



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 665/2022 - \*BPF - Boas Práticas de Fabricação - ANVISA requirements.



## Vitale Class CD 12/21 Autoclave

### CRISTÓFOLI'S MISSION

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To develop innovative solutions to protect life and promote health.

### CRISTÓFOLI QUALITY AND ENVIRONMENTAL POLICY

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











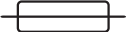
Cristófoli Equipamentos de Biossegurança Ltda., established at Rua São José, 3209, Área Urbanizada II in Campo Mourão, Paraná, Brazil, manufactures biosafety equipment to assist the health care, having the following policy: "To develop innovative solutions for health care by using agile, robust, and 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)

## INDEX

Meaning of Symbols .....	03
Applicable Regulations .....	04
Introduction .....	05
Intended Use .....	05
Recommendations and Warnings .....	05
How to Identify your Autoclave .....	06
Installation Instructions .....	07
Altitude Adjustment .....	08
Safety Devices .....	08
How to Use the Vitale Class CD Autoclave .....	09
Programs and Messages .....	11
Performing a New Altitude Adjustment .....	12
Quality Control .....	13
Technical Data .....	13
Preventive Maintenance / Monitoring .....	14
Fuse Replacement .....	14
Troubleshooting .....	15
Failure Messages .....	16
Initialization Errors .....	16
How To Proceed When Service Is Needed .....	17
Guidance for Final Disposal of the Equipment .....	17
Warranty Terms .....	18
Use Instructions - Quick Guide .....	19

## MEANING OF SYMBOLS

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

## **APPLICABLE REGULATIONS**

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ABNT NBR 11817:2023 – 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 N°665, de 30 de março de 2022 - Dispõe sobre as Boas Práticas de Fabricação de Produtos Médicos e Produtos para Diagnóstico de Uso In Vitro.

## 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 cup, 1 hose (1,5 m), 1 clamp, and 1 manual.

## INTENDED USE

This equipment was developed for sterilization of packed and unpacked 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/cm<sup>2</sup>) 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.
- ▶ Perform tests with biological indicators on your autoclave upon first use, routine (daily, weekly, or in accordance with the legislation of your state or city for your type of service) and after preventive or corrective maintenance.
- ▶ It is recommended that the equipment be unplugged at the end of the workday.

### MANUFACTURER

**Cristófoli Equipamentos de Biossegurança Ltda.**

Rua São José, 3209 - Campo Mourão - PR - Brasil.  
CEP 87307-799

CNPJ 01.177.248/0001 - 95 - Inscr. Est. 90104860-65

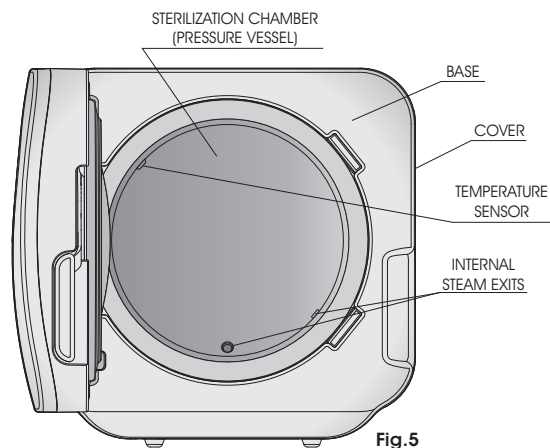
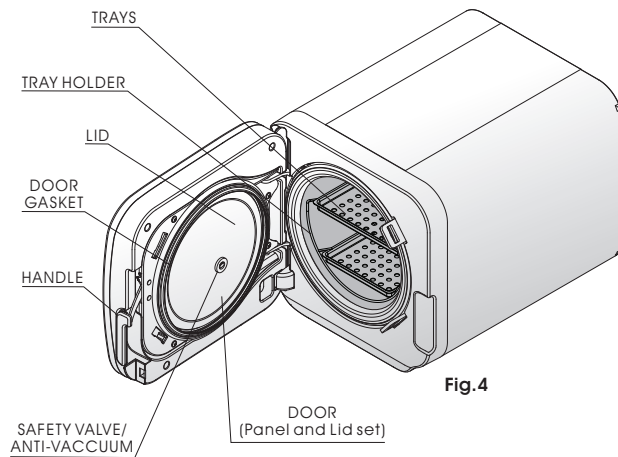
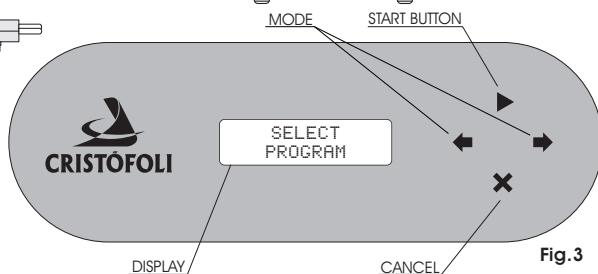
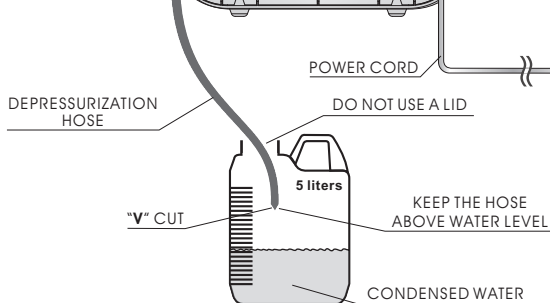
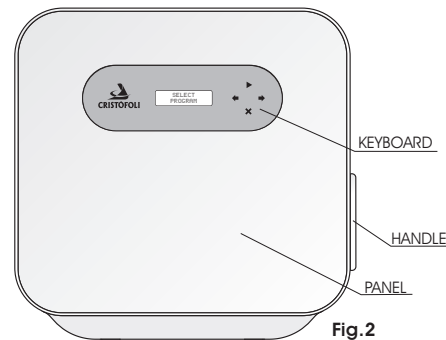
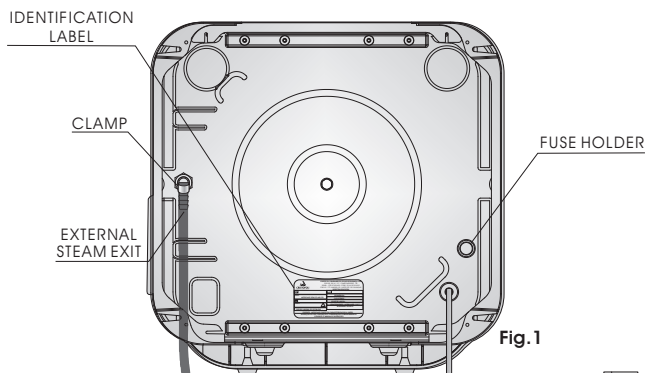
Website: [www.cristofoli.com](http://www.cristofoli.com) - e-mail: [cristofoli@cristofoli.com](mailto:cristofoli@cristofoli.com)

### Responsible Technician

Eduardo Luiz Soppa  
CREA-PR: 109201/D

## 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 cord 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	9,5 A	15 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	12,6 A	20 A		

**Table 1**


## DRAINAGE

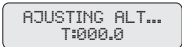
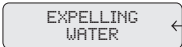
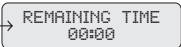
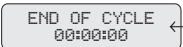
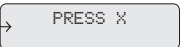
Connect the provided hose to the external steam exit (Fig. 1, page 6), put the clamp and fasten it with a screwdriver. The other side must be connected to the plumbing system (on a pipe that is able to tolerate the depressurizing temperature of the equipment) or to an open and empty container, with a "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 **with empty chamber (no materials, trays or tray holder)**, 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 cup, pour the right amount of **distilled water** directly into the chamber (pressure vessel), until the water reaches the "Level" mark. Close the door and press ► to begin.
- 2► During heating, the display will show the message  and  ↔ . The adjustment is automatically completed.
- 3► The autoclave will beep 2 times and show  ↔ , it means the procedure was successfully accomplished.
- 4► Press ✕, the autoclave will be turned off.

**Note:** If any problems occur during the adjustment, press ✕ to return to the Altitude Adjustment screen and perform the process again, or check "Failure Messages" (Page 16), following the recommendations related to the shown failure message.

⚠ If the equipment is **transferred from location (building, city or state) or undergoes technical maintenance**, see the topic "Performing a New Altitude Adjustment" (Page 13) to perform a new Altitude Adjustment.

## SAFETY DEVICES

Vitale Class CD autoclave has the following safety devices:

- 1► **FUSE** - Device whose purpose is to protect electrical installations against excess current. If replacement is necessary, refer to the table below for needed information. See "Fuse Replacement" (Page 14).



AUTOClave	AC VOLTAGE	FUSE
Vitale Class CD 12	95 V - 254 V	10 A (250 V)
Vitale Class CD 21	95 V - 254 V	15 A (250 V)

Table 2

- 2► **DOOR KEY** - Internal device that prevents the equipment from functioning if the door is not closed correctly.
- 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 is pressure 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 whose function is to prevent excessive heating of the chamber (pressure vessel) in the event of a malfunction in the electronic circuit.
- 7► **DOOR GASKET** - If the pressure inside the chamber (pressure vessel) exceeds 3 kgf/cm<sup>2</sup> (294 kPa), the door gasket will escape through the edge of the lid, causing 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).

## HOW TO USE THE VITALE CLASS CD AUTOCLAVE

- a► Connect the power cord 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 cup (Fig. 6) to pour the correct amount of **distilled water** directly into the chamber (pressure vessel) **before** each cycle. **The water must reach the "water level" mark** (Fig. 6).

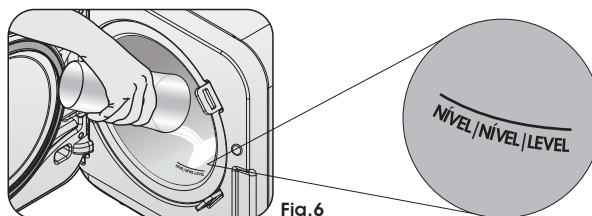


Fig.6

⚠ **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 equipment is **transferred from location (building, city or state) or undergoes technical maintenance**, see the topic "Performing a New Altitude Adjustment" (Page 13) 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 walls or internal steam exits, as this will cause interference in the cycle and damage to materials. **Do not overload the autoclave.** Do not overload the autoclave, the amount of articles to be sterilized must not exceed 1,2 kg for Vitale Class CD 12 liters, and 2,1 kg for Vitale Class CD 21 liters (table 3). **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.

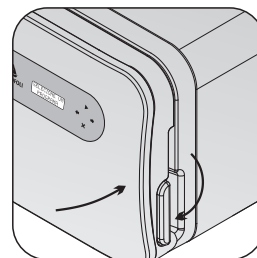


Fig.7

CHAMBER (PRESSURE VESSEL) MAXIMUM CAPACITY						
MODEL	USING TRAYS	USING 1 SUPPORT	USING 2 SUPPORTS	MAX. WEIGHT (PACKED AND UNPACKED INSTRUMENTS)	MAX. WEIGHT (COTTON)	MAX. VOLUME (LIQUIDS)
CLASS CD 12	5 envelopes (10 x 23 cm)*	13 envelopes (10 x 23 cm)*	-	1,2 kg	0,5 kg	500 mL
CLASS CD 21	12 envelopes (10 x 23 cm)*	13 envelopes (10 x 23 cm)	26 envelopes (10 x 23 cm)	2,1 kg	1,0 kg	1000 mL

\*Each envelope with 6 instruments at most. \*\*The supports are sold separately. Contact your local dealer.

Table 3



Fig.8

- 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
1- Wrapped Instruments	10 a 40 min.	134 °C / 216 kPa (2,2 kgf/cm <sup>2</sup> )	10 min.	45 min.
2- Unwrapped Instruments	10 a 40 min.	134 °C / 216 kPa (2,2 kgf/cm <sup>2</sup> )	6 min.	30 min.
3- Plastic and Cotton	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm <sup>2</sup> )	30 min.	55 min.
4- Surgical Kit and Fabrics	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm <sup>2</sup> )	30 min.	60 min.
5- Liquids	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm <sup>2</sup> )	30 min.	- - - - -
6- Extra Drying	-----	-----	-----	15 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).

- 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 continuously 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.

**Note:** For the UNWRAPPED INSTRUMENTS program, after the depressurization, the message ← NO DRY YES → will be displayed, the autoclave will beep until the user chooses one of the options. Press ▶ to perform the drying process or press ◀ to cancel it.

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

- 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.

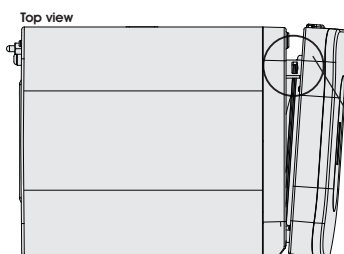
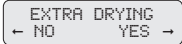


Fig.9

**Note:** If the door is opened during drying, the display will show the following message: DRY WITH DOOR OPEN?. To continue drying with the door open, press ◀, or press ▶ to cancel the cycle. If no option is selected, the cycle will be canceled automatically.

**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.

- 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.
- j ▶ At the end of this process, the autoclave will beep 5 times, the display will show the message . If the materials are still humid, press ➡ for an extra drying.
- k ▶ At the end of the cycle, the autoclave will beep 5 times, the display will show CYCLE CONCLUDED and the cycle total time. Only remove the materials when they get cool enough to be handled. **Note:** Remember to use safety gloves for thermal protection.
- l ▶ Press ✕ to return to the program selection mode.
- m ▶ After use, turn off the equipment pressing ✕ for 2 seconds.

## PROGRAMS AND MESSAGES

Below are the available programs and messages displayed by the autoclave.

### WHEN TURNING ON (brand and model)

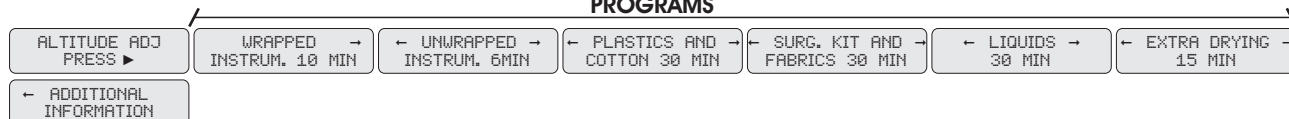
CRISTÓFOLI  
BIOSAFETY

VITALE CLASS CD  
12 LITERS

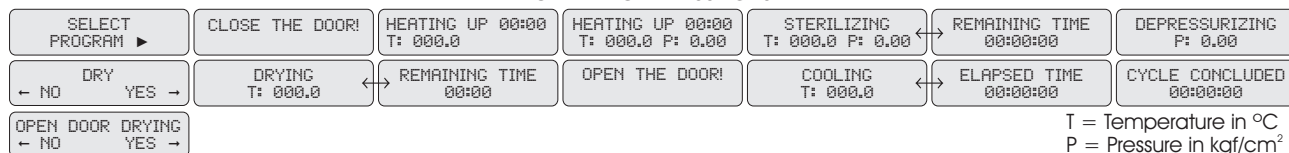
Or

VITALE CLASS CD  
21 LITERS

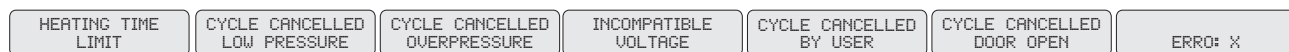
### PROGRAMS



### OPERATION MESSAGES



### FAILURE MESSAGES



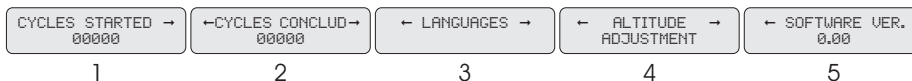
See the topic "Failure Messages" (Page 17).

### 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:
 

PORTUGUES →

← ESPANOL →

← ENGLISH →

 . 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 from location (building, city or state) or undergoes technical maintenance**, perform the Altitude Adjustment again. For this procedure, the autoclave chamber must be **empty (no materials, trays or tray holder)**. **Note:** Perform this process only when the autoclave is cool.

- 1► Connect the power cord to an outlet and press ► to turn the autoclave on.
  - 2► Open the door of the autoclave and, using the cup, pour the right amount of **distilled water** directly into the chamber (pressure vessel), until the water reaches the "Level" mark.
  - 3► Select trough the keys ◀ ▶ the menu
 

← ADDITIONAL INFORMATION

 and press ►. After that, choose
 

← ALTITUDE ADJUSTMENT →

 and press ► to start.
  - 2► During heating, the display will show the message
 

ADJUSTING... T:000.0

 and
 

EXPELLING WATER ↔ REMAINING TIME 00:00:00

 . The adjustment is automatically completed.
  - 3► The autoclave will beep 2 times and show
 

END OF CYCLE 00:00:00 ↔ PRESS X

 , it means the procedure was successfully accomplished.
  - 4► Press ✕, the autoclave will be turned off.
- Note:** If any problems occur during the adjustment, press ✕ to return to the Altitude Adjustment screen and perform the process again, or check "Failure Messages" (Page 16), following the recommendations related to the shown failure message.
- 5► Press ✕ to return 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

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.

Pressure Vessel Serial Production following the highest quality standards recommended in the quality technical regulation and conformity evaluation requirements for Boilers and Pressure Vessels of Serial Production suggested by INMETRO - Portaria 120/2021.

## TECHNICAL DATA

	VITALE CLASS CD 12 LITERS	VITALE CLASS CD 21 LITERS
Capacity .....	12 liters	21 liters
Net weight .....	17,8 kg	23,9 kg
Gross weight .....	19,5 kg	26,5 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) .....	21,6 x 33,7 cm	24,6 x 45,2 cm
Autoclave external dimensions (W x H x D) .....	35,3 x 35,3 x 51 cm	38 x 38 x 59 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	127/220 V AC
Operating Voltage Range .....	127 V: 95 V - 140 V, 220 V: 190 V-254 V	127 V: 95 V - 140 V, 220 V: 190 V-254 V
Frequency .....	50/60 Hz	50/60 Hz
Power .....	1200 Watts	1600 Watts
Power consumption* .....	127 V - 0,413 Kilowatts/hour 220 V - 0,466 Kilowatts/hour	0,658 Kilowatts/hour 0,708 Kilowatts/hour
Maximum operation pressure .....	216 kPa (2,2 kgf/cm <sup>2</sup> )	216 kPa (2,2 kgf/cm <sup>2</sup> )
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.	Carbon steel with electrostatic painting
ANVISA .....	10363350017	10363350017
Fluid Class .....	C (Water Steam)	C (Water Steam)
Potential risk group .....	5 (PxV < 1)	5 (PxV < 1)
Pressure vessel category .....	V	V
Class .....	S	S
Certification .....	Vitale Class CD Autoclaves are manufactured by Cristófoli Biossegurança, company whose the Quality Management System is certified by ISO 13485, and in accordance with RDC 665/2022 - BPF - Boas Práticas de Fabricação - ANVISA (Brazilian standard similar to GMP - FDA/US).	

\*Values obtained using the Surgical Kit and Fabrics program starting from room temperature.

**Table 5**

## 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**, that must be done periodically by the consumer's costs.

When performing any kind of maintenance, including cleaning, remember to unplug the power cord, including cleaning.



Perform tests with biological indicators on your autoclave after each preventive or corrective maintenance.

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 <b>nonabrasive</b> 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. <b>It's forbidden the use of any descaler product</b> 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 <a href="http://www.cristofoli.com">www.cristofoli.com</a> 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 or 70% alcohol. After cleaning, fit 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 <a href="http://www.cristofoli.com">www.cristofoli.com</a> at the session "Support" of your product.
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 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 6

## FUSE REPLACEMENT



To replace the fuse (Fig. 1, page 6), use only fuses that doesn't contain ferrous alloy. Verify using a magnet, the fuse must not be attracted by it. The non observing of this recommendation will cause **loss of warranty of the autoclave**. The used fuse is 6,35x32 AGLF Glass, Fast Action. For Vitale Class CD 12, use a 10 A (250 V) fuse, and for Vitale Class CD 21, use a 15 A (250 V) fuse.

## TROUBLESHOOTING

For any replacement of parts, contact your local dealer or authorized technical assistance office. It's not recommended the replacement by non-authorized 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"> <li>• Lack of power -----</li> <li>• The autoclave is not connected to the outlet -----</li> <li>• The ► key was not pressed to turn the autoclave on -----</li> <li>• Blown fuse -----</li> <li>• There is voltage fluctuation -----</li> </ul>	<ul style="list-style-type: none"> <li>• Verify if there's a power failure in your area.</li> <li>• Connect the power cord to the outlet properly.</li> <li>• Press ►.</li> <li>• See "How to proceed when service is needed" (Page 17).</li> <li>• Consult your local energy provider.</li> </ul>

### THE AUTOCLAVE SWITCHES ON BUT DOES NOT HEAT UP

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

### THE AUTOCLAVE PRESSURE GETS TOO HIGH, ACTIVATING THE SAFETY DEVICES

POSSIBLE CAUSES	SOLUTION
<ul style="list-style-type: none"> <li>• Obstruction of the hose connected to the external steam exit -----</li> </ul>	<ul style="list-style-type: none"> <li>• 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 it firmly. <b>ATTENTION!</b> 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).</li> </ul>

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

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

POSSIBLE CAUSES	SOLUTION
• Equipament installed in altitudes higher than 1.000 m -----	• Perform a new Altitude Adjustment, see "Performing a New Altitude Adjustment" (Page 12). For this procedure, the autoclave chamber must be empty (no materials, trays or tray holder).

**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 **✕**.

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).
INCOMPATIBLE VOLTAGE	When identifying an incompatible voltage level, the equipment will remain on this screen until the network is completely normalized. See "Installation Instructions" (Page 7) under "Electrical". If the problem persists, 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).
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).

## INITIALIZATION ERRORS

If, when connecting the autoclave to the electrical network, the display shows an error message such as

ERR0: ✕

, see

"How to Proceed When Service is Needed". (Page 17).

## HOW TO PROCEED WHEN SERVICE IS NEEDED

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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](http://www.cristofoli.com).

## GUIDANCE FOR FINAL DISPOSAL OF THE EQUIPMENT

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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** reaffirming its concern for the environment, advises the 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.

## 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](http://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 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.
- Melting of the fuse holder due to the use of a fuse with ferrous alloy, failing to comply with the manual's recommendations.
- 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.

## USE INSTRUCTIONS - QUICK GUIDE

### VITALE CLASS CD 12 / 21

 **Read carefully the Instruction Manual**

1. Connect the power cord to an outlet and press ► to turn the autoclave on.
2. Open the door and use the cup to pour the correct amount of **distilled water** directly into the chamber (pressure vessel), **until the water reaches the "Level" mark**.
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
1- Wrapped Instruments	10 a 40 min.	134 °C / 216 kPa (2,2 kgf/cm <sup>2</sup> )	10 min.	45 min.
2- Unwrapped Instruments	10 a 40 min.	134 °C / 216 kPa (2,2 kgf/cm <sup>2</sup> )	6 min.	30 min.
3- Plastic and Cotton	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm <sup>2</sup> )	30 min.	55 min.
4- Surgical Kit and Fabrics	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm <sup>2</sup> )	30 min.	60 min.
5- Liquids	8 a 40 min.	121 °C / 118 kPa (1,2 kgf/cm <sup>2</sup> )	30 min.	- - - - -
6- Extra Drying	-----	-----	-----	15 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.**

