several of its parameters, proceed as follows:

1. Select **PROGRAMS** using the ↵ 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 ↵ key.

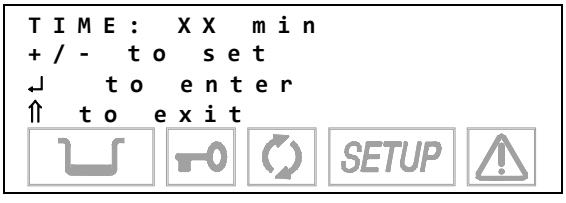
2. From here, you enter the list of available cycles:



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

3. Confirm the selection with the ↵ key.

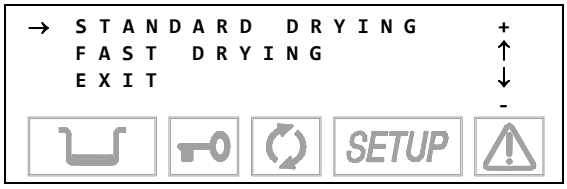
When the **PRION** program is selected, you will go to a screen for selecting the sterilization time.



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):

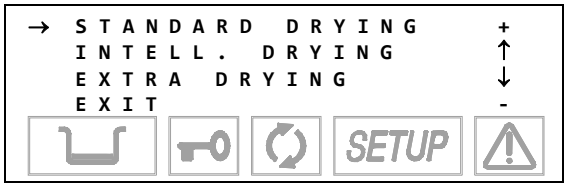


It is possible to select **STANDARD** mode (the default setting) or **FAST** (reduced drying, recommended for light loads). Move using the **+** and **-** keys and confirm with the ↵ key.

NOTE

THE EMERGENCY PROGRAM PROVIDES ONLY FAST DRYING.

b) Programs with long drying (WRAPPED, PRION):

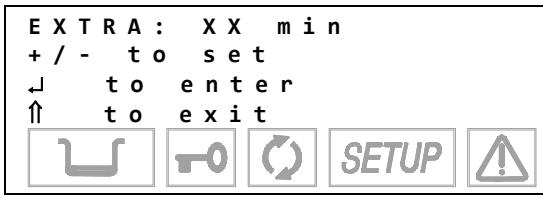


It is possible to select **STANDARD** (default setting), **INTELLIGENT** (automatic drying that adjusts its duration longer or shorter than standard drying on the basis of the volume and/or quantity and type of load) or **EXTRA** (drying extended by a selectable value, recommended for critical loads). Move using the **+** and **-** keys and confirm with the ↵ key.

NOTE

WITH LARGE LOADS OR SPECIAL MATERIALS, THE STANDARD OPTION MAY NOT PROVIDE A PERFECT RESULT. IN THIS CASE, EXTEND THE DRYING PHASE BY USING THE EXTRA MODE.

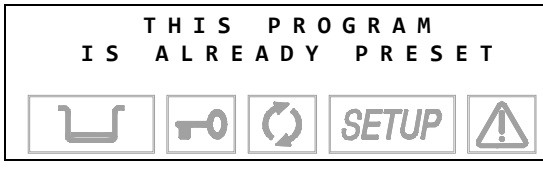
When the **EXTRA** option is activated, the following screen appears:



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 ↵ key.

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:

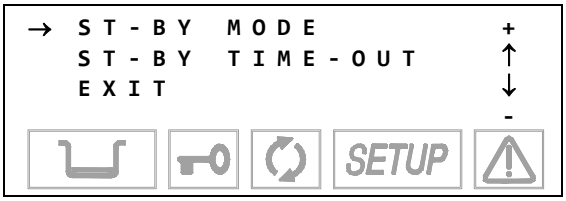


NOTE

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 ↵ key, you access the following menu:



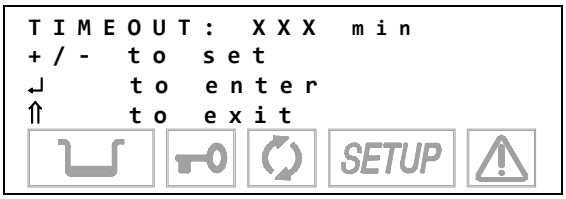
When you select **STAND-BY MODE**, an additional menu appears where you can set the heating level:

Select **HIGH** (high 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** (deactivate 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 ↵ 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 ↵ key.

NOTE

THIS OPTION IS ALSO ACTIVE WITH **STAND-BY OFF**. HOWEVER, IN THIS CONDITION THE TIMER VALUE OBVIOUSLY HAS NO EFFECT SINCE THE HEATING ELEMENTS ARE TURNED OFF ANYWAY AT THE END OF THE STERILIZATION PROGRAM.

WHEN ANY CYCLE SELECTION KEY (STERILIZATION OR TEST) IS PRESSED, OR THE MACHINE IS TURNED OFF AND ON WITH THE MAIN SWITCH, THE ORIGINAL **STAND-BY** MODE (**HIGH** OR **LOW**) IS IMMEDIATELY REACTIVATED.

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 ↵ key and the following menu appears:

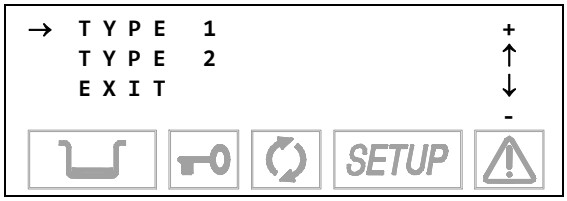
Select **PRINTER** to select the settings for the printer used, or **REPORT** to set the number of copies to print and to reprint data from the last program executed.

a) Item **PRINTER**

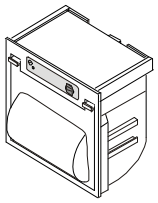
The following screen appears:

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:

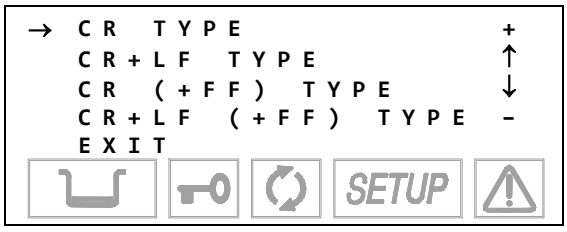


Printer model 1



Select Type 1 for the model 1 of the printer installed.
Select Type 2 for the model 2 of the printer installed (currently not available).

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



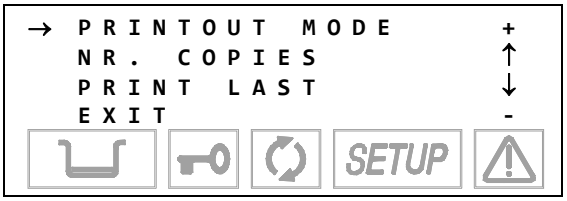
Activate **CR** to use printers that advance the paper only on the CR (*Carriage Return*) command, or **CR+LF** for that require the CR+LF (*Carriage Return* + *Line Feed*) commands, or with **+FF** (Form-Feed) for printers that require the addition of this command.

NOTE

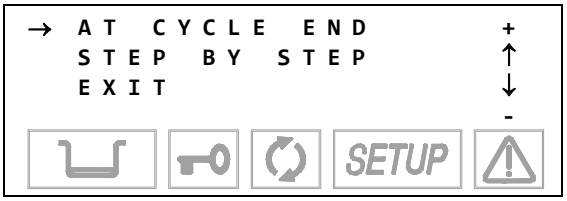
CONSULT THE PRINTER MANUAL TO DETERMINE THE TYPE OF COMMAND USED. IF THIS INFORMATION IS NOT AVAILABLE, TRY PRINTING WITH THE VARIOUS OPTIONS TO IDENTIFY THE CORRECT SETTING.

b) Item **REPORT**

The following screen appears:



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



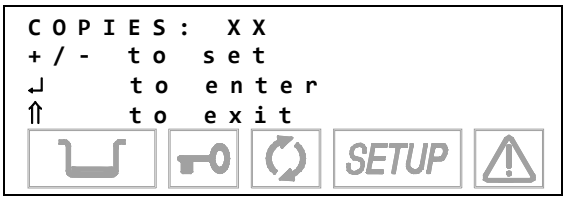
Select **AT CYCLE END** to print the report al the end of the cycle.
Select **STEP BY STEP** to print the data at each phase of the cycle, as result in the normal printout (see Examples of printed report in Appendix B).

NOTE

IN STEP BY STEP MODE IS NOT POSSIBLE MORE REPORT COPIES.

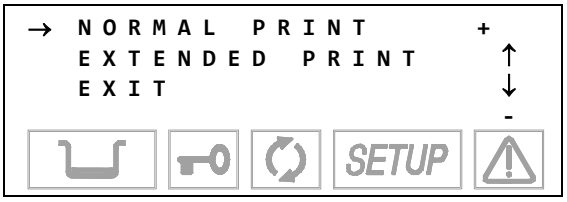
THE VACUUM TEST REPORT PRINT IS CARRIED OUT ONLY IN MODE "AT CYCLE END".

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 maximum of **5**). Confirm with the ↵ 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:

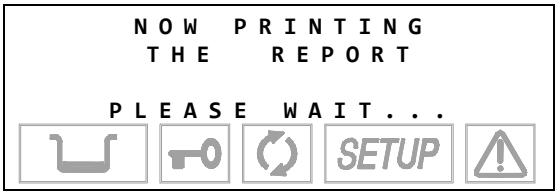


The **NORMAL PRINT** command activates normal printing (that with salient cycle data produced at the end of a correctly executed cycle), while **EXTENDED PRINT** activates complete printing (including all the data typical of a cycle interrupted by an alarm).

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.

Setting the water draining mode (DRAIN OPTIONS from the ADVANCED menu)

The water used for the sterilization cycle can be drained into either the **internal** tank (standard configuration) or an **external** tank of greater capacity (offered as an option – see chapter "Installation") so as to reduce the frequency of emptying the used water.

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

When **INTERNAL DRAIN** is enabled, the reading of the MAX level sensor in the internal tank is enabled.

The **EXTERNAL DRAIN** command also activates the MAX level sensor located in the external tank.

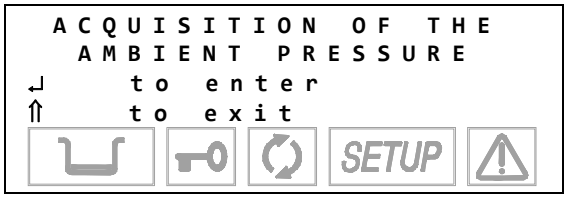
NOTE

THE LEVEL SENSOR IN THE INTERNAL TANK REMAINS ACTIVE IN ANY CASE, TO PREVENT A POSSIBLE MALFUNCTION OF THE EXTERNAL TANK OR A MISSING OR FAULTY CONNECTION OF THE OPTIONAL EXTERNAL DRAIN TANK.
IN THE CASE OF AN INSTALLATION WITH THE DRAIN CONNECTED TO THE CENTRAL SYSTEM, SELECT **INTERNAL DRAIN.**

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

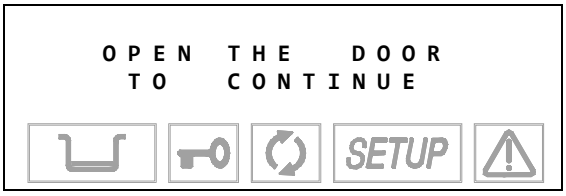
Acquisition of the ambient pressure (AMBIENT PRESSURE on the SPECIAL menu)

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:



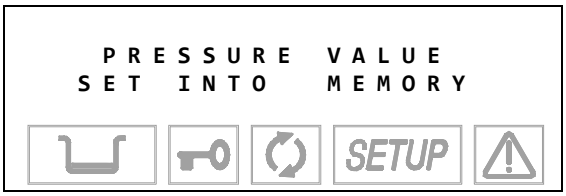
NOTE

CHECK THAT THE STERILIZER DOOR IS COMPLETELY **OPEN.** IF YOU TRY TO ACQUIRE THE PRESSURE WITH THE DOOR CLOSED THE FOLLOWING MESSAGE WILL BE DISPLAYED:



which remains until the door is opened.

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



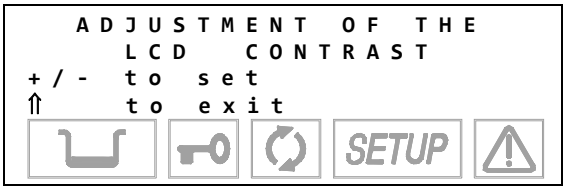
accompanied by a beep. The ambient data pressure has been acquired.

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

Adjusting the contrast of the liquid crystal display
(LCD CONTRAST on the SPECIAL menu)

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.

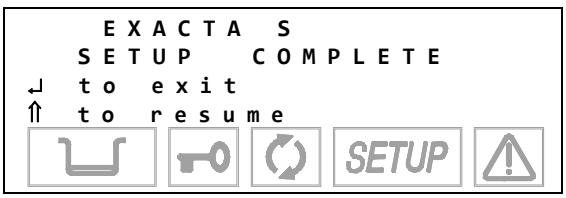
EXIT THE CONFIGURATION MODE

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

- Go to the first-level menu
  (see the **SETUP layout**).

> **NOTE**
>
> **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 ↵ key.
  This text appears on the display:



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

PREPARING THE MATERIAL

INTRODUCTION

The sterilization process can be considered effective, reliable and repeatable so long as the material is suitably treated first and then correctly arranged in the sterilization chamber in an orderly manner.

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 MATERIAL BEFORE STERILIZATION

First of all, it should be recalled that, when **handling** and **managing** contaminated material, it is a good idea to take the following precautions:

- Wear rubber gloves of adequate thickness;
- 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.

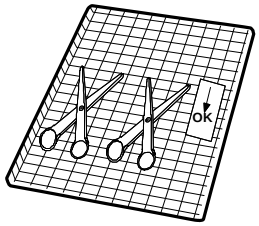
WARNING

CONSULT THE INSTRUCTIONS PROVIDED BY THE MANUFACTURER OF THE INSTRUMENT/MATERIAL TO BE STERILIZED BEFORE 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.

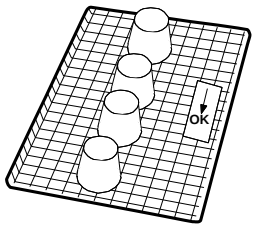
ARRANGING THE LOAD

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

General notes for positioning on trays.



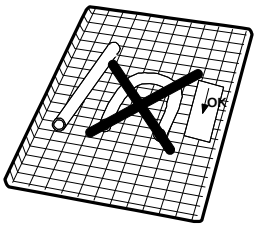
- Arrange instruments made of different metals (stainless steel, tempered steel, aluminum, etc.) on different trays or well separated from each other.
- In the case of instruments **not** made of stainless steel, place a paper sterilization napkin or a muslin cloth between the tray and the tool, avoiding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

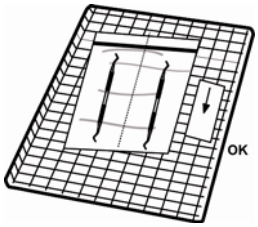
NOTE

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 NON-STERILIZED MATERIAL. IF PROCESSING *WRAPPED MATERIAL*, PLACE THE INDICATOR *INSIDE* 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 wrapped material

- Wrap instruments individually or, when more than one instrument are placed in the same wrapping, make sure that they are made of the same metal;
- 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 down (tray side) and the paper side up.**
- If possible, place the envelopes edgewise to the tray, with a suitable support.
- **Never superimpose envelopes on top of each other.**

WARNING

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

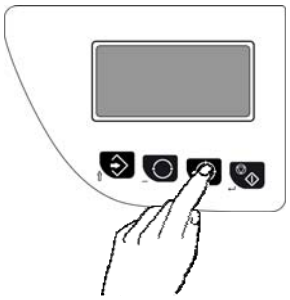
PROGRAM SELECTION

INTRODUCTION

Program selection is fundamental for a successful sterilization process.

Since each instrument, or material in general, has different shape, consistency and properties, it is important **to identify the most suitable program for it**, 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 **Appendix B (Programs)**

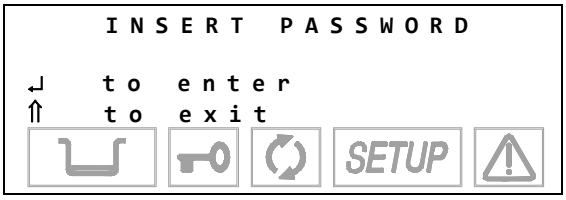
PROCEDURE



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 ↵ key.

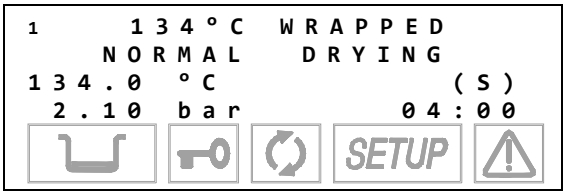
The display does not offer any active preselection.
The device is waiting for the user to select a program.

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).

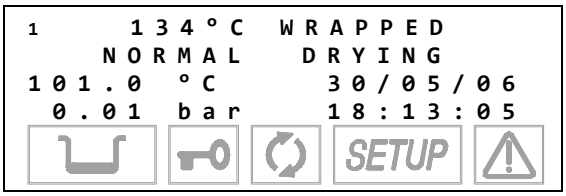
NOTE

WHEN THE SELECTION KEY IS PRESSED, THE FIRST STERILIZATION PROGRAM PROPOSED IS THE ONE USED FOR THE LAST CYCLE EXECUTED.

In the two lines above the description, the display shows the description 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 ⇑ on the control panel.

NOTE

IF NO STERILIZATION PROGRAM IS SELECTED, THE EQUIPMENT CANNOT START A STERILIZATION CYCLE, AND THE FOLLOWING MESSAGE APPEARS ON THE DISPLAY, WITH A BEEP:

WARNING

IF YOU USE A PROGRAM THAT IS INAPPROPRIATE FOR THE TYPE OF MATERIAL TO BE STERILIZED (*SEE APPENDIX B*) THE EFFECTIVENESS OF THE STERILIZATION PROCESS IS NOT GUARANTEED.

RUNNING THE CYCLE

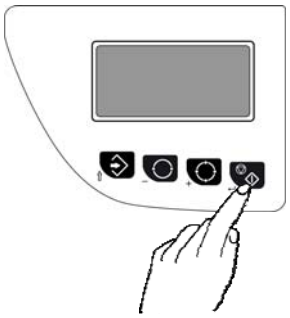
INTRODUCTION

A sterilization cycle consists of a determined number of phases. The number and duration of the phases can differ for the programs, based on sterilization process and drying method.

The electronic control system monitors the various phases, at the same time checking that the various parameters are respected; if any type of anomaly is encountered during the cycle, the program is immediately interrupted, generating an alarm identified by a code, with a relative message explaining the nature of the problem.

With this type of control, when you select a suitable sterilization program, you are guaranteed perfect sterilization under any conditions.

STARTING THE CYCLE



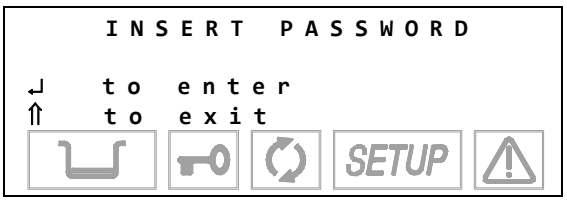
Password check

After placing the load in the sterilization chamber and selecting the desired program, **close the door until you hear the click**.

The door status icon **flashes** (door closed). Press the **START** button.

NOTE

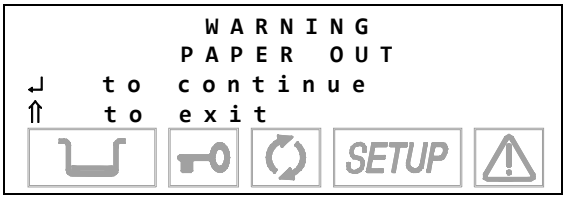
IF A PASSWORD HAS BEEN ENABLED WITH THE OPTION **ANY CYCLE START** (SEE THE CHAPTER CONFIGURATION - SETTING THE PASSWORD), YOU WILL BE ASKED TO ENTER THE ACCESS CODE:



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

Printer paper-out check (option)

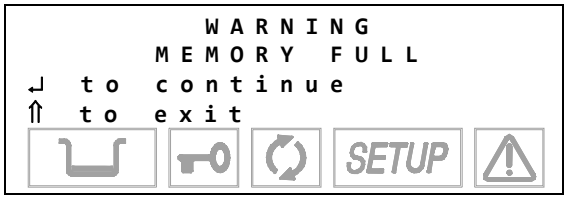
The equipment checks the presence of the paper into the on-board printer (if installed); if out or ended the following message will be displayed:



Push key ↵ to continue however (replace the paper during or at the end of the sterilisation cycle).
Push key ⇑ to return in Stand-by mode.

If Millflash is connected

In case of card memory full or insufficient to store the new cycle data, the following message will be displayed:



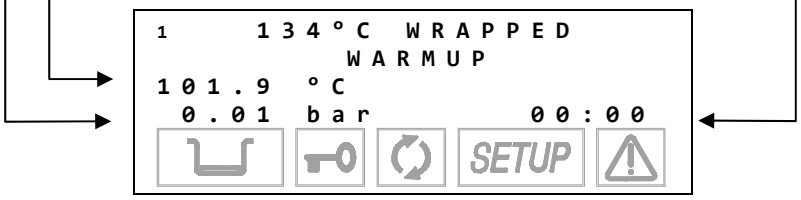
Push key ↵ to continue without recording the cycle data.
Push key ⇑ to interrupt the start command; download the files on PC and delete the memory content according to the instructions of the Millflash Operating Manual.
Repeat the **Start** command.

Door locking

The equipment locks the door.

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)



The time is counted from the start of the sterilization cycle (first vacuum phase), excluding the preheating phase.

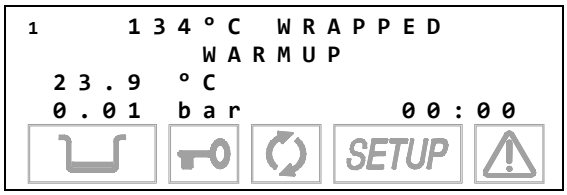
PROGRAM EXECUTION

Now, we will analyze the execution of a sterilization cycle, phase by phase.

For our example, let's take the most complete and important cycle, i.e., the program **134 °C WRAPPED**.

Preheating

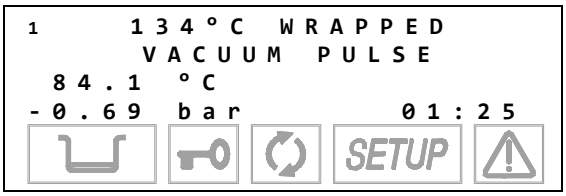
When the **START** button is pressed, the first phase is **PREHEATING**, which brings the chamber to temperature required for starting the cycle. The display shows the following:



The icon that shows the status of the sterilization process is off.

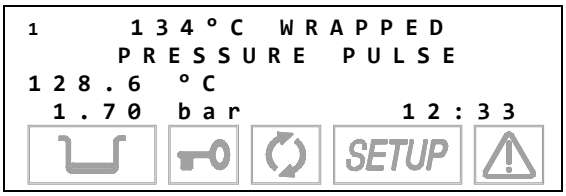
Vacuum phase

When the optimum temperature is reached, the vacuum phase (**VACUUM PULSE**) is started and brings the chamber pressure down to the established value. The display shows:



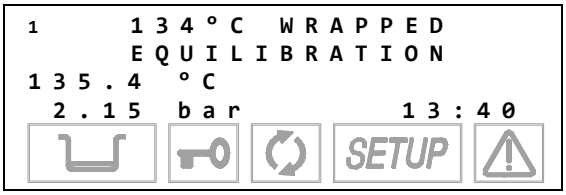
Rise in pressure

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



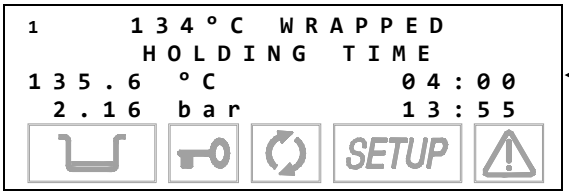
Thermodynamic equilibrium

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:



Sterilization time

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 **constant** within the limits required by the program. The display shows the following:



countdown

The icon **flashes** to indicate that the treatment of the load is in progress.

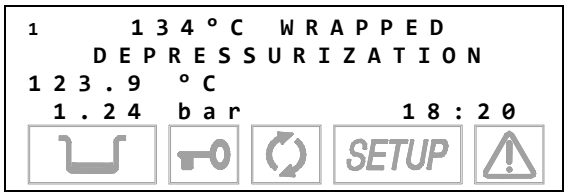
At the end of the sterilization phase, the icon remains steady on to indicate the complete sterilization of the material in the sterilization chamber.

WARNING

IF, FOR ANY REASON, THE STERILISATION PHASE IS INTERRUPTED BEFORE ITS COMPLETION, THE ICON WILL CONTINUE TO FLASH.
IN THIS CASE, THE MATERIAL CANNOT BE CONSIDERED STERILE AND MUST ABSOLUTELY NOT BE USED.

Steam discharge

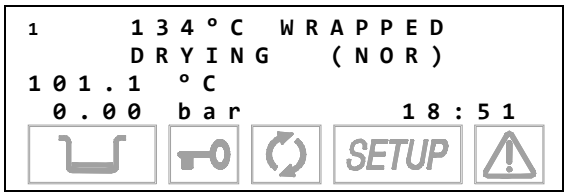
At the end of the sterilization phase, the steam is released from the sterilization chamber (**STEAM DISCHARGE**). The liquid crystal display shows:



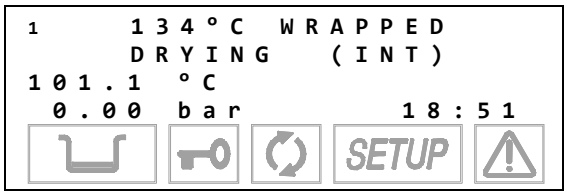
The icon for the sterilization process status  is **steady on**.

Drying

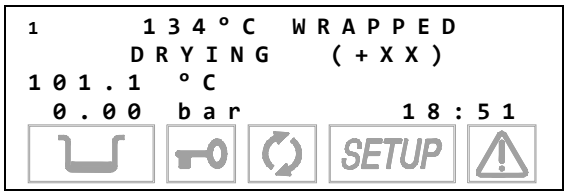
After the steam under pressure is released, its forced removal begins with the vacuum pump (**DRYING**): for this purpose, low pressure is created in the sterilization chamber to facilitate the evaporation of the steam and its consequent elimination. As a function of the type of drying set, one of the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



Standard drying



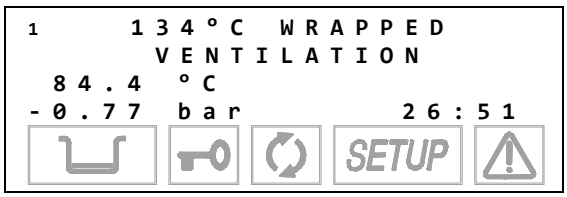
Intelligent drying



EXTRA DRYING (+XX) is the time set

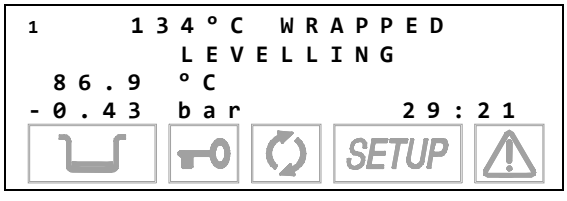
Ventilation

When the drying phase is finished, it is followed by a **VENTILATION** phase in which fresh sterile air is injected, while maintaining a vacuum in the chamber, to eliminate condensate and cool the load.



Leveling to the atmospheric pressure

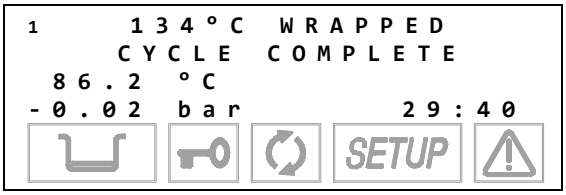
At the end of the ventilation phase, the chamber is brought back to atmospheric pressure (**LEVELLING**) by injecting sterile outside air to allow the opening of the door and the retrieval of the load.



Completion of the cycle

When the pressure in the sterilization chambers returns within the pre-set safety limits, the door lock system is released.

The door status indicator **flashes**. At the same time, it also beeps.



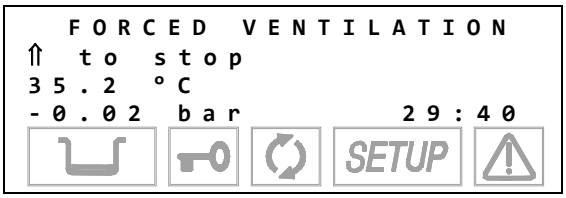
The icon for the sterilization process status is **steady on**.

NOTE

AT THE END OF THE CYCLE, AND UP TO THE OPENING OF THE DOOR, THE HEATING ELEMENTS ARE OFF. THE DEVICE IS COOLING SLOWLY.

NOTE

WHENEVER THE STERILIZER'S' DOOR IS NOT OPENED AT THE END OF THE CYCLE, THE VACUUM PUMP IS PERIODICALLY ACTIVATED TO REMOVE ANY TRACES OF CONDENSATE FROM THE STERILIZATION CHAMBER. THE DISPLAY SHOWS:



Press ⇑ to interrupt ventilation and open the door.

Open the door

Open the door and retrieve the sterilized material, using the extractor provided.

The icon symbol **goes off**.

When the door is opened, the device goes to STAND-BY mode as previously set.

Report print (option)

When the door is opened, the report for the sterilization cycle executed is automatically produced (if the printer is installed). Check the document, initial it in the space provided and file it in a suitable place. Refer to the print report examples shown in Appendix B, Programs.

NOTE

IF SELECTED THE PRINTOUT **STEP BY STEP** OPTION, THE REPORT WILL BE PRINTED DURING THE PHASES OF THE CYCLE.

Equipment ready

The device is **ready** to execute a **new cycle**.
Repeat the procedures explained in the Chapter, “Program Selection” for executing a new sterilization cycle.

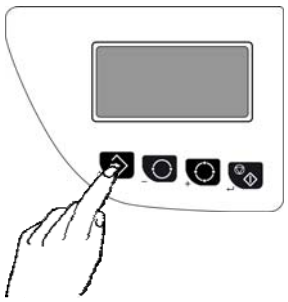
RESULT OF THE CYCLE

After the cycle is finished, it is important to check the sterilization results.

Whenever a cycle finishes (message **CYCLE COMPLETE** and icon on), without, therefore, being interrupted by any type of alarm, you are guaranteed to have **completely aseptic** material.

The report (option) of the sterilization parameters is an additional check tool.

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.

NOTE

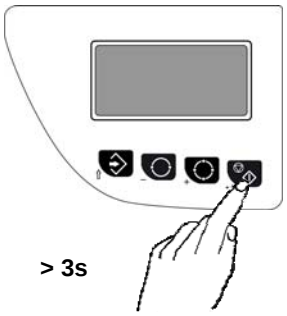
TO SELECT THE NUMBER OF COPIES TO PRINT, CONSULT CHAPTER 6, CONFIGURATION - SETTING THE PRINTING MODE.

NOTE

TO START THIS PRINT FUNCTION, HOLD DOWN THE ⇑ (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.

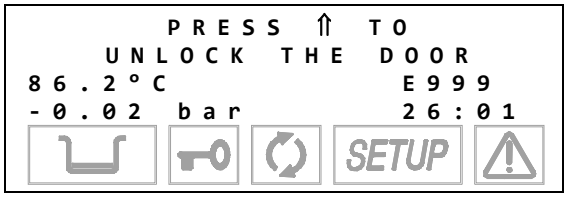
For complete details about printing the summary, please refer to the report examples shown in **Appendix B**, **Programs.**

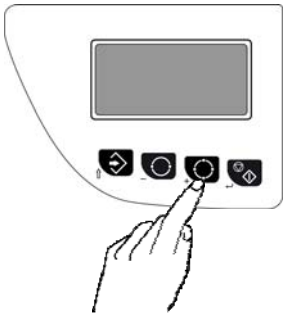
MANUAL CYCLE INTERRUPTION



The operator can manually interrupt the cycle at any time by pressing the START/STOP key for three seconds.
The command generates the error **E999**, given that the cycle did not finish correctly. As a consequence, until safe conditions are reached, the display shows, along a beep:

When safe conditions are reached, the machine activates a special procedure, first asking the user to manually unlock the door by displaying the following instruction:

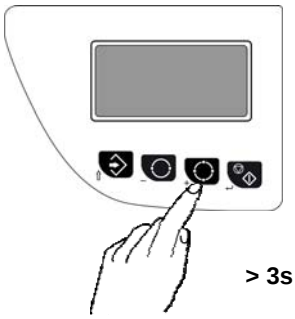




Press the ⇑ key to unlock the door.
The following message is then displayed:

Finally, when the door is opened, you will be asked to **reset** the device by the following message:

To **RESET** the system, **hold down, for at least three seconds,** the ***PROGRAM SELECTION*** key until you hear the confirming beep.
When the door is opened, the report for the sterilization cycle executed is produced, including the error code (**E999**). Check the report, initial it in the space provided and file it in a suitable place. Refer to the print report examples shown in **Appendix B**, **Programs**.



After the **RESET**, the device goes to **STAND-BY** mode, ready to execute a **new program**.

NOTE

WHENEVER AN ALARM IS GENERATED IN CERTAIN PHASES OF THE CYCLE, AN AUTOMATIC PROCEDURE IS ACTIVATED TO CLEAN THE PLUMBING CIRCUIT. FOR A COMPLETE DESCRIPTION OF THE ALARMS, SEE APPENDIX E "ALARMS".

WARNING

AFTER A PROGRAM IS MANUALLY INTERRUPTED (MANUAL STOP) ALWAYS CHECK THE STATUS OF THE ICON BEFORE USING THE MATERIAL IN THE STERILIZATION CHAMBER.
IF THE ICON IS STEADY ON, THE MATERIAL IN THE STERILIZATION CAN BE CONSIDERED STERILE AND, THUS, BE USED. WE RECOMMEND USING IT IMMEDIATELY.

HOWEVER, IF IT IS OFF, THE MATERIAL IN THE STERILIZATION CHAMBER CANNOT BE CONSIDERED STERILE AND ABSOLUTELY MUST NOT BE USED.

STORING STERILIZED MATERIALS

INTRODUCTION

The sterilized material must be adequately treated and stored to maintain its sterility over time, until its use.

Inadequate storage **can** cause **rapid recontamination**.

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 handling and/or carrying sterile material:

1. Remove the load from the sterilization chamber wearing gloves and a clean, or even better, sterilized smock. As an additional precaution, wear a protective mask on your face;
2. Rest the tray on a dry, suitably clean and disinfected surface. *Take care to distance or, at any rate, separate the sterile material from the area where contaminated material is kept waiting to be sterilized;*
3. Touch the material and/or instruments as little as possible, taking extreme care **not** to cut or damage the wrappings;
4. Let the instruments cool before any transport (and subsequent storage). If necessary for transport, transfer the material using dry, clean and disinfected containers. The containers must be closed or, if open, covered with clean cloths.

STORAGE

Sterile material waiting for used must be stored using the appropriate techniques. These will significantly **slow** recontamination:

1. Store the material and/or instruments in the protective wrappings that were used during sterilization. **Do not** wrap the instruments after sterilization since, in addition to being useless and completely senseless, is also potentially damaging;
2. Store the material in a dry, suitably clean and disinfected place, far from the area where infected material passes. If possible, use closed compartments equipped with ultraviolet light;
3. Identify 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 homogeneously stored, avoiding storing for too long, with the consequent risks.
5. **Never** store material for too long. 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.

TEST PROGRAMS

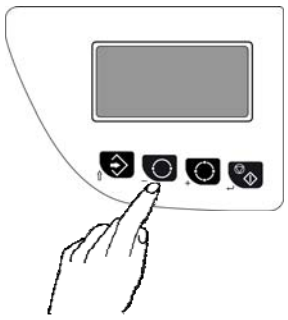
INTRODUCTION

Exacta offers the possibility of, simply and automatically, executing the test program:

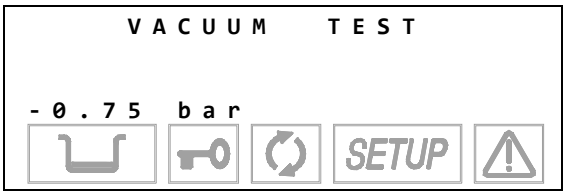
- Vacuum Test

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 **sterilization chamber empty**, 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.

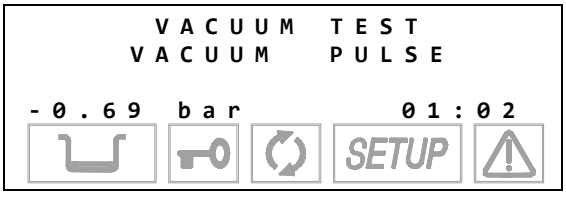
Close the door and start the program with the **START** key.

NOTE

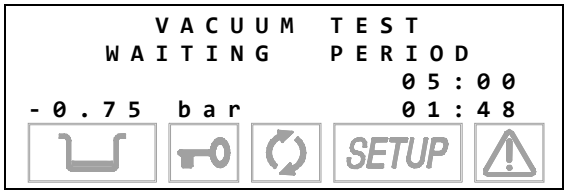
IF A PASSWORD HAS BEEN SET WITH THE ANY CYCLE START OPTION (SEE THE CHAPTER, CONFIGURATION, SETTING THE PASSWORD), YOU WILL BE ASKED TO ENTER THE ACCESS CODE. IN ADDITION, THE EQUIPMENT CHECKS THE PRINTER PAPER PRESENCE AND, IF MILLFLASH IS CONNECTED AND ITS MEMORY CAPACITY.

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 immediately and the display shows the pressure (**bar**), and the total time from the start of the program.:

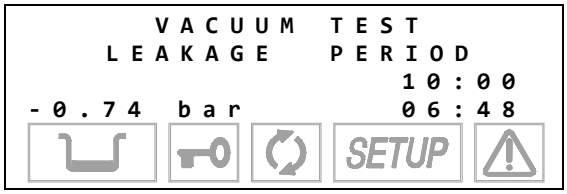


When the pre-set pressure is reached (**-0.75** bar) the pump stops and the pressure stabilization phase begins (**WAITING PERIOD**), which lasts 5 minutes (shown on the display as a scalar value):



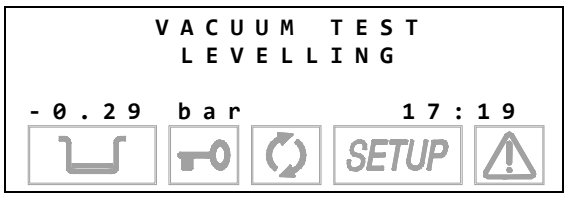
During this phase, a variation of the maximum low pressure is allowed of **not more than 10%**, without this causing the test to fail.

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

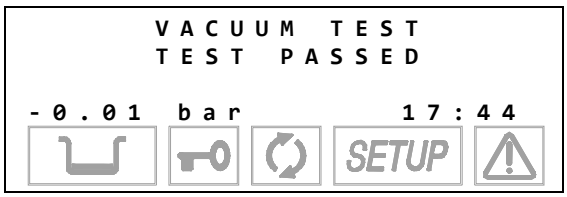


In this phase, a variation of **up to ±0.02 bar** is allowed, compared to the initial phase value. Higher variations cause the test to fail.

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:



NOTE

IF 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 APPENDIX E .

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 **Appendix B**, **Programs**.

SUMMARY TABLE

Device	Steam Sterilizer	
Classification (according to the Directive 93/42/EEC and subsequent changes)	IIb	
Model	**Exacta S**	**Exacta S²**
Manufacturer	**M.O.COM. S.r.l.** Via delle Azalee, 1 20090 BUCCINASCO (MI) - ITALY	
Power supply voltage	**220V – 240 V~**	
Frequency	**50 Hz**	
Mains fuses *(6.3 x 32 mm)*	**F 16A 250V**	
On-board fuses *(5 x 20 mm)*	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)* *(excluding rear connections)*	**420** x **480**x **560 mm**	**420 x 480x 660 mm**
Nominal power	**1600 W (7A)**	**2300 W (10°)**
Insulation class	Class **I**	
Installation category	Cat. **II**	
Environment of use	Internal **use**	
Noise level	**<65 db(A)**	
Environmental operating conditions	Temperature: **+15 °C ÷ +40 °C** Relative humidity: max **80%**, non-condensing Altitude: max **3000 m** *(a.s.l.)*	
Net weight: *(empty):* *(empty with trays and support)* *(empty, with trays and supports and water at MAX level)*	about **52** kg about **53** kg about **57** kg	about **56** kg about **58** kg about **62** kg
Sterilization chamber dimensions *(D x D)*	**250** x **350** mm	**250** x **450** mm
Sterilization chamber total volume	about **17 l** (0.017 m^3)	about **22 l** (0.022 m^3)
Sterilization chamber useful volume *(with tray supports inserted)*	about **10 l** (0.010 m^3)	about **13 l** (0.013 m^3)
Distilled water tank capacity *(supply)*	about **4.6 l** *(water at **MAX** level)* about **0.8 l** *(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**	
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.

- **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*

NOTE

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.

INTRODUCTION

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

The following material can normally 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 – EXACTA S

PROGRAM DESCRIPTION	NOMINAL VALUES				BASIC PROGRAM PARAMETERS					STERILIZABLE MATERIAL				NOTES
	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_2O (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)	
134 °C PRION	134	2,10	>18	S	S	L	59÷62	350	0.7	Solid instruments in single package	**3.00**	1.00	0.25	We recommend using the 3-tray configuration
134 °C WRAPPED	134	2,10	4	S	S	L	45÷48	300	0.6	Solid instruments in single package	**3.00**	1.00	0.25	
121 °C WRAPPED	121	1,10	20	S	S	L	59÷62	325	0.6	Solid instruments in single package	**3.00**	1.00	0.25	
134 °C SOLID	134	2,10	4	N	S	C	34÷37	300	0.5	Unpackaged solid instruments	**6.00**	1.20	0.50	
121 °C SOLID	121	1,10	20	N	S	C	48÷51	325	0.5	Unpackaged solid instruments	**6.00**	1.20	0.50	
134 °C EMERGENCY	134	2,10	3	N	S	Fast	26÷28	300	0.45	Unpackaged solid instruments	**0.50**	0.50	0.50	
VACUUM TEST	-	-0.75	-	-	-	-	29	-	-	Empty chamber	-	-	-	

PROGRAM SUMMARY TABLE – EXACTA S²

PROGRAM DESCRIPTION	NOMINAL VALUES				BASIC PROGRAM PARAMETERS					STERILIZABLE MATERIAL				NOTES
	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_2O (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)	
134 °C PRION	134	2,10	>18	S	S	L	52÷55	350	0.7	Solid instruments in single package	**3.00**	1.00	0.25	We recommend using the 3-tray configuration
134 °C WRAPPED	134	2,10	4	S	S	L	38÷41	300	0.6	Solid instruments in single package	**3.00**	1.00	0.25	
121 °C WRAPPED	121	1,10	20	S	S	L	50÷54	325	0.6	Solid instruments in single package	**3.00**	1.00	0.25	
134 °C SOLID	134	2,10	4	N	S	C	26÷29	300	0.5	Unpackaged solid instruments	**6.00**	1.20	0.50	
121 °C SOLID	121	1,10	20	N	S	C	40÷43	325	0.5	Unpackaged solid instruments	**6.00**	1.20	0.50	
134 °C EMERGENCY	134	2,10	3	N	S	Fast	18÷20	300	0.45	Unpackaged solid instruments	**0.50**	0.50	0.50	
VACUUM TEST	-	-0.80	-	-	-	-	29	-	-	Empty chamber	-	-	-	

NOTES

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

2) LONG = TYPICAL OF **WRAPPED** CYCLES
   SHORT = TYPICAL OF **SOLID** CYCLES

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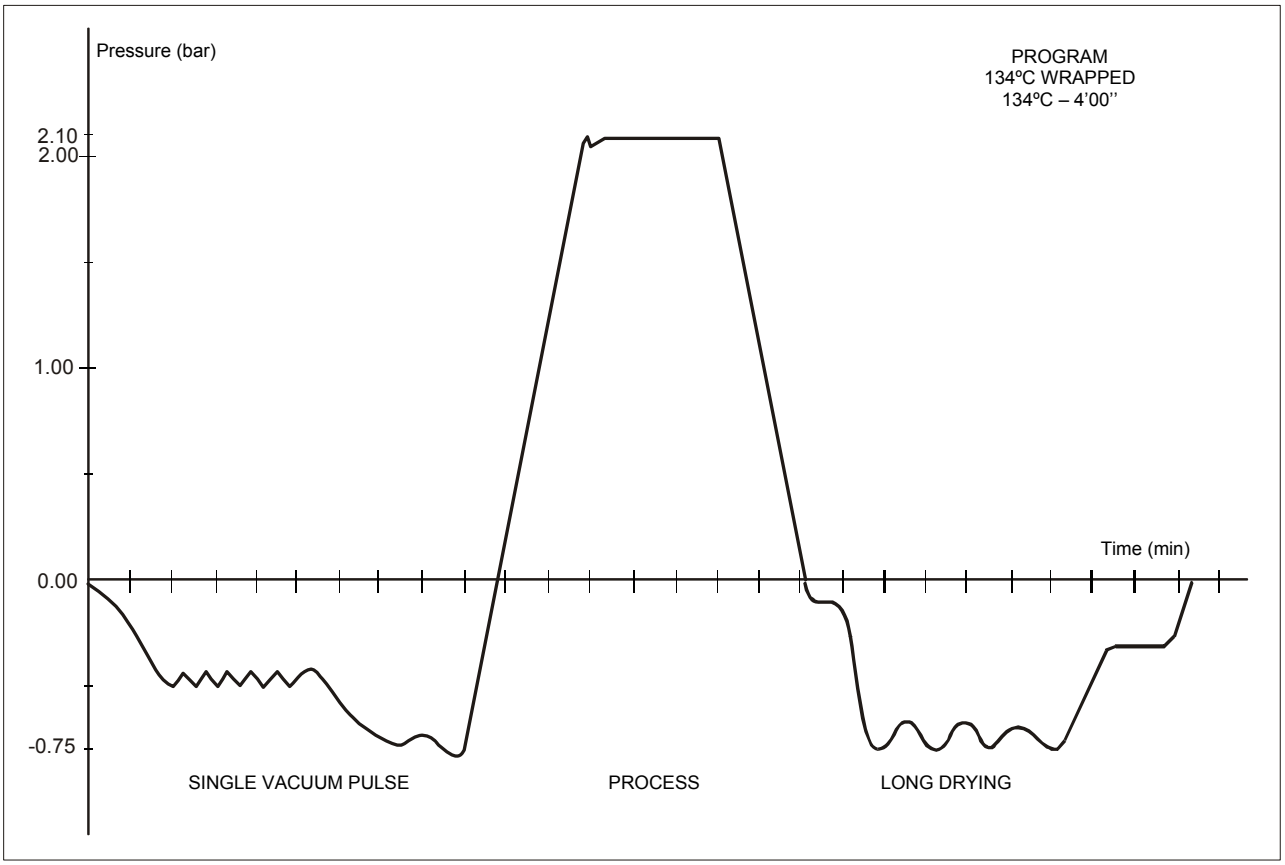
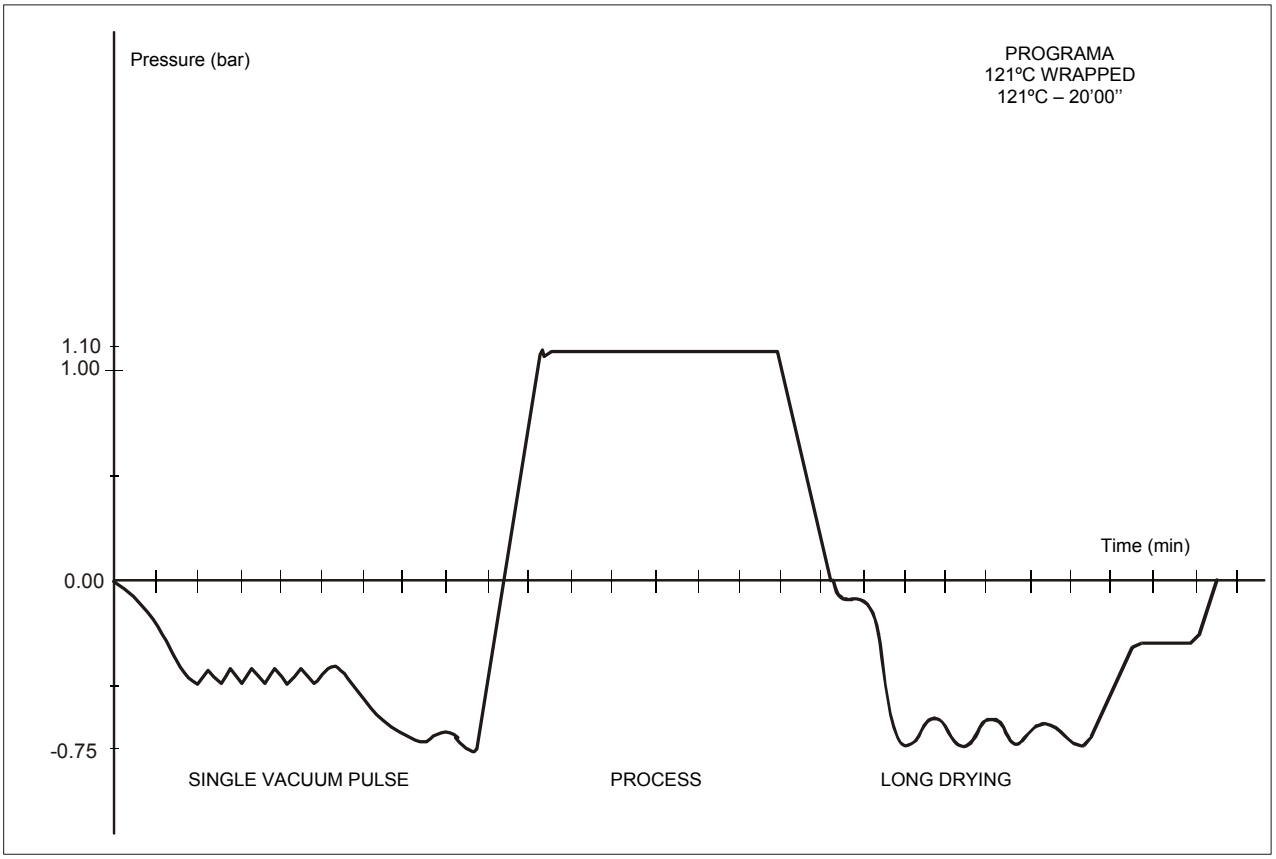
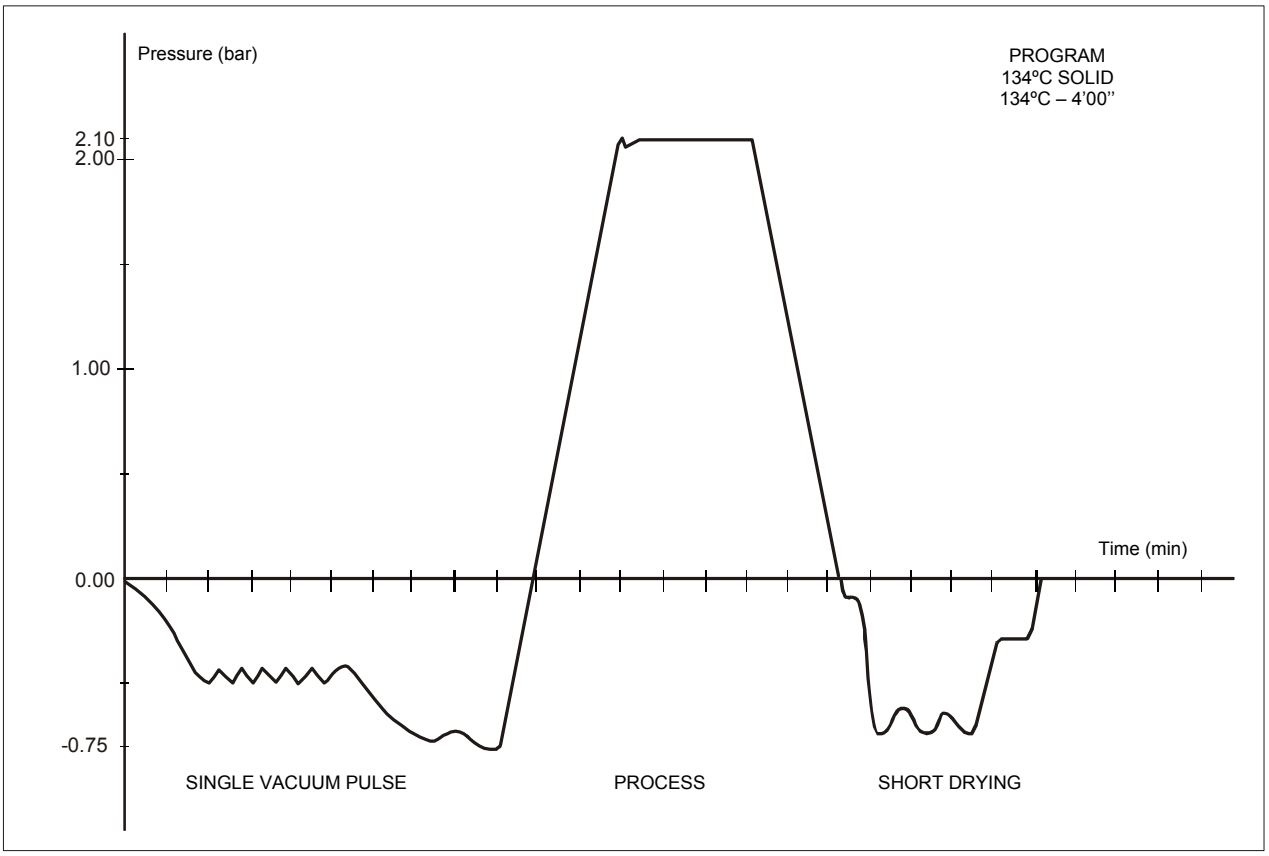
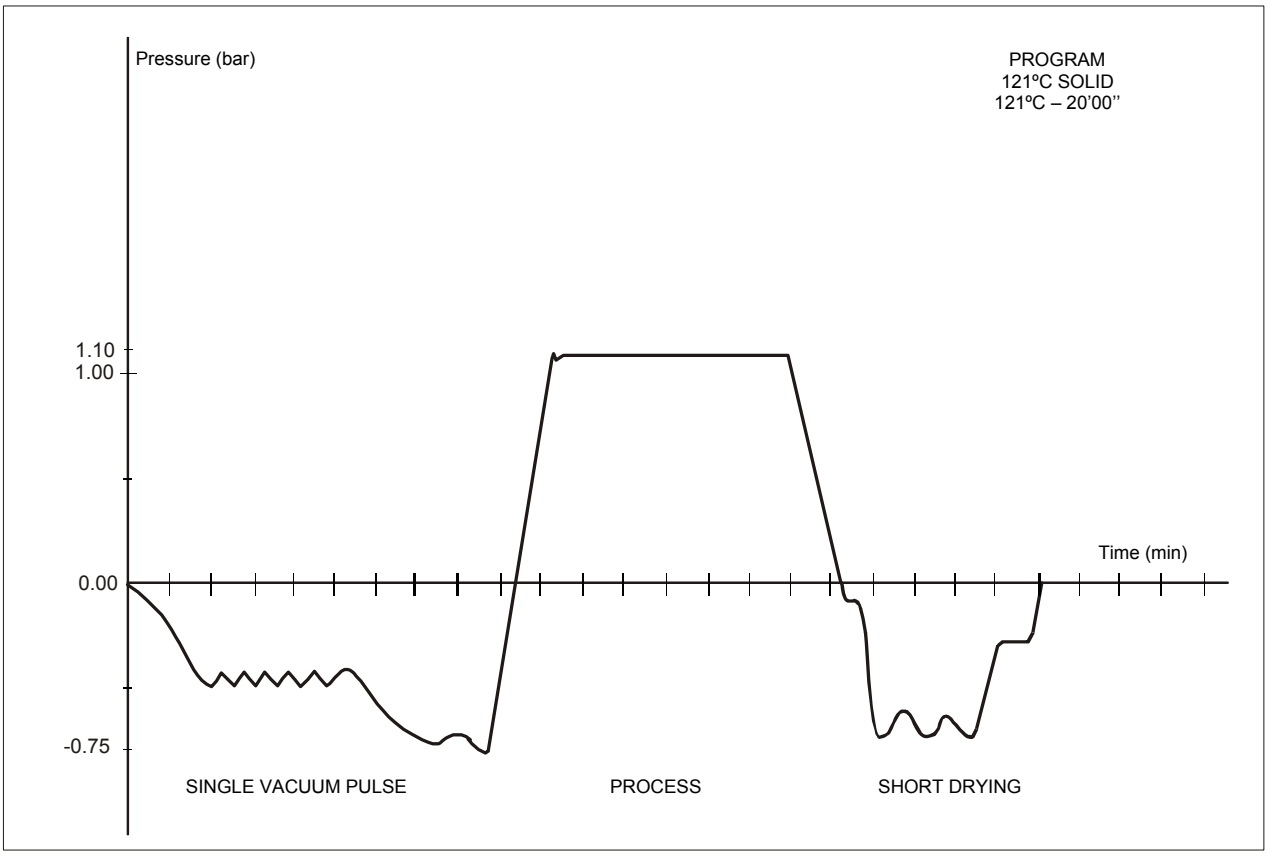
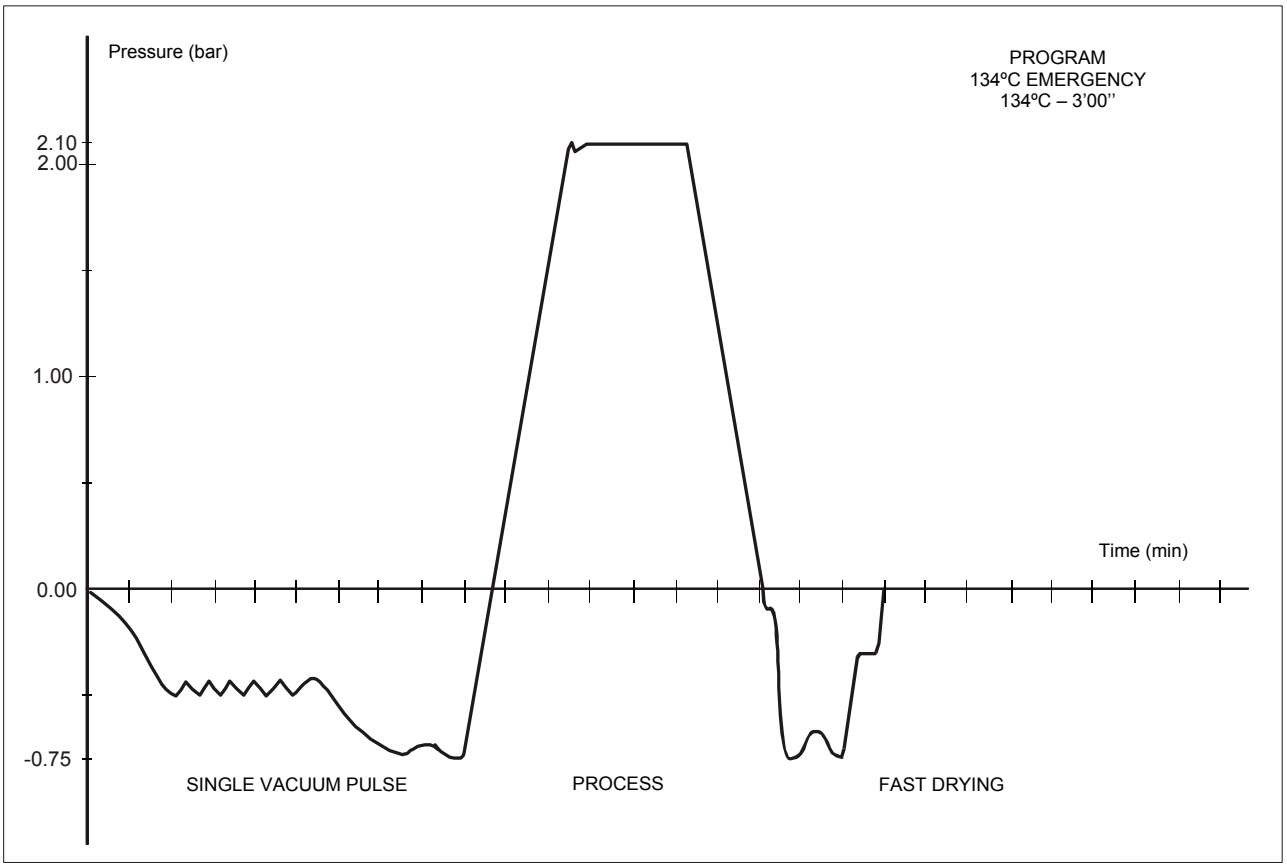
STERILIZATION PROGRAM DIAGRAMS

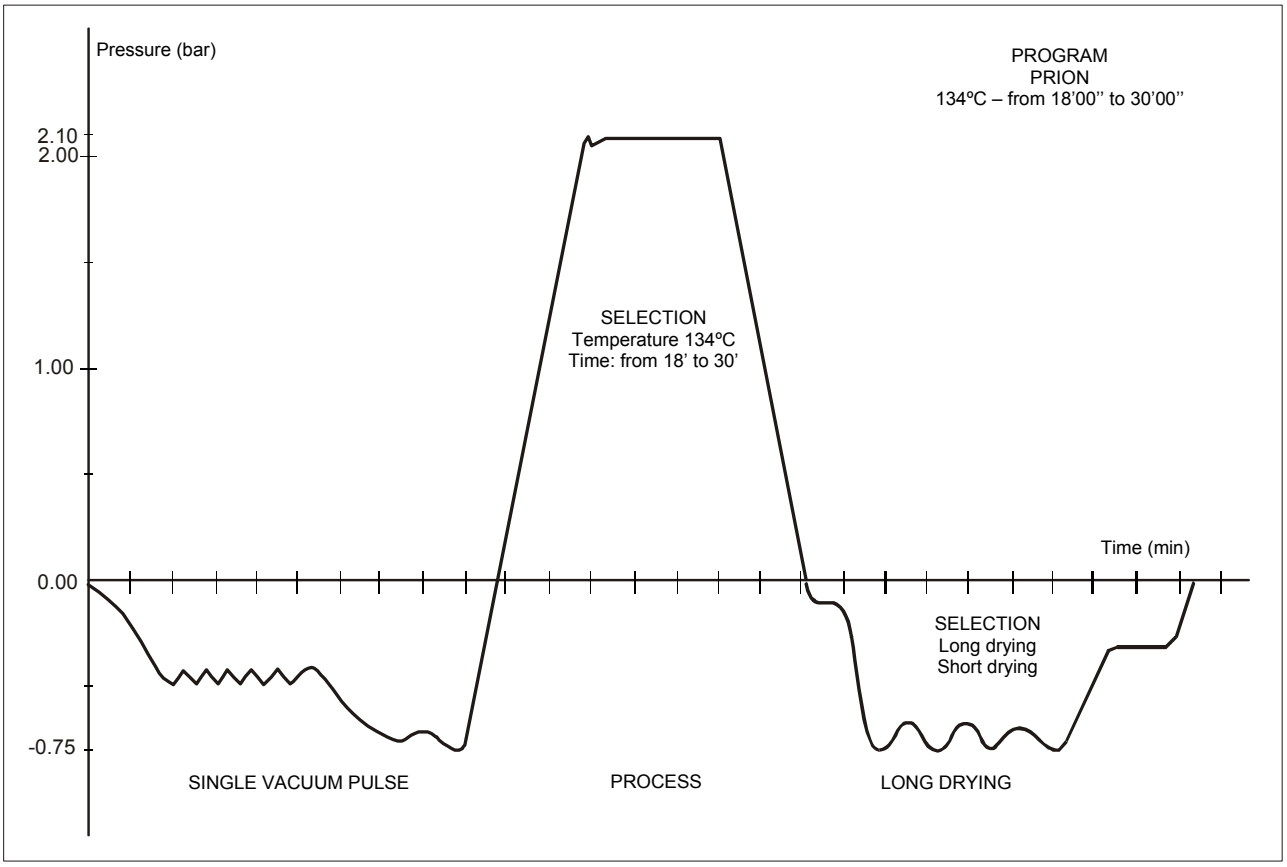




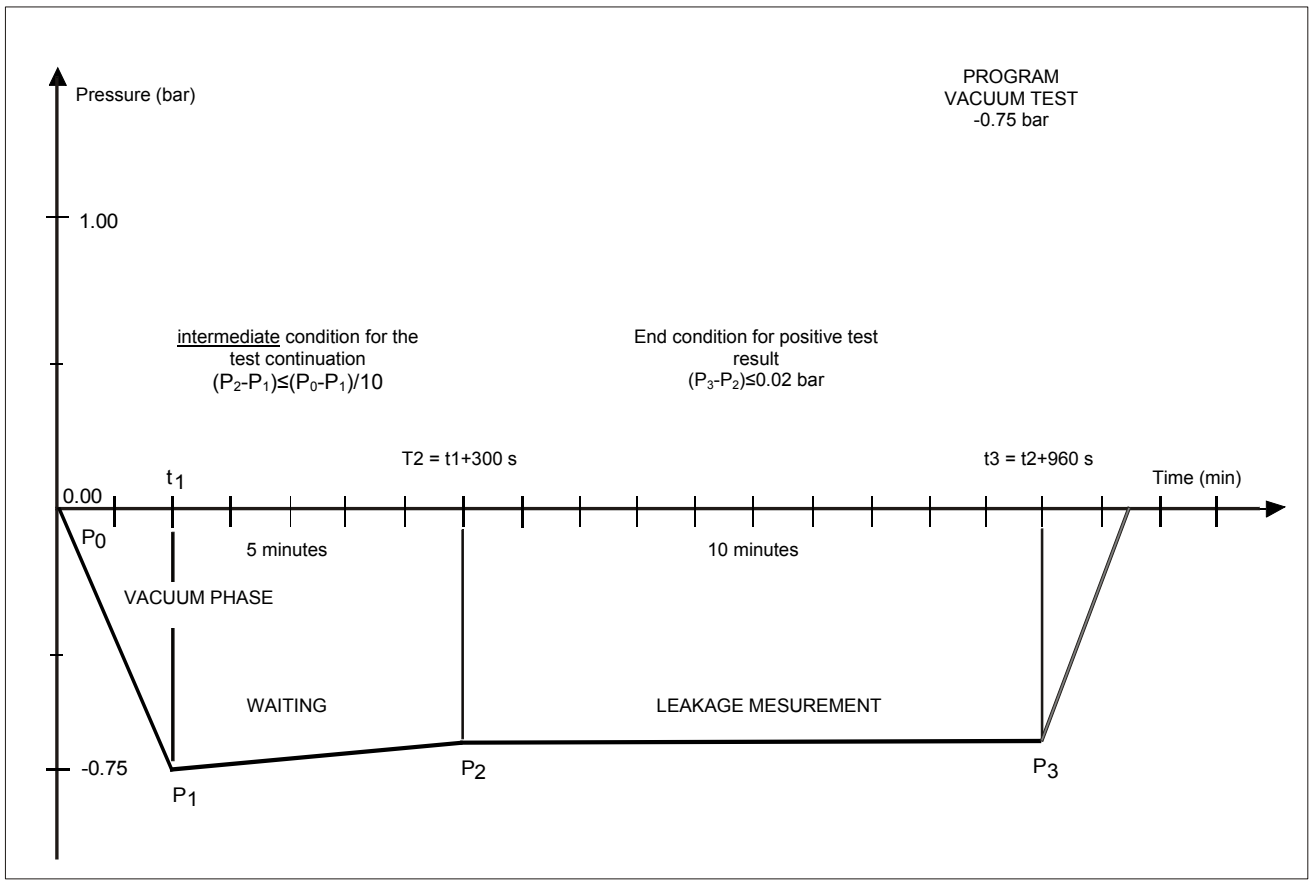

Pressure (bar)
PROGRAM
134ºC SOLID
134ºC – 4'00''
2.10
2.00
1.00
0.00
-0.75
Time (min)
SINGLE VACUUM PULSE
PROCESS
SHORT DRYING


Pressure (bar)
PROGRAM
121ºC SOLID
121ºC – 20'00''
1.10
1.00
0.00
-0.75
Time (min)
SINGLE VACUUM PULSE
PROCESS
SHORT DRYING


Pressure (bar)
PROGRAM
134ºC EMERGENCY
134ºC – 3'00''
2.10
2.00
1.00
0.00
-0.75
Time (min)
SINGLE VACUUM PULSE
PROCESS
FAST DRYING


Pressure (bar)
PROGRAM
PRION
134ºC – from 18'00'' to 30'00''
2.10
2.00
1.00
0.00
-0.75
SELECTION
Temperature 134ºC
Time: from 18' to 30'
Time (min)
SELECTION
Long drying
Short drying
SINGLE VACUUM PULSE
PROCESS
LONG DRYING

TEST PROGRAM DIAGRAM



EXAMPLES OF PRINTED REPORTS

Cycle Report (normal)

Model	EXACTA S
S/N	10 BX 0001
Ver. SW	E1002/BX000012
Counter	00099/00101
Selection	134°C WRAPPED
Temperature	134°C
Pressure	2.10 bar
Process time	4 min
Stand-by	HIGH
Pre-vacuum	SINGLE
Drying	STANDARD
CYCLE START	09/05/2006 16:48

Time		°C	bar
00:00	CSV	073.1	-0.02
05:38	1PV	076.0	-0.77
10:19	ET	135.5	+2.14
10:34	SS	135.8	+2.13
11:34		135.8	+2.13
12:34		135.8	+2.14
13:34		135.7	+2.14
14:34	SE	135.7	+2.13
15:33	DS	105.3	+0.00
17:33	SPD	085.9	-0.07
30:33	EPD	088.1	-0.62
31:33	DE	093.6	-0.07
31:48	CE	093.2	-0.03
10:34	MAX	135.8	
11:42	MIN	135.6	

Drying Pulses	14
CYCLE END	09/05/2006 17:20
STERILIZATION:	POSITIVE

OPERATOR

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Cycle Report (extended) *at the operator's request*

Model	EXACTA S
S/N	10 BX 0001
Ver. SW	E1002/BH000012
Counter	00099/00101
Selection	134°C WRAPPED
Temperature	134°C
Pressure	2.10 Bar
Process t ime	4 min
Stand-by	HIGH
Pre-vacuum	SINGLE
Drying	STANDARD
CYCLE START	09/05/2006 16:48

Time		PT1	P	PT2	PT3	PT4
00:00	CSV	073.1	-0.02	161.0	166.2	044.8
00:10	030	073.2	-0.09	163.2	165.4	045.1
00:20	030	073.1	-0.15	166.2	164.6	045.4
00:30	030	073.1	-0.20	169.8	163.7	045.7
00:40	030	073.0	-0.25	173.3	162.8	046.0
00:50	030	073.0	-0.29	175.7	162.0	046.3
01:00	030	072.9	-0.33	177.1	161.1	046.6
01:20	030	072.8	-0.41	177.9	159.8	047.1
01:52	040	074.5	-0.30	172.1	158.9	048.1
02:02	040	074.6	-0.36	172.5	159.0	048.6
02:12	040	074.9	-0.41	175.1	159.3	049.0
02:22	040	075.0	-0.44	179.2	159.5	049.4
		.....				
		.....				
08:16	110	121.0	+1.01	144.6	146.3	095.3
08:26	110	122.5	+1.11	144.8	144.6	097.1
08:36	110	123.9	+1.21	145.0	142.9	098.7
08:46	110	125.3	+1.31	145.4	141.3	100.3
		.....				
		.....				
15:04	130	121.7	+0.75	167.2	132.8	118.5
15:24	130	109.2	+0.18	167.3	132.3	111.8
15:33	DS	105.3	+0.00	167.0	132.4	109.6
		.....				
		.....				
19:13	140	077.3	-0.60	157.9	168.1	090.9
19:33	140	073.3	-0.67	157.0	167.2	089.8
19:49	140	071.3	-0.60	156.4	166.4	089.0
19:59	140	070.3	-0.62	156.0	165.9	088.6
20:09	140	069.5	-0.65	155.6	165.3	088.1
20:19	140	068.2	-0.68	155.2	164.7	087.7
20:32	140	067.9	-0.60	154.7	163.8	087.1
20:42	140	066.6	-0.63	154.3	163.3	086.7
20:52	140	065.8	-0.66	153.9	162.7	086.2
21:02	140	065.0	-0.68	153.5	162.3	085.9
23:29	140	080.8	-0.67	148.2	162.8	080.6
		.....				
		.....				
26:57	140	085.9	-0.65	141.5	163.2	075.6
27:17	140	085.5	-0.69	140.8	162.9	075.2
27:32	140	086.9	-0.60	140.3	162.9	074.9
		.....				
		.....				
29:16	140	086.2	-0.70	137.3	163.0	073.3
29:36	140	087.6	-0.62	136.7	162.9	073.0
29:46	140	087.3	-0.64	136.4	163.1	072.9

10:34	MAX	135.8
11:42	MIN	135.6

Drying pulses	14
CYCLE END	09/05/2006 17:20
STERILIZATION:	POSITIVE

OPERATOR. . . . . .

EXTENDED REPORT
REQUESTED BY THE OPERATOR

Report following a Manual Stop

Model	EXACTA S
S/N	10 BX 0001
Ver. SW	E1002/BH000012
Counter	00105/00111
Selection	134°C WRAPPED
Temperature	134°C
Pressure	2.10 bar
Process time	4 min
Stand-by	HIGH
Pre-vacuum	SINGLE
Drying	STANDARD
CYCLE START	11/05/2006 09:07

Time		°C	bar
00:00	CSV	079.5	-0.02
05:10	1PV	085.3	-0.77
08:31	ET	135.5	+2.14
08:46	SS	135.7	+2.14
09:46		135.7	+2.13
10:46		135.8	+2.14
11:46		135.8	+2.14

STERILIZATION:	NEGATIVE
ALARM CODE:	E999
DESCRIPTION	MANUAL STOP
DATE	11/05/2006
TIME	09:19

CAUTION
Please refer to the user manual

OPERATOR

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Report following a Blackout

Model	EXACTA S
S/N	10 BX 0001
Ver. SW	Exxxx/Bxyyyyyy
Counter	0006/0012
Selection	**134°C** PRIONE
Temperature	134 °C
Pressure	2.10 bar
Process time	18 min
Stand-by	HIGH
Pre-vacuum	SINGLE
Drying	FAST
CYCLE START	19/05/06 15:31
BLACK OUT	19/05/06 15:45
STERILIZATION	NEGATIVE

OPERATOR

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ALARM CODE:	E000
DESCRIPTION	BLACK-OUT

Cycle Report VACUUM TEST

S/N	10 BX 0001
Ver. SW	Exxxx/BHyyyyyy
Counter	0011/0019
Selection	VACUUM TEST
CYCLE START	19/05/06 11:37

Time		C	bar
00:00	CS	035.0	+0.00
01:39	E1F	037.4	-0.75
6:39	E2F	038.4	-0.74
22:39	E3F	042.0	-0.74
23:54	CE	045.5	-0.01

CYCLE END	19/05/06 12:01
VACUUM TEST:	POSITIVE

OPERATOR

. . . . . .

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 **periodic sterilizer validation**, 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.

WARNING

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

ORDINARY MAINTENANCE PROGRAM

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:

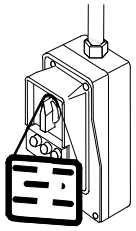
DAILY	Clean the gasket on the porthole Clean external surfaces
WEEKLY	Clean the sterilization chamber and relative accessories Disinfect external surfaces
MONTHLY	Clean the internal distilled water tank Safety valve maintenance Clean (or replace) the drain filter
ANNUALLY	Validate sterilizer (***see dedicated paragraph***)

Keep the following **general warnings** in mind:

- **Do not** 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;
- **Do not** use abrasive cloths, metal brushes (or other aggressive materials) or metal-cleaning products, whether solids or liquids, to clean the device or sterilization chamber;
- **Do not** use chemical products or disinfectants to clean the sterilization chamber. In fact, these products can damage the sterilization chamber, even irreparably;
- **Do not** allow lime residue or other substances to accumulate in the sterilization chamber or on the door and its gasket, but periodically remove them. In fact, they can damage these parts over time in addition to *compromising* the operation of the components installed along the plumbing circuit.

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

BEFORE 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.

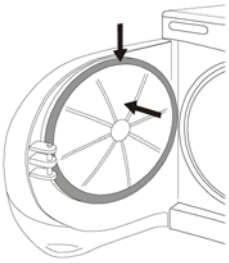
IF THE EXTERNAL BREAKER IS FAR AWAY OR, AT ANY RATE, NOT VISIBLE TO THE MAINTAINER, PLACE A WORK IN PROGRESS SIGN ON THE EXTERNAL BREAKER AFTER TURNING IT OFF.

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.

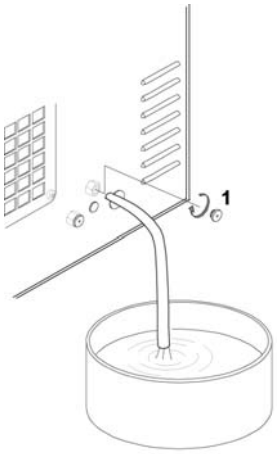
NOTE

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 APPENDIX A*).

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



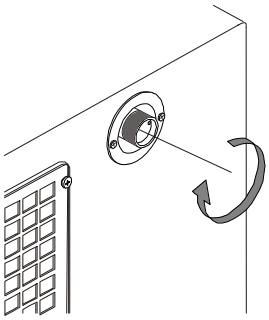
1. Arrange an empty container on the floor near the sterilizer and put the free end of a tube into it.
2. Unscrew the plug (1) from the rear draining point and plug-in the other end of the tube.
3. Wait until the internal tank is completely drained; close the draining point with the plug.
4. Prepare 4 liter of distilled water mixed with 10% of pure alcohol and fill the supplied standard container
5. Now fill completely the internal tank with this solution (see chapter "***Filling distilled water***" for the procedure) and allow the solution to sit for 30 minutes.

WARNING

DO NOT RUN ANY CYCLE DURING THIS PERIOD.

6. Drain again the internal tank and discard the solution. Close the draining point with the plug.

Safety valve maintenance

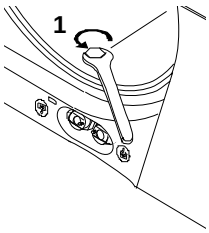


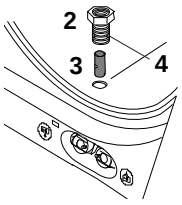
1. Access the safety valve located on the rear of the machine.
2. Loosen the knurled locking ring with your fingers (or a suitable tool inserted in the two holes in the ring itself), turning counter-clockwise until it reaches the end and turns loosely.
3. Retighten the locking ring and repeat the operation a couple of times.
4. **Definitively** tighten the locking ring all the way down.

WARNING

THIS OPERATION IS NECESSARY 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.

To clean (or replace) the filter, open the sterilizer door and remove the cap (**1)** with a 12mm hex. wrench (supplied).
Loosen the fitting (**2)** that contains the filter(**3)**.
Take the filter off the support and put it under running water to thoroughly clean. Use a sharp tool, if necessary, to remove the larger foreign objects(use jets of compressed air, if possible, to ease this operation).

If it is impossible to reuse the filter, replace it with a new one.

NOTA

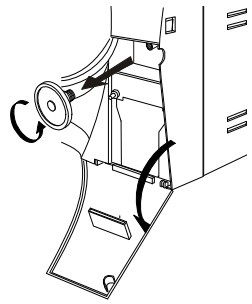
A REPLACEMENT BACTERIOLOGICAL FILTER IS SUPPLIED WITH THE DEVICE. TO REQUEST OTHERS, PLEASE REFER TO *APPENDIX Z, TECHNICAL SUPPORT*..

Reinstall all the parts performing the procedure in reverse order, and being **careful** to screw the fitting(**2**) in order to leave the drain holes (**4) at the same level as the wall of the boiler**.

NOTA

PROPERLY INSERT THE FILTER INTO ITS HOUSING; PARTIAL INSERTION MAY CAUSE DAMAGE TO THE COMPONENT.

Replace bacteriological filter



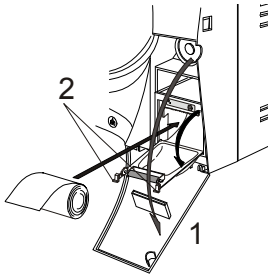
When it is due to be changed, or when you notice visible clogging of the filter (indicated by a color markedly tending towards gray) unscrew the bacteriological filter from its support and replace it with a new one by screwing it all the way down on the connector on the front of the machine.

NOTE

A REPLACEMENT BACTERIOLOGICAL FILTER IS SUPPLIED WITH THE DEVICE. TO REQUEST OTHERS, PLEASE REFER TO *APPENDIX Z, TECHNICAL SUPPORT*.

Replacing the paper in the printer (option)

Printer type 1



To replace a used-up roll of paper in the printer:

1. open the door (1) of the service compartment to access the printer
2. Press the tabs and the green button at the same time to open the door and access the paper compartment.
3. remove the empty roll and place a new roll of **thermal paper** so that the paper unrolls off the top;

   the roll must have the following dimensions:
   - width 57 mm / diameter max 50 mm
4. unroll about 15 cm of paper and close the compartment door,
5. thread the paper in the slot of door of the service compartment and reclose.

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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 **verify** the **thermodynamic process parameters** (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 17665** (*Sterilization of the medical devices - Method for the validation and systematic control of the steam sterilization*) and **EN 556** (*Sterilization of the medical devices – Requirements for the medical devices marked with "STERILE" indication*) supply an effective guide tool for carrying out the verifications on the steam sterilizers.

Since, 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 **company specializing** 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.*

DISPOSAL AT END-OF-LIFE

In accordance with Directives 2002/95/ EC, 2002/96/ EC and 2003/108/ EC, regarding the reduction in use of dangerous substances in electrical and electronic equipment, as well as waste disposal, such equipment may not be disposed of as normal urban waste and must be separated accordingly. When purchasing a new, equivalent piece of equipment, the old piece of equipment that has reached its end-of-life must be handed over to the reseller for proper disposal. The Manufacturer will carry out the functions defined by individual national legislation with respect to the reuse, recycling and other forms of salvaging of the above-mentioned waste.
The proper collection and separation of such equipment for recycling, treatment and disposal helps avoid any possible negative effects on the environment and health and facilitates the recycling of the materials of which the equipment is made. The crossed out rubbish can symbol indicates that the product, at the end-of-life, must be collected separately from other types of waste.

WARNING!

Improper disposal of the product results in the application of sanctions which are defined by individual national laws..

INTRODUCTION

If you run into a problem or alarm while using the device, you should **not** 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 sterilizer does **not** power-on.	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 main switch and/or differential switch are OFF.	Turn the switch ON.
	The mains fuses are blown.	Replace with good fuses of equal nominal value. (See the *Summary Table* in ***Appendix A***, ***Technical Characteristics***).
After pressing **START**, the sterilization cycle does **not** start.	The device is preheating.	Wait for the sterilizer to reach the proper operating conditions for starting the program. **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 (*or, at any rate, until the MIN* level signal turns off).
The **alarm** icon is lit.	An **alarm** was triggered, with the generation of the relative code and message (see *LCD*).	Check the alarm code and take the appropriate action. (See the *following paragraphs*, ***Alarms***, ***Alarm Codes*** and ***Troubleshooting***).
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. **DANGER** **LET THE DEVICE COOL, OR WEAR GLOVES TO AVOID BEING BURNED WHEN TOUCHING THE 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. **NOTE**: the display shows: NOW LEVELLING PLEASE WAIT…	Wait several minutes, until the pressure returns to 0.00 bar, and try 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
There is water on the support surface of the sterilizer.	Drain connectors or tubing (option) not correctly connected.	Check the tightness of the fittings; if necessary, reassemble, paying more attention to sealing. Check that the tubes are completely pushed onto the connectors; make sure that the plastic ties have been applied.
	The tube for the automatic water supply (option) not correctly connected.	Check the tightness of the connector; if necessary, reassemble, paying greater attention to sealing (see the ***Chapter,*** *"**Installation"***). 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.
The sterilizer has problems creating a vacuum in the chamber (drying problems, presence of water in the sterilization chamber at the end of the cycle, etc.).	Drain filter of the sterilization chamber obstructed.	Clean or replace the drain filter (See ***Appendix C*** *"**Maintenance"***).
	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.
	The air intake on the frame and/or the cover are obstructed or the heat exchanger is not sufficiently ventilated.	Remove all possible obstructions from the air intake and heat exchanger. Check that the device is not in direct contact with walls or surfaces (see the ***Chapter,*** *"**Installation"***).
Excessive humidity on the material and/or instruments at the end of the program.	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 *Summary Table* in ***Appendix A***, ***Technical Characteristics"***).
	Material **not** correctly positioned.	Position the material, and especially wrapped material, according to the instructions. (See the ***Chapter,*** *"**Preparing the Material"***).
	Wrong sterilization program selection	Select the appropriate sterilization program for the type of material to be treated. (See the *Summary Table* in ***Appendix B***, "***Programs***").
	Drain filter of the sterilization chamber obstructed.	Clean or replace the drain filter (See ***Appendix C*** *"**Maintenance"***).
Traces of oxidation or spots on instruments	Quality of the instruments is **not** adequate.	Check the quality of the instruments with the problem, checking whether the material they are made of can tolerate steam sterilization.
	Quality of the distilled water **not** adequate.	Empty the tank and fill it with high-quality distilled water. (See the *Water Supply Characteristics* in ***Appendix A***, "***Technical Characteristics"***).
	Organic or inorganic residues on the instruments	Carefully clean the material before subjecting it to the sterilization cycle. (See the ***Chapter,*** *"**Preparing the Material"***).

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

NOTE

SHOULD THE PROBLEM PERSIST, CONTACT THE CUSTOMER SERVICE (SEE *APPENDIX Z*) PROVIDING THE MODEL OF THE STERILIZER AND THE SERIAL NUMBER.
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 **three categories**:

- **E =** **ERROR**
  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 =** **ALARM**
  First-level fault, **not linked** to safety.
  A problem that normally is fixed by a specialized technician on-site.
  Code format: **Axxx** **(xxx = identifying number from 000 ÷ 999)**

- **H =** **HAZARD**
  Second-level fault, **linked** to safety.
  A problem generally fixed by the Technical Support Center.
  Code format: **Hxxx** **(xxx =** identifying number from 000 ÷ 999)

ALARM INTERVENTION

NOTE

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 **alarm** 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

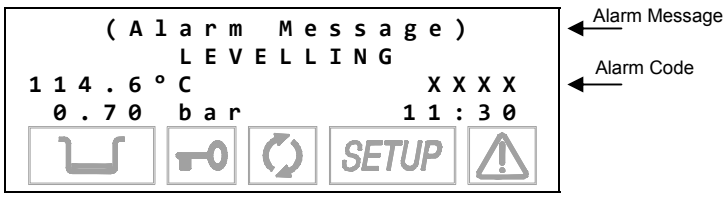
DURING THE ALARM PROCEDURE, THE DISPLAY ALWAYS SHOWS THE CURRENT TEMPERATURE AND PRESSURE IN THE STERILIZATION CHAMBER.

This procedure is designed so as **not** to allow the user to **mistake** an anomalous cycle for a correctly completed cycle and, as a consequence, **involuntarily using non-sterile material**.

The alarm procedure is **differentiated** depending on whether it occurs **during** the execution of the program or **outside**, and is structured to guide the user to the necessary **RESET** of the sterilizer.

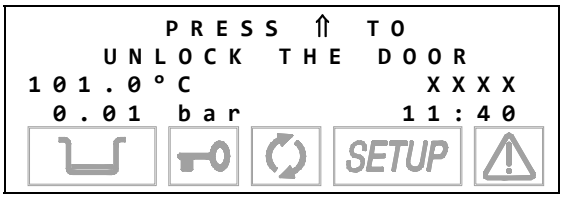
Alarm during a cycle

If the alarm intervenes **during a program**, the display will show the message:

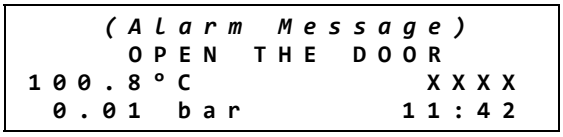


Whenever an alarm is generated in certain phases of the cycle, an automatic procedure is activated to clean the internal water circuit. The display will contain the notice:

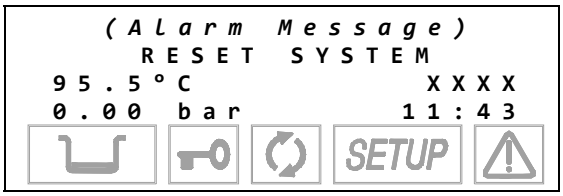
At the end of what has been described and having reached safe conditions, the machine activates a special procedure, that asks the user to manually unlock the door:



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



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.

NOTE

WHEN THE DOOR IS OPENED, THE REPORT (NORMAL OR EXTENDED DEPENDING ON THE TYPE OF ALARM) WILL BE PRINTED FOR THE INTERRUPTED STERILIZATION PROGRAM AND THE ALARM THAT INTERVENED. CHECK THE DOCUMENT, INITIAL IT IN THE SPACE PROVIDED AND FILE IT IN A SUITABLE PLACE. REFER TO THE PRINT REPORT EXAMPLES SHOWN IN APPENDIX B, PROGRAMS".

Alarm outside the cycle

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

Turn-off the equipment and check the alarm.

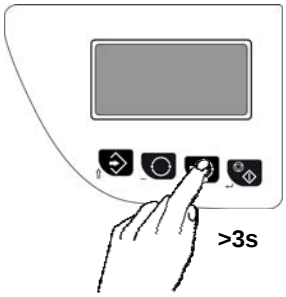
Or, depending on the type of alarm:

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

NOTE

ALARMS THAT INTERVENE OUTSIDE OF A PROGRAM DO NOT PRODUCE A PRINTED REPORT.

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;

<u>WARNING</u>

NEVER TURN THE DEVICE OFF BEFORE EXECUTING A RESET.

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 (category E)			
E 000	Blackout	BLACK-OUT	Press key + ***(> 3 seconds)***
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	
E 041 (option)	Filling the tank too frequently (*automatic filling*)	FILLING PROBLEM	

CODE	ALARM DESCRIPTION	LCD INDICATION	RESET MODE
HAZARDS (category H)			
H 150	MPX pressure sensor broken	MPX BROKEN	Turning-off device
H 160	MPX pressure sensor short-circuited/not connected	MPX SHORTCIRCUIT	
H 400	Ratio P_{conv}/T not balanced (P_{conv}>T) (*Phase **PROCESS***)	P/T PROBLEM	Press key + ***(> 3 seconds)***
H 401	Ratio T/P_{conv} not balanced (T>P_{conv}) (*Phase **PROCESS***)	T/P PROBLEM	
H 402	Temperature above MAX limit (*Phase **PROCESS***)	T OVER LIMIT	
H 403	Temperature below MIN limit (*Phase **PROCESS***)	T UNDER LIMIT	
H 404	Temperature fluctuating over the limit (*Phase **PROCESS***)	PT1 FLUCTUATING	
H 405	Pressure above MAX limit (*Phase **PROCESS***)	P OVER LIMIT	
H 406	Pressure below MIN limit (*Phase **PROCESS***)	P UNDER LIMIT	
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	

ANALYSIS AND RESOLUTION OF PROBLEMS

Based on the **type of alarm**, 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 ***(blackout)***.	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 *Summary Table* in ***Appendix A***, ***Technical Characteristics"***). Turn-on the device and perform **RESET** following the instructions.
E 010	Door open (or **not** properly closed) at the start of the program (***START***).	Perform **RESET** following the instructions. Close the door properly and restart the program.
	Door position microswitch broken.	**Contact the Technical Support Department (*see Appendix Z*).**
E 020	Limit microswitch (***CLOSED*** position) of the door lock mechanism broken.	Perform **RESET** following the instructions. Try to start the program a second time. If the problem persists **contact the Technical Support Department (*see Appendix Z*)**.
	Door lock system gear motor broken.	
E 021	Limit microswitch (***OPEN*** position) of the door lock mechanism broken.	Perform **RESET** following the instructions. **Contact the Technical Support Department (*see Appendix Z*)**.
	Door lock system gear motor broken.	
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 Appendix Z*).**
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 (*see Appendix Z*)**.
	Problem in the plumbing circuit.	
E 900	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.
	Problem in the plumbing circuit.	**Contact the Technical Support Department (*see Appendix Z*)**.

CODE	POSSIBLE CAUSE	PROPOSED SOLUTION
E 901	Excessive humidity in the sterilization chamber.	Perform **RESET** following the instructions. Carefully dry the inside of the sterilization chamber and start the program again.
	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.
	Problem in the plumbing circuit.	**Contact the Technical Support Department (*see Appendix Z*).**
E 902	Excessive humidity in the sterilization chamber.	Perform **RESET** following the instructions. Carefully dry the inside of the sterilization chamber and start the program again.
	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.	**Contact the Technical Support Department (*see Appendix Z*).**
	Problem in the plumbing circuit.	
E 999	**Manual interruption of sterilization or test** program. (*Also see the **Chapter,** "**Running the Program**"*)	Perform **RESET** following the instructions. Check that the **load has been correctly sterilized** (see LCD indicators) before using the material.
ALARMS (category A)		
A 022	Limit microswitch(es) on the door lock mechanism broken.	**Contact the Technical Support Department (*see Appendix Z*).**
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 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).	

CODE	POSSIBLE CAUSE	PROPOSED SOLUTION
A 200	Intervention of the steam generator safety thermostat.	Manually rearm the thermostat located on the back of the device (see the ***Chapter,*** "***Product Introduction"***).
	Steam generator malfunction.	Unscrew the black plastic protection cap, press the **red button** until you hear a click and replace the cap. Turn-off (**RESET**) and then turn-on the device. If the problem persists **contact the Technical Support Department (*see Appendix Z*)**.
A 250	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. **Do not** put material impregnated with water, or liquids in general, in the chamber.
	Drain filter of the sterilization chamber obstructed.	Clean or replace the drain filter (See ***Appendix C*** *"**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.	**Contact the Technical Support Department (*see Appendix Z*).**
	Problem in the plumbing circuit.	
A 251	Water injection pump malfunction.	**Contact the Technical Support Department (*see Appendix Z*).**
	Problem in the plumbing circuit.	
	Intervention of the steam generator safety thermostat.	See A 200. **Contact the Technical Support Department (*see Appendix Z*)**.
	Steam generator malfunction.	
A 258	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.
	Excessive load.	Perform **RESET** following the instructions. 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 ***Appendix A***, ***Technical Characteristics***).
	Problem in the plumbing circuit.	**Contact the Technical Support Department (*see Appendix Z*).**
A 259	Excessive load.	Perform **RESET** following the instructions. 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 ***Appendix A***, ***Technical Characteristics***).
	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.
	Problem in the plumbing circuit.	**Contact the Technical Support Department (*see Appendix Z*)**.
A 260	Problem in the plumbing circuit.	

CODE	POSSIBLE CAUSE	PROPOSED SOLUTION
HAZARDS (category H)		
H 150	Pressure sensor (MPX) broken.	**Contact the Technical Support Department (*see Appendix Z*)**.
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.	
	Problem in the plumbing circuit.	
H 404	Problem in the plumbing circuit.	
	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.	

Sistemi innovativi di sterilizzazione

DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY
DECLARATION DE CONFORMITE
KONFORMITÄTSBESCHEINIGUNG
DECLARACION DE CONFORMIDAD

Applicazione della Direttiva 93/42/CEE e successive modifiche intervenute
Application of the EEC Directive 93/42 and subsequent changes.
Application de la Directive CEE 93/42 et modifications ultérieures.
Anwendung der EWG Vorschriften 93/42 und nachfolgende Änderungen.
Aplicación de la Directiva CEE 93/42 y los subsiguientes cambios.

Descrizione del materiale: **Sterilizzatrice a vapore d'acqua**
Description of goods: **(Steam sterilizer)**
Description des marchandises:
Warenbezeichnung:
Descripción del material:

Modello: **EXACTA S**
Model:
Modèle:
Modell:
Modelo:

Classe dispositivo (93/42) e successive modifiche intervenute: **II b**
Device class (93/42) and subsequent changes:
Classe du dispositif (93/42) et modifications ultérieures:
Dispositifklasse (93/42) und nachfolgende Änderungen:
Clase del dispositivo (93/42) y los subsiguientes cambios:

Numero di serie:
Serial number:
Numéro de série:
Seriennumer:
Número de serie:

Nome del Fabbricante: **M.O.COM. s.r.l.**
Name of Manufacturer:
Nom du Fabricant:
Name des Herstellers:
Nombre del Fabricante:

Indirizzo del Fabbricante: **Via delle Azalee, 1 - 20090 Buccinasco (MI) - ITALIA**
Address of Manufacturer:
Adresse du Fabricant:
Adresse des Herstellers:
Dirección del Fabricante:

Dichiariamo sotto la nostra esclusiva responsabilità che i prodotti ai quali questa dichiarazione si riferisce sono conformi ai requisiti essenziali (Allegato I) presenti nella seguente direttiva: 93/42/CEE Dispositivi Medici (D.Lgs.46/97) e successive modifiche intervenute.
We declare on our own responsibility that the products which this declaration refers to are in accordance with the essential requirements (Annex I) to the following directive: 93/42/EEC Medical Devices and subsequent changes.
Nous déclarons sous notre exclusive responsabilité que le produit auquel cette déclaration se refère est conforme aux exigences essentielles (Annexe I) de la directive suivante: 93/42/CEE Equipements Médicaux et modifications ultérieures.
Auf unsere Alleinverantwortung erklären wir, dass das Produkt, worauf sich diese Zustimmung bezieht, grundlegenden Anforderungen (Anhang I) der folgenden Richtlinie gemäss ist: 93/42/EWG Medizinprodukte und nachfolgende Änderungen.
Declaramos bajo nuestra exclusiva responsabilidad que el producto al que esta declaración se refiere, está conforme a los requisitos esenciales (Anexo I) de la siguiente directiva: 93/42/CEE Equipos Médicos y los subsiguientes cambios.

Il prodotto sopra indicato è interamente conforme alla norma EN 13060: 2009.
The above mentioned product entirely conforms to the EN 13060: 2009 standard
Le produit cité plus haut est èntierement conforme à la norme EN 13060: 2009
Der obengenannte Produkt entspriecht vollständig der Norm EN 13060: 2009
El producto sobreindicado es enteramente conforme a la norma EN 13060: 2009

Altre norme di riferimento: EN 61010-1:2001 EN 61010-2-040:2005
Other reference standards: EN 61326-1:2006
Autre normes de référence:
Weitere Angewendete Normen:
Otras normas de referencia:

Data - Date - Le - Datum - Fecha

Firma - Signature - Signature - Unterschrift - Firma

Nome e Cognome - Name and Surname
Nom et Prenom - Nach und Vorname - Nombre y Apellido

Il Legale Rappresentante
(M.O.COM. S.r.l.)
(Funzione - Position - Fonction - Stellung - Función)

DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY
DECLARATION DE CONFORMITE
KONFORMITÄTSBESCHEINIGUNG
DECLARACION DE CONFORMIDAD

Applicazione della Direttiva 93/42/CEE e successive modifiche intervenute
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Description of goods: **(Steam sterilizer)**
Description des marchandises:
Warenbezeichnung:
Descripción del material:

Modello: **EXACTA S^2**
Model:
Modèle:
Modell:
Modelo:

Classe dispositivo (93/42) e successive modifiche intervenute: **II b**
Device class (93/42) and subsequent changes:
Classe du dispositif (93/42) et modifications ultérieures:
Dispositifklasse (93/42) und nachfolgende Änderungen:
Clase del dispositivo (93/42) y los subsiguientes cambios:

Numero di serie:
Serial number:
Numéro de série:
Seriennumer:
Número de serie:

Nome del Fabbricante: **M.O.COM. s.r.l.**
Name of Manufacturer:
Nom du Fabricant:
Name des Herstellers:
Nombre del Fabricante:

Indirizzo del Fabbricante: **Via delle Azalee, 1 - 20090 Buccinasco (MI) - ITALIA**
Address of Manufacturer:
Adresse du Fabricant:
Adresse des Herstellers:
Dirección del Fabricante:

Dichiariamo sotto la nostra esclusiva responsabilità che i prodotti ai quali questa dichiarazione si riferisce sono conformi ai requisiti essenziali (Allegato I) presenti nella seguente direttiva: 93/42/CEE Dispositivi Medici (D.Lgs.46/97) e successive modifiche intervenute.
We declare on our own responsibility that the products which this declaration refers to are in accordance with the essential requirements (Annex I) to the following directive: 93/42/EEC Medical Devices and subsequent changes.
Nous déclarons sous notre exclusive responsabilité que le produit auquel cette déclaration se refère est conforme aux exigences essentielles (Annexe I) de la directive suivante: 93/42/CEE Equipements Médicaux et modifications ultérieures.
Auf unsere Alleinverantwortung erklären wir, dass das Produkt, worauf sich diese Zustimmung bezieht, grundlegenden Anforderungen (Anhang I) der folgenden Richtlinie gemäss ist: 93/42/EWG Medizinprodukte und nachfolgende Änderungen.
Declaramos bajo nuestra exclusiva responsabilidad que el producto al que esta declaración se refiere, está conforme a los requisitos esenciales (Anexo I) de la siguiente directiva: 93/42/CEE Equipos Médicos y los subsiguientes cambios.

Il prodotto sopra indicato è interamente conforme alla norma EN 13060: 2009.
The above mentioned product entirely conforms to the EN 13060: 2009 standard
Le produit cité plus haut est èntierement conforme à la norme EN 13060: 2009
Der obengenannte Produkt entspriecht vollständig der Norm EN 13060: 2009
El producto sobreindicado es enteramente conforme a la norma EN 13060: 2009

Altre norme di riferimento: EN 61010-1:2001 EN 61010-2-040:2005
Other reference standards: EN 61326-1:2006
Autre normes de référence:
Weitere Angewendete Normen:
Otras normas de referencia:

Data - Date - Le - Datum - Fecha

Firma - Signature - Signature - Unterschrift - Firma

Nome e Cognome - Name and Surname
Nom et Prenom - Nach und Vorname - Nombre y Apellido

Il Legale Rappresentante
(M.O.COM. S.r.l.)
(Funzione - Position - Fonction - Stellung - Función)

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 available to customers to provide 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 at@mocom.it
website www.mocom.it

To help us in the indispensable work of improving 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.