CRISTÓFOLI
BIOSSEGURANÇA

Cristófoli is the only Brazilian Autoclave Manufacturing Company to have the certifications ISO 9001 - Quality Management System, ISO 13485 - Medical Devices - Quality Management System - Requirements for Regulatory Purposes, ISO 14001-Environmental Management and BPF* (ANVISA/RDC Nº59).

ISO 9001:2008
FS 509853

ISO 13485:2003
MD 531811

ISO 14001:2004
EMS 509854

Autoclave Vitale Plus

CRISTÓFOLI'S MISSION

Protect life through biosafety.

CRISTÓFOLI QUALITY AND ENVIRONMENTAL POLICY

Cristófoli Equipamentos de Biossegurança Ltda., established at Rodovia BR-158, nº 127, Jardim Curitiba in Campo Mourão, Paraná, Brasil, manufactures biosafety equipment to assist the health field having as policy: "Fulfill better and better its mission as an institution, seeking for continuous improvement of its products and processes, adopting preventive and corrective measures in the company's functional and administrative areas to serve even better its clients.

This commitment implicates in accomplishing the applicable legislation, standards and environmental requirements with the purpose of preventing pollution and minimizing the impacts caused by its productive activities, contributing this way to enhance people's health".

*BPF - Boas Práticas de Fabricação: Brazilian standard similar to the GMP - Good Manufacturing Practices (FDA / US).

"Cristófoli. Valuing Life!"

Thanks for choosing us. You, our clients, are the reason of Cristófoli's commitment.

We put together this manual to guide you as best as possible, in the use and maintenance of your Cristófoli Autoclave.

We would like to thank all our customers, partners and employees for helping us to continually improve and innovate our products and services. Special thanks to Liliana J.P. Donatelli, Cristófoli's Biosafety Consultant who provides a valuable assistance in the coordination of Cristófoli's Biosafety Project; complementary products research; training of our employees, representatives and technicians; and as a lecturer of Biosafety Courses for professionals, academics and assistants.

For any commentaries or suggestions about our products, please get in touch with our **CSD** - Customer Service Department, through the address below.

CSD - CUSTOMER SERVICE DEPARTMENT
Cristófoli Equipamentos de Biossegurança Ltda.
Rodovia BR-158, nº127, Campo Mourão, Paraná - Brasil.
CEP 87309-650
Fax: 55 (44) 3518-3438
E-mail: comex@cristofoli.com

INTRODUCTION

This equipment was developed to assist you in the procedure of steam sterilization of articles/instruments by using steam under pressure. We have intensively dedicated ourselves in order to guarantee your total safety. We hope in this way to obtain your full satisfaction.

The purpose of this manual is to familiarize you with the features and proper operation of your autoclave so you know how to take good care of it, obtain the best results in sterilization and drying, as well as increase the equipment's life span.

For those who have used only the dry heat sterilizer (Pasteur's oven) for sterilization, we recommend extra attention to this manual. Autoclave sterilization, although quicker and more efficient, requires totally different procedures and handling, while still keeping a simple operation.

All the data on Biosafety in this manual were obtained through the research on relevant and reputable national and international publications about Biosafety, with the objective of providing updated information on the subjects related to infection control and sterilization process. The Brazilian Legislation, National and International Standards were also taken into consideration.

It is important to know some aspects that can jeopardize this warranty as a result of negligence, improper use, unauthorized repairs, etc.

The Warranty Certificate can be found on page 34.

MANUFACTURER
Cristófoli Equipamentos de Biossegurança Ltda.
Rod. BR 158, nº127 - Campo Mourão - PR - Brasil
CEP 87309-650
CNPJ 01.177.248/0001-95 - Inscr. Est. 90104860-65
Website: www.cristofoli.com - e-mail: cristofoli@cristofoli.com

Responsible Technician
Eng. Marcos Fuchs
CREA PR - 70700/D

CONTENTS

PLEASE READ ALL THE INSTRUCTIONS IN THIS MANUAL BEFORE USING YOUR CRISTÓFOLI AUTOCLAVE.
INCORRECT USE MAY RESULT IN STERILIZATION FAILURE AND/OR ACCIDENTS!

LEGEND OF SYMBOLS


Caution! Consult accompanying documents

Autoclavable

*Boas Práticas de Fabricação


Alternate Current


Caution! Hot Surface


Date of manufacture

Maximum pile


Class II Equipment


This side up


Manufacturer

*BPF: Brazilian standard similar to the GMP - Good Manufacturing Practices (FDA / US)


Fragile - Handle with care

ISO 9001:2008
ISO 9001

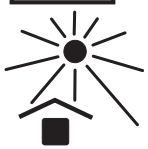
ISO 13485:2003
ISO 13485

ISO 14001:2004
ISO 14001


Keep dry

Batch code

Serial Number


Keep away from sunlight


Reciclable


Dangerous electrical tension

IMPORTANT SAFETY INFORMATION

Before using your autoclave **Vitale Plus**, it is necessary to observe some safety measures. Autoclaves are equipment which work at high temperature and pressure, therefore they must be handled by qualified and well-informed personnel, regarding their features and functioning. It is essential for such qualification that the operators read all the instructions carefully before using the autoclave to make sure to understand them correctly. The intended use of this equipment is to perform sterilization on dental, medical and hospital instruments/articles resistant to the temperature of 135ºC, steam and pressure.

WARNINGS!

►Before sterilizing any articles, make sure you first check with their manufacturer if they are autoclavable (resistant to the temperature of 135ºC and the presence of steam and pressure).

►**Do not** allow patients or especially children to get close to the autoclave.

►Install the autoclave in an exclusive sterilization room.

►**Never** warm up or sterilize any kind of food in the autoclave.

►**Never** make any kind of experiment with animals in the autoclave.

►**Never** make any kind of use of this equipment other than the ones described in this manual.

SPECIAL MEASURES AND OBSERVATIONS DURING THE USE OF THE AUTOCLAVE:

►Always make sure the door handle is properly locked before switching the autoclave on. See "*How to Use the Autoclave Vitale Plus* " (Item c, page 14). **Not following this procedure may cause the door gasket to pop off**.

►When sterilizing instruments that with different autoclaving specifications simultaneously, as instruments that support different levels of pressure (1.2 or 2.1kgf/cm^2) or temperature (121 or 135ºC) the operator must choose the cycle of lower temperature/pressure offered by autoclave.

►When unlocking the handle, the autoclave door should open easily. **Never** force the door to open the autoclave!

►When the door is opened at the end of the cycle to accelerate the cooling process, it is normal that some steam comes out through the door.

IMPORTANT! Always make sure you unplug the equipment to perform any kind of maintenance, (like everyday cleaning or simply changing the fuse).

►**We recommend** reading this manual until it is fully understood. Keep it at hand and use it as a constant reference source.

INSTALLATION INSTRUCTIONS

The equipment must be always carried by two people to prevent it from falling or causing an accident. The storage/installation must be done in a place protected from the weather action (indoors) in normal temperature conditions on a counter that can bear the weight of the autoclave.

Cristófoli Autoclave Vitale Plus can be easily installed. Check if the wiring and voltage of your building are in accordance with the specifications below by consulting a professional electrician **or** Cristófoli Authorized Technical Assistance. See *"Warranty Certificate"* and *"How to Proceed When Service is Needed"* (Page 34).

PHYSICAL INSTALLATION

Install the autoclave on a flat, leveled and firm surface at a proper height for the operator to handle it (approximately 80 cm / 2.6 feet from the ground). Leave enough room close to the autoclave for the proper handling of the materials to be sterilized. Install the autoclave in a ventilated and clean place, apart from the room where the patients are treated. The ideal place for the installation of the autoclave should be a separate sterilization room.

Important! Install your autoclave where it can be easily unplugged.

ELECTRICAL INSTALLATION

1►Check if the voltage of the autoclave is the same of the place where you are going to install it. To do that, simply look at the identification label in the back of the autoclave. See *"How to Identify your Autoclave"* (Fig.24, page 26).

2►For the installation use a grounded outlet (3 pins, 2P +T, 20A) connecting phase/neutral or phase/phase on the side pins and grounding on the central pin (Fig. 2, page 8). **Never connect the grounding on neutral**.

ATTENTION! As in any other electrical device, grounding is very important for the safety of the operator and the warranty of your equipment. Therefore, **never** remove or cut the plug's central (grounding) pin off. **Non-compliance with this requirement may damage your autoclave**. **Cristófoli is not responsible for damages caused by inadequate installations and/or voltage**.

3►**Never** use extensions, voltage transformers or any kind of adapters (Fig.2A, page 8).

4►For the proper functioning of your autoclave, the electrical voltage must be stable, in other words, without oscillations. Consult a professional electrician to check the electrical wiring in your building and make sure they are according to the specifications required. **It is mandatory the use of an exclusive circuit breaker for the outlet where you intend to install your autoclave**. If after following all the specifications, the electrical current is still oscillating, contact your local electricity company for repairs.

The electrical installation must follow the data from table below.

MODEL	NOMINAL CURRENT	CIRCUIT BREAKER	VOLTAGE	WIRING GAUGE
Vitale Plus 12 - 127 V	10 A	1 Breaker 15 A.	(Brazil) 127 V AC » 114 V - 140 V 220 V AC » 198 V - 242 V (Europe) 230 V AC » 207 V - 253 V	For distance of up to 5 m (16 ft from) the circuit breaker to the outlet used by the equipment, use 2,5 mm wiring. For 5 to 15 m (16 to 46 ft): 4 mm. For 15 to 50 m (46 to 164 ft): 6 mm.
Vitale Plus 12 - 220 V	6 A	1 Breaker 10 A.		
Vitale Plus 21 - 127 V	12 A	1 Breaker 20 A.		
Vitale Plus 21 - 220 V	8 A	1 Breaker 15 A.		

Table 1

Note: In areas where voltage is 220V:
PP (Phase-Phase) use a "bipolar" breaker
PN (Phase-Neutral) use a "unipolar" breaker connected to Phase.

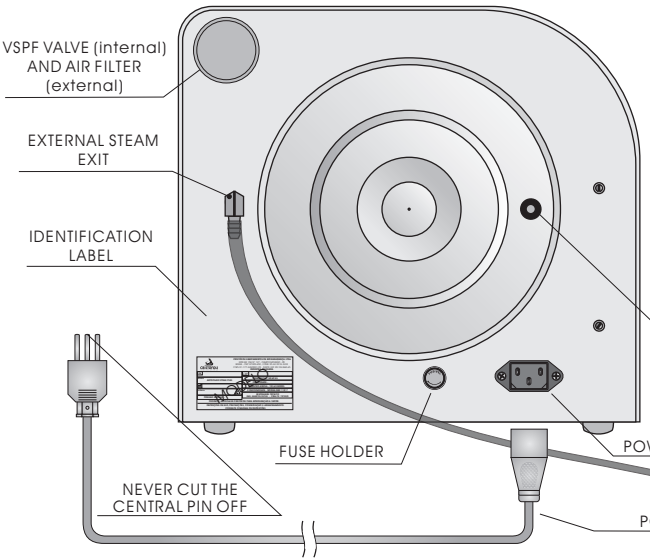


Fig.1

ATTENTION!
GROUNDING IS ESSENTIAL

Bipolar plug e wall outlet with grounding
(three pins or 2P+T) 20 A.

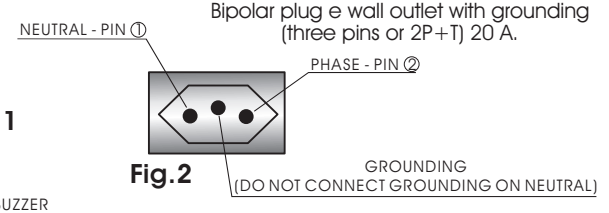


Fig.2

CONNECTION	PIN ①	PIN ②
127 V	NEUTRAL	PHASE (127 V)
220 V	PHASE (127 V)	PHASE (127 V)
220 V	NEUTRAL	PHASE (220 V)

Table 2

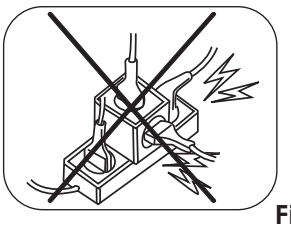


Fig.2A

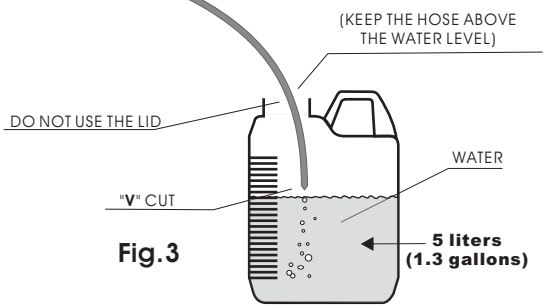


Fig.3

HYDRAULIC INSTALLATION

IMPORTANT! For the correct connection of the components, it is essential to read the Instruction Manual.

Purchase a heat resistant rubber hose (5"/16, 300 psi as sample provided) and connect it to the external steam exit (Fig.1) located in the back part of the autoclave, put the clamp on (also provided, Fig.15, page 12) and fasten it with a screwdriver. The other end must be connected to the plumbing system, into a special pipe that can tolerate at least 100ºC (212ºF) or to an open container positioned about 40 cm below the level of the autoclave with water inside for steam discharge (Fig.3), in this case, the hose must be **above the water level** with a **"V"** cut on its end. It also must be inspected **yearly** for obstructions and general condition.

NOTE: To replace the hose of the external steam exit, make sure the autoclave is cold and unplugged from the electrical outlet, loosen the clamp and replace the old hose by the new one, put the clamp back on and fasten it.

WARNING! Never use a plastic hose, the heat will melt it causing an obstruction of the external steam exit.

UNLOCKING THE EQUIPMENT

For your safety and traceability of the equipment, the autoclave Vitale Plus 12/21 is electronically locked by the manufacturer, therefore, in order to use the autoclave for the first time, the owner will have to unlock it. When the autoclave is turned on, the display will 4 messages alternately:

EQUIPMENT LOCKED → E-MAIL: COMEX@CRISTOFOLI.COM → OR ACESS CRISTOFOLI.COM → SERIAL NUMBER VPN*-00000/00

How to receive the unlocking code:

The owner/operator must access Cristófoli Biossegurança website, www.cristofoli.com, menu "*Technical Assistance*", Unlocking the Autoclave and provide the following information: serial number shown in the autoclave display, name of the company or owner's full name; contact; full address; telephone number, cell phone number; fax number; e-mail and FEIN number. After a few minutes, the e-mail address mentioned at the time of the registration will receive the unlocking code. In case there's any kind of difficulty, please contact Cristófoli through the e-mail comex@cristofoli.com.

How to unlock the autoclave:

1. Once you have the unlocking code, press **START**.

2. The display will show INSERT CODE and VPN*- the cursor will be flashing. Press **MODE** to change the numbers from 0 to 9 and press **START** to confirm the number shown and move to the next step, press **CANCEL** to return to the previous number.

3. By confirming the last number, the system will check if the code is correct. If it's ok, the display will show EQUIP. UNLOCKED!. The autoclave will be ready for use after a few seconds.

4. In case the code inserted is not correct, the display will show CODE ERROR for some seconds and return to the code insertion stage.

5. If an incorrect code is inserted for 3 consecutive times, the system will reset the operation and show the 4 initial messages again, the owner/operator must then begin the whole process again.

*** -** digit which varies according to the model of the equipment.

DATE AND TIME ADJUSTMENT

Right after unlocking the equipment and whenever it is unplugged from the power supply and plugged in again, the system will ask for the time and date adjustment, the display will show the message: ADJUST DATE/TIME?

Adjustment Procedure:

1. To adjust, press **START**. To skip this part, press **CANCEL**, the time will not be adjusted and the default values will be selected (January 1st 2009, 6h).

2. The display will then show INSERT DATE and the default date (01/JAN/2009). The information to be adjusted will be flashing.

3.Press the **MODE** key or **CANCEL** to adjust the information.

4. Press **START** quickly to alternate between the information (day, month and year) and keep it pressed until you hear the confirmation beep of the data inserted.

5. The display will then show INSERT TIME and the default (06:00 AM). The item to be adjusted will be flashing.

6. Press **MODE** or **CANCEL** to adjust the information. **Note:** The am/pm mode cannot be adjusted directly.

7. Press **START** quickly to alternate between hours and minutes, keep it pressed until you hear the confirmation beep of the data inserted.

AUTOCLAVE COMPONENTS IDENTIFICATION

1► **PANEL -** It is located the front part of the autoclave, It's made with ABS injected plastic (Fig.4).

2► **LID -** Located right behind the panel, it's made of aluminum and it is responsible for closing the autoclave chamber (Fig.7).

3► **KEYBOARD -** Located in the panel, it is where the autoclave display and controls keys are (Figs. 4 and 5).

4► **DISPLAY -** It is where all the functions/messages of the autoclave are shown, it has two lines with 16 characters each. It's located in the center of the keyboard (Figs. 4 and 5).

5► **HANDLE -** Located in the front part of the autoclave (Figs. 4 and 5), it's used to open, close and lock the autoclave door (panel/lid set). To check the door correct locking position see Figs.17 and 18 (Page 13).

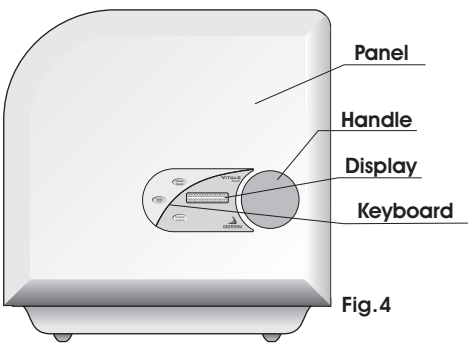


Fig.4

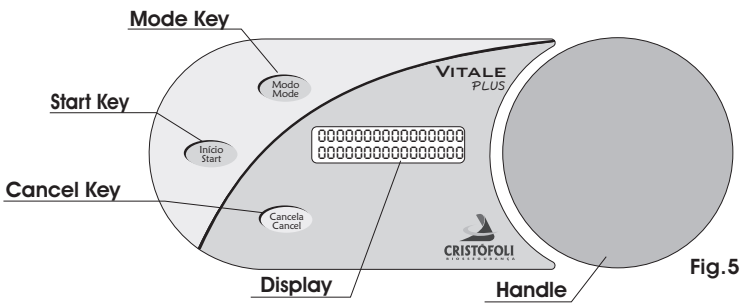


Fig.5

6► **DOOR GASKET -** Attached to the door, its function is to seal it with the chamber (Figs. 6 and 7), it also works as a safety device. See *"Safety Devices"* (Item 2, page 11). It requires **weekly** maintenance. See *"Preventive Maintenance"* (Page 25).

Fig.6

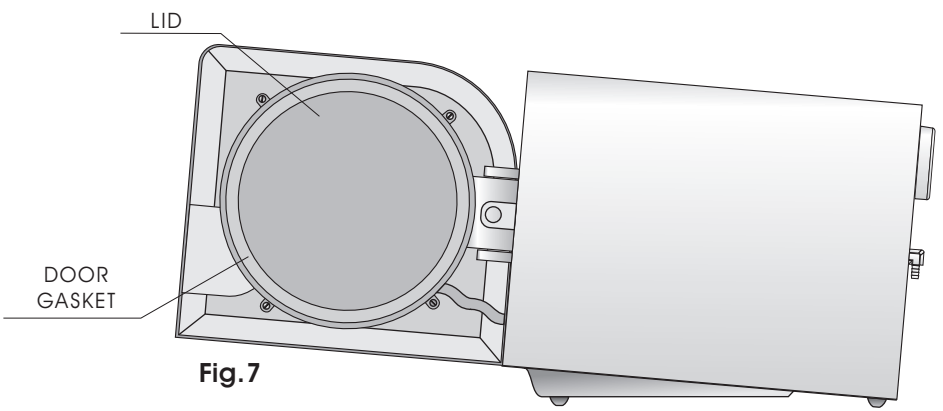


Fig.7

7► **VSPF VALVE -** The VSPF valve (patent pending) is one of the devices responsible for relieving the pressure inside the chamber in case it goes beyond 2,7 kgf/cm^2 or eliminate vacuum from the chamber when it is formed (Fig.27, page 31).

8► **INTERNAL STEAM EXITS -** There are two orifices inside the chamber (Fig.8) that work as conduits for the steam from the chamber to the solenoid valve. They must be inspected **daily** to be kept free from obstructions.
ATTENTION! When loading the autoclave, be careful not to put any instruments, packages or other articles against or too close to the internal steam exits. This will cause interference in the cycle. See item 6.4 (Page 22).

9► **EXTERNAL STEAM EXIT** - Located in the back part of the autoclave (Fig.1, page 8), it has a diameter of 5/16" for the connection of the discharge hose, which is then connected to the plumbing system or proper container for this purpose. It releases the cold air in the beginning of the cycle and the steam at the end of it. See "*Installation Instructions*" topic "*Hydraulic Installation*" (Page 8).

10►**SOLENOID VALVE -** Internal component of the equipment responsible for the deareration and depressurization. It opens it the beginning of the heating stage eliminating the cold air from the chamber, then it shuts down to allow pressure build up for the sterilization and opens again at the end of the cycle for the depressurization of the chamber (Fig.28, page 31).

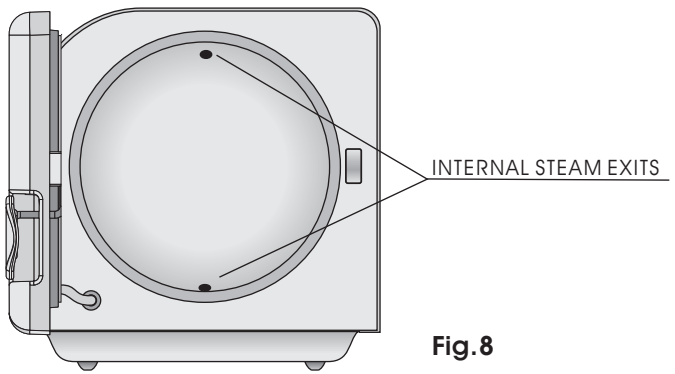


Fig.8

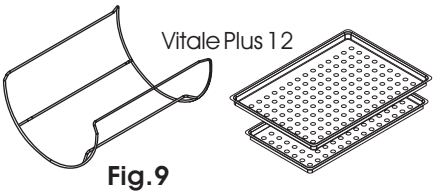


Fig.9

Fig.10

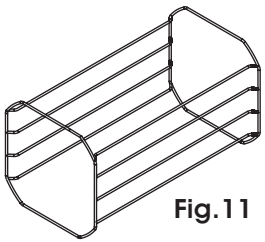


Fig.11

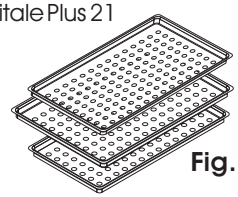


Fig.12

11►**TRAYS HOLDER -** It's provided 1 tray holder for each model, Vitale Plus 12 (Fig.9) e Vitale Plus 21 (Fig.11).

12►**TRAYS -** Provided are 2 trays for Vitale Plus 12 (Fig.10) and 3 trays for Vitale Plus 21 (Fig. 12), to keep the instruments to be sterilized free from any direct contact with the water and internal surface of the autoclave.

13►**MEASURING CUP -** Used to measure the right amount of **distilled water** necessary for the sterilization process (Fig.13, page 12).

14►**POWER CABLE** - Used to connect the equipment to the electrical outlet, (Fig.14, page 12).

15►**CLAMP** - Used to fasten the discharge hose to the external steam exit, (Fig.15, page 12).

16►**BUZZER** - Device used to emit the beeps produced by the autoclave, (Fig. 1, page 8).

Fig.13

Fig.14

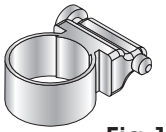


Fig.15

SAFETY DEVICES

The autoclaves **Vitale Plus** have the following safety devices:

1► **TEMPERATURE X PRESSURE DATA CROSSING ELECTRONIC SYSTEM -** Internal system of the equipment which will check the cycle, in case any problem is detected while reading the pressure in the chamber or if the autoclave pressure exceeds the safety limit, the cycle will be cancelled automatically.

2► **DOOR GASKET -** In case the pressure goes beyond 3 kgf/cm^2 or 294 kPa, the door gasket will detach from the edge of the door making a loud noise. See *"Autoclave Components Identification"* (Figs. 6 and 7, page 10).

3► **VSPF VALVE* -** Valve that works as an anti-vacuum system, (Fig.27, page 31).

4► **FUSE -** Safety device which purpose is to protect the building electrical wiring against peaks of energy. The fuse used is the 20 Glass AGLF- Quick Action (Fig.1, page 8). In case the operator wishes to replace the fuse personally, the table below will provide the necessary information;

VOLTAGE	~ VOLTAGE LINE	FUSE (Vitale Plus 12)	FUSE (Vitale Plus 21)
127 V	127 V (114 V - 140 V)	10 A (250 V)	12 A (250 V)
220 V	220 V (198 V - 253 V)	6 A (250 V)	8A (250 V)
230 V (Europe)	230 V (207 V - 253 V)		

Table 3

5► **THERMOSTAT** - Internal safety device of the equipment. Its function is to limit the excessive heating of the chamber during the sterilization cycles or in case of a circuit board malfunction (Fig.26, page 30).

6► **POWER CONTROL ELECTRONIC SYSTEM** - Internal system of the equipment which monitors the temperature and the pressure of the autoclave throughout the operation.

7► **MAINTENANCE MESSAGES -** From time to time, the autoclave display will show some specific preventive maintenance messages to warn the user about the biological test, air filter replacement and cleaning cycle. See *"Preventive Maintenance "* (Item 9, page 25);

***** Patent pending.

SAFETY NOTES

Warning! - During the autoclave operation, it is perfectly normal to hear some noises, some low, some loud. The noises are generated by the valves opening and closing, deaeration and depressurization, they are part of the proper functioning of the equipment. The door gasket and the VSPF valve, are safety mechanisms that when activated discharge pressure automatically producing a loud noise. This autoclave must be installed in a proper and exclusive sterilization room. Cristófoli is not responsible for accidents that might occur due to the starts caused by the noises produced by the autoclave.

The symbol 14 ⚠ appears in some places on the autoclave. This means those items require special attention and that the user must observe their references in the Instruction Manual provided with the equipment regarding potential hazards offered by them and any actions to be taken should an adverse situation occur.

The same applies to the symbol 13 ⚠ that calls the attention of the user/operator to the fact that the target surface is hot.

Cristófoli Equipamentos de Biossegurança Ltda, does not take any responsibility for failures and/or accidents caused by the non-observance of this warning.

HOW TO USE THE AUTOCLAVE VITALE PLUS

a► Open the door of the autoclave and use the measuring cup provided to pour the right amount of **distilled water** directly in the chamber **before** each cycle (Fig.16) according to the table below.

Amount of Distilled Water Used for Each Cycle	
Vitale Plus - 12 liters	Vitale Plus - 21 liters
150 ml / 5 fl.oz.	250 ml / 8.5 fl.oz.

Table 4

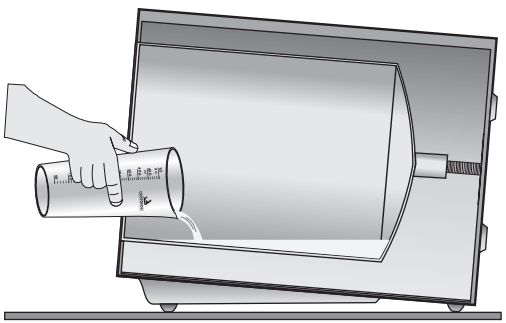


Fig.16

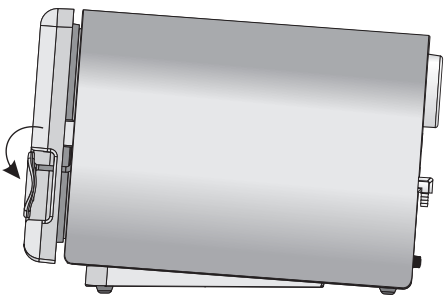


Fig.17

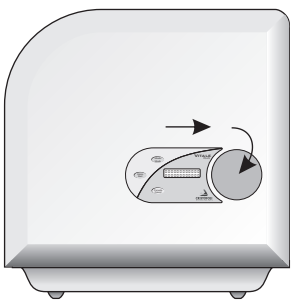


Fig.18

ATTENTION! Use only distilled water for sterilization. Non compliance with this recommendation may cause obstructions of the hydraulic system of the autoclave (internal pipes and/or valves), stains on the instruments and loss of warranty.

b► Load the autoclave with the materials to be sterilized, be careful not to lean them against the chamber walls or internal steam exits, that will cause interference in the cycle. Do not overload the autoclave. See "*Autoclave Proper Loading*" (Item 6.4, page 22).

c► Close the door of the autoclave. To close it correctly, having the door open and the handle all the way to the left, close the door by pressing it against he chamber, slide the handle to the right, and then press it all the way down until it's aligned with the panel, (Figs.17 and 18, page 13). To open the autoclave, follow the same procedure reversing this sequence.
ATTENTION! Non-observance of this recommendation may jeopardize the best functioning of your autoclave, it may even cause the door gasket to pop off. It is very important to have the autoclave properly closed and locked to avoid accidents and burns.

d► Plug the autoclave in and press the **START** key for 2 seconds, at this moment, the display will show the initial information (brand, model and software version), then the autoclave will beep twice and the display will show SELECT PROGRAM.

e► Select the cycle desired by pressing the **MODE** key. Each cycle has a specific operation time/temperature. Each time this key is pressed, the display will show the preset programs in the following order:

Pressing once:	WRAPPED INSTRUMENTS	10 min.
Pressing twice:	UNWRAPPED INSTRUMENTS	6 min.
Pressing three times:	PLASTIC AND COTTON	18 min.
Pressing four times:	FABRICS	30 min.
Pressing five times:	SURGICAL KIT	18 min.
Pressing six times:	LIQUIDS	30 min.
Pressing seven times:	CLEANING	3 min.
Pressing eight times:	ADDITIONAL INFO	(see "*Cycles and Messages*", page 16)

After choosing one of the preset cycles through the **MODE** key, press the **START** key.

In case this is not the first cycle of the day and the temperature of the autoclave is above 70 °C, the display will show COOLING and the respective temperature. As soon as the ideal temperature for the new cycle is reached, the autoclave will resume operation showing HEATING UP;

When the solenoid valve shuts down, the display will show the temperature and pressure rising gradually. When the autoclave reaches the ideal temperature/pressure for the selected sterilization cycle, it will beep 3 times and the display will show STERILIZING, remaining like that for the preset time according to the cycle chosen.

If the **Cleaning Cycle** is selected, the display will show the message: REMOVE TRAYS AND SUPPORT. Press **START** to confirm. Next, the display will show another instruction: ADD DILUTED CRUST REMOVER. Press **START** again to confirm. At the end of the depressurization, the autoclave will beep continuously and the display will show two messages alternately: CLEAN THE CHAMBER and READ CRUST REMOV. INSTRUCTIONS. See additional instructions in "*Preventive Maintenance* " (Item 10, page 25). After the cleaning cycle, the autoclave will carry out an automatic rinsing stage.

At the end of the sterilization, the solenoid valve will open producing a low metallic noise and the autoclave will beep 4 times. The display will show DEPRESSURIZING. During the heating and drying stages, the solenoid valve makes a humming

noise, similar to the one produced by electric motors, it may also open/close automatically during the drying stage.

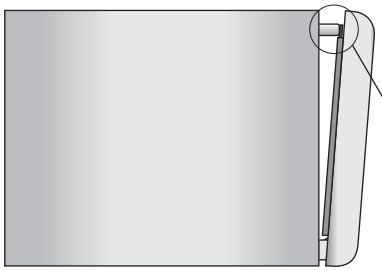
Note: For the autoclave model Vitale Plus 21, when selecting the **Surgical Kit** cycle, the surgical case must be placed in the central tray. For the Vitale Plus 12, the case (which must be compatible with the size of the autoclave) must be put on the top tray.

For the **Unwrapped Instruments** cycle, after the depressurization, the autoclave will show the message:

Press the **Start** key to proceed with drying. By pressing the **CANCEL** key, there will be no drying, (flash sterilization). **Important!** This option must be used only for immediate use of the instruments.

f► When the depressurization is over, the drying stage will begin automatically, the display will show the message DRYING and the temperature of the chamber. **The autoclave Vitale Plus dries with the door closed**. At the end of the drying process, the autoclave will beep 3 times and the display will show the message COOLING. At this moment, the operator must open autoclave door and leave it ajar to accelerate the cooling process of the sterilized articles. Within 5 minutes the autoclave will beep continuously and the display will show the message CYCLE CONCLUDED, only then, remove the sterilized articles. Press the **CANCEL** key to return to the program selection mode.

Upper view



ATTENTION!
When opening the autoclave for cooling, observe the correct position of the door in the picture. The autoclave Vitale Plus **dries with the door closed**, its opening is only necessary to speed up the cooling process of the instruments/articles sterilized).

Fig.19

ATTENTION! Even after the continuous beeps that indicate the conclusion of the cycle, the contents of the chamber will still be hot. **Never** touch the internal parts of the autoclave (chamber, trays, materials, etc.) when hot, wait for them to be cool enough before removing/handling. Remember to use proper gloves to handle the sterilized articles.

g► Turn the autoclave off after use. To do that, press the **CANCEL** key for 2 seconds. It's not recommended to disconnect the equipment from the outlet so that it is not necessary to adjust the time and date again.

The table below provides information about the equipment heating time, sterilization temperature, pressure and time as well as drying time of each cycle and maximum drying temperature.

Mode	Heating Time	Sterilization Temperature and Pressure	Sterilization Time	Drying Time
1- Wrapped Instruments	10 to 35 min.	134 °C / 216 kPa (2.1 kgf/cm²)	10 min.	35 min.
2- Unwrapped Instruments	10 to 35 min.	134 °C / 216 kPa (2.1 kgf/cm²)	6 min.	30 min.
3- Plastic and Cotton	8 to 35 min.	121 °C / 118 kPa (1.2 kgf/cm²)	18 min.	35 min.
4- Fabrics	8 to 35 min.	121 °C / 118 kPa (1.2 kgf/cm²)	30 min.	40 min.
5- Surgical Kit	8 to 35 min.	121 °C / 118 kPa (1.2 kgf/cm²)	18 min.	50 min.
6- Liquids	8 to 35 min.	121 °C / 118 kPa (1.2 kgf/cm²)	30 min.	- - - - -
7- Cleaning	10 to 35 min.	134 °C / 216 kPa (2.1 kgf/cm²)	3 min.	- - - - -
Maximum Drying Temperature: 121 or 134 °C (depending on the cycle chosen)				

Note: Heating time values are expressed considering the technical data chart (Table 8, page 33) regarding the autoclave proper working temperature range.

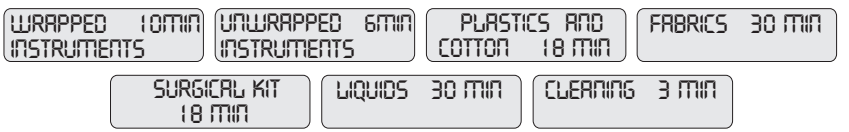
Table 5

CYCLES AND MESSAGES

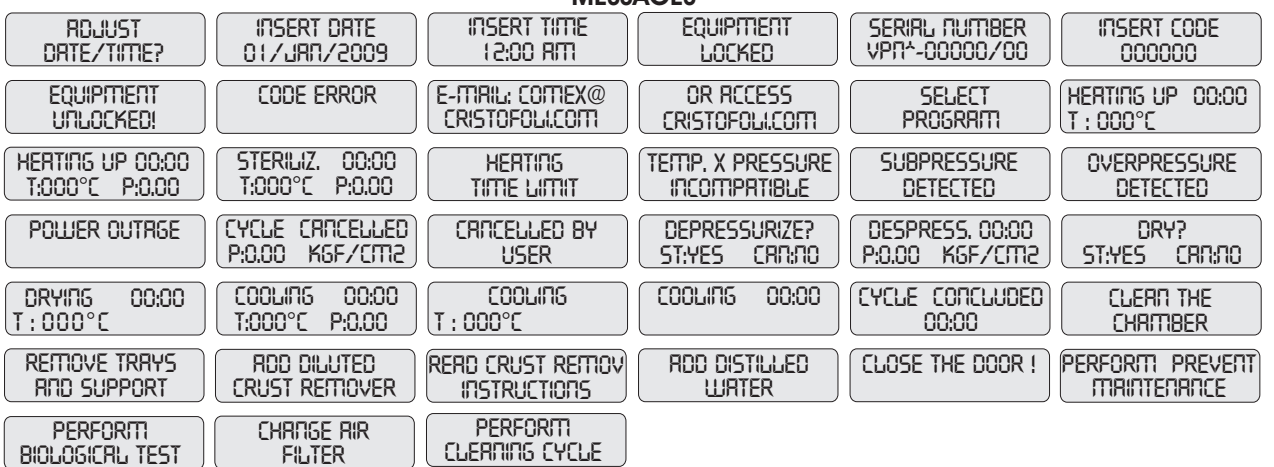
We have listed below the various messages displayed by the autoclave. The display represented below also shows the initial information (brand, model and software version) when the autoclave is turned on.

WHEN TURNED ON

CYCLE OPTIONS



MESSAGES



* Pressing **Start** on additional info mode, will show a submenu with some information about the equipment.

1 - Cycles initiated by the user;
2 - Cycles concluded by the equipment;
3 - Shows how many days ago and how many times the user was notified about performing the biological test;
4 - Shows how many days ago and how many times the user was notified about performing the preventive maintenance;
5 - Shows how many days ago and how many times the user was notified about the replacement of the air filter;
6 - Shows the software version.

ADVERSE SITUATIONS

1 ► Some situations may cause interruption and automatic cancellation of the cycle when:

a ► the ideal pressure/temperature is not reached due to steam/pressure leak, lack of water or overloaded chamber. In this case, the cancellation will occur within 35 minutes at the most;

b ► there's a power outage or voltage fluctuations. **Note:** The depressurization will occur when power returns;

c ► turning the autoclave on, there's already some pressure in the chamber. When that happens, the autoclave will beep continuously, the display will show CYCLE CANCELLED and the autoclave will depressurize;

► Confirm the cancellation of the cycle manually by pressing the **CANCEL** key;

► Check the possible causes, take the necessary measures to correct the problem and perform a new cycle to reprocess the articles according to the instructions on *"How to Use the Autoclave Vitale Plus"* (Page 13). Before starting a new cycle, the operator must check if there is water left in the chamber, which must be removed manually through the door with a clean and dry cloth that does not shed. **Attention!** For your safety, remember to use PPE (Personal Protective Equipment, like proper latex gloves);

Note: In the situations **b** and **c** above, if there's pressure inside the chamber, the display will show the question:

By pressing the **START** key, the valve opens for depressurization; by pressing the **CANCEL** key, the depressurization will happen with the valve closed, this will prevent the liquid from boiling over inside the containers when the liquids sterilization cycle was selected;

2 ► If the operator needs to interrupt/cancel the heating, sterilization or drying cycle, just press the **CANCEL** key. In this case, after the beep and the indication CYCLE CANCELLED on the display, the autoclave will beep continuously until the pressure falls to 0,0 kgf/cm^2 and the **CANCEL** key is pressed again to confirm the cancellation of the cycle (there will be no effect in case the **CANCEL** key is pressed while there's still pressure in the chamber);

3 ► **Cancellation of the Cycle -** If the cycle is cancelled, for any reason, the display will alternate between two messages, the message indicating the cycle cancellation (CYCLE CANCELLED P:0.00 KGF/CM2) and the message indicating the possible cause for that, which can be:

HEATING TIME LIMIT - the heating time limit was reached and there was no sterilization;

INCOMPATIBLE TIME X PRESSURE - The relation between the temperature and pressure of the chamber is incoherent;

SUBPRESSURE DETECTED - During the sterilization, the pressure decreased below the acceptable level;

OVERPRESSURE DETECTED - During the sterilization, the pressure increased above the acceptable level;

CANCELLED BY USER - The operator pressed the **CANCEL** key;

NO POWER - There was a power outage at the workplace (during the sterilization stage only).

4 ►In case of activation of one of the safety devices (sudden steam escape), generally caused by obstruction of the internal steam exit or by an obstruction of the solenoid valve, wait for complete depressurization before opening the door. The display will show CYCLE CANCELLED.

REQUIREMENTS TO BE OBSERVED FOR THE STERILIZATION PROCESS AND ITS STAGES

ATTENTION! Before beginning the sterilization procedures, the operator must be wearing thick latex gloves long enough to cover the sleeves of the long-sleeved apron, a plastic apron over the conventional one, a mask, protection goggles, cap and proper closed shoes.

The sterilization requires prior arrangements and it is part of a whole process. We suggest that the professional involved standardize his/her process. Prepare a written routine to avoid leaving any requirement behind. The preparation stages for sterilization are the following: Soaking; Cleaning; Visual Inspection; Rinsing; Drying; Packaging, Packing and Loading; Sterilization, Storage; Sterilization Monitoring and Sterilization Expiring Time.

1. SOAKING

Immediately after using the instruments/articles, the ideal is to soak them in a vat with enzymatic detergent, (preferably a double one with a drainer). Leave them soaking for 10 minutes, always follow the manufacturer instructions for dilution and soaking). If the instruments/articles are seriously contaminated with an excess of organic matter, it is advisable to rinse them previously so they do not render the solution ineffective. After that, remove them and proceed with the manual cleaning or use an automated method like the ultrasonic cleaners.

Do not use commercial (domestic use) detergents for soaking or washing instruments or other articles, these products may damage them.

Do not mix different kinds of metal at the same time during the soaking period, there could be electrolytic corrosion.

2. CLEANING

A rigorous cleaning of all the materials is one of the key elements for the success of the sterilization. The presence of organic matter (blood, pus, body fluids/secretions, fat, oil or any other type of dirt) protects the microorganisms, impairing and making sterilization very difficult. Inadequate cleaning or use of improper products may damage the instruments causing staining, darkening and corrosion.

New materials (just bought from the store) must be submitted to the cleaning process before sterilization for the removal of any kind of dirt or chemical products. This is necessary to avoid that they become darkened, stained or yellowish.

The enzymatic detergents are very efficient in removing organic matter, however some products used in dentistry adhere to the instruments and require mechanical removal (cement, for example). This manual removal (using a brush) must be performed with the instruments immersed in water to avoid the production of harmful aerosols (this happens when the cleaning procedure is performed with running water, e.g. under the faucet).

Besides being careful when removing materials adhered to the instruments, the operator must avoid the use of steel

wool, abrasive sponges or sponges with abrasive products because they will damage the instruments.

Automated cleaning systems like ultrasonic cleaners can be used to ease the removal of dirt, these are especially useful for cleaning diamond-tipped burs, whose grooves are inaccessible to the bristles of regular brushes.

The cleaning of high speed handpieces (turbines) and low speed handpieces (contra-angles) among other manual instruments must follow the manufacturers' recommendations, and be performed separately from other devices. Their lubrication must be done before the sterilization using proper and water-soluble lubricants.

3. VISUAL INSPECTION

The operator must perform a visual inspection of all the instruments, checking areas of greater difficulty of access, such as dented parts, gears recesses, grooves, etc., and proceed to mechanical removal if necessary.

4. RINSING

Rinse the instruments thoroughly. **Filtered** water for rinsing is **strongly recommended**.

5. DRYING

Dry the devices with a type of cloth which does not shed or good quality paper towels. The instruments may be dried in a dry heat sterilizer specially regulated for this purpose (50ºC / 122ºF). Do not let the devices dry naturally, besides the operational risk, this can cause staining.

6. ARTICLES, PACKAGING MATERIALS, PACKING AND LOADING

6.1 Recommendations about the kind of packaging and articles to be used in the autoclave

Before loading any instruments/articles into the autoclave, check the manufacturer's indications. Usually, autoclavable articles and/or packaging materials have an indication of resistance up to **135ºC / 275ºF** or the symbol 

on them.

Gauze and cotton: They must be wrapped **individually** for each patient.

Fabrics in general: They must be wrapped **individually**.

Small and/or light articles: Articles like **burs, cannulas, files** and **silicone identification rings**, must be **mandatorily** wrapped in a proper way (in sterilization envelopes), otherwise, they can be sucked during the process, causing an obstruction the autoclave valves and/or internal tubes.

Burs and files: Nowadays they generally have their **own casing** which protects them during the sterilization process. Another option are sterilization envelopes (pouches). Carbon steel burs are not appropriate for autoclave sterilization. When acquiring new burs, remember to wash them before autoclaving.

Boxes and trays: They must be **completely perforated** to allow good steam circulation and facilitate drying. They can be packed in pouches of plastic and paper (envelopes) or sterilization wraps (surgical grade paper), according to the specifications on this manual. The use of boxes is not mandatory but they protect the instruments and the packages integrity, since many of them are very easily perforated or cut by pointy and/or sharp instruments/articles. To sterilize non-perforated trays, sterilize them apart from other materials, leaving enough space between them to allow good steam circulation.

The **packages/bags** must be **small and compatible with the kind of job to be performed** (clinical set, periodontics set, etc), to avoid unnecessary reprocessing of the instruments that were not used. They must be **carefully prepared and completely sealed** to prevent their opening during the sterilization process, which may cause obstruction of the steam exit, jeopardizing the sterilization and causing damage to the equipment. Remove all the excess of air from the bags, it makes the steam flow more difficult.

Pointy or sharp Instruments: Exploratory probes, millimetric probes, periodontics instruments, etc, must be protected

with gauze or cotton to avoid cuts or holes in the bags, rendering them useless.

6.2 Types of Wrapping for Autoclave Sterilization

Pouches of plastic and paper (sterilization envelopes): Wrap the instruments directly into the pouches specially designed for this purpose. The microbe barrier of this material is over 90%. It has the advantage of allowing visual inspection of the instruments and they also contain chemical process indicators. Their correct opening provides a sterile surface for the placement of the instruments. There are also rolls of this same material which may come in a variety of widths and side folds to allow them to accommodate boxes. To seal the envelopes/packages use a sealing machine which gives you proper sealing quality (wider than 6 mm). The sealing may be simple, double or triple. Do not use autoclave tape to seal the envelopes, this procedure may compromise the packaging integrity and consequently the sterilization. The sterilization envelopes are for **single use only**, their reuse is **prohibited**.

Note: It's recommended the use of packaging produced in accordance with the EN 868 and/or NBR 13386/95 standards.

Sterilization Wraps: The advantage of the sterilization wraps is to be more resistant than the sterilization envelopes (surgical grade papers) because they are made with double sheets. They have a microbe barrier effectiveness of over 90%. They are sold in sheets and have as a disadvantage the need of preparation of the packages and use o appropriate tape to seal them. They are recommended for large boxes and can be used only once.

Perforated boxes especially designed for autoclaves: They can be made of stainless steel or autoclaving resistant plastic. Bur-guards and file racks must also be specific for autoclaving. Sometimes, bur boxes can fit bur-guards inside them. The dentist will evaluate if this is the best method to avoiding multiple packages. These boxes do not eliminate the need of involving the instruments to be autoclaved in a type of microbe barrier, represented by the materials mentioned above (envelopes or sterilization wraps). The professional in charge who is autoclaving instruments for immediate use may skip the final wrapping, but he/she must remember to take all the control measures, but remember this is advisable **for semi-critical articles only**.

When you acquire packaging materials, make sure they are registered with the competent health department of your country.

Other options: The market offers new products every day, so if you know there's a new product available, check its cost, benefits and if it was developed for the purpose you need. Contact the manufacturer if you have any doubts.

Never improvise different packaging materials (BRASIL 2006). All wrappings designed for the sterilization of dental, medical and hospital articles follow quality standards that assure steam penetration, absence of contaminants and sterilization maintenance during storage.

ATTENTION! Non-textile packaging or similar materials, although available on the market and even being registered at the competent health department of your country, are not recommended for gravitational autoclaves.

6.3 Instruments/Articles Packing Technique

There is a technique for packing instruments and other articles for autoclave sterilization when using sterilization wraps, it must follow a folding sequence as shown bellow (Fig.20).

The following folding sequence is not done at random. Its goal is to facilitate handling the packages during their use and avoid contamination when they're open.

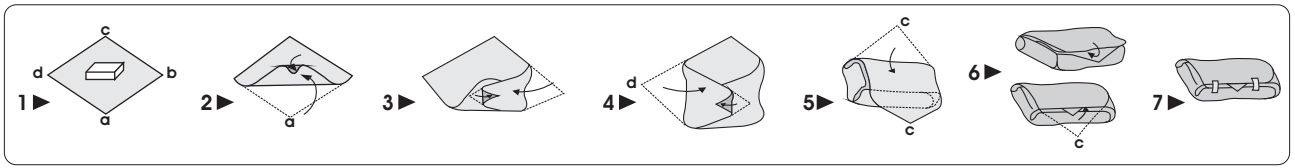


Fig.20

1► Place the article diagonally in the center of the wrapping;

2► Fold the corner "**a**" covering the article completely, leave a little tip outside the wrapping;

3► Fold the corner "**b**" the same way;

4► Repeat the procedure on corner "**d**";

5► Fold the corner "**c**" towards the operator;

6► Tuck the "**c**" corner into the folds already made and leave a little tip outside to facilitate handling and avoid contamination when opening;

7► Seal the package with appropriate autoclave tape for sterilization (process indicator) and identify the package by writing on the outside which articles it contains and the person responsible for the sterilization.

Note: When using sterilization envelopes, they must be placed on the trays with the **paper side facing up** (Fig.22), this favors the steam evaporation resulting in a quick and efficient drying. Get to know the Cristófoli support for envelopes (Fig.23) besides favoring the drying process, it will optimize the internal capacity of the autoclave allowing the sterilization of 13 packages (1 support, Vitale Plus 12) or 26 packages (2 supports, Vitale Plus 21). Never overlap the envelopes.

WRONG - Envelopes with plastic side up

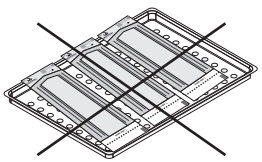


Fig.21

CORRECT - Envelopes positioned with paper side up

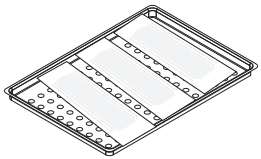


Fig.22

Cristófoli envelopes support
(accessory sold separately)

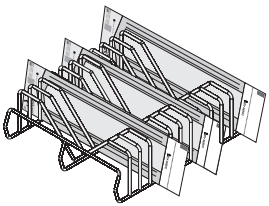


Fig.23

6.4 Autoclave Proper Loading

IMPORTANT! Use three barriers at the most for packing. For example, sterilization envelopes containing burs, inside a perforated box with other instruments involved in sterilization wraps.

6.4.1► Place the packages parallel to each other leaving spaces of at least half inch (1,3 cm) from each other. This arrangement allows good steam circulation and optimizes drying;

6.4.2► The standardization for loading the autoclave must be based on monitoring (Item 8, page 23). The autoclave can be loaded up to 75% of its chamber capacity, that means 5 envelopes for Vitale Plus 12 or 13 envelopes when using the support. The model Vitale Plus 21 can hold 12 envelopes or 13 with the support, it can also hold 2 supports simultaneously, allowing the sterilization of 26 envelopes at a time (packages 9 x 26 cm containing 6 instruments each).

6.4.3► Do not lean plastics or any other type of material against the chamber walls, there is a chance of overheating and that will damage the contents and/or the chamber's internal surface. It can also impair the steam flow, jeopardizing the sterilization and/or drying;

6.4.4► Make sure both instruments and packaging materials are appropriate for autoclaving and registered at the competent health department of your country.

6.4.5► Unwrapped Instruments:

- Use the unwrapped instruments **immediately after** their sterilization to avoid contamination. This must not be a routine procedure, it should be used for semi-critical articles exceptionally and only for immediate use;
- When placing unwrapped instruments on the autoclave's perforated tray, put some sterilization wraps in between them to avoid development of galvanic current;
- **Never** sterilize small articles without packing them.

6.4.6► **Do not** place hot instruments recently removed from the autoclave on cold surfaces. This may condense the steam inside the packages. Before handling them, cover the surface with paper towels or fabric, preferably sterile ones.

6.4.7► Handle the packages **carefully** so they are not ripped during loading and/or unloading procedures.

6.4.8► If you are using sterilization envelopes, place the packages on the tray with the paper side facing up (this makes drying more efficient), avoid leaning the packages on each other.

6.4.9► Use a special non-toxic marker to write the sterilization date, validity of the sterilization and the person responsible for it on the envelope top edge, out of the area where the instruments are. In case the package is made with fabric, write the data on the autoclave tape, use the same non-toxic marker.

7. STORAGE OF STERILE ARTICLES

The storage area should contain enclosed storage for sterile items and disposable (single-use) items. Storage practices for wrapped sterilized instruments can be either date or event related. Sterilized items and clean dental supplies should be stored preferably in closed cabinets (with the interior covered with Formica®, if possible) made exclusively for this purpose with doors and wire shelves. They must be easy to clean (cleaning should be done **weekly**) and located in a dry room with fresh air, free from odors or humidity. Dental supplies and instruments should not be stored under sinks, close to water pipes connections and/or drainage system or in other locations where they might become wet.

8. STERILIZATION MONITORING PROCESS

Monitoring is nothing more than controlling the sterilization. If all the indicators approve the cycle, that means the autoclave was used correctly. In order to do that, we use physical, chemical and biological parameters.

a) Physical - Time and pressure as established by this manual, they have to be watched by the operator and properly recorded for all cycles.

b) Chemical - It's suggested the use of indicator tapes for steam autoclaves (process indicators like autoclave tape and envelopes with indicators) on all packages/bags. They do not ensure sterilization, they only show that the package went through the process. Nowadays the market offers a variety of multi parametric indicators which evaluate more than just the sterilization factor, e.g. time and temperature. Others, more sophisticated, integrate time, temperature and presence of steam. Ideally, they have to be used in all cycles, or at least on a daily basis. The tests performed by Cristófoli show that the ideal position to place the test package is the upper tray, close to the door. Be careful when purchasing chemical indicators. Although most of them are reliable, some are specific for determined cycles.

c) Biological - Biological indicators (BIs, e.g. spore tests) are the most accepted method for monitoring the sterilization process because they assess it directly by killing known highly resistant microorganisms (e.g. Geobacillus Stearothermophillus, generally self-contained), rather than merely testing the physical and chemical conditions necessary for sterilization. Because spores used in BIs are more resistant and present in greater numbers than the common microbial contaminants found on patient care equipment, an inactivated BI indicates other potential pathogens in the load have been killed. Correct functioning of sterilization cycles should be verified for each sterilizer by the periodic use (at least weekly) of BIs. Every load containing implantable devices should be monitored with such indicators, and the items quarantined until the BI results are known.

However, in an emergency, placing implantable items in quarantine until spore tests are known to be negative might be impossible. Manufacturer's directions should determine the placement and location of BI in the sterilizer. A control BI, from the same lot as the test indicator and not processed through the sterilizer, should be incubated with the test BI; the control BI should yield positive results for bacterial growth. For your own safety, all tests must be documented and filed. The costs for the control measures such as the chemical and biological tests are the autoclave owner's entire responsibility.

9. STERILIZATION EXPIRATION TIME

Packages containing sterile supplies should be inspected before use to verify barrier integrity and dryness. Although some healthcare facilities continue to date every sterilized package and use shelf-life practices, other facilities have switched to event related practices. This approach recognizes that the product should remain sterile indefinitely, unless an event causes it to become contaminated (e.g., torn or wet package). Even for event-related packaging, minimally, the date of sterilization should be placed on the package, and if multiple sterilizers are used in the facility, the sterilizer used should be indicated on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure. If packaging is compromised, the instruments should be recleaned, packaged in new wrap, and sterilized again, (CDC 2003).

HOW TO AVOID INSTRUMENTS SUPERFICIAL STAINS AND/OR CORROSION

Stains on the instruments may have many different causes which can occur simultaneously, that makes it hard to identify them. The most common reasons are the use of non-distilled water and the use of instruments not appropriate for autoclaving.

SUPERFICIAL STAINS

1► Superficial round stains without a defined outline are caused by incorrect drying of the instruments before packing;

2► Yellow and dark brown stains located in the extremities of the instruments (do not mistake them with corrosion stains) are caused by inadequate soaking (pre-wash), which left some organic matter behind;

3► Yellow stains all over the instruments surface are caused by overheating during the sterilization process;

4► Grey-bluish stains are caused by inadequate removal of detergent and/or chemical substances;

CORROSION

Corrosion points are the most frequent damages. They cause breaking of the instruments and have their origins in halogen ions from saline solutions, chlorides, iodine, residues of body fluids/secretions, detergents and dirty or altered disinfecting solutions.

Another determinant factor is the quality of the instruments. Make sure the material you are acquiring/using is effectively the right one for all different purposes you may need.

The market offers an instruments protector which works as a stain and oxidation remover (*Surgi-Stain*) it is recommended by Guandaline (1999). The same author suggests subsequent lubrication with a mineral oil (*Premix-Slip*). **Attention!** These products are recommended only for stainless steel instruments.

POSSIBLE STERILIZATION FAILURES

1► Presence of residual air in the chamber and/or in the package;

2► Packages are too big and heavy;

3► Inappropriate wrappings (material composition) for sterilization in steam autoclaves;

4► Insufficient exposure time to the sterilizing agent;

5► Incorrect handling of the autoclave by the operator;

6► Obstruction of the internal orifices and/or steam exit of the autoclave due to the lack of daily cleaning;

7► Overloaded autoclave. The autoclave can be loaded up to 75% of its chamber capacity, that means 5 envelopes for Vitale Plus 12 or 13 envelopes when using the support. The model Vitale Plus 21 can hold 12 envelopes or 13 with the support, it can also hold 2 supports simultaneously, allowing the sterilization of 26 envelopes at a time (packages 9 x 26 cm containing 6 instruments each). The use measures should be standardized for all cycles and offices. For this standardization see "*Sterilization Monitoring Process*",(Item 8, page 23). Never overlap packages;

8► Tearing/puncturing of the packages while loading or removing them from the autoclave;

9► Lack of autoclave's preventive maintenance;

10►The chosen cycle is not suitable for the articles to be sterilized;

11►Equipment failure, it must be observed by the operator during the cycle.

ATTENTION - Sterilization failures are detected during the monitoring process.

QUALITY CONTROL

Cristófoli equipment are tested and monitored individually, according to the parameters of the Table 5 (Page 16). Besides the physical parameters, all autoclaves are tested with chemical emulators class 6. The tests with biological indicators are performed on a batch basis.

PREVENTIVE MAINTENANCE

Some preventive procedures are necessary for the best functioning and durability of your autoclave, the preventive maintenance corresponds to the **fulfilment of all procedures listed** below. See also pages 27 and 28:

1► **Use only distilled water**;

2► Keep the autoclave clean. For **aluminum chamber** autoclaves, wash inside the chamber with distilled water, neutral soap (in bar) and an **abrasive** synthetic fiber sponge, optionally, a stainless steel sponge may be used to add some shine;

3► To clean **stainless steel chamber** autoclaves, use only a soft, **non-abrasive** sponge with neutral soap (in bar) and distilled water, to remove the foam use a cloth that does not shed. Finish the cleaning with alcohol 70%;

ATTENTION! To clean the anodized aluminum trays use only a cloth that does not shed with alcohol 70%. The use of other materials and/or products may scratch or damage them.

4► The outside cleaning of the autoclave must be done daily using a soft cloth and neutral soap (in bar). Next, clean it thoroughly with a cloth and alcohol 70%. The handle must be also cleaned the same way before removing the material from the autoclave, after the sterilization;

5► Clean the door gasket **weekly** with a clean cloth that does not shed, dampened in warm water. Replace the door gasket of your autoclave **every 6 months;**

6► Perform the preventive maintenance on the VSPF valve **every 6 months** (it consists of replacing the internal safety valve that comprehends the seal and pin), replace the air filter of the VSPF valve **monthly**.

7► Replace the thermal paste of the heating element **every 6 months**;

8► The component "lid" (Item 2, page 10) must be replaced each 5 years;

9► **Biological tests, air filter replacement and preventive maintenance:**

The autoclave Vitale Plus 12/21 was programmed to alert the user/operator about some very important sterilization procedures:

- A biological test will be requested every 7 days, the display will show the message: PERFORM BIOLOGICAL TEST. For further information about how to perform the biological test in your autoclave, visit our site, ww.cristofoli.com, and go to the Biosafety menu;
- The autoclave will request the replacement of the air filter every 30 dias, the display will show the message: CHANGE AIR FILTER. See *"How to Proceed When Service is Needed "* (Page 34);
- The cleaning cycle will be requested every 30 days with the message: PERFORM CLEANING CYCLE. See item 10 below;
- The equipment will request the preventive maintenance every 180 days by showing the message: PERFORM PREVENT. MAINTENANCE. See *"How to Proceed When Service is Needed "* (Page 34);

10► We recommend a monthly cleaning of your autoclave with an anticrust product (*Clean Plus*), this product was successfully tested by Cristófoli. It promotes the cleaning of the chamber, internal valves and tubes and can be

purchased through your local Cristófoli dealer. The cleaning procedure is made through the autoclave cleaning cycle, the essential instructions shown on the display are described below.

***Clean Plus* - Use instructions:**

- Remove the trays and their support from the autoclave chamber;
- Put the product in a glass and add the correct amount of water for one regular cycle, according to the autoclave model (150 ml for Vitale Plus 12 liters and 250 ml for Vitale Plus 21 liters);
- After having added water to the *Clean Plus*, dissolve the mixture until it gets homogeneous and pour it in the autoclave chamber;
- Turn the autoclave on and select the cleaning cycle. As soon as the autoclave finishes the sterilization, it will depressurize. There's no drying stage for the cleaning cycle.
- Wait for the autoclave to cool down and clean it adequately as previously described on items 2 **or** 3 above;
- Run a new cleaning cycle again without the trays, support or instruments, using only distilled water this time. The cleaning process is then concluded.

HOW TO IDENTIFY YOUR AUTOCLAVE

The purpose of the metallic label located in the back of the equipment is to identify the autoclave technical data.

ATTENTION! - The removal of the identification label and/or any other labels/stickers affixed to the product will cause automatic loss of warranty.

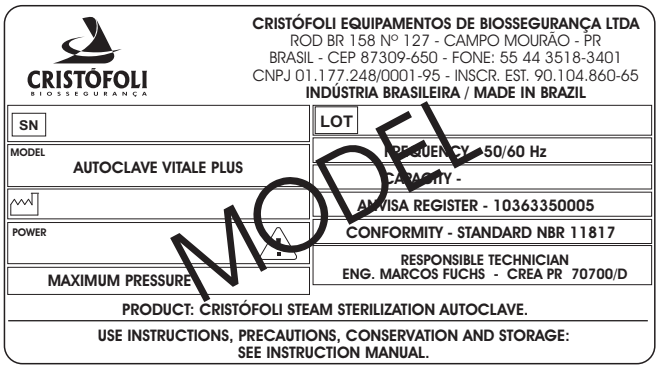


Fig. 24

Note: The label presented above is just a sample model for your reference.

PREVENTIVE MAINTENANCE TABLE

In order to help the operator to identify the several maintenance and monitoring procedures, we have organized them below in a table with their respective periodicity.

MAINTENANCE	DAILY	WEEKLY	MONTHLY	SEMESTRAL	ANNUAL	EVERY 5 YEARS
External cleaning	X					
Preventive cleaning (aluminum chamber)	X					
Preventive cleaning (stainless steel chamber)	X					
Door gasket cleaning		X				
Door gasket replacement				X		
Preventive Maintenance of the VSPF valve and replacement of the internal safety valve				X		
Air filter replacement			X			
Replacement of the thermal paste from the heating elements				X		
Replacement of the component "lid"						X
Performance of biological test		X				
Cleaning of chamber with anticrust product (*Clean Plus)*			X			
General maintenance at a technical assistance office				X		

Table 6

PREVENTIVE MAINTENANCE - FOLLOW-UP TABLE (operator use*)

The table below has the purpose to make it easier to follow the maintenance and monitoring procedures of the autoclave. The operator is supposed to fill out the blanks below in order to keep an organized written record.

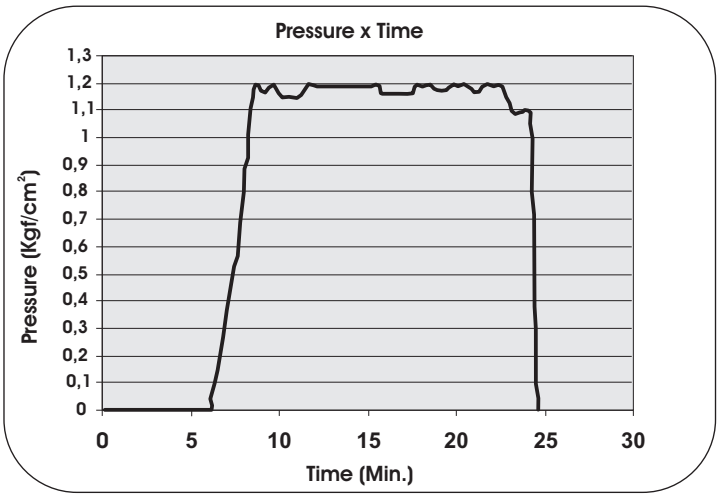
MAINTENANCE PROCEDURES	DATE	DATE	DATE	DATE	DATE	DATE
External cleaning	/ /	/ /	/ /	/ /	/ /	/ /
Preventive cleaning (aluminum chamber)	/ /	/ /	/ /	/ /	/ /	/ /
Preventive cleaning (stainless steel chamber)	/ /	/ /	/ /	/ /	/ /	/ /
Door gasket cleaning	/ /	/ /	/ /	/ /	/ /	/ /
Door gasket replacement	/ /	/ /	/ /	/ /	/ /	/ /
Preventive Maintenance of the VSPF valve and replacement of the internal safety valve	/ /	/ /	/ /	/ /	/ /	/ /
Air filter replacement	/ /	/ /	/ /	/ /	/ /	/ /
Replacement of the thermal paste from the heating elements	/ /	/ /	/ /	/ /	/ /	/ /
Replacement of the component "lid"	/ /	/ /	/ /	/ /	/ /	/ /
Performance of biological test	/ /	/ /	/ /	/ /	/ /	/ /
Cleaning of chamber with anticrust product (*Clean Plus*)	/ /	/ /	/ /	/ /	/ /	/ /
General maintenance at a technical assistance office	/ /	/ /	/ /	/ /	/ /	/ /

Table 7

***** We suggest making copies of this page so the operator may fill out and file all maintenance procedures and tests carried out in the autoclave. The form above is available for download in our website: www.cristofoli.com.

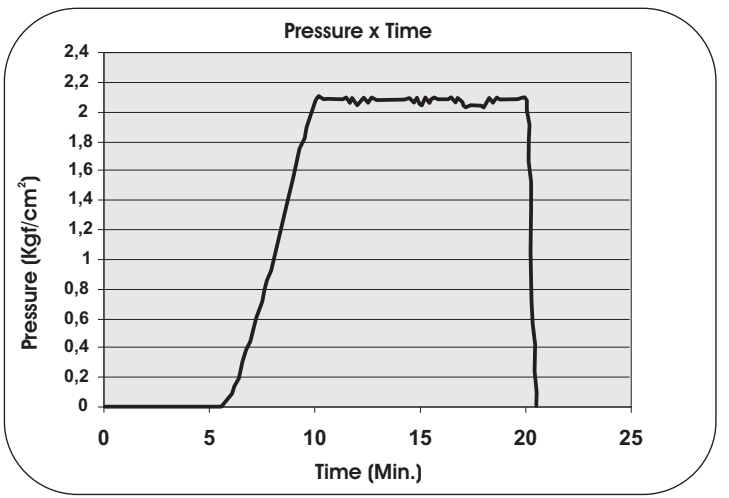
TIME X PRESSURE GRAPHS

Low Pressure Cycle



Graph 1

High Pressure Cycle



Graph 2

ELECTRICAL SCHEMATICS

Electronic circuit wiring positioning

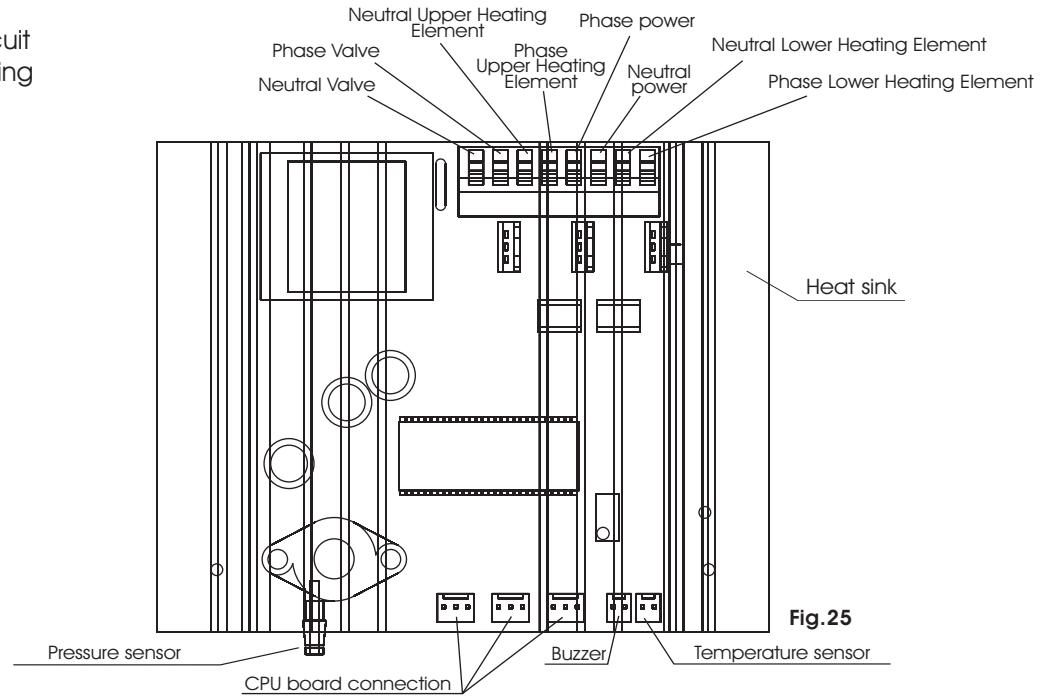


Fig.25

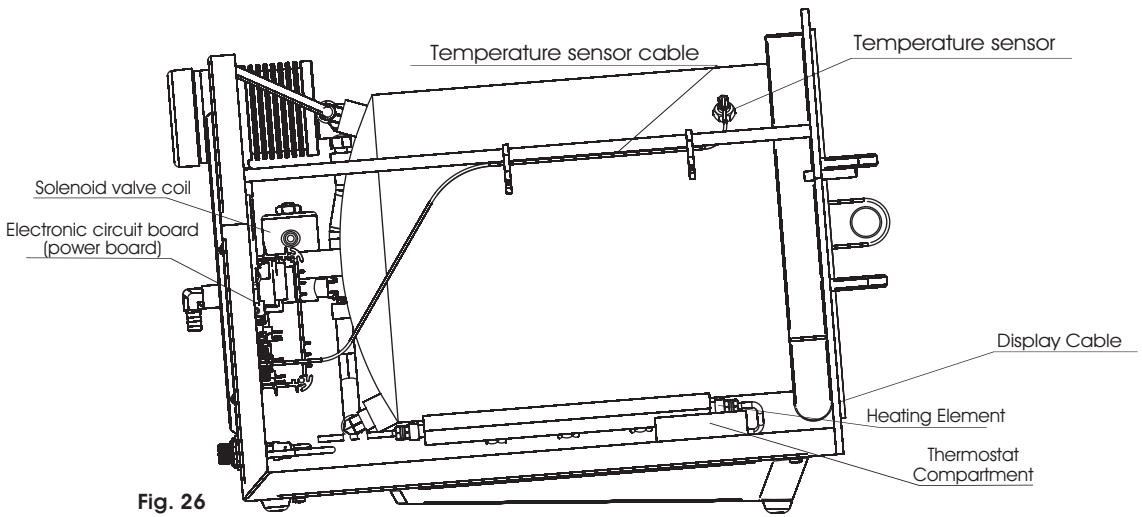


Fig. 26

HYDRAULIC SCHEMATICS

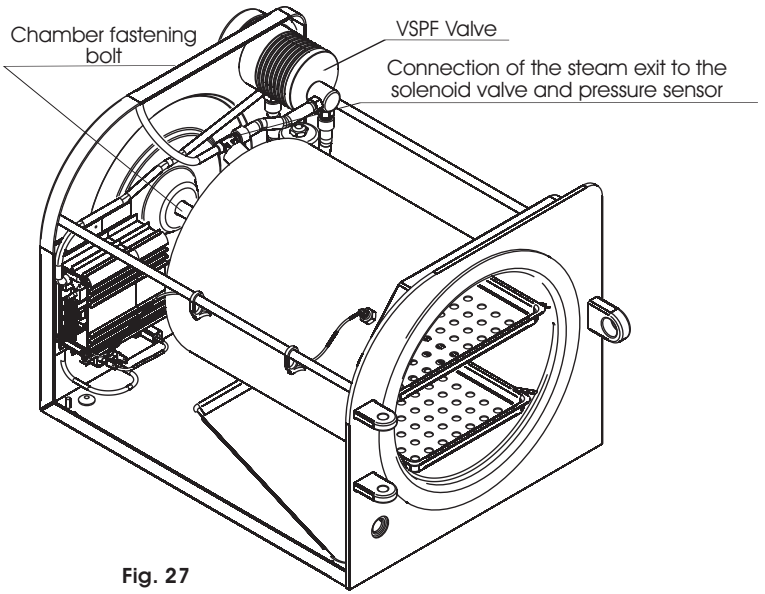


Fig. 27

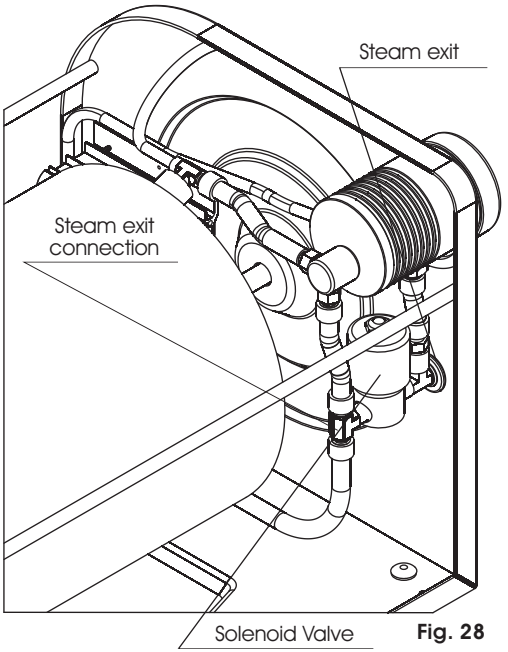


Fig. 28

TROUBLESHOOTING

ATTENTION! For any replacement of parts, contact your local dealer or the authorized technical assistance office. It's **strongly not recommended** the replacement of **any** parts by non-qualified people. We have listed below the most frequent problems and possible solutions the operator can try in his/her own office:

THE AUTOCLAVE DOES NOT SWITCH ON

POSSIBLE CAUSES	SOLUTION
• No power	• Check if there's a power outage in your area/building;
• The autoclave is not connected to the outlet	• Connect the power cable to the electrical outlet;
• The **Start** key was not pressed for 2 seconds to turn the equipment on	• Press the **Start** key for 2 seconds (until the initial information is shown on the display (brand, model and software version);
• The fuse has burned out	• Replace the fuse next to the power connector. See *"Installation Instructions"*, (Fig.1, page 8) and *"Safety Devices"*, (Item 4, page 12);
• Defective electronic circuit	• See *"How to Proceed when Service is Needed"* (Page 34);.

If the problem persists after the verification of all the items listed, contact your local dealer.

THE AUTOCLAVE SWITCHES ON BUT DOES NOT HEAT UP

POSSIBLE CAUSES	SOLUTION
• The operator connected the autoclave to the power source but didn't press the **Start** key	• Press the **Start** key after selecting the cycle on the **Mode** key;
• Nothing happens when the **Start** key is pressed	• See *"How to Use the Autoclave Vitale Plus"* (Page 13).
• The heating element has burned out • Defective thermostat • Defective electronic circuit	• See *"How to Proceed when Service is Needed"* (Page 34);

If the problem persists after the verification of all the items listed, contact your local dealer.

THE AUTOCLAVE PRESSURE GETS TOO HIGH, ACTIVATING THE SAFETY DEVICES

POSSIBLE CAUSES	SOLUTION
• Partial obstruction of the solenoid valve • Defective electronic circuit	• See *"How to Proceed when Service is Needed"* (Page 34);
• Obstruction of the hose connected to the external steam exit	• Remove the hose connected to the external steam exit and clear any obstruction. **ATTENTION**! Never use a plastic hose. See *"Installation Instructions ", topic "Hydraulic Installation"* (Page 8).

If the problem persists after the verification of all the items listed, contact your local dealer.

THE AUTOCLAVE TAKES TOO LONG TO BUILD UP PRESSURE OR DOES NOT KEEP IT, SHOWING THEN THE MESSAGE "CYCLE CANCELLED"

POSSIBLE CAUSES	SOLUTION
• The wiring voltage is lower than the one needed for the autoclave	• Have a professional electrician to make the necessary modifications of your workplace wiring. See *"Installation Instructions"* (Page 7).
• Pressure/steam leak through the VSPF valve	• See *"How to Proceed when Service is Needed"* (Page 34);
• Pressure/steam leak through the door gasket	• Perform preventive maintenance (Page 25);
• Overloaded chamber	• Do not put more instruments than specified in each bag /package. Use up to 75% of the chamber's capacity, that means, 5 envelopes (9 x 26 cm containing 6 instruments each) for Vitale Plus 12 or 13 envelopes when using the support. The model Vitale Plus 21 can hold 12 envelopes or 13 with the support, it can also hold 2 supports simultaneously, allowing the sterilization of 26 envelopes at a time . Remember to leave some space between the envelopes to allow good steam circulation and optimize drying;

If the problem persists after the verification of all the items listed, contact your local dealer.

TECHNICAL DATA

TECHNICAL DATA CHART	Vitale Plus 12 liters	Vitale Plus 21 liters
CERTIFICATIONS	The Autoclaves Vitale Plus are manufactured by Cristófoli Biossegurança, company which Quality Management System is certified and in accordance with the ISO 9001:2008, ISO 13485:2003, BPF- Boas Práticas de Fabricação (ANVISA/RDC-059, Brazilian standard similar to GMP-FDA/US) and ISO 14001:2004 - Environmental Management standards.	
CAPACITY	12 liters	21 liters
WEIGHT	Aluminum - 19,7 kg (including components) Stainless steel - 20 kg (including components)	Aluminum - 26.7 kg (including components) Stainless steel - 29,5 kg (including components)
WEIGHT PER AREA OF SUPPORT (N/m^2)	42,9 N/m^2	45,9 N/m^2
OVERALL CLEARANCE	10 cm for each side of the autoclave	10 cm for each side of the autoclave
CLEARANCE REQUIRED FOR THE MOVEMENT OF THE DOOR	34 cm	40 cm
CHAMBER INTERNAL DIMENSION (W x D)	22 x 33 cm	25 x 46,5 cm
CLEARANCE BETWEEN THE TRAYS	67 mm (approximately)	28,5 mm (approximately)
AUTOCLAVE EXTERNAL DIMENSION (W x H x D)	33,5 x 33 x 48,5 cm	39,5 x 38 x 61 cm
VOLTAGE (Brazil) (Europe)	127 **or** 220V AC 230V AC	127 **or** 220V AC 230V AC
FREQUENCY	50/60 Hz	50/60 Hz
POWER	1200 Watts	1600 Watts
POWER CONSUMPTION	285 Watts per cycle	500 Watts per cycle
MAXIMUM AND MINIMUM STEAM PRESSURE	0 to 4 kgf/cm^2	0 to 4 kgf/cm^2
TEMPERATURE OF DRAINED WATER	100ºC	100ºC
TOTAL HEAT IN JOULES TRANSMITTED IN ONE HOUR	771 KJ	1.672 KJ
PROPER WORKING TEMPERATURE RANGE	15ºC to 40ºC	15ºC to 40ºC
PROPER WORKING ALTITUDE	Up to 3500 m	Up to 3500 m

Table 8

* In case the altitude and/or temperature of your workplace is different from the values mentioned in this manual, contact Cristófoli by the e-mail: comex@cristofoli.com.

WARRANTY CERTIFICATE

- The autoclave Vitale Plus is warranted to be free from defective materials and workmanship under normal use and service, for a period of two (2) years from the date of delivery to the buyer (purchase receipt required). The manufacturer's sole obligation under this warranty is to replace the defective part or exchange the whole product, whatever the manufacturer judges adequate.
- The manufacturer will not pay for technician dislocation costs, parts replacement or product exchange. As per manufacturer discretion, defective parts or product may have to be returned to Cristófoli or kept on the dealer for future inspection. In the event warranty service must be performed to correct any defect; only the manufacturer's authorized distributor shall provide this service.
- The manufacturer and its distributors will not accept the return of goods unless authorized in writing prior to the return of any shipment. The shipment must be made in accordance with the distributor's instructions.
- **Cristófoli Equipamentos de Biossegurança Ltda**, is not liable for damages caused by any different use from the intended purpose of the equipment or by the use of articles/materials not proper for autoclaving or their natural wearing out due to low resistance to the autoclaving process.
- This warranty is void when failure or defect is caused by conditions beyond the distributor or the manufacturer's control, such as: damage resulting from mishandling, neglect, lack of fulfillment of any item in the topic *"Preventive Maintenance"* (Page 25), misuse, improper maintenance, electrical surge accident or alteration/repairs by anyone other than an authorized dealer.
- The door gasket, fuse, trays, trays support, measuring cup, hoses and power cable are not covered by this warranty. The chamber and the solenoid valve (internal valve responsible for the steam elimination) lose their warranty when regular tap water (non distilled) and/or battery water is used for the sterilization process; or when instruments parts or wrapping residues get loose inside the chamber obstructing the valve and/or inner pipes. This warranty will cover the VSPF valve **only as long as the preventive maintenance is fulfilled (replacement of the internal safety valve that comprehends the seal and pin, to be done every six months) and monthly replacement of the air filter of the VSPF valve).**
- No person, agent, distributor or dealer is authorized to change, modify or extend the terms of this warranty in any manner, whatsoever.

HOW TO PROCEED WHEN SERVICE IS NEEDED

Before contacting your local dealer, please, have in hands, your autoclave's model, voltage, serial number and the date of manufacture found on the Identification Label located in the back of the autoclave, according to the model presented (Fig.24, page 26) and a description of the problem.

It will be also necessary to have the original invoice from your dealer to confirm the date of purchase. In order to protect your rights, fill out the Warranty Certificate Form which is inside the autoclave, attach a copy of the invoice and send it to your dealer who will refer it to Cristófoli. Do not send products directly to any addresses mentioned in this manual. Always contact your local dealer.

If you have problems contacting your dealer, contact us by e-mail: comex@cristofoli.com, Fax: 55 (44) 3518-3438 or through our website: www.cristofoli.com

CRISTÓFOLI
BIOSSEGURANÇA

Cristófoli Equipamentos de Biossegurança Ltda.
Rod. BR 158, nº127 - Campo Mourão - PR - Brasil
CEP 87309-650
Website: www.cristofoli.com - e-mail: comex@cristofoli.com

WARRANTY FORM

Name			
Specialty			
FEIN - (Company Register Number)		E-mail	
Address			
City	Country		
Zip Code	Phone	Fax	
Receipt Nº		Date of Issue	/ /
Dealer			
Model	Vitale Plus 12☐ Vitale Plus 21☐	Voltage	
Serial Number / Lot		Manufacture Date	/ /
Description of the Problem			

Do not detach this form, fill it out and keep it for your records in case you need Technical Assistance. Send the Product Registration Form located inside the autoclave and a copy of the purchase receipt back to your local dealer as soon as possible. In case of any changes in the address, please, inform Cristófoli immediately through the e-mail comex@cristofoli.com.

GUIDANCE FOR FINAL DISPOSAL OF THE EQUIPMENT

The environment is something that belongs to everyone, therefore, it is up to each one of us to make the decisions that will help in its preservation and reduction of the damages resulting from human activities.

All products have a useful life span, but it is not possible to determine how long, as it varies according to the intensity and how the equipment is used or handled. Exception made for the component "lid" (Item 2, page 10) which must be replaced every 5 years in accordance to "*Preventive Maintenance*" (Item 8, Page 25).

Cristófoli Equipamentos de Biossegurança Ltda, makes clear its concern, already demonstrated by the implementation of the Environmental Management System, according to standard NBR ISO 14001:2004, strongly recommends users of their products to seek the best destination when disposing your equipment or its components, taking into account the materials recycling legislation effective in your country.

We advise you to take your equipment to specialized recycling companies that, due to the continuous and fast paced development of new recycling technologies and materials reuse, provide the best way of disposing the equipment. Cristófoli contributes this way to reduce the consumption of non-renewable raw materials.

It is worth reminding you that your autoclave packaging, as indicated on the box itself, is recyclable.
Other items to be observed for the preservation of our planet:

- Reduce the amount of consumption material;
- Reuse all durable goods for as long as possible;
- Properly dispose the amalgam residues because they contain mercury, which contaminates the soil;
- Recycle all possible materials at the end of their useful life span.
- Perform the correct separation of all waste.

On behalf of all users, we thank you for your comprehension and cooperation.

LINKS OF INTEREST

Keep yourself updated with information about the latest changes in legislation and publication of relevant scientific literature through the links below.

www.anvisa.gov.br	ANVISA - National Health Surveillance Agency.
www.ccih.med.br	Site of the book *"Hospitalar Infection and its Interfaces in the Health Area"* coord. Dr. Antonio Tadeu Fernandes, medical field.
www.cdc.gov	Centers for Disease Control and Prevention Office of Heath and Safety - (Atlanta, USA).
www.cristofoli.com	Cristófoli Website.
www.cvs.saude.sp.gov.br	São Paulo Health Surveillance Department.
www.fob.usp.br	Bauru Dentistry College.
www.riscobiologico.org	Site with talks about the theme of Health Services.
www.saude.gov.br	Brazilian Health Ministry.
www.saude.pr.gov.br	Paraná Health Department.
www.saude.sp.gov.br	São Paulo Health Department.
www.who.int/emc	WHO - World Health organization website

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