



Cristófoli, Brazilian importing company and manufacturer of health products certified by ISO 13485 - Health Products - Quality Management System - Requirements for Regulatory Purposes and compliance with RDC 16/2013 - *BPF - Boas Práticas de Fabricação - ANVISA requirements.



Vitale Class CD 12/21 Autoclave

CRISTÓFOLI'S MISSION

To develop innovative solutions to protect life and promote health.

CRISTÓFOLI QUALITY AND ENVIRONMENTAL POLICY

















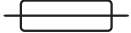

Cristófoli Equipamentos de Biossegurança Ltda., established at Rodovia BR-158, nº 127, Área Urbanizada III in Campo Mourão, Paraná, Brazil, manufactures biosafety equipment to assist the health care, having the following policy: "To develop innovative solutions for health care by using agile, robust, and objective processes to better serve its customers. To fulfill all the requirements of the applicable standards, promote the continuous improvement of its quality and environmental standards, prevent pollution, reduce its environmental impact, and continuously train its staff, achieving, therefore, a sustainable and profitable maximization of its value." Rev. 2.

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

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MEANING OF SYMBOLS

	Warning		ISO 13485		Keep out of Sunlight
	Autoclavable		Grounding Protection Terminal		Keep Dry
	Alternating Current		Lot number		Recyclable
	Dangerous Electrical Tension		Serial Number		Fragile - handle with care
	Date of Manufacture		This side up		Antimicrobial Painting
	Manufacturer		Fuse		
	Maximum Pile				

APPLICABLE REGULATIONS

ABNT NBR 11817:2001 – Esterilização - Esterilizador a Vapor - Esterilizadores Pequenos - Requisitos

ABNT NBR 16035-1:2012 - Caldeiras e vaso de pressão - Requisitos mínimos para a construção - Parte 1: Geral

ABNT NBR IEC 60601-1:2010 - Equipamento Eletromédico - Parte 1: Requisitos gerais para segurança básica e desempenho essencial;

ABNT NBR IEC 60601-1-8:2010: Equipamento eletromédico Parte 1-8: Requisitos gerais para segurança básica e desempenho essencial - Norma colateral: Requisitos gerais, ensaios e diretrizes para sistemas de alarme em equipamentos eletromédicos e sistemas eletromédicos.

ABNT NBR ISO 17665-1:2010 - Esterilização de produtos para saúde — Vapor Parte 1: Requisitos para o desenvolvimento, validação e controle de rotina nos processos de esterilização de produtos para saúde

CISPR 11:2010 Ed, Equipamentos industriais ,científicos e médicos - Características de perturbação da frequência de rádio – Limites e métodos de medição.

EN 13060:2014 - Small Steam Sterilizers;

EN 980:2008 (Ed. 2) - Símbolos gráficos para utilização na rotulagem dos dispositivos médicos

EN ISO 14971:2007 - Dispositivos médicos - Aplicação da gestão de risco médica dispositivos

IEC 60601-1-2:2007 : Equipamento Eletromédico - Parte 1-2: Prescrições gerais para segurança: compatibilidade eletromagnética.

ISO 9687: 1993 - Matériel dentaire - Symboles graphiques

NBR 14136:2012 – Plugues e tomadas para uso doméstico e análogo até 20 A/250 V em corrente alternada - Padronização.

NBR ISO 11134:2001 – Esterilização de produtos hospitalares – Requisitos para validação e controle de rotina – Esterilização por calor úmido;

NR 13 – Manual Técnico de Caldeiras e Vasos de Pressão;

RDC Nº16, de 28 de março de 2013 - Regulamento Técnico de Boas Práticas de Fabricação de Produtos Médicos e Produtos para Diagnóstico de Uso In Vitro e dá outras providências;

INTRODUCTION

The complete reading of this manual is indispensable for safe use of the equipment and preventive maintenance orientation.

Autoclaves work with high temperature and pressure, so must be handled by health care professionals, well aware of the equipment operation.

Box content: 1 autoclave, 1 tray holder, 2 trays (Vitale Class CD 12) or 3 trays (Vitale Class CD 21), 1 measuring cup, 1 hose (1,5 m), 1 clamp, and 1 manual.

INTENDED USE

This equipment was developed for sterilization of heat-resistant articles/instruments using saturated steam under pressure.

RECOMMENDATIONS AND WARNINGS

- ▶ Read all instructions of this manual before using your autoclave. The incorrect use may result in sterilization failure and/or accidents.
- ▶ For your safety, when performing any kind of maintenance, remember to unplug the power cord and use PPE (Personal Protective Equipment).
- ▶ Do not allow patients, especially kids, to get close to your autoclave.
- ▶ Before starting any sterilization program, make sure that the sterilization load is autoclavable (resistant to temperatures up to 135° C under presence of steam and pressure).
- ▶ When simultaneously sterilizing instruments with different autoclaving specifications, such as instruments that support different pressures (1,2 or 2,2 kgf/cm²) or temperature levels (121 or 134°C), the operator must choose the program which works with the lower temperature/pressure offered by the autoclave.
- ▶ During the autoclave operation, it's perfectly normal to hear noises, which are generated by the valve opening, closing, deaerating, and depressurizing. These processes are part of the proper functioning of the equipment. Cristófoli is not responsible for accidents that might occur due to the jolts caused by the noises produced by the autoclave.
- ▶ When pulling the handle to open the door, the operator must do it easily. **Never use too much force**, for it may damage the equipment's internal mechanisms.
- ▶ It is normal, when the operator opens the door at the end of the cycle to cool down the sterilized load, that some steam comes out of the chamber (pressure vessel).
- ▶ The owner is responsible to perform, through a competent laboratory, the thermometric validation of the autoclave.
- ▶ Use totally perforated boxes and trays only, as it allows steam circulation and makes the drying process more efficient.
- ▶ It is recommended that the equipment be unplugged at the end of the workday.

MANUFACTURER

Cristófoli Equipamentos de Biossegurança Ltda.

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CEP 87303-327

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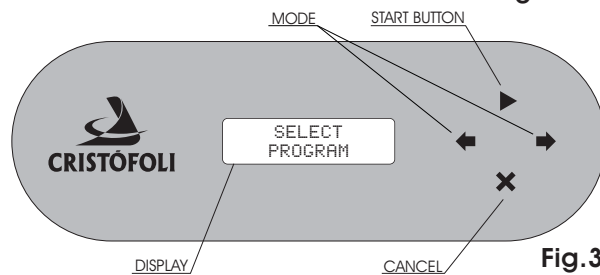
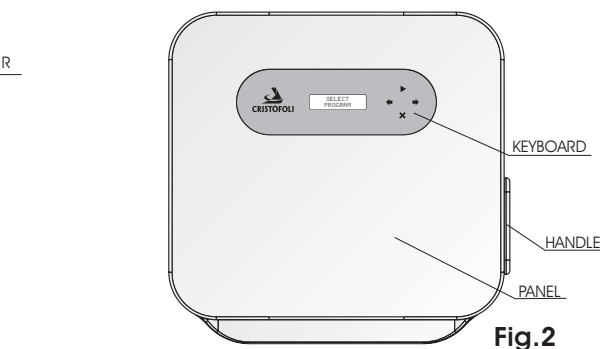
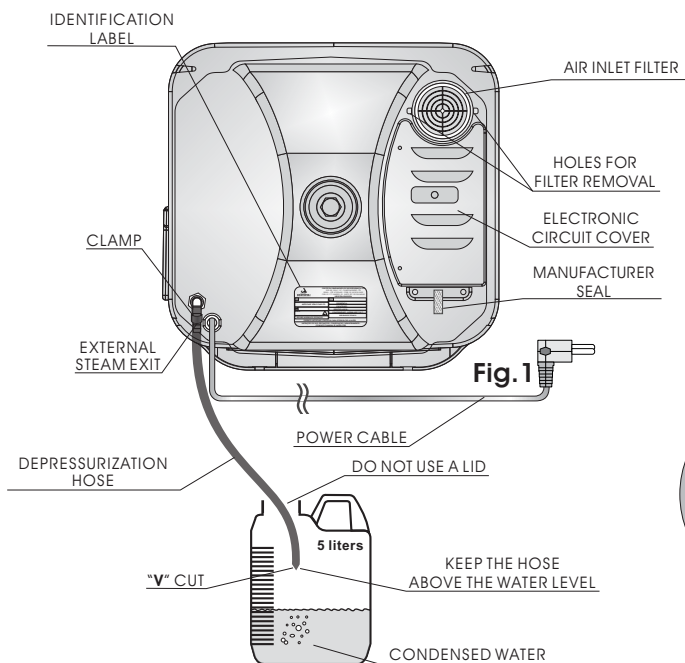
Responsible Technician

Eduardo Luiz Soppa

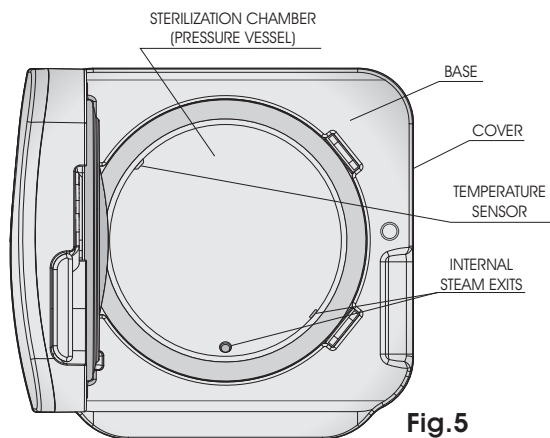
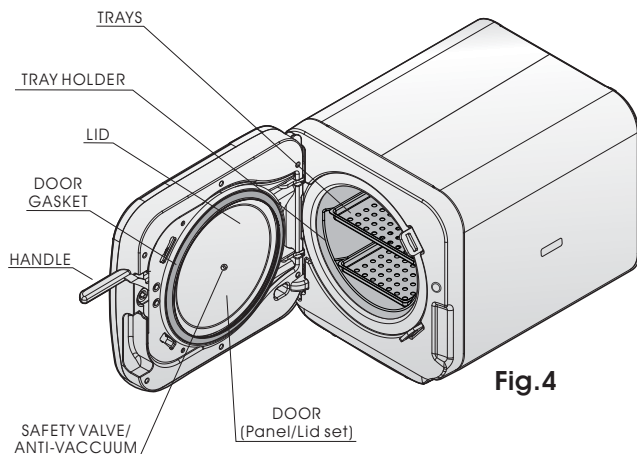
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HOW TO IDENTIFY YOUR AUTOCLAVE

⚠ The Identification label or manufacturer seal removal will cause automatic loss of warranty.



Images for illustrative purposes only



The manufacturer reserves the right to make changes and/or improvements to this product at any moment without prior notice

INSTALLATION INSTRUCTIONS

The equipment must always be carried by two people to prevent it from falling down. The storage/installation must be performed indoors, under room temperature, on a counter that can bear the weight of the autoclave.

Install the autoclave in a room that is exclusive for sterilization.

Install the autoclave on a flat, levelled and firm surface, and at a proper height for the operator to handle it (approximately 80 cm / 2.6 feet from the floor). Leave enough room around the autoclave for proper handling of the sterilization load.

ELECTRICAL INSTALLATION

See "How to Proceed When Service is Needed" (Page 17). If the owner performs the installation with a non-authorized electrician or technician, Cristófoli will not be responsible for services done in disagreement with the orientations described in this manual.

- 1►The Vitale Class CD autoclave is an automatic dual voltage device (able to operate at 127 and 220 V), as shown in the identification label, placed on the back of the equipment. See "How to Identify Your Autoclave" (Fig. 1, page. 6).
- 2►For installation, use a grounded outlet (2 Pins + Grounding, 20 A), plugging phase/neutral or phase/phase at the side pins and grounding at the middle pin: **Never plug the grounding on neutral.**

⚠ The Electrical Grounding is very important for the operator's safety and for your equipment's functionality. Therefore, the center pin (grounding) must **never** be removed or cut. **The failure to observe this procedure may damage your autoclave.** Install the equipment where the power cable can be easily disconnected.

- 3►**Never** use electric extensions, adapters or voltage transformers.

- 4►For the proper functioning of the autoclave, the electrical wire must be stable, in other words, without oscillations. **It is mandatory the use of an exclusive circuit breaker for the outlet where the autoclave will be installed.** If after following all the specifications, the electrical wire still oscillates, contact the local electricity company.

The electrical installation must follow the data from table below.

AUTOClave	NOMINAL CURRENT	CIRCUIT BREAKER	VOLTAGE	WIRING GAUGE
Vitale Class CD 12	10 A	25 A	127 / 220 V AC (95 V - 254 V)	For distances 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) use 6 mm. NOTE: For the 21 liters model (127V), for distances up to 15 to 35 m (49 to 114 ft) use 6 mm wiring, and 8mm for 114 to 164ft distance.
Vitale Class CD 21	15 A			

Table 1

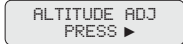
DRAINAGE

Connect the provided hose to the external steam exit (Fig. 1, page 6), put the clamp and fasten it with a screwdriver. The other side must be connected to the plumbing system (on a pipe that is able to tolerate at least 100°C) or to an open and empty container, with a "V" cut at its end and placed about 40 cm above the autoclave level (Fig. 1, page 6). Keep the hose slightly stretched to avoid it from bending. Empty the container when the water reach the hose and wash it with water and biodegradable neutral detergent.

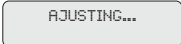
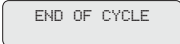
⚠ If a hose change is needed, use only heat resistant rubber hose (5/16", 300 psi as sample provided).

ALTITUDE ADJUSTMENT

The performance of the autoclave is directly related to the atmospheric pressure, which varies according to the altitude of where it is installed. The following instructions will guide you on how to perform the Altitude Adjustment of your autoclave. This reinforces that your autoclave will efficiently work at the location where it is installed.

When turning the autoclave on for the first time, the display will show the message . The Altitude Adjustment is the first cycle of the autoclave, which must be done **without any materials**, that is, only water must be inside the chamber (pressure vessel). To perform this process, follow the instructions below:

1►Open the door of the autoclave and, using the measuring cup, put the correct amount of **distilled water** directly inside the chamber (pressure vessel) (150 ml for the Vitale Class CD 12 or 250 ml for the Vitale Class CD 21). Close the door and press ► to begin.

2►During heating, the display will show the message . The adjustment is automatically completed. The autoclave will beep 5 times and show , it means the procedure was successfully accomplished. Press ✕ to return to the main menu. If there are any problems during the adjustment, press the ✕ key to return to the Altitude Adjustment screen and repeat it, or see "Failure Messages" (Page 16), following the recommendations related to the shown failure message.

⚠ If the equipment is transferred to another place, see the topic "Performing a New Altitude Adjustment" (Page 12) to perform a new Altitude Adjustment.

SAFETY DEVICES

The **Vitale Class CD** autoclave has the following safety devices:

- 1►**FUSE** - Located at the electronic circuit, this device protects the electrical installations and equipment against peaks of energy. If substitution is needed, see "How to Proceed When Service is Needed" (Page 17).
- 2►**DOOR KEY** - Internal device that prevents the functioning of the equipment if the door is not properly closed.
- 3►**TEMPERATURE VS PRESSURE DATA CROSSING ELECTRONIC SYSTEM** - Internal system that automatically cancels the cycle if any problem is detected with pressure reading.
- 4►**DOOR LOCKING** - Internal device which prevents the handle from opening if there are high pressure levels inside the chamber (pressure vessel).
- 5►**POWER CONTROL ELECTRONIC SYSTEM** - Internal system that monitors the voltage fluctuation, keeping the autoclave power constant.
- 6►**THERMOSTAT** - Internal device that limits the excessive heating of the chamber (pressure vessel).
- 7►**DOOR GASKET** - If the pressure inside the chamber (pressure vessel) reaches 3 kgf/cm² (294 kPa), the door gasket will detach from the edge of the door, having a loud noise (Fig. 4, page 6).
- 8►**SAFETY VALVE/ANTI-VACCUUM** - Device that, when needed, eases the vacuum inside the chamber (pressure vessel). It also eases the pressure if it exceeds the limits established (Fig. 4, page 6).
- 9►**MAINTENANCE MESSAGES** - Periodically, messages that warn the user about performing preventive maintenance will be shown. See "Preventive Maintenance." (Page 14).
- 10►**AIR INLET FILTER** - Responsible for filtering the air used in the drying process. (Fig. 1, page. 6).

HOW TO USE THE VITALE CLASS CD AUTOCLAVE

- a► Connect the power cable to an outlet and press ►, the display will show the initial information (beeping 3 times for brand, once for model and capacity) and the message **SELECT PROGRAM**.
- b► Open the door of the autoclave by pushing the handle upwards and pulling it (Fig. 8).

⚠ When moving the handle to open the door, the operator must do it easily. If the handle is locked, it means that there's pressure inside the chamber (pressure vessel), therefore, **never use too much force** because it may damage the internal mechanisms of the equipment.

- c► Use the measuring cup (Fig. 6) to pour the correct amount of **distilled water** directly inside the chamber (pressure vessel) **before** each cycle, according to the table below:

AMOUNT OF DISTILLED WATER FOR EACH CYCLE	
VITALE CLASS CD 12 150 ml	VITALE CLASS CD 21 250 ml

Table 2

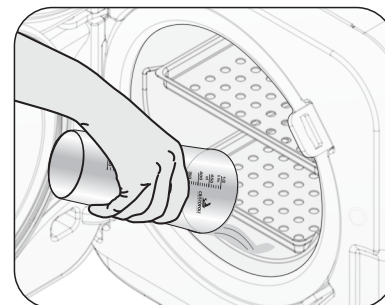


Fig.6

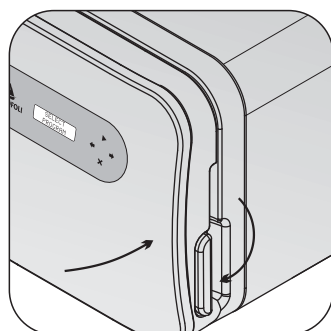


Fig.7

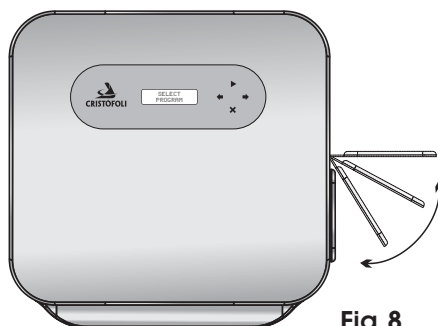


Fig.8

⚠ **Use only distilled water for sterilization.** The non-compliance of this recommendation may cause obstruction of the autoclave's hydraulic system (internal pipes e/or valves), stains on the instruments, and loss of warranty.

If the autoclave is transferred to another location, see the topic "Performing a New Altitude Adjustment" (Page 12) to perform a new Altitude Adjustment.

- d► Load the autoclave with the materials to be sterilized, be careful to not lean them against the chamber (pressure vessel) walls or internal steam exits, failure to follow these instructions may interrupt the sterilization cycle. **Do not overload the autoclave.** Do not exceed 75% of the chamber (pressure vessel) capacity: 5 envelopes (10 x 23 cm containing 6 instruments each) for Vitale Class CD 12 or 13 envelopes using the Support, and 12 envelopes for Vitale Class CD 21 or 26 packages using two supports (the supports are sold separately. Contact your Cristofoli authorized local dealer). **Place the envelopes always with the paper side upturned**, it eases the steam penetration, resulting on a fast and efficient drying process, for the same reason, **boxes and trays must be totally perforated.**

When using the trays, remember to leave small spaces between the envelopes to allow a good steam circulation and optimize the drying process. Never overlap the packages. For the Vitale Class CD 21 model, when using the program **Surgical Kit and Fabrics**, the case must be placed on the center tray. For the Vitale Class CD 12 model, the case must be placed on the bottom tray.

- e►Close the door of the autoclave pressing it against the chamber (pressure vessel) and move the handle all the way down (Figs. 7 and 8).
- f►Press ► and select the desired program through ◀ and ▶. After each touch, the display will change between the programs, according to the table below, which shows the default values for each program:

PROGRAMS	AVERAGE HEATING TIME	STERILIZATION TEMPERATURE AND PRESSURE	STERILIZATION TIME	DRYING TIME	
				12 LITERS	21 LITERS
1- Wrapped Instruments	10 a 40 min.	134 °C / 216 kPa (2,2 kgf/cm ²)	10 min.	40 min.	50 min.
2- Unwrapped Instruments	10 a 40 min.	134 °C / 216 kPa (2,2 kgf/cm ²)	6 min.	35 min.	45 min.
3- Plastic and Cotton	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm ²)	30 min.	45 min.	55 min.
4- Surgical Kit and Fabrics	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm ²)	30 min.	50 min.	60 min.
5- Liquids	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm ²)	30 min.	-----	-----

Note: The heating time relies on the altitude and temperature of the installation location. According to ABNT NBR 11816: 2003, the sterilization temperature interval must have the inferior limit defined by the sterilization temperature and superior limit of + 3°C. Drying max. temperature: 121 or 134 °C (depending on the selected program).

Table 3

- g►Press ► to start the program. If the door of the autoclave is not properly locked, the program will not initiate. The display will show the message **CLOSE THE DOOR!** and the autoclave will beep until the operator closes the door correctly.

If this is not the first cycle of the day and the temperature inside the autoclave is above 70 °C, the display will show **COOLING** and the corresponding temperature. As the ideal temperature for the new cycle is reached, the autoclave will automatically start the **HEATING** stage.

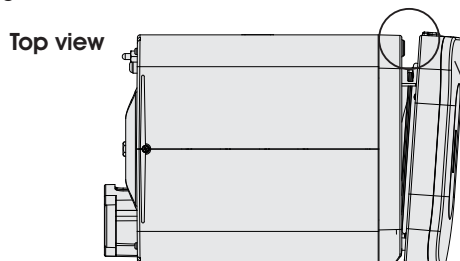
When the autoclave reaches the sterilization temperature/pressure, the display will change between the messages : **STERILIZING** (with temperature and pressure), **REMAINING TIME**, and **ELAPSED TIME**.

At the end of the sterilization, the display will show **DEPRESSURIZING**. The drying process will start automatically, **with the door closed**. The display will change between the messages **DRYING**, **REMAINING TIME**, and **ELAPSED TIME**.

For the **UNWRAPPED INSTRUMENTS** cycle, after the depressurization, the message **DRY** will be shown and the autoclave will beep until the user chooses one of the options. Press ► to perform the drying process or ◀ to cancel it.

⚠ After the execution or cancellation of the drying process, **the instruments must be used immediatly**.

- h►If a cycle interruption/cancellation is needed, press ✕. In this case, the autoclave will depressurize after 2 beeps and show the message **CYCLE CANCELLED BY USER**.



ATTENTION!
When opening the autoclave for cooling, see the correct position for the door at the figure. At this moment, it is normal that some steam comes out of the chamber.

Fig.9

- i ▶ At the end of the drying process, the autoclave will sound a sequence of beeps that indicates the need of opening the door, leave it slightly opened to accelerate the cooling process. Then, the display will alternate between the messages COOLING (with temperature), REMAINING TIME, and ELAPSED TIME. At the end of this process, the autoclave will beep 5 times, the display will show the message CYCLE CONCLUDED and the cycle total time. Only remove the materials when they get cool enough to be handled.

Note: Use gloves for thermal protection.

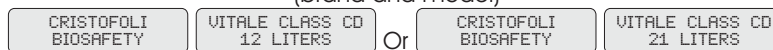
- j ▶ Press **X** to return to the program selection mode.

- k ▶ After use, turn off the equipment pressing **X** for 2 seconds.

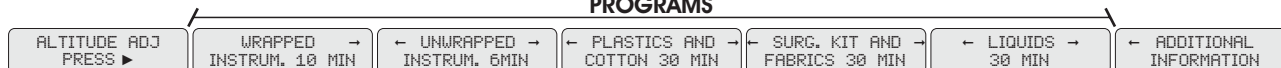
PROGRAMS AND MESSAGES

Related below are the available programs and messages shown by the autoclave.

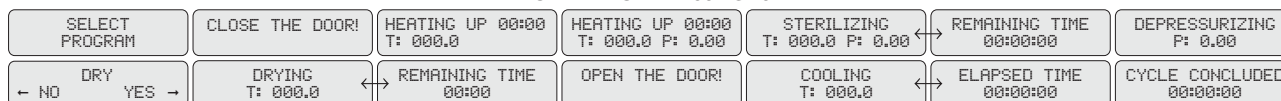
WHEN TURNING ON (brand and model)



PROGRAMS

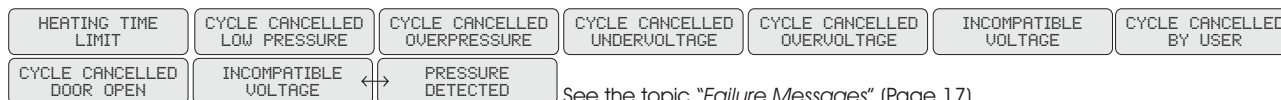


OPERATION MESSAGES



T = Temperature in °C
P = Pressure in kgf/cm²

FAILURE MESSAGES



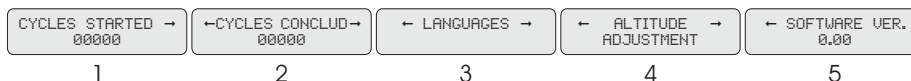
See the topic "Failure Messages" (Page 17).

MAINTENANCE MESSAGES



ADDITIONAL INFORMATION

Pressing ► on ADDITIONAL INFORMATION will show a submenu with information about the autoclave.



- 1 - Cycles started.
- 2 - Cycles concluded.
- 3 - Shows the available languages (Portuguese, Spanish and English). To change the language, press ►, then the display will show the messages: . Select the desired language pressing ◀ or ▶, then press ► to confirm.
- 4 - Altitude Adjustment (procedure described below).
- 5 - Shows the equipment software version.

PERFORMING A NEW ALTITUDE ADJUSTMENT

If the equipment is transferred to another place, perform the Altitude Adjustment again. For this procedure, the autoclave must be **empty** (without any materials). **Note:** This process must be performed with the autoclave in **cool temperature**.

- 1► Connect the power cable to the power source and press ► to turn it on.
- 2► Open the door and, using the measuring cup, pour the correct amount of **distilled water** directly inside the chamber (150 ml for Vitale Class CD 12 or 250 ml for Vitale Class CD 21) and close the door.
- 3► Select trough the keys ◀ ▶ the menu and press ►. After that, choose and press the key ► to initiate.
- 4► During the heating stage, the display will show the message . The adjustment is automatically finished. The autoclave will beep 5 times and the display will show , it indicates that the procedure was successfully accomplished. If there's any problem during the adjustment, the display will show the related failure message as informed in "Failure messages" (Page. 16).
- 5► Press ✕ to get back to the program selection menu.
- 6► Open the door of the autoclave and wait it to cool down. Then, the equipment is ready to be used.

QUALITY CONTROL

The Vitale Class CD autoclaves are individually monitored according to the physical parameters of the Table 3 (Page 10) and tested with class 5 chemical indicators. The tests with biological indicators are done by lot sampling.

TECHNICAL DATA

TECHNICAL DATA CHART	VITALE CLASS CD 12 LITERS	VITALE CLASS CD 21 LITERS
Capacity	12 liters	21 liters
Net weight	18,5 kg	24,1 kg
Gross weight	20,5 kg	27,3 kg
Material of the chamber (pressure vessel) / lid	Stainless Steel	Stainless Steel
Free space between trays	67 mm (approximately)	28,5 mm (approximately)
Chamber internal dimensions (W x D)	22 x 30 cm	25 x 43 cm
Autoclave external dimensions (W x H x D)	35,4 x 35,7 x 53,1 cm	38,2 x 38,5 x 60,4 cm
Dimensions of the trays (W x H x D)	15,5 x 1,2 x 28 cm (small) / 20 x 1,2 x 28 cm (large)	19 x 1,2 x 38 cm (single size)
Voltage (Automatic dual voltage)	127/220 V AC (95 - 254 V)	127/220 V AC (95 - 254 V)
Frequency	50/60 Hz	50/60 Hz
Power	1200 Watts	1600 Watts
Power consumption	127 V - 0,354 Kilowatts/hour 220 V - 0,348 Kilowatts/hour	0,455 Kilowatts/hour 0,511 Kilowatts/hour
Maximum operation pressure	216 kPa (2,2 kgf/cm ²)	216 kPa (2,2 kgf/cm ²)
Temperature of drained water	100°C	100°C
Proper room temperature	15°C a 40°C	15°C a 40°C
Proper working altitude	Up to 3500 m	Up to 3500 m
Base (metal structure)	Carbon steel with electrostatic painting with antimicrobial properties (Nobak).	
Fluid Class	C (Water Steam)	C (Water Steam)
Potential risk group	5 (PxV < 1)	5 (PxV < 1)
Pressure vessel category	V	V
ANVISA	10363350017	10363350017
Certification	The Vitale Class CD Autoclaves are manufactured by Cristófoli Biossegurança, company whose the Quality Management System is certified by ISO 13485, and in accordance with RCD 16/2013 - BPF - Boas Práticas de Fabricação - ANVISA (Brazilian standard similar to GMP - FDA/US).	

Table 4

PREVENTIVE MAINTENANCE / MONITORING

For better functioning and durability of your autoclave, some procedures are needed. Monitoring and preventive maintenance correspond to the **accomplishment of all procedures below**.

PERIODICITY	MAINTENANCE / MONITORING
DAILY	External cleaning: Must be performed with a soft cloth, water and biodegradable neutral detergent. After that, clean the autoclave with a moistened with 70 % alcohol cloth or 1% peracetic acid. The handle must be cleaned the same way before each material removal, after sterilization cycle.
	Tray and chamber (pressure vessel) cleaning: Use a soft nonabrasive sponge with biodegradable neutral detergent and distilled water. To remove the foam use a cloth that does not shed. Finish the cleaning with 70% alcohol or 1% peracetic acid. It's forbidden the use of any descaler product for cleaning, because this kind of products will damage the chamber (pressure vessel), trays, and internal pipes.
	Sterilizing monitoring (chemical test): The display will show the message CHEMICAL TEST DAILY. To obtain more information about how to perform the chemical tests, consult www.cristofoli.com at the session "Support" of your product.
WEEKLY	Door gasket cleaning: Remove the gasket by pulling it, after that, clean it with a cloth (which does not shed) moistened with water, and place it on the lid again.
	Sterilizing monitoring (biological test): The display will show the message: BIOLOGICAL TEST EACH 7 DAYS. To obtain more information about how to perform the biological tests, consult www.cristofoli.com at the session "Support" of your product.
MONTHLY	The display will show the message: PERFORM MONTHLY MAINTENANCE. Do the air inlet filter inspection (Fig. 1, page. 6), observing if there's presence of humid spots, yellowish coloring, dirt, tears or holes. If any of these characteristics is observed, replace the filter immediately, as described below in "Semiannually".
SEMIANNUALLY	Air Inlet Filter replacement (Fig. 1, page. 6): The filter must be replaced every 6 months or 360 cycles. To replace, remove the old filter with help of an instrument, positioning its tip inside one of the side holes at the edge of the filter (Fig. 1, page 6), lifting it carefully. After, fit in the new filter and press it tightly. To buy extra filters, consult your local Cristofoli authorized dealer.
YEARLY	Verification of the items: door gasket, safety valve/anti vacuum, thermal grease of the electrical resistance, door locking, internal hoses, and external (drain hose).
EVERY 3 YEARS	Replacement of the "thermostat" (Item 6, page 8). See "How To Proceed When Service Is Needed" (page 17). See "How To Proceed When Service Is Needed" (page 17).
EVERY 10 YEARS	Replacement of the "lid" (Fig. 4, page 6) and "chamber (pressure vessel)" (Fig. 5, page 6). See "How To Proceed When Service Is Needed" (page 17).

Table 5

TROUBLESHOOTING

For any replacement of parts, contact your local dealer or authorized technical assistance office. It's **not recommended** the replacement by non-qualified people.
Listed below are the most frequent problems and possible solutions, which could be solved by the user.

THE AUTOCLAVE DOES NOT SWITCH ON

POSSIBLE CAUSES	SOLUTION
<ul style="list-style-type: none">• Lack of power -----• The autoclave is not connected to the outlet -----• The ► key was not pressed to turn the autoclave on -----• Blown fuse -----• There is voltage fluctuation -----	<ul style="list-style-type: none">• Verify if there's a power failure in your area.• Connect the power cord to the outlet properly.• Press ►.• See "How to proceed when service is needed" (Page 17).• Consult your local energy provider.

THE AUTOCLAVE SWITCHES ON BUT DOES NOT HEAT UP

POSSIBLE CAUSES	SOLUTION
<ul style="list-style-type: none">• The operator selected the program but didn't press ► -----• The operator selected the program but there's no actuation when pressing ► -----	<ul style="list-style-type: none">• Press ►.• See "How to Proceed When Service Is Needed" (Page 17).

THE AUTOCLAVE PRESSURE GETS TOO HIGH, ACTIVATING THE SAFETY DEVICES

POSSIBLE CAUSES	SOLUTION
<ul style="list-style-type: none">• Obstruction of the hose connected to the external steam exit -----	<ul style="list-style-type: none">• Remove the hose that is connected to the external steam exit and clear any obstruction. If replacement is needed, proceed as following: certify that the autoclave is cold and disconnected from the power grid. Release the clamp, remove the old hose and place the new one, place the clamp, and fasten if firmly. ATTENTION! Never use common plastic hose. If the problem persists even with the application of this solution, see "How to Proceed When Service Is Needed" (Page. 17).

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

POSSIBLE CAUSES	SOLUTION
<ul style="list-style-type: none">• Pressure/steam leak through the door gasket -----• Overloaded chamber (pressure vessel) -----	<ul style="list-style-type: none">• Perform "Preventive Maintenance" (Page 14);• See "How to Use the Vitale Class CD Autoclave" (Item d, page 9).

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

POSSIBLE CAUSES	SOLUTION
• Equipment installed in altitudes higher than 1.000 m -----	• Perform a new Altitude Adjustment, see "Performing a New Altitude Adjustment" (Page 12).

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

FAILURE MESSAGES

When a cycle is cancelled, the display will show a message related to the possible cause of cancelling. Follow the instructions at the right side of each message below to solve them:

To get back to the main menu after the exhibition of a failure message, press **X**.

POSSIBLE CAUSES	SOLUTION
HEATING TIME LIMIT	Lack of water or excess of material. See "How to Use Your Autoclave Vitale Class CD" (Page 9). If the problem persists even after following the recommendations, see "How to Proceed When Service is Needed". (Page 17).
CYCLE CANCELLED LOW PRESSURE	Lack of water or excess of material. See "How to Use Your Autoclave Vitale Class CD" (Page 9). If the problem persists even after following the recommendations, see "How to Proceed When Service is Needed". (Page 17).
CYCLE CANCELLED OVERPRESSURE	Obstruction of the internal steam exits (Fig. 5, page 6). See "How to Use Your Autoclave Vitale Class CD" (Page 9). If the problem persists even after following the recommendations, see "How to Proceed When Service is Needed". (Page 17).
CYCLE CANCELLED UNDERVOLTAGE	Wait the normalization of the electrical grid. See "Installation Instructions" (page 7), item "Electrical". If the problem persists even after following the recommendations, see "How to Proceed When Service is Needed". (Page 17).
CYCLE CANCELLED OVERVOLTAGE	Wait the normalization of the electrical grid. See "Installation Instructions" (page 7), item "Electrical". If the problem persists even after following the recommendations, see "How to Proceed When Service is Needed". (Page 17).
INCOMPATIBLE VOLTAGE	When the cycle is cancelled by UNDERVOLTAGE or OVERVOLTAGE and the user cancels its respective failure message, the display will show INCOMPATIBLE VOLTAGE, keeping like this until the normalization of the electrical grid. See "Installation Instructions" (page 7), item "Electrical". If the problem persists even after following the applying the recommendations, see "How to Proceed When Service is Needed". (Page 17).
CYCLE CANCELLED DOOR OPEN	Close the door properly. See "How to Use Your Autoclave Vitale Class CD" (Page 9). If the problem persists even after following the applying the recommendations, see "How to Proceed When Service is Needed". (Page 17).
INCOMPATIBLE VOLTAGE ↔ PRESSURE DETECTED	Wait the normalization of the electrical grid. See "Installation Instructions" (page 7), item "Electrical". If the problem persists even after following the recommendations, see "How to Proceed When Service is Needed". (Page 17).
CYCLE CANCELLED BY USER	The user cancelled the program. The material must be reprocessed (remove it from the package, wash the material, dry it, put it in a new package, and sterilize it).

HOW TO PROCEED WHEN SERVICE IS NEEDED

First, have in hands the model of your autoclave, voltage, serial number, and the date of manufacture, found in the identification label located at the back of the autoclave (Fig. 1, page 6), 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 through our website: www.cristofoli.com.

GUIDANCE FOR FINAL DISPOSAL OF THE EQUIPMENT

The environment belongs to everyone, therefore, it is up to each one of us to make 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 is it, as it varies according to the intensity and how the equipment is used or handled. Exception made for the component "lid" which must be replaced every 10 years.

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, and strongly recommends users of their products to seek the best destination when disposing their equipment or components, taking into account the materials recycling legislation effective in each country.

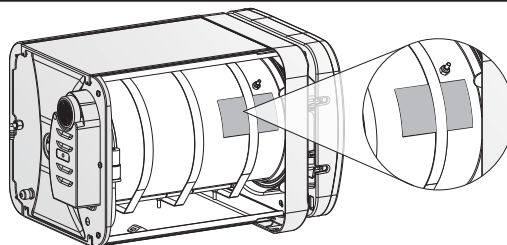
We advise you to take your equipment to specialized recycling companies that, due to the continuous and fast paced development of new recycling technologies and materials reuse, provide the best way of disposing the equipment. Cristófoli contributes this way to reduce the consumption of non-renewable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

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

RESCUE OF THE CONSTRUCTION CONTROL MANUAL (MCC)

To rescue the Construction Control Manual, Pressure Vessel Log Book, or any other document relative to the pressure vessel, see the data marked in the pressure vessel indelible label, as shown in the image.

Access www.cristofoli.com/mcc and insert the pressure vessel serial number (NS), example: AB01200000000 and click on search, the search will show a link to download the file.



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, Brazil). 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

If any item from preventive maintenance needs to be replaced, the cost will be responsibility of the owner, for those are parts/products susceptible to wear and tear.

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, or problems caused by absence of preventive maintenance, when it is indispensable.
- Use of non-original or not acquired at the **CRISTÓFOLI** Authorized Service Network parts;
- 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.

USE INSTRUCTIONS - QUICK GUIDE

VITALE CLASS CD 12 / 21

 **Read carefully the Instruction Manual**

1. Connect the power cable to an outlet and press ► to turn the autoclave on.
2. Open the door and use the measuring cup to pour the correct amount of **distilled water** directly inside the chamber (pressure vessel), 150 ml for Vitale Class CD 12, and 250 ml for Vitale Class CD 21.
3. Load the autoclave with the materials to be sterilized and close the door correctly.
4. Press ► and select the desired program through the keys ◀ and ▶. Press ► to initiate.
The autoclave will automatically perform heating, sterilization, depressurization, and drying, according to the table below data. At the end of the drying process, the autoclave will beep until the operator open the door.
5. Let the door ajar, the display will show **COOLING** by 5 minutes. Remove the material only after the message **CYCLE CONCLUDED**.
6. Turn off the autoclave by pressing ✕ for 2 seconds.

PROGRAMS	AVERAGE HEATING TIME	STERILIZATION TEMPERATURE AND PRESSURE	STERILIZATION TIME	DRYING TIME	
				12 LITERS	21 LITERS
1- Wrapped Instruments	10 a 40 min.	134 °C / 216 kPa (2,2 kgf/cm ²)	10 min.	40 min.	50 min.
2- Unwrapped Instruments	10 a 40 min.	134 °C / 216 kPa (2,2 kgf/cm ²)	6 min.	35 min.	40 min.
3- Plastic and Cotton	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm ²)	30 min.	45 min.	55 min.
4- Surgical Kit and Fabrics	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm ²)	30 min.	50 min.	60 min.
5- Liquids	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm ²)	30 min.	-----	-----

Maximum drying temperature: 121 or 134 °C (depending on the chosen program).

The Autoclave is an equipment for steam sterilization, it works with high temperature and pressure. The autoclave must be handled by trained professional and kept at a location with controlled access.

Attention! Perform preventive maintenance on the autoclave according to the instruction manual specifications.
Test your autoclave with biological indicators every 7 days.

