Sterifast
sterilization & disinfection

INSTRUCTION MANUAL

Hydrogen Peroxide
Low Temperature Plasma Sterilizers

Models:
STERIFAST S50, S110, S160
ECOPLASMA E50, E110, E160
(AUTOMATIC SLIDING DOORS)

IMP.92.0 Ed. 4, Rev. 3 – 01/2026

“Original Instruction”

CE 2460

Sterifast
sterilization & disinfection

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“STERIFAST”and “ECOPLASMA” are registered trademarks that were created to give name to the newest low temperature sterilizers and the range of consumables used in their sterilization processes.

Either the sterilizer and the sterilization process using hydrogen peroxide are protected by **Patent N.º PCT/PT2007/000029, International Publication N.º WO2009/008755.**

The STERIFAST and ECOPLASMA Low Temperature Sterilizers are CE marked by DNV Product Assurance AS, Notified Body N.º 2460.
Please note that CE 2460 mark is applicable for Sterilizers only and not applicable for any accessories mentioned on this Manual.

This manual is divided in chapters and sections that are referred on the TABLE OF CONTENTS. In order to make a faster and easier consult of the manual, please look for the respective section in the table of contents.

This Instruction Manual must be consulted in all cases where this symbol  **is marked on the equipment, in order to understand the nature of any potential hazards and any actions which have to be taken to avoid them.**

Sterifast Lda. has performed a Clinical Evaluation of the Sterilizers and implemented a Vigilance System in order to obtain clinical data about their safety and performance. This Instruction Manual is consistent with that clinical data and covers all the hazards and other clinically relevant information that may impact on the use of the Sterilizers.
For this reason, this Instruction Manual may be subject to revision and updates without prior notice.

For legal purposes, the English version of this Manual prevails over any other language.

Your Sterilizer model is:

insert model, example **ECOPLASMA E110 2SD-B**

With SN:

insert SN, example **EDPT20250001**

Year of Production:

insert year, example **2026**

CE 2460

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1 - Sterilizers Description

1.1 - What is the STERIFAST Low Temperature Plasma Sterilizer?

STERIFAST is a Low Temperature Sterilizer studied and prepared to sterilize medical devices in general and thermo-sensitive medical devices. STERIFAST sterilization process is based on the Hydrogen Peroxide Vapor injection in a sterilization chamber at a controlled temperature.

This equipment has two doors that work in "interlock" allowing the sanitary barrier and includes a high vacuum system.

The automation system is composed of a computer with a touch screen and a PLC with analogical and digital outputs.

Thanks to the vaporizer used in the STERIFAST, it is possible to sterilize medical devices with **50% H_2O_2 Aqueous Solution Sterilizing Agent**.

One of the characteristics of the STERIFAST Sterilizer is to enable fast sterilization cycles and a system that allows the dosing inside the vaporizer in a complete absence of air.

The sterilization chamber is filled with hydrogen peroxide vapor after the relative humidity inside the chamber has been reduced. The sterilization occurs inside the Sterifast chamber by means of hydrogen peroxide saturation.

The vaporization drop device has advantages in comparison to the traditional devices, like the precision obtained with the Sterilizing Agent dripping, by using a capillary tube inside the vaporizer, and the doses' variability applied through a computer control system, which permanently monitors the device functioning through several pressure and temperature probes. Regarding the injection, the sterilizer has a capillary tube inside the vaporizer, which transforms the liquid into pulverized gas.

The sterilization process occurs after reaching 1 mbar pressure in the vaporizer and the whole process occurs in vacuum.

The vaporizer is physically open to the chamber and there is no valve between the vaporizer and the chamber. The vaporizer is part of this same chamber.

The control system is based on the chamber pressure.

1.2 - What is the ECOPLASMA Low Temperature Plasma Sterilizer?

ECOPLASMA is a Low Temperature Sterilizer with low concentration of Hydrogen Peroxide (**35% H_2O_2 Aqueous Solution Sterilizing Agent**), prepared to sterilize medical devices in general and thermo-sensitive medical devices.
ECOPLASMA sterilization systems have the same design of STERIFAST sterilization systems but operate with a lower concentration of Hydrogen Peroxide.


1.2.1 - What is the Basic version Sterilizer?

Basic version is the same sterilization systems as the *Regular* version, but with the following differences:

The drawer for the sterilizing agent supplying system is manual, not automatic.
Sliding Door Sensor (Pedal) is not available.
Sterilizing agent tank is different.
Thermal Printer instead of Matrix Printer.
USB connection on the panel is not available.
Sterifast Mobile APP Software is not available.


1.3 – Intended Use:

STERIFAST and ECOPLASMA are low temperature sterilizers that use an aqueous solution of hydrogen peroxide as sterilizing agent, specifically intended to sterilize medical devices in general as well as temperature sensitive medical devices in a medical environment, according to instructions provided in the Instruction Manual.

1.4 – Intended Users / Target Groups:

The intended users are specifically health-care professionals.
Only qualified and trained personnel can operate the devices.
The devices are not to be used by lay persons.

1.5 – Models / Versions Description

STERIFAST	50%	Regular version	It is a low temperature sterilizer that uses an aqueous solution of hydrogen peroxide 50% concentration as sterilizing agent, specifically intended to sterilize medical devices in general as well as temperature sensitive medical devices in a medical environment, according to instructions provided in the Instruction Manual.	S50 1SD	50 liter chamber, 1 automatic sliding door	STF00501SD	5600778703100	5600778703STF0000H5
				S50 2SD	50 liter chamber, 2 automatic sliding doors	STF00502SD	5600778703117	
				S110 1SD	110 liter chamber, 1 automatic sliding door	STF01101SD	5600778703148	
				S110 2SD	110 liter chamber, 2 automatic sliding doors	STF01102SD	5600778703155	
				S160 2SD	160 liter chamber, 2 automatic sliding doors	STF01602SD	5600778703186	
		Basic version	STERIFAST *Basic* is the same sterilization system as the regular STERIFAST, but with the following differences: - The drawer for the sterilizing agent supplying system is manual, not automatic; - Sliding Door Sensor (Pedal) is not available; - Sterilizing agent tank is different; - Thermal Printer instead of Matrix Printer; - USB connection on the panel is not available; - Sterifast Mobile APP Software is not	S50 1SD-B	50 liter chamber, 1 automatic sliding door	STF00501SD-B	5600778703124	
				S50 2SD-B	50 liter chamber, 2 automatic sliding doors	STF00502SD-B	5600778703131	
				S110 1SD-B	110 liter chamber, 1 automatic sliding door	STF01101SD-B	5600778703162	
				S110 2SD-B	110 liter chamber, 2 automatic sliding doors	STF01102SD-B	5600778703179	
				S160 2SD-B	160 liter chamber, 2 automatic sliding doors	STF01602SD-B	5600778703193	
ECOPLASMA	35%	Regular version	The design and construction of the ECOPLASMA sterilizers is the same that STERIFAST sterilizers have but they operate with a lower concentration of Hydrogen Peroxide (35% instead of 50%). ECOPLASMA sterilizers have the exact same sterilization cycles that STERIFAST sterilizers have. Just "Vaporizer entry valve opening times" is different with Sterifast Model	E50 1SD	50 liter chamber, 1 automatic sliding door	STFE0501SD	5600778703018	5600778703STFE000MH
				E50 2SD	50 liter chamber, 2 automatic sliding doors	STFE0502SD	5600778703001	
				E110 1SD	110 liter chamber, 1 automatic sliding door	STFE1101SD	5600778703049	
				E110 2SD	110 liter chamber, 2 automatic sliding doors	STFE1102SD	5600778703056	
				E160 2SD	160 liter chamber, 2 automatic sliding doors	STFE1602SD	5600778703087	
		Basic version	ECOPLASMA *Basic* is the same sterilization system as the regular ECOPLASMA, but with the following differences: - The drawer for the sterilizing agent supplying system is manual, not automatic; - Sliding Door Sensor (Pedal) is not available; - Sterilizing agent tank is different; - Thermal Printer instead of Matrix Printer; - USB connection on the panel is not available;	E50 1SD-B	50 liter chamber, 1 automatic sliding door	STFE0501SD-B	5600778703025	
				E50 2SD-B	50 liter chamber, 2 automatic sliding doors	STFE0502SD-B	5600778703032	
				E110 1SD-B	110 liter chamber, 1 automatic sliding door	STFE1101SD-B	5600778703063	
				E110 2SD-B	110 liter chamber, 2 automatic sliding doors	STFE1102SD-B	5600778703070	
				E160 2SD-B	160 liter chamber, 2 automatic sliding doors	STFE1602SD-B	5600778703094	

2 – Safety Symbols and Personal Protective Equipment (PPE)

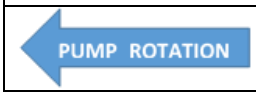
Symbol	Definition	Position
	Caution (Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)	In IFU,
	Wear Safety Gloves	Inside of the product
	Caution - Corrosion	Behind of agent insert area
	Caution - Electric Shock - High Voltage	On High Voltage Transformer
	Caution - Hot Surface	On Heater element
	Do not remove the thermostat	On thermostat
	Sliding Door going up	On sliding door
	Sliding Door Sensor (Pedal)	Front of device beside of the Pedal
	Earth Terminal	On Earth terminal inside of the product
	Protective Conductor Terminal	On Protective Conductor Terminal
	Vacuum Pump rotation direction	On Vacuum pump path

Table 1 – Safety Symbols

! IMPORTANT NOTICE !

The following Personal Protective Equipment (PPE) must be used when operating / servicing the STERIFAST or ECOPLASMA Sterilizers:

OPERATORS – Chemical resistant Protective Gloves; Goggles; Apron

TECHNICIANS (Installation, Maintenance, Repair) - Protection Gloves; Goggles; Apron

3 - Residual Risks and Report of Incidents

Sterifast Lda. has performed a Risk Analysis of the STERIFAST and ECOPLASMA sterilization systems. For each identified hazard, the risk has been estimated and measures and have been taken to reduce those risks as far as possible. These measures cover all the aspects related either to whole life cycle of device in design, manufacturing, storage, transportation, installation, usage, maintenance, and disposal. Also, in each phase of life cycle of device, design, usability, materials used for production, production procedures, instructions and recommendations on the devices to sterilize, as well as the safety warnings either on the equipment itself and on the use instructions, are considered.
The team for risk management review found the benefit to patients to be higher than the potential risk. There are however, some residual risks.

The table below lists the residual risks for the STERIFAST and ECOPLASMA sterilization systems during installation, usage and maintenance:

Phase / Activity	**Risk**	**Affected Person**	**Control Measures**
Installation moving the sterilizer	Falling device because of failure to observe safety precautions, can cause fracture or slight injury	Installation Technician	Installation must be done by duly trained technician following Instruction Manual **Sterilizers Instruction Manual, Chapter I - Sterilizer Installation**, gives adequate instructions on how to move and install the sterilizer.
Installation electrical connections	Electric shock / Burnings	Installation Technician	Use of personal protective equipment, appropriate tools and insulation **Sterilizers Instruction Manual, Chapter I - Sterilizer Installation**, gives adequate instructions on how to install the sterilizer.

Phase / Activity	Risk	Affected Person	Control Measures
Installation refilling sterilizing agent	In case of direct contact with sterilizing agent aqueous solution: Skin burns /irritation In case of inhalation of sterilizing agent vapours: Upper airway irritation, inflammation of the nose, hoarseness, shortness of breath, and a sensation of burning or tightness in the chest. Exposure to high concentrations can result in severe mucosal congestion of the trachea and bronchi and delayed the accumulation of fluid in the lungs.	Installation Technician	Installation must be done by duly trained technician following Instruction Manual. **Sterilizers Instruction Manual, Chapter II, part 7 – Sterilizing Agent Refill**, gives adequate instructions on how to supply the sterilizing agent to the sterilizer. **Sterilizers Instruction Manual, Chapter V, part 2 – Warnings and Notes about the Sterilizing Agent**, gives adequate instructions on how to handle the sterilizing agent. Also please refer to the sterilizing agent technical data sheet.
Usage Fire caused by Electrical connections / presence of flammable materials in the installation site	Severe burn	Operator / anyone who is near the sterilizer	Users must always be trained by Sterifast or its Distributor. Never smoke around the sterilizer installation site. Always have Firefighting equipment near the sterilizer. Do not store flammable materials around the sterilizer installation site.

Phase / Activity	Risk	Affected Person	Control Measures
Usage Handling / refilling sterilizing agent	In case of direct contact with sterilizing agent aqueous solution: Skin burns /irritation In case of inhalation of sterilizing agent vapours: Upper airway irritation, inflammation of the nose, hoarseness, shortness of breath, and a sensation of burning or tightness in the chest. Exposure to high concentrations can result in severe mucosal congestion of the trachea and bronchi and delayed the accumulation of fluid in the lungs.	Operator	Operation of the sterilizers must be done only by duly trained operators following Instruction Manual. **Sterilizers Instruction Manual, Chapter II, part 7 – Sterilizing Agent Refill**, gives adequate instructions on how to supply the sterilizing agent to the sterilizer. **Sterilizers Instruction Manual, Chapter V, part 2 – Warnings and Notes about the Sterilizing Agent**, gives adequate instructions on how to handle the sterilizing agent. Also please refer to the sterilizing agent technical data sheet.
Usage Residues of sterilizing agent on sterilized devices	Skin burns / irritation	Operator	Wear protective gloves
Usage Contact with hot surface (doors and chamber parts)	Slight skin burns	Operator	Wear protective gloves
Usage Cycles control	Non- sterility of medical device used on patient can cause infection	Patient	Operators must always be trained on how to control de sterilization process, this way avoiding non-sterile devices to be released for use on patients

Phase / Activity	Risk	Affected Person	Control Measures
Maintenance electrical connections	Electric shock / Burnings	Maintenance Technician	Use of personal protective equipment, appropriate tools and insulation. **Sterilizers Instruction Manual, Chapter III - Maintenance**, gives adequate instructions on how to perform maintenance and repair activities. **Sterilizers Instruction Manual, Chapter III, part 5 – Electrical Safety**
Maintenance handling sterilizing agent	Upper airway irritation, inflammation of the nose, hoarseness, shortness of breath, and a sensation of burning or tightness in the chest. Exposure to high concentrations can result in severe mucosal congestion of the trachea and bronchi and delayed the accumulation of fluid in the lungs.	Maintenance Technician	Maintenance must be done by duly trained technician following Instruction Manual. **Sterilizers Instruction Manual, Chapter II, part 7 – Sterilizing Agent Refill**, gives adequate instructions on how to supply the sterilizing agent to the sterilizer. **Sterilizers Instruction Manual, Chapter V, part 2 – Warnings and Notes about the Sterilizing Agent**, gives adequate instructions on how to handle the sterilizing agent. Also please refer to the sterilizing agent technical data sheet.
Maintenance Contact with hot surface	Burns	Maintenance Technician	Do not touch the parts with this sign  without protective gloves

Table 2 – Residual Risks Table

Note: Please refer also to Chapter VIII – FAQs for more information on residual risks.

! IMPORTANT NOTICE !

In case of occurrence of any serious incident in relation to STERIFAST or ECOPLASMA Sterilizers, you should report it to the manufacturer (please report immediately to Sterifast Lda. by email, to address **info@sterifast.com,** describing the details of the incident) and to the Competent Authority of the Member State in which the User is established.

4– Shipping Packaging and Product Label Symbols

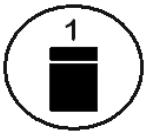
Symbol used on Packaging	Definition	Application Spot
	Keep in Upright Position	All 4 side panels of Pallet Box
	Centre of Gravity	All 4 side panels of Pallet Box
	Do not overload	All 4 side panels of Pallet Box
	Keep dry	Front Panel of Pallet Box
	Keep away from sunlight	Front Panel of Pallet Box
	Fragile, handle with care	Front Panel of Pallet Box
	Consult instructions for use	Front Panel of Pallet Box

Table 3 – Shipping Packaging Symbols

Symbol used on Packaging	Definition	Application Spot
	Manufacturer of medical device	Product Label on Sterilizer
	Medical Device	Product Label on Sterilizer
	CE Mark – (Notified Body DNV Product Assurance AS)	Product Label on Sterilizer
	Reference Number	Product Label on Sterilizer
	Serial Number	Product Label on Sterilizer
	Unique Device Identifier	Product Label on Sterilizer
	Manufacturing Date	Product Label on Sterilizer
	Voltage	Product Label on Sterilizer
	Power	Product Label on Sterilizer
	Frequency	Product Label on Sterilizer

Table 4 –Product Symbols

Introduction

This chapter explains indispensable checkpoints for the initial installation of STERIFAST or ECOPLASMA Sterilizers.
The sterilizers must always be installed by duly trained technicians.

1 - How to unpack the sterilizer

If the box/packaging has been damaged during the transport, inform your supplier immediately.
Also verify if the two **TIP&TELL indicators** and the two **SHOCKWATCH** indicators applied on the front and side panels are well or if there is indication that the package has been on its side or tipped over during transit, also if the package has been impacted.

to detect overturning/inclination – TIP&TELL

to detect impact – SHOCWATCH®2

Figure 1-1

If one or more of these indicators was activated during transport, do not refuse the shipment. Make notation in the delivery receipt and inspect for damage. Any claims depend on this notation.
Leave items in the original packaging and request immediate inspection from carrier within 3 days of delivery.
If a damage is found (even slight), take photos and report to Sterifast, for our risk management.

Position of the indicators on your shipment:

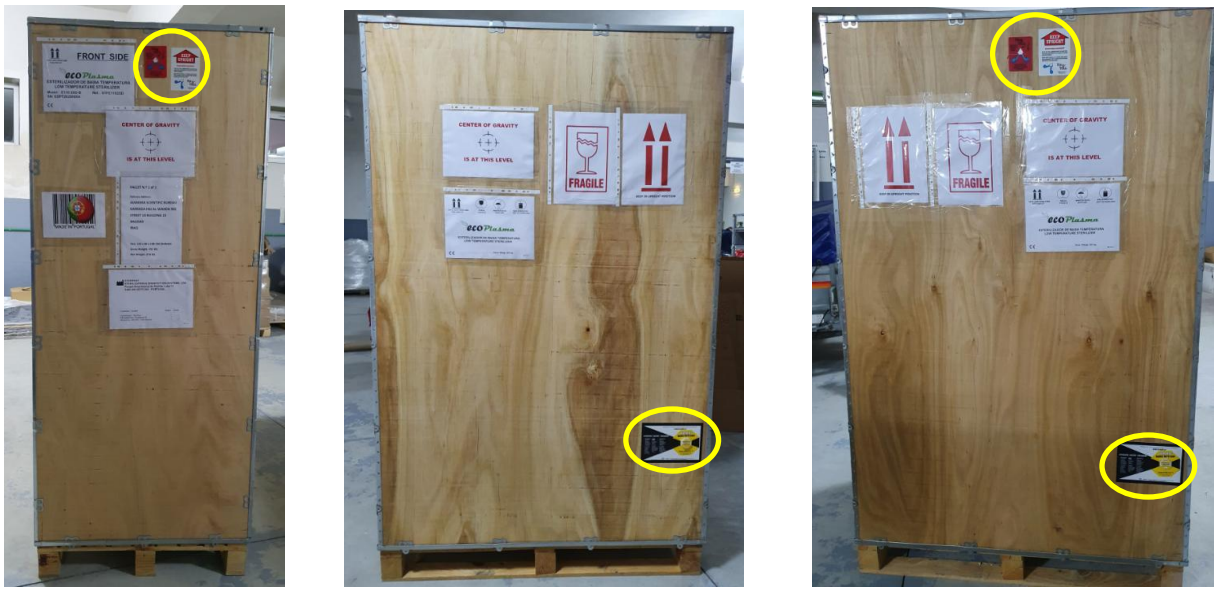


Figure 1-2

Always perform visual inspection of your shipment. The fact that the indicators are not activated does not invalidate the possibility of damage during transport.

Unpack the sterilizer in a wide space.

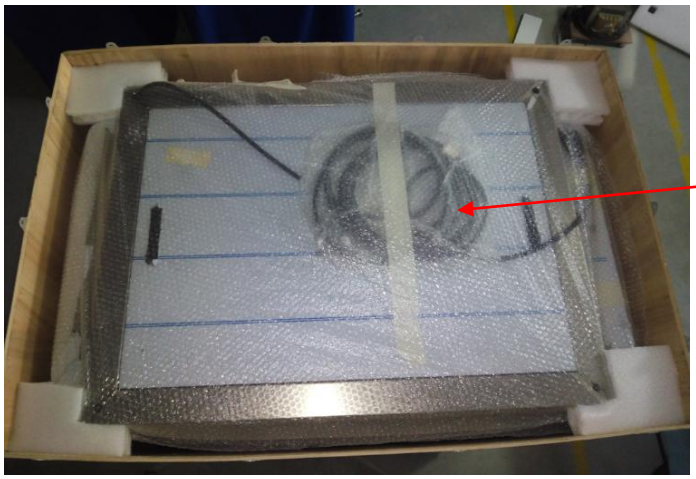
Figure 1-3

To start, you must unscrew the screws on the bottom. In the four sides of the pallet.

Then, using a screwdriver, lift all metal fittings that are bended to the side of the panels, according the images bellow, starting with the top panel:

Figure 1-4

When all the fittings are “opened” you can remove the panels.
Take out the top panel first, and also remove the protections of the four upper corners.



Note: Cable might be on the bottom, between sterilizer and pallet.

Figure 1-5

Take out the four external panels and then the protection plastics which wrap the sterilizer.

Figure 1-6

Figure 1-7

Remove all plastic foils, which are covering the stainless steel panels.

Remove the side panels of the sterilizer and cut the **straps** that secure the sterilizer structure to the pallet.

Figure 1-8

Lift the machine using a winch and lifting belts. Insert the belts in the lifting eyebolts which are installed on the top of the machine.

Before placing the machine on the ground check if the wheels are down and the feet are up. To turn up the feet, turn the orange/red notched ring on each foot clockwise (Red Arrow of Figure 1-9).

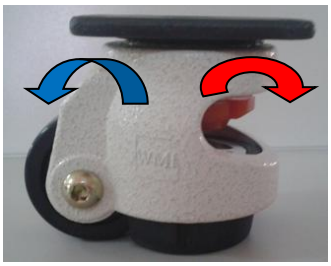


Figure 1-9

FOOT DOWN **FOOT UP AND WHEEL DOWN**

Figure 1-9.1

2- Moving the Sterilizer

The machine must be moved on its own wheels with utmost care.

- Thanks to the levelling wheels, it is very easy to move the sterilizer to the place it is going to be installed.
- Once on the installation site, turn the orange/red notched ring on each foot, counter-clockwise (Blue Arrow of Fig. 1-9), to lower down the feet and lift the wheels. Make sure that the sterilizer is levelled.
- The feet are made of anti-skidding material.

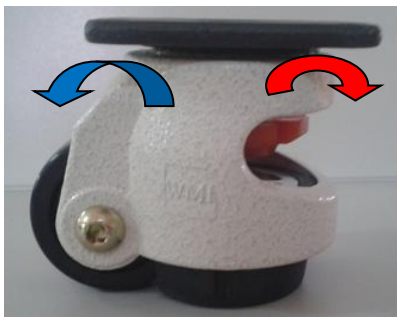


Figure 1-10

Turn Clockwise (Red Arrow) – Move Foot Up.

Turn Counterclockwise (Blue Arrow) – Move Foot Down.

3- Installation Requirements

- The Sterifast electric supply is 230V AC single-phase (frequency 50/60 HZ). The voltage must correspond to the required one;
- The sterilizer energy consumption depends on the model. The available power on the place where the sterilizer is being installed must be adequate;
- Verify if this place offers the required electrical specifications;
- Confirm the supplied voltage, verify with the identification plate;
- The voltage must be single phase or three phase;
- The mains supply that feeds the sterilizer must have a differential protection mains switch and load mains switch appropriate to the machine.
- The sterilizer must be positioned in a way so that it is not difficult to disconnect it from the main power supply.
- In a normal situation the room temperature should be kept between 15 to 30ºC for the cycles to run efficiently;
- The installation place must be ventilated;
- 5 air renewals per hour are necessary in case of a single door model. In case of double door models, 5 air renewals per hour in the loading and unloading areas and 5 air renewals in the technical area are necessary;

Important Note: For operator safety reasons, if you decide to move the sterilizer to another location, the Sterifast Company or his distributor should be informed before, in order to guarantee that exist the necessary safety conditions in the new location.

Installation plan:

Sterifast and ECOPlasma sterilizers must be installed according to the plans in **ANNEX 1** of this manual.
Installation Qualification and Operational Qualification Checklist and Safety Instructions - To Start can be found in **ANNEX 3**.

At the installation in the user institution, the sterilizers should be validated according to EN ISO 14937.

If in the same room there are two sterilizers installed side by side, there should be enough space between them for maintenance purposes by the side (1,5 meters between the two sterilizers).

Note:

Packaging materials shall be disposed-off according to the institution's waste circuit.
Packaging, equipment, parts or accessories shall not be sent to common waste.

4- Operation and Storage Environmental Conditions

The Operational Environmental conditions recommended for Sterifast and ECOPlasma Sterilizers are the following:

- Temperature: 5ºC to 40ºC
- Relative humidity: 10 to 80% RH, non-condensing
- Altitude: 2000 m maximum

If the sterilizer is not installed in the operation site immediately when delivered, and needs to be stored for some time, the Storage Environmental Conditions are the following:

- Temperature: 5ºC to 40ºC
- Relative humidity: Maximum up to 80% RH, non-condensing
- Altitude: 2000 m maximum

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Introduction

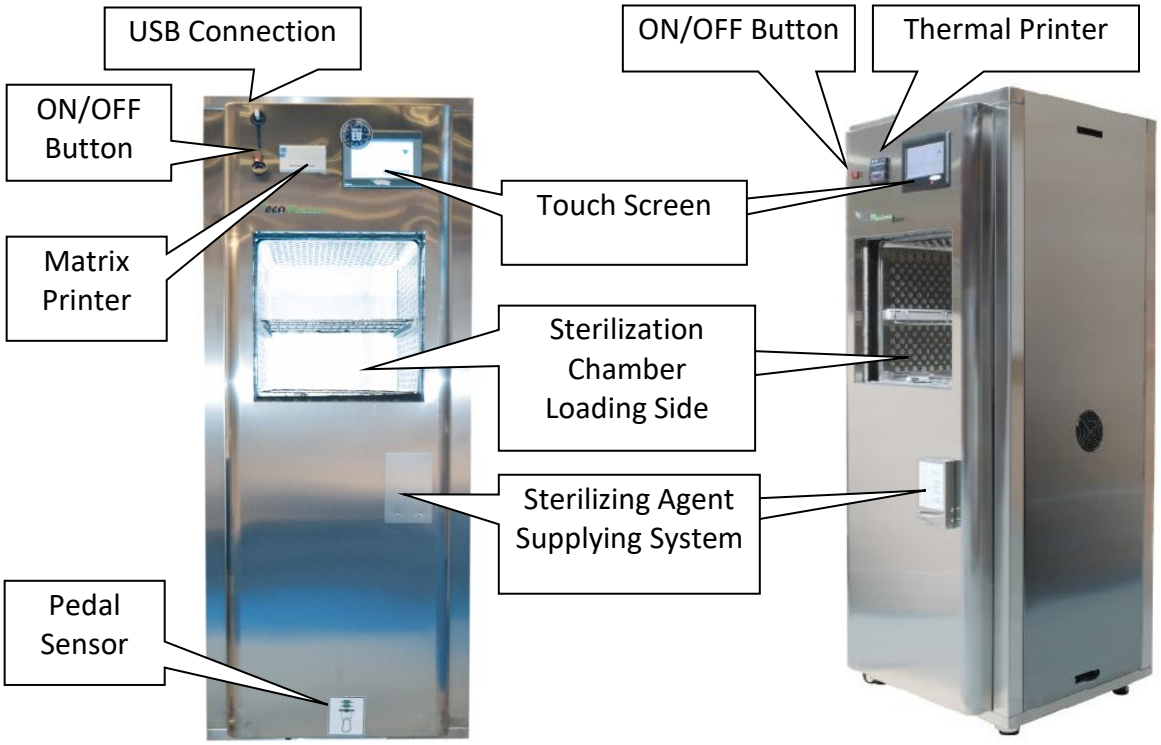
Inside this chapter you can find information on the Sterilizer External Appearance, how to prepare the sterilizers for operation and how to prepare the sterilization processes.

If the Sterilizers are not operated as specified in this Instruction Manual, the protection provided by the equipment may be impaired.

IMPORTANT WARNING

The Institution where the Sterilizer will be installed shall ensure that all the personnel who operate or maintain the equipment are duly trained by Sterifast Lda. (or its representative/distributor) in its operation and safe use. This includes instructions on safety related to the handling of the sterilizing agent.
The institution must ensure that records of attendance at that training are maintained and that evidence of understanding is demonstrated.
Sterifast Lda. declares that will accept no responsibility for damages caused to personnel who operates or maintains the equipment without the aforementioned training.

1 - Sterilizer External Look



STERIFAST and ECOPLASMA regular version Figure 2-1 **ECOPLASMA Basic version**

2 - Start-up (for Installation Technician)

- Remove the touch screen protection;

Important:

Please do never use cutting objects or objects that leave marks when touching the screen.

- Take out the right and left panels and verify the vacuum pump oil level. The oil must be between minimum and maximum level marks;

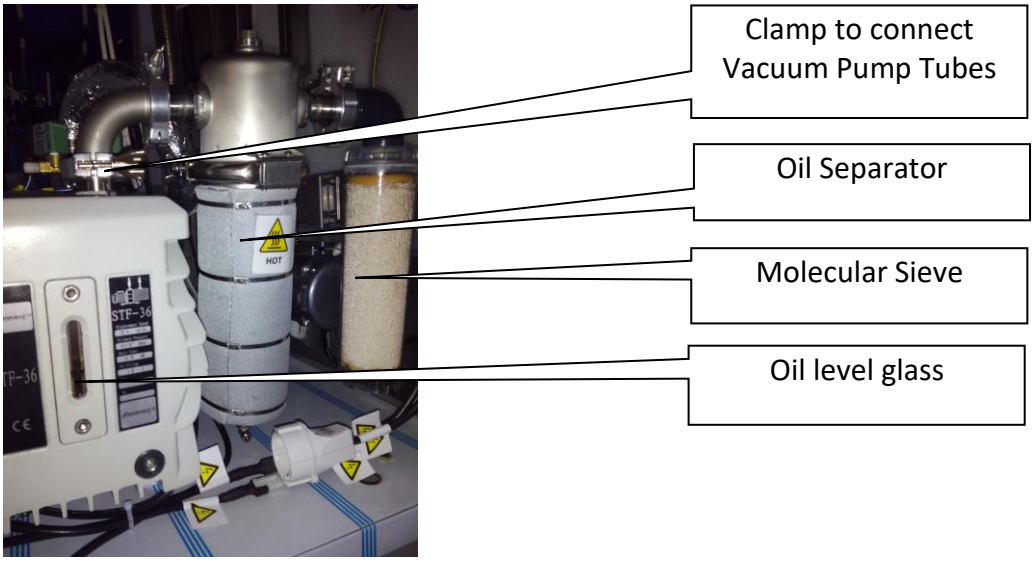


Figure 2-2

- The Vacuum Pump tubes are disconnected. Remove caps that seal the inlet and outlet of the Vacuum Pump, place the connection tubes and tighten the clamps.
- Apply the molecular sieve at the oil separator outlet.
- Fit the connection of the chamber heater to the thermostat.

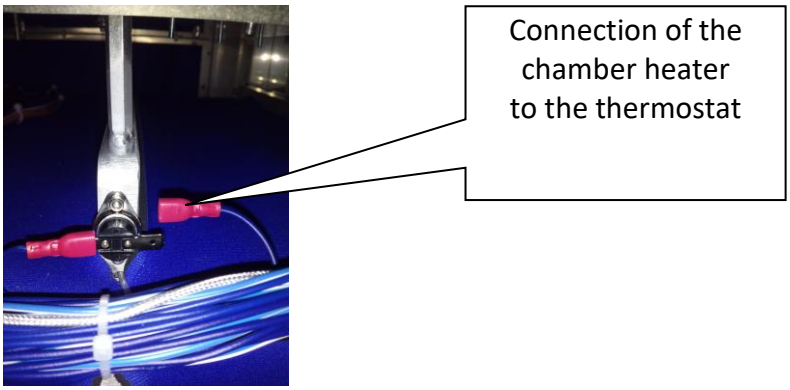


Figure 2-3

- Turn the PLC button to the “RUN/PROG” position, because it is in “STOP” position.

Figure 2-4

- Install the external panels back on place.

<u>The doors are blocked for transport/shipping.</u> To unblock them:

- Connect the sterilizer to electric power;
- Push ON/OFF button on the Unclean Side panel;
- Select one of the programs and the unclean side (loading) door will be unblocked.

Open the door and remove the items that have eventually been placed inside the chamber.

Note 1: The menus of the sterilizers can be activated in the following languages:

Portuguese, English, Spanish, German, French, Indonesian, Persian.

Note 2: The pictures may be different depending on the model and screen resolution of the computer.

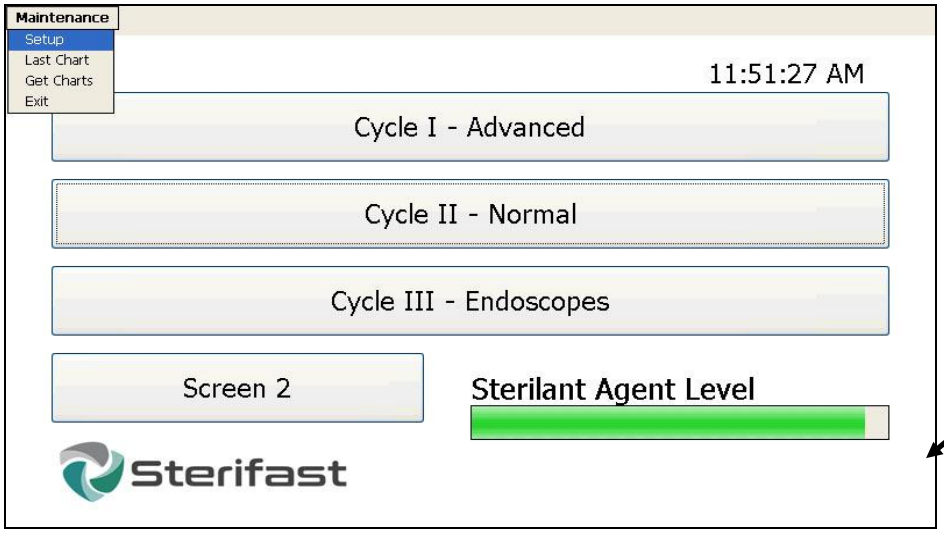
Note 3: Please use a *stilo* to press on the touchscreen. Please avoid touching with fingers.

3 - Preparing the Sterilizer for Operation (for Installation Technician)

3.1- Adjusting Date and Time

To adjust date and time:

- Press **"Maintenance"** button in the left upper side of the touch screen;
- Press **"Setup"** button;
- Press **"Date/Time"**;
- Adjust the Time using the buttons "+" and "-";
- Adjust the Date using the buttons "+" and "-";
- Press "**Exit**" to save and return to the Main Menu;



NOTE: This bar can appear in green or blue, depending on the model of the touch screen.

Figure 2-5

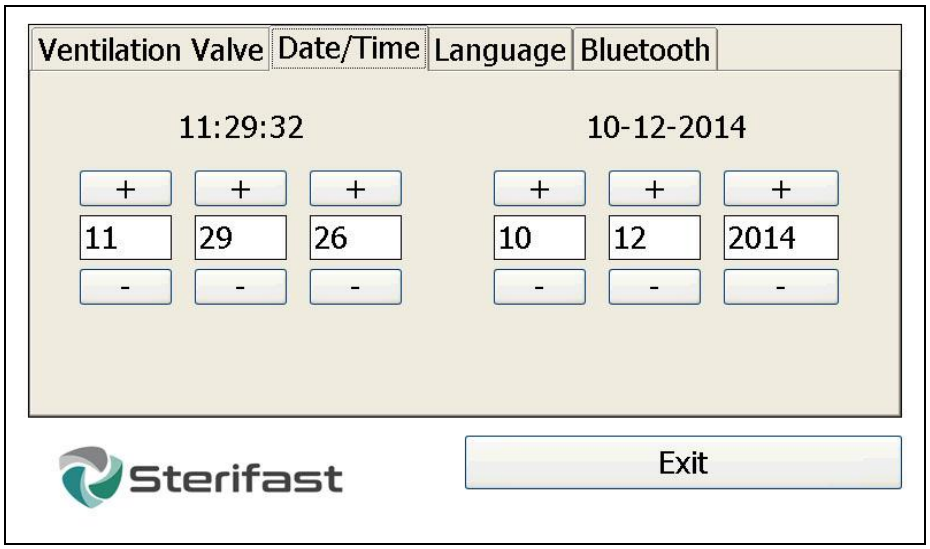


Figure 2-6

3.2- Language Selection

- Press **“Maintenance”** button in the left upper side of the touch screen;
- Press **“Setup”** button;
- Press **“Language”**;
- Select the Language using the buttons “«” and “»“;
- Press “**Exit**” to return to the Main Menu

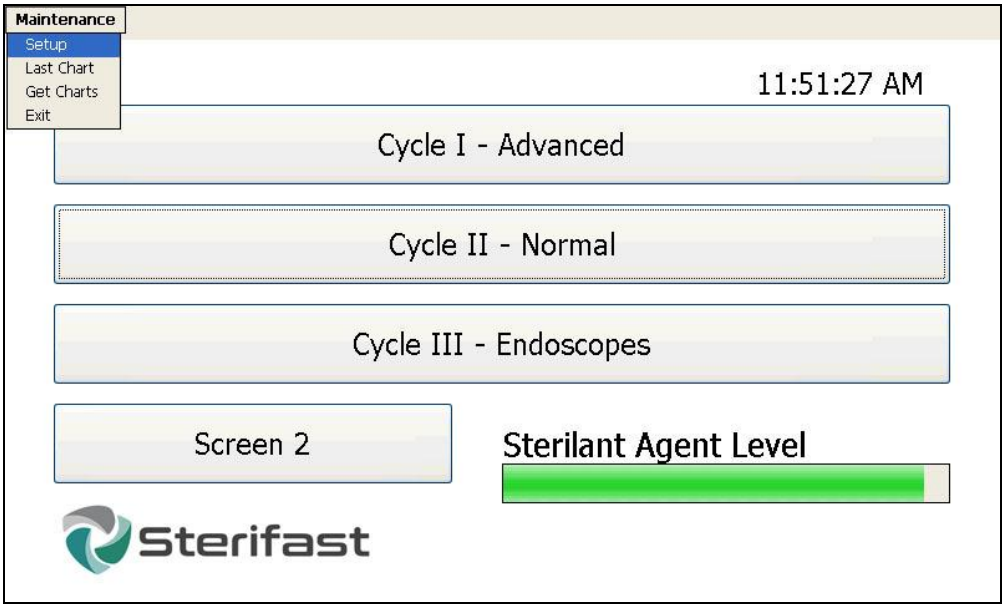


Figure 2-7

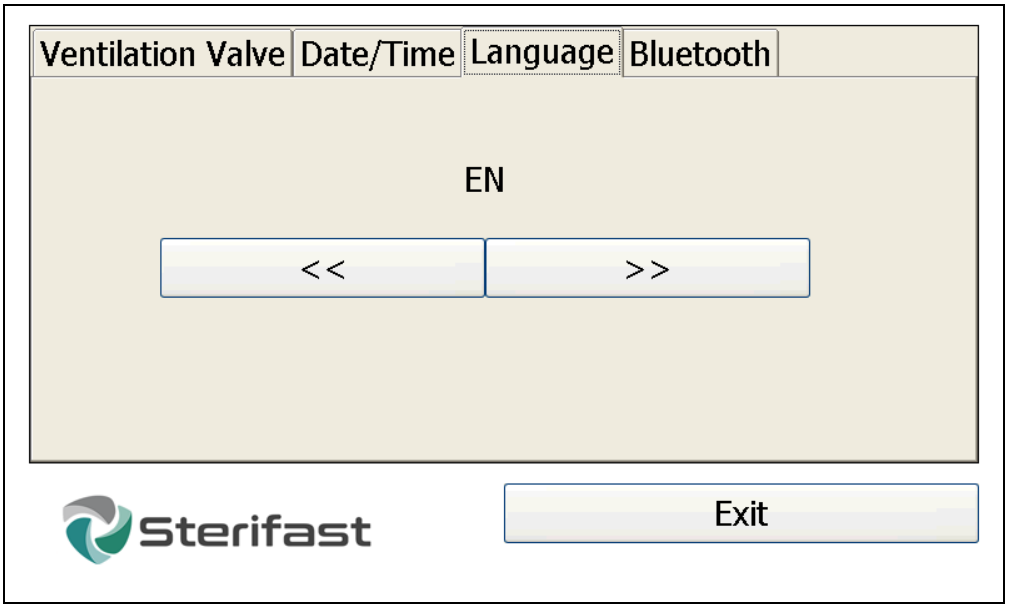


Figure 2-8

3.3 – Bluetooth (*Sterifast Mobile App is not available for ECOPLASMA Basic Sterilizers*)

- Press **"Maintenance"** button in the left upper corner of the touch screen;
- Press **"Setup"** button;
- Press **"Bluetooth"**;

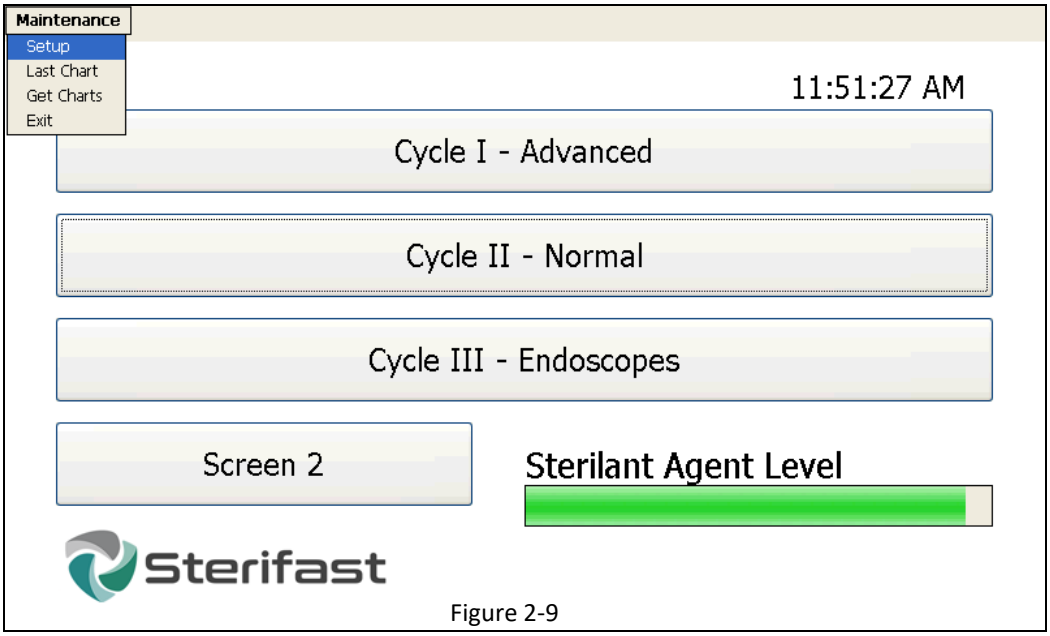


Figure 2-9

Go to the Mobile Phone and select "Sterifast Mobile" icon

Figure 2-10

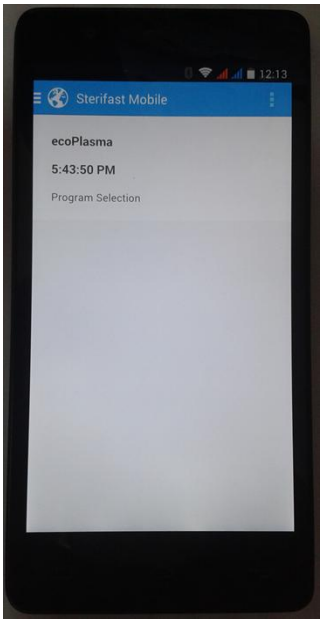


Figure 2-11

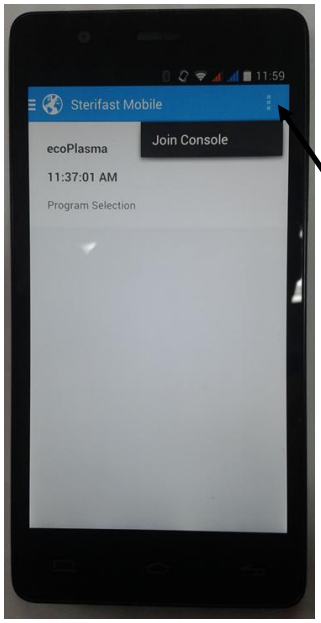


Figure 2-12

Press the button on the right upper corner of your mobile phone

Figure 2-13

Figure 2-14

Please copy the code that appears and write it on the touch screen (but without the “colons”)

If you did not have enough time to copy the code, please repeat the operation and the code will appear again.

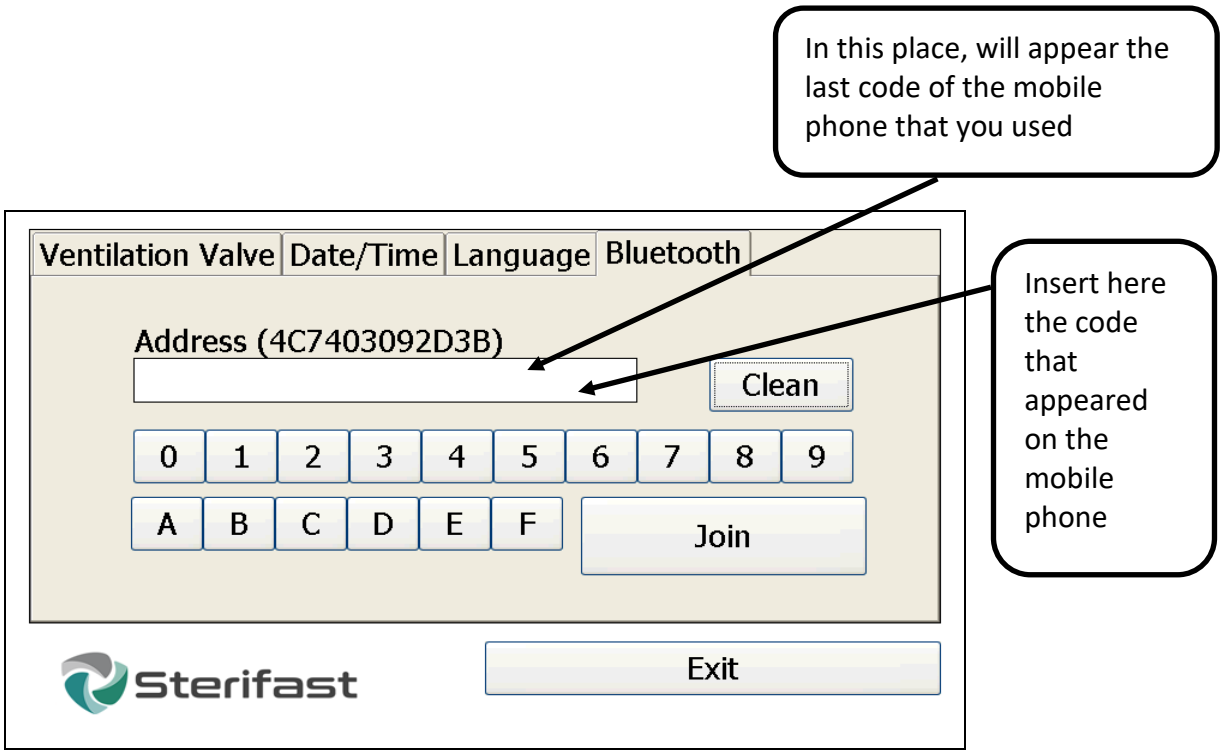


Figure 2-15

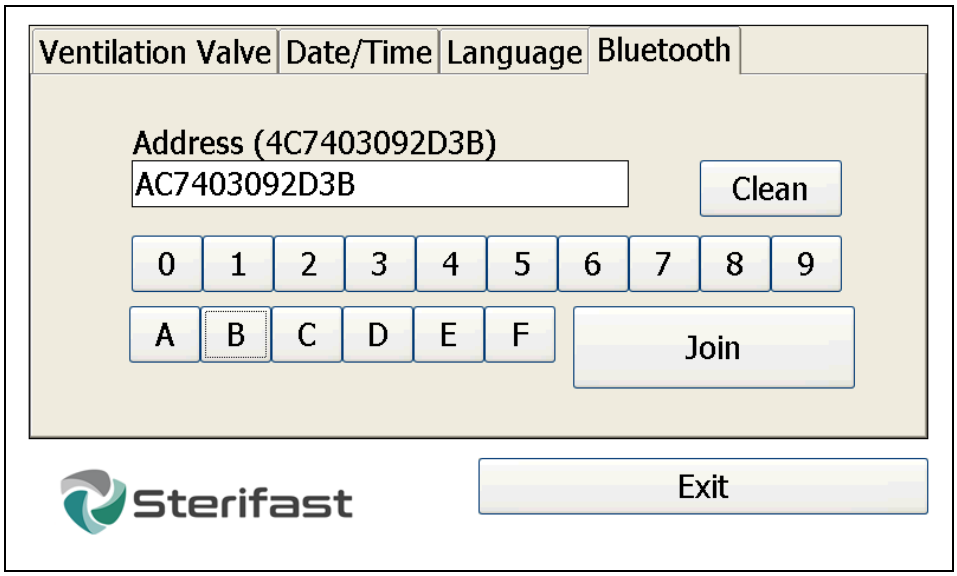


Figure 2-16

After inserting the code, please press **"Join"**.

After pressing "Join", the machine and the mobile are connected. Now you can see all the phases of the cycle in real-time.

Press **“Exit”** and return to Main Screen to continue.

Note: Once the connection with a certain mobile phone is done, it is not necessary to repeat this operation because it will be memorized.

If you want to use a different mobile phone for the connection, it will be necessary to press **“Clean”** button to clean the previous code and then follow the steps described above.

IMPORTANT: No more than one mobile phone should be connected with the machine at the same time.

For the STERIFAST MOBILE APP Features please see Annex 6

3.4 - Last Chart

- Press **“Maintenance”** button on the left upper side of the touch screen;
- Press **“Last Chart** button;

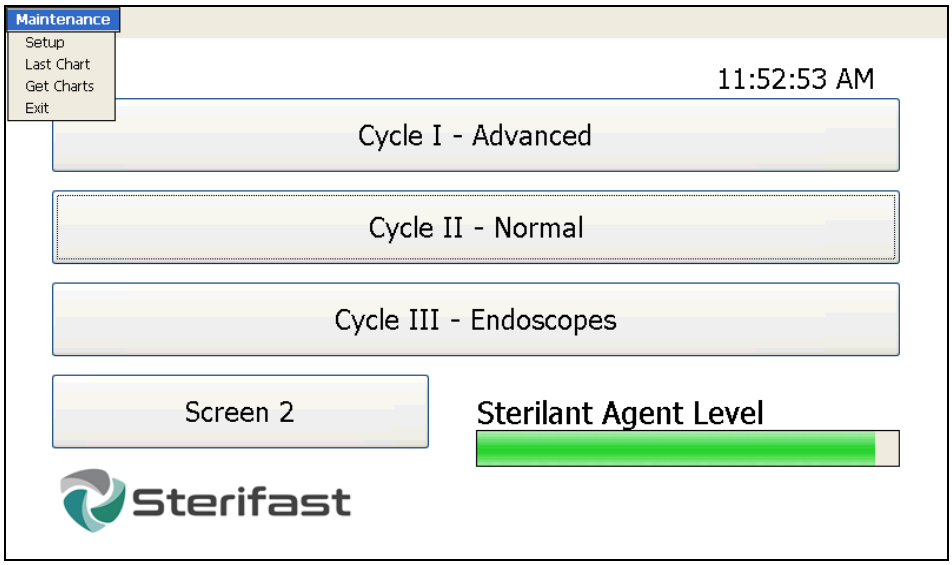


Figure 2-17

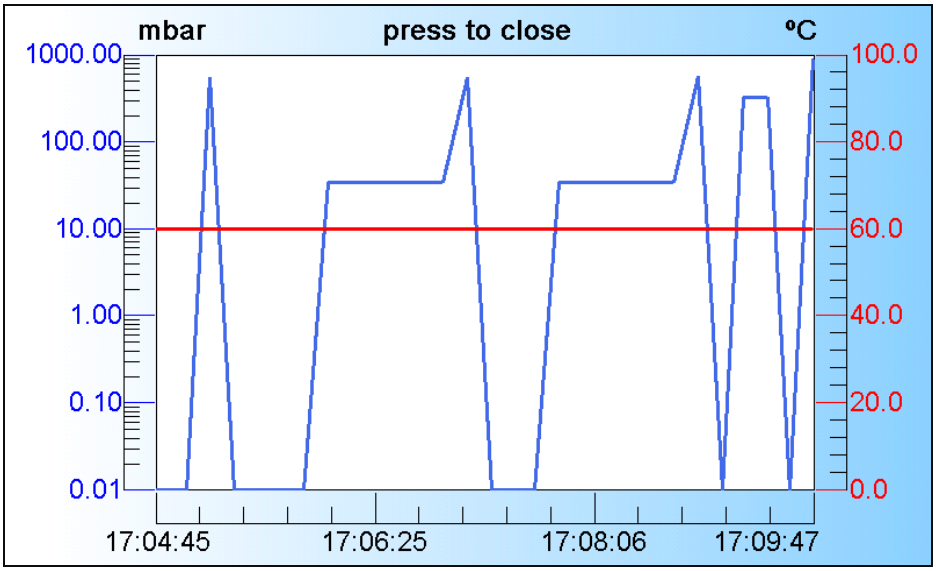


Figure 2-18

3.5 - Export the cycle reports

- Press **“Maintenance”** button on the left upper side of the touch screen;
- Press **“Get Charts”** button;
- Select the files to export;
- At the end, the touch screen will show if the files were exported successfully.

Note 1: The system saves the last 1000 cycle reports on its internal memory.
Note 2: It is possible to select / send 20 files at a time.

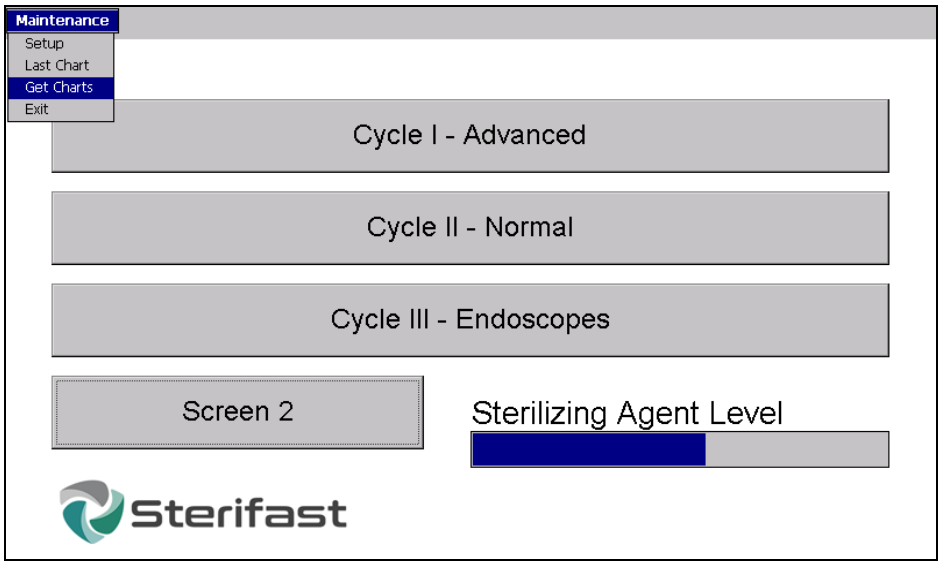


Figure 2-19

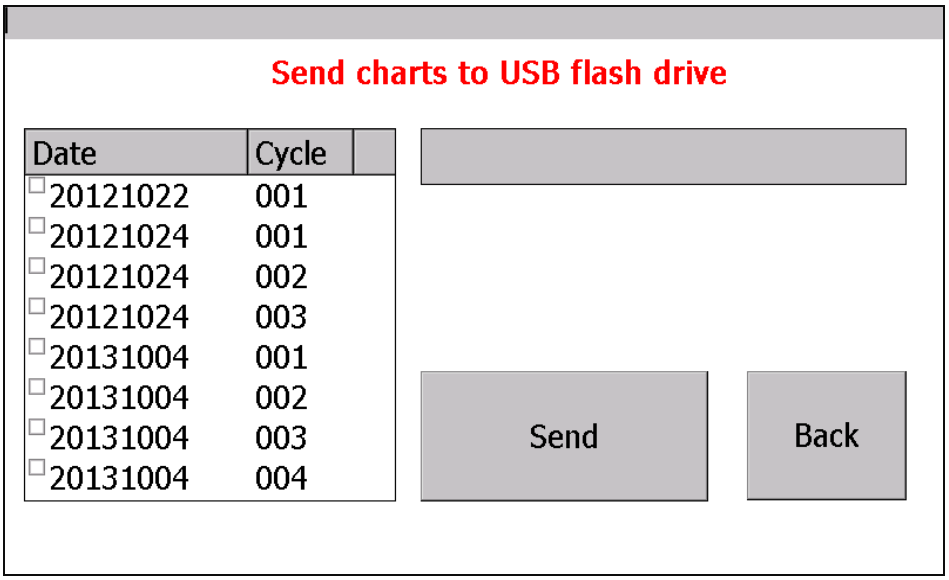


Figure 2-20

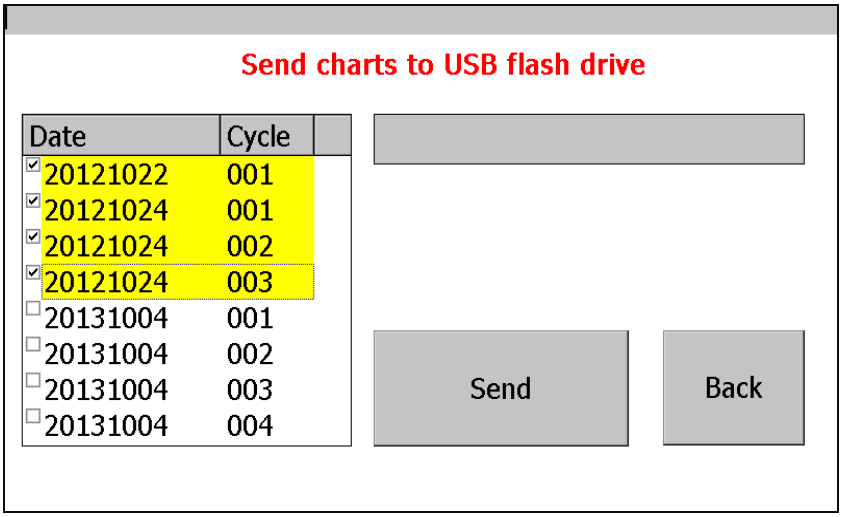


Figure 2-21

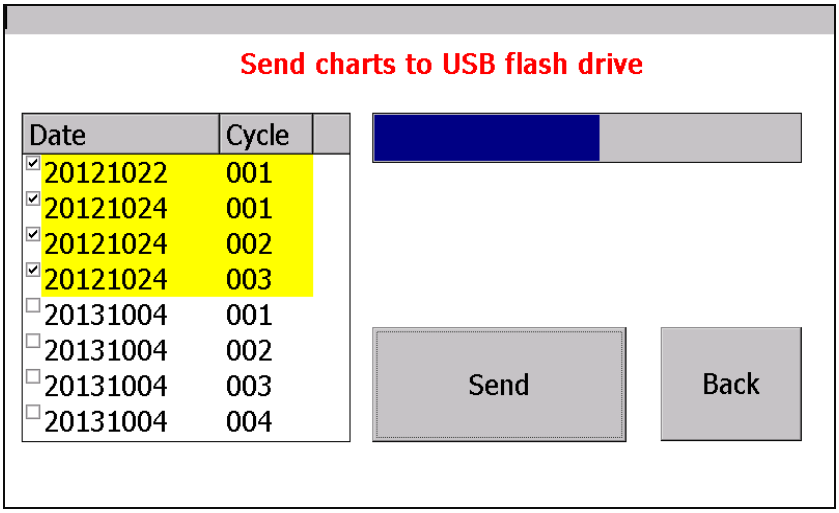


Figure 2-22

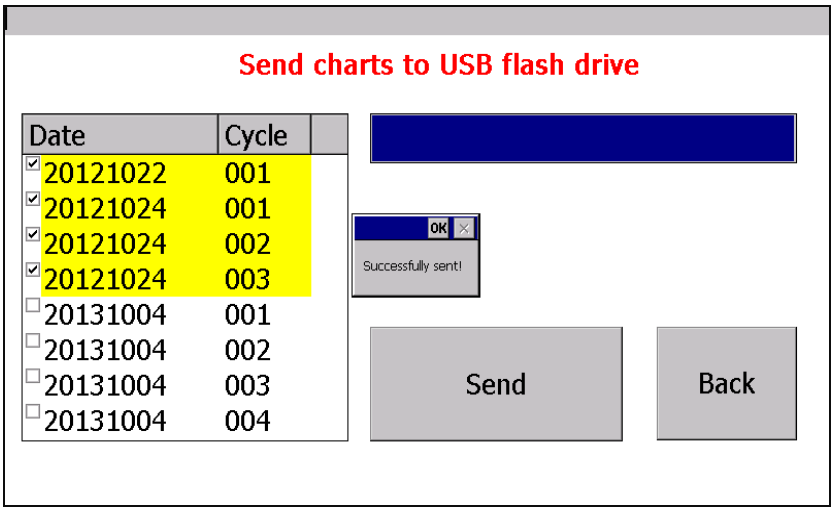


Figure 2-23

Note 1: When we save these files inside the flash drive , the folder (stf-ECOPlasma (110)"is created and the files stored as stv.

Note 2: To open these files, you need to acquire the "Sterifast Viewer" software from Sterifast Lda.

Note 3: In some versions of the software, the number of the cycle will appear instead of the sequential number (like the immages shown here).

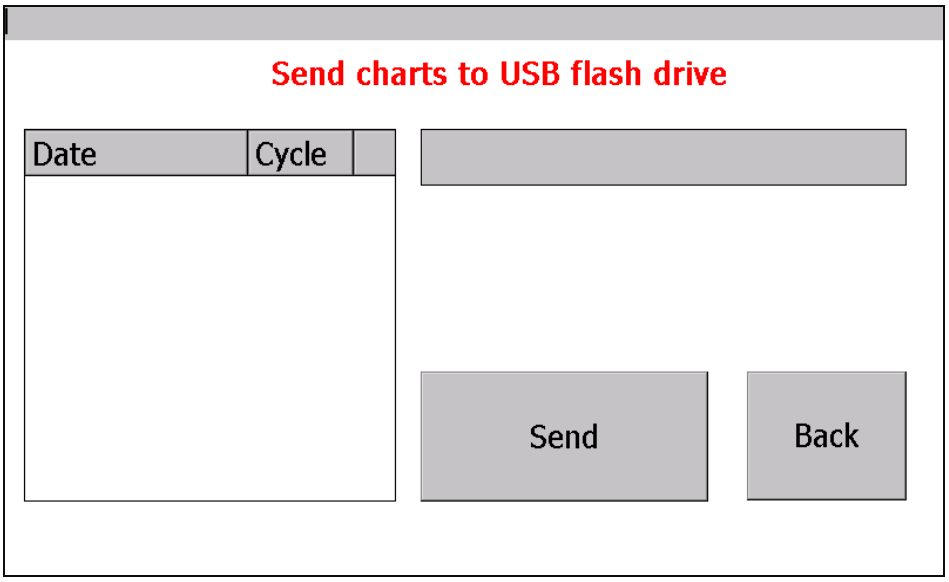


Figure 2-24

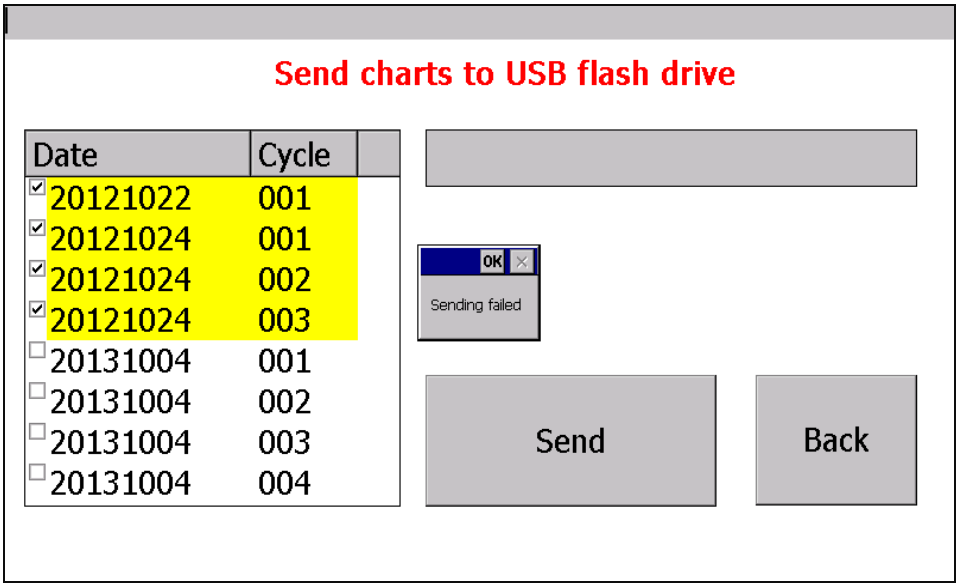


Figure 2-25

3.6– Door opening in case of failure

- Press **“Maintenance”** button in the left upper side of the touch screen;
- Press **“Setup”** button;
- Press **“Door”**;

It is possible to open the door, through this window

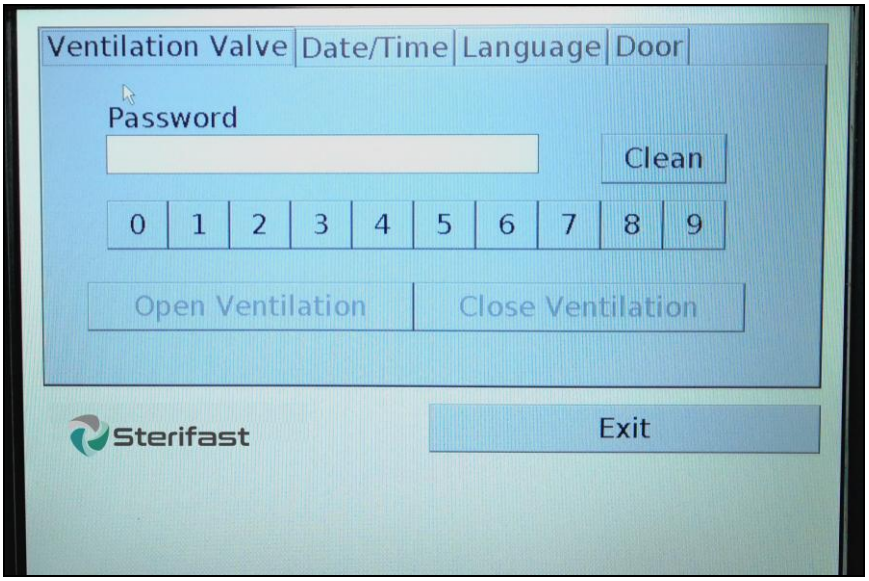


Figure 2.26

- Insert Code A (see Annex 2);

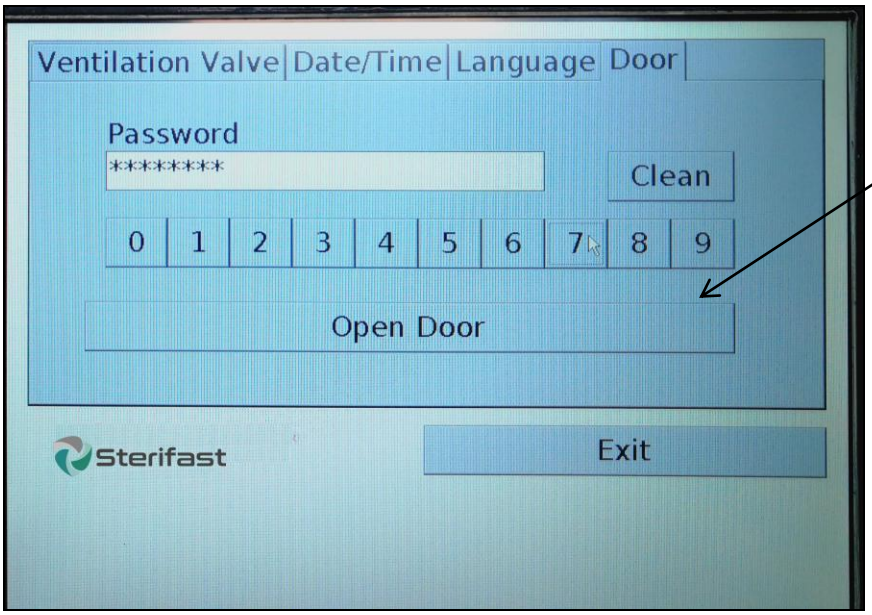


Figure 2.27

- Press “**Open Door**”; Press “**Exit**” to return to the Main Menu.

3.7 – Programs

Screen 1

- **Cycle I – Advanced**
- **Cycle II – Normal**
- **Cycle III – Endoscopes**

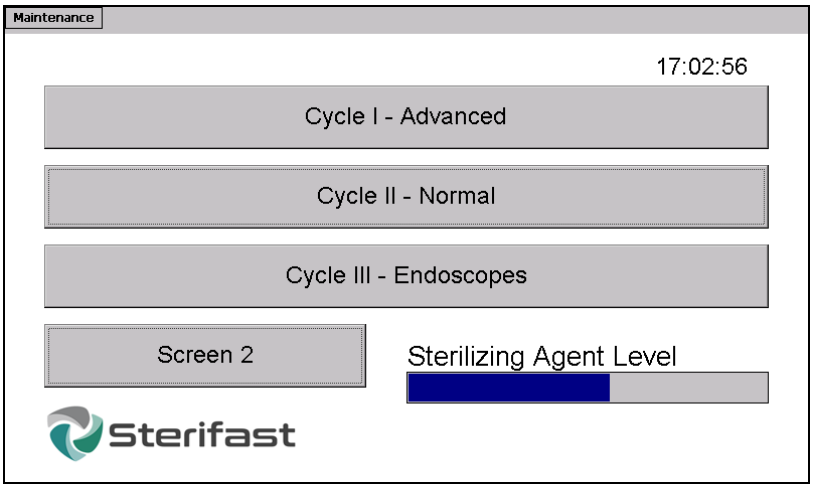


Figure 2-28

Screen 2

- **Cycle IV – Out of service**
- **Cycle V – Penetration TEST**
- **Cycle VI – Leakage TEST**
- **Cycle VII – Leakage and Penetration**

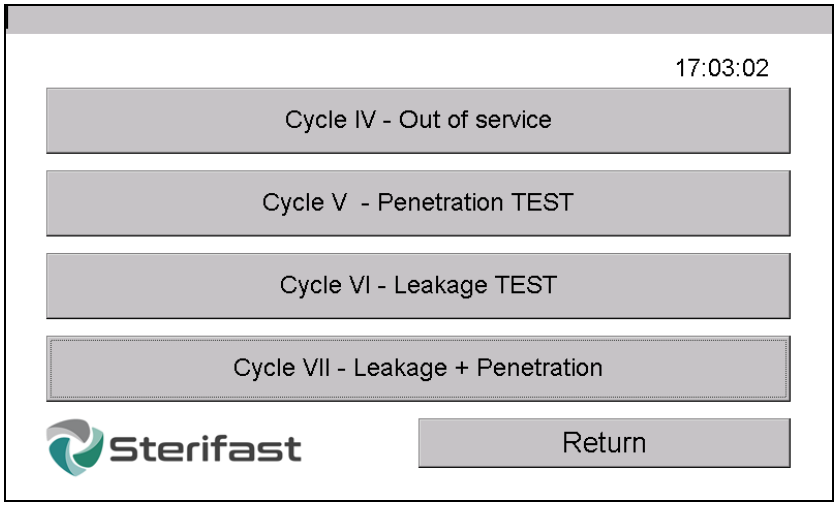


Figure 2-29

4 - Preparation of the sterilization process

Alert 

Under any circumstances, you should start the heating of machine with load inside the chamber. If you do it, you will damage the sterilizer.

- Turn on the Sterilizer with the ON/OFF button;
- Cycle selection and door opening only accessible when the buttons start to flash / change the colour.
- Select the intended cycle on the touch screen:

- Cycle I – Advanced Cycle
- Cycle II - Normal Cycle
- Cycle III – Endoscopes Cycle
- Screen 2 – Test Cycles

IMPORTANT: The doors remain locked until one cycle is selected.

NOTE: When the words on the screen appear to change the colour (red/black/red), it means that the machine is still warming up. It is not ready yet to start the cycle. If you choose a cycle, the cycle will not start and the words continue to appear red/black/red until the machine is ready. If you insist to start the cycle it will appear “program starts after conditions exist” and the words will continue to appear (red/black/red) until the conditions to start the cycle exist. Then the words will appear only in black and the cycle can start.

If the cycle is started in these conditions, the time between the warming up and the cycle is unpredictable.
This method to start the cycle without the sterilizer with the necessary temperature is not recommended.

NOTE 1: If there is a power supply interruption, the sterilizer re-starts automatically when the power returns and makes a ventilation cycle, to be able to open the door.
(NOTE: the materials inside the chamber cannot be considered sterile).

Main Screen:

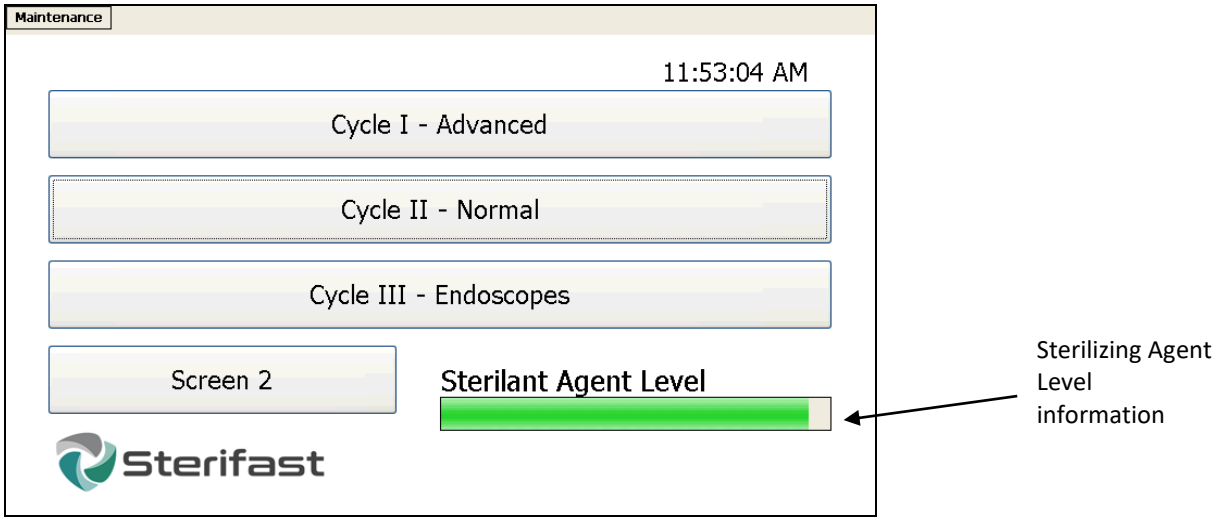


Figure 2-30

To start a sterilization cycle:

- Open the door and place the material baskets inside the chamber
- Choose the intended cycle
- Close the door and press "**Start Cycle**" on the touch screen.

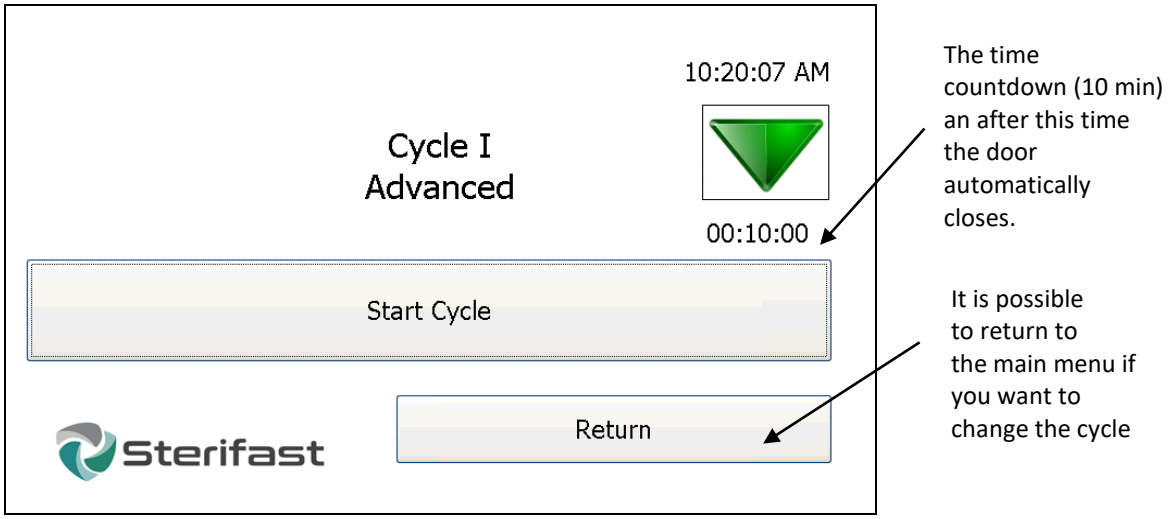


Figure 2-31

Note: If you wish to run a different cycle than the selected one, you can do that without the need to open the doors. Instead of pressing "**Start Cycle**" press "**Return**". You can now select the desired cycle on the Main Menu.

In case the sterilizer has been switched off for a long time it will take 5 to 10 minutes to warm up.

If there are no conditions to start the cycle, the screen will inform that the sterilizer is waiting for conditions.

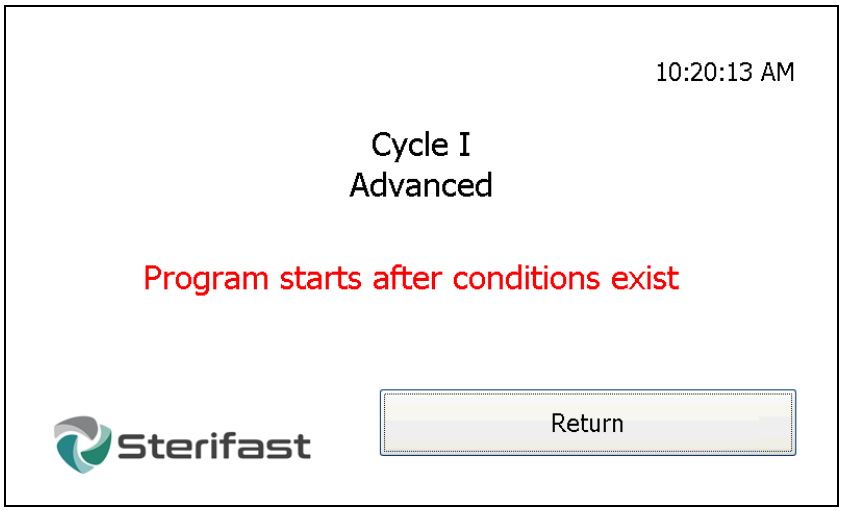


Figure 2-32

If the sterilizer does not still warm up and you insist to start the cycle it will appear “program starts after conditions exist” and the word “return” continues to appear (red/black/red) until the conditions to start the cycle exist.

When the conditions exist, the cycle starts automatically.

- **<u>Exhaustion Phase</u>:**

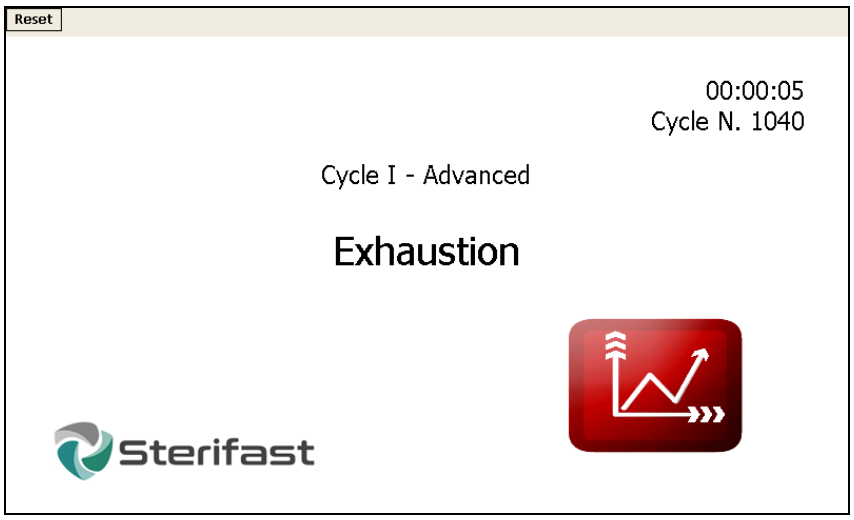


Figure 2-33

Note: When touching this button  , the cycle graph will be shown (Fig. 2.41).

- **Preparation for Diffusion Phase**:

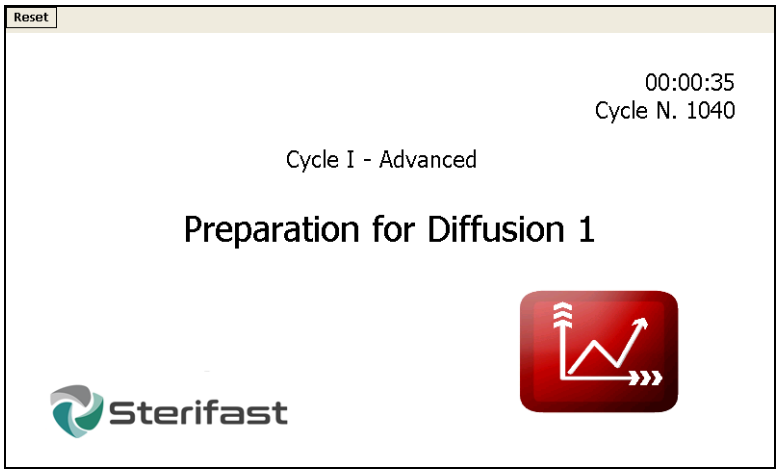


Figure 2-34

- **Diffusion Phase**:

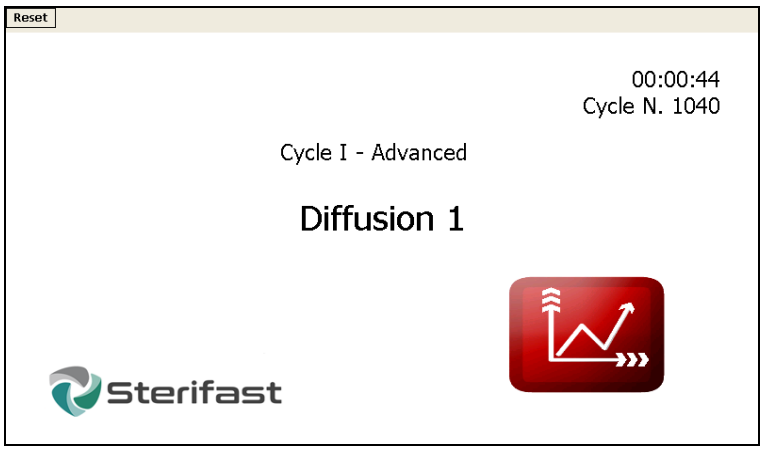


Figure 2-35

- **Plasma Exhaustion Phase:**

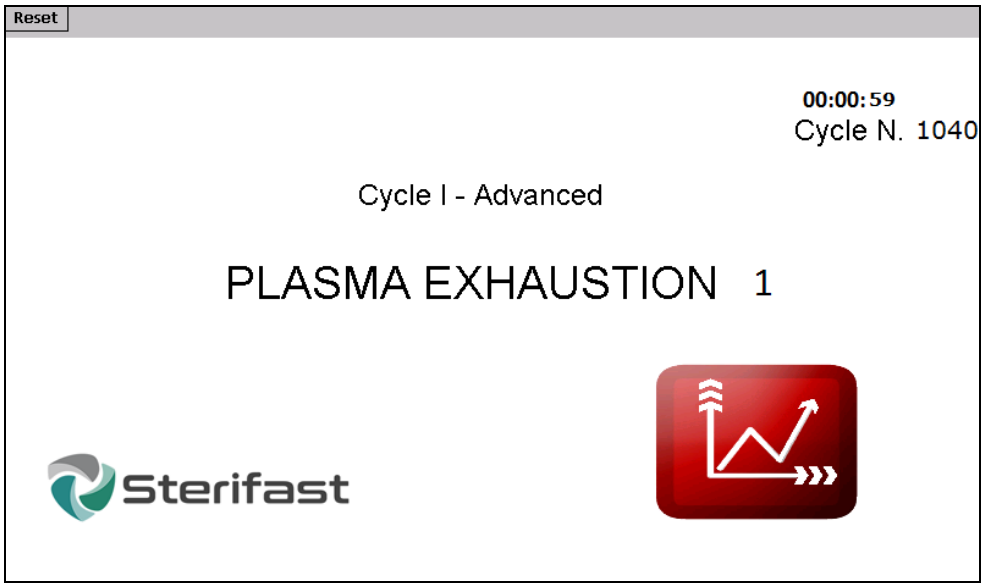


Figure 2-36

- **Preparation for new Diffusion:**

Figure 2-37

- **Diffusion 2 Phase**:

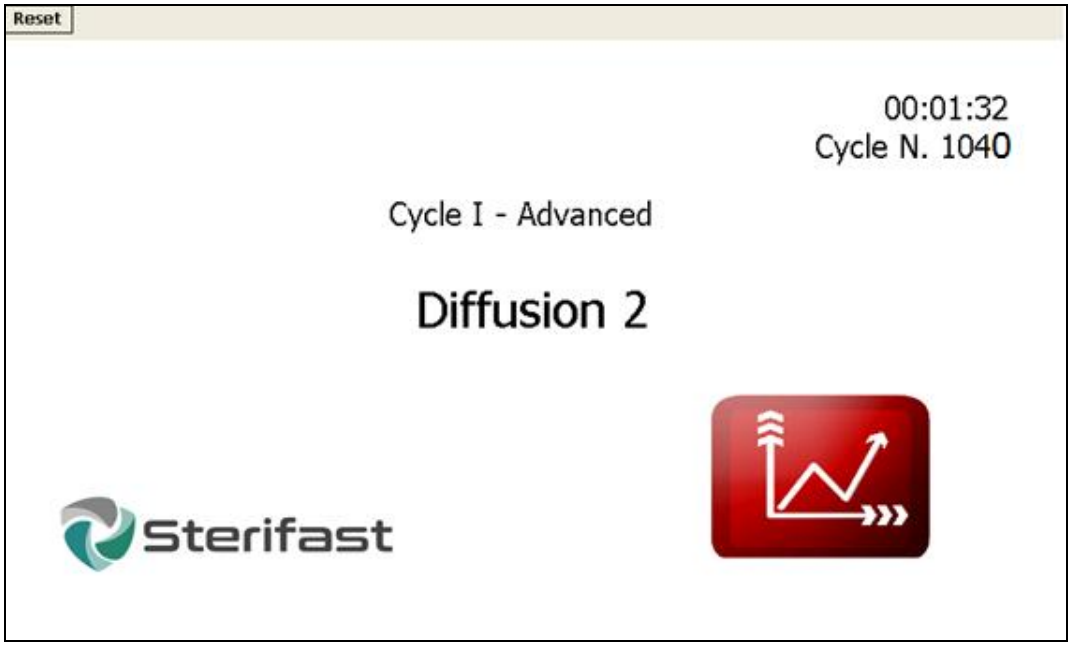


Figure 2-38

- **Plasma Exhaustion 2 Phase**:

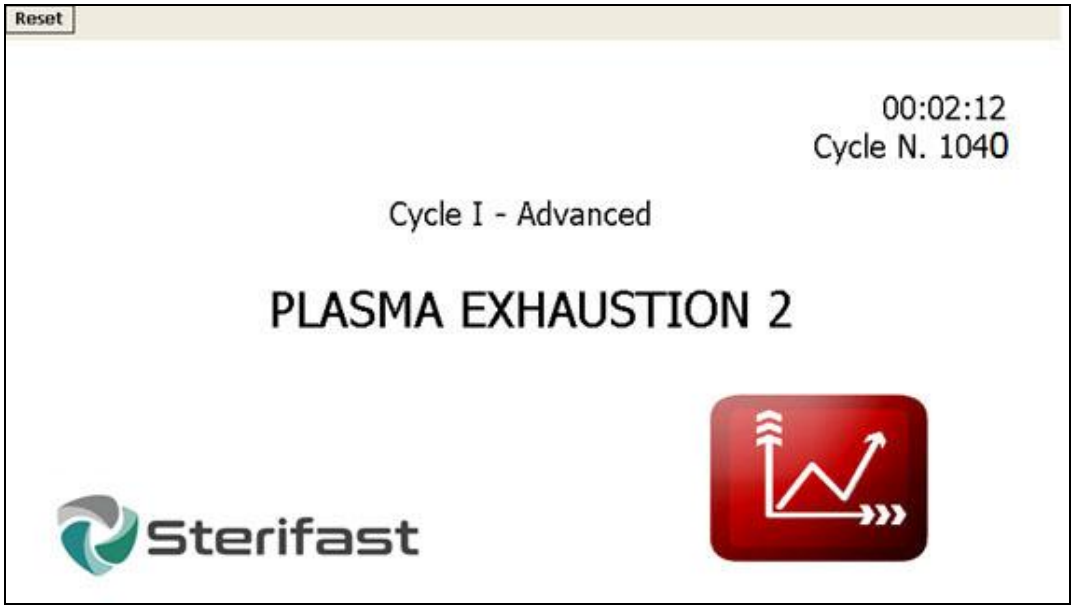


Figure 2-39

- **<u>Sterilization Chamber Ventilation Phase</u>:**

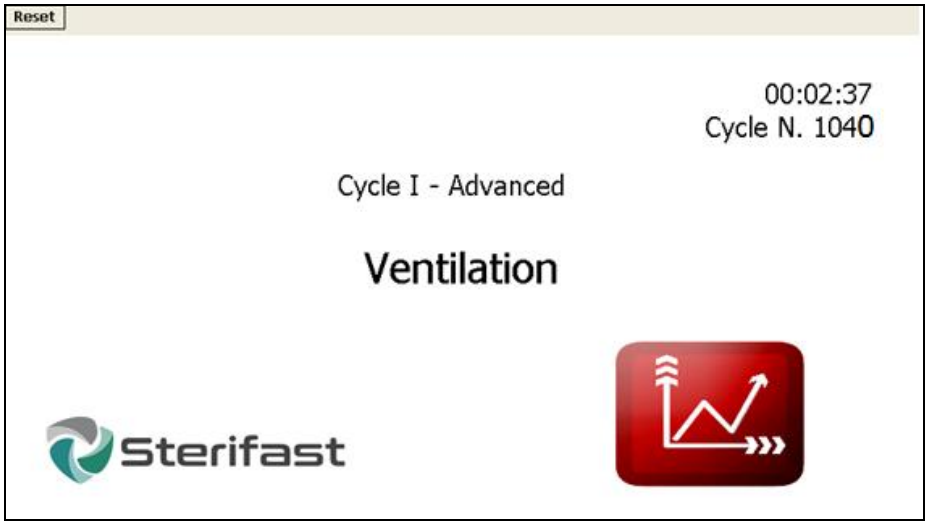


Figure 2-40

- **<u>Chart with all phases of the cycle</u>:**

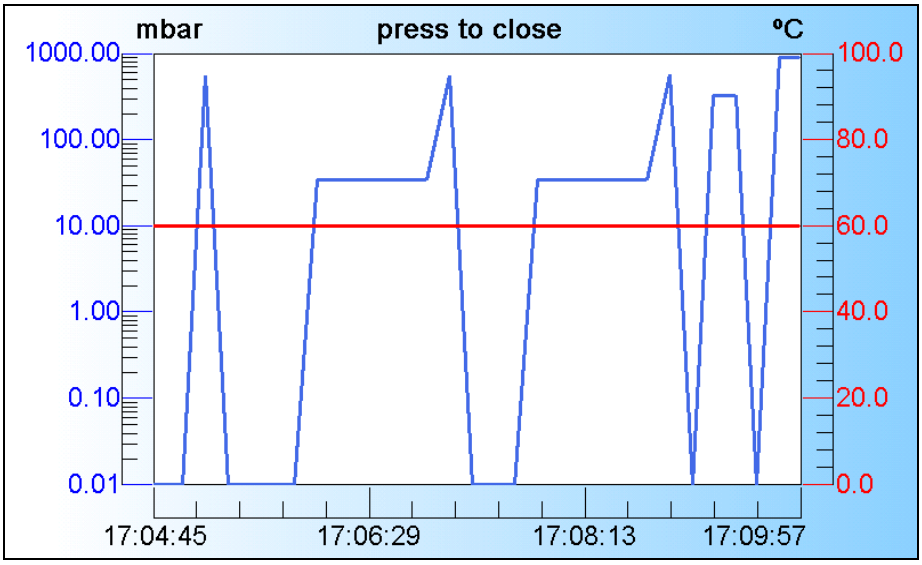


Figure 2-41

Note 1: By touching anywhere on the screen the previous menu will appear.

Note 2: After seeing the chart, you should return to the previous menu. The reason is that the chart view spends much more memory of the screen.

- **End of Program**:

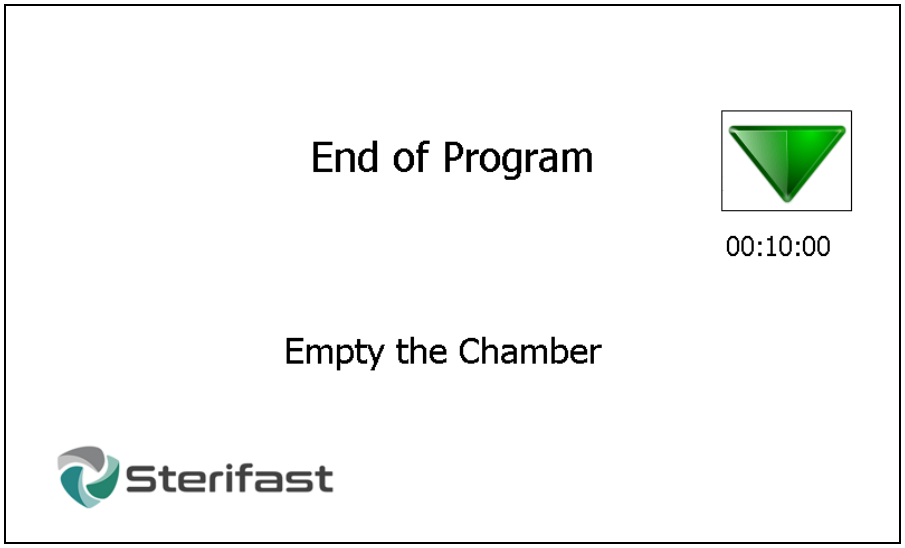


Figure 2-42

The screen shows the message to empty the chamber.

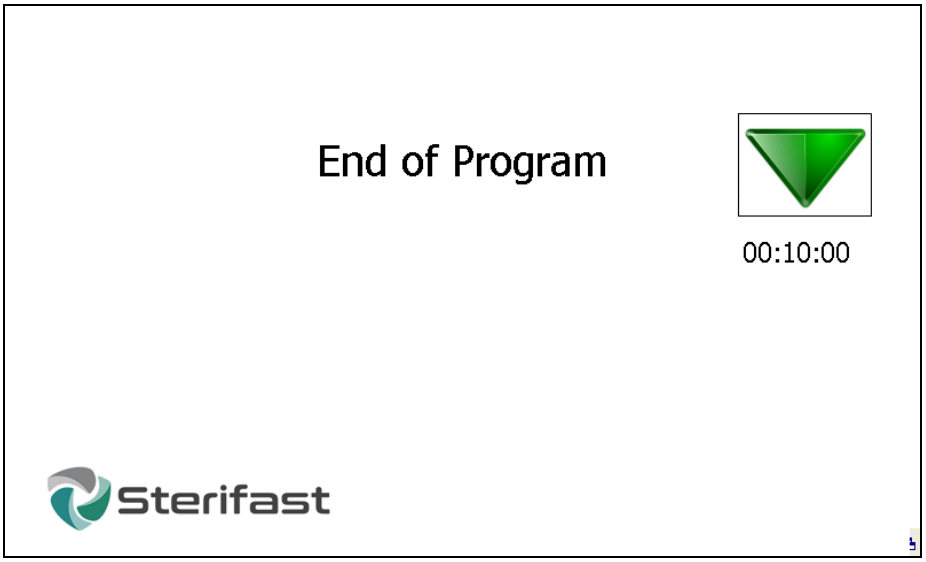


Figure 2-43

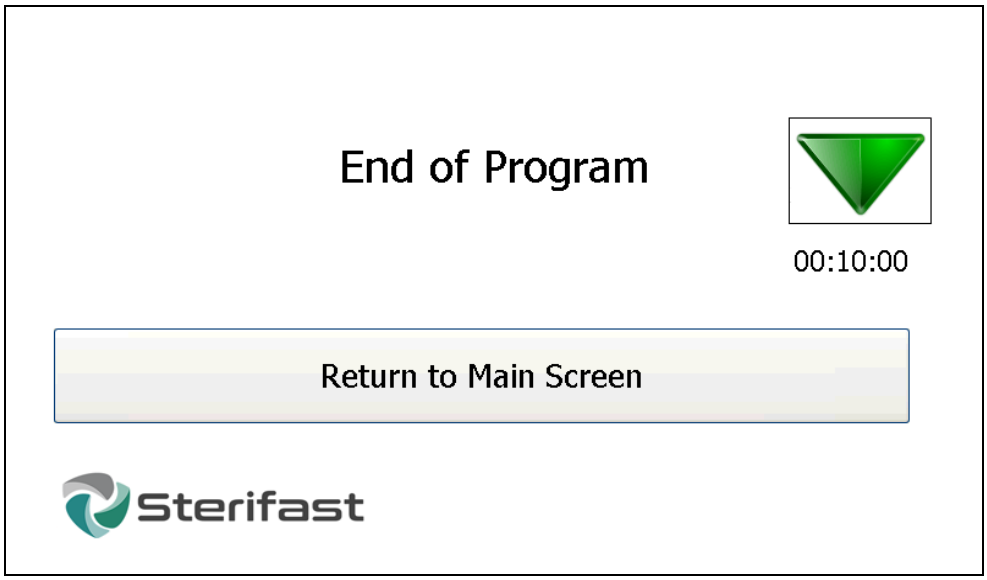


Figure 2-44

Cycles run automatically. At the end of a properly concluded cycle, you will hear an intermittent sound alarm, and the printer will printout a report with the cycle data. The operator must check the message on the touch screen and the data on the printout.
In case of failure, this will be displayed on the screen and you will hear a continuous sound alarm. The report will be printed out, too.

The sound alarm also appears when the door is opening or closing.

 When this signal (botton to close the door) appears flashing, it means that something is pressing the safety rubber of the door or the door safety system is damaged. Please verify if something is pressing the safety rubber. If the door does not close, please switch off and switch on the machine. If the error persists please contact the technician (after a short time the door will not close anymore).

5 – Test Cycles

To enter the Test Cycles, press "**SCREEN 2**" on the Main Menu

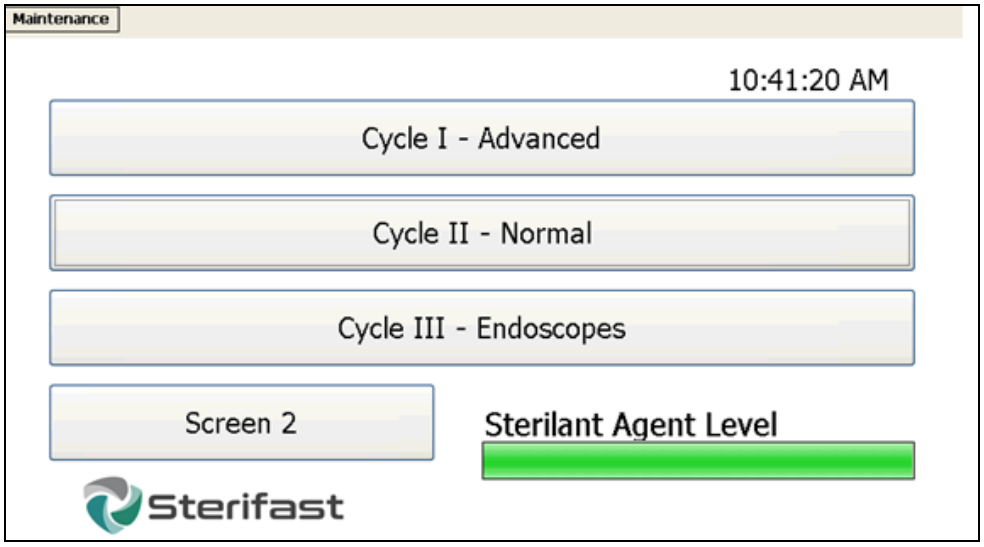


Figure 2-45

Then you can choose the desired test cycle by pressing the related button.

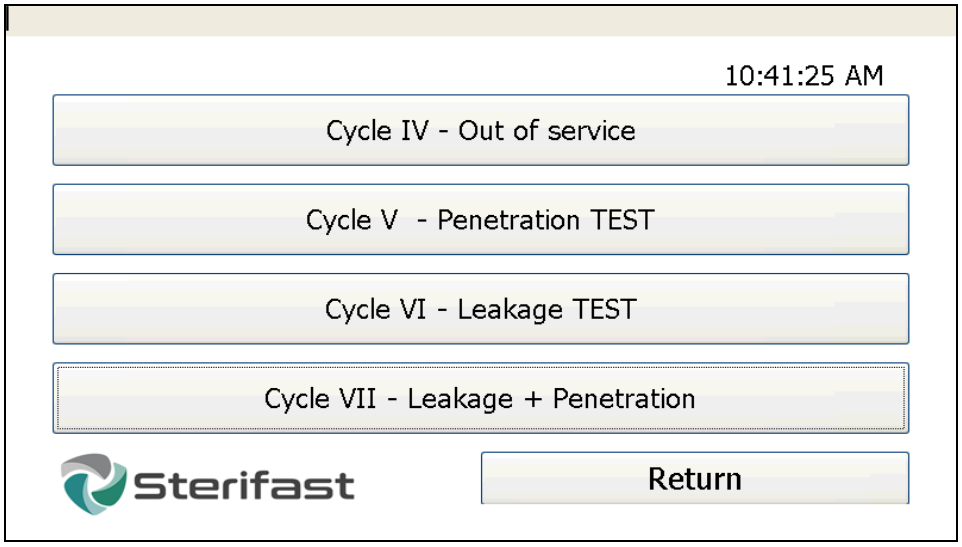


Figure 2-46

Note: For the Leakage Test Cycle the screen will display "Test Properly Concluded" or "FAILED Test" (as described below in paragraphs 5.1 and 5.2.). The operator must confirm with OK on the screen. The printout will always say "Material is not in Conformity" because from the sterilization point of view a test cycle is always a failed cycle.

5.1 – Leakage Test Ok

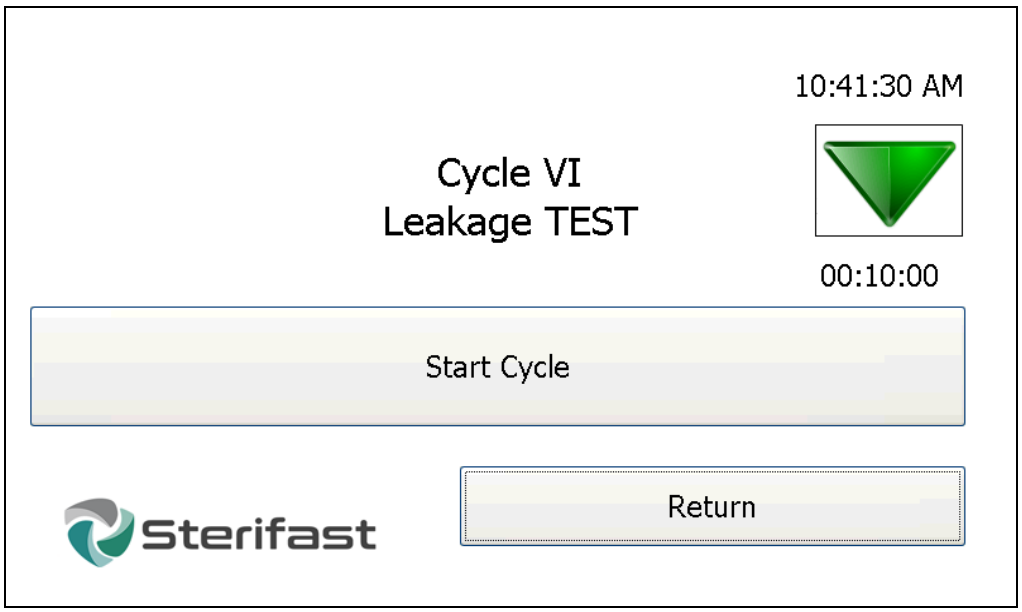


Figure 2-47

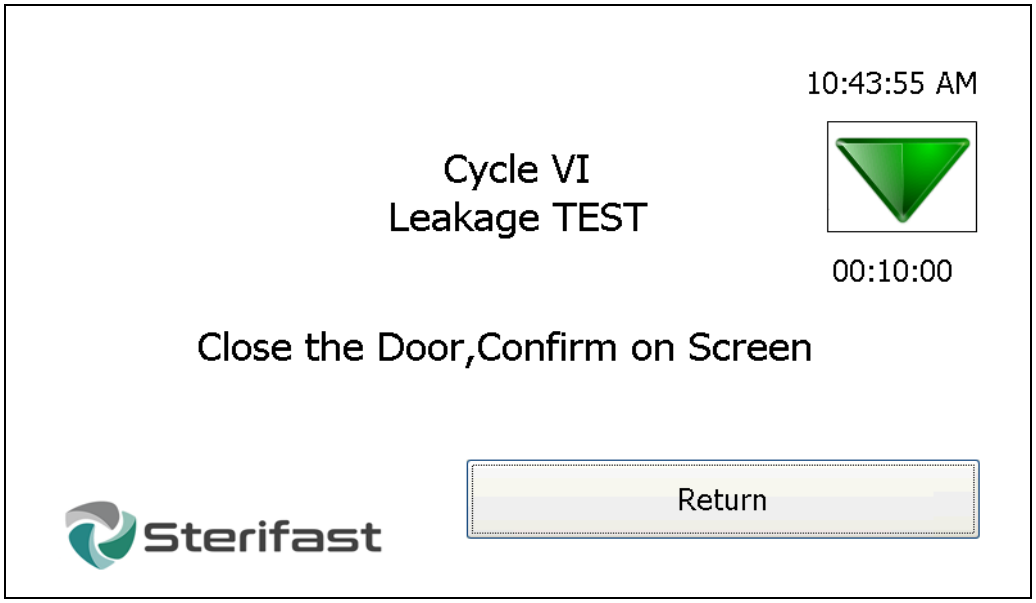


Figure 2-48

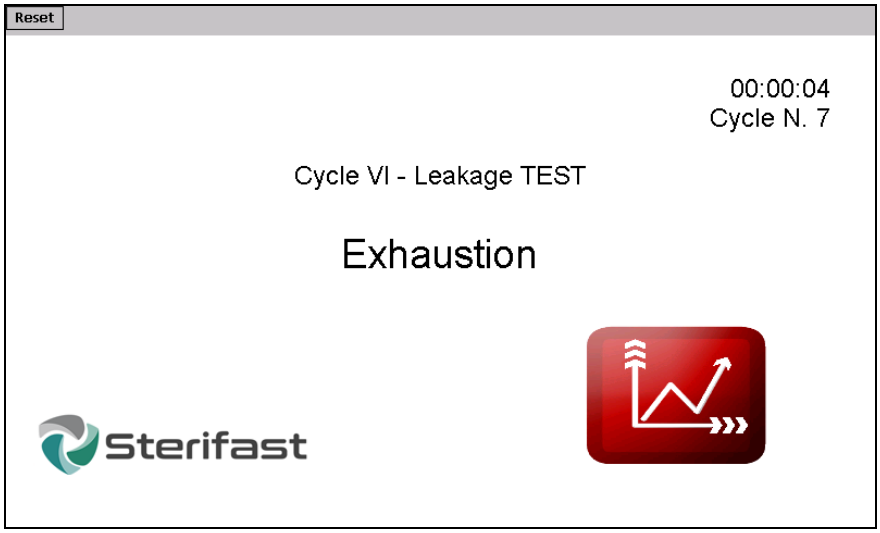


Figure 2-49

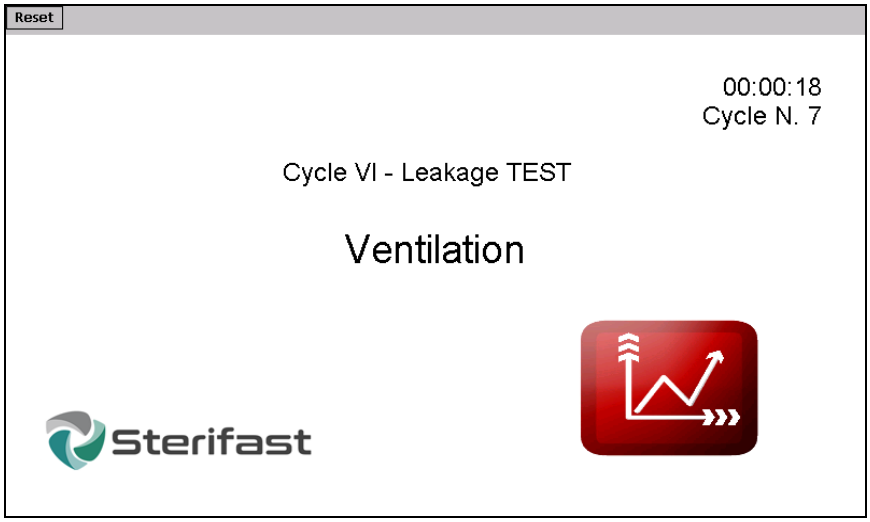


Figure 2-50

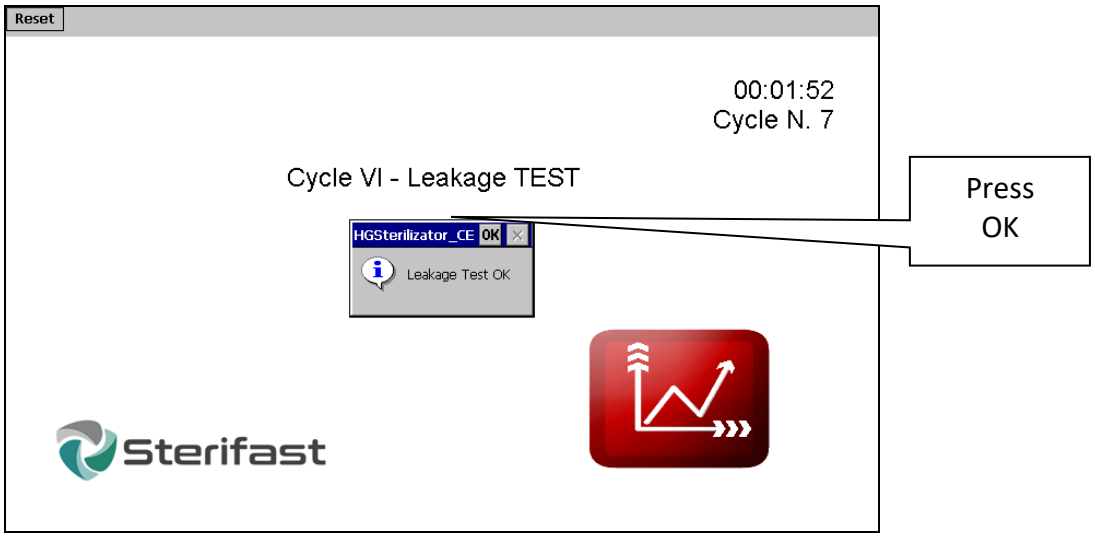


Figure 2-51

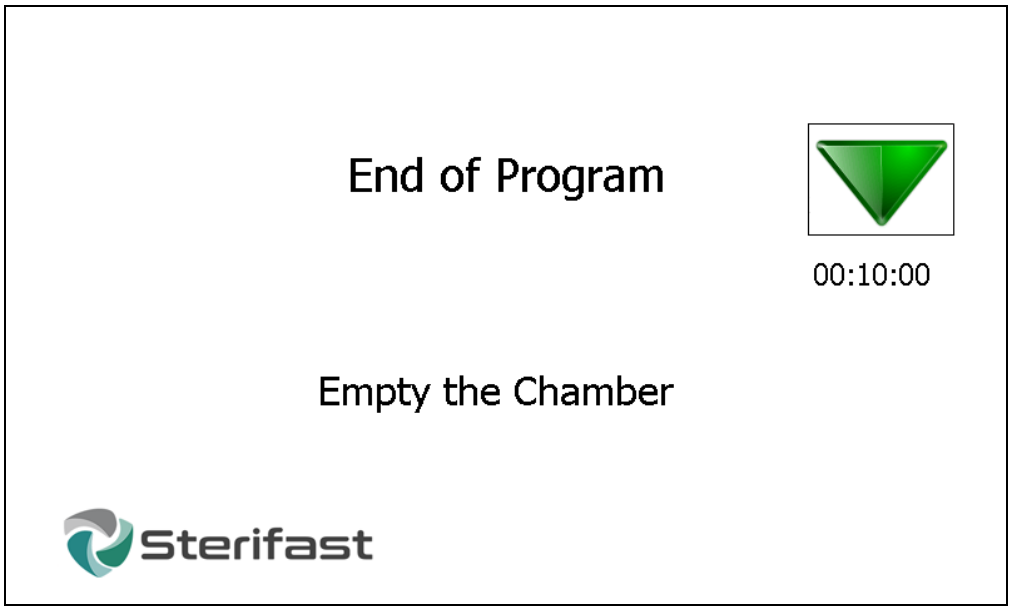


Figure 2-52

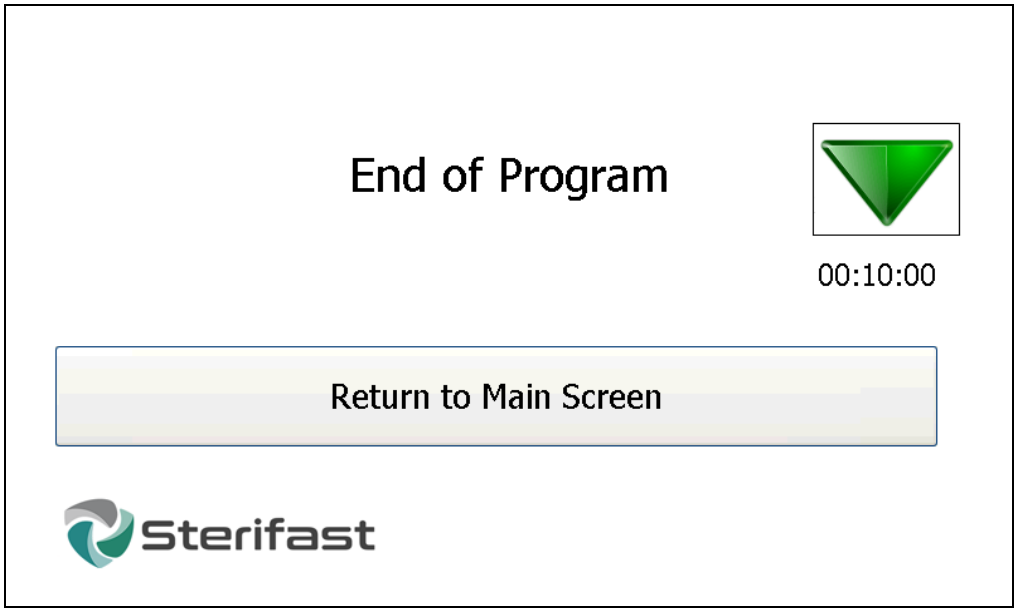


Figure 2-53

5.2 – Leakage Test Failed

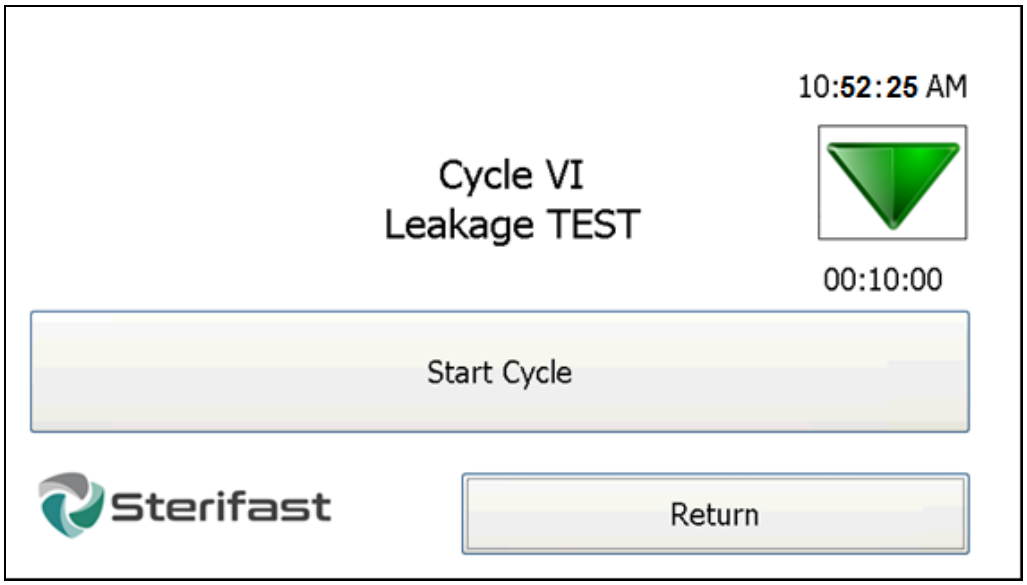


Figure 2-54

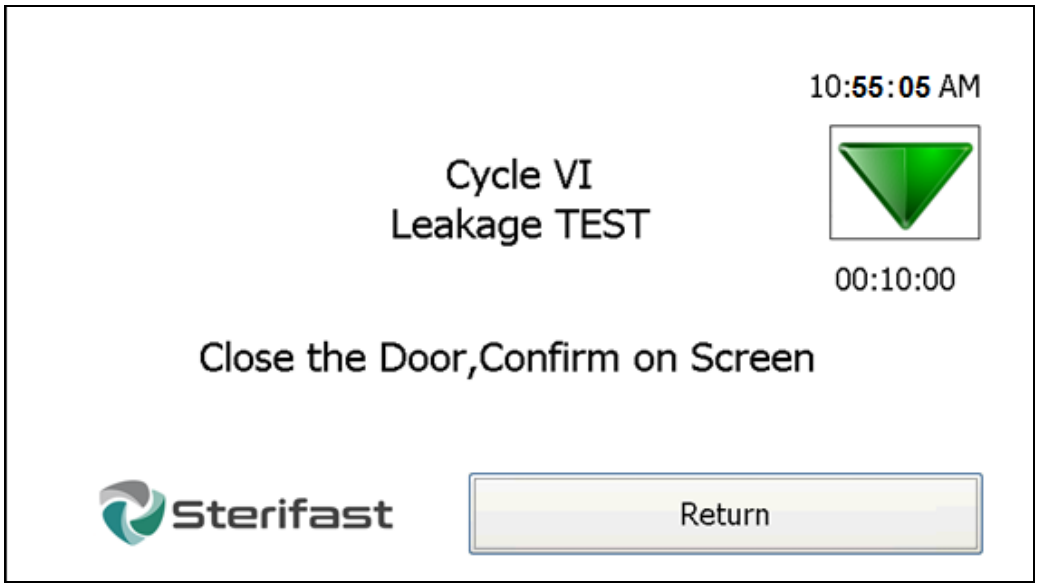


Figure 2-55

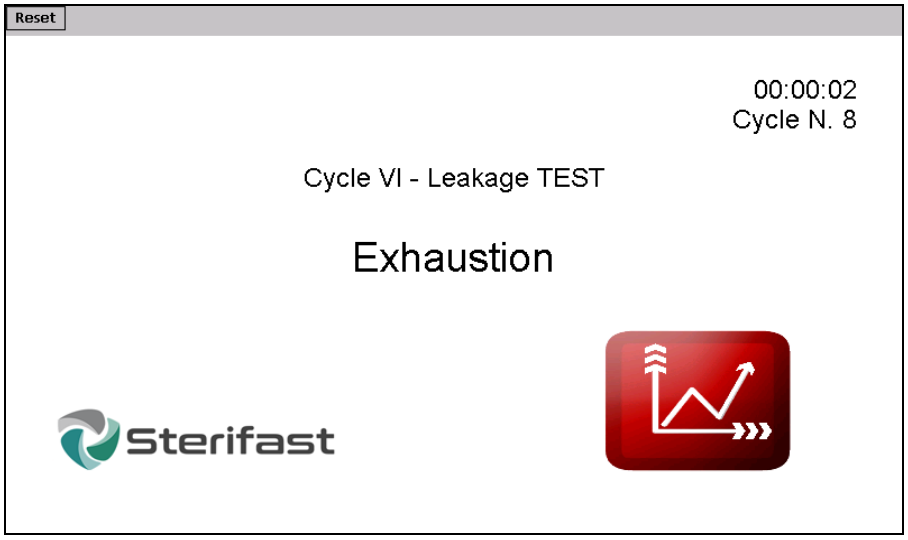


Figure 2-56

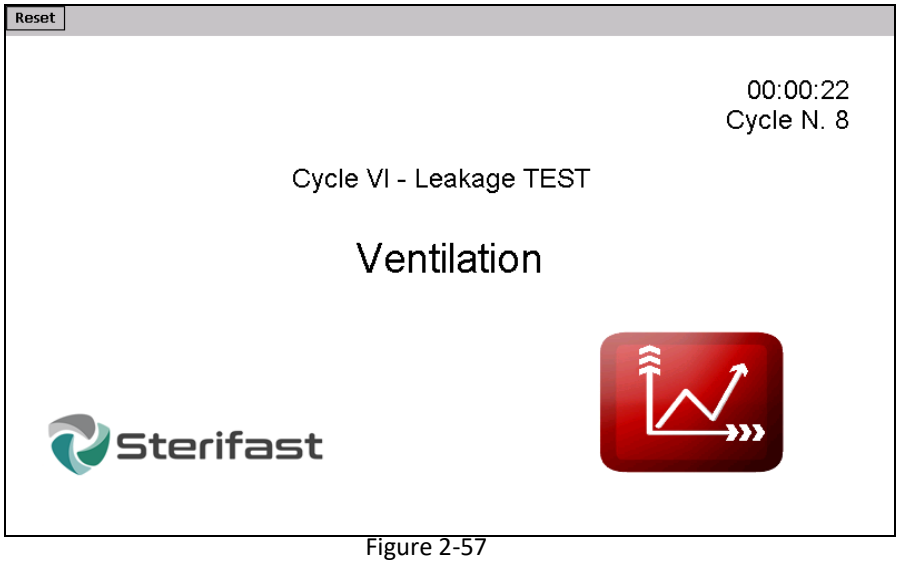


Figure 2-57

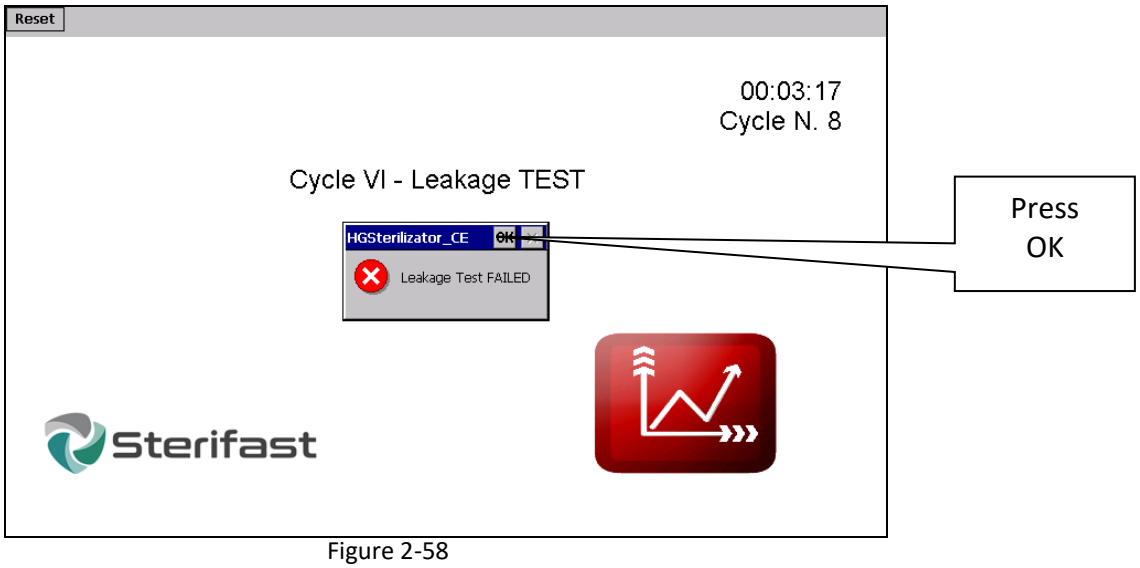


Figure 2-58

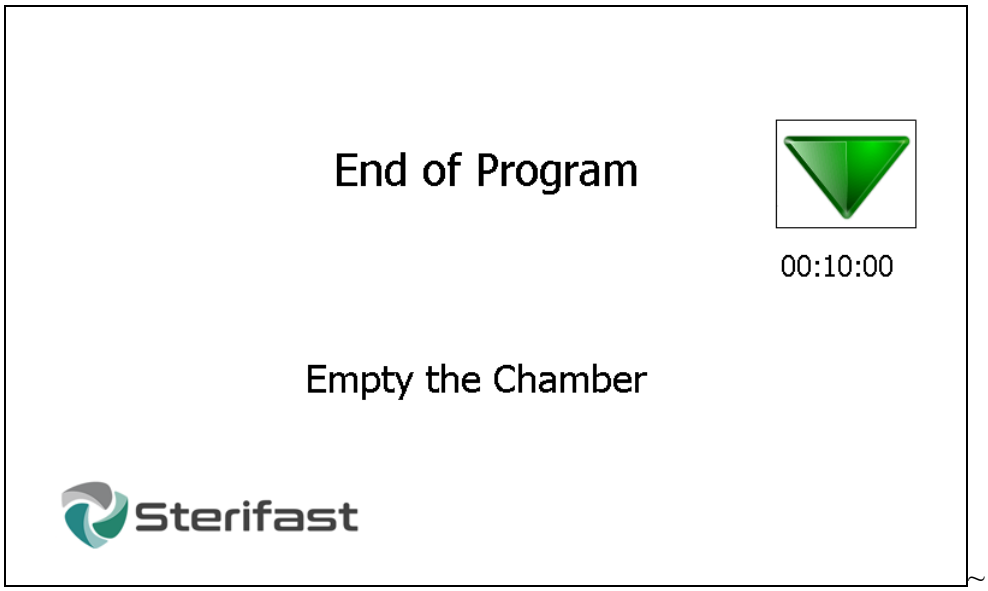


Figure 2-59

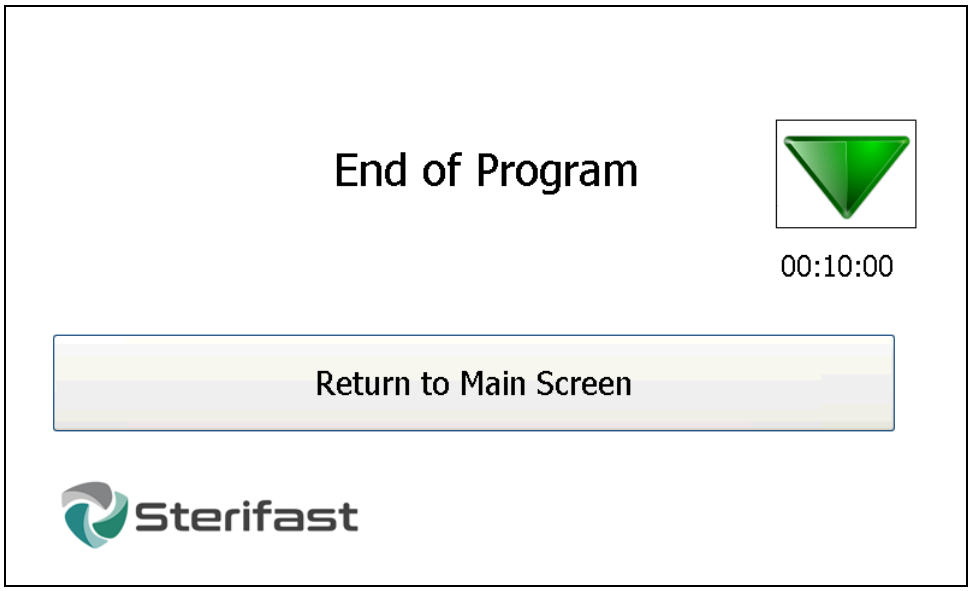


Figure 2-60

6 – Reset

The Reset allows canceling a cycle, placing the Sterilizer back in position of starting a cycle.
By pressing the “Reset” button, the system opens a new window
- Press “Restart Program”

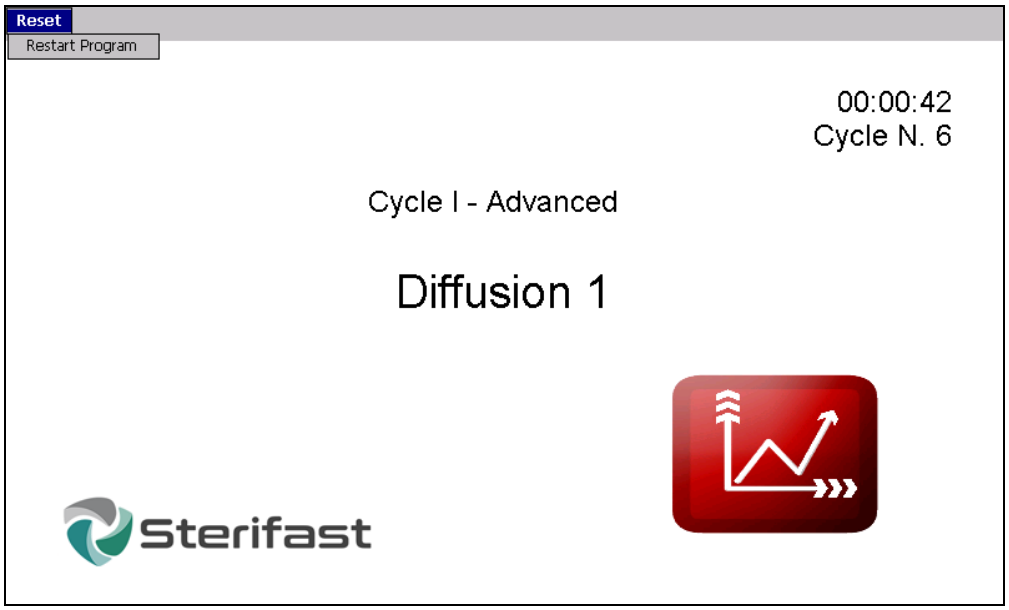


Figure 2-61

The systems will ask for a password.
Insert CODE B that can be found in Annex 2 of this Manual.

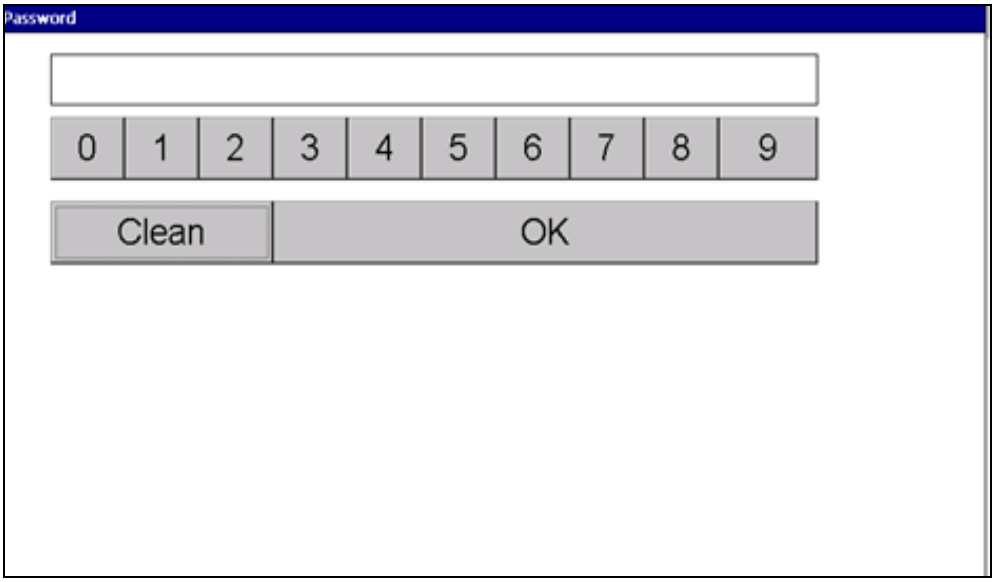


Figure 2-62

If the reset button is pushed and there has been no sterilizing agent in the chamber yet, the system jumps to aeration phase, and returns to the “start Cycle” phase.

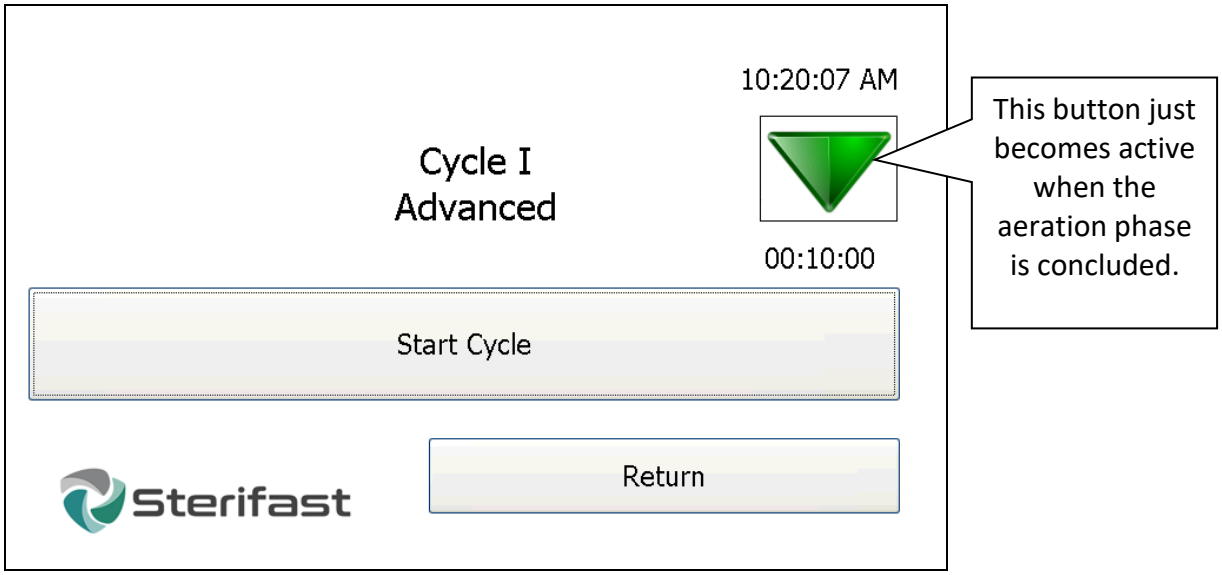


Figure 2-63

If the reset button is pushed after there has been sterilizing agent in the chamber, the system will do a cleaning cycle, marked on the screen as “Emergency Ventilation”.

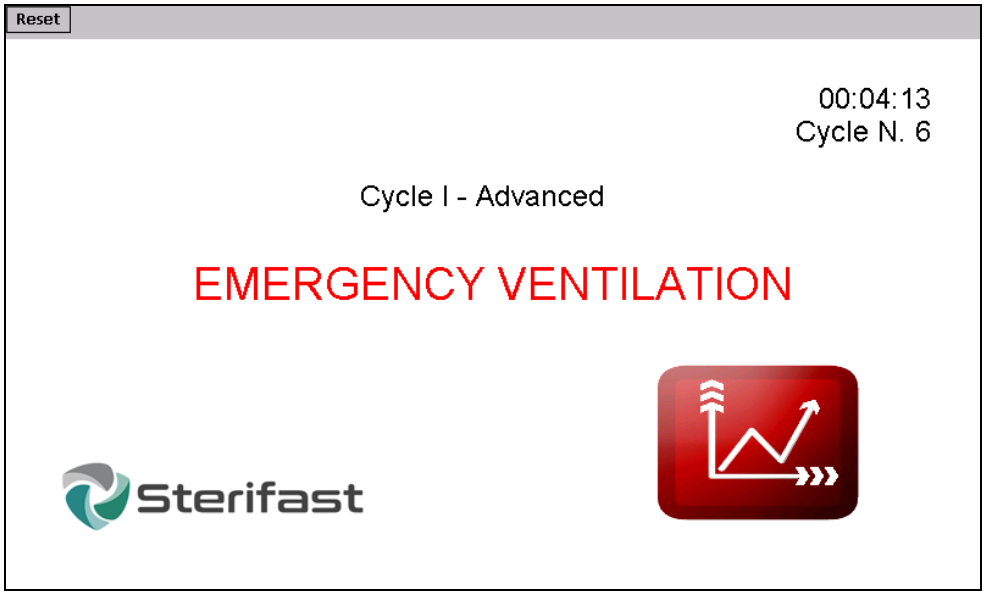


Figure 2-64

This operation may take some minutes, since only after the completion of this phase the sterilizer will allow the door to be openned and ensure the operator’s safety.

6.1 – To force the cycle to stop

To stop the emergency cycle press “Reset” again.
If necessary, please contact the technician.

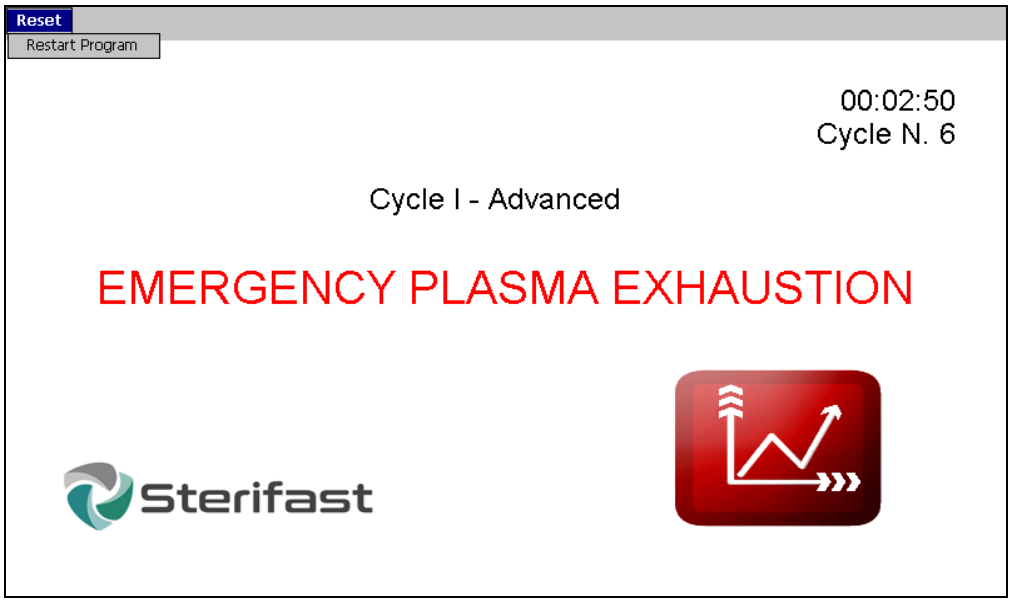


Figure 2-65

The systems will ask for a password.
Insert CODE B again (that can be found in Annex 2 of this Manual).

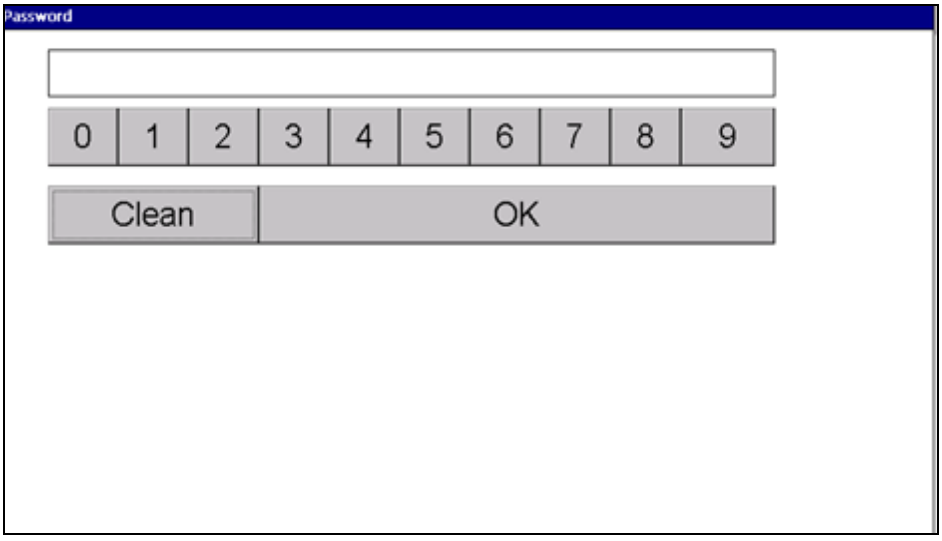


Figure 2-66

A window will appear asking to confirm the operation.

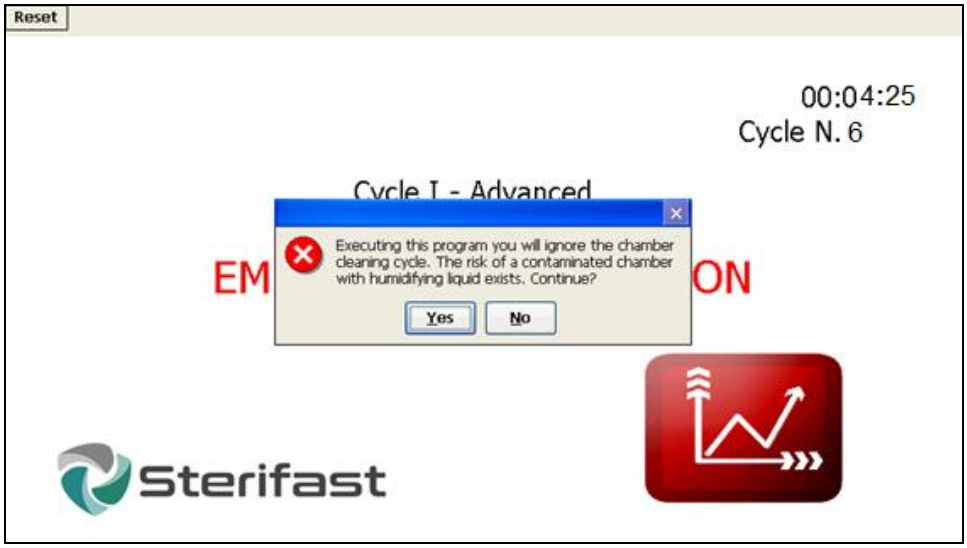


Figure 2-67

If confirmed the access code will be asked for - **CODE C** (that can be found in Annex 2 of this Manual).

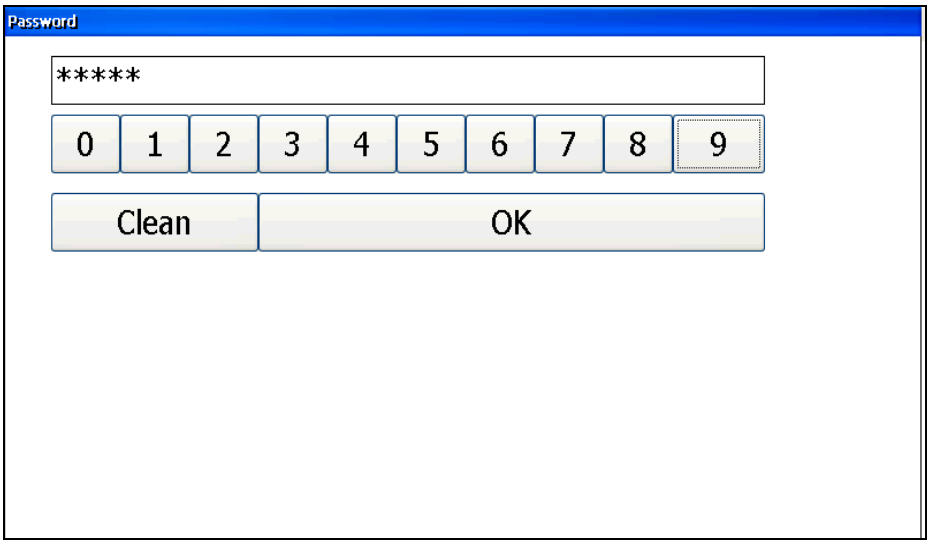


Figure 2-68

The Sterilizer will stop to insert air in the chamber (Aeration phase) and return to Main Menu for cycle selection.
In this case, you should take precautions to open the door and unload the material, because it is possible that there is sterilizing agent inside the chamber. This method, is not a normal procedure, it should be used in an emergency situation only.

This procedure allows to unlock the sterilizer when there is a breakdown that is preventing the sterilizer to run the final phases of the cycle or in case of forced unlock that allows the door to be opened. In any case of breakdown, the chamber will be in vaccum.
To open the door, you may have to open the Ventilation Valve manually.

To open the Ventilation Valve manually, please take the following steps:

- Press the “Maintenance” button, on the Main Menu;
- Press “Setup”;

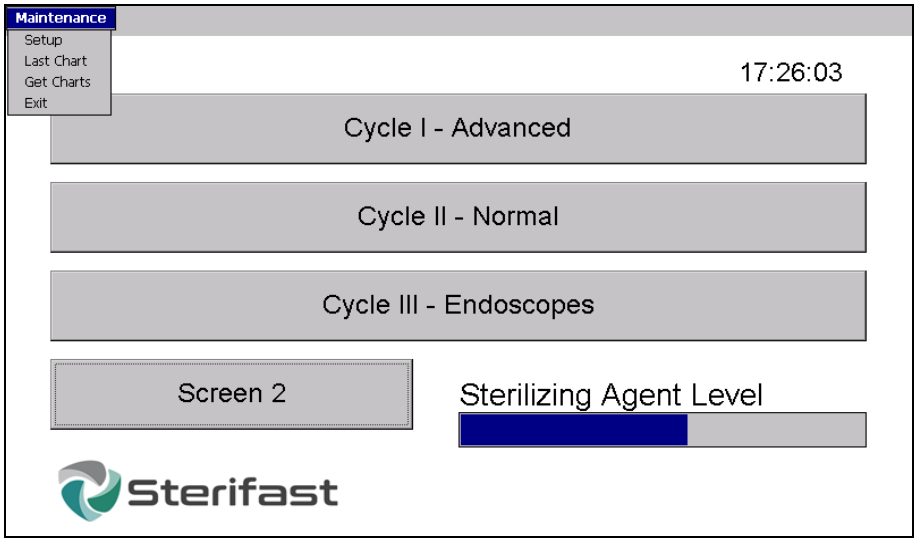


Figure 2-69

The system opens a window that gives access to the Ventilation Valve opening.

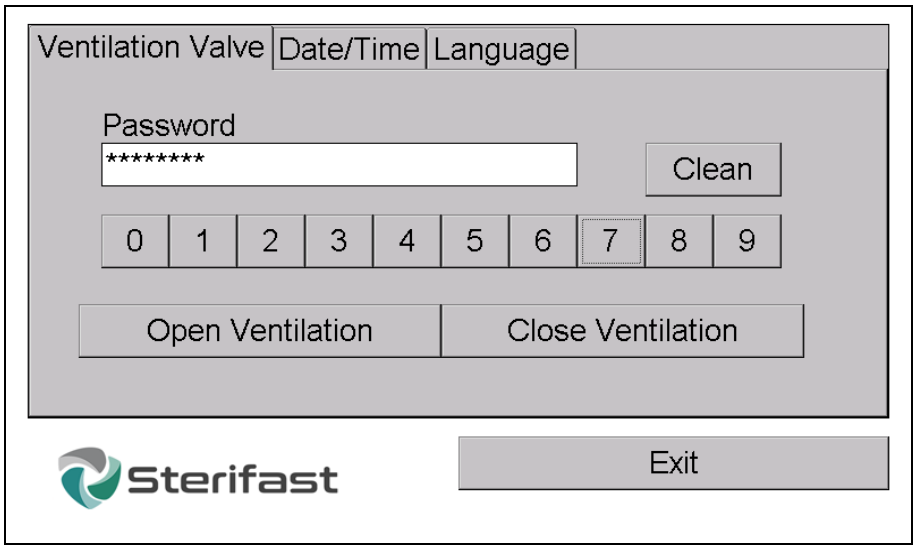


Figure 2-70

- Press “**Ventilation Valve**”;

- Insert CODE A that can be found in Annex 2 of this Manual, using the number buttons;

- After inserting the code, the buttons “**Open Ventilation**” and “**Close Ventilation**” become active;

- Press “**Open Ventilation**”, wait some time for the chamber to get to atmospheric pressure;

- Wait till the button to open the door appears in the screen; → 

- Open the door;

- Remove the material;

ATTENTION: You should take precautions to open the door and unload the material, because it is possible that there is sterilizing agent inside the chamber.

- Press “**Exit**” to return to the Main Menu;

7 - Sterilizing Agent Refill

The sterilizer has a tank where the Sterilizing Agent is stored, dosing it automatically into the sterilization chamber.
A level indicator displays on the touch screen real time information to the operator. A warning message "**Sterilizing Agent Missing**" will be displayed if the level of Sterilizing Agent in the tank is too low for a new cycle.
The sterilizer will not operate if the tank does not have enough sterilizing agent to run a cycle.
The Sterilizing Agent refilling can only be done before starting a cycle and when the "**Refill Sterilizing Agent**" button is active.

If the sterilizer tank still has enough sterilizing agent, the sterilizer will not allow a n70ew refilling.

Figure 2-71

To refill the Sterilizing Agent tank, press **"Refill Sterilizing Agent"** button:

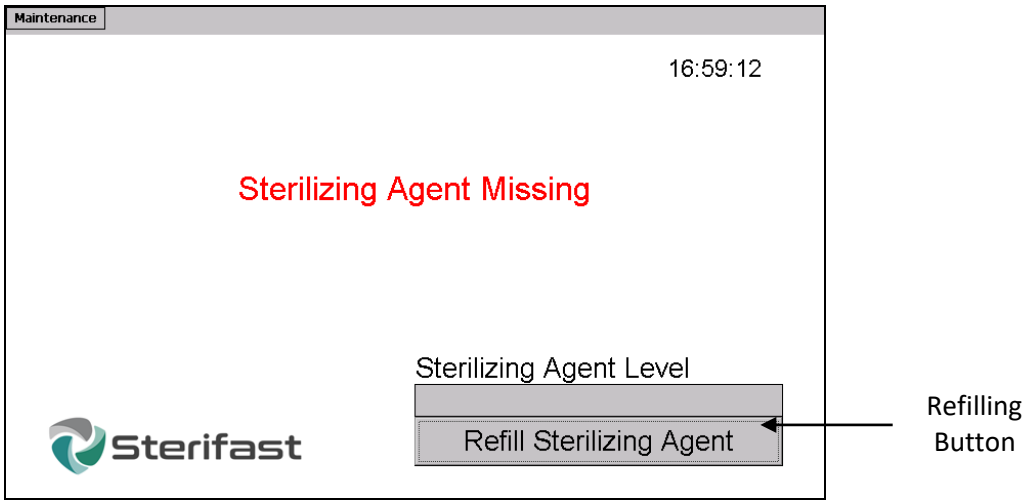


Figure 2-72

IMPORTANT:

Follow the handling instructions for the Sterilizing Agent that are inside the Sterilizing Agent package.

Do not use the Sterilizing Agent bottle if you note that it has been adulterated. The special seal on the bottle must be uniform on its entire surface, without any vestige of being perforated.

DO NOT PUNCH THE BOTTLE MANUALLY, UNDER ABSOLUTELY NO CIRCUMSTANCE.

DO NOT USE THE BOTTLES THAT HAVE EXPIRED VALIDITY.
(If someone tries to change the sterilizer date for a refilling with a RFID with expired validity, the sterilizer will not refill any more).

Note: When placing a new recharge of Sterilizing Agent, the system will recognize it automatically, due to the chip installed on each bottle that contains the information about the expiry date, lot number and packaging date. When passing on the refilling system, the chip will change its program preventing the use of the same bottle again.
The tank can support only one bottle.
For extra precaution, gloves should be used when placing the bottles in the drawer.

ATTENTION:
You should never press **"Exit"** during the refilling phase. If refilling is cancelled, it will disable the CHIP and the bottle becomes unusable.
If refiling is cancelled please follow the instructions on the screen to open the drawer and remove the bottle.

Depending on the sterilizer version, it will be equipped with different supplying systems:

Automatic Drawer	**Manual Drawer**
(regular version sterilizers)	(*Basic* version sterilizers)

Figure 2-73

Figure 2-73.1

- To refill, press the button **“Start Refilling**

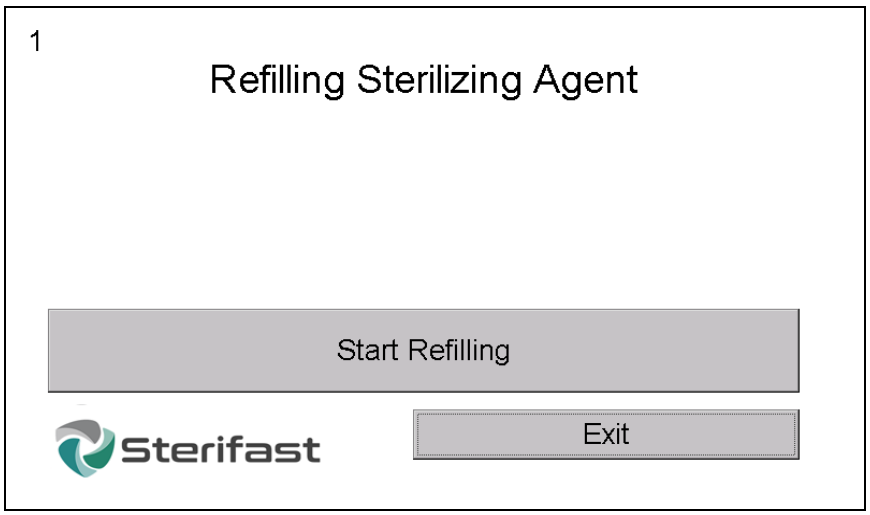


Figure 2-74

In the regular version sterilizers, the supplying drawer will open and you can place the bottle in the holder.
(Only the recommended bottles will allow the operation to proceed. Without the recommended bottle, the drawer will not close.)

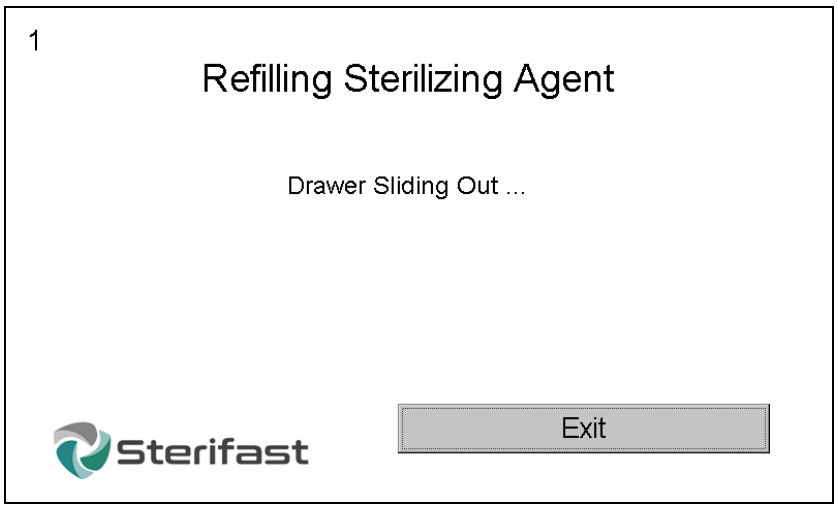


Figure 2-75

In the *Basic* version sterilizers, it is necessary to open the drawer manually and take out the bottle of the previous refilling (and please put the cap of the new bottle on the old empty bottle). Then, insert the new bottle (without the cap) in the holder and then close the drawer. After this, the refilling process in also automatic.
Please pay attention to the information on the screen.

Figure 2-76

Place the bottle in the holder and remove the bottle cap. (In the case of *Basic* version you must remove the bottle cap before placing the bottle in the holder).

Figure 2-77

Once the system recognizes the bottle, confirm that you have removed the plastic cap. Afterwards the drawer slides in again. (In the case of *Basic* version you must close the drawer manually).

Once the drawer is closed, the internal refilling process begins.

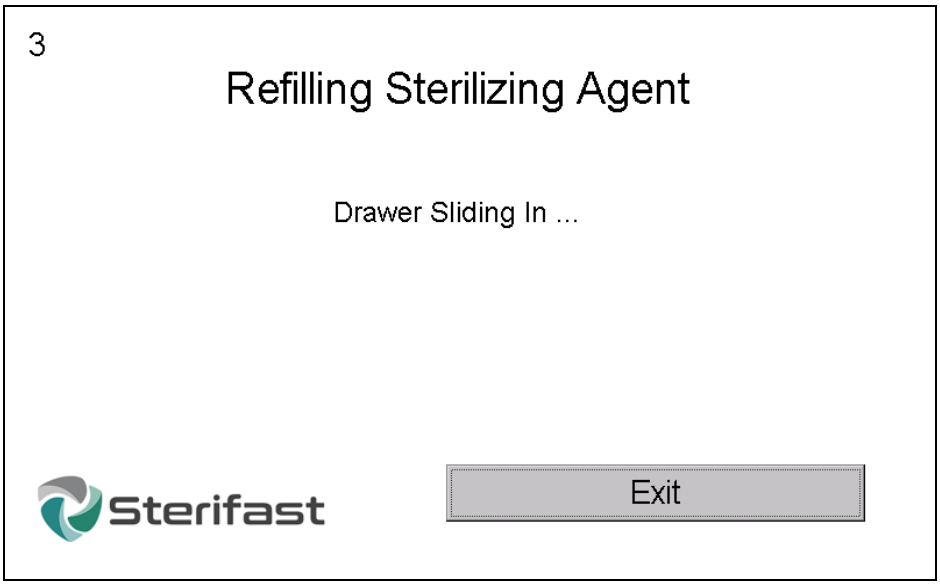


Figure 2-78

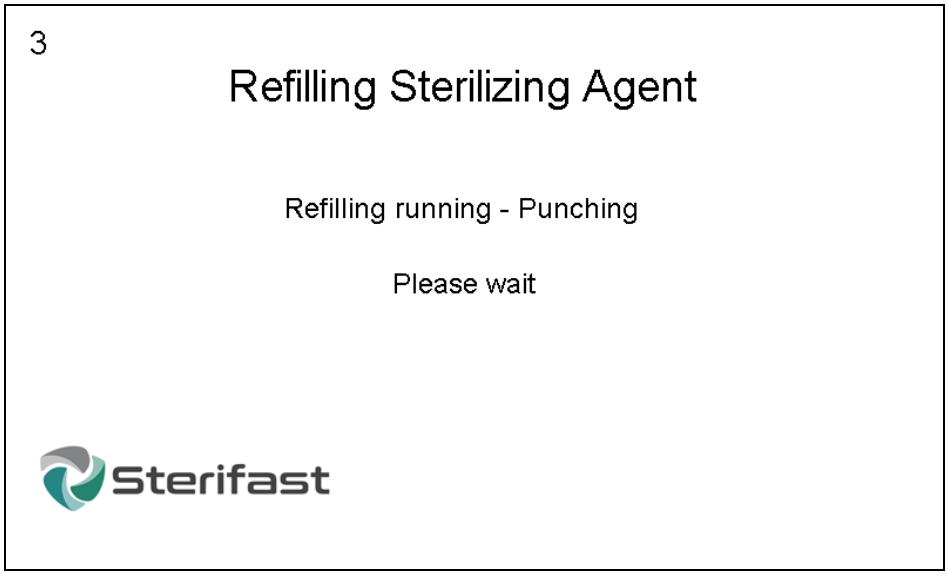


Figure 2-79

During this phase, the needle will punch the bottle membrane.
Note: The needle tip must not be damaged.

Figure 2-80

During this phase the system is aspirating the agent to the tank.

PLEASE NOTE: If during aspiration phase you press **"Jump Aspiration",** the refilling process will be cancelled. You must follow the instructions given by the system to open the drawer

and remove the bottle, but that bottle cannot be used anymore because the system already disabled the chip. If for any reason you remove the bottle right after its recognition, the chip will possibly be disabled and the system will no longer recognize it. In spite of that, the system will printout the data of the recharge initially recognized.

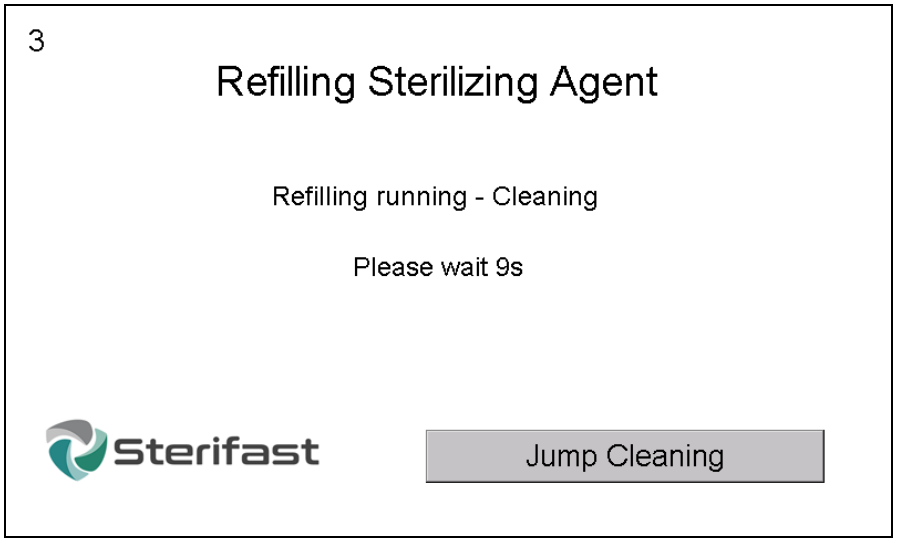


Figure 2-81

During this phase the system is cleaning the Sterilizing Agent tubing.

When the refilling is concluded, the drawer will slide out and a message will be displayed on the screen indicating that the bottle can be removed.

Figure 2-82

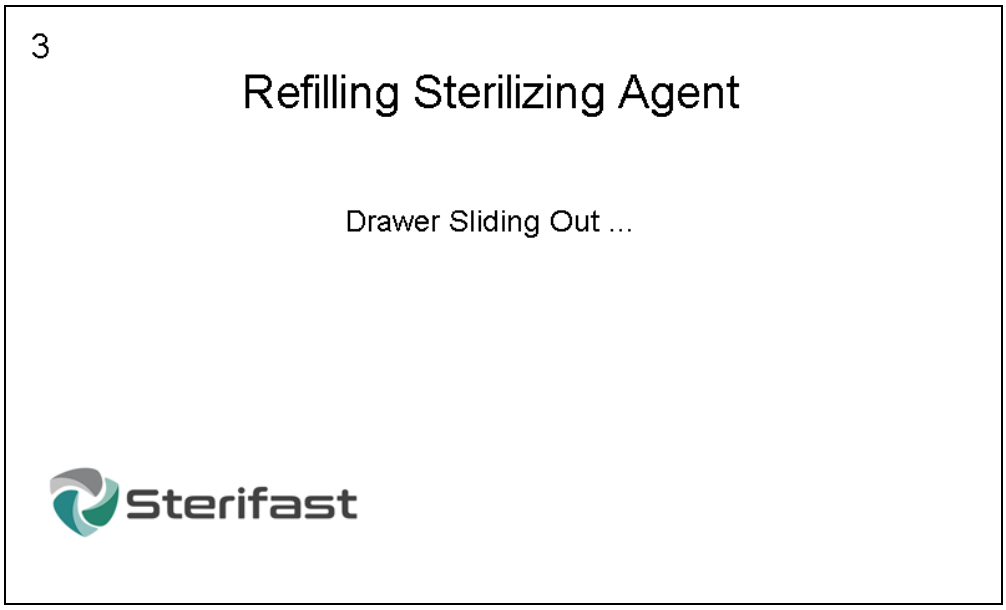


Figure 2-83

- Place the cap on the bottle;

Automatic Drawer
(regular version sterilizers)

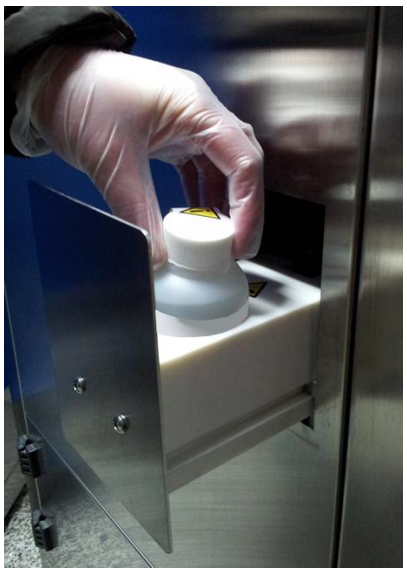


Figure 2-84

Manual Drawer
(*Basic* version sterilizers)

Figure 2-84.1

- Remove the bottle from the drawer;
- Press **“Slide In Drawer”** and the system will close the drawer automatically;
- The refilling is concluded;

Note: At the end of the refilling, please confirm if the Sterilizing Agent level increased on the touch screen indication. If it did not increase, please take care when taking out the bottle because there may be sterilizing agent residues more than usual.

For the *Basic* version sterilizers:

Please keep the bottle inside the support with the drawer closed until next supply.

Important Note: In case of failure during refiling, do not insist on inserting new sterilizing agent bottles. Please call the technician.

Press “**Exit**” to return to the Main Menu

Figure 2-85

After each refilling operation, the system will print a report with the refilling data.

During the refilling operation, the bottle is recognized and in the upper left corner of the screen the following numbers may appear:

1) Tag
2) Tag is Read
3) Burned Tag
4) Reader not found
5) Tag OK

All windows showed above are of Unclean Side. The window below is the Clean Side (this is applicable to Sterilizers with two doors).

Figure 2-86

! IMPORTANT NOTICE !

Sterilizing Agent validity inside the Tank

STERIFAST and ECOPLASMA regular versions Tank:

If the place where the sterilizer is installed does not have the temperature above 30ºC, the maximum time that the liquid should be inside the tank is 60 days. After this time, the sterilizing agent should be replaced.

ECOPLASMA Basic version Tank:

If the place where the sterilizer is installed does not have the temperature above 30º C, the maximum time that the liquid should be inside the tank is 30 days. After this time, the sterilizing agent should be replaced.

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Introduction

In this chapter, the different types of maintenance, warning messages and electrical safety are explained.
Maintenance of STERIFAST or ECOPLASMA Sterilizers must always be performed by duly trained technicians.

Note: For the maintenance, it is necessary to have 80 cm of free space on the side of each side panel.

The maintenance purpose is to keep the good operating conditions of the machine.
It consists of periodically verifying or replacing parts of the Sterifast sterilizer.
Maintenance MUST be done by authorized technicians, following the instructions of this Manual. When maintenance is not periodically followed, a warning message will be printed out on the cycle report.
From the Main Menu you can access some maintenance activities.

Button to access Setup.

With **code A (See annex 2)** the technician will be able to open or close the ventilation valve. To enter press **"Ventilation Valve"**.

To set the Date and Time press **"Date and Time"**.

To select the desired language press "**Language**".

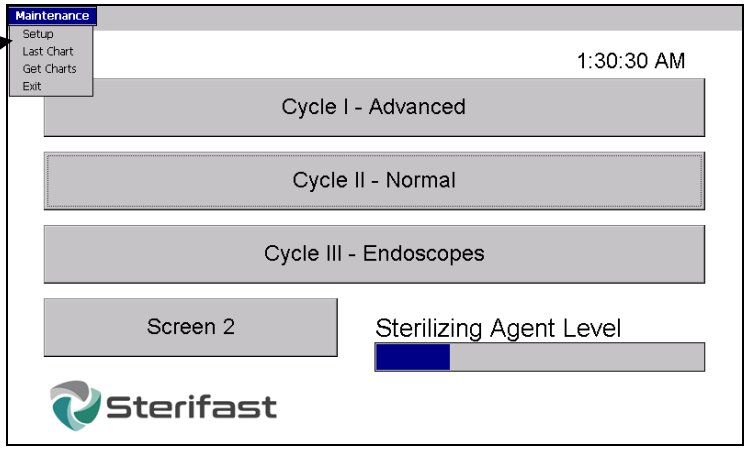


Figure 3-1

Note: The Maintenance button is for the operator to access basic settings.

If by mistake the technician presses the "**Exit**" button instead of "**Setup**", the system will ask for a password. In this case press "**Ok**" to get back to the Main Menu.

If necessary, Sterifast, Lda will provide the password to exit the system. In this case all the instructions given by our technicians must be followed.

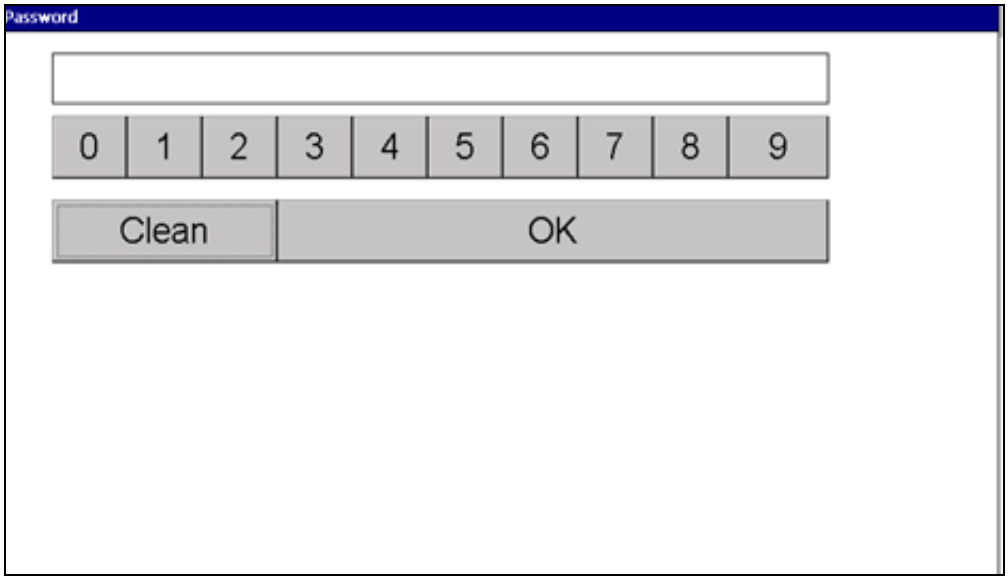


Figure 3-2

Under no circumstance should the technician access any of the files on WIN CE, unless with specific instructions from STERIFAST, LDA employees. This could cause the sterilizer to stop working.

1 - Preventive Maintenance

Before removing the cover panels for Preventive Maintenance, the equipment must be turned OFF on the Main Switch in order to make it safe.

The maintenance of the equipment must be done by Sterifast, Lda technicians or personnel with Sterifast training.
Periodically, it is necessary to do Preventive Maintenance, such as:

- Cleaning and/or replacement of some components;
- Cleaning of the electrical board zone.

Preventive Maintenance must be done as shown in the tables of **ANNEX 4**.

It is the Institution's or Hospital where the sterilizer is installed the responsibility to guarantee that the sterilizers are maintained and spare parts are replaced according to Annex 4 of this manual.
After every intervention, a test with biological indicators must be done, with either the Sterifast Lumen PCD or an equivalent testing process of the customer, in order to verify the safe state of the equipment.

2 - Repairing Procedures

Before removing the cover panels for Repairing Procedures, the equipment must be turned OFF on the Main Switch in order to make it safe.

All repairing must be done by Sterifast, Lda technicians or personnel with Sterifast training.
We recommend the use of protective gloves every time components containing Sterilizing Agent need to be handled.
In this manual, you can find photos of the sterilizer components' position with instructions of how to dismount them.
After every intervention, a test with biological indicators must to be done, either with the Sterifast Lumen PCD or an equivalent testing process of the customer, in order to verify the safe state of the equipment.

3 - Transducer Calibration

This calibration Kit is available under request (**only for Maintenance Technicians**). With this kit it is possible to calibrate the sterilizer pressure.

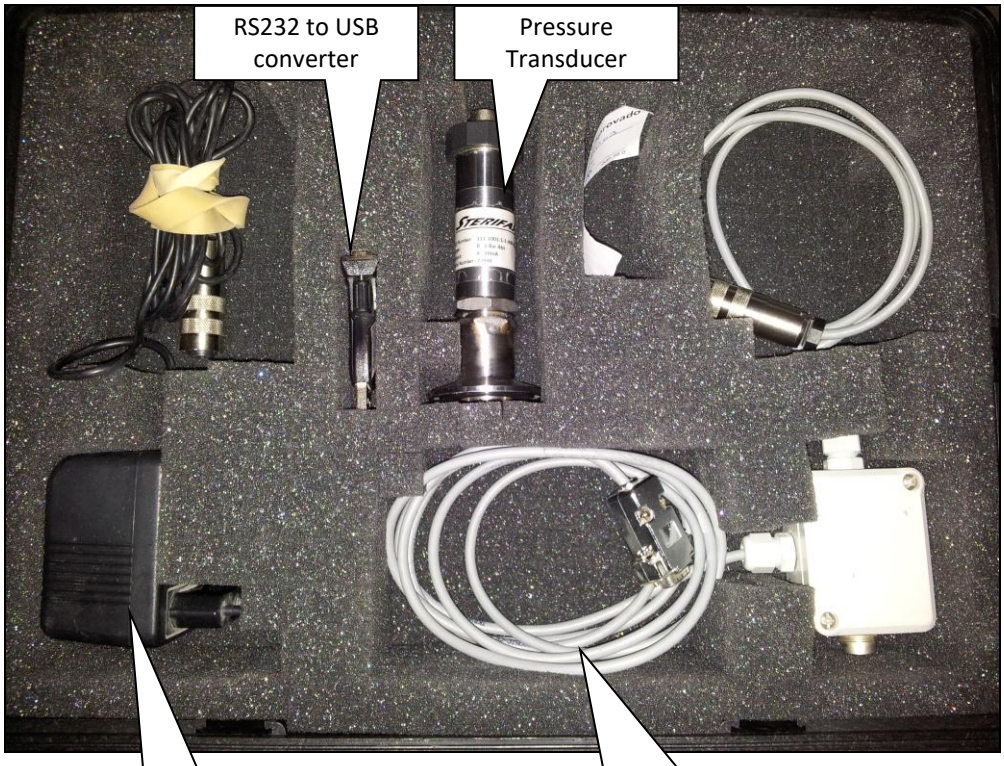


Figure 3-3

4 - Warning Messages

The sterilizer makes a permanent validation on the different phases. In case of phase failure, the sterilizer will indicate that through a warning message on the screen.

Note: Whenever a failure occurs after the cycle start, the sterilizer processes an emergency aeration or a cleaning cycle.

Whenever there is a failure in a cycle that takes the machine to abort, the cycle printout will have printed the chamber pressure value at the moment of the failure.

The cycle printout also mentions the time at which the error occurred.

Missing Sterilizing Agent (on the screen)
If this message persists after refilling, please call technical assistance.

Missing Start Up Conditions (on the screen)
This message shows up when a cycle is started having the sterilizer cold. The sterilizer is waiting for the correct temperatures. When the necessary conditions are achieved, the sterilizer starts up automatically. If this message persists on the screen there is a problem on a probe. Please call technical assistance.

PLASMA Temp. FAILURE (on the printout)
Please call technical assistance.

Cycle Manually Stopped (on the screen)
This message shows up on the screen every time you RESET the cycle. If a cycle was running, the sterilizer will perform automatic functions to allow the doors to open and will indicate FAILED CYCLE.

PLASMA FAILURE during Ventilation (on the printout)
Please call technical assistance.

Maximum Phase Time Achieved (on the screen and on the printout on the phase that failed)
Please verify if:
- Too much material was loaded.
- The doors are closed.

PLASMA FAILURE during Exhaustion (on the printout)
Please call technical assistance.

FAILURE DURING DIFFUSION (on the printout)
Please check the load to verify if you eventually loaded materials which cannot be sterilized in the Sterifast sterilizer or if you loaded too much material.
Please check on the printout, the pressure at the moment the phase failed.

The Sterilizer will stop to insert air in the chamber (Aeration phase) and return to Main Menu for cycle selection.
In this case, you should take precautions to open the door and unload the material, because it is possible that there is sterilizing agent inside the chamber. This method, is not a normal procedure, it should be used in an emergency situation only.

Material is NOT IN CONFORMITY (on the printout)
This message shows up at the Test Cycles to indicate the operator that it is not possible to sterilize devices in those cycles. If by mistake materials are loaded on those cycles, these won't be sterilized.
Whenever a sterilization cycle fails, this message also comes on the printout.

FAILED Leakage Test (on the screen and report)
Repeat the cycle to confirm if the failure persists. In that case, call technical assistance.

System in Alarm (on the screen)
This message is shown on the touch screen in case of failure of a temperature sensor or over temperature. Press "Restart". If the system does not restart call technical assistance.

If the REMOTE SUPERVISION software shows exorbitant temperature (ex. 3277ºC), it means "Probe missing".

The other failures are reported in the supervision program.

Note: Whenever a failure is mentioned in the cycle report, the person responsible of the service must approve or refuse the material processed in the cycle failed.

4.1 - Error Messages

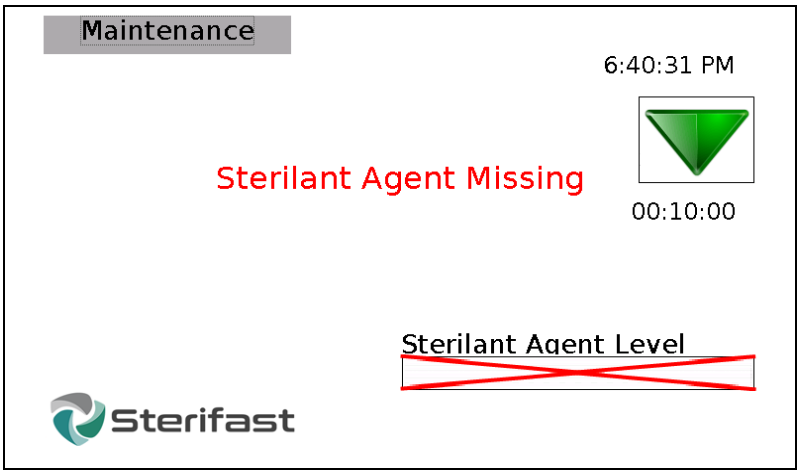


Figure 3-4

This sign indicates failure of the tank transducer (not applicable for the Basic Version)
The connector of the transducer is off or the transducer is damaged.
The system is not able to read the transducer.

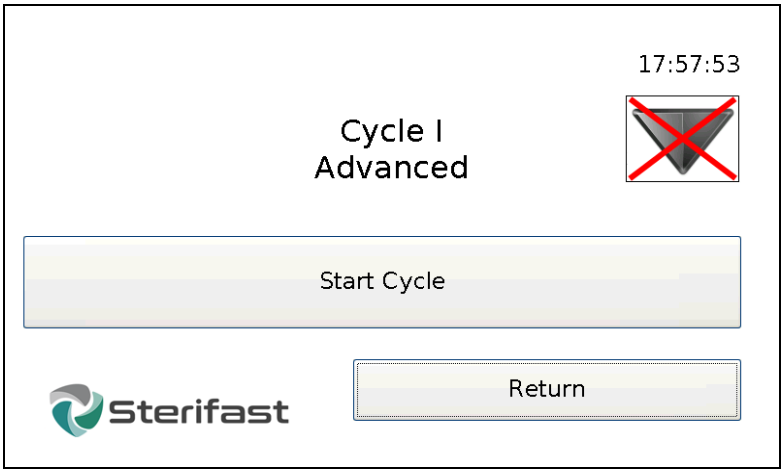


Figure 3-5

Failure on the door (Opening)
Time for the opening was exceeded
Possible causes:
Internal security system of the electrical motor disarmed by excess of temperature.
Relay of the door opening movement burned.
Microswitch damaged or out of position.
Brocken wires in the connection of microswitches.
Motor of door unlocking, burned.
Control board of the motor of door unlocking, burned.

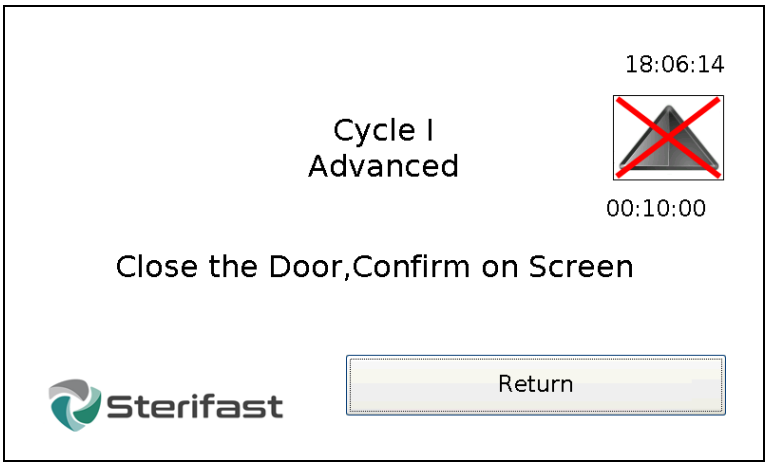


Figure 3-6

Failure on the door (Closing)
Time for the closing was exceeded.
Possible causes:
Internal security system of the electrical motor disarmed by excess of temperature.
Relay of the door closing movement, burned.
Microswitch damaged or out of position.
Brocken wires in the connection of the microswitches.
Motor of door unlocking, burned.
Control board of the motor of door unlocking, burned.

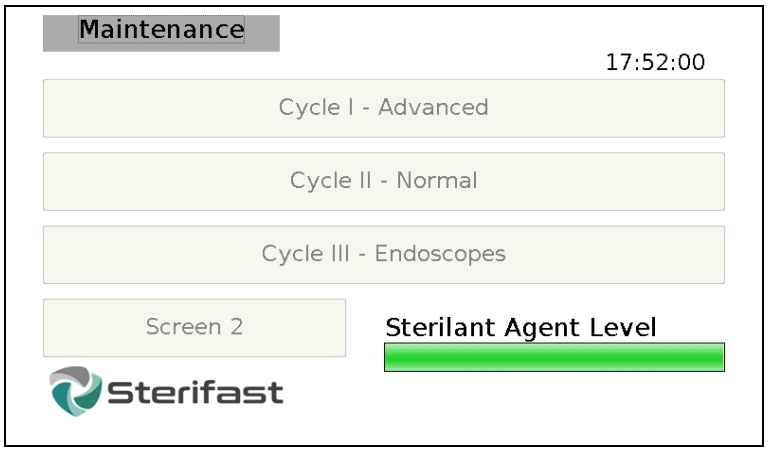


Figure 3-7

This image appears while the sterilizer is re-starting and verifying all peripheral elements.
Touch screen of clean side appears offline during this operation.

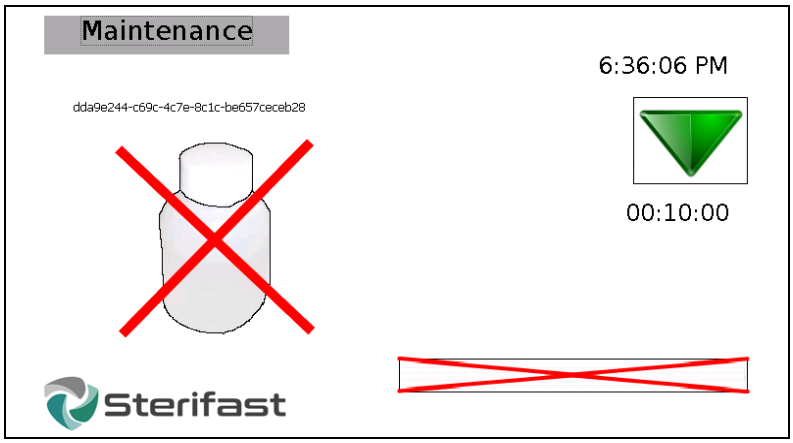


Figure 3-8

If this sign appears, you must take a photo of the image that has an associated code and send it to Sterifast, Lda company.

Possible causes:

The sterilizer is spending little hydrogen peroxide per cycle. There is the risk that the material will not be sterilized. The sterilizer is inhibited to work.

H2O2 dosing system is not correctly set or is damaged.

Vaporizer valve, dosing pump or capillary tube have problems.

The sterilizer is doing more diffusions per bottle than it should.

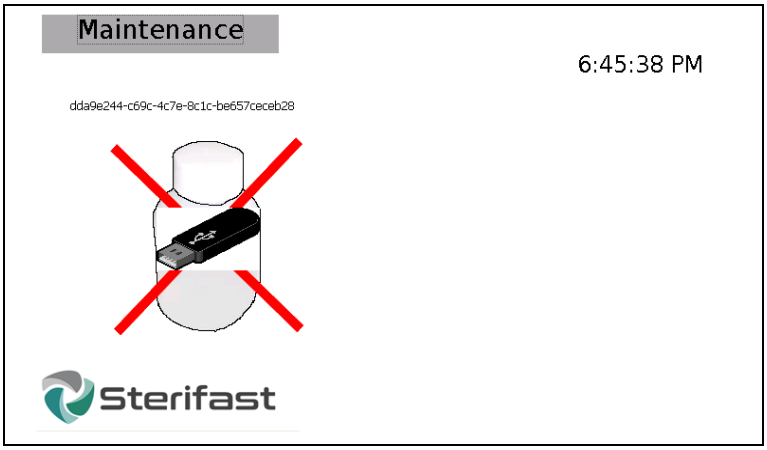


Figure 3-9

Insert a USB Flash Drive with the unlocking file in the USB Connection.

Press the bottle button on the screen. A second bottle button will appear with the sign of a flash drive in the center. Press the flash drive button and the sterilizer will re-start automatically. A reset was done to the supply system.

NOTE: The sterilizer will not refill if the tank is at its maximum level. When the sterilizer is refilled automatically, the refilling system will stop when the maximum level of the tank is reached.

5 - Electrical Safety

The Sterilizers were designed in order to supply a high level of electrical safety concerning the operator and the technician. The complete control system is 24V DC. All the places which can result in electrical risk are signalled, i. e. high voltage current transformer and respective connections to the electrodes and safety thermostats.

All Sterifast ventilation components are 24V DC. There are only few 230V connections: sterilization chamber's heating elements, doors' heating elements, vaporizer's heating element, exhaustion tube, high voltage transformer and vacuum pump. The rest of the components are 24V DC.

The Sterifast electrical board has protection and safety components as circuit breakers and relays. There is also a cover over the electrical board to avoid accidental contact.

Note: If someone disconnects the internal Ethernet network cable of the machine, three seconds after all PLC outputs will turn off. When the cable is connected again, the machine will try to connect. If this operation does not happen, it is necessary to turn OFF the machine and turn ON again and the machine will connect.

6 - Supervision software (only for Maintenance Technicians)

This software has been developed in order to make it easier for the technician to access all the operations occurring in the sterilizer software.

The supervision software is able to display the pressure and temperature values of the components and it permits verification if the components are ON or OFF (when the component is ON it is shown in blue colour, when it is OFF it is shown in red colour). The software is also able to verify the time spent for each phase.

To work, this software must be installed on a portable PC and be connected to the Touch Screen with a Crossover Cable like shown below or to the Ethernet switch in case of a double door model (with two screens):

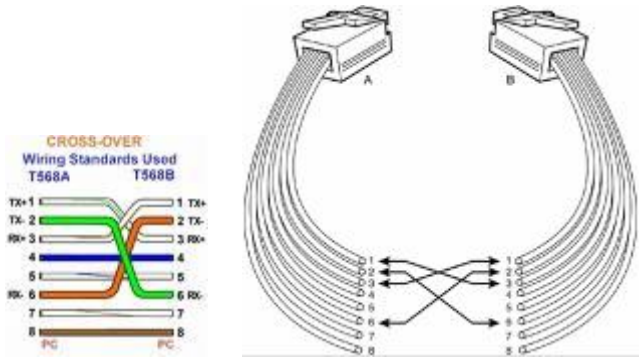


Figure 3-10

The computer where the software will be installed must have the correct connection properties.

WIN XP windows:

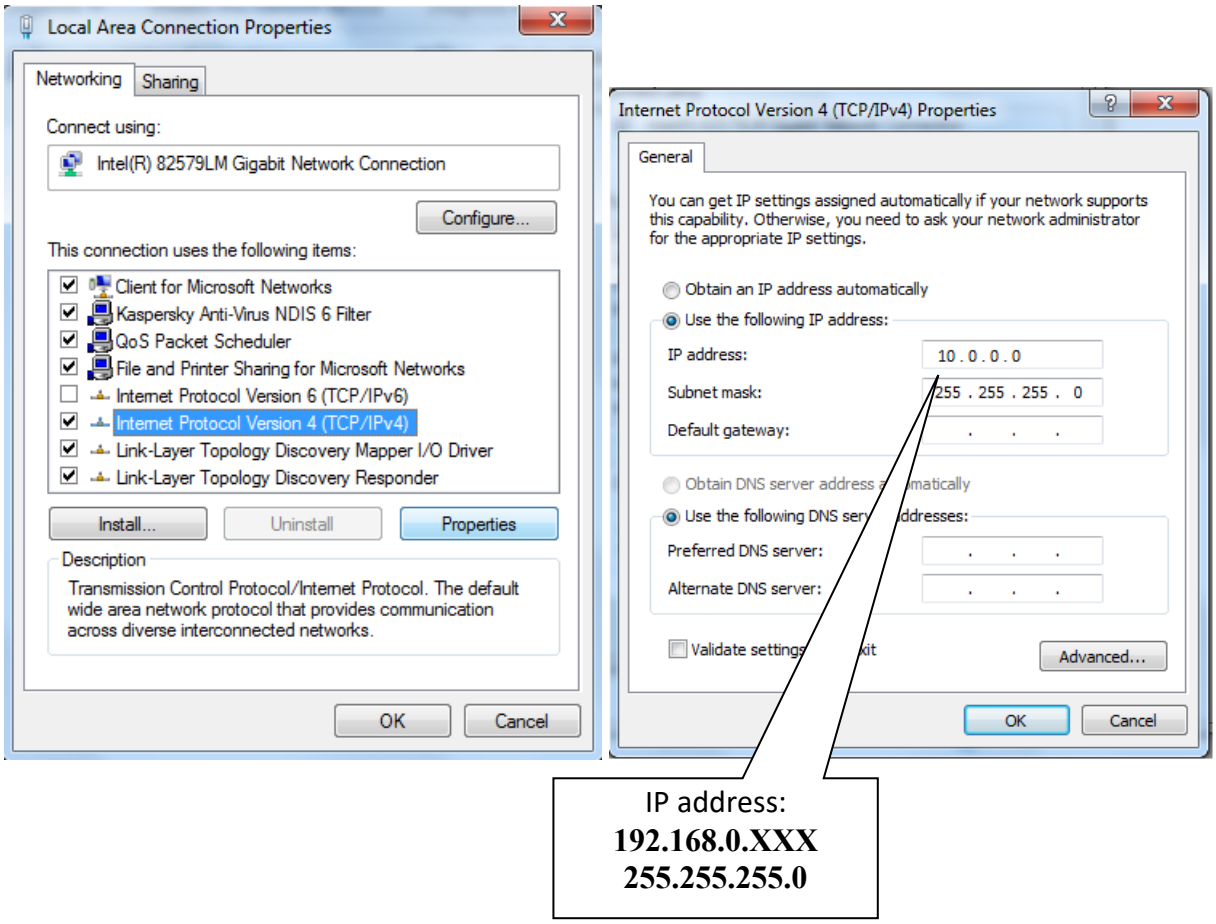


Figure 3-11

Note: In case of doubt, please verify the IP Address on the screen. Then verify which IP Address is on the remote control file because both have to be in the same net.
The IP Address of screen must never be changed.

SUPERVISION SOFTWARE WINDOW

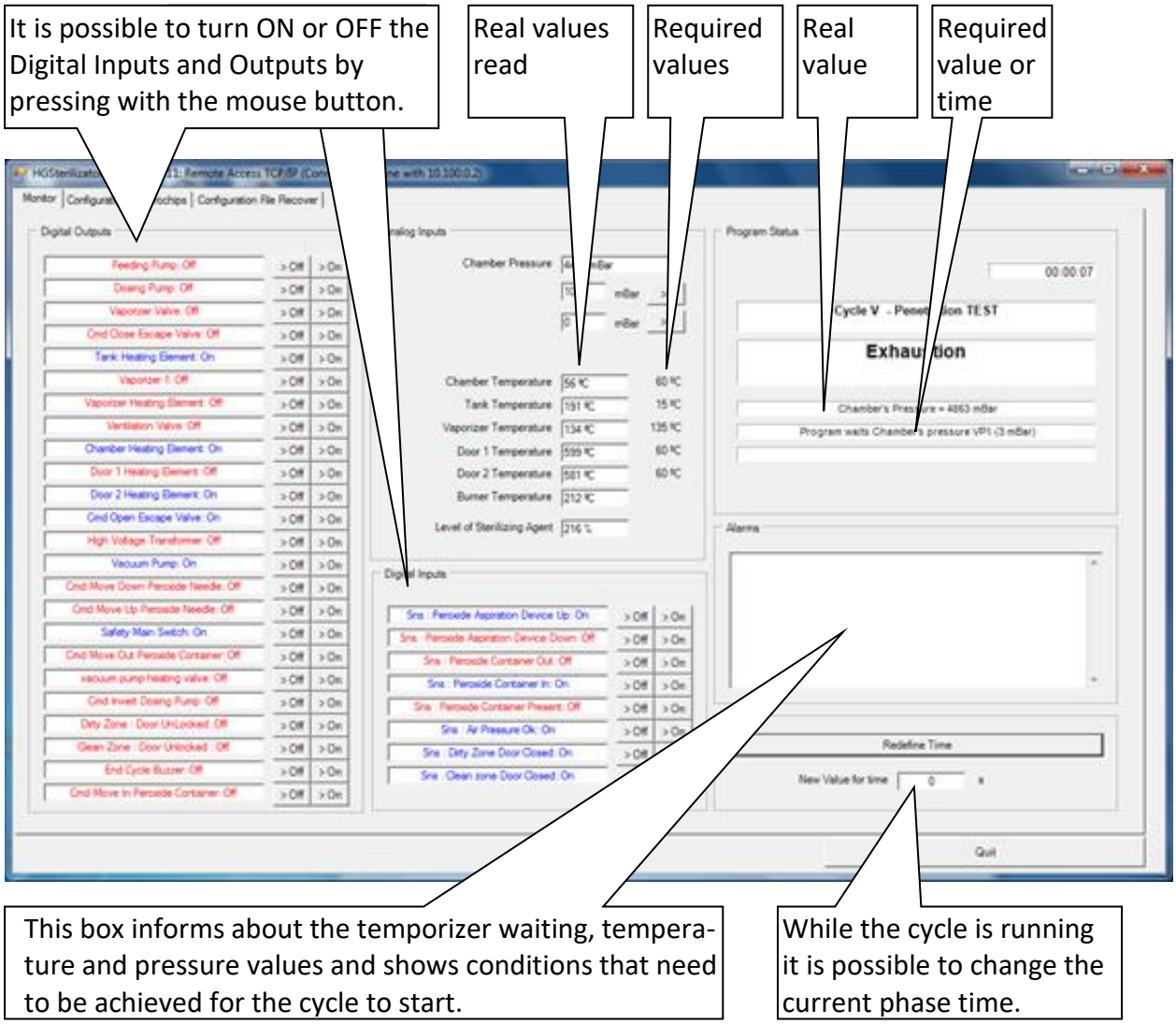


Figure 3-12

Note: It is not possible to turn ON a heating element if the temperature is equal or higher than the internal control of the machine.
If a cycle is not running, it is possible to open or close every element in this window.

SUPERVISION SOFTWARE AUXILIARY WINDOW

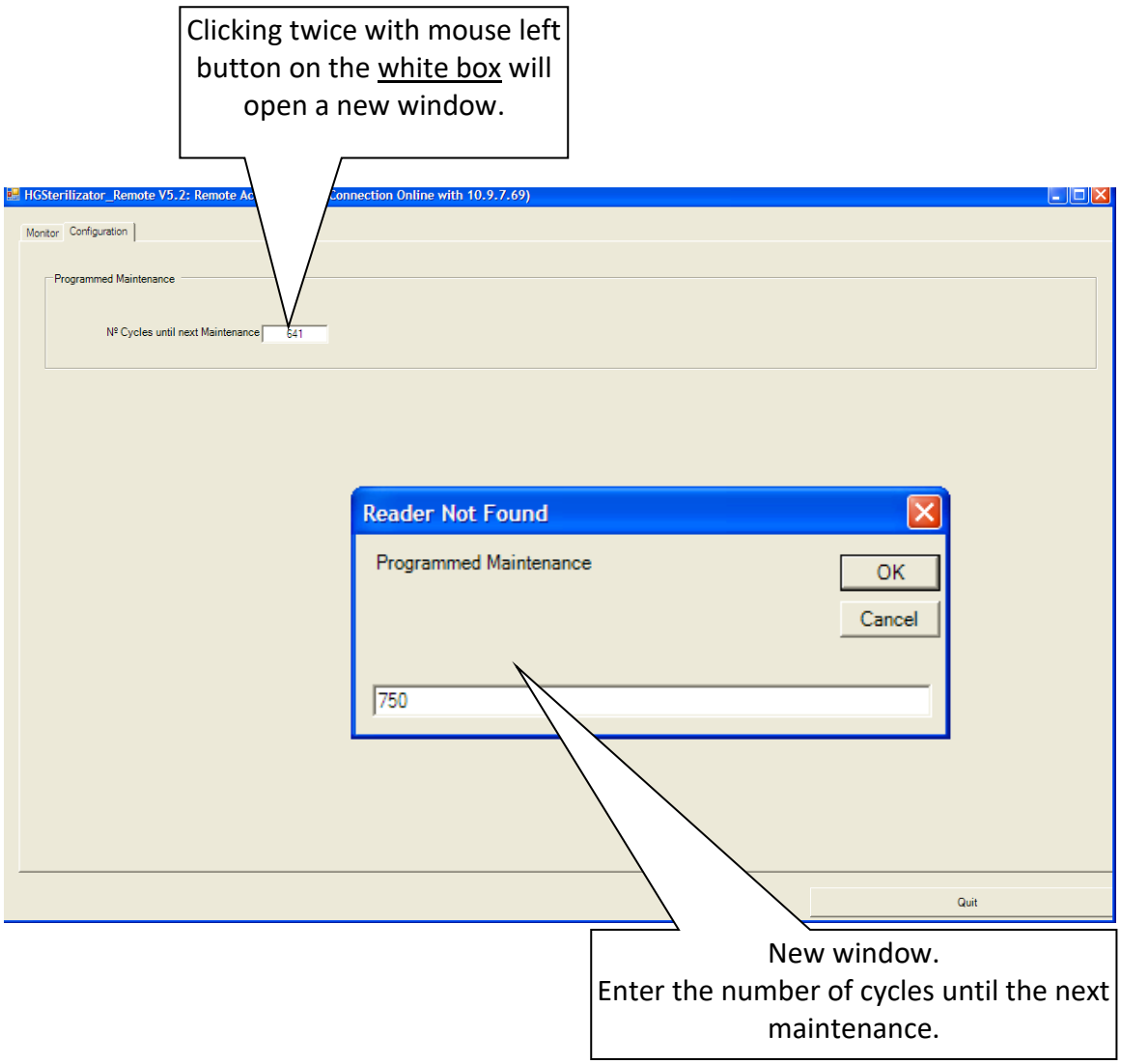


Figure 3-13

There are two supervision software versions, one of them allows you to transfer encrypted files to the Touch Screen and the other one allows the connection and disconnection of the valves.

This manual includes only the one that allows the connection and disconnection of the valves.

The whole software is in English but might be translated to your local language (to change the language contact Sterifast, Lda).

7 – Cleaning the STERIFAST or ECOPLASMA Sterilizers

Precautions:
To clean the sterilizer chamber, you must turn on the sterilizer and select one of the cycles, in order to open the doors. Turn off the sterilizer until the cleaning is finished.

Note: When doing the cleaning of the sterilizers, you must be wearing the adequate Personal Protective Equipment, according to your Institution's recommendation for the cleaning of electric and electronic equipment.

Cleaning procedure:
The sterilization chamber can be cleaned with a wet cloth and water. The water should not be placed directly into the chamber because it would damage the vacuum pump. After the cleaning, the door should be kept open until the chamber is completely dry.
Periodically, the chamber exhaustion filter must be cleaned or replaced.
The chamber must be cleaned every week due to natural deposit of dust.
The outside surfaces can be cleaned with appropriated cleaners. In our Sterifast range of products we have the suitable cleaners.
All the cleaning actions must be done at the beginning of the day when the machine is cold.

Touch screen:
First you have to turn OFF the machine and then you can clean it with a wet cloth or with some special product for cleaning PC screens.

Note: Due to Covid-19 pandemic, it is necessary to disinfect the external surfaces of the sterilizer, according the WHO recommendations, or the internal protocol of the institution.
In case of the touch screen, you should not spray directly on the touch screen.

8 – Validation

The validation of the sterilizers sterilization process should be performed only by Sterifast, Lda. Company.

Introduction

In this chapter the spare parts of the machine are described.

For safety reasons, only components recommended by Sterifast Lda. shall be used in the Sterilizers.

1 - Components Description with Part Number

Touch Screen

A 7”touch screen is placed on the Loading Side panel. In this element you can select the desired cycles and visualize all the cycle phases.

This computer has a Windows CE operating system

Note: The software is in a folder (ResidentFlash) inside the WIN CE Operating System.

The software’s name is “Sterifast_PHP_CE_V5”.

Figure 4-1

Note: If the network cable is disconnected from the touch screen, the touch screen will restart systematically.

Note: In case of touch screen failure, it is necessary to turn OFF the sterilizer, wait 10 seconds at least, and turn ON the sterilizer again.

ON/OFF Button

There is an ON/OFF button on the front panel for turn on and turn off the sterilizer.

Figure 4-2

Once turned ON, the sterilization chamber and the doors take around 5 - 10 minutes (for 40 litres model) to warm up and keep at a predefined temperature.

If minimum conditions don't occur the cycle will not run and a message will be displayed on the touch screen warning the operator about it. When minimum conditions are attained the cycle will run automatically.

The cycle starts when the temperatures are 2ºC below the required value.

Printer

Thermal Printer (only for ECOPLASMA Basic Sterilizers)

Easy operation. All the cycle is printed, including the cycles' phases and the time spent for each phase. The printout indicates if the cycle passed or failed.
This printer uses thermal paper (57x40x11mm). When the paper roll is finishing, it will appear a red line along the paper. You should then replace the paper roll.

Thermal Printer
Part Nº **401604**

Figure 4-3

Note: There are thermal printers with 5V and 12V. When you need to order a new printer, it is necessary to inform exactly which unit you have in your sterilizer.

Matrix Printer (for STERIFAST and ECOPLASMA Sterilizers)

This is a matrix panel printer with memory, where all the cycle data is registered. At the end of each cycle a report is printed including all the cycle phases and the time spent for each phase. The report indicates if the cycle passed or failed.
The paper missing is indicated by the red lamp (3) on the front cover.

Matrix Printer
Part Nº **401601**

Figure 4-4

Note: More information about the matrix printer, like printer external appearance, printer parts description, etc, you will find in Annex 7 of this Manual.

USB Connection *(not available for ECOPLASMA Basic version Sterilizers)*

Figure 4-5

Electrical Switch Board - BECKOFF (installed in the sterilizers in the previous years)

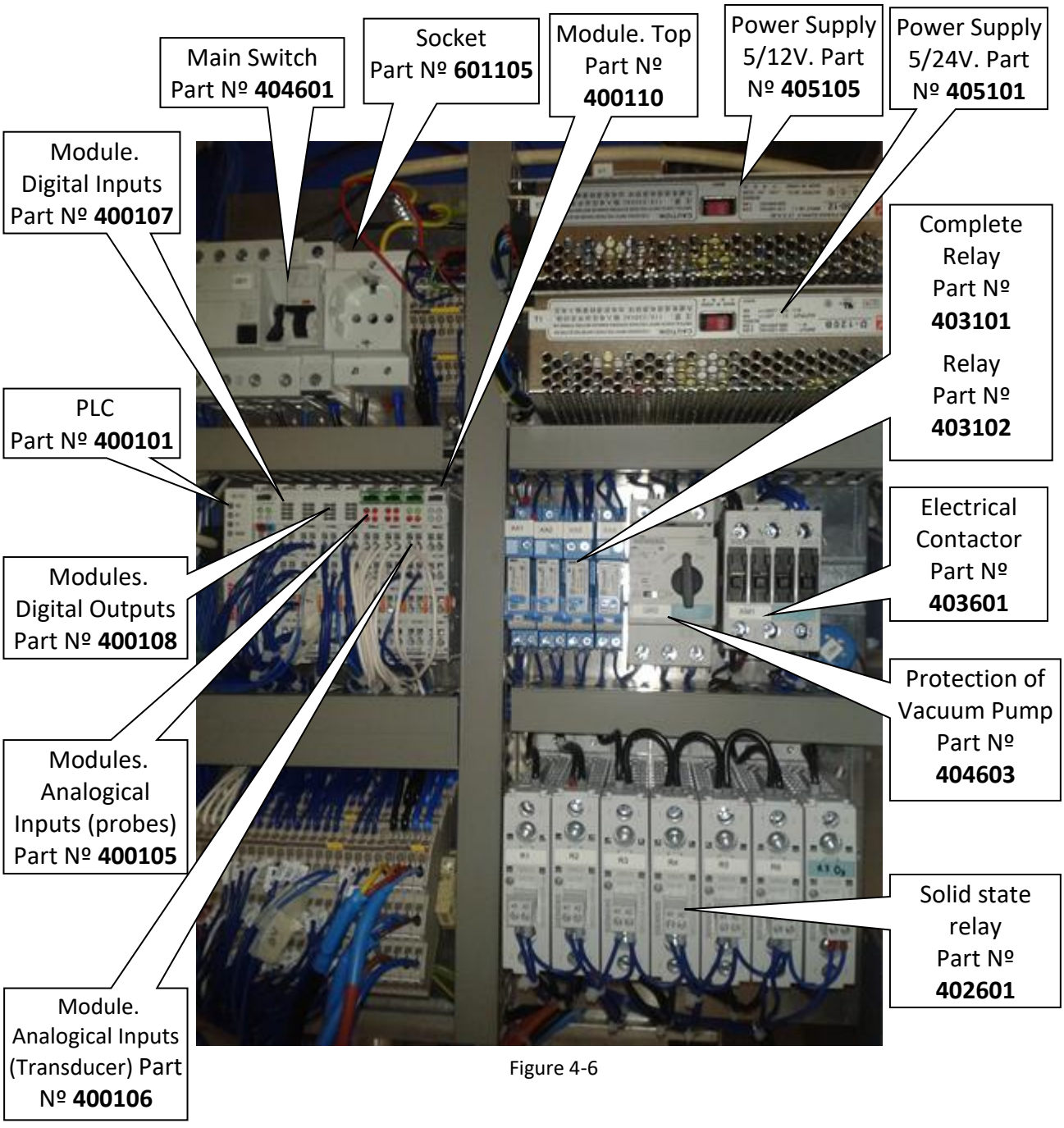


Figure 4-6

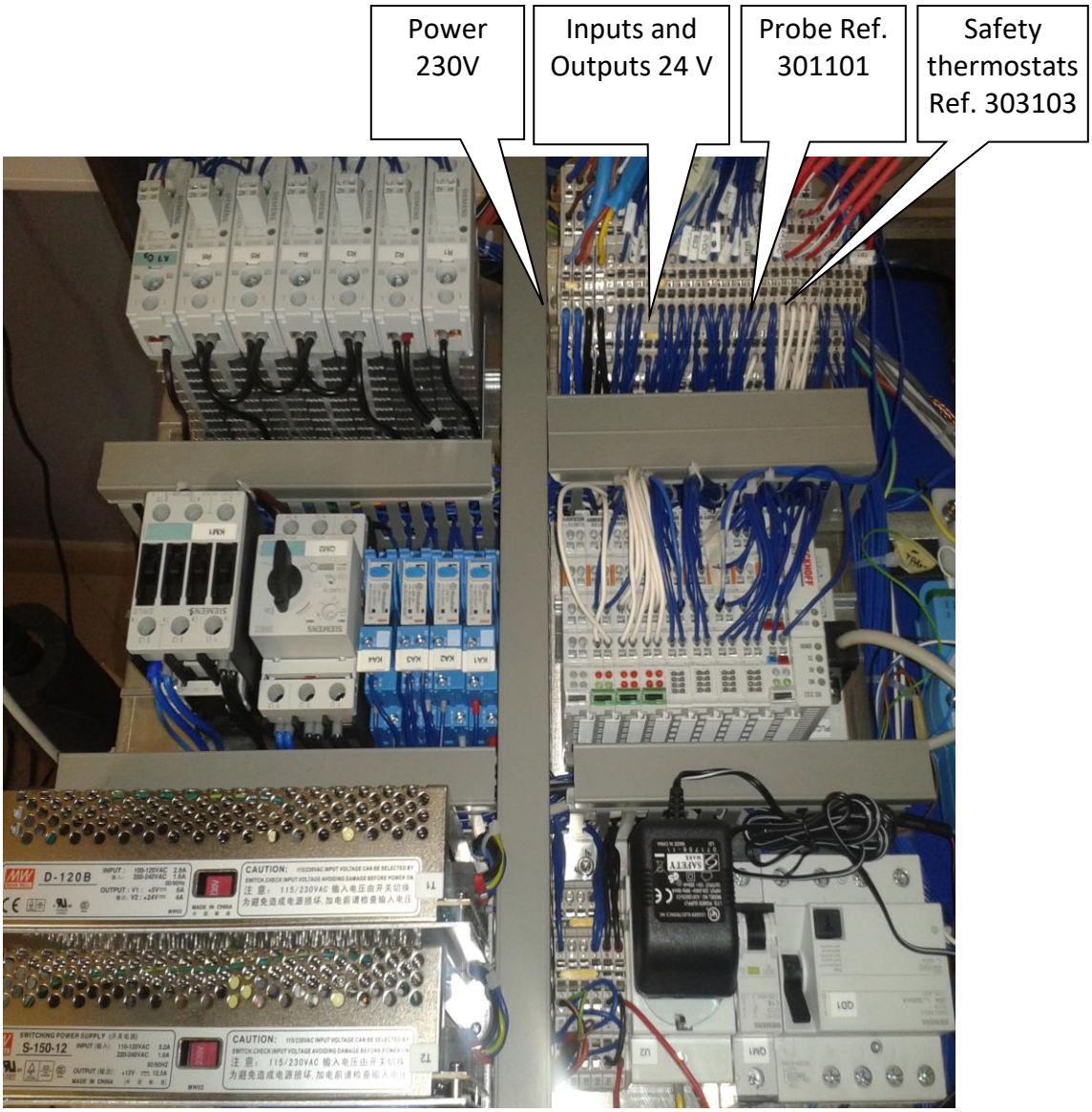


Figure 4-6.1

Abbreviations of the Electrical Board

FA1	Power Supply 24V & 5V
FA2	Power Supply 12 V
FA3	Power Supply 5V
PP1	Peltier Plate
EU1	Ventilation Valve
EU2	Vaporizer Valve
PLC	Automation
IM1	Printer
ET1	Touch Screen
VV1	Vacuum Valve
BV1	Vacuum Pump
C1	Safety Contactor
PB1	Pump Protection
TA1	High Voltage Transformer
BE1	Buzzer
PC1	Electrical board for Needle
PC2	Electrical board for Drawer
DOS1	Refill Pump
DOS2	Dosing Pump
RA1	Vaporizer Heating Element
RA2	Dirty Zone Door Heating Element
RA3	Clean Zone Door Heating Element
RA4	Chamber Heating Element
R1	High Voltage Transformer Relay
R2	Vacuum Pump Relay
R3	Vaporizer Heater Relay
R4	Dirty Zone Door Heating Element Relay
R5	Clean Zone Door Heating Element Relay
R6	Chamber Heating Element Relay
R7	Ventilators Relay
R8	Inversion Relay of the Dosing Pump (DOS2)
R9	Peltier Plate Relay
VT1	Ventilator of the Peltier Plate (Tank)
VT2	Top Ventilator
VT3	Lateral Ventilator
VT4	Lateral Ventilator
IG1	Main Switch
MI1	Micro Switch of the Dirty Zone Door
MI2	Micro Switch of the Clean Zone Door
MI3	Micro Switch of the Needle

MI4	Micro Switch of the Drawer
ST1	Temperature Probe of the Vaporizer
ST2	Temperature Probe of the Dirty Zone Door
ST3	Temperature Probe of the Clean Zone Door
ST4	Temperature Probe of the Chamber
ST5	Temperature Probe of the Burner (Plasma)
ST6	Temperature Probe of the H_2O_2 tank
TS2	Safety Thermostat of the Dirty Zone Door
TS3	Safety Thermostat of the Clean Zone Door
TS4	Safety Thermostat of the Chamber
TS1	Safety Thermostat of the Vaporizer
TM1	Plug Socket
GP1	Plasma Generator
EL1	Electrodes for Plasma Generator
CH1	Humidity Condenser (Optional)
SO1	Oil Separator
FM1	Molecular Sieve
FV1	Ventilator Filter
PO1	Dirty Zone Door
PO2	Clean Zone Door
CAM	Sterilization Chamber
VAP	Vaporizer of the Sterilizing Agent
TA1	Sterilizing Agent Tank
SM1	Servomotor of Needle
SM2	Servomotor of Drawer
DEP	Sterilizing Agent Tank

Table 4

Electrical Switch Board - PHOENIX

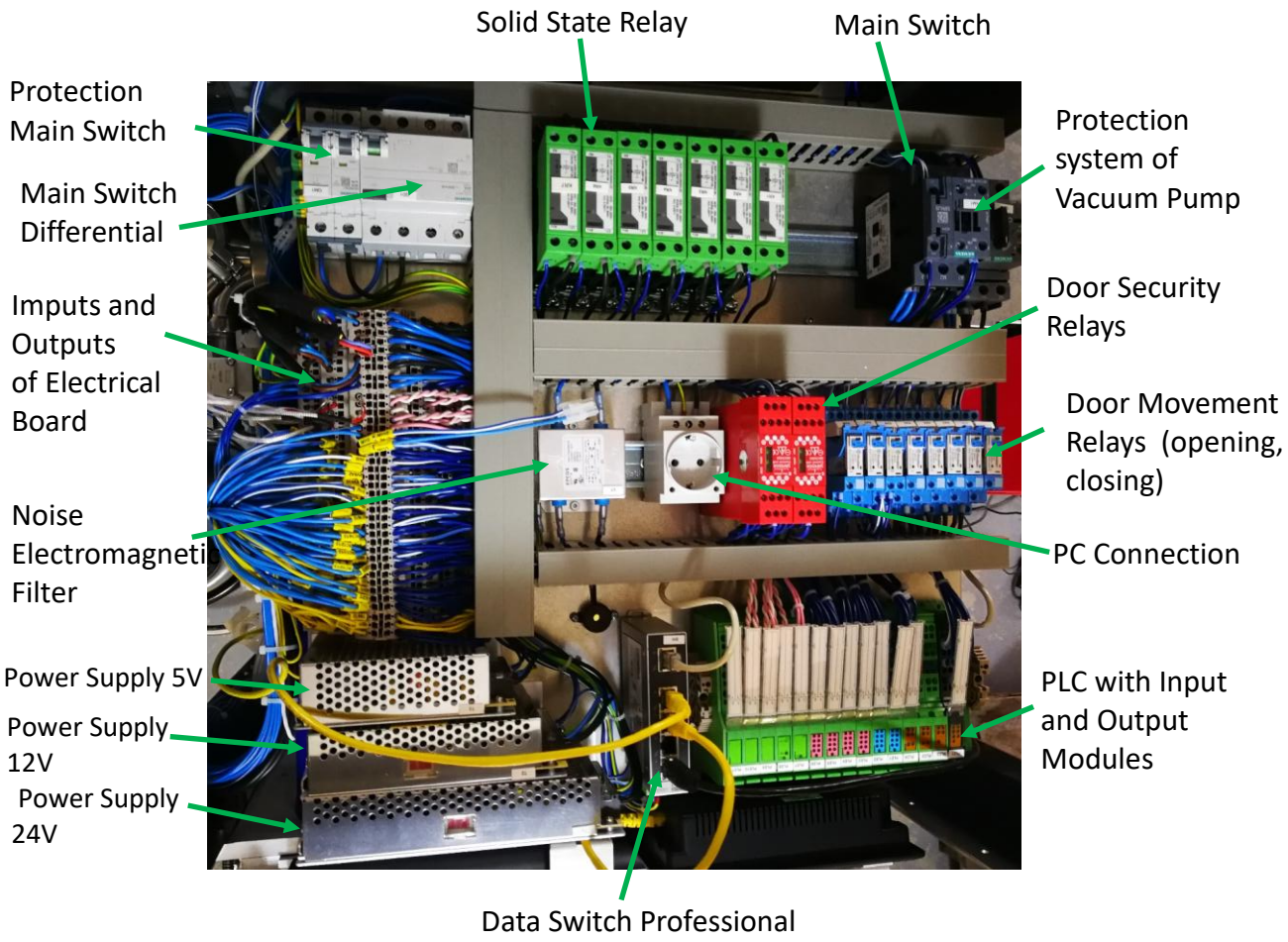


Figure 4-7

Sterilization Chamber

The sterilization chamber is totally made of material resistant to corrosion. Inside the chamber there are 4 Teflon rails (Option 1) applied on an internal cover in order to ensure that there is enough space between the chamber and the basket, providing a correct circulation of the Sterilizing Agent.

The chamber walls may be hot depending on the chosen temperature, so direct contact must be avoided. You should use gloves to unload the chamber.

The chamber heating is made electrically and the temperature is controlled by the control system.

As Option 2, there are 2 Teflon rails in the bottom and 4 special Teflon rails in the walls, with many levels for the shelves that allows optimization of the chamber space.

The heating elements are installed around the chamber as a coat and are made of high quality and safe silicone with fibre glass material.

The chamber has a safety thermostat that disarms in case of overheating.

STERILIZATION CHAMBER

Option 1

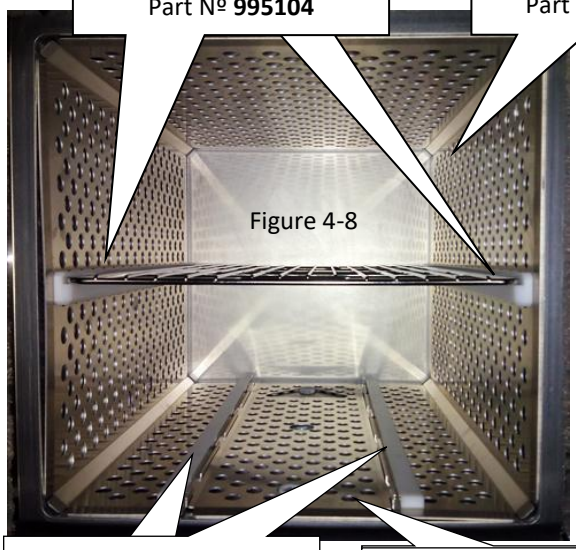


Figure 4-8

Option 2

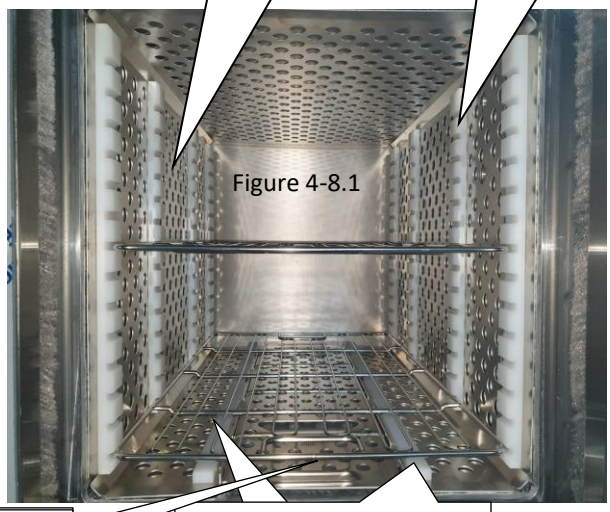


Figure 4-8.1

CHAMBER ACCESS (Optional)

It is possible to apply external sensors to access the chamber with Probes and Transducer through clamp connections shown below.

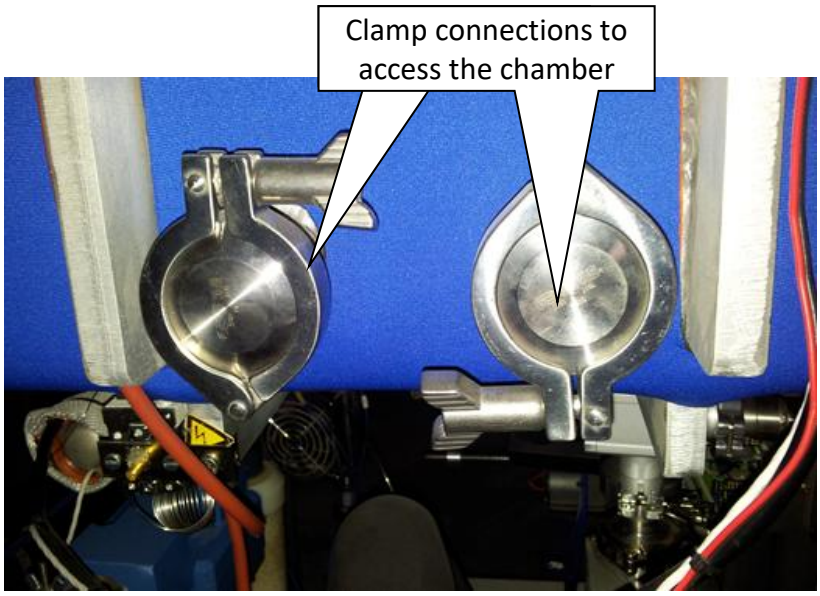


Figure 4-8.2

INTERNAL COVER

The internal cover should exit and enter the unclean left side of the machine, so that the holes (indicated below) coincide with the holes in the chamber;
To put or remove the internal cover, first the humidity sensor has to be removed (*if applicable*).
Before placing the internal cover, please verify the holes' positions.
At the end replace the humidity sensor again (*if applicable*).

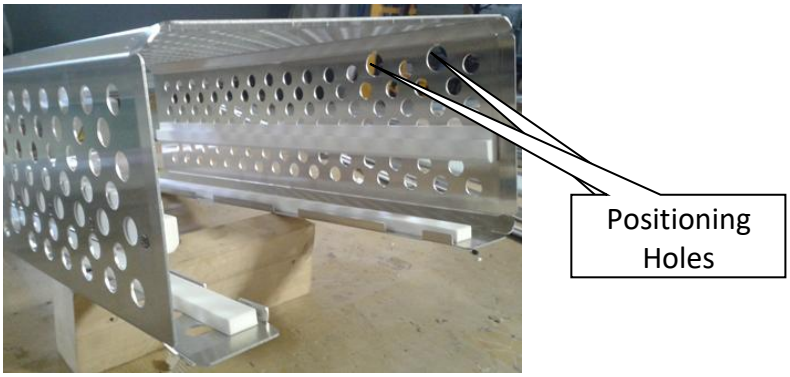


Figure 4-8.3

Vacuum Pump with Oil Separator

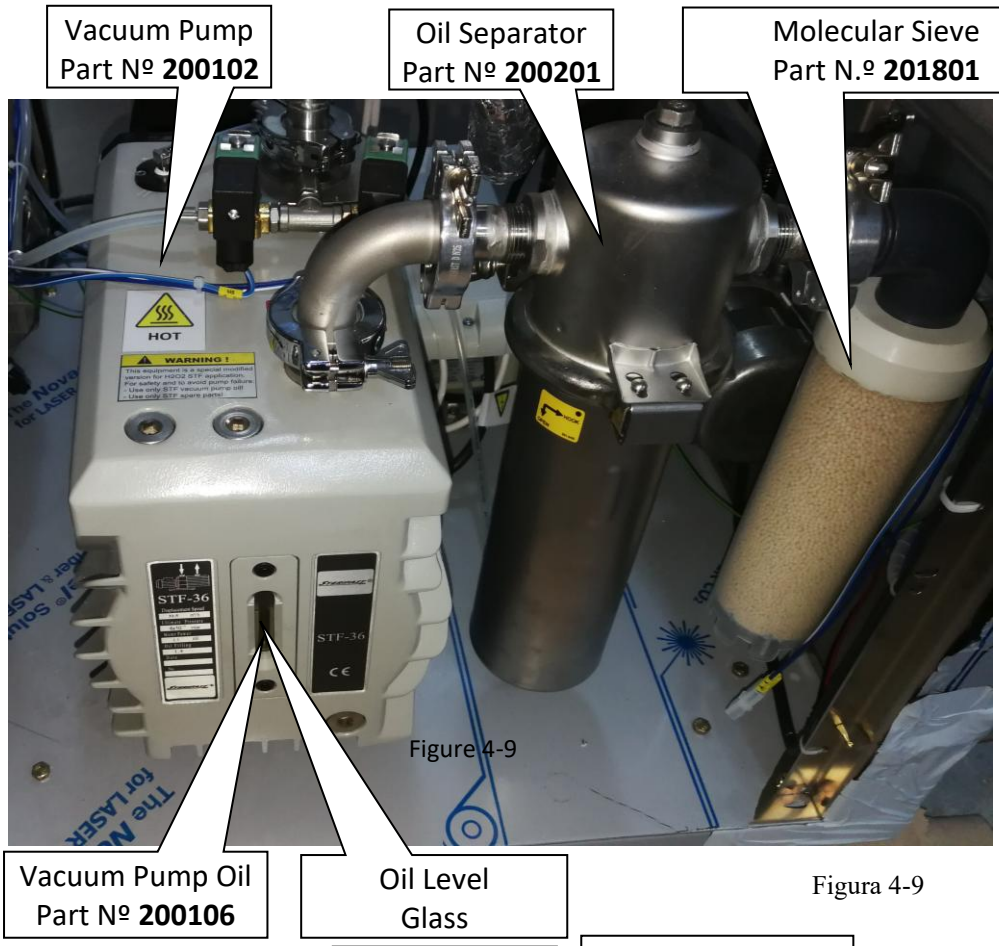


Figure 4-9

Figura 4-9

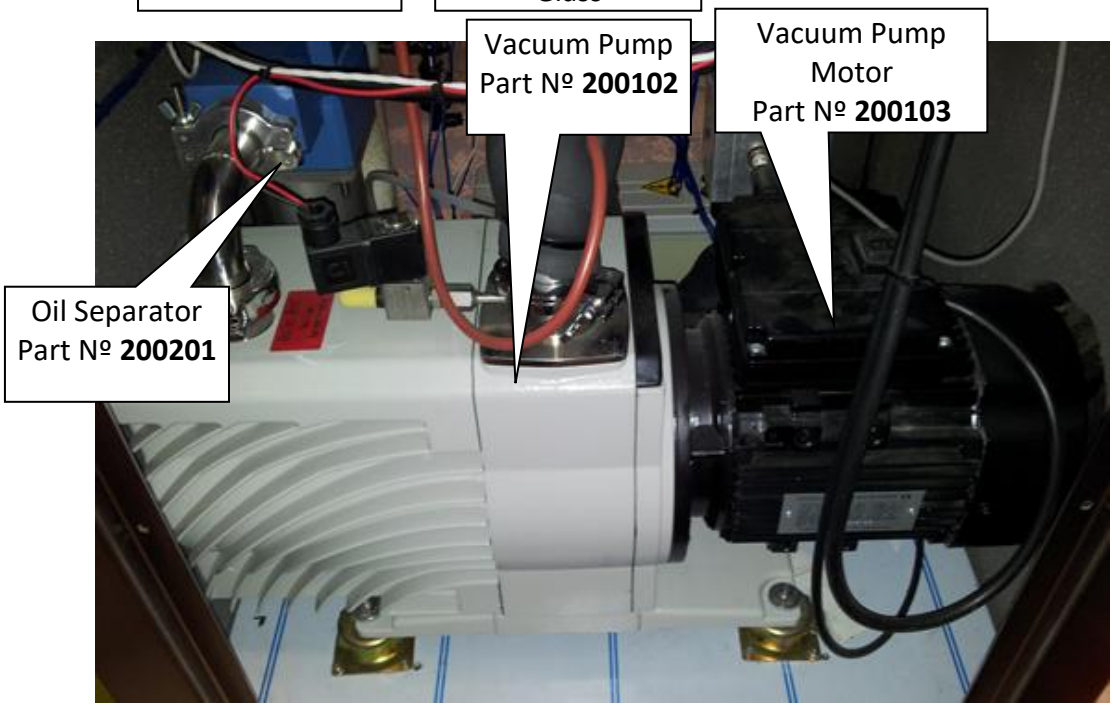


Figure 4-9.1

CE 2460

Sterifast sterilization & disinfection

ecoPlasma

Option for Basic version Sterilizers

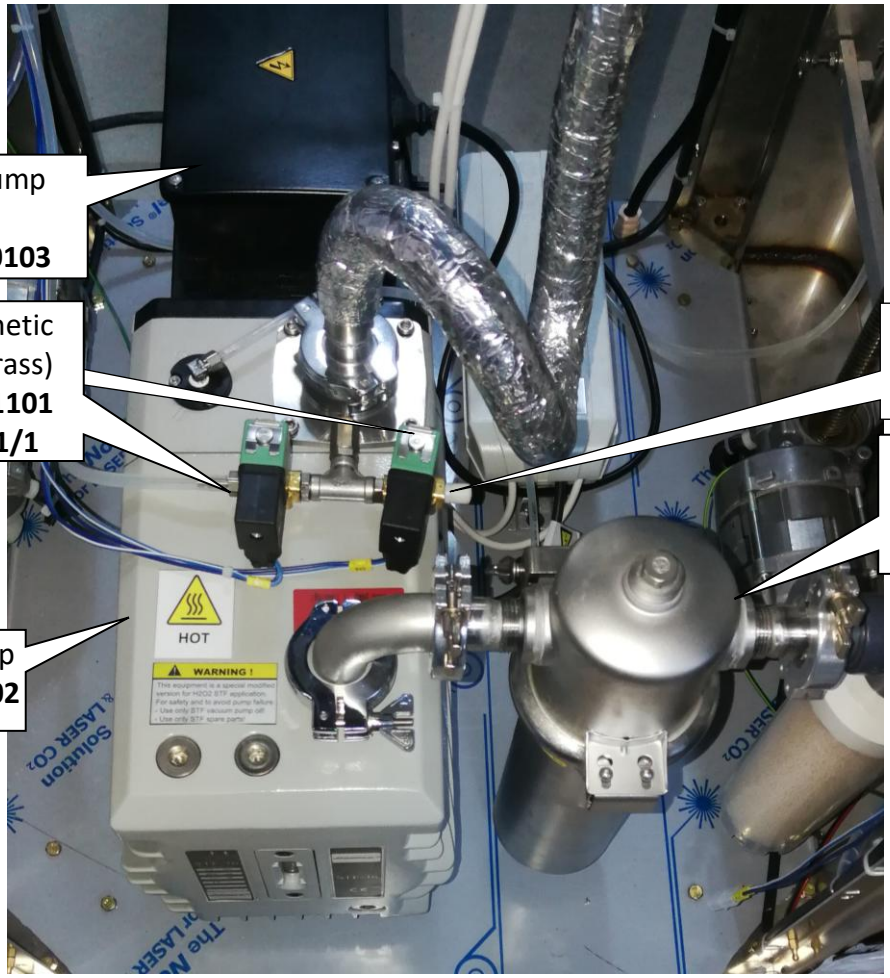


Figure 4-9.2

The Vacuum System comprises:

- One Exhaust Valve,
- One Vacuum Pump Heated Exhaust Tube,
- One Vacuum Pump Inlet Filter,
- One electromagnetic valve for pump inlet (or two valves for Basic version),
- One Vacuum Pump,
- One Oil Separator,
- One Molecular Sieve.

The vacuum pump works with oil inside, which must be changed periodically.
The oil level must be verified monthly.
Periodically verify if the oil contains water (if rising oil level is a sign of water mixed with the oil.
The oil separator has to be verified periodically, and if necessary, replace the filter element.
The vacuum pump inlet filter sieve has to be cleaned and the vacuum pump connections must be replaced periodically (please see Annex 4).
We recommend that when the oil is replaced, the oil separator filter and the molecular sieve should also be replaced.

Valve Inlet Filter – Part No.: 104106

This Filter should be verified/replaced periodically (according the Preventive Maintenance Plan – Annex 4) in order to prevent some damages in the vacuum pump, like not heating.

Attention: Pay attention to the type of oil the vacuum pump is supplied with. Always use the same type of oil. Ask Sterifast, Lda company in case of doubt about the type of oil.

Sterifast Vacuum pumps may be suplied with the following oil:

STERIFAST Oil, Ref. 200106

Note: The Vacuum Pump will lose the guarantee if this type of oil is not replaced every 6 months.

Note: You can find the Installation and Operating Manual of Vacuum Pump Sterifast in **ANNEX 8** of this Manual.

Figure 4-9.3

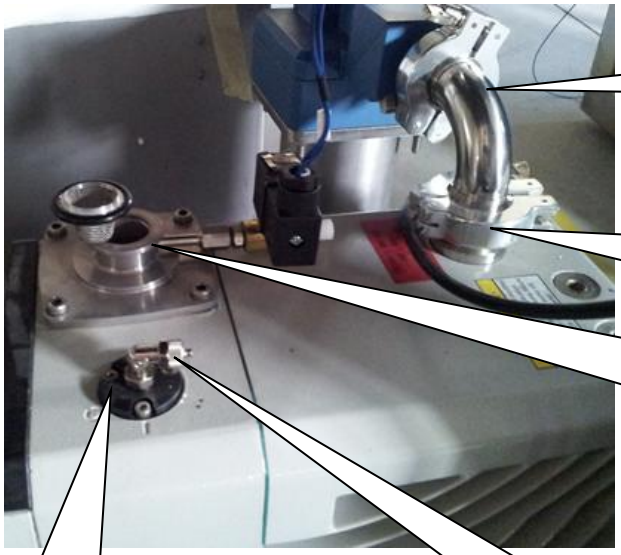


Figure 4-9.4

Figure 4-9.5

Exhaust Valve

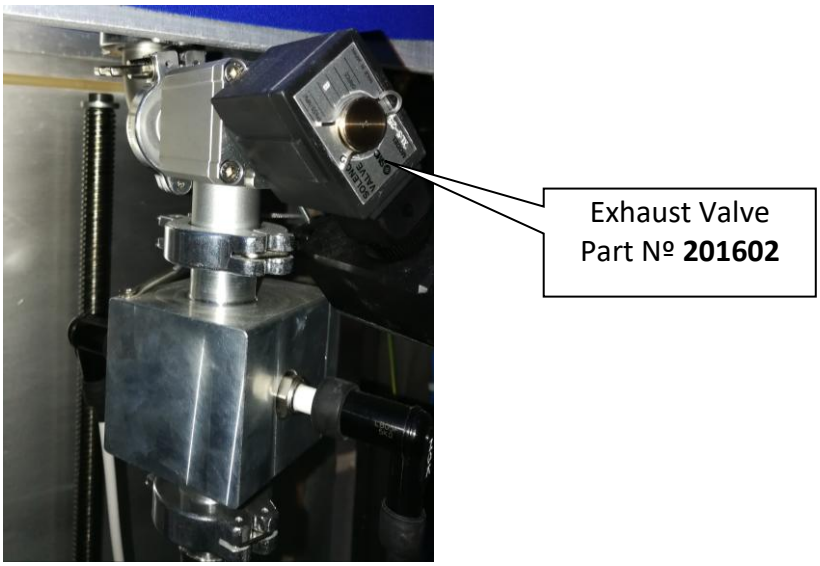


Figure 4-10

Protection Filters

a) Vacuum Pump Inlet-filter – Part Nº **104108**

This filter is between the humidity condenser and the Vacuum Pump. It must be cleaned or replaced periodically. It is composed by:

1- Centring-ring and filter assembly
2- O-ring
3- Inlet-port.

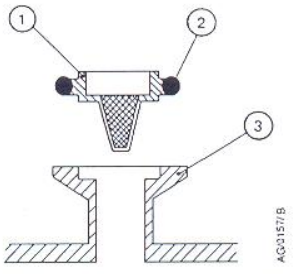


Figure 4-11

b) Chamber Exhaust Filter – Part Nº **104104**
Clean the mesh filter on the bottom of the chamber periodically.

c) Injection circuit Filter
This filter is inside the tube that comes from the peristaltic pump to the injection valve. Use gloves to remove the tube. Clean the filter with abounding water.

Aeration Filter

The Filter must be replaced annually.

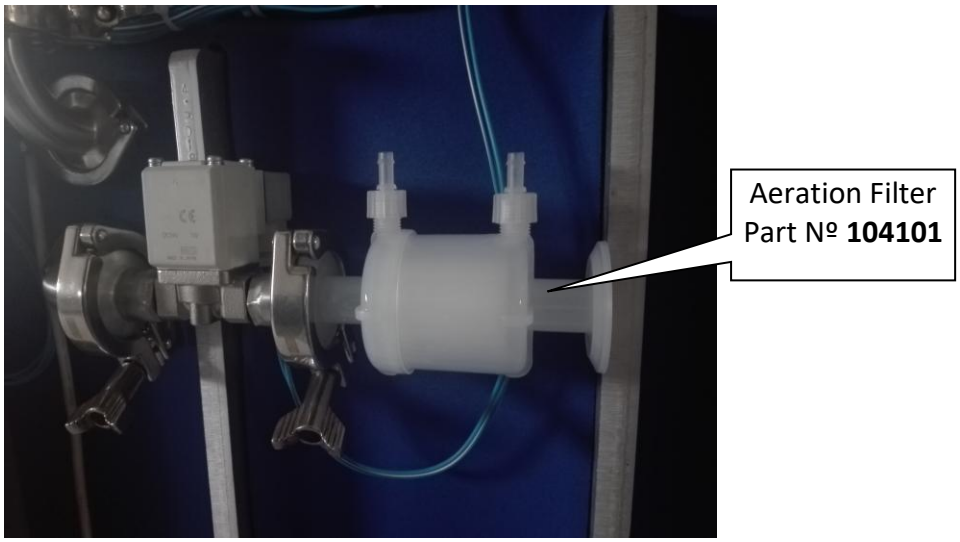


Figure 4-12

Aeration Valve

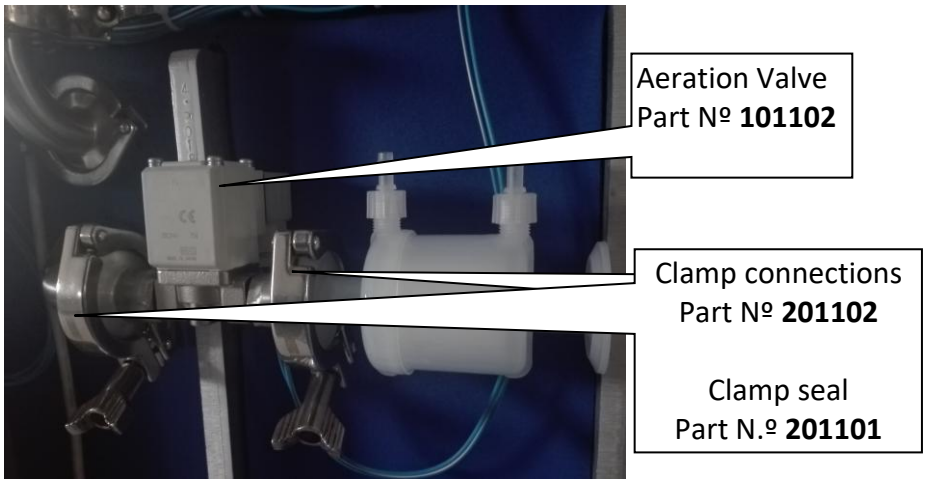


Figure 4-13

Chamber Pressure Transducer

Figure 4-14

Notes:

- If when turning on the Sterilizer, it does not read the transducer, the sterilizer does not continue. It will restart continuously.
- The transducer calibrates automatically based on the atmospheric pressure, when the sterilizer is turned on and opens the door. The sterilizer automatically checks the atmospheric pressure.

Sliding Doors

Automatic Sliding doors (single or double) characteristics:

- Controlled automatic heating of the doors with energy saving system;
- The doors may be hot depending on the chosen temperature. Avoid touching them. You can use gloves for unloading material from the chamber, especially if you have sensitive skin.
- The doors ensure correct operation and provide a sanitary barrier thanks to the Intelligent Sliding Door Control System.
- The doors are totally made of material resistant to corrosion and warmed up to a controlled temperature.
- Automatic verification of the Doors' position.
- Timing and notice of automatic door closing.
- Safety System avoiding pinching during door closing.
- By the end of the cycle, the operator is informed that the cycle has been concluded and the door opening is now available for unloading the sterilizer.
- The operator can choose the door through which he wants to do the unloading.
- The two doors cannot be opened simultaneously.
- The doors have safety thermostats.

Note: In case the button to open/close the door does not appear on the screen, it means that the chamber may be in vacuum, or the micro-switches are not giving information about the doors position because the actuator is not in correct position, or the chamber transducer may be malfunctioning, or even, the aeration valve did not open. In this case, you must follow the instructions on Chapter II, section 6.1 of this manual. If after following those steps, the button to open the doors still doesn't appear on the screen you must call the technician.

I_SD_C System (Intelligent Sliding Door Control System)

- The operator chooses the door he wants to open.
- If the Unclean Side Door is open, the system does not allow the opening of the Clean Side Door;
- Sliding Door of Clean Side will not open in the Test Cycles;
- Sliding Door of Clean Side will not open in case of failed or aborted cycles;

- In order to save energy, the door is close automatically after 10 minutes;

- Information on the screen about the 10 minutes countdown time to close the door;

- Acoustic signal warning that the door is closing, 5 seconds before it starts closing (in development);

- If the door is opened and the pedal is pressed, the countdown time will restart;

- During the upwards movement, if something touches the door sensor, the movement will be reversed. The door opens again for 10 minutes.

Sliding door opening system activated by pedal (not applicable for Basic version).

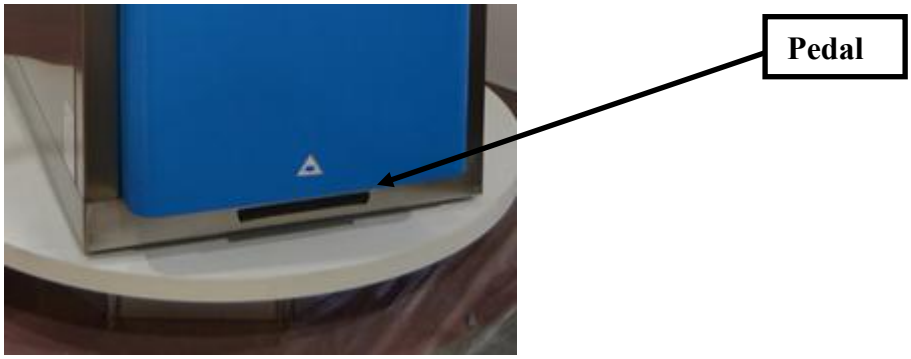


Figure 4-15

Note: If the time for closing the door is finishing and you need more time, you just need to press the pedal. The countdown time will restart.

Door Lock Adjustment

Model 1

Vertical movement Adjustment Screws

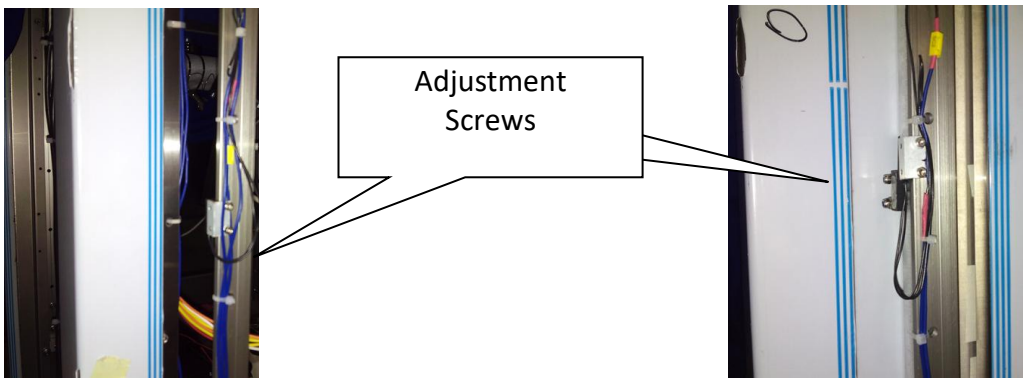


Figure 4-15-1

Figure 4-15-1/A

Model 2

Door adjustment screws

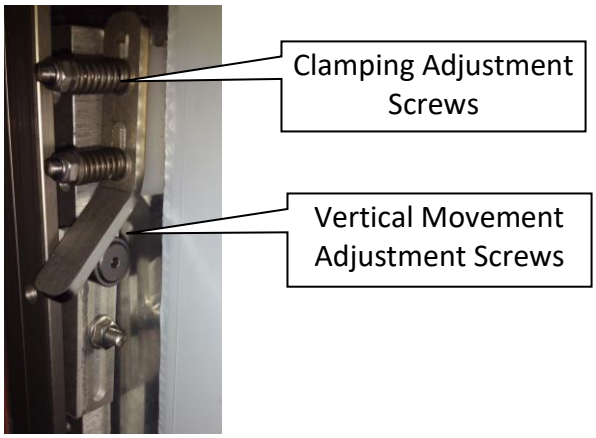


Figure 4-15-2

Door lock/unlock adjustment nuts

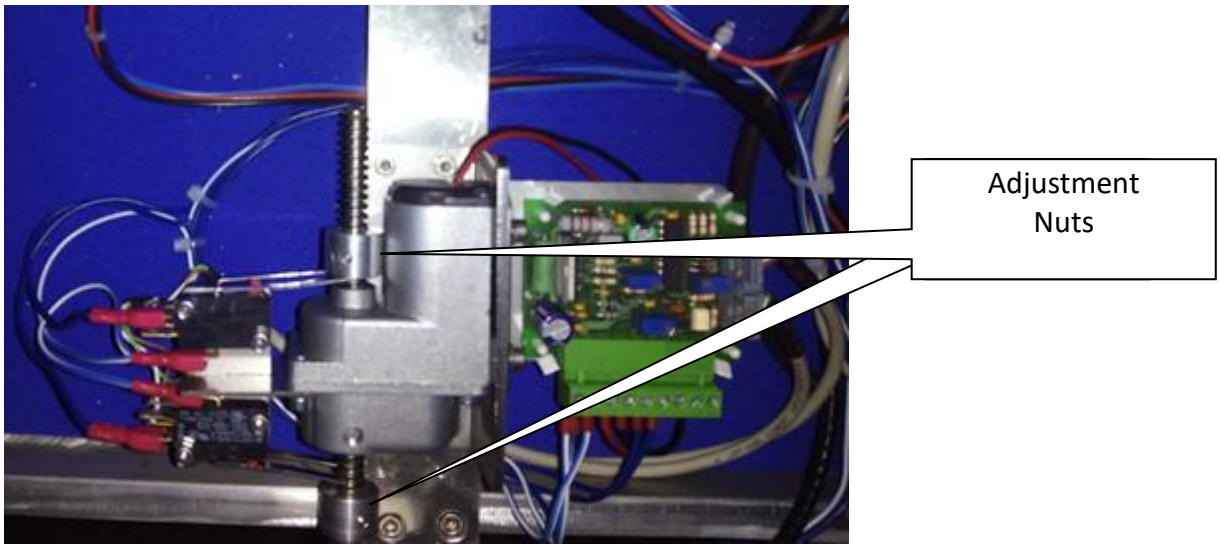


Figure 4-15-2/A

- To adjust the door lock, you need to unscrew the small screws inside the nuts.

Door gasket

Figure 4-15.3

Note: After installing the door gasket, you must put the talc powder on the external side.

Instructions to replace the door gasket:

1- Open the door;

2- Remove the door gasket;

3- Clean the gasket rail in order to remove the glue waste. You can clean it with a Scotch-Brit;

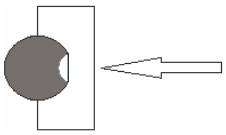
4- Place the gasket without stretching or shrinking;

5- First, put the gasket in the four points of the gutter with care to avoid stretching, as it may increase in size.

Note: The gasket has a small face. This side should be towards the bottom of the gutter (see drawing below).

6- Place a silicone glue thread in the centre of the rail;

7- Close the door and wait the silicone glue to dry before using the sterilizer.



Sterilizing Agent Tank of regular version Sterilizers

The Sterilizing Agent tank has been designed specifically to store the Sterilizing Agent. Inside the tank there is an electronic reader that informs the PLC and the operator (on the screen) about the Sterilizing Agent level available in the tank.

The tank is totally insulated and has a device inside, that controls and keeps temperature stability.

This tank has been studied so that no pressure can be generated inside.

The temperature of the tank is around 25ºC

Image 1 – Complete Tank installed on the machine

Image 2 – Complete Tank

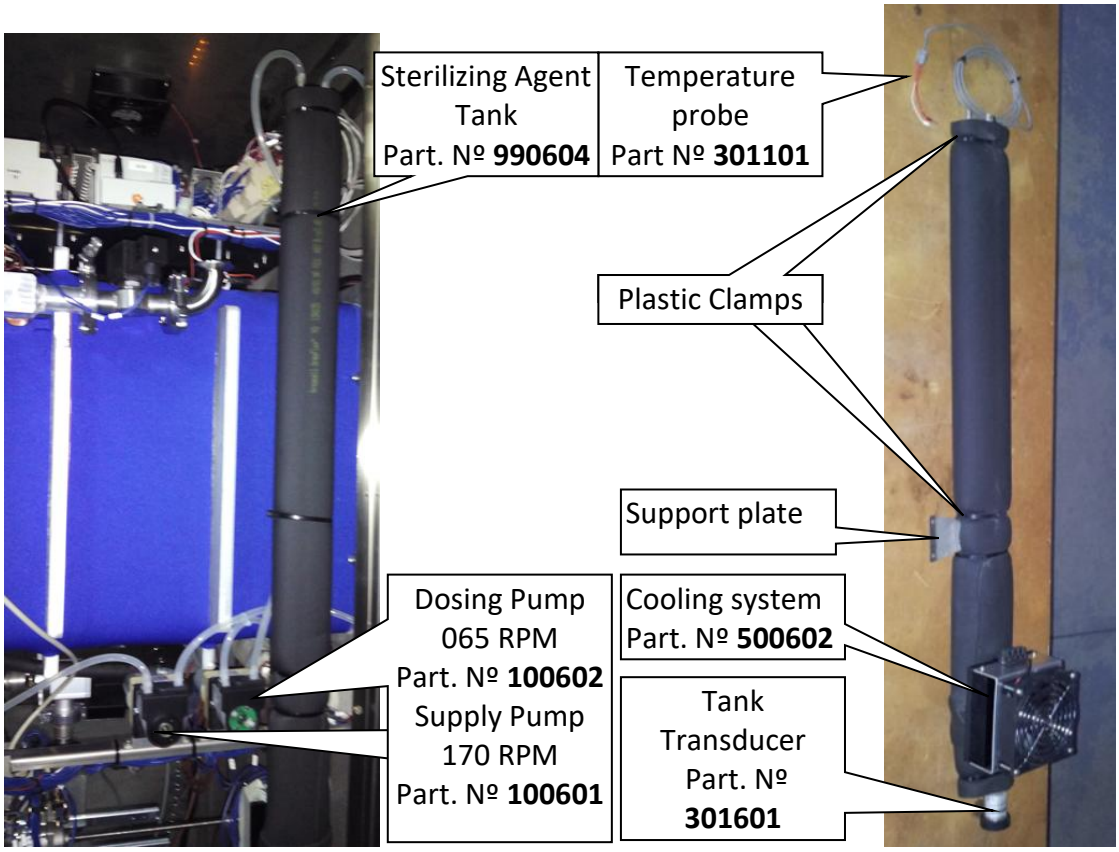


Figure 4-16

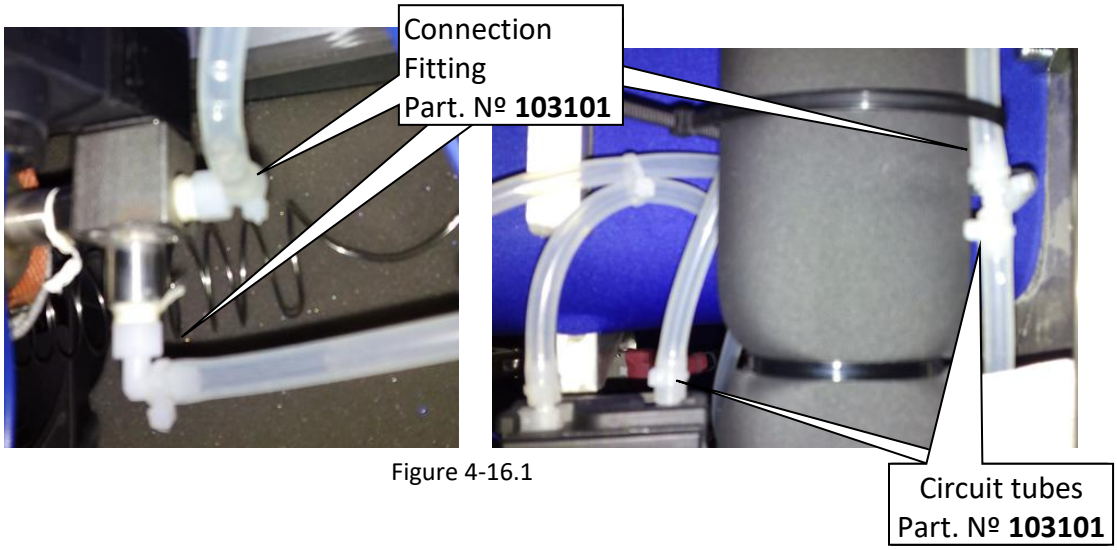


Figure 4-16.1

List of Connectors per Machine:

2 – Screw
1 – T

The connectors must be replaced annually.

Sterilizing Agent Tank of Basic version Sterilizers

The *Basic* version sterilizers are equipped with a different Sterilizing Agent Tank

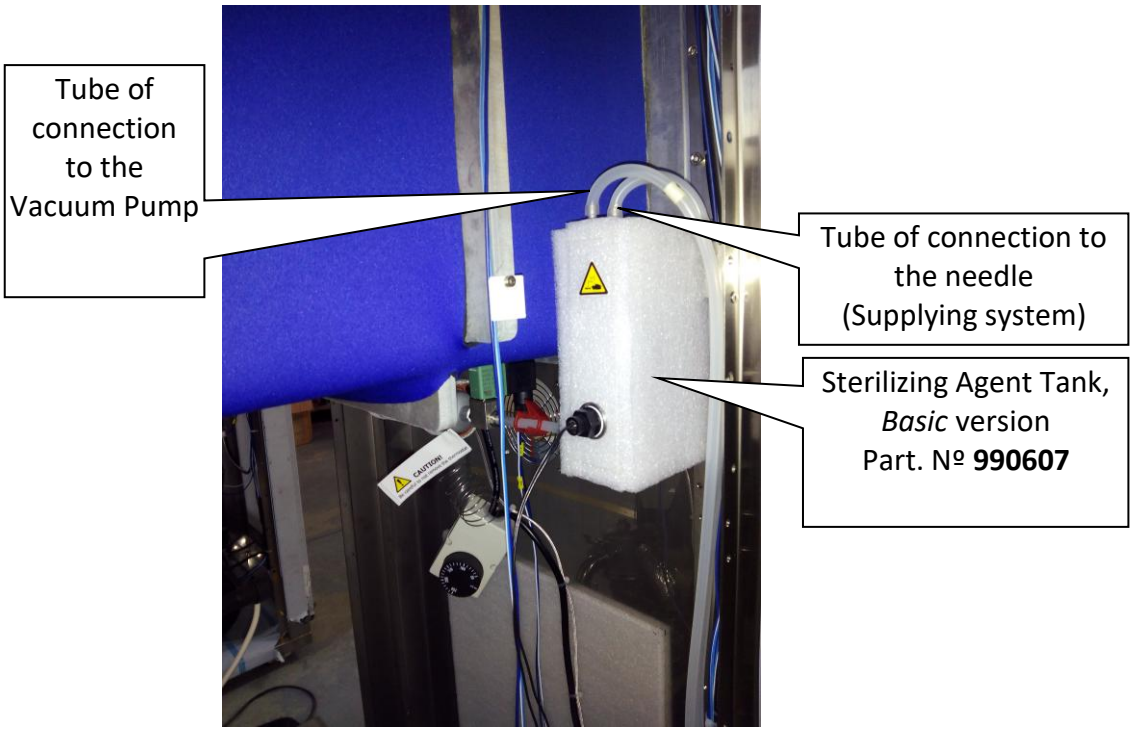


Figure 4-17

This tank has a level sensor.

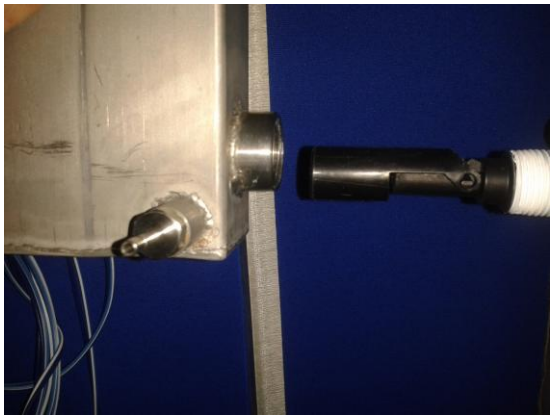


Figure 4-17.1

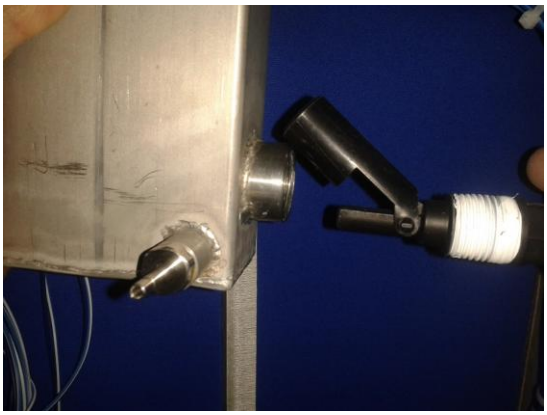


Figure 4-17.2

Important Note:

How to disassamble the level sensor of the tank

In order to disassamble the level sensor, it is necessary to put the tank in a horizontal position (according to images below). Otherwise, the level sensor will break inside the tank and it will be necessary to replace the tank.

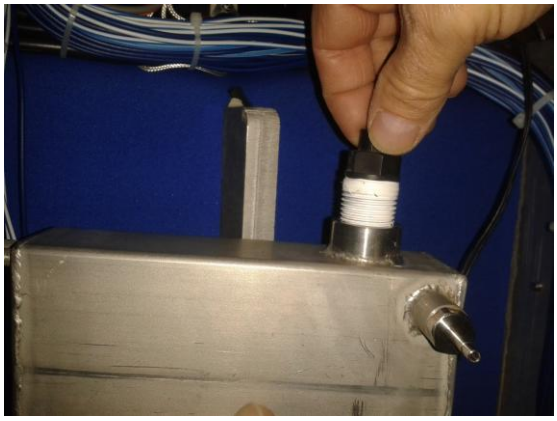


Figure 4-17.3

Figure 4-17.4

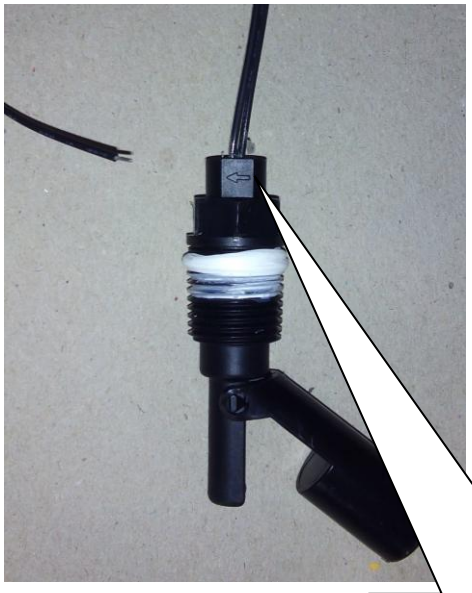


Figure 4-17.5

Figure 4-17.6

Please pay attention to the position of the arrow marked on the level sensor when assembled on the tank

Note 1: It is necessary to close the plastic clamp before removing the tube.

Plasma Generator

The Plasma Generator is totally made of aluminium with two ceramic electrodes and it is fed by a high voltage transformer.

In order to ensure that the device works correctly it includes a PT 100 probe.

The Plasma Generator has clamps in its entry and exit. This element is placed under the sterilization chamber near the exhaust valve in the clean side.

The burning is done inside the burner's chamber where the high tension is placed in order to burn the Sterilizing Agent. The Plasma Generator alters the composition of the Sterilizing Agent, decomposing it into oxygen, water and free radicals.

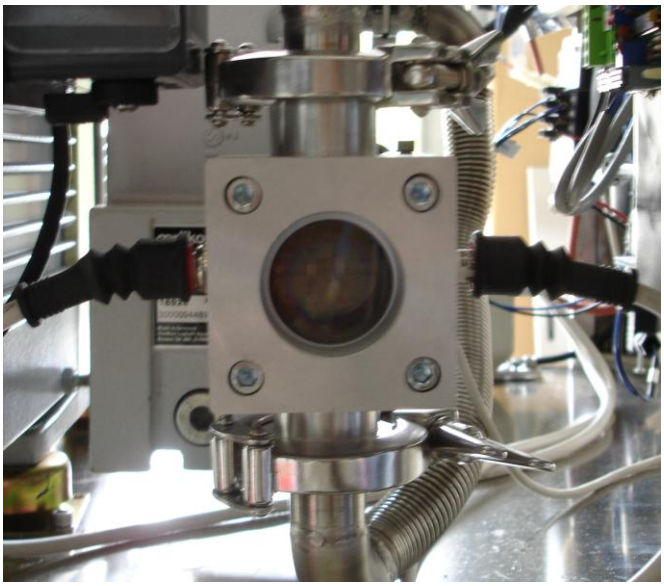


Figure 4-18

The electrodes must be replaced annually. Remove the cover to check their condition.
Note: To tighten and loosen the electrodes, the Plasma Generator must be taken out of the machine to avoid damage of the clamp that is welded to the chamber.
Note: the PTFE gasket should be assembled against the glass.

Plasma Generator spare parts

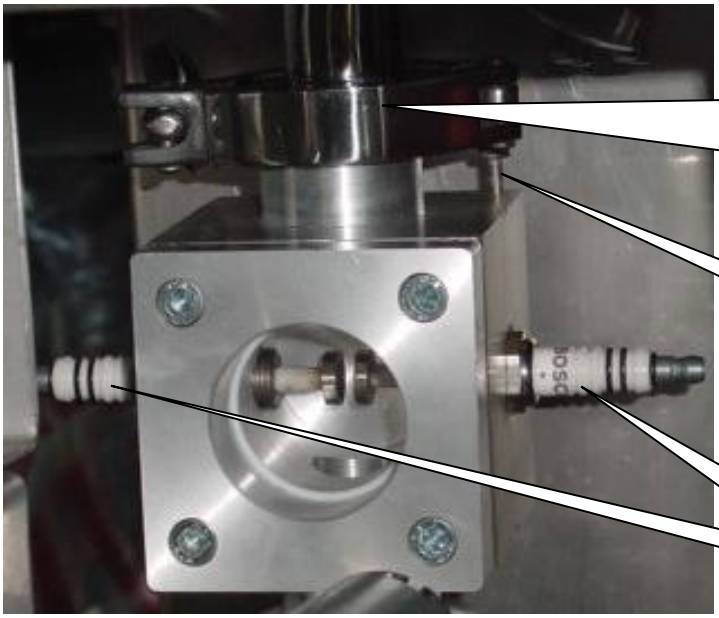


Figure 4-18.1

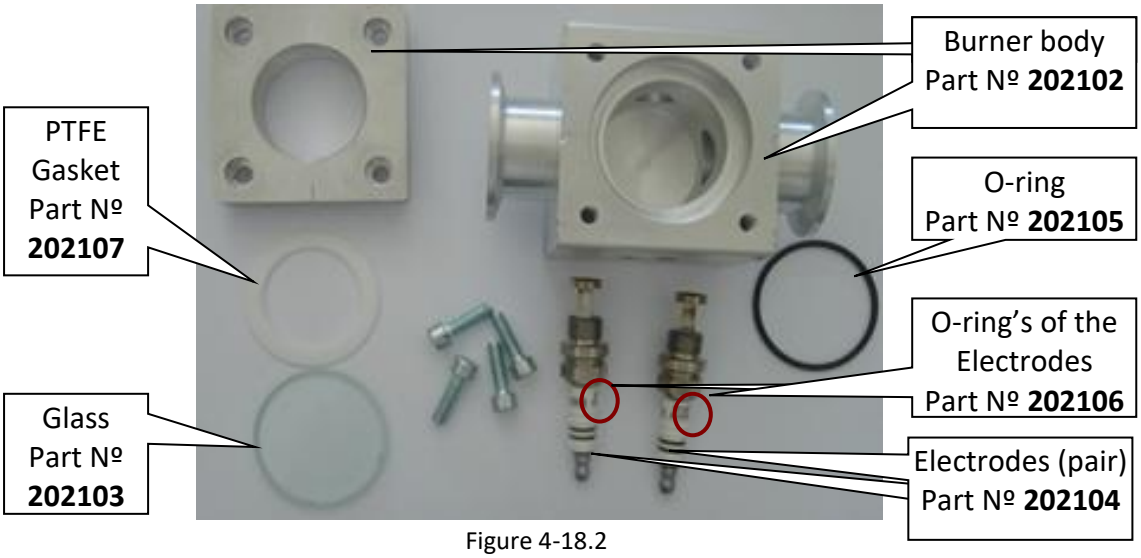


Figure 4-18.2

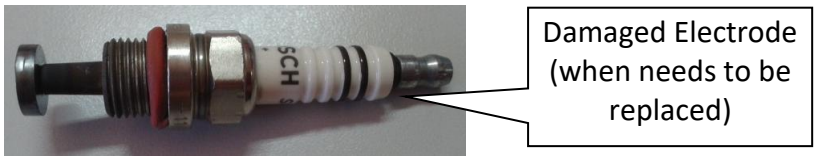


Figure 4-18.3

CE 2460

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High voltage Transformer

High voltage can cause fatal injuries. The high voltage is used to begin the burning of the Sterilizing Agent at the sterilization chamber exit.

It is dangerous to touch the items with High Voltage sign when the power is “ON”.

Verify that the high voltage is “OFF” before doing any related repairing and always disconnect the power supply.

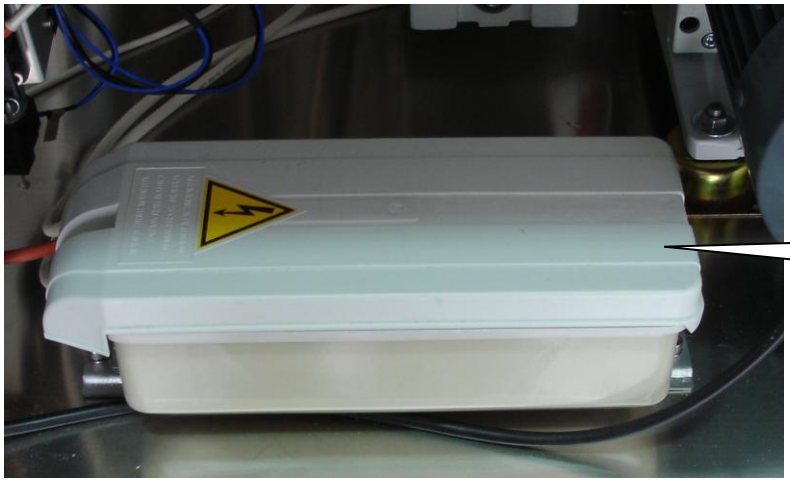

Figure 4-19

WARNING

Never check the output of the High Voltage Transformer with equipment that is not prepared to measure 10.000V on the output. Please use adequate protection.

For the tecnician safety, remove the High Voltage Transformer if it is confirmed that it gets 230/115V at the transformer input.

Unscrew the screw that fixes the High Voltage Transformer cover. Open the cover and check with appropriate tool if their is voltage at the input.

With the sterilizer turned OFF on the main switch, check if there is continuity on the primary and secundary of the High Voltage Transformer.

DANGER OF DEATH KEEP OFF **Attention:** There is risk of death during these operations.

Vaporizer

The vaporizer unit is installed on the bottom of the sterilizer's chamber.

The vaporizer is totally made of stainless steel and is covered by a heating element.

The heating is automatic.

That type of heating element never flames up by itself, even when submitted to excessive temperatures. If eventually the temperature exceeds 20ºC more than it's normal temperature, the Main Switch will disconnect, by automation system or mechanically by a safety thermostat.

The external side is protected to prevent accidental contact. Temperature is controlled by the control system.

The vaporizer is composed by a cylinder with a clamp connection. All electrical and mechanical connections are of rapid dismantling and the following elements are part of the Vaporizer:

- Heater;
- Vaporizer Valve;
- Capillary tube;
- Probe;
- Filter;
- Safety Thermostat;
- PTFE Connection to chamber;

The vaporizer is mounted on one of the exits of the sterilization chamber and it is controlled by the internal software.

In the beginning of each cycle, the sterilizer will verify the heating status and the temperature of the vaporizer heating components, including the vaporizer heater.

The maximum temperature of the vaporizer is ≤ 140ºC.

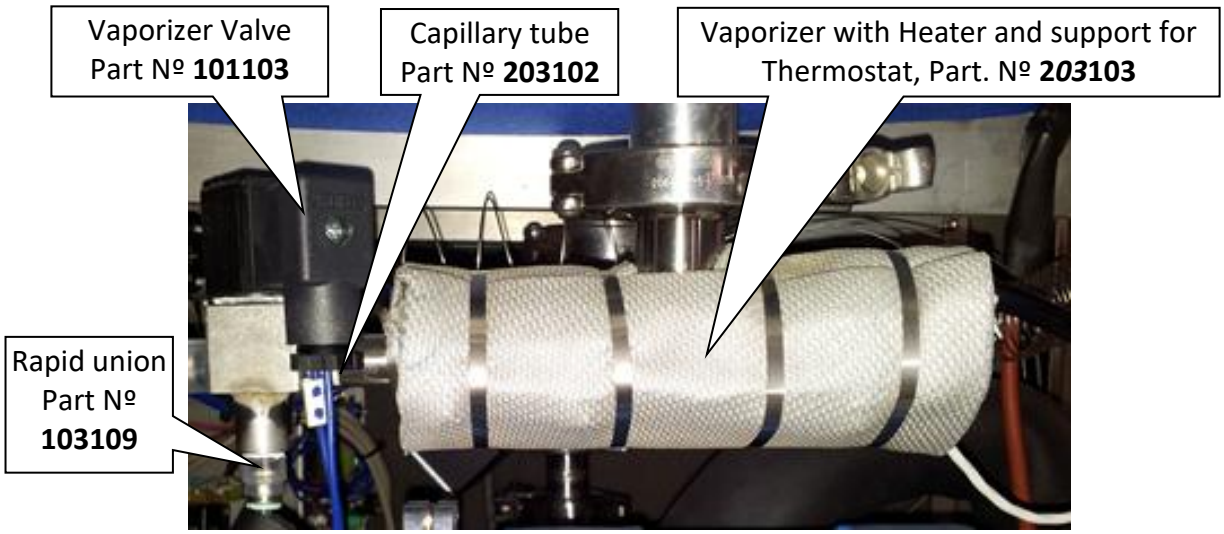

Figure 4-20

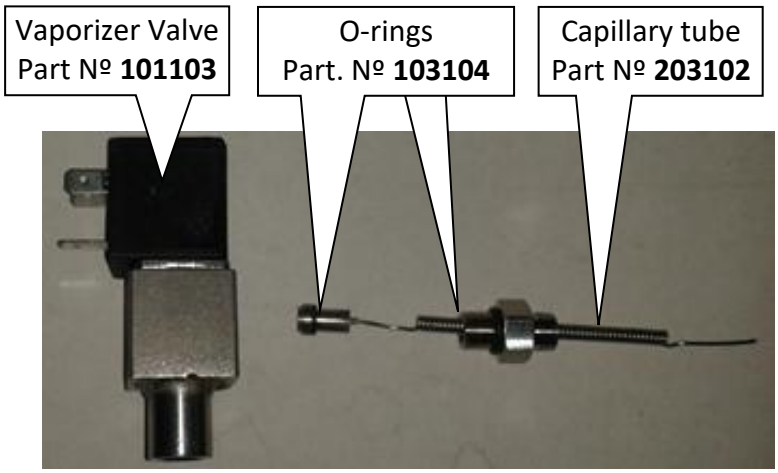

Figure 4-20.1

Note: While assembling all connections must be well sealed with PTFE strip (not liquid) and the O-rings must be verified.

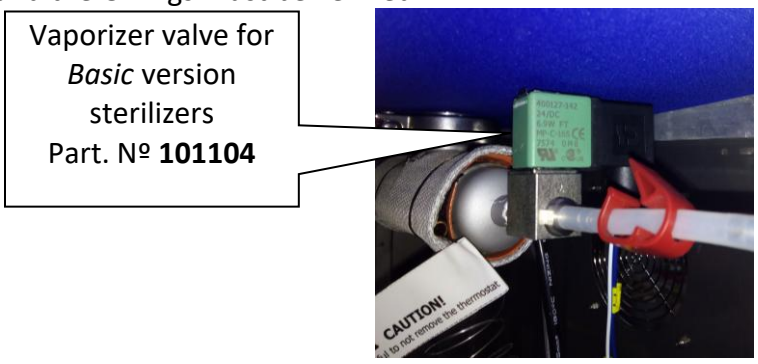

Figure 4-20.2

Note: We recommend that the vaporizer valve should be replaced every 6 months.

Peristaltic Pumps *(not applicable to ECOPLASMA Basic version sterilizers)*

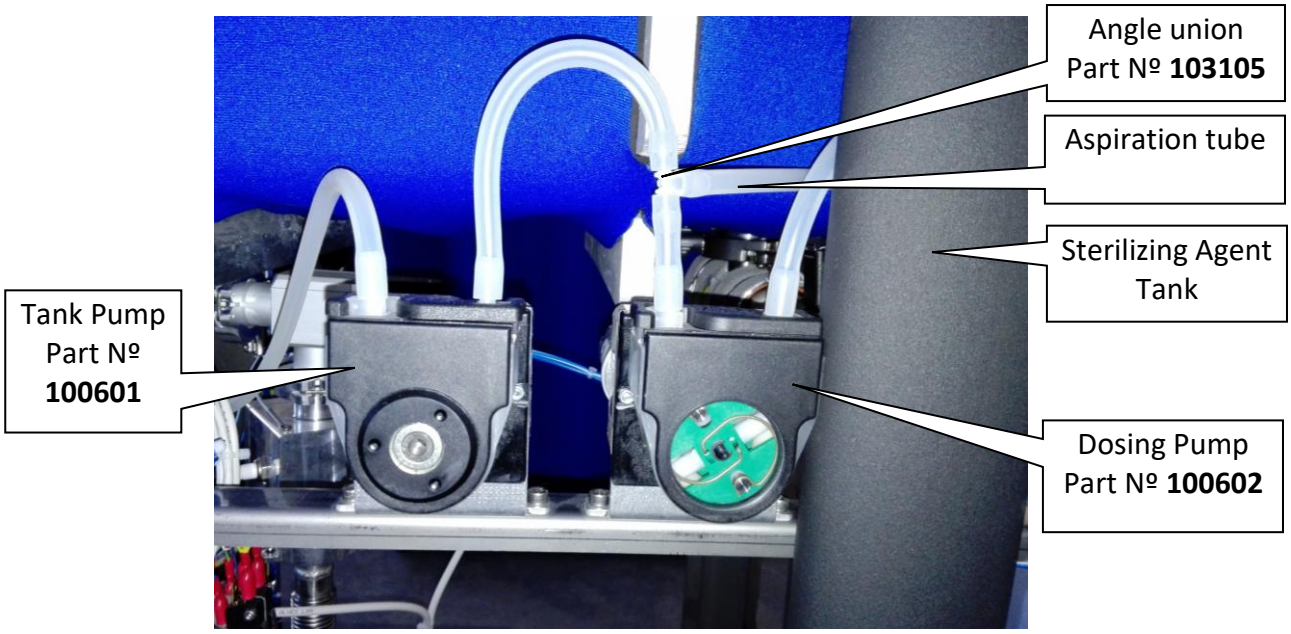

Figure 4-21

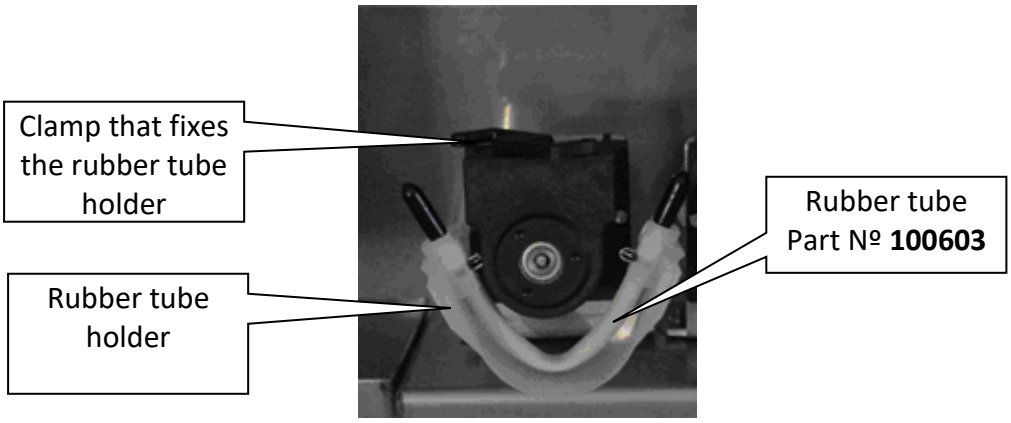

Figure 4-21.1

To replace the rubber tube, rotate the clamp to loosen the holder. Then remove the rubber tube from the holder, replace the tube and put it back on the holder. Fix the holder again with the clamp.

The Basic version sterilizers do not have peristaltic pumps. Instead, this version takes a brass valve that activates the vacuum to take the liquid from the tank.

Sterilizing Agent Supplying System

(depending on the version of the sterilizer, it may be drawer model 1 or model 2).

Model 1 *(for STERIFAST and ECOPLASMA regular* version sterilizers)

The supplying system is composed by the drawer that opens to install the recharge bottle on the holder, the RFID reader, and an Electrical System (or a Compressed air system) to move the Drawer and the Needle that punches the Sterilizing Agent bottle.

Drawer and Holder for the Recharge Bottle

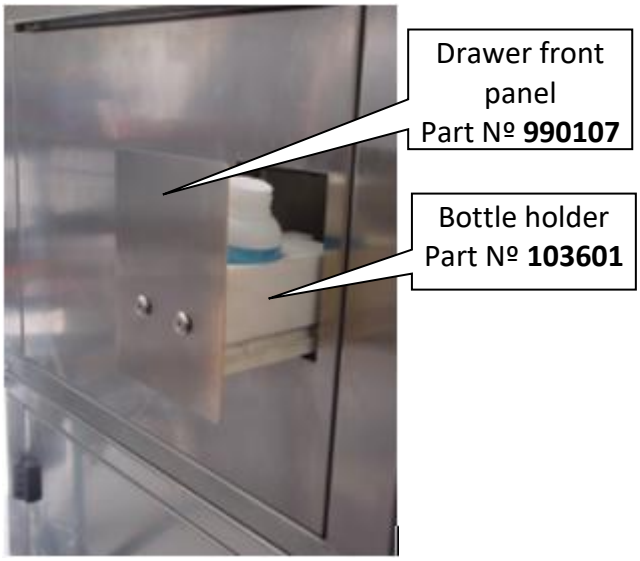

Figure 4-22

RFID Reader for sterilizing agent recharge recognition

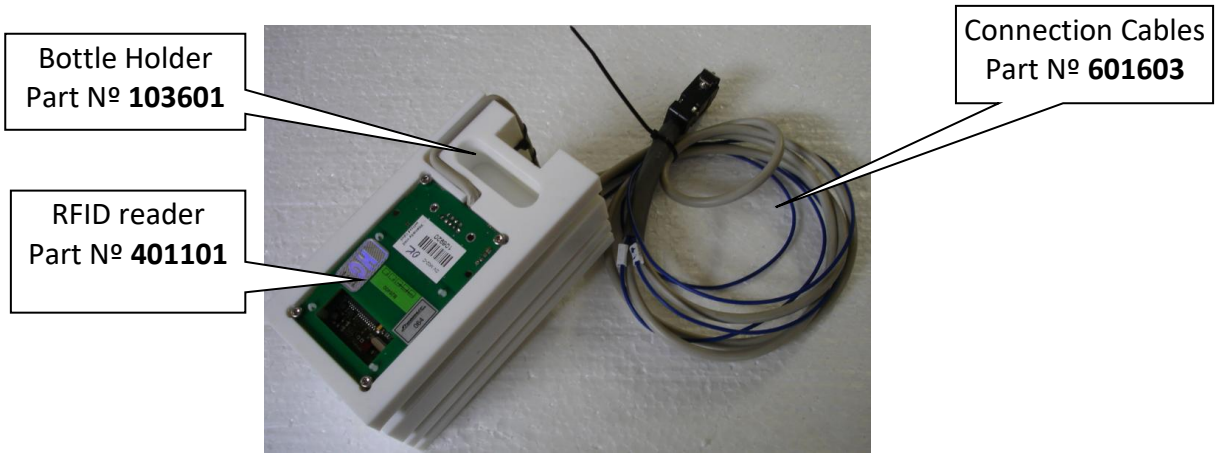

Figure 4-22.2

Instructions to replace the RFID Reader:

- Remove the drawer front panel untying the screws;
- Remove the sterilizer lower front panel;
- On the Supervision Software move the drawer out;
- Turn OFF the sterilizer;
- Untie the fixing nut that fixes the holder to the servo motor screw (the screw must be fixed, it cannot rotate while doing this operation);
- Disconnect the PLC cable and the Touch Screen cable;
- Disconnect the power;
- Disconnect the Connectors “G” wires 2 and 3 corresponding to the RFID reader cable;
- Take the bottle holder with the RFID Reader out of the machine and unscrew the reader from the holder and replace it with the new reader with cables;
- Assemble all the components again.

Drawer with electrical system

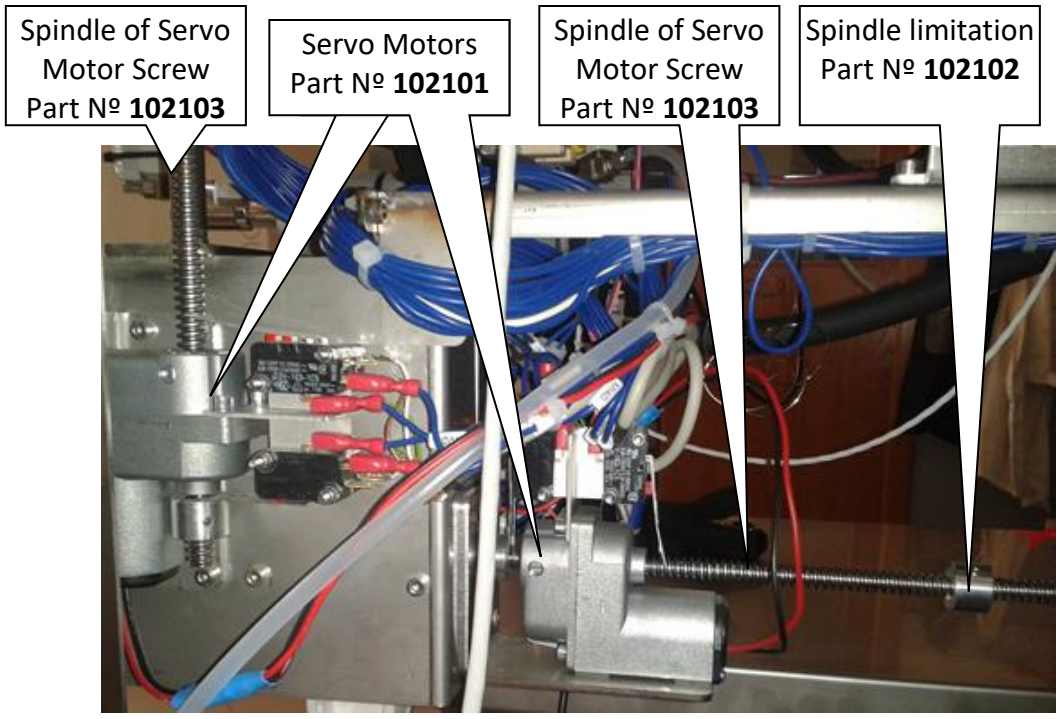

Figure 4-22.3

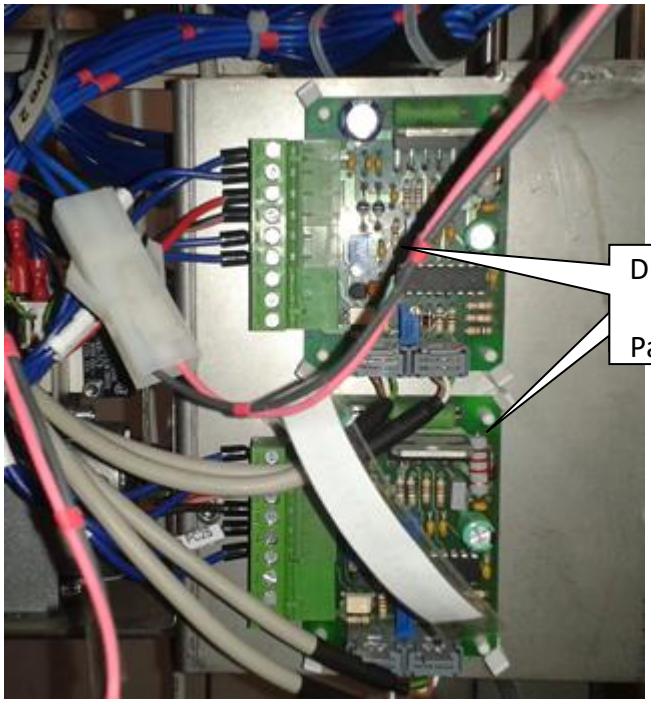

Figure 4-22.4

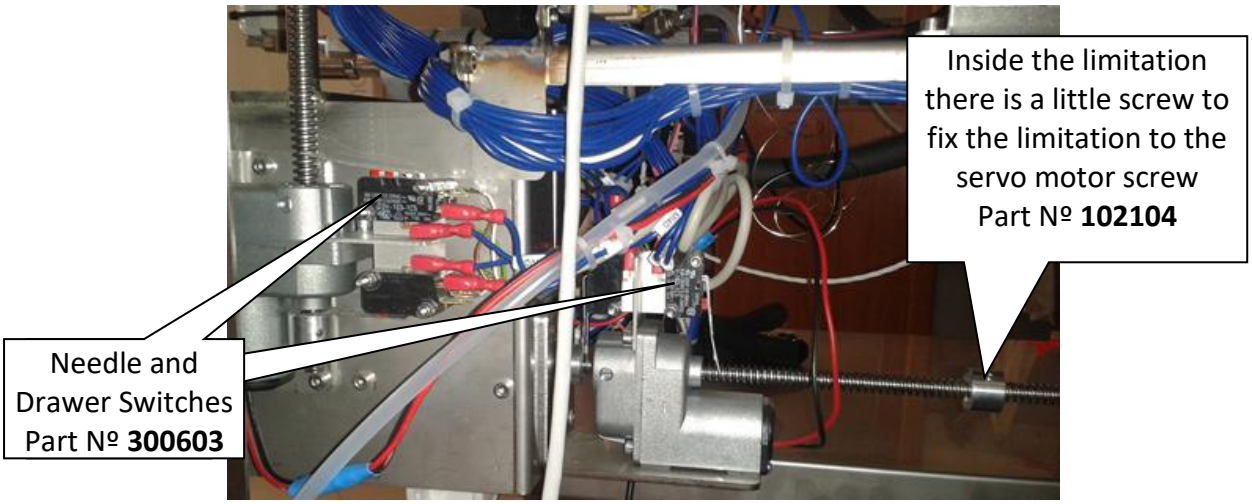

Figure 4-22.5

Instructions to disassemble the Drawer and Needle Servo Motors

- Remove the nuts on the tip of the servo motor screws;
- Disconnect the switch's plugs from the command boards;
- Unscrew the servo motors and remove them;
- Assemble the new servo motor and make the required connections;
- Adjust the servo motors movement according to the instructions below.

Instructions to adjust the Drawer movement

Loosen the little screws that fix the limitations to the servo motor screw. Rotate the limitations to the left or to the right to limit the total movement of the servo motor screw. The drawer opening movement must be adjusted in a way that allows the operator to insert the Sterilizing Agent bottle in the drawer holder in a comfortable way. The closing movement must close the drawer till the drawer panel touches the sterilizer panel without forcing it.

After the adjustments, tighten the little screws of the limitations.

Attention: Make sure that the needle is up and does not impede the drawer to open and close.

Instructions to adjust the Needle movement

Loosen the little screws that fix the limitations to the servo motor screw. Rotate the limitations to the left or to the right to limit the total movement of the servo motor screw. The up movement must be adjusted in a way that the needle does not come out the guide. The down movement must allow the needle to touch the bottom of the agent bottle without forcing it.

After the adjustments, tighten the little screws of the limitations.

Model 2 (for ECOPLASMA *Basic* version sterilizers)

Manual Drawer

Anatomic holder for the sterilizing agent bottle.
Manual perforation of the recharge bottle.

Figure 4-22.6

Figure 4-22.7

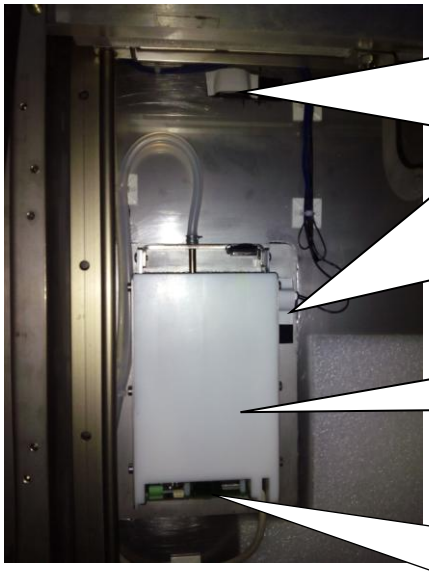

Figure 4-22.8

Figure 4-22.9

After inserting the bottle in the holder, please close the drawer in order to punch the bottle seal. Then the supplying of the sterilizing agent is totally automatic.

Heating Elements

Sterifast sterilizer is equipped with the following heating elements:

a) Sterilization chamber heaters

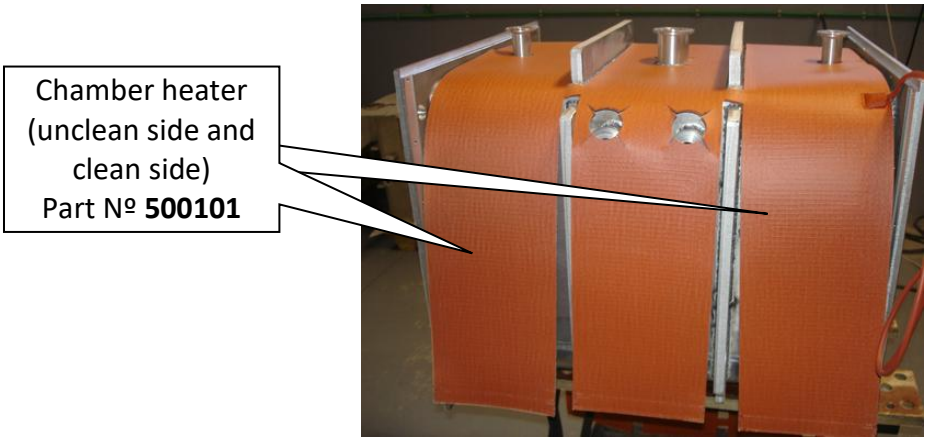

Figure 4-23

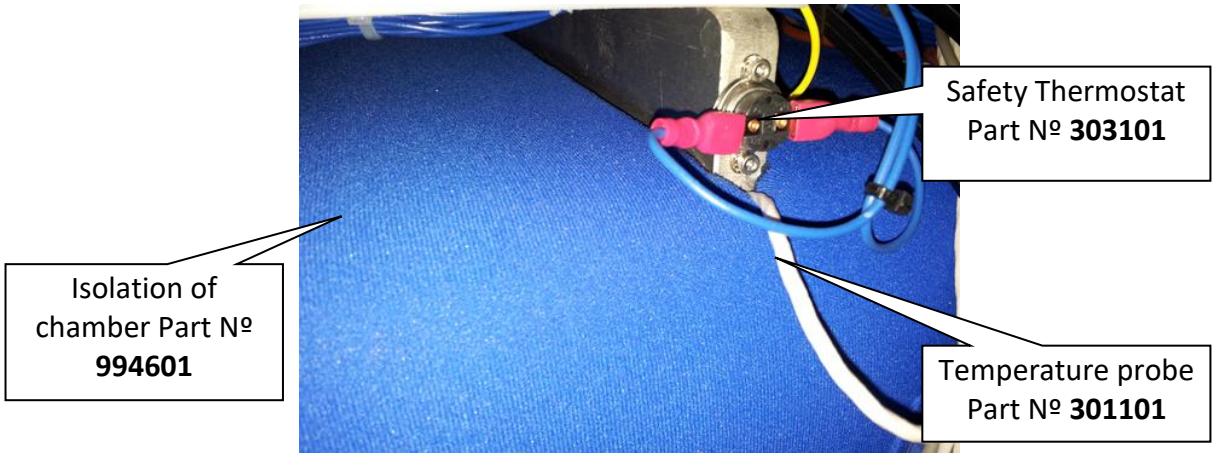

Figure 4-23.1

In order to disassemble the heater it is necessary to remove the insulation that covers the chamber.

Note: For heating element replacement please contact Sterifast, Lda.

b) Door's heaters

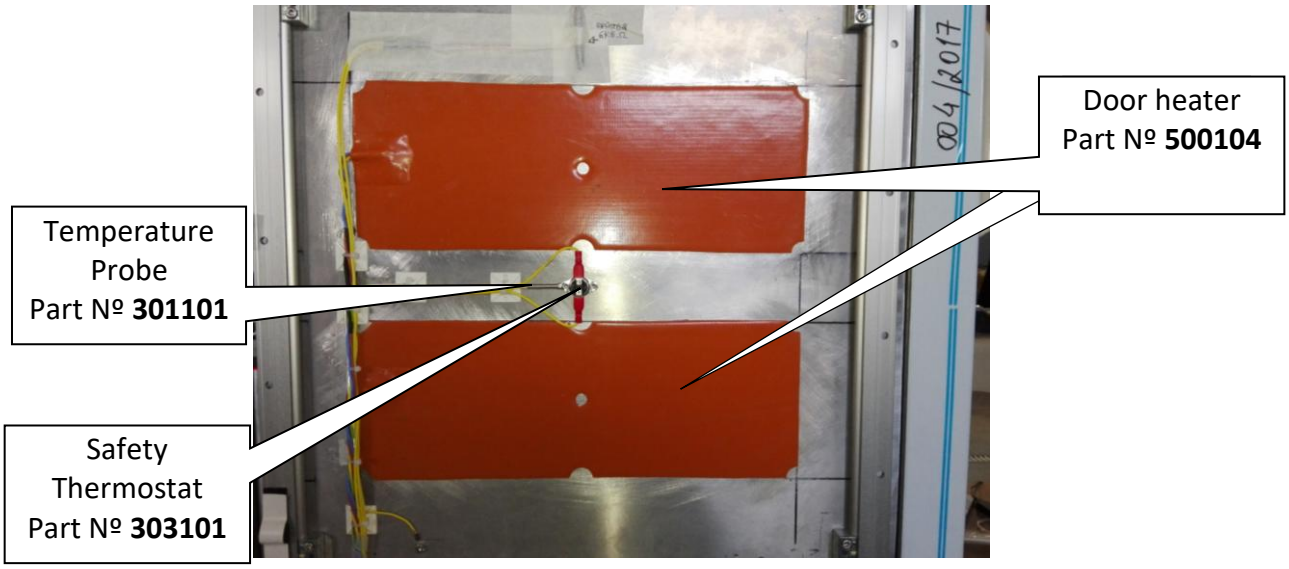

Figure 4-24

Instructions to replace the door heater:

- Disconnect the heater cable.
- Take out the old door heater, clean the place.
- Place the new heater and connect the cable.

Note: The temperature of the chamber and the doors should be the same to ensure temperature homogeneity.

c) Vaporizer heater

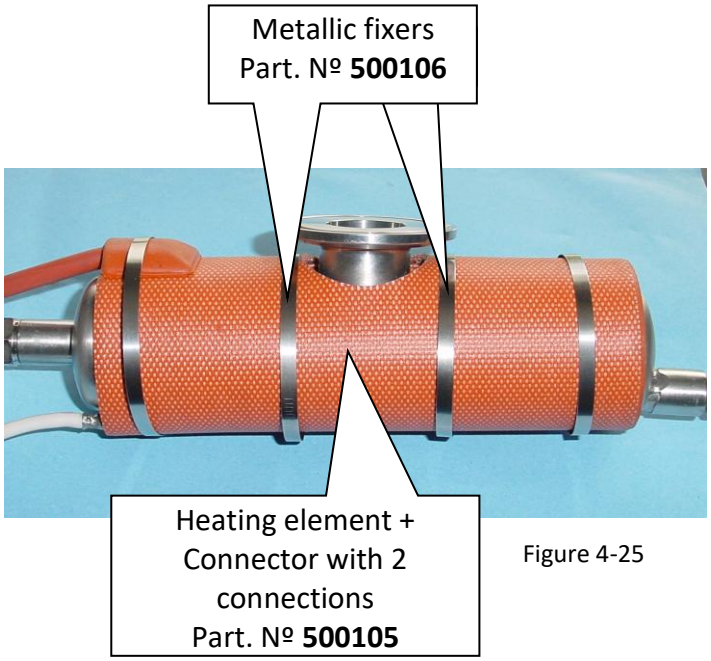

Figure 4-25

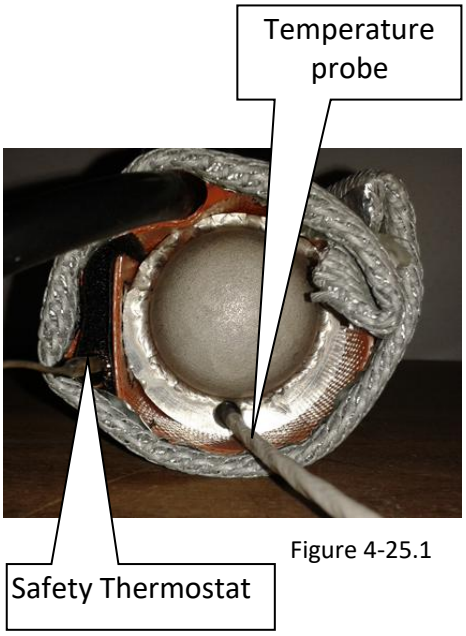

Figure 4-25.1

To replace the Vaporizer Heating Element, you must remove the vaporizer isolation and cut the metallic fixers. Disconnect the heater connector. Remove the heater and place the new one.
Note: The temperature probe and the thermostat and holder must be placed in the same position again.

Temperature Probes

The Sterifast sterilizers have several temperature probes at the following components:

- **Chamber;**
- **Doors;**
- **Vaporizer;**
- **Burner;**
- **Tank.**

All the probes are equal and all have the same **Part Nº 301101.** The probes have connectors with 3 connections.
All points will PT100 probes have a safety thermostat for maximum temperature (except in the burner and the tank). The safety thermostats turn off the main switch, disarm with temperature above the set value and automatically rearm with temperature reset.

Sterilizing Agent Tank Cooling System (only for regular version sterilizers)

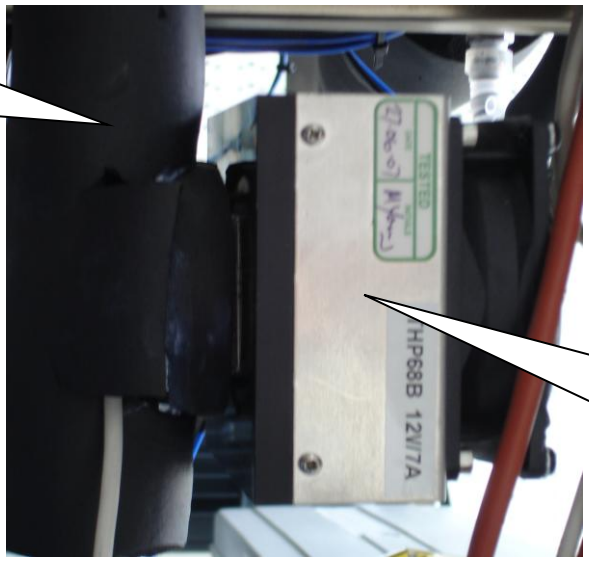

Figure 4-26

Cooling block is fixed to the tank with two screws behind the tank isolation.

External Ventilators

The ventilators installed in Sterifast equipment, although equal, they work differently.
One is permanent and it is placed on the top of the sterilizer and the others are located on the side panels of the sterilizer and they only work during the cycle.
All the Ventilators are 24V.

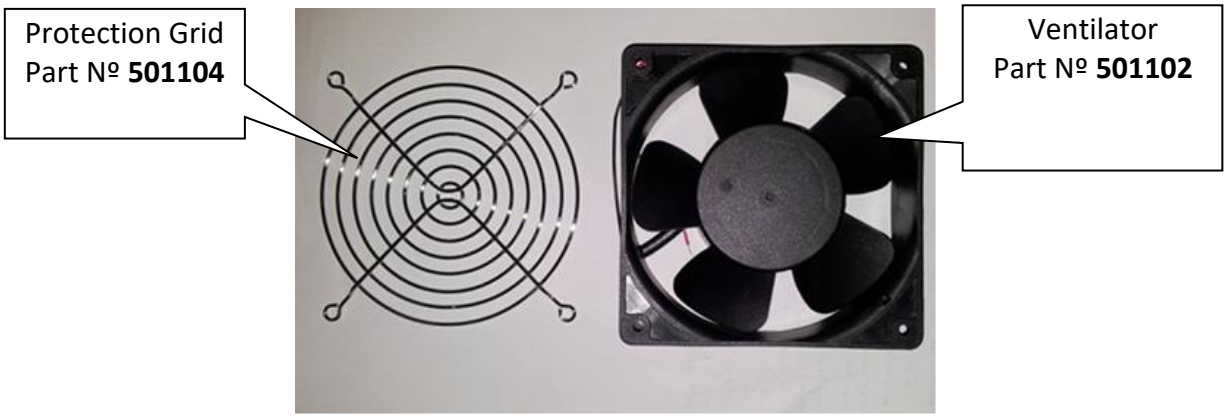

Figure 4-27

Feet /Wheels

- The feet are made of anti-skidding material.
- Thanks to the levelling wheels, it is very easy to move the sterilizer to the place it is going to be installed. To move up the feet turn the orange/red notched ring on each wheel clockwise.
- Once on the installation site, turn the orange/red notched ring on each wheel counter-clockwise to move down the feet and lift the wheels. Make sure that the sterilizer is levelled.

Figure 4-28

Figure 4-28.1

Rotate in a clockwise direction (red arrow) – The Foot moves Up

Rotate in a counter-clockwise direction (blue arrow) – The Foot moves Down

Note: If you need to move the machine to another place, please take the following safety measures:
- Disconnect the electric power;
- Remove the H2O2 that is inside the tank;

Panel's Knobs

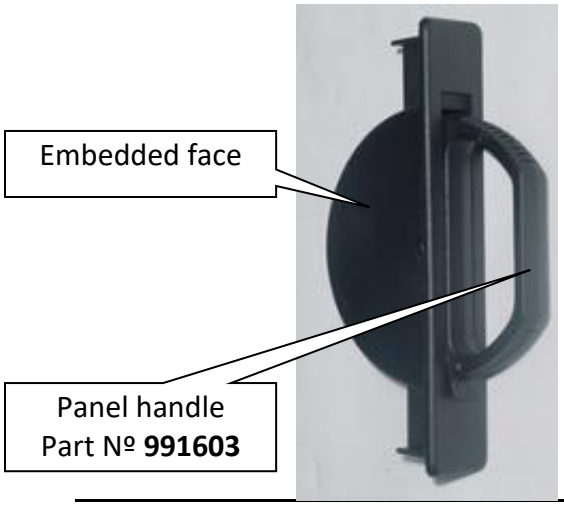

Figure 4-29

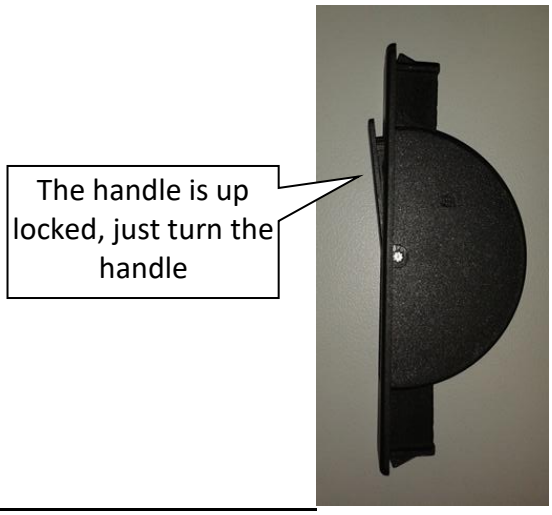

Figure 4-29.1

Panel fixing system

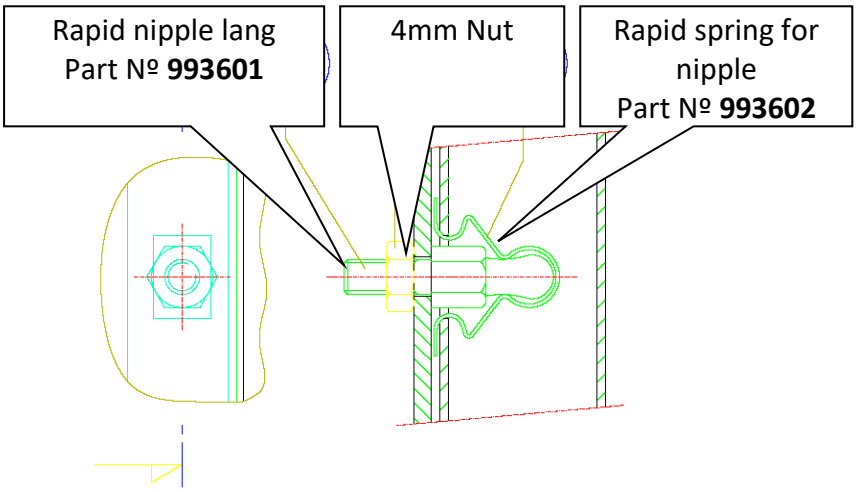

Figure 4-29.2

CE 2460

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Structure of Sterilizer and Cover Panels

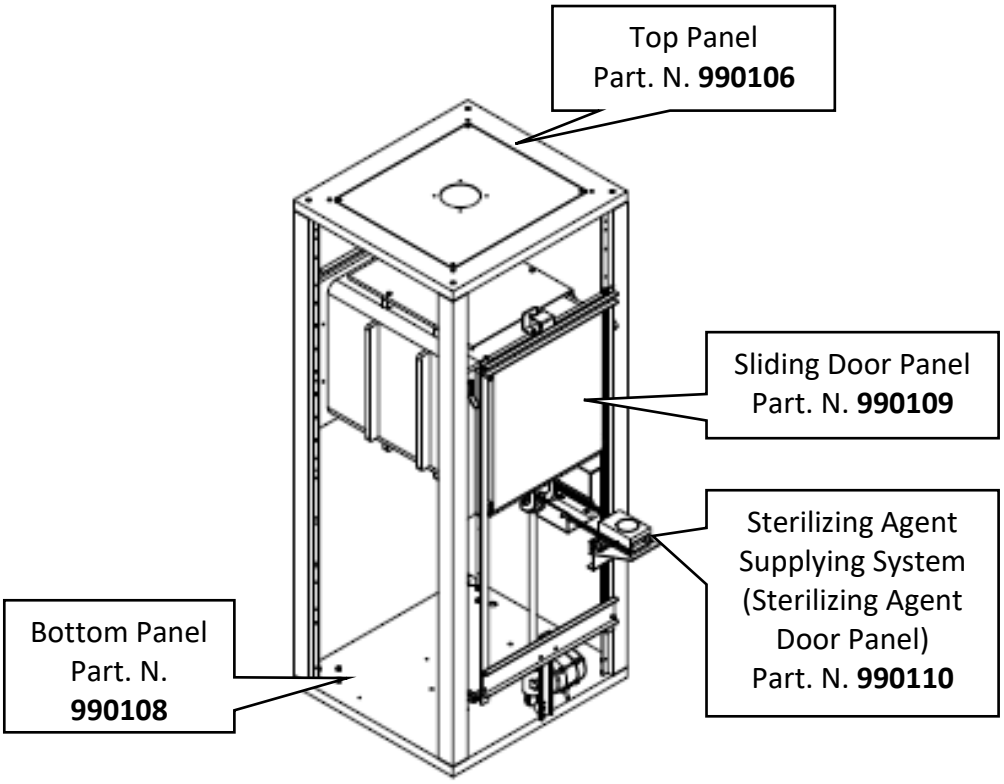

Figure 4-30

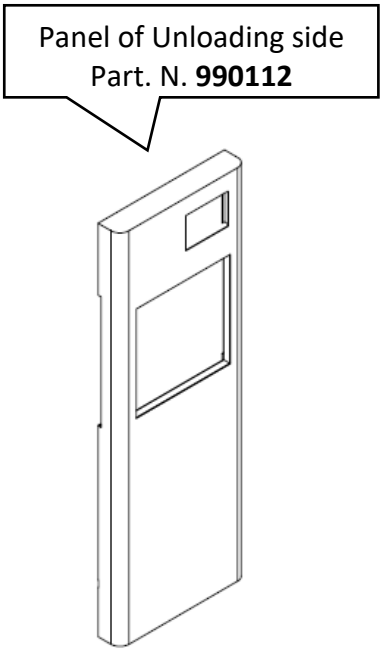

Figure 4-30.1

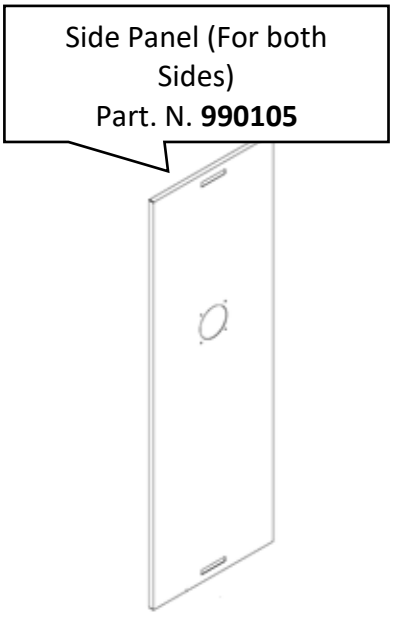

Figure 4-30.2

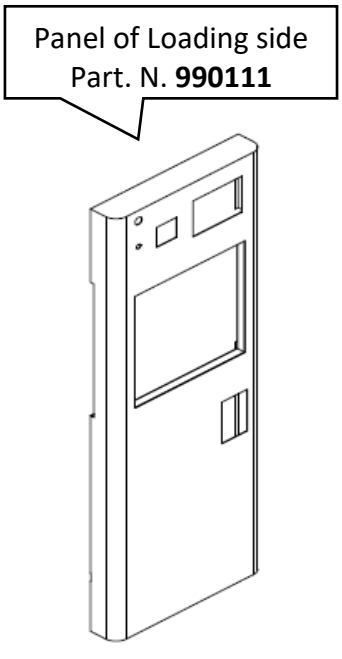

Figure 4-30.3

Introduction

In this chapter all characteristics, packaging, warnings and notes and action method of the Sterilizing Agent are described.

STERIFAST		ECOPLASMA	
Model	Reference	Model	Reference
S50	AS050400	E50	AE050400
S110	AS110400	E110	AE110400
S160	AS160400	E160	AE160400

Sterilizing Agent – Number of cycles per bottle:

STERIFAST		ECOPLASMA	
Model	Nº of cycles per bottle	Model	Nº of cycles per bottle
S50	20	E50	13
S110	10	E110	6
S160	6	E160	5

1 – Exclusive Sterilizing Agent

A- Sterilizing Agent safety

The Sterilizing Agent safety is assured at two levels:

Only the use of recommended Sterilizing Agent is allowed as the sterilizer reading system will only recognize the bottles of Sterilizing Agent produced by STERIFAST Company.
Any contact of the operator with the Sterilizing Agent is prevented since the recharge drawer only opens after the operator's indication when the sterilizer warns about the need of a new supply of Sterilizing Agent. The supplying is possible only after placing a new bottle.
The refilling begins automatically after the operator's instruction on the touch screen.
The refilling process of the sterilizer is completely automatic, avoiding any accidental contact with the operator.
After the automatic emptying of the bottle the drawer opens, allowing the closure of the bottle - using a cap supplied within the recharges kit – and then its removal from the drawer. The bottle can be disposed-off in the domestic waste or can be sent to the residual circuit recommended by the hospital's infection control.
Note: In the Basic version sterilizers, please keep the bottle inside the holder, with the drawer closed until next supply. Before discarding the bottle, wash it with water and place the cap.

The Sterilizing Agent is nontoxic but corrosive as it is hydrogen peroxide (H_2O_2).

Each box of recharges includes instructions and recommendations on convenient handling of the Sterilizing Agent. Please read them carefully.
The Sterilizing Agent should be stored away from the sun light, at room temperature, preferably in a dry and cool place.

B - Packing of the Sterilizing Agent *(Patent n. WO 2014/178740 A1)*

After being labelled and its RFID ship recorded each bottle is put inside a zip bag.

Figure 5-1

In each box there are four bottles, four pairs of gloves and the instructions for use.

Figure 5-1.1

After this process, the box is closed, labelled and placed in the external box.

When receiving the product, the client must follow the instructions of the “Safety Warning” (see page 139).

C - Supplying system and perforating unit

The supplying system is ensured by an assembly of components that includes the drawer for the bottle placing, the perforating unit and the bottle identification unit. A peristaltic pump places the Sterilizing Agent into the sterilizer tank. The feeding unit also removes the residues remaining in the tubes.

The support where the Sterilizing Agent recharge is placed is made of nylon. When required the drawer opens to allow the bottle insertion. This bottle is automatically transported to the perforation unit and the Sterilizing Agent is pumped into the tank. To know if the bottle was correctly placed there is a detector that checks the validity and that makes its authentication.

The perforator is an electric or pneumatic system which actuates a needle that perforates the bottle and removes the Sterilizing Agent from its interior.

To ensure that no Sterilizing Agent remains in the tubes, the system injects air into the aspiration circuit.

The perforator has an electric or pneumatic cylinder with sensors which determine the position of the movements related with the feeding of the Sterilizing Agent and inform the operator of any possible malfunction.

Model 1 (regular version)

Figure 5-2

Model 2 (Basic version)

Figure 5-3

D - Sterilizing Agent dosing

The sterilizer has a tank which storages the Sterilizing Agent, from which it is dosed into the sterilization chamber. When the Sterilizing Agent is missing in the tank, a message is displayed on the touch screen.

While inside the tank, the Sterilizing Agent keeps all its properties.

The operator should supply the sterilizer with Sterilizing Agent whenever the screen indicates that. The sterilizer does not work if there is not enough Sterilizing Agent to process one cycle.

The Sterilizing Agent feeding can only be done before the cycle start and when the “Refill Sterilizing Agent” button is active.

If the recommended bottle is inserted, the system will allow the drawer to close, the bottle is punched and the refill of the Sterilizing Agent into the tank is accomplished. At the end of the operation, the information is transmitted to the operator on the screen.

For extra security, when placing the recharges in the drawer, you can use safety gloves.

The bottle containing the Sterilizing Agent has a programmed microchip including the validity and packaging date of the bottle. When the bottle passes through the refilling unit, the chip program is updated, preventing the reutilization of the same bottle. At the end of the refilling process, the system prints the related data.

D- Sterilizing Agent leakage

Be sure that the Sterilizing Agent is the one recommended by Sterifast Lda. for the STERIFAST or ECOPLASMA Sterilizers. The use of wrong bottles of Sterilizing Agent may cause leakage. In case of leakage, use protection gloves and clean with abounding water.

2 - Warnings and Notes about the Sterilizing Agent

The Sterilizing Agent is not a toxic product but it is corrosive as it is a hydrogen peroxide (H_2O_2) aqueous solution. There are risks associated to the use of the Sterilizing Agent.

A risk management has been implemented in order to identify every hazard or hazardous situations. The risks have been estimated and measures have been taken to reduce the risks as far as possible. After the risk reduction measures have been taken all the residual risk became improbable or occasional with despicable or moderate severity.

However, in order to mitigate the residual risk, the following recommendations must be carefully followed:

1. Safety gloves

When directly handling the Sterilizing Agent, you should use safety gloves despite the Sterilizing Agent being in a closed bottle and the perforation being done automatically.

2. Inhalation

The long exposure to the Sterilizing Agent can be dangerous. The Sterilizing Agent vapour inhalation can cause burning and irritation of the respiratory tract. If vapour is inhaled, you should breathe fresh air and if there was a prolonged inhalation, seek medical advice.

3. Contact with the eyes

The long exposition to the Sterilizing Agent can cause irritation and damage to the eyes. The Sterilizing Agent and its components are not poisonous but can cause irritation. The vapour causes discomfort to the mucous membrane and to the eyes. The contact of the eyes with the Sterilizing Agent can be very dangerous because it can burn the cornea.

4. Contact with skin

The Sterilizing Agent can cause skin irritation and itching.
In case of contact with skin, immediately rinse with plenty of water and seek medical advice.

5. Accidental ingestion

Sterilizing Agent ingestion can cause serious damages and even death.
You must prevent the contact of your mouth with the Sterilizing Agent. If the Sterilizing Agent is ingested drink water to dilute it; do not induce vomit and seek medical advice.

6. Storage

We recommend that the bottles are stored in a fresh and dry place (between 15º-30ºC) and kept in the upright position, and away from sun light.

7. Spillage of Sterilizing Agent

In case of spill, it is necessary to pour over sterilizing agent water in a big quantity.

In the next page, you will find the “Safety Warning” file that is delivered with all loads of sterilizing agent and must be carefully read and which directions have to be followed.

PLEASE READ THIS INFORMATION CAREFULLY

Safety Warning

Product: **Sterilizing Agent**

Dear Customer,

As mentioned in the Sterilizing Agent labeling, the product must be stored in a place at a temperature between 15º and 30ºC. This only applies if the product is stored vertically.

If the bottles are not stored in the correct position, there is a risk of leakage of liquid inside the boxes, especially if the temperature in the storage is high. This may potentiate a fire of the materials stored near the sterilizing agent, since it is a chemical and oxidizing agent. By these reasons, we would like to reinforce the importance of the correct handling and storage of the Sterilizing Agent.

- Check the product immediately after reception. Open the boxes and confirm that the boxes and the bottles are completely dry. If there was a spill and depending on the damages, you must behave according to the instructions that can be found inside the boxes. After closing the boxes that are in perfect conditions store them as indicated until using the bottles.

- Transport and storage of the boxes / bottles in the upright position (as indicated by arrows labeling).
- Stored in a place at a temperature between 15º-30ºC or inside a refrigerated place if the area of storage has too high temperatures.
- Verify the product regularly.
- Be sure that the product is not stored along with flammable materials.

Please see the Safety Data Sheet that is sent together, especially point 7 (Handling and Storage).

Thank you for your cooperation.

3 - Sterilizing Agent action method

The STERIFAST and ECOPLASMA sterilizers inactivate the micro-organisms due to the low temperature Sterilizing Agent vapour, without leaving toxic waste. The Sterilizing Agent is an essential factor for the micro-organisms' inactivation. This technology can be used for the sterilization of a wide range of medical devices, particularly appropriated for heat and humidity sensitive instruments.

3.1- New generation sterilization method

Our sterilizers are often called the new generation sterilization method due to the following main reasons:

Fastness:

- The process takes less than 25 minutes for the normal cycle, approximately 35 minutes for the advanced cycle and approximately 35 minutes for endoscopes cycle, depending of model;
- The sterilization method only requires electrical energy;
- The ventilation is not necessary, contrary to the sterilization by gas;
- The material maximum temperature is less than 55ºC;

Safety:

- The operator has no contact with the Sterilizing Agent;
- Greater adequacy to lumen sterilization;
- The injection method interacts by considering the quantity of material inside the chamber, allowing a safe sterilization in every possible loading;
- Sterifast performs self-testing cycles;

Environment friendly:

- The packaging material is totally recyclable;
- The chemical product used is not toxic;

Low cost:

- Sterifast cycles are very economic;

High Tech produced from leading company in Europe. Patented Process;

3.2- Sterilizing Agent properties

The Sterilizing Agent is clear, colourless and it looks like water and has a proper odour. It is not flammable; it is soluble with water independently of the Sterilizing Agent concentration.
The Sterilizing Agent degrades at temperatures above 30ºC.
The Sterilizing Agent is nontoxic even being corrosive.
The STERIFAST and ECOPLASMA sterilizers use the Sterilizing Agent vapour in order to rapidly sterilize medical instruments without leaving toxic waste.
Regarding the validity of the Sterilizing Agent inside the sterilizer's tanks, please refer to Chapter II, Section 7, Important Warning, of this manual.

3.3 - Sterilizing Agent Instructions for Use

- Before taking the bottle out of the plastic bag, verify that there are no liquid drops or leakage inside this bag (in case of Sterilizing Agent leakage, use safety gloves in order to take the bottle off the plastic bag and clean it before putting it onto the drawer holder).
- Take the bottle out of the plastic bag;
- Place the bottle in the drawer holder.
- Take the bottle cap off, only after placing the bottle in the holder.
- After automatic supply, you can leave the bottle in the holder. When removing the bottle put the screw cap.

In case of skin contact with the Sterilizing Agent, clean immediately with abounding water. In case of injury or feeling unwell, seek medical advice, and if possible, show the product label.

DO NOT PUNCH THE BOTTLE MANUALLY UNDER ANY CIRCUMSTANCE.

DO NOT USE THE BOTTLES THAT HAVE EXPIRED VALIDITY.
If you have bottles of Sterilizing Agent that have expired validity, you must follow the protocol of your Institution' Infection Control Department to discard the bottles.

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Introduction

In this chapter all sterilization cycles, test cycles and sterilization process monitoring are described.

1 – Sterilization Cycles Description

The sterilizers have three pre-defined Sterilization Cycles and one Cycle which can be adjusted to customer needs.

Cycle I – Advanced

The **Advanced Cycle** is used for the general medical devices' sterilization, including lumen and hollow instruments, in containers or pouches with single or double packaging. It takes approximately 35 minutes.
The essays made with the Sterifast PCDs (Lumen Kit) confirm that Advanced Cycle has the capacity to sterilize the following lumen:
- Diameter ≥ 1 mm and extension ≤ 3 meters, with one closed end
- Diameter ≥ 1 mm and extension ≤ 10 meters, with both ends opened.

Cycle II - Normal

The **Normal Cycle** is used for sterilize general medical devices. This cycle is not recommended for flexible lumens with diameter less than 1mm and with extension more than 1 meter.
The process takes approximately 25 minutes.

Cycle III - Endoscopes

The **Endoscopes Cycle** is used for the sterilization of Flexible Endoscopes only. It sterilizes one or two endoscopes. Endoscopes packed in paper sheets non-woven, without cellulose or inside of appropriate box.
The endoscopes must be washed previously and disinfected and they must be completely dry before they processed in the sterilizer.
The process takes approximately 35 minutes.

Important note:
The Hydrogen Peroxide can interact with the anodized aluminum. Endoscopes with parts of aluminum with color, should not be sterilized on STERIFAST or ECOPLASMA sterilizers because the Hydrogen Peroxide can discolor the anodized aluminum components.

ATTENTION:
Only sterilize endoscopes, multichannel endoscopes and colonoscopes, according to their manufacturer's instructions, with the guarantee of manufacturer that the endoscope can be subject to sterilization processes with hydrogen peroxide.

Cycle IV - Cycle Not Activated

This cycle can be adjusted to customer needs.

1.1 – Sterilization Cycles' Phases

The cycle's phases are described below.

Cycle I - Advanced Cycle

The Advanced Cycle is composed by two phases of Preparation for Diffusion, two phases of Diffusion, two phases of Exhaustion of the Sterilizing Agent and Ventilation.
It is similar to the Normal Cycle, but with longer Diffusion phases.
This is how the cycle runs:

- *Phase 1: Exhaustion:*

This is a vacuum and humidity exhaustion phase and it runs during a few minutes.

- *Phase 2: Preparation for Diffusion:*

This phase consists on creating, in the chamber and vaporizer, conditions for the diffusion.

- *Phase 3: Diffusion:*

In this phase, an aqueous solution of Sterilizing Agent is injected into the chamber and diffused after being vaporized.
The Sterilizing Agent diffuses in the chamber by surrounding the items to sterilize and starting de micro-organisms inactivation.

- *Phase 4: Sterilizing Agent (Plasma) Exhaustion:*

In this phase, the chamber is in exhaustion and all the gas removed from the chamber is burned.

- *Phase 5: Preparation for Diffusion 2*
- *Phase 6: Diffusion 2*
- *Phase 7: Sterilizing Agent (Plasma) Exhaustion 2*
- *Phase 8: Ventilation:*

Here the chamber is ventilated so no waste of Sterilizing Agent remains on the material.

- *End of Program:*

At the end of the cycle a report about the cycle phases is processed and the operator is informed if the cycle was done successfully or if it failed.
At the end of the cycle, it is possible to open one door.

Cycle II – Normal Cycle

The Normal Cycle is composed by two phases of Preparation for Diffusion, two phases of Diffusion and two phases of Sterilizing Agent Exhaustion.
The cycle runs as follows:

- *Phase 1: Exhaustion;*
- *Phase 2: Preparation for Diffusion;*
- *Phase 3: Diffusion;*
- *Phase 4: Sterilizing Agent (Plasma) Exhaustion;*
- *Phase 5: Preparation for Diffusion 2;*
- *Phase 6: Diffusion 2;*
- *Phase 7: Sterilizing Agent (Plasma) Exhaustion 2;*
- *Phase 8: Ventilation;*
- *End of Program.*

At the end of the cycle, a report is generated with the cycle phases and informing if the cycle was done successfully or if it failed. At the end of the cycle, you can open one door.

Cycle III – Endoscopes Cycle

Endoscopes Cycle is similar to Advanced Cycle but the Exhaustion phase is longer and temperatures are lower.

Cycle IV - Cycle Not Activated

This cycle can be adjusted to customer needs.
These adjustments will be done under request, during the production.

1.2 – Sterilization Cycles Parameters and Tolerances

The Sterilization Cycles Parameters and Tolerances are as follows:

Chamber temperature – 55º to 65ºC

Initial vacuum time – minimum 60 seconds

Vacuum pressure – < 1 mbar

Diffusion time – minimum 180 seconds

Diffusion pressure – 30 mbar

Hydrogen peroxide quantity injected in the chamber:
– 4 ml to 12 ml per diffusion, for STERIFAST sterilizers
– 6 ml to 14 ml per diffusion, for ECOPLASMA sterilizers

Ventilations – 1 to 6 ventilations

Hydrogen peroxide concentration:
– 50% for STERIFAST sterilizers
- 35% for ECOPLASMA sterilizers

Final vacuum time – minimum 180 seconds

2 – Test Cycles Description

Besides the sterilization cycles the sterilizers also perform Test Cycles:

Cycle V – Penetration Test

Composed by one phase of Preparation for Diffusion, one phase of Diffusion and one phase of Sterilizing Agent Exhaustion. The cycle runs as follows:

- *Phase 1: Exhaustion;*
- *Phase 2: Preparation for Diffusion;*
- *Phase 3: Diffusion;*
- *Phase 4: Sterilizing Agent (Plasma) Exhaustion;*
- *Phase 5: Ventilation;*
- *End of Program.*

This test is validated by the technician or operator, by placing lumen PCDs (Process Challenge Devices) with chemical and biological indicators dismantled (disc) 10^6, inside the sterilization chamber, and by checking the indicators results at the end of the cycle.
In this cycle you must use the following PCDs:
Lumen with 10 meters, with both ends opened
Lumen with 5 meters, with both ends opened
Lumen with 3 meters, with one end closed
Lumen with 2 meters, with one end closed

This cycle is used whenever the sterilizer had an intervention (service or repair), or when the operator needs to confirm the sterilizer keeps the original features.

Cycle VI – Leakage Test

This is to check the sterilization chamber's tightness. It consists of a submission of the chamber to a vacuum, with a stop of the Vacuum Pump and the drain valve closed, on a time counting, and on a verification of the pressure variations inside the chamber.

Cycle VII – Leakage + Penetration Test

It is possible to perform both Leakage and Penetration Tests simultaneously. The operator must remember to place the PCDs with the chemical and biological indicators, inside the chamber, as indicated for the Penetration Test.

3 – Sterilization Process Monitoring

The operator has a responsibility to verify the efficiency of the sterilizer. The use of chemical and biological indicators in each load is mandatory. All cycles shall take a biological indicator inside a pack or a pouch.

The sterilizers have test cycles; these are used to verify its efficiency. We recommend to process the Penetration Test at least once a week, using the PCD – Process Challenge Device, (Lumen Kit), as indicated in point 4.

Sterifast sterilization process can be monitored by four different means:

- **Cycle Printout**
- **Chemical Indicators**
- **Biological Indicators**
- **Lumen Test – PCD**

Note 1: The institution should implement other means of control according to its own protocol for load release.

Note 2: For the Monitoring Process the guidelines of ISO 11737-2 can be followed.

3.1- Cycle Printout

After the sound signal which informs about the end of the cycle, the sterilization process data is printed out. The operator must check the cycle result on the report printed out to verify that the cycle was concluded properly.

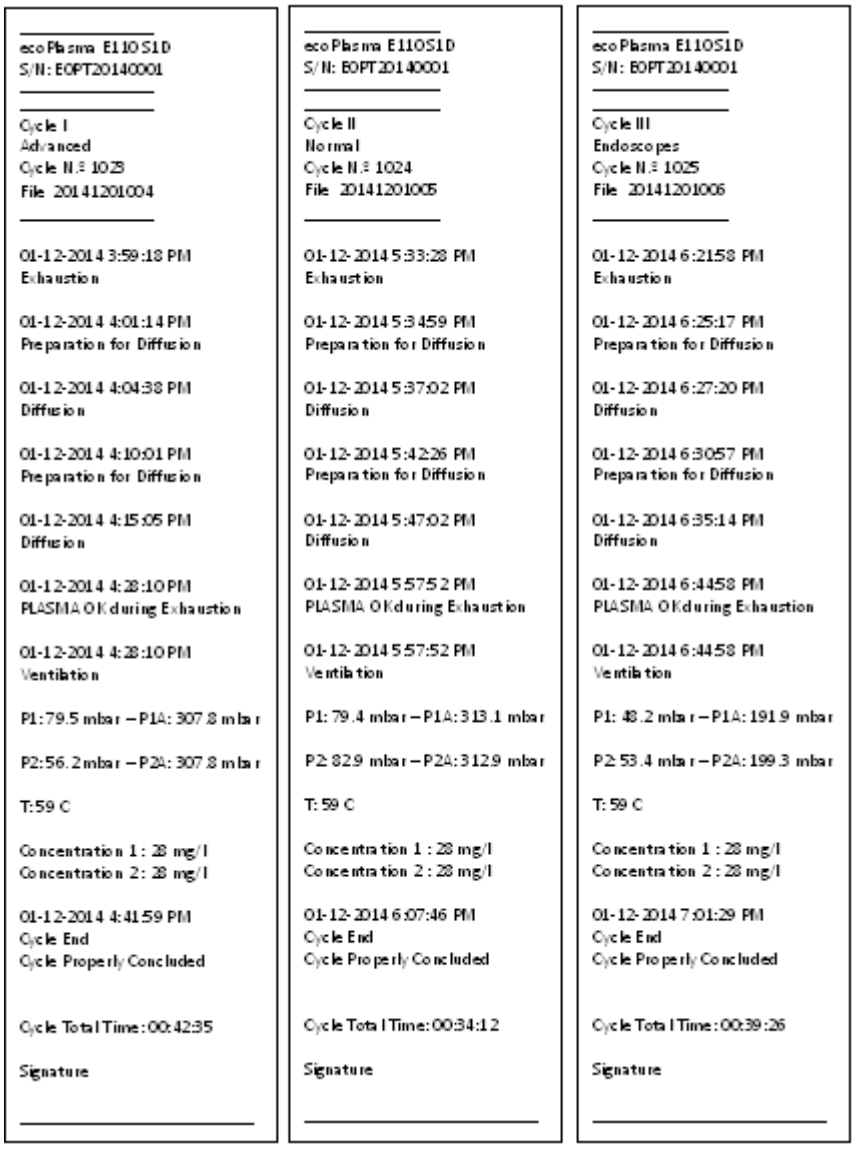
Examples of reports can be found on the next page.

Whenever the sterilizer needs maintenance, a message will be written in the cycle report warning about this fact.

After each refilling of Sterilizing Agent the system will print the refilling data also.

At the end of the cycle remove the printout from the printer.

3.1.1- Examples of Sterilization Cycle Printout



ecoPlasma E110S1D
S/N: EOPT20140001

Cycle I
Advanced
Cycle N.° 1023
File 20141201004

01-12-2014 3:59:18 PM
Exhaustion

01-12-2014 4:01:14 PM
Preparation for Diffusion

01-12-2014 4:04:38 PM
Diffusion

01-12-2014 4:10:01 PM
Preparation for Diffusion

01-12-2014 4:15:05 PM
Diffusion

01-12-2014 4:28:10 PM
PLASMA OK during Exhaustion

01-12-2014 4:28:10 PM
Ventilation

P1: 79.5 mbar – P1A: 307.8 mbar

P2: 56.2 mbar – P2A: 307.8 mbar

T: 59 C

Concentration 1 : 28 mg/l
Concentration 2 : 28 mg/l

01-12-2014 4:41:59 PM
Cycle End
Cycle Properly Concluded

Cycle Total Time: 00:42:35

Signature

ecoPlasma E110S1D
S/N: EOPT20140001

Cycle II
Normal
Cycle N.° 1024
File 20141201005

01-12-2014 5:33:28 PM
Exhaustion

01-12-2014 5:34:59 PM
Preparation for Diffusion

01-12-2014 5:37:02 PM
Diffusion

01-12-2014 5:42:26 PM
Preparation for Diffusion

01-12-2014 5:47:02 PM
Diffusion

01-12-2014 5:57:52 PM
PLASMA OK during Exhaustion

01-12-2014 5:57:52 PM
Ventilation

P1: 79.4 mbar – P1A: 313.1 mbar

P2: 82.9 mbar – P2A: 312.9 mbar

T: 59 C

Concentration 1 : 28 mg/l
Concentration 2 : 28 mg/l

01-12-2014 6:07:46 PM
Cycle End
Cycle Properly Concluded

Cycle Total Time: 00:34:12

Signature

ecoPlasma E110S1D
S/N: EOPT20140001

Cycle III
Endoscopes
Cycle N.° 1025
File 20141201006

01-12-2014 6:21:58 PM
Exhaustion

01-12-2014 6:25:17 PM
Preparation for Diffusion

01-12-2014 6:27:20 PM
Diffusion

01-12-2014 6:30:57 PM
Preparation for Diffusion

01-12-2014 6:35:14 PM
Diffusion

01-12-2014 6:44:58 PM
PLASMA OK during Exhaustion

01-12-2014 6:44:58 PM
Ventilation

P1: 48.2 mbar – P1A: 191.9 mbar

P2: 53.4 mbar – P2A: 199.3 mbar

T: 59 C

Concentration 1 : 28 mg/l
Concentration 2 : 28 mg/l

01-12-2014 7:01:29 PM
Cycle End
Cycle Properly Concluded

Cycle Total Time: 00:39:26

Signature

Legend

Name of Machine
Serial Number of Machine

Type of the Cycle
Name of Cycle
Number of the Cycle
Number of File

Date and Time of Exhaustion Phase

Date and Time of Preparation for Diffusion 1 Phase

Date and Time of Diffusion Phase

Date and Time of Preparation for Diffusion 2 Phase

Date and Time of Diffusion Phase

Date and Time of Plasma Exhaustion Phase

Date and Time of PLASMA OK during Exhaustion Phase

Date and Time of Ventilation Phase

P1 and P1A: Value of Pressure during Diffusion 1 Phase

P2 and P2A: Value of Pressure during Diffusion 2 Phase

T: Temperature during the Cycle

Theoretical Concentration
Theoretical Concentration

Data and time of the Cycle End Phase

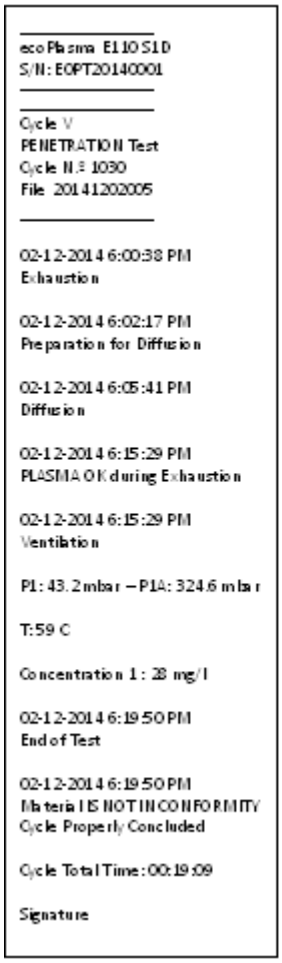
Time and duration of the Cycle

Signature

The Report includes data like the type and number of the cycle, the several phases, the result, total time of the cycle, temperature, pressure of the cycle phases and space for the operator's signature.

Note: In case of software failure, the printout is interrupted in the phase where the failure occurred. Please call the technician.

3.1.2 - Examples of Test Cycle Printout



ecoPlasma E110S1D
S/N: E0PT20140001

Cycle V
PENETRATION Test
Cycle N.° 1030
File 20141202005

02-12-2014 6:00:38 PM
Exhaustion

02-12-2014 6:02:17 PM
Preparation for Diffusion

02-12-2014 6:05:41 PM
Diffusion

02-12-2014 6:15:29 PM
PLASMA OK during Exhaustion

02-12-2014 6:15:29 PM
Ventilation

P1: 43.2 mbar – P1A: 324.6 mbar

T:59 C

Concentration 1 : 28 mg/l

02-12-2014 6:19:50 PM
End of Test

02-12-2014 6:19:50 PM
Material IS NOT IN CONFORMITY
Cycle Properly Concluded

Cycle Total Time: 00:19:09

Signature

ecoPlasma E110S1D
S/N: E0PT20140001

Cycle VI
VACUUM Test
Cycle N.° 1031
File 20141202006

02-12-2014 7:10:20 PM
Exhaustion

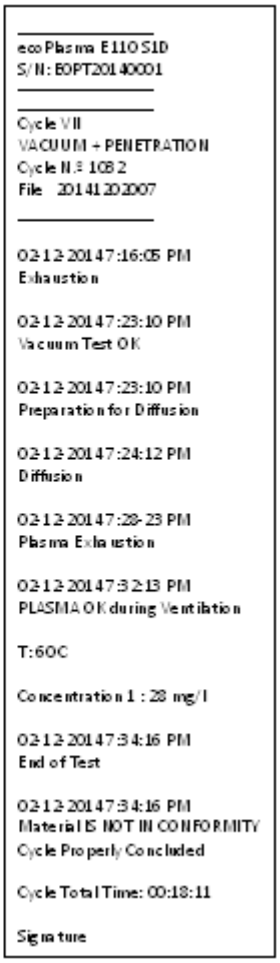
02-12-2014 7:12:24 PM
Vacuum Test OK

02-12-2014 7:14:36 PM
End of Test

02-12-2014 7:14:36 PM
Material IS NOT IN CONFORMITY
Cycle Properly Concluded

Cycle Total Time: 00:04:16

Signature



ecoPlasma E110S1D
S/N: E0PT20140001

Cycle VII
VACUUM + PENETRATION
Cycle N.° 1032
File 20141202007

02-12-2014 7:16:05 PM
Exhaustion

02-12-2014 7:23:10 PM
Vacuum Test OK

02-12-2014 7:23:10 PM
Preparation for Diffusion

02-12-2014 7:24:12 PM
Diffusion

02-12-2014 7:28:23 PM
Plasma Exhaustion

02-12-2014 7:32:13 PM
PLASMA OK during Ventilation

T:60C

Concentration 1 : 28 mg/l

02-12-2014 7:34:16 PM
End of Test

02-12-2014 7:34:16 PM
Material IS NOT IN CONFORMITY
Cycle Properly Concluded

Cycle Total Time: 00:18:11

Signature

3.2 - Chemical Indicator (CI)

All cycles shall be monitored with H2O2 Chemical Indicator inside a pack (as proof that the sterilizing agent entered in the pack or pouch).

You can use any H2O2 chemical indicator, manufactured according to ISO 11140.

In case the H2O2 Chemical Indicator does not change colour inside a pack, the user should look for the result of the incubation of Biological Indicator and for cycle report.
The CSSD manager will decide if the package where the chemical indicator did not change colour is accepted or not, according to the institution's protocol.

3.3- Biological Indicator (BI)

BIs must be used for the sterilization process monitoring. Place at least 1 indicator inside the chamber for each cycle. All cycles shall take at least 1 indicator inside a pack or pouch.
NOTE: The Biological Indicator must be placed in a sealed pouch before being placed in the chamber.

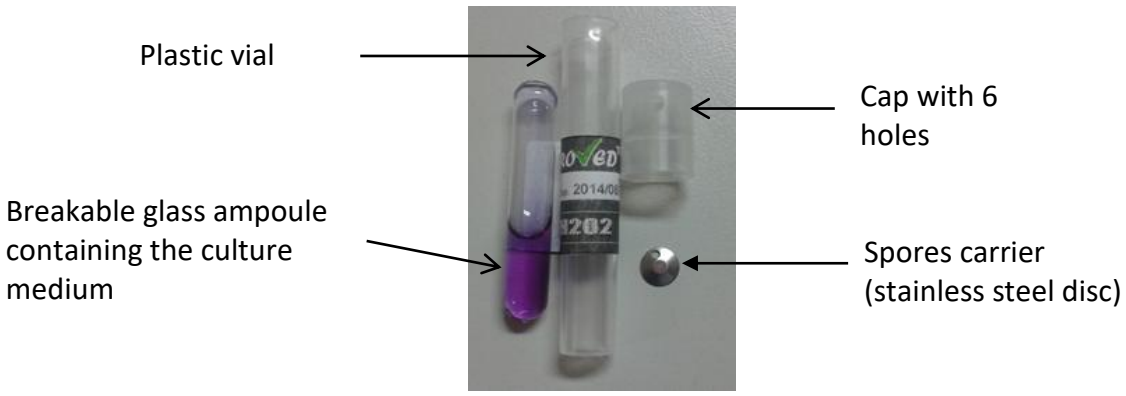


Figure 6-1

The APPROVED® SAFEtest Biological Indicators have a defined quantity of inoculated spores on a small stainless steel disc placed inside a plastic vial with a breakable glass ampoule which includes a culture media.
We recommend the use of APPROVED® SAFEtest Plasma (ref.ª PHP/6) biological indicators.
They are available for hydrogen peroxide plasma sterilization processes, and have *Geobacillus Stearothermophilus* spores. The culture medium changes its colour from purple to yellow when the culture is positive.
After the sterilization process, the Biological Indicator must be incubated. Break the glass ampoule and place the indicator in an incubator.

No colour change means that there is no bacteriological growth.

Figure 6-1.1

Colour change to yellow means that the sterilization process failed.

Figure 6-1.2

In case the Chemical Indicator of the biological indicator cap does not change its colour in a pack, the sterilization of this pack should be repeated and it should be verified if the chamber has been loaded correctly.

3.4 – Lumen Test – PROCESS CHALLENGE DEVICES (PCD)

3.4.1.- Lumen Kit Description

NOTE:
All the sterilization cycles have two diffusions.
The Penetration Test is a half cycle. It has only one diffusion.
The purpose of the Lumen Kit is to test the half cycle – Penetration Test.
This kit is used to confirm that the sterilizer keeps its original features.

The sterilization process monitoring can be performed with flexible lumen kits.

In the kit, there are two types of lumen: opened on both sides and opened only on one side.

The difference is only the total length of the lumen.

- *10 meter Lumen:*

Consists of a chamber for the indicators positioning and of a capillary of 5 meters length and a diameter of 1 millimetre on each side.

- *5 meter Lumen:*

Consist of a chamber for the indicators positioning and of capillary of 2.5 meters length and a diameter of 1 millimetre on each side.

- *3 meter Lumen:*

Consists of a chamber for the indicators positioning, sealed on one side and having a capillary of 3 meters length with a diameter of 1 millimetre on the other side.

- *2 meter Lumen:*

Consists of a chamber for the indicators positioning, sealed on one side and having a capillary of 2 meters length with a diameter of 1 millimetre on the other side.

Figure 6-2

Note: Each PCD has a seal that must be replaced after approximately 500 uses.

3.4.2- How to use the lumen kit (Process Challenge Device)

1) Prepare the Process Challenge Device (PCD);

2) Verify if the lumen is clean (free of water drops and/or dust);

3) Place a chemical indicator strip inside the PCD chamber;

Figure 6-2.1

4) Place a spores' carrier from the Self Contained Biological Indicator 10^6 inside the PCD chamber. (To take the spores' carrier from the SCBI you must take out the vial cap and the media ampoule and then the carrier).

Figure 6-2.2

5) Place the PCD with the indicators inside the sterilizer chamber.

6) Put the media ampoule, the vial and the cap inside a sterilization reel or pouch.

Figure 6-2.3

7) Place the pack with the SCBI components also inside the sterilization chamber;

IMPORTANT: *Process the test without load.*
Our PCDs were developed to confirm the efficiency of the cycles without load; They do not have the purpose to verify the load.
Besides the biological and chemical indicators, there are no other devices that comply to the standards to monitor cycles with loaded chamber.

8) Process the Penetration Test cycle, using 4 PCD's (10 meters, 5 meters, 3 meters and 2 meters)

9) Remove the PCDs and the pack with the SCBI components from the chamber;

10) Open the PCDs and verify the chemical indicators results;

11) Take out the spores' carriers from the PCDs with gloves (sterilized gloves) and reassemble each SCBI placing the spores' carrier in the bottom of the vial, then the media ampoule and then the cap.

12) Incubate the biological Indicators in a suitable incubator.

3.4.3- What to do in case of lumen test failure

If the chemical indicator does not show colour change, repeat the cycle to confirm if the failure remains. In that case, contact your Sterifast distributor for technical assistance.

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Introduction

This chapter describes the materials that can be sterilized by STERIFAST and ECOPLASMA Sterilizers, and those that cannot. It also describes the correct loading of the sterilization chamber.

1. Material's Sterilization

The materials inside the chamber do not go over 55ºC.

1.1 - Materials than can be sterilized by STERIFAST or ECOPLASMA Sterilizers

Any material that manufacturers of instruments recommend to be sterilized by hydrogen peroxide sterilization process.

Metals
Stainless steel 300 series, aluminum 6000 series, titanium
Nonmetals
Glass, silica, ceramic
Plastics and Elastomers
Polyethylene (LDPE, HDPE, UHMPE), polypropylene copolymer, polymethylpentene, Tefzel, chlorinated polyvinyl chloride, polystyrene, polyethersulfone, polyvinylidene fluoride, polyetherketone, Viton, trifluorochloroethylene resins, fluoroelastomer, polypropylene, polyphenylene oxide, Teflon (PTFE, PFA, FEP), polyvinyl chloride, polycarbonate, polysulfone, acrylonitrile butadiene styrene, polyetherimide, most silicones and fluorinated silicones, ethylene-propylene rubber

1.2 - Materials that cannot be sterilized by STERIFAST or ECOPLASMA Sterilizers

- Instruments with lumen, having less than 1 mm diameter and / or over 10 m length.
- Absorbent materials (cellulose);
- Wood, linen, paper, spongeous materials;
- Liquids;
- Iron, copper, and heavy metals.

Please review the instructions provided by the manufacturer of the instruments you use, to make sure about their compatibility with hydrogen peroxide process, and timeline of re-processing.

SINGLE USE MEDICAL DEVICES SHALL NOT BE STERILIZED IN THESE STERILIZERS.

2. Loading the sterilization chamber

The sterilizers chambers have PTFE guiding rails to assure the existence of space between the chamber walls and the materials, allowing the free circulation of the Sterilizing Agent.
Sterifast Lda. supplies as **loading accessories** the following shelves:

- For 50 litres models – 1 Shelve
- For 110 and 160 litres models – 2 Shelves

All devices should be packed in polypropylene or polyethylene pouches. We do not recommend the use of cellulose variations or fabrics for the packaging of the medical devices, because these materials are Sterilizing Agent absorbent and turn the ventilation more difficult.

The devices to be sterilized must have been properly processed before being sterilized in the STERIFAST or ECOPLASMA Sterilizers. The procedures are mechanical wash, thermal disinfection, high-level chemical disinfection, drying and packaging in appropriate materials.

The devices to be sterilized should be at a temperature between 20º and 26ºC when being placed in the chamber.

Note: If you overload the sterilizer, you must close the door and wait for 5 minutes before starting the cycle. The door should always be kept closed if not loading the chamber.

2.1 – Maximum weight by chamber size

160 Liters chamber – 12 Kg
110 Liters chamber – 10 Kg
50 Liters chamber – 4 kg
Note: Heavy items should be placed in the bottom shelve or on the sides of the chamber.

3 - Unloading sterilized devices

When the cycle is finished correctly, the operator is informed that one of the doors can be accessed. The operator has the possibility to choose which door will be opened, knowing that opening one of the doors prevents the opening of the opposite one.
In case of a failed cycle, it is only possible to open the loading door (Unclean Side).
The shelves or baskets should always be kept inside the chamber.

Recommendation: There should be a protocol in the institution to control and verify all these procedures.

A risk management has been implemented in order to identify every hazard or hazardous situations related to the use of our Sterilization Systems. The risks have been estimated and measures have been taken to reduce those risks as far as possible. After the risk reduction measures have been taken all the residual risk became improbable or occasional with despicable or moderate severity. However, in order to mitigate the residual risk, this chapter of the Instruction Manual has been prepared with information regarding performance, but also including safety and protective measures:

1. Can I sterilize flexible endoscopes?

Yes, but they must not be rolled inside the involucres and they must have the lumen ends open (please see the Chapter VI of this manual, on point 1 - Sterilization Cycles – Cycle 3 – Endoscopes). This type of material to sterilize must be packed in PE Sheets.

2. Can I use common paper in the Sterifast sterilizers?

Yes, but it must be in very small amounts, for example, very small labels.
The common paper absorbs the Sterilizing Agent removing it from the chamber, especially near the labels, and will result in more Sterilizing Agent waste (please see the chapter VII of this manual, on point 2 – Loading the Sterilization Chamber).

3. What kind of material should I use for the packaging?

For the packaging, you should use polypropylene or polyethylene
You should use pouches or paper prepared for this sterilization method, recommended by Sterifast, Lda (please see the chapter VII – on point 1- Material's Sterilization – Materials that can be sterilized in the Sterifast).

4. What kind of biological indicators should I use?

The Sterifast, Lda Company recommends the use of APPROVED® Biological Indicators (SCBI) with a population 10^6 *Geobacillus Stearothermophilus* in the chamber and packed in the PE Reel.
Our range of indicators also includes Biological Indicator with a population of 10^6 which have been developed with the purpose to be placed inside a lumen Process Challenge Device indicator.

5. What kind of Chemical indicators should I use?

You can use any H2O2 chemical indicator, manufactured according to ISO 11140.
One chemical indicator should be placed in each package.
We do not recommend the placement of chemical indicators inside of the Process Challenge Device.

6. How can I validate the sterilizer?

Our Company's service department has qualified personnel to validate the sterilizers.
The validation kit is a small equipment which can be mounted near the STERIFAST or ECOPLASMA Sterilizer. It is independent of the automation and validates independently all the cycle data, informing the operator if the cycle passed according to the manufacturer graphs and a complete executed cycle report is supplied.

7. How can I interpret the sterilizer's report?

At the end of the cycle, the Sterifast prints out a report of values of the various cycle phases, diffusion phases and the time spent in each phase. The report also has the maximum values of the pressure of the air entry in the diffusion and the temperature during the cycle. It records any fail during the cycle and a blank space is available so the operator can sign and validate the report.
If necessary, other prints can be done by accessing saved data. In each report are included the cycle file name saved in the system (that will be year, month, day and cycle number processed in this particular day - e.g. 20131022 001). This operation is only possible if no cycle is running at the moment.
Basically, the report informs that all the phases have been passed.
In case of phase failure, it will appear in the report. The report indicates if the cycle passed or not.
The Sterilizing Agent refilling can also be recorded.

8. What is the danger level of this sterilizer?

The Sterifast sterilizers do not emit toxic gas. (Sterilizing Agent is corrosive, but nontoxic).

9. What precautions should be considered for cleaning the sterilizers?

To clean the sterilizer chamber, you must turn on the sterilizer and select one of the cycles, in order to open the doors. Turn off the sterilizer until the cleaning is finished.

The sterilization chamber can be cleaned with a wet cloth and water. The water should not be placed directly into the chamber because it damages the vacuum pump. After the cleaning, the door should be kept open until the chamber is completely dry.
Periodically, the chamber exhaustion filter must be cleaned or replaced.
The chamber must be cleaned every week due to natural deposit of dust.
The outside surfaces can be cleaned with appropriated cleaners. In our Sterifast range of products we have the suitable cleaners.
All the cleaning actions must be done at the beginning of the day when the machine is cold.

10. How should I clean the touch screen?

First you have to turn the machine "OFF" and then you can clean it with a wet cloth or with some special product for cleaning PC screens.

11. Can I burn myself when operating these sterilizers?

No.
The chamber and doors temperature is 55ºC maximum which cannot lead to accidental burnings. Nevertheless, if you have a sensitive skin, you should use gloves when unloading the chamber at the end of the cycle as the material could still be hot.

12. Is there any risk of explosion?

There is no danger. The cycle runs in vacuum.
The equipment was developed with high concern about the personnel safety.
When refilling the Sterilizing Agent, it is not possible to touch it directly.
If you have any question, please contact the production and manufacturing department for further information.

13. Who should do these sterilizers maintenance?

The maintenance should only be done by the manufacturer and recommended companies with a Sterifast training.
The Sterifast sterilizers may have tele-maintenance service. This service is activated according to the agreement between the manufacturer and the hospital.
It's possible, using an Ethernet connection, to verify from our facilities the functionalities of the sterilizers and show all the information in the sterilizer screen and all the steps that should be followed. By these means, any qualified technician can replace the damaged parts that were recommended by the machine's report.

14. Can I use some other kind of Sterilizing Agent in these sterilizers?

No.
You cannot use any product which is not recommended for use with this equipment.
The STERIFAST and ECOPLASMA sterilizers have been studied and developed together with the Sterilizing Agents. Sterilizing agent provided by Sterifast is recommended for this sterilization.
It is not possible to introduce any other kind of Sterilizing Agent in the sterilizer tank because it has a safety system that detects if any non-recommended Sterilizing Agent has been introduced.
Any attempt to refill manually the Sterifast tank will be detected and the machine will be blocked after some cycles until the authorized technician's intervention.
Sterifast Lda company will not take responsibility for the use of any non-recommended Sterilizing Agent.

15. What is the shelf life of the Sterilizing Agent inside the tank?

STERIFAST and ECOPLASMA regular version: Due to the type of tank, if the place where the sterilizer is installed does not have the temperature above 30º C, the maximum time that the sterilizing agent should be inside the tank is 60 days. After this time, the sterilizing agent should to replaced.
ECOPLASMA Basic version: If the place where the sterilizer is installed does not have the temperature above 30º C, the maximum time that the sterilizing agent should be inside the tank is 30 days. After this time, the sterilizing agent should to replaced.

16. What should I do if there is a breakdown?

You have to read and note any information given by the machine display.
Refer to the Instruction Manual for any help. If you do not find the needed information, you should contact the manufacturer or the authorized agent.
Together with your Instruction Manual you will get a Non Conformity record sheet. Please record on it all verified malfunctions, breakdowns or strange situations. These must be reported to your Sterifast supplier or manufacturer. This information is very important and will support us on constant improvement of Sterifast equipment, and for customer's satisfaction.

17. How can I buy Sterifast products?

You can buy directly from the manufacturer, or from the exclusive distributors. http://www.sterifast.com

18. Who has developed these sterilizers?

STERIFAST and ECOPLASMA Sterilizers have been developed by a large and young team. The basis was the new method of using hydrogen peroxide as a Sterilizing Agent, which has been patented. This team worked hard to make the machine performing, ergonomic, safe and also attractive.

If you have an opinion about the Sterifast sterilizers performance, do not hesitate to sending it to the manufacturer and we will be pleased to take it into consideration.
Our customer's opinion is very important to us.

19. What is the best place to install these sterilizers?

The sterilizers should be installed in a ventilated room as they release heat.
Furthermore, concerning the two doors' units, they must be assembled in sanitary barrier zones, like CSSD.
The STERIFAST and ECOPLASMA sterilizers do not require any specific connection. Its only necessary to have an electrical power supply.
The sterilizers include, as an option, stainless steel sections to fix the sterilizer to the wall.
Please refer to Annex 1.

20. How does the cycle run?

The sterilizer has been studied in order to have fast cycles and even to be able to sterilize lumen devices.
Basically, in the chamber, the cycle runs in high vacuum which is attained thanks to the most innovative vacuum technology and a double stage vacuum pump.
After an initial vacuum, air is injected into the chamber by a HEPA filter in order to remove any possible humidity from the instruments to be sterilized and to lead it to the drain trap by means of the vacuum system.
After the second vacuum phase, the Sterilizing Agent is injected into the chamber and the diffusion phase begins. Then the exhaustion and the Sterilizing Agent burning phases begin.
After the burning phase, a chamber ventilation phase follows and the cycle is concluded.
Finally, a report is printed out.

21. If the printer does not print the report, what do I do? Do I validate the cycle or not?

Once the monitoring of the cycle is done also with biological indicators (for proof of effective sterilization) and chemical indicators (for proof of the penetration of sterilizing agent in the package), the cycle can be validated, if the two points above have good results. In the

sterilizers regular version, it is possible to copy the cycle chart through a flash drive and to open it on the Sterifast Viewer software.

22. The door does not seal, what should I do?

Open the door completely and close it again.
If the problem persists, please call a Sterifast Technician.
Check the gasket for damage and dirt.

23. Do the automatic sliding doors have safety system for stopping the sliding movement in case of any obstacle? If yes, what happens next?

The sliding door only opens when the operator gives the instruction on the screen or by pressing the foot pedal.
If the door is open for more than 10 minutes, the door closes automatically to save energy (the minute's countdown is shown on the screen). If the time (10 minutes) is ending and the operator needs the door opened for more time it is necessary to press the pedal again. It will count 10 minutes more.

There is a bar sensor in the door, sensitive to 150 grams. During the close movement, once pressed this sensor reverts the movement of the door and waits 10 more minutes. With the indication of the operator the door closes.

24. Is there more humidity inside the chamber for the fact that the plasma generator is outside the chamber?
There would be more humidity if there was no control of temperature in the chamber and in the vaporizer. The plasma happens during the exhaust phase.

25. If the door opens but does not close automatically, what should I do?

The door opening movement micro switch may not be active. It can be damaged or unadjusted.
The system will close the door if you turn it OFF and turn it ON again.
If you do open and close the door with the Supervision Software (just for technicians), check if the output to the motor movement remains active after the movement ends.
Check if the inputs in the Supervision Software are correct.
Check if there are any broken wires.

26. The bottle has liquid after refilling procedure. What is happening?

The needle may be out of position. Probably it is pressing the bottle bottom, or the dosing pump is damaged or the rubber of the dosing pump is deteriorated.
Call a Sterifast technician.

27. The system aborts. Why?

The system may abort in various phases of the cycle because of reaching the maximum time for the phase.

28. The system aborts in the exhaustion 1 phase. Why?

The reasons may be: Humidity in the load, too many metallic devices in the load, vacuum pump is not working, temperature safety is disconnected, exhaustion valve is not opening, or a package is obstructing the chamber exhaust outlet.

29. Vacuum pump works, but it does not make vacuum. Why?

The reasons may be: A package is stuck in the door, the door is not completely blocked, or there is water inside the vacuum pump.

30. There are drops of H2O2 in the sterilized packages. What is happening?

Check in each refilling if one bottle is doing the correct number of diffusions.
Check in the printout if the pressure (P1 and P2) is the usual pressure when sterilizing that type of devices.

31. The sterilizer is injecting more hydrogen peroxide than usual. What can I do?

The vaporizer valve may not be sealing properly or the O-rings do not seal on the connection of the capillary tube. Call a Sterifast technician.

32. The system heats the chamber and doors but it does not start the cycle, or if it starts, it stays on the phase "Program starts after conditions exist". What is happening?

One of the door's safety thermostats may be disarmed, or the safety thermostat of maximum temperature of the vaporizer may have turned OFF the main switch and it will only turn ON if the temperature goes lower.
Possible Causes: The sensor of one of the doors may be damaged, or the vaporizer sensor may be out of place, or one of the safety thermostats failed.

Check with the Supervision Software if the main switch is ON. If it is not ON it may be a failure in one of the sensors. (just for technicians)
If the temperature does not evolve, one of the probes or the PLC may be damaged.
It is necessary to call the Sterifast technician.

33. If the system stays too much time in the phase "Program starts after conditions exist" what should I do?

Check the load. Possibly the load has too much metallic devices.

34. If the touch screen is not working well, what should I do?

Please contact Sterifast Company or your local distributor to know what to do.

35. If the sterilizing agent supplied, and recognized by the supplying system through the RFID does not have the correct concentration, what will happen?

There can be two possible situations:
- The machine injects more quantity of sterilizing agent to achieve the correct pressure, (therefore performing less cycles per bottle), or,
- The machine aborts the cycle, since it does not achieve the pressure within the time it is established.

36. What is the level of noise produced by the Sterifast sterilizers?

The level of acoustic power of the machine when in operation is 70,1 dB (L_{WA}). The level of acoustic pressure is 54,5 dB (L_{pfA}).

37. Could I install a sensor of Hydrogen Peroxide (H2O2) close to the sterilizer to measure the ppm (parts per million) of H2O2 in the sterilizer room ambient?

Yes. You could and you should.
The sterilizers produced by Sterifast, Lda. have ventilators and the installation site itself must have at least 5 air renewals per hour.
The purpose of the H2O2 sensor at the sterilizer room ambient is to monitor the quantity of H2O2 to which the operators will be subject.
The international standards define the Exposure Limit Values (ELV) to chemical agents and recommend the reading of level of gases in the air.
The ppm readings, according to the international standards are always presented in terms of occupational exposure. The Threshold Limit Value – Timeweighted Average TLV-TWA (Weighted average concentration for a normal 8-hour day of work and for a 40-hour week, to which workers may be repeatedly exposed, day after day without adverse health effects) defined for the hydrogen peroxide is 1 ppm.

This means that a momentary reading does not reflect the real occupational exposure determined by the standards.
The sensor should not be installed on the sterilizer itself because that positioning would not reflect the environment around the sterilizer and would be circumscribed to the sterilizer.
The sensor you use must allow validation and calibration according to the applicable standards.
The sterilizers produced by Sterifast, Lda. have been assessed by an independent laboratory and the results show that the readings are below the exposure limit values defined by the standards.

38. What happens if the electric power fails?

If there is a power failure, the sterilizer re-starts automatically. When the power returns, the sterilizer makes a ventilation cycle to be able to open the door.
(NOTE: the materials inside the chamber cannot be considered sterile).

39. What happens if the chamber transducer fails?

If the cycle is running, the sterilizer aborts the cycle.
If the sterilizer is turned off, when turned on, the sterilizer will not continue.

40. What happens if the software fails?

If there is a software failure, the printout will be interrupted in the phase where the failure occurred. Please call the technician.

41. What is the Lifetime of the Sterilizers?
Sterifast assures the lifetime of the sterilizers until 10 years.
Also, we assure the supplying of the spare parts for the sterilizers during 10 years.

42. How to dispose of the sterilizer at the end-of-life?

Contact the companies responsible for Waste Collection of Electrical and Electronic Equipment, or Follow the institution's protocol for the equipment at the end of life.

FAQ's Just for Technicians

T1. The door does not open automatically. What should I do?

Check in the Supervision Software, the position of the microswitches of the door's movement.
Check if the relays of opening and closing movements are properly seated.
Check if there is a burned relay.
Check if the chamber transducer is giving the atmospheric pressure value. If the transducer connector is disconnected, the doors will not open.
Check if the door motor is damaged.

T2. It does not reach the necessary pressure in the chamber during the diffusion. What can I do?

The chamber pressure may not fluctuate during the diffusion if the devices are cold or if there is condensation of H2O2 in the chamber.
The vaporizer valve may not be opening, the capillary tube may be obstructed, there may be lack of H2O2 in the tank (the dosing peristaltic pump may not be pumping the liquid, it can be burned or the rubber of the pump can be deteriorated, or the wire of the dosing pump can be disconnected). Check with the Supervision Software if the output to the dosing pump is active.
If the system does not reach the pre-determined pressure during the diffusion, the system will abort for maximum time of the phase and jumps to emergency ventilation. The devices will not be sterilized.
If during the diffusion phase, the system reaches a higher pressure than the first pre-determined, it fails to open the vaporizer valve.
If the pressure during the diffusion is in the correct range, the cycle will proceed.
If the pressure evolves to a positive value, above a second pre-determined value, the system will abort and jumps to emergency ventilation.
Note: If the machine does not pass this phase, it can be stopped manually, using the codes indicated in this manual.

T3. The vacuum pump heating valve is not sealing. Chamber pressure does not go below 200mbar. What can I do?

Check the solid-state relay.

T4. The sterilizer gives maximum time in the aeration phase. What to do?

The aeration filter may be obstructed. You should replace the aeration filter.

T5. The sterilizer does not make aeration. What should I do?

The aeration valve is not opening. Please check the valve.

T6. There is a smell of oil near the machine during the regular operation. What should I do?

It is necessary to replace the filter of the oil separator and the molecular sieve.
If there is a lack of tightness of the doors, the vacuum pump will work more time than the normal at atmospheric pressure. It will overheat and vaporize the oil, and the oil separator will not condense the oil in it.
In the place where the machine is installed, there should be 5 air renovations per hour.

T7. The Supervision Software is not showing the temperature value. What should I do?

The reason may be a broken wire or failure sensor. A button will appear to inform that the sensor is damaged. Please replace the sensor and press “reset”.

T8. Touch Screen of unclean side does not start the program. What should I do?

It does not have communication with the PLC. Please check the connections, change the wires or check the DATA Switch.

T9. Heating element does not heat. What should I do?

Check if the heating element has 230/110V, and if there is no cutting on security between solid state relay and the heating element connection.
Check the related solid-state relay, and also if the doors have no broken wires.

T10. Safety door lock is no working. What can I do?

Check the connections to the electrical board. Possibly there is a broken wire.

T11. The Plasma generator is not working during the cycle. What is happening?

Check the electrodes of the generator. Check if the isolation between the electrode and the screw still exists. Check if there is continuity between the end of the electrode and the connection of the high voltage wire. If not, please replace the electrodes.

Check the solid-state relay.

Note: For this action, it is necessary to confirm that the sterilizer is turned OFF.

Check the output to the Supervision Software. If the pressure is less than 1mbar, the system will disconnect the High Voltage Transformer.

T12. The glass of the Plasma Generator is dark. What should I do?

Disassemble the plasma generator from the sterilizer and on a worktable disassemble all the generator components. Clean the glass with a scotch brit mop. Replace the gaskets and the electrodes.

Note: The glass has one mark of position in relation to the generator body. When assembling back the components take in consideration that mark.

T13. How should I replace the oil of the vacuum pump?

First of all, disconnect the Sterilizer before removing the external panels. Use a tray to remove the oil. Loosen the screw indicated on the vacuum pump.

Wait the necessary time to let the maximum quantity of oil to come out.

Before refilling with the new oil, disassemble and clean the oil level glass. Loosen the two screws that fix the glass base, clean all pieces carefully and re-assemble the oil level glass. Put the glass cap and refill with the new oil until it reaches the indicated level.

Replace the oil separator filter and also the molecular sieve

Technical Specifications

Models: S - STERIFAST E - ECOPLASMA		**S50 / E50** **1SD**	**S50 / E50** **2SD**	**S110 / E110** **1SD**	**S110 / E110** **2SD**	**S160 / E160** **2SD**
Automatic Sliding Doors		1	2	1	2	2
Useful Volume		44 Liters		107 Liters		158 Liters
Total volume		47 Liters		109 Liters		162 Liters
Chamber Dimensions (mm)	W	420		420		420
	H	180		420		420
	D	620		620		920
Sterilizer External Dimensions (mm)	W	700	700	700	700	700
	H	1700	1700	1800	1800	1800
	D	790	840	790	840	1140
Weight (Kg)		200	210	260	270	310
Power Supply	Voltage	230V / 380V + N + Earth	230V / 380V + N + Earth	230V / 380V + N + Earth	230V / 380V + N + Earth	230V / 380V + N + Earth
	Frequency	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz
	Power	2,9 kW	2,9 kW	3,3 kW	3,3 kW	3,7 kW

Table 5

Note: Different voltages are available only under request.

Warranty

Duration: 24 months.

STERIFAST and ECOPLASMA sterilizers are covered by a warranty against manufacturing defects.

To keep the warranty valid, the Sterifast sterilizers must be used under the recommendations instructed by Sterifast, Lda in this Instruction Manual and none but the trained and authorized technicians do the service and maintenance.

The sterilizers will lose their warranty if the instructions in this manual are not followed.

Sterilizers Lifetime

Sterifast assures the lifetime of the sterilizers until 10 years.

Also, we assure the supplying of the spare parts for the sterilizers during 10 years.

Dispose of the sterilizer at the end-of-life

Contact the companies responsible for Waste Collection of Electrical and Electronic Equipment, or Follow the institution's protocol for the equipment at the end of life.

Manufacturer Contacts

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CE 2460

Sterifast sterilization & disinfection

ecoPlasma

INSTRUCTION MANUAL

CE 2460

Sterifast sterilization & disinfection

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