CRISTÓFOLI
BIOSSEGURANÇA

Cristófoli, Brazilian company importer and manufacturer of health products certified by ISO 9001 - Quality Management System, ISO 13485 - Medical Devices - Quality Management System - Requirements for Regulatory Purposes, ISO 14001 - Environmental Management and *BPF - Boas Práticas de Fabricação - ANVISA.

Autoclave Baby

CRISTÓFOLI'S MISSION

Develop innovative solutions to protect life and promote health.

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: "Develop innovative solutions for the health field by using agile, robust and objective processes to better serve its clients. Fulfill the requirements for regulatory purposes of the applicable standards, promote the continuous improvement of its quality and environmental systems, prevent pollution, reduce its environmental impacts and continuous training of its employees, achieving this way, a sustainable profitability and the maximization of the company's value". Rev. 2.

*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.
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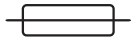
INDEX

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

LEGEND OF SYMBOLS

	Caution! Consult accompanying documents		*Boas Práticas de Fabricação		Keep away from sunlight
	Autoclavable		ISO 9001		Keep dry
	Alternate Current		ISO 13485		Recyclable
	Dangerous Electrical Tension		ISO 14001		Fragile - Handle with care
	Date of manufacture		Grounding Protection Terminal		This side up
	Manufacturer		Batch code		Fusible
	Maximum pile		Serial Number		Class II Equipment
	Antimicrobial Painting				

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

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.

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

The Warranty Terms can be found on Page 24.

Box contents: 1 autoclave - 1 power cable - 1 envelope support - 1 measuring cup - 1 samples kit (hose and clamp) and 1 instruction manual.

MANUFACTURER
Cristófoli Equipamentos de Biossegurança Ltda.
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Responsible Technician
Eder William Costa Camacho
CREA/PR – 87826/D

IMPORTANT SAFETY INFORMATION

Before using your autoclave **Baby**, It is necessary to observe some safety measures. Autoclaves are pieces of 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, as well as articles and instruments used in the aesthetics, beauty, manicure, podiatry, tattoo and body art areas resistant to the temperature of 121ºC and/or 135ºC, steam and pressure.

ATTENTION! TO OPEN THE AUTOCLAVE

1 - Press the door forward; **2 -** Lift the handle; **3 -** Slide it to the left.

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 Baby*", (Item c, page 13). **Not following this procedure may cause the door gasket to pop off**.

►When sterilizing instruments that have different autoclaving specifications simultaneously, as instruments that support different levels of pressure (1.2 or 2.1 kgf/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 simply changing a fuse or performing an everyday cleaning).

►**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 carefully 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 equipment.

Cristófoli Autoclave Baby 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 Terms* " (Page 24) and "*How to Proceed When Service is Needed*" (Page 23). In case the end user chooses an unauthorized technician to install the autoclave, such technician should follow all the guidelines described in the instruction manual for the physical, electrical and hydraulic installation of the equipment. Cristófoli is not responsible for any services performed in disagreement with the instruction manual that accompanies the product.

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. 17, page 18).

2►For the installation use a grounded outlet (2P + T, 10A) 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. 3, 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 the table below.

MODEL	NOMINAL CURRENT	CIRCUIT BREAKER	VOLTAGE	WIRING GAUGE
Baby - 127 V	6,3 A	1 Breaker 10 A.	127 V AC » 114 V - 140 V 220 V AC » 198 V - 242 V	For distance up to 5 m (16 ft) from the circuit breaker to the outlet used to connect the equipment, use 2,5 mm wiring. From 5 to 15 m (16 to 46 ft) use 4 mm, and from 15 to 50 m (46 to 164 ft) 6 mm.
Baby - 220 V	3,7 A	1 Breaker 10 A.		

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

Table 1

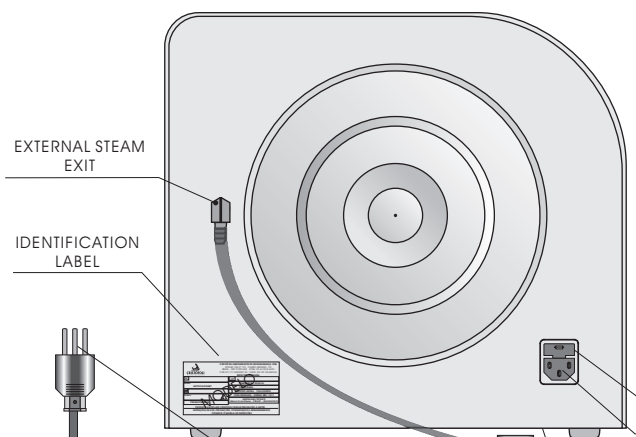


Fig. 1

ATTENTION

GROUNDING IS ESSENTIAL

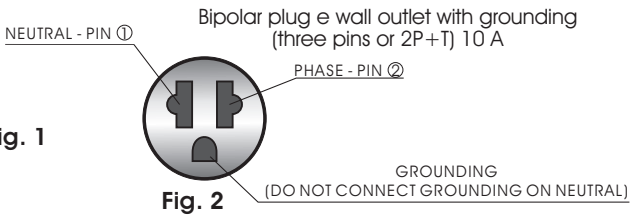


Fig. 2

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

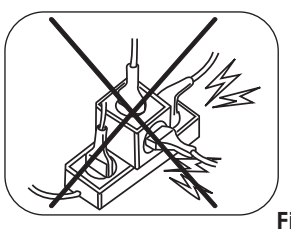


Fig. 3

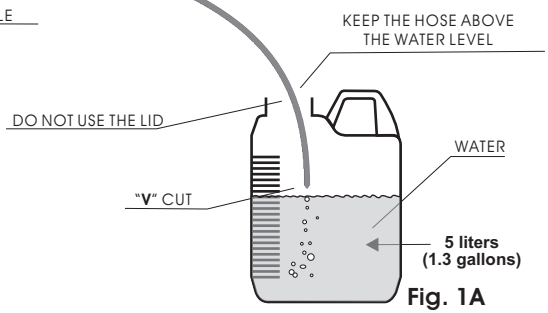


Fig. 1A

HYDRAULIC INSTALLATION

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. 12, page 10) 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. 1A), in this case, the hose must be **above the water level** with a **"V"** cut on its end and 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.

AUTOCLAVE COMPONENTS IDENTIFICATION

1►**PANEL -** It is in the front part of the autoclave, made with ABS injected plastic, it is where the keyboard and display are located (Fig. 4).

2►**LID -** Located right behind the panel, it's made of stainless steel and it is responsible for closing the autoclave chamber. The lid must be replaced each 10 years (Fig. 7).

3►**KEYBOARD -** Located in the panel, it is where the control keys and display of the autoclave 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 (Fig. 5).

5►**HANDLE -** Located in the front part of the autoclave (Fig. 4). It's used to open, close and lock the autoclave door (panel/lid set). To check the door correct locking position see Figs.14 and 15 (Page 13).

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 21).

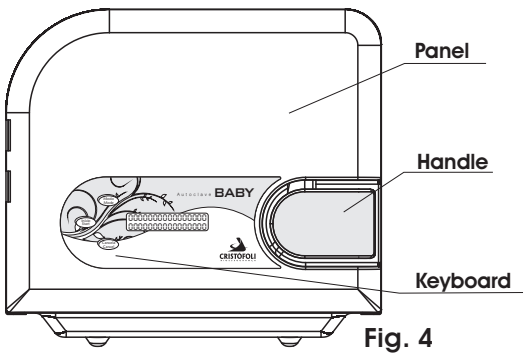


Fig. 4

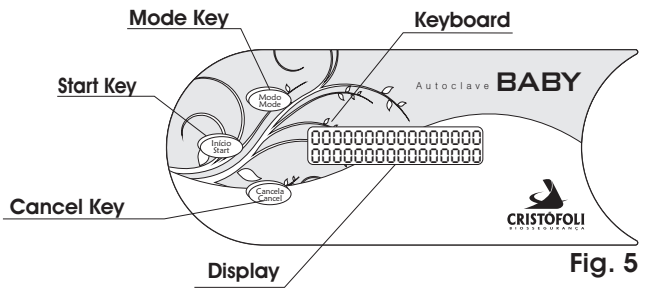


Fig. 5

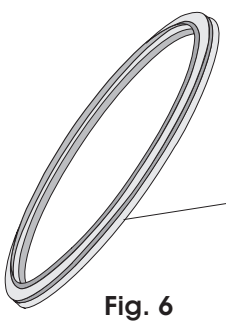


Fig. 6

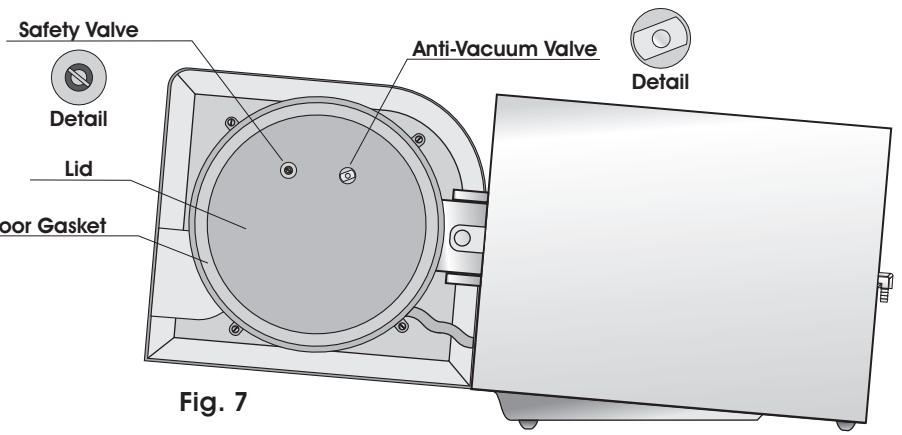


Fig. 7

7►**SAFETY VALVE AND ANTI-VACCUM VALVE -** The safety valve is one of the devices responsible for relieving the pressure inside the chamber in case it goes beyond the established limits. The anti-vacuum valve has the same function, it releases the vacuum inside the chamber when needed (Fig. 7, page 9). See "*Safety Devices*" (Items 3 and 4, page 11).

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 instruments/articles into the autoclave, be careful not to put them against or too close to the internal steam exits, that will cause interference in the cycle.

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 in 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.

11►**BASE (metallic structure) -** The base of the autoclave is produced in carbon steel with textured electrostatic painting. The paint used (Nobak) has antimicrobial properties (Fig. 8);

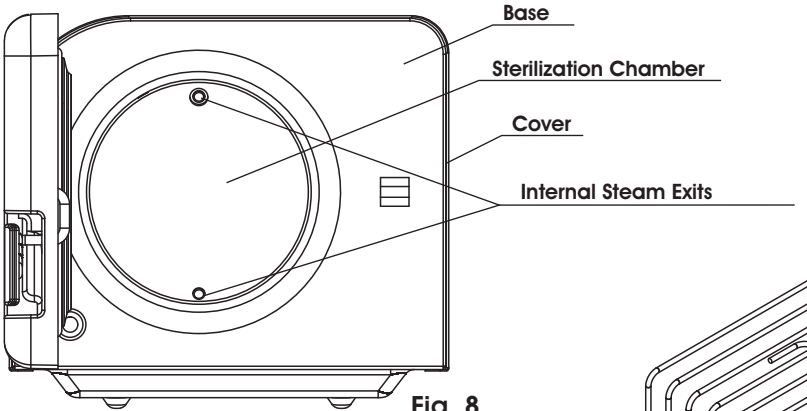


Fig. 8

Note: When using sterilization envelopes, arrange them side by side on the support provided (Fig. 9A).

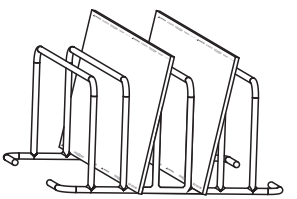


Fig. 9A

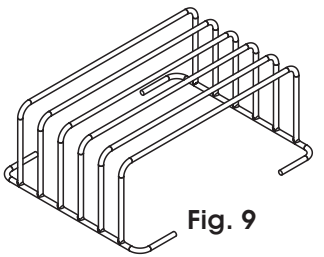


Fig. 9

Fig. 10

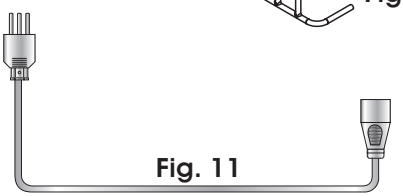


Fig. 11

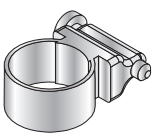


Fig. 12

12►**COVER -** It is produced in carbon steel with textured electrostatic painting. The paint used (Nobak) has antimicrobial properties (Fig. 8, page 10);

13►**ENVELOPE SUPPORT -** It is provided 1 stainless steel support to keep the instruments to be sterilized free from any direct contact with the water and internal surface of the autoclave chamber (Fig. 9, page 10);

14►**MEASURING CUP -** It's used to measure the right amount of **distilled water** necessary for the sterilization process (Fig. 10, page 10);

15►**POWER CABLE** - Used to connect the equipment to the power outlet (Fig. 1, page 8 and Fig. 11, page 10);

16►**CLAMP** - Used to fasten the discharge hose to the external steam exit (Fig. 12, page 10);

17►**BUZZER** - Internal device located under the base of the autoclave. Its function is to emit the beeps produced by the autoclave (Fig. 1, page 8);

18►**CHAMBER -** Produced in anodized aluminum, the sterilization chamber is where the instruments/articles to be sterilized are placed (Fig. 8, page 10).

SAFETY DEVICES

The autoclaves **Baby** 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 it 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"* (Item 6, page 9);

3►**SAFETY VALVE -** It opens when the pressure reaches from 2 to 2,5 Kgf/cm^2 or 200 to 250 kPa. See *"Autoclave Components Identification"* (Item 7, page 10);

4►**ANTI-VACUUM VALVE -** It works the same way of the safety valve by releasing the vacuum build-up inside the chamber. See *"Autoclave Components Identification"* (Item 7, page 10);

5►**FUSE -** Safety device which purpose is to protect the electrical wiring against peaks of energy. The fuse used is the 20 AGLF Glass - Quick Action. In case the operator wishes to replace the fuse personally, the table below will provide the necessary information. See *"Troubleshooting"* (Page 19);

VOLTAGE	AC VOLTAGE LINE	FUSE
127 V	127 V (114 V - 140 V)	8 A (250 V)
220 V	220 V (198 V - 253 V)	5 A (250 V)

Table 3

6►**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 a circuit board malfunction occurs;

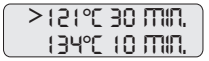
7►**POWER CONTROL ELECTRONIC SYSTEM -** Internal system of the equipment which monitors the temperature and pressure of the autoclave throughout the operation.

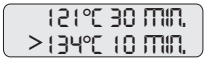
CYCLES AND MESSAGES

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.

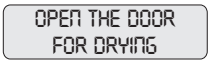
WHEN TURNED ON

CYCLE OPTIONS





MESSAGES



Note: The manufacturer reserves the right to update the software version, as well as make changes and/or improvements to this product at any moment without prior notice.

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 safety and anti-vaccum valves 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.

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 BABY

Before using the autoclave for the first time, it is necessary to perform the altitude calibration procedure.
See *"Altitude Calibration"* (Page 16).

a► Open the door of the autoclave and use the measuring cup provided to pour 100 ml of **distilled water** directly into the chamber **before** each cycle (Fig. 13) according to the table below.

ATTENTION! Use only distilled water. 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.

Amount of distilled water for each cycle
100 ml

Table 4

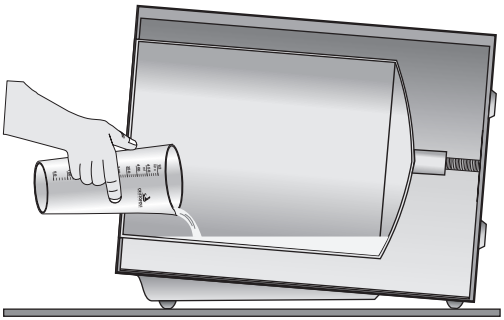


Fig. 13

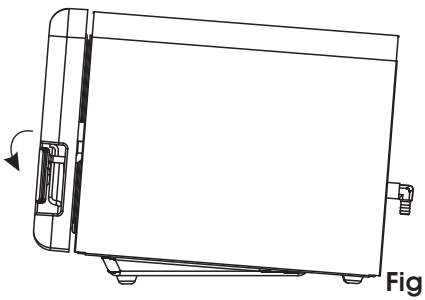


Fig. 14

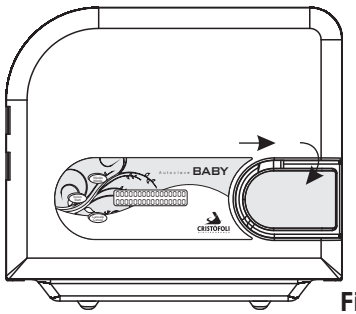


Fig. 15

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 and damages to the articles. Do not overload the autoclave.

c► Close the door of the autoclave. To close it correctly, with the door open and the handle all the way to the left, close the door by pressing it against the chamber, slide the handle to the right, and then press it all the way down until it's aligned with the panel (Figs. 14 and 15). 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 detach from the door. 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, at this moment, the display will show the initial information (brand, model and software version), the autoclave will then beep twice and select the 121°C cycle automatically, the display will show: `>121°C 30 min. 134°C 10 min.`

e► To select the 134°C cycle, press the **MODE** key. Each cycle has a specific operation time/temperature. Each time this key is pressed the arrow will switch between the preset programs in the following order: `121°C 30 min. >134°C 10 min.` **or** `>121°C 30 min. 134°C 10 min.`. Regardless of the program selected, the packages must always be wrapped individually with surgical grade paper for each client/procedure.

Utilize the 134°C program for kits which have metallic instruments. Example:

- kits for manicure, podiatry (nippers and metal pushers protected by cotton wrapped in surgical grade paper);
- tattoo or body-piercing materials (metallic tips, piercings and/or tweezers wrapped in surgical grade paper).

The 121°C program is longer and suitable for more sensitive materials. Example:

- plastics or gauze. In case it's necessary to prepare packages with different contents such as metallic instruments and plastics, choose the 121°C program;

Before sterilizing any article, make sure you first check with its manufacturer if it is autoclavable (resistant to the temperature of 135°C and the presence of steam and pressure);

The table below provides information regarding the autoclave programs.

Mode	Heating Time	Sterilization Temperature and Pressure	Sterilization Time	Drying Time
1- 121 °C	6 to 35 min.	121 °C / 118 kPa (1.2 kgf/cm²)	30 min.	15 min.
2- 134 °C	6 to 35 min.	134 °C / 210 kPa (2.1 kgf/cm²)	10 min.	15 min.
Maximum Drying Temperature: 121 or 134 °C (depending on the cycle chosen).				

Table 5

Obs: Heating time values are expressed considering the technical data chart (Table 6, page 17) regarding the autoclave proper working temperature range.

f► After choosing one of the programs 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 50 °C, the autoclave will beep twice and the display will show the message `WAIT FOR COOLING T:000°C` and the corresponding temperature.

As soon as the ideal temperature for the new cycle is reached, the autoclave will beep three times and switch automatically to `HEATING UP 00:00 T:000°C`;

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 program, the autoclave will beep twice and the

display will show `STERILIZ. 00:00 T:000°C P:0.00` remaining like that for the preset time according to the program chosen.

At the end of the sterilization, the solenoid valve will open producing a characteristic click sound and the autoclave will beep three times. The display will show `DEPRESSURIZING P:0.00` .

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.

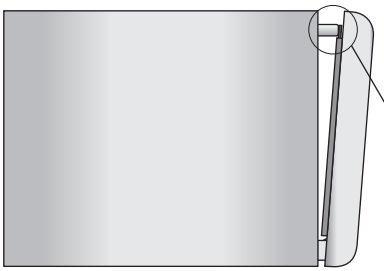
g► When the depressurization is over, the drying stage will follow automatically, the autoclave will beep 7 times and the display will show the message `OPEN THE DOOR FOR DRYING` . During the drying stage the display will show `DRYING. 00:00` .

At this moment, the operator must open the door of the autoclave and leave it ajar for the drying cycle (Fig. 16).

h► At the end of the drying stage, the autoclave will beep 5 times and the display will show `CYCLE CONCLUDED` . Press the **CANCEL** key, that will bring the system back to the program selection mode.

ATTENTION! Even after the beeps that indicate the conclusion of the cycle, the contents of the chamber will still be very hot. **Never** touch the internal parts of the autoclave directly (chamber, support, materials, etc.) when hot, wait for them to be cool enough before handling. Remember to use safety gloves for thermal protection.

Upper view



ATTENTION!
When opening the autoclave for drying, observe the correct position of the door in the picture. The autoclave Baby **dries with the door ajar**, its opening is necessary to allow steam evaporation and provide an efficient drying process.

Fig. 16

i► Turn the equipment off after using it. To do that, hold the **Cancel** key pressed, the autoclave will beep once and turn off. At the end of the work shift, unplug the equipment.

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 Baby"* (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);

2 ► To interrupt/cancel the heating, sterilization or drying stage, 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 ► 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. We recommend consulting an authorized technician to check the possible causes of the problem.

ALTITUDE CALIBRATION

In order for the autoclave to work properly, it is necessary to perform the altitude calibration procedure. Calibrate the altitude of the autoclave as shown below, for this procedure the autoclave must be empty.

1 ► Unplug the autoclave;

2 ► Open the door of the autoclave, use the measuring cup to add the correct amount of **distilled water** directly into the chamber **before** each cycle (100 ml);

3 ► Press and hold the **START** key and plug the autoclave in;

4 ► Release the **START** key, the display will show the message 

;

5 ► Close the door;

6 ► During the heating stage, the display will show the chamber temperature while the altitude is being measured, the calibration will finish automatically, the autoclave will beep twice and the display will show 

, that means the calibration procedure was successfully performed;

7 ► Open the door, unplug the equipment and allow it to cool down;

8 ► The autoclave is ready to be used.

Note: In case the autoclave is taken to another workplace where the altitude is different, a new calibration procedure must be performed.

TECHNICAL DATA

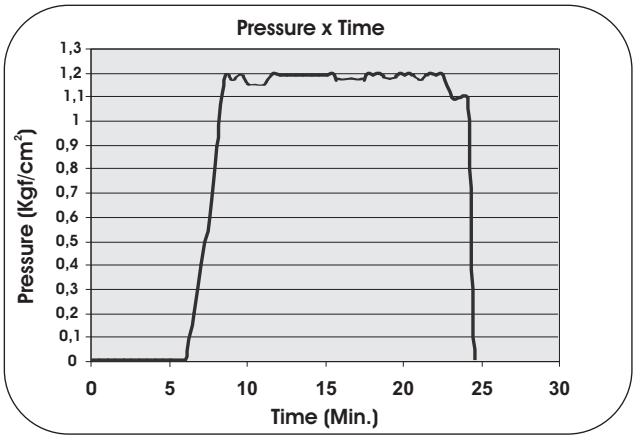
TECHNICAL DATA CHART	Baby
Certifications	The Autoclaves Baby are manufactured by Cristófoli Biossegurança, company which Quality Management System is certified and in accordance with the ISO 9001:2008, ISO 13485:2003, BPF- Boas Práticas de Fabricação - ANVISA (Brazilian standard similar to GMP - FDA/US) and ISO 14001:2004 - Environmental Management standards.
Capacity	4 liters
Net Weight	Aluminum - 9 kg (including components)
Gross Weight	Aluminum - 12 kg (including components)
Overall clearance	10 cm for each side of the autoclave
Clearance required for the movement of the door	30 cm
Chamber internal dimensions (W x D)	15 x 24 cm
Autoclave external dimensions (W x H x D)	29,1 x 26,3 x 37,3 cm
Voltage	127 **or** 220V AC
Frequency	50/60 Hz
Power	750 Watts
Power consumption	178 Watts/hour
Maximum operation pressure	216 kPa (2.2 kgf/cm^2)
Temperature of drained water	100ºC
Total heat in joules transmitted in one hour	771 KJ
Proper working temperature range	15ºC to 40ºC
Proper working altitude	Up to 3500 m

Table 6

* 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: cac@cristofoli.com.
The manufacturer reserves the right to make changes and/or improvements to this product at any moment without prior notice.

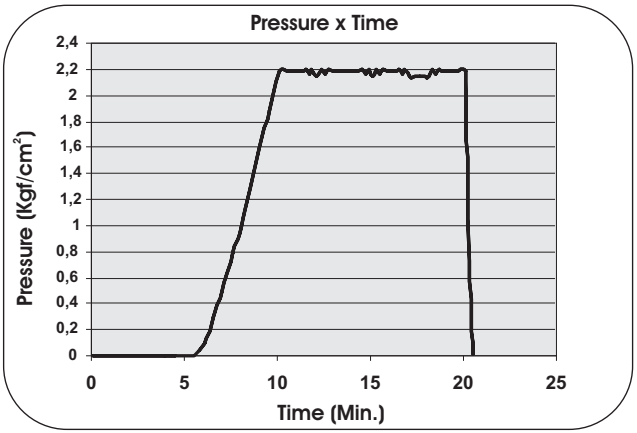
TIME X PRESSURE GRAPHS

Low Pressure Cycle



Graph 1

High Pressure Cycle



Graph 2

QUALITY CONTROL

Cristófoli equipment is tested and monitored individually, according to the parameters of the Table 5 (Page 14). Besides the physical parameters, all autoclaves are tested with class 5 chemical indicators. The tests with biological indicators are performed on a batch basis.

HOW TO IDENTIFY YOUR AUTOCLAVE

The purpose of the 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.

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

CRISTÓFOLI
BIOSSEGURANÇA

CRISTÓFOLI EQUIPAMENTOS DE BIOSSEGURANÇA LTDA
ROD BR 158 Nº 127 - CAMPO MOURÃO - PR
BRASIL - CEP 87309-650 - FONE: 55 44 3518-3401
CNPJ 01.177.248/0001-95 - INSCR. EST. 90.104.860-65
MADE IN BRAZIL

SN	LOT
MODEL	FREQUENCY -
	CAPACITY -
POWER	ANVISA REGISTER -
	CONFORMITY -
MAXIMUM OPERATION PRESSURE -	RESPONSIBLE TECHNICIAN -

MODEL

PRODUCT: CRISTÓFOLI STEAM STERILIZATION AUTOCLAVE.

USE INSTRUCTIONS, PRECAUTIONS, CONSERVATION AND STORAGE: SEE INSTRUCTION MANUAL.

Fig. 17

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 may 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 power cable of the autoclave is not properly connected to the autoclave or to the outlet	• Connect the power cable properly;
• The **Start** key was not pressed to turn the equipment on	• Press the **Start** key, the display must show the initial information (brand, model and software version);
• The fuse has burned out	• Replace the fuse which is right next to the power connector. First, unplug the equipment, next, remove the fuse holder by pulling it out with a small screwdriver as shown below (Fig. 18), replace the defective fuse (in use - from the external side of the fuse holder) by the new one (spare - located inside the fuse holder (Fig. 19). Finish the procedure by inserting the fuse holder back into place and turn the equipment on;
• Defective electronic circuit	• See *"How to Proceed when Service is Needed"* (Page 23).

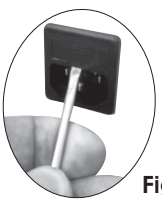


Fig. 18

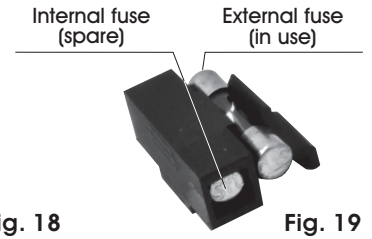


Fig. 19

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 program on the **Mode** key;
• Nothing happens when the **Start** key is pressed	• See *"How to Use the Autoclave Baby"* (Page 13);
• The heating element has burned out	
• Defective thermostat	• See *"How to Proceed when Service is Needed"* (Page 23).
• Defective electronic circuit	

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

THE AUTOCLAVE SWITCHES ON, HEATS UP BUT THERE'S NO PRESSURIZATION

POSSIBLE CAUSES	SOLUTION
• Defective temperature sensor	• See *"How to Proceed when Service is Needed"* (Page 23).
• Equipment installed where the altitude is above the recommended • Equipment shows the message 	• In order for the autoclave to work properly, it is necessary to perform the altitude calibration procedure. See *"Altitude Calibration"* (Page 16).

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 23).
• 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).

THE AUTOCLAVE TAKES TOO LONG TO BUILD UP PRESSURE OR DOES NOT KEEP IT, INDICATING "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 safety or anti-vacuum valve	• Turn the autoclave off and wait for it to cool down, remove the safety and anti-vacuum valves, clean the valves and their fitting orifices and put them back into place, replace them if necessary;
• Pressure/steam leak through the door gasket	• See *"How to Proceed when Service is Needed"* (Page 23);
• 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.

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

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:

1► **Use only distilled water**;

2► Keep the autoclave clean. For the **anodized aluminum chamber** and the stainless steel envelope support, use a soft, **non-abrasive** sponge with biodegradable neutral detergent and distilled water, the use of other materials and/or products may scratch or damage these parts, To remove the foam use a cloth that does not shed. Finish the cleaning with another cloth and alcohol 70% or peracetic acid at 1%;

3► The external cleaning of the autoclave must be done **daily** using a soft cloth and biodegradable neutral detergent, next, clean it thoroughly with a cloth and alcohol 70% or peracetic acid at 1%, exception must be made for the panel, because as time goes by, these products may render the panel with a yellowish shade. The handle must be also cleaned the same way before removing the material from the autoclave, after the sterilization;

4► Clean the door gasket, safety valve and anti-vacuum valve **weekly** with a clean cloth that does not shed, dampened in warm water.

5► Replace the door gasket and the safety and anti-vacuum valves of your autoclave **annually**;

6► Replace the thermal paste of the heating element **annually**;

7► The component "lid" (Item 2, page 9) must be replaced **every 10 years**;

8► Replace the internal hoses **annually**;

9► **Once a year**, a general preventive maintenance of the equipment must be performed by an authorized Cristófoli technician. See *"How to Proceed When Service is Needed "* (Page 23);

10► **Attention!** the aluminum chamber of the autoclave is anodized, hence, **it is forbidden to use any anticrust product** to perform the internal cleaning. This type of product will damage the chamber of the autoclave.

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	ANNUAL	* EVERY 10 YEARS
External cleaning	X			
Preventive cleaning (aluminum chamber)	X			
Door gasket cleaning		X		
Door gasket replacement			X	
Safety and anti-vacuum valves cleaning		X		
Safety and anti-vacuum valves replacement			X	
Replacement of the thermal paste from the heating elements			X	
Replacement of the internal hoses			X	
Replacement of the component "lid"				X
Performance of biological test		X		
General maintenance at a technical assistance office			X	

Table 7

HOW TO PROCEED WHEN SERVICE IS NEEDED

First, please have in hands the model of your autoclave, voltage, serial number and the date of manufacture found on the identification label located in the back of the autoclave (Fig. 1, page 8 and Fig. 17, page 18) and a description of the problem. Next, **contact your local dealer** for an evaluation and possible repair your equipment. It will be also necessary to have the original invoice from your dealer to confirm the date of purchase.

Always contact your local dealer. If you have problems contacting your dealer, contact us by e-mail: cac@cristofoli.com or through our website: www.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 9) which must be replaced every 10 years in accordance to "*Preventive Maintenance*" (Item 7, Page 21).

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.

WARRANTY TERMS

CRISTÓFOLI EQUIPAMENTOS DE BIOSSEGURANÇA LTDA., warranties the Cristófoli Autoclaves for 01 (one) year against any manufacturing defect from the date of the purchase receipt (provided it contains the serial and lot numbers of the equipment), of which 03 (three) months refer to the legal warranty (established by section II, art. 26, CDC, Brasil) and nine (09) months to the contractual warranty (arranged in art. 50, CDC, Brasil). Visit our website www.cristofoli.com and register your product online.

Traveling costs (based on the distance traveled in km) and the stay of the authorized technician for installation, repair or maintenance **before or after the warranty period** will be responsibility of the buyer/owner as well as the costs related to the autoclave sterilization monitoring (tests with biological indicators) and freight charges for shipping the equipment to the authorized technical assistance office for repairs or, if necessary, to the factory itself.

CRISTÓFOLI EQUIPAMENTOS DE BIOSSEGURANÇA LTDA., is not liable for damages / accidents caused by improper use, operation or installation of its products, in this case the equipment will lose its warranty and the repair will be paid by the buyer / owner.

The warranty will be voided in cases of:

- Problems arising from natural causes (such as floods, lightning, etc.);
- Use of non-distilled water for the operation of the autoclave;
- Damage caused by accidents, such as: dents, drops, short circuits, fire, etc.;
- Damage caused by humidity, excessive exposure to sun light and salinity;
- Sinister (theft or robbery);
- Improper use / installation of the equipment and/or plugging it into an incorrect voltage outlet;
- Problems due to failure of the power supply and/or building wiring;
- Removal and/or tempering of the serial number shown in the identification label of the product;
- Signs of tampering and/or blotted out data on the purchase or service receipt of the equipment;
- Tampering and/or modification of the equipment;
- Signs of external violation of the product or broken factory seal;
- Lack of annual preventive maintenance of the equipment, which must be proved by the service receipt or neglect regarding any item presented on the topic "*Preventive Maintenance*" of this instruction manual;
- Use of non-original parts or parts not acquired at the Cristófoli Authorized Service Network;
- Repairs performed by technicians who are not part of the Cristófoli Authorized Service Network;
- Noncompliance with any measure or caution recommended in the instruction manual of the product.

ATTENTION! In order to validate the contractual warranty of the product it is necessary to send a copy of the purchase receipt to the following e-mail address: garantia@cristofoli.com.

The door gasket, safety valve, anti-vacuum valve, measuring cup and the internal hoses are not covered by the warranty, these items are part of the preventive maintenance of the equipment (except the measuring cup), they are continuously subjected to high pressure and temperature, therefore, they must mandatorily be replaced annually at the owner's expenses. They will be covered by the warranty, however, in case it is a matter of manufacturing defect.