

**PLAZADENTE**  
*Industry*



# **STERILIZER BOX**

## **MANUAL**

**ANVISA authorization 8.20.590-9  
since February/2023**

Atualização 2024



# INSTRUCTION MANUAL AND WARRANTY TERM

## **Manufacturer:**

Plazadente, IND. E COM. DE PRODUTOS DE TOUCADOR LTDA – ME – EIRELI  
CNPJ 03.871.990/0001-21, Rua Luiz Consentino, 7275, Londrina-PR.  
[www.plazadente.com](http://www.plazadente.com) / contato.plazadente@gmail.com.br

## Equipment:

The PLAZADENTE STERILIZER BOX operates based on UV-C ultraviolet light – 254nm. The Sterilizer Box was notified by ANVISA as a “Class II Medical Device/5106107229,” through Resolution No. 613 of 02/23/2023. Full content access at the address:

<https://consultas.anvisa.gov.br/#/saude/25351669432202202/?cnpj=03871990000121>

## **Sterilization Time:**

Five-minute cycle.  
Ciclo de cinco minutos.

## **Models:**

- CE 01 – 21 UVC/Ultra – In Resin – ABS
- Internal dimensions: 190mm x 100mm x 50mm
- External dimensions: 200mm x 115mm x 160mm
- Capacity: instruments with dimensions up to 150mm (length) x 90mm (width) x 40mm (height) if it is a single object or, if there are several, it must accommodate the number of instruments compatible with the usable working area (100mm x 90mm x 40mm), observing their arrangement so that they are not overlapped and are at least 10mm away from the internal walls.



### CE 01 – 22 UVC/Ultra – In Metal – Carbon Steel:

- Internal dimensions: 190 mm x 200 mm x 90 mm
- External dimensions: 210 mm x 430 mm x 200 mm
- Capacity: instruments with dimensions up to 180 mm (length) x 190 mm (width) x 90 mm (height), if it is a single object or, if there are several, it must accommodate the number of instruments compatible with the usable working area, observing their arrangement so that they are not overlapped and are at least 10 mm away from the internal walls. It has two quartz glass trays.



## PURCHASER IDENTIFICATION:

Name/Company Name: \_\_\_\_\_  
Tax ID (CPF/CNPJ): \_\_\_\_\_  
Phone Number: ( ) \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_  
Postal Code: \_\_\_\_\_

## Equipment Identification:

Serial Number: \_\_\_\_\_  
Year of Manufacture: \_\_\_\_\_  
Model: \_\_\_\_\_

## STERILIZER BOX DIMENSION CATALOG

### CE 01 - 21 UVC/Ultra - In Resin - ABS

- Internal dimensions: 190 mm x 100 mm x 50 mm
- External dimensions: 200 mm x 115 mm x 160 mm
- 1 glass tray: 190 mm x 100 mm
- Usable area for sterilization of surgical instruments: 170 mm x 90 mm

### CE 01 - 22 UVC/Ultra - In Metal - Carbon Steel

- Internal dimensions: 190 mm x 200 mm x 90 mm
- External dimensions: 210 mm x 430 mm x 200 mm
- 2 quartz glass trays: 190 mm x 100 mm
- Usable area for sterilization of surgical instruments: 170 mm x 400 mm



## Precautions regarding ultraviolet rays

UV-C lamps emit ultraviolet light which is harmful to human health when exposed directly to the eyes and skin.

The Plazadente Sterilizer Box (model CE01- 21/Ultra and model CE01 – 22/Ultra) does not allow the operator access to the light emitted by the active lamps so that they are not exposed to Ultraviolet rays. If the access lid to the inside of the equipment is open, the lamps will not turn on. And if the lid is opened during the 5 (five) minute cycle, the lamps will turn off. In this case, the display will indicate this situation and request that the lid be closed and the 5 (five) minute cycle be redone.

## Mains Voltage: 127V or 220V?

The equipment must be connected to 127V or 220V, depending on the model, to prevent damage when connected to the electric current. Check the correct voltage on the casing and on the power cord.

## STERILIZER BOX COMPONENTS

These are the components of the Sterilizer Box:

- **DISPLAY – SCREEN**
- **QUARTZ GLASS TRAY**
- **UV-C GERMICIDAL LAMPS**
- **PIEZOELECTRICS**
- **LID:**

## DISPLAY - SCREEN

The screen is installed on the outside of the Sterilizer Box and will indicate the start and end of the sterilization cycle. It will also indicate if all components are in full operation, especially if the lamps lit up regularly throughout the entire 5 (five) minute cycle. It will also indicate the date and time in Brasília. And in case of malfunction of one of the items in the Sterilizer Box, the display will inform which item presented a problem and instruct the operator to seek technical assistance authorized by the manufacturer.



## GLASS TRAY

The sterilizer box uses quartz glass plates as trays, which will serve to receive the objects/instruments to be sterilized.

The glass tray must always be sanitized and free of stains, grease, and dust. For its sanitization, use a sponge or cloth lightly dampened with isopropyl alcohol, taking care not to leave residue such as lint, as this completely inhibits the emission of the rays. Use PPE during this handling. Never replace the quartz tray with common glass. In common glass, the rays are reflected, inhibiting the sterilization process of the bottom part of the objects.

## THE UV-C GERMICIDAL LAMPS

In the STERILIZER BOX, UV-C lamps are installed on the upper and lower parts. The specifications of the ultraviolet – UV-C lamps, with 254nm radiation, according to information from their manufacturers:

Models: G8T5/G15-T8-15w

Power: 8W/15w

Durability: 5 to 6 thousand hours, according to information from each manufacturer

Radiation: 254nm

## PRECAUTIONS

As mentioned, UV-C lamps emit ultraviolet light, and it is important to note that it is harmful to human health when exposed directly to the eyes and skin. Throughout the entire operating cycle, the lamps are inaccessible to the user.

If the user opens the lid while the equipment is running, the lamps will immediately turn off. In this case, the display will report this situation and instruct the user to close the lid and restart another 5 (five) minute cycle.



When the display indicates the non-functioning of one or more lamps, the Sterilizer Box will not operate until the problem is resolved. If this happens, the operator must restart the Box at least 1 (one) more time. If the problem persists, PLAZADENTE's technical assistance must be called for guidance and problem resolution.

If the display shows a SUCCESS message at the end of the 5 (five) minute cycle, it will indicate that all components of the Sterilizer Box functioned, and thus the objects/instruments will be sterilized and ready for immediate use.

Only the Technical Assistance accredited by PLAZADENTE may remove the UVC lamps and perform maintenance on the other components.

## **THE PIEZOELECTRICS**

The STERILIZER BOX has piezoelectrics on the upper and lower parts of the equipment. They are responsible for emitting ultrasonic waves, which contribute to the efficiency of the Ultraviolet rays from the UV-C lamp.

If one or all of the piezoelectrics present some anomaly, the ultrasonic sensor will identify it and a message will appear on the display reporting the problem. Consequently, the Sterilizer Box suspends its operation. The User must make one more attempt to initialize the 5 (five) minute cycle. If the problem with the piezoelectrics persists, the technical assistance authorized by the Industry must be called.



## STEP-BY-STEP STERILIZATION PROCESS

The PLAZADENTE STERILIZER BOX's main function is to sterilize smooth, non-porous objects/instruments for immediate use.

It does not sterilize objects/instruments with complex shapes, recesses, or cannulas. They also cannot be wrapped in surgical pouches or films, even if transparent.

Its standard cycle is five minutes, as per unique programming. For the final result to be successful, it is necessary to observe details that will safely confirm to the user that their instruments are sterile and suitable for clinical and surgical use. Therefore, the following must be observed:

- Install the equipment in a safe place, easily accessible to the user; it must be placed on a level surface. Plug the box into a power outlet, observing the voltage of the Box and the outlet.
- The "display" will initially show the need to update the date and time, which must be done via a WI-FI connection, using a device available in the environment such as a computer, notebook, or cell phone connected to WI-FI.
- Open the lid and place the objects/instruments to be sterilized, after cleaning and drying, onto the quartz glass tray; use gloves and clinical forceps to handle them.
- Pre-cleaning of instruments: Before placing the instruments in the Sterilizer Box for the sterilization process itself, they must, mandatorily, undergo sanitization.

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## The entire instrument pre-cleaning process is described below.

- **Instrument immersion** – Contaminated instruments must be washed as soon as possible after use (before biofilm forms), starting with the immersion procedure for 5 to 10 minutes in a solution of water + ammonium quaternary-based disinfectant or isopropyl detergent in the proportions indicated by the manufacturer, in a container with a hermetic lid.
- **Manual cleaning** – Following the immersion of the instruments, with the aid of a soft-bristled brush, remove macro residues from the entire surface of the instrument, with extra attention to any grooves and fissures that may exist in the instrument.
- **Mechanical cleaning** – After manual cleaning of the instruments, the operator must obligatorily use an ultrasonic bath for a period of 7 to eight minutes, according to the manufacturer's instructions.
- **Use of the ultrasonic bath** – Prepare in it a solution of water and detergent or enzymatic disinfectant in the proportions according to the manufacturer's recommendations. Before inserting the instruments, the solution must be degassed, with the purpose of removing the gas which, incorporated into the water, hinders the action of the ultrasound waves during cleaning, according to the manufacturer's instructions
- **Rinsing and drying of instruments** – Rinse and dry the instruments well with a lint-free cloth.
- **Use of PPE** – Throughout the entire instrument sanitization process, as well as when placing and removing them from the STERILIZER BOX, the operator must use clinical forceps, rubber gloves, and other PPE related to the operation.

- **Sanitization of the glass tray** – The operator must inspect the quartz glass tray and the lamps. And, if necessary, must sanitize the glass tray and lamps with a cloth soaked in isopropyl alcohol for the removal of dust and possible micro-elements. Use a lint-free cloth
- **Placing objects/instruments with distance from each other** – The user must place the objects/instruments, already properly sanitized and dry, onto the glass tray of the Sterilizer Box, maintaining a distance between them so that the UVC light can touch the sides of each instrument. Likewise, they must remain distant from the side walls of THE PLAZADENTE STERILIZER BOX so that the Light can touch the entire surface.

It is suggested that the objects/instruments should be equidistant at least 1 (one) centimeter from each other, as well as a minimum of 1 (one) centimeter distant from the internal walls. The instruments must never overlap.

- **Immediate use of Instruments** – the objects/instruments sterilized in the Sterilizer Box must be removed for immediate use. That is, the instruments, after the conclusion of the 5 (five) minute cycle, and with the expression SUCCESS showing on the display, must be removed from the Sterilizer Box immediately to be used in the current procedure. They must never be stored for later use. In this event, there will be a loss of the sterile state of the objects/instruments; the loss of sterility may also occur at the time of packaging, and because the packaging, by principle, is not sterile.

Objects/instruments should not be wrapped in surgical grade pouches, plastics, or films for the 5 (five) minute cycle, as the packaging will prevent ultraviolet light from reaching their entire surface with the necessary intensity and promoting the elimination of microorganisms.

Therefore, the objects/instruments must be placed on the quartz tray of the Sterilizer Box without any packaging or wrapping and must be used immediately in the procedure.

- **The display and its stages:** After placing the instruments on the quartz tray, the operator must close the lid and press the button to turn on the equipment. The display will indicate all phases of sterilization until its end.

*During the 5 (five) minute cycle, the equipment will emit sound signals and at the end, upon conclusion of the process, it will emit a sequence of sound signals and the display will show the message SUCCESS. If this expression is not on the display, it will indicate a cycle failure and will show the cause. The Operator must make a new attempt to start the cycle, and if the problem persists, the technical assistance indicated by the Industry must be called.*

When the 5 (five) minute cycle is interrupted, the display will indicate the reason for the malfunction, which may be the following:

- a) power outage;**
- b) problem(s) with the lamp(s);**
- c) problems with the ultrasound;**
- d) lid opened before the start of the 5 (five) cycle;**
- e) lid opened before the conclusion of the cycle.**

*As stated above, if the SUCCESS message does not appear in the 5 (five) minute cycle, the objects/instruments have not been sterilized. In this situation, the display will report the reason and recommend redoing the cycle. If the problem message remains, the equipment will not function, and technical assistance must be called.*

Only the technical assistance indicated by the manufacturer may promote the maintenance of the equipment.

- **Standard 5 (five) minute cycle:** After the 5 (five) minute cycle is concluded, the equipment will automatically turn off with audible warnings and the display will inform that the instruments are already sterilized with the message SUCCESS.
- **Improper use of the Sterilizer Box:** Do not use the equipment as an instrument storage unit to avoid potential damage to the glass tray and the equipment structure itself.
- **Transport of the Sterilizer Box:** When transporting the Sterilizer Box, be careful not to suffer jolts, avoiding damage to the lamps and the quartz tray. It is recommended to protect it with bubble wrap for transport in the original shipping box/packaging.
- **Sterilizer Box Lid:** It is recommended not to open the equipment lid during the cycle. However, if it is opened, the cycle will be interrupted and the equipment will shut down (the lamps will turn off). In this case, the cycle will not be completed, and the sterilization process will be compromised and must be redone.
- **Technical assistance:** equipment maintenance: The Sterilizer Box user must observe its correct functioning, paying attention to the messages on the equipment display and seeking technical assistance authorized by the Industry when informed of any anomaly and non-functioning of the equipment elements.

Equipment maintenance must be called when the display indicates failures in one or more components. In this event, the equipment will not function until the problem is investigated and resolved by the accredited technical assistance.

The main problems that will lead to a call for technical assistance are: malfunction of the piezoelectrics; malfunction of the lamps; malfunction of the WI-FI; malfunction of the lid sensor; malfunction of the display.

## CONCLUSION OF THE 5 MINUTE CYCLE – CHEMICAL INDICATOR

The operator must observe the full functioning of the equipment according to the messages reported on the display!

Once the 5 (five) minute cycle is concluded with the expression SUCCESS reported on the display, the operator has the guarantee that the objects/instruments are effectively sterilized and can be used immediately.

Furthermore, the operator may also perform lamp functionality tests periodically, using chemical tests to control the functionality and intensity of Ultraviolet ray emission during the 5 (five) minute cycle.

The chemical test aims to provide the operator with another element of verification of the efficiency of the 5 (five) minute cycle with the functioning/efficiency of the lamps conducting the sterilization process.

For the chemical test to certify that the cycle is in compliance (full functioning of the lamps), paper slips with chemical products that react to the presence of UV light are used. Initially, the paper slip is yellowish. In the presence of Ultraviolet light, there will be color changes.

According to the Manufacturer, the color should change from yellow to orange or red when exposed to ultraviolet light (UV-C) radiation, and this will certify that during the 5 (five) minute cycle, the lamps functioned fully, concluding that the procedure was a SUCCESS. If this does not occur, there is evidence that the lamps presented problems during the cycle and technical assistance should be called. In this event, the display will also indicate the problem with the lamps.

The Operator may use the chemical test in all cycles performed with the Sterilizer Box or by sampling, since the equipment sensors already provide these safety data on cycle conclusion with the expression SUCCESS or by reporting the existence of anomalies and that the cycle was not effective, requiring the cycle to be redone or, if the problems indicated by the display persist, technical assistance should be called.

Therefore, whenever the 5 (five) minute cycle is conclusive and the expression SUCCESS appears on the display, it means that the objects/instruments submitted to the equipment are ready for clinical/surgical use since they are sterile.



Merely illustrative figures Data obtained from the Manufacturer's website, at the address

<https://terragene.com/pt/product/uv-dosimeter-for-uv-c-radiation-disinfection-1000/>



## Technical assistance and identification label

When needing technical assistance, have the equipment number at hand and access the website [www.plazadente.com](http://www.plazadente.com) or call SAC **+55 (43) 3325-5000**, which will indicate the accredited technical assistance. Do not violate the identification seals, as they guarantee the originality of the Sterilizer Box components.

## Component lifespan

The lamps have an estimated lifespan between 5 and 6 thousand hours, as specified by the manufacturers. They must be replaced as soon as the equipment identifies a malfunction, signaled by a message on the display. Furthermore, the lamps must be periodically verified using chemical indicators, specific for UV-C rays, available on the market.

The quartz tray has an indefinite lifespan, provided its maintenance is performed properly, without damage. For cleaning, use a sponge lightly dampened with isopropyl alcohol. Remember to use PPE during the process.

The piezoelectric pellets also have an indefinite lifespan. Any operational problem will be informed on the equipment display

## Warranty Certificate

PLAZADENTE offers a guarantee against eventual defects/faults in raw material or manufacturing for a period of one year, counting from the date of receipt.

Within the warranty period, replaced parts will be free of charge. The lamps are not part of the warranty, as it is in their nature to burn out according to use and variations in electrical currents in each location.

If no manufacturing defect/fault and/or electronic components are found, a quote will be sent.

Whether covered or not by the warranty, expenses related to freight and insurance for sending/returning the STERILIZER BOX will be the responsibility of the consumer. The Box must always be transported in the original protective packaging and wrapped in bubble wrap.

- **This warranty certificate may be voided in the following events:**
- **Non-compliance with the recommendations contained in the manual;**
- **Product damaged due to transportation accidents, inadequate storage, or handling;**
- **Improper installation of the product;**
- **Replacement of components not in accordance with original factory specifications or carried out outside of PLAZADENTE's accredited technical assistance;**
- **Removal and/or alteration of the identification serial number.**

This warranty certificate replaces all other warranties without restrictions, and no third party is authorized to assume any obligation related to the sale of PLAZADENTE products.

Londrina, \_\_\_ of \_\_\_\_\_ of 20

PLAZADENTE



## PURCHASE AGREEMENT EQUIPMENT IDENTIFICATION AND WARRANTY

MANUFACTURER: PLAZADENTE, CNPJ 03.871.990/0001-21, headquartered at Rua Luiz Consentino, 7275, Parque Ouro Branco, Londrina-PR. CEP 85.042-010.

CONSUMER/PURCHASER:

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### PRODUCT:

- CE 01-21-UVC/Ultra
- CE 01-22-UVC/Ultra

### NUMBERS:

- Date of manufacture: -----
- Serie: -----
- Batch: -----

### COMPONENTS:

#### EQUIPMENT NUMBERS:

- Date of Manufacture: -----
- Serie: -----
- Batch: -----

#### INCLUDED COMPONENTS:

- ----- UVC tubular lamps
- ----- Quartz glass trays (190mm x 100mm x 2mm)
- Quartz Tray Identification Number: -----



## **Warranty Period – One year**

The manufacturer, identified on the Invoice accompanying the equipment, will guarantee the full functioning of the components of the STERILIZER BOX for a period of 90 days, except in case of misuse, falls, or damage due to willful misconduct or gross negligence equivalent to intent. The quartz glass tray contains an identification seal that must be kept intact to guarantee its validity.

Technical Responsible: Antônio Valentin Sella  
-----, of ----- of 20

PLAZADENTE



## ANNEXES

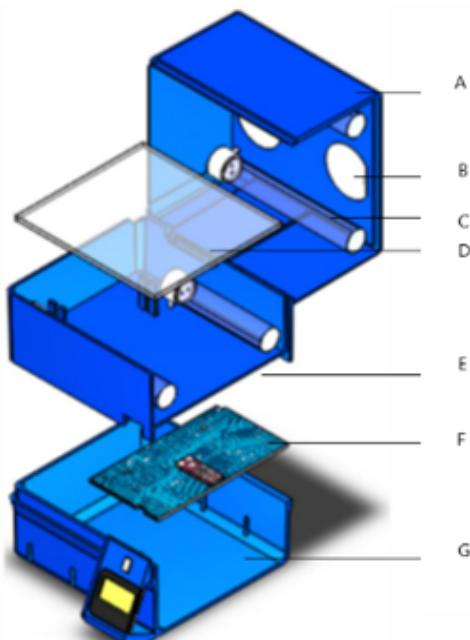


image merely illustrative of the  
CE01-21 UVC/Ultra

A - Lid

B - Piezoelectric Sensors

C - UV-C Lamps

D - Quartz glass tray

E - Intermediate part of the box that accommodates the two lower lamps

F - Electrical/electronic components

G - Lower part of the box

The Sterilizer Box must be installed near a power outlet and on a level surface.

Instruments must be pre-sanitized in an ultrasonic bath for at least 7 to 8 minutes, according to the standard procedures used for autoclave sterilization.

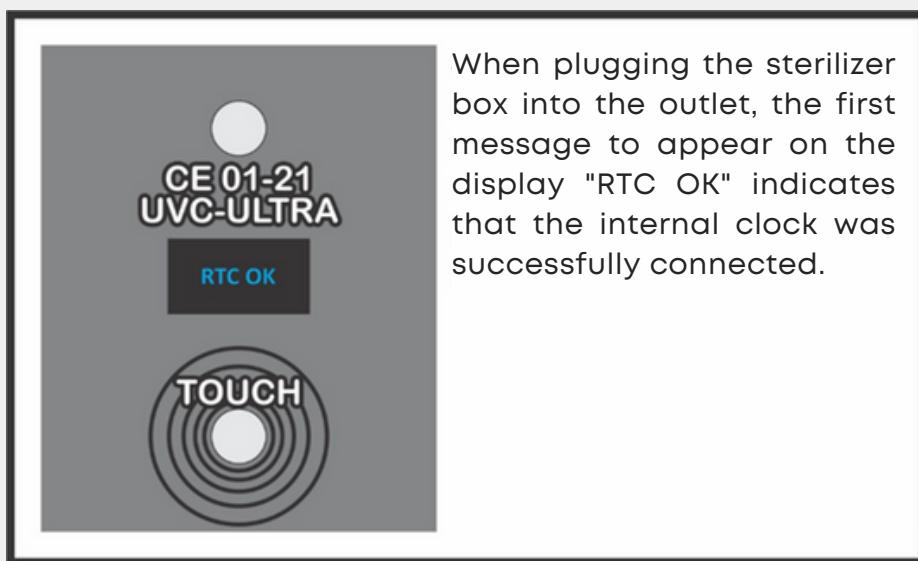




Only after rinsing and drying can the instruments be placed on the glass tray of the Sterilizer Box.

## Messages During the 5 Minute Cycle of the UV-C Sterilizer Box

### MESSAGE 1



When plugging the sterilizer box into the outlet, the first message to appear on the display "RTC OK" indicates that the internal clock was successfully connected.



## MESSAGE 2



If there is no success in initializing the internal clock, the message "RTC FALHOU" (RTC FAILED) will be displayed and the box will not initialize. In this case, contact technical assistance.

## MESSAGE 3



If there is success in initializing the internal clock, the next message to appear is the WIFI connection message. The box will try 5 times to connect to a WIFI network already previously registered in its internal memory by the box's exclusive APP.



## MESSAGE 4



If there is a WIFI network previously registered in the box's internal memory, and if it is within range and available, the box will connect to the network and the success message "WIFI CONECTADO" (WIFI CONNECTED) will be displayed on its screen. The system will then connect to the on-line server to automatically update the internal clock with the date and time. Upon successfully completing the process, the box will begin its initialization cycle.

## MESSAGE 5



If there is no WIFI network previously registered in the box's internal memory, or if there is one but the box is not within its reach, or if for any other reason the connection is unsuccessful, the message "WIFI CONECTANDO FALHOU" (WIFI CONNECTING FAILED) will be displayed.



## MESSAGE 6



If there is no success in the WIFI connection, or if the on-line server is not accessible even with WIFI connected, the system will not automatically update the internal clock, displaying the following message: "ATUALIZE A DATA/HORA PELO APPLICATIVO" (UPDATE DATE/TIME VIA APPLICATION) requiring the operator to use the application to perform the update. See instructions for the application in the manual.

## MENSAGEM 7



Immediately after the DATE/TIME update automatically performed by WIFI using the on-line server or updating via the application, the system will enter the initialization mode, loading all the box's resources.



## MESSAGE 8



Having successfully loaded all resources, without any error message, the box will display the current DATE AND TIME on its screen, informing the operator that it is ready for sterilization procedures.

## MESSAGE 9



When there is a power outage during the sterilization cycle, upon restarting the box, immediately after the initializing screen, an error message will appear containing these three screens interspersed with a short beep, notifying the box operator that the last sterilization cycle was interrupted by a power outage, requiring a touch on the touch sensor to be performed so that the restart understands that the error message was successfully received by the operator. After touching the touch sensor, the display will show the clock and your box will be ready to operate.



## MESSAGE 10



Before starting the sterilization process, the operator must verify the hygiene conditions of the equipment, which must be in accordance with the protocol for the decontamination of surgical instruments. Following all hygiene and preparation recommendations, simply place the instruments to be sterilized on the quartz tray according to the instructions for use, close the box lid, and touch the touch sensor with a finger for the sterilization process to begin.

## MESSAGE 11



When the touch sensor is activated, the system will read the lid sensor to ensure it is correctly closed, emitting an audible signal with 5 beeps; the display will turn off for 2 seconds, the time necessary for the lamps to heat up and light up completely.

## MESSAGE 12



If, after touching the touch sensor, the system identifies that the lid is open or not closed correctly, the following error message will appear on the display: "TAMPA ABERTA FECHE A TAMPA" (LID OPEN CLOSE THE LID). This message will remain until the lid is correctly closed, and the display returns to showing the clock with DATE/TIME, requiring the operator to touch the touch sensor again to restart the sterilization process.

## MESSAGE 13



If, after touching the touch sensor, the system does not identify any error in reading the lid sensor, the sterilization process will start normally. The time required for the sterilization process to be performed successfully is 5 minutes, and for this time to be tracked, the display will show a sequence of screens every 10% (ten percent) of the elapsed time, and an audible signal (beep) will be emitted with each screen change, so that the operator remains attentive to the equipment's operation.

## MESSAGE 14

CE 01-21  
UVC-ULTRA

90

TOUCH

2º Tela

SUCESSO

3º Tela

FECHE  
A TAMPA

Upon reaching the end of the sterilization process, the last screen in the percentage sequence will be 90%. Concluding this last part, a quick sequence of 10 short beeps will be emitted by the equipment, announcing that the sterilization process has reached its end, where a screen with the message "SUCESSO" (SUCCESS) will continuously emit a short beep every 1 second until the operator opens the box and removes the sterilized instruments. After the box is opened, another screen will appear with the following alert message, "FECHE A TAMPA" (CLOSE THE LID) accompanied by a beep every 2 seconds, notifying the operator that it is necessary to keep the equipment lid closed.

## MESSAGE 15

CE 01-21  
UVC-ULTRA

70

TOUCH

If the safety system identifies an error during the sterilization process, the process will be immediately interrupted, the lamps will turn off, and an error screen will be shown on the display, followed by audible alerts (beeps) notifying the operator what type of failure occurred during the procedure and instructing them to perform the sterilization process again. Possible failures:

**Lid error:**

**Lamp error:**



## MESSAGE 16

**ELid Error:** This occurs when the lid sensor detects that the lid was opened before the end of the procedure, or that the lid was not closed correctly at the beginning of the process, causing possible sensor reading errors during sterilization, thus interrupting the entire process. Below is the sequence of screens related to this error.

1°	2°	3°	4°
TAMPA ABERTA	FECHE A TAMPA	PARA REINICIAR	O PROCESSO

## MESSAGE 17

**Lamp Error:** This occurs when the UV-C sensor detects that the lamps are not lit or, even if lit, are not emitting UV-C radiation during sterilization, thus interrupting the entire process, requiring the operator to restart the sterilization process.

## Consultas

ANVISA - Agência Nacional de Vigilância Sanitária

Detalhes do Produto	
Nome da Empresa Detentora da Notificação ou do Registro do Dispositivo Médico	PLAZADENTE INDUSTRIA DE PRODUTOS DE TOUCADOR - LTDA - EPP
CNPJ do Detentor da Notificação ou do Registro do Dispositivo Médico	03.871.990/0001-21
Autorização de Funcionamento da Empresa	8.20.590-9
Nome do Dispositivo Médico	CAIXA ESTERILIZADORA UVC/ULTRASÔNICA
Nome Técnico do Dispositivo Médico	Esterilizador
Número da Notificação ou do Registro do Dispositivo Médico	82059099001
Situação da Notificação ou do Registro do Dispositivo Médico	Válido
Processo da Notificação ou Registro do Dispositivo Médico	25351669432202202
Fabricante Legal do Dispositivo Médico	FABRICANTE: PLAZADENTE INDUSTRIA DE PRODUTOS DE TOUCADOR - LTDA - EPP - BRASIL / Código Único: 0387199000121 - Endereço: RUA LUIZ CONSENTINO, 172 (COMPLEMENTO Nº 7275) OURO BRANCO 86042010
Classificação de Risco do Dispositivo Médico	II - MEDIO RISCO
Data de Início da Vigência da Notificação ou do Registro do Dispositivo Médico	27/02/2023
Data de Vencimento da Notificação ou do Registro do Dispositivo Médico	VIGENTE

Tipo de Arquivo	Arquivos	Expediente, data e hora de inclusão
INSTRUÇÕES DE USO OU MANUAL DO USUÁRIO DO PRODUTO	MANUAL-EM-AUDITORIA - 1 de 1.PDF	0283558237 - 22/08/2024 16:36:42

### Modelo Produto Médico

CE01-21/Ultra

CE01-22/Ultra

Impreso el 11 de septiembre de 2024 a las 10:38 a. m.

<http://consultas.anvisa.gov.br/api/consulta/downloadPDF/25351669432202202>

02

access the link here



## TECHNICAL ASSISTANCE AND SUPPORT

To request technical assistance, have the equipment number at hand and contact SAC by phone **+ 55 (43) 3325-5000** or access the website [www.plazadente.com](http://www.plazadente.com).

Our team will indicate the nearest accredited technical assistance to you.



## CONTACTS

📞 55 43 98823113 / 43 3325-5000

🌐 [www.plazadente.com](http://www.plazadente.com)

📍 R. Luiz Consentino, 7275 – Ouro Branco, Londrina – PR, 86042-010

📷 [@plaza.dente](https://www.instagram.com/plaza.dente)