cvdentus

INSTRUCTION MANUAL

Clinical PLUS

Presentation

This Instruction Manual contains the information required for the correct use of CLINICAL PLUS ultrasound equipment.

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Product Registration with the Ministry of Health

Technical Name: Clinical Plus
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ANVISA/MS Registration Number: 80179320007

Table of Contents

Presentation

Great news in ultrasonic dentistry with CVDVale technology.

CLINICAL PLUS includes two handpieces that enable frequency auto tuning in a range from 25 to 32 kHz. With the **CVDentus** ultrasonic tips technology, they extend the use of the ultrasound equipment for all types of cavity preparation, offering the following benefits:

- It eliminates the noise of the traditional high-speed motor, improving the working condition of the dentist and inhibiting the possible fear of the patient.
- It is a treatment that causes less pain, reducing the need for anesthesia in most dental treatments, as well as ensuring greater accuracy and protecting the original tooth structure.
- As it allows dental treatment with less pain, it makes a larger portion of the population seek preventive treatments.
- It does not cut the soft tissue, i.e., it allows subgingival treatment without anesthesia and bleeding.
- Better final finish with a single tip. There is no need for frequent tip replacement.
- It allows access to hard-to-reach regions compared to traditional high-speed tips, or by any other preparation technique.
- It allows better visibility during the treatment, ensuring a less-risky procedure, preserving the healthy tissue.
- Much longer durability (if used correctly), as it is a single diamond stone chemically bonded to the metal rod.

Intended use of CLINICAL PLUS

The **CLINICAL PLUS** equipment, together with the **CVDentus** tips, are intended for ultrasonic dentistry. It enables a wide range of dental interventions assisted by ultrasound, including procedures in Endodontics and Periodontics.

Contraindications to use CLINICAL PLUS

It has been found that electronic devices and electromedical equipment can interfere with the normal operation of pacemaker devices.

Patients with pacemakers are recommended to avoid treatment with **CLINICAL PLUS** equipment.

ATTENTION: People with cardiac pacemakers must not be treated with **CLINICAL PLUS**, or even get close to it when in operation.

For further readings on the subject, please refer to:

- "Advances in Cardiac Pacemaker", The New York Academy of Sciences, Vol. 167, Article 2, pp. 515-1075.
- "Electromagnetic Radiation Interference with Cardiac Pacemaker", U.S. Department of Health, Education and Welfare.
- "The Individual with a Pacemaker in the Dental Environment" Journal of the American Dental Association, Vol. 91, No. 6 pp. 1224-1229.

IMPORTANT

CLINICAL PLUS equipment must be operated solely by a qualified dental professional, familiar with the currently known risks and benefits of using electromedical equipment and dental offices. No specific training is required. Reading the manual is mandatory before use.

We recommend the professional to guide the patient or other people with access to the equipment about the caution during its handling.

Do not attempt to repair or assemble defective or inoperative parts or replace with parts of another device. Only by using original parts can the original technical specifications and safety of the device be guaranteed.

To ensure the electrical safety of the device throughout its service life, the device should be verified by the authorized service center on a regular basis of at least once a year.

There are no other contraindications, however, there may be people sensitive to the use of ultrasound in dental treatments. The professional must always watch the patient's reactions at first use and evaluate its applicability.

CLINICAL PLUS Operating Principle

CLINICAL PLUS is a piezoelectric ultrasound device for dental use. Inside its handpieces, there are piezoelectric transducers that, under the action of an electrical stimulus, vibrate at an ultrasonic frequency (between 25 and 32 kHz). This vibration is amplified by the handpiece and transmitted to the insert, which vibrates with high intensity. The ultrasonic vibration is used for the many processes of endodontic and periodontal cleaning and disinfection. With the addition of **CVDentus** diamond tips, this vibration is used to cut hard materials such as dentin, enamel, bone material and dental restorative materials.

WARNING

CLINICAL PLUS equipment may cause electromagnetic interference to other equipment or electronic devices.

ATTENTION: Equipment not suitable for use in the presence of a flammable anesthetic mix with air, oxygen or nitrous oxide.

The equipment must be connected to the power grid through an individual outlet that has a ground port (third prong).

WARNING

Do not dispose of the equipment in household waste.
Use the appropriate disposal system as per your country's law.

If not disposed of properly, electrical devices can pose serious risks to the health of nature and man.

You can find collection and recycling points all over Brazil at http://www.e-lixo.org/. If you prefer, contact CVD Vale.

ATTENTION – ULTRASONIC ENERGY NOISE:

Prolonged exposure to noise can cause physiological effects such as stress, loss of concentration and hearing loss.

The use of hear plugs is recommended.

Equipment Classification

CLINICAL PLUS dental ultrasound equipment and its parts, including APPLIED PARTS, are classified as follows.

Technical Specification:

- **PROTECTION AGAINST ELECTRIC SHOCK:**
  - Electromedical equipment (CLASS I).

- **MAIN UNIT:**
  - INPUT: 127 – 220V ~ 50/60Hz 41VA – 51VA;
  - Fuse-protected power supply (not accessible to the user);
  - Power cable length: 2 meters;
  - Rated ultrasound power: 10W non-continuous
  - Dimension: width = 290mm, height =115 mm and depth =230 mm;
  - Weight: 1.380 kg;

- Microprocessor circuit with internal power control;
- Hardware version: 1.0 (Oct/2019) / Software version: 1.0 (Oct/2019).
- It has initial resonance frequency search from 25 to 32 kHz and with auto power adjustment under normal operating conditions.
- Automatic limiter for power control in case of excessive pressure on the active tip during use in ENDO mode.

- **FOOT SWITCH:**
  - **Wireless**
  - Microswitch normally open, i.e. closes contact when turned on;
  - Encrypted radio frequency communication;
  - Acoustic signals when the battery charge level is low;
  - Dimensions: width = 70mm, height = 35mm and depth = 100mm;
  - Weight: 0.314 kg.
  - **Wired Version**
  - Microswitch normally open, i.e. closes contact when turned on;
  - Cable length: 2m
  - Dimensions: width = 70mm, height = 35mm and depth = 100mm;
  - Weight: 0.350 kg.

This product is approved by the National Telecommunications Agency (Anatel), as per the procedures regulated by Resolution 242/2000, and complies with the technical requirements applied (For reference: www.anatel.gov.br).
This equipment is not entitled to protection against harmful interference and may not cause interference to properly authorized systems.

- **HANDPIECE:**
  - Piezoelectric with 4 PZT ceramic transducers;
  - 3000V Insulation / Autoclavable aluminum finish;
  - Nominal frequency from 25 - 32 kHz;
  - Approximate length of 114mm;
  - Maximum diameter of 20 mm and approximate weight of 40g.

- **RATCHET WRENCH**
  - Tool to tighten the inserts in the handpiece;
  - Made of autoclavable plastic material and metal centerpiece;
  - Inner diameter 35mm, height 30mm, thickness 2.5mm;
  - Torque 1 ± 0.1 N/m.

- **PROTECTION AGAINST HARMFUL PENETRATION OF WATER OR PARTICULATE MATTER:**
  - Main unit – degree of protection: IP21;
  - Foot switch – degree of protection: IP21;

- **METHODS OF STERILIZATION:**
  - Moist heat sterilization (autoclave).
  - Check procedure: Cleaning and Sterilization

ATTENTION: Sterilization must not be done in an oven

- **OPERATING MODE:**
  - Non-continuous operation: “ON” 10min. on / “OFF” 5min. off;

- **ENVIRONMENTAL CONDITIONS:**
  - Temperature: - Operation: +10ºC to +30ºC.
    - Storage: +10 to +40ºC;
  - Humidity - Operation: 30%
    - 80% non-condensing;
    - Storage: 10% - 90% non-condensing;
  - Atmospheric Pressure: - Storage: 860-1060 hPa
    - Operation/use: 860-1060 hPa
    - Transport: 860-1060 hPa

EQUIPMENT WITH TYPE B APPLIED PART

Equipment NOT intended for use in oxygen-enriched atmosphere.

Application Specification

- **Indication:**

  Procedures in.
  - Endodontics,
  - Periodontics,
  - Dentistry,
  - Prosthesis.

- **Target Population (Patients):**

  Patients of all ages.

  As it does not cut soft tissue and reduces the use of anesthesia in most procedures, it can be used on children, special patients and patients who have some kind of allergic reaction to anesthetics.

- **Contraindication:**

Patients with pacemakers are not recommended to be treated with CLINICAL PLUS equipment.

- **Part of the body:**

  Used in the oral cavity for dental treatment.

- **Intended user profile:**

  CLINICAL PLUS equipment must be operated solely by a qualified dental professional, familiar with the currently known risks and benefits of using electromedical equipment and dental offices. No specific training is required. Reading the manual is mandatory before use.

- **Intended conditions of use:**

  CLINICAL PLUS must be used in a dental office compliant with Brazilian Sanitary Surveillance Agency (ANVISA) sanitary standards. The office must have electrical installations that are appropriate and dimensioned with the grounding grid.

  The room must meet the hygiene and sterilization requirements as well as its furniture, tools and other equipment.

  Lighting, ventilation and temperature must meet the sanitary requirements of a dental office.

  The equipment is **NOT** intended for use in oxygen-enriched atmosphere.

- **Estimated useful life of the equipment:**

  05 (five) years (respecting the guidelines described in this manual).

Notes prior to use

1. The power outlet used must be grounded. If this requirement is not met, damage to the equipment and, above all, to the patient may occur.
2. The equipment must NOT be placed in a dusty environment.
3. Direct contact with water must be avoided.
4. Do not use the equipment in the presence of flammable gases.
5. The equipment must be placed on a steady platform or table. Placing the equipment on an unstable and/or tilted table may degrade performance and/or accidentally damage the system.
6. The equipment can be disassembled by certified technicians only. Failure to meet this requirement shall cause immediate loss of warranty, damage to the user and/or damage to the equipment.
7. For electrical safety, the equipment’s cables must not be placed under heavy objects, and high-temperature heat sources must also be avoided.
8. If any abnormal situations are noticed when the equipment is in use, disconnect the cable from the power grid.

Preface

CLINICAL PLUS equipment was developed to achieve the maximum performance of the handpiece together with high-precision mechanical components, causing the insert to vibrate axially to the handpiece.

The high frequency to which the insert is subjected and using it in conjunction with a saliva sucker enable the most resistant calculus and tartar to be removed more easily.

CLINICAL PLUS can conveniently and quickly clean the teeth and is electrically safe.

The electromechanical efficiency of this piezoelectric system is much higher than that of traditional magnetostrictive systems. Piezoelectric systems release small amounts of heat, make it possible to work with lower volumes of water for cooling, ensure excellent cavitation, and make it comfortable for both patient and professional use.

It is possible to control the operating mode of power and water flow. There are two operating modes: the constant-frequency mode, suitable for endodontic procedures, and the constant-power mode, suitable for periodontics. This allows a very fine tune for each clinical situation. With a wide range of tips, the unit is suitable for different types of work.

CLINICAL PLUS configuration is especially suitable to use **CVDentus** tips. Its circuit operates in a self-adjusting frequency mode, which always provides the required power. Never use with overpressure. The best protection and cutting efficiency when using **CVDentus** tips is to let the tip’s own vibration promote wear, without pressing excessively.

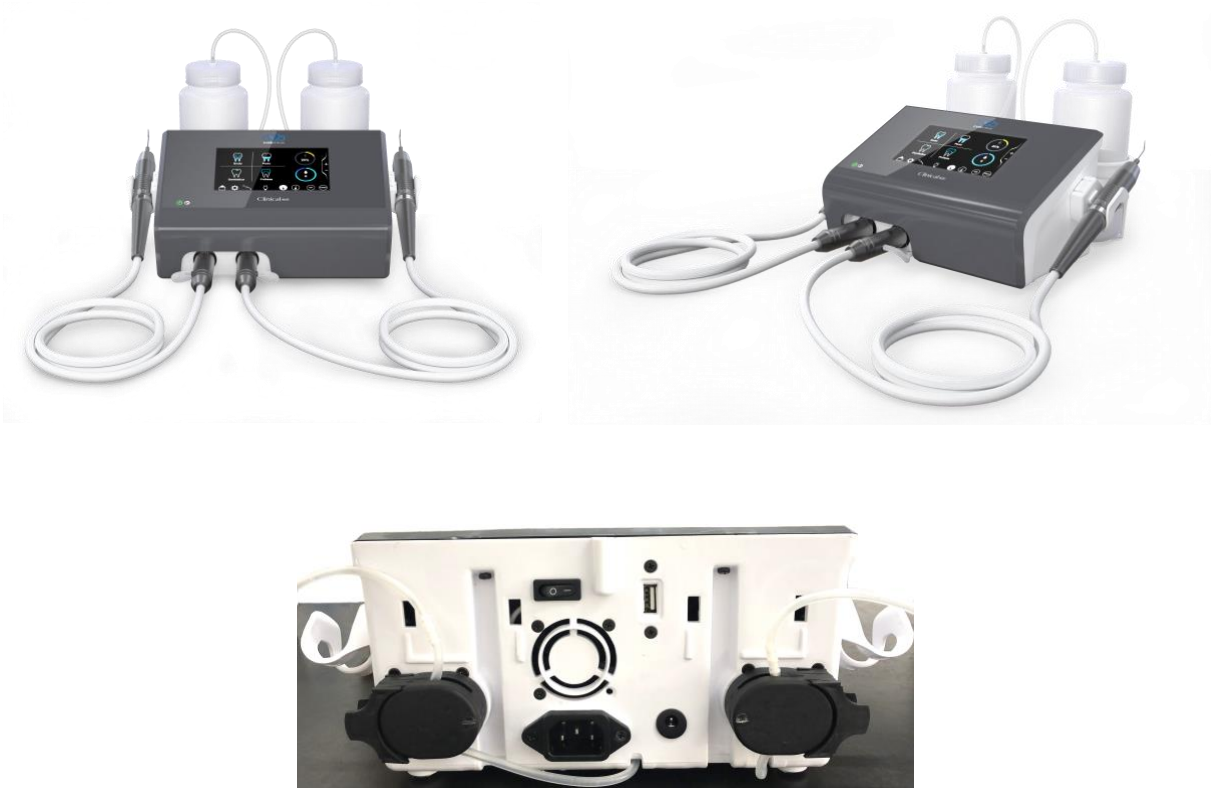
Note to Dental Surgeon

To better use all functions and maximize the performance of **CLINICAL PLUS**, dentists are recommended to practice on artificial models before using it on patients in order to be familiar with the use of the tips, the movement and the optimal force to be applied on the inserts.

Description of Components

Figure 1 shows the main components of **CLINICAL PLUS**, which are indicated by the letters A, B, C, D and E.

A



B

C	D	E
		

Figure 1: CLINICAL PLUS components: A – Main Unit, B – Handpiece, C – Peristaltic pump, D – Foot switch, E – Bottle.

A – Main Unit

Operationally, the main unit generates the signal needed for operation at around 30 kHz and transmits it to the handpiece, inducing enough power to excite the piezoelectric ceramics inside. This action vibrates the tip of the insert at the ultrasound frequency.

Its next-generation circuit is capable of detecting the changes in the handpiece's resonance frequency, with the most varying shapes and folds of the work inserts, adjusting so that the handpiece always operates in an optimized condition between 27 and 32 kHz.

The high efficiency of the circuit has resulted in a compact, light, ergonomic and power-efficient equipment. The main unit adjusts the water flow to the handpiece through the internal control of the peristaltic pump.

All controls are digital and showed in a liquid-crystal display.

B – Handpiece

This consists of an ultrasonic actuator and insert. The ultrasonic actuator is composed of piezoelectric elements that when excited, move the tip "forward" and "backward" in the axial direction at high speed, based on the change of the control signal waveform coming from the main unit.

According to the insert movement, a flow of water comes out of it, which is needed to, for example:

(a) Wash tooth calculus and tartar;
(b) Cool the insert (heat generated by the insert vibration);
(c) Wash the cavity preparation debris;
(d) Cool the treated area.

This handpiece allows the exclusive use of **CVDentus** tips.

The handpieces are connected to the main unit through an electrical connector, as shown in Fig. 2.

Figure 2: Detail of the handpiece electrical connector, tube and irrigation and its connection methods.

The connectors are designed to connect the handpieces, thus preventing its improper use.

CVDentus handpieces are fully autoclavable at 135ºC, including their cable and electrical connector.

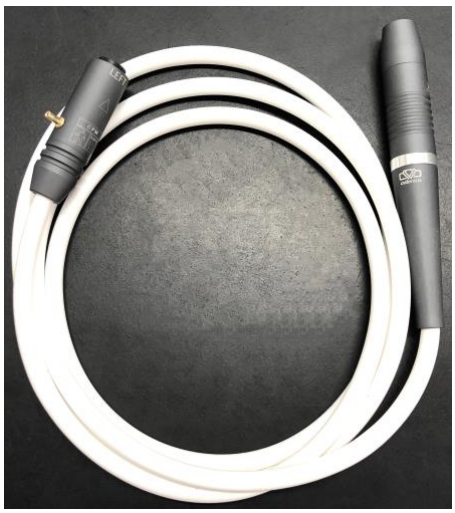


Figure 3: Handpiece detail.

WARNING
We recommend the handpiece is reviewed/inspected once a year or when the operator notices a reduction in cutting speed.

C – Peristaltic Pump.

CLINICAL PLUS has two independent peristaltic pumps to supply water to each of the two handpieces. The peristaltic pumps are easily accessible at the back of the main unit. **There is no need to remove the peristaltic pump coupled to the unit**. It consists of a “drawer” part that can be detached in order to release the silicone tube. The water connection is also

very simple. The purpose of the easy access and the simple water connections is to allow disassembling and assembling the entire water circuit for autoclaving.

Figure 4 shows the cooling circuit assembled in the main unit.

Figure 4: Cooling circuit assembled in the main unit.

ATTENTION: Only the items that make up the cooling circuit can be taken to autoclave as shown in figure 4 (bottle, silicone tube and handpiece). **The autoclave temperature must not exceed 135ºC.**

PERISTALTIC PUMP INSTRUCTIONS FOR USE:

The peristaltic pump body is fixed to the device and therefore **does not need to be removed**. The peristaltic pump is made up by the main body that is fixed to the device, the silicone tube that can be removed and/or replaced where required and a drawer part responsible for keeping the silicone tube attached to the pump. See figure 5.

Figure 5: Items that make up the peristaltic pump.

In figure 6 below, we can see how the peristaltic pumps assembled on CLINICAL PLUS device look like.

Figure 6: Peristaltic pumps assembled on CLINICAL PLUS equipment.

To remove the silicone tube, just unclip the drawer of the peristaltic pump and release it as described in figure 7.

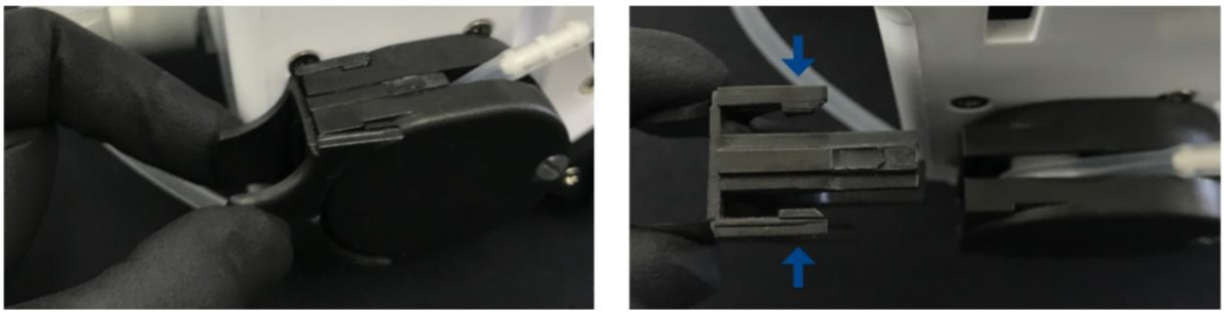


Figure 7: Press the drawer fins (one against the other) and pull it out, allowing free access to the silicone tube.

After removing the silicone tube, it is possible to autoclave it or simply replace it if necessary.

ATTENTION: It is recommended to release the silicone tube and clean it before each procedure so that no wear debris will form during continuous use for a long period.

To replace the silicone tube, just put it inside the pump body and press the drawer fins again. Push it until it completely fits in the main body of the peristaltic pump, as shown in figure 8.

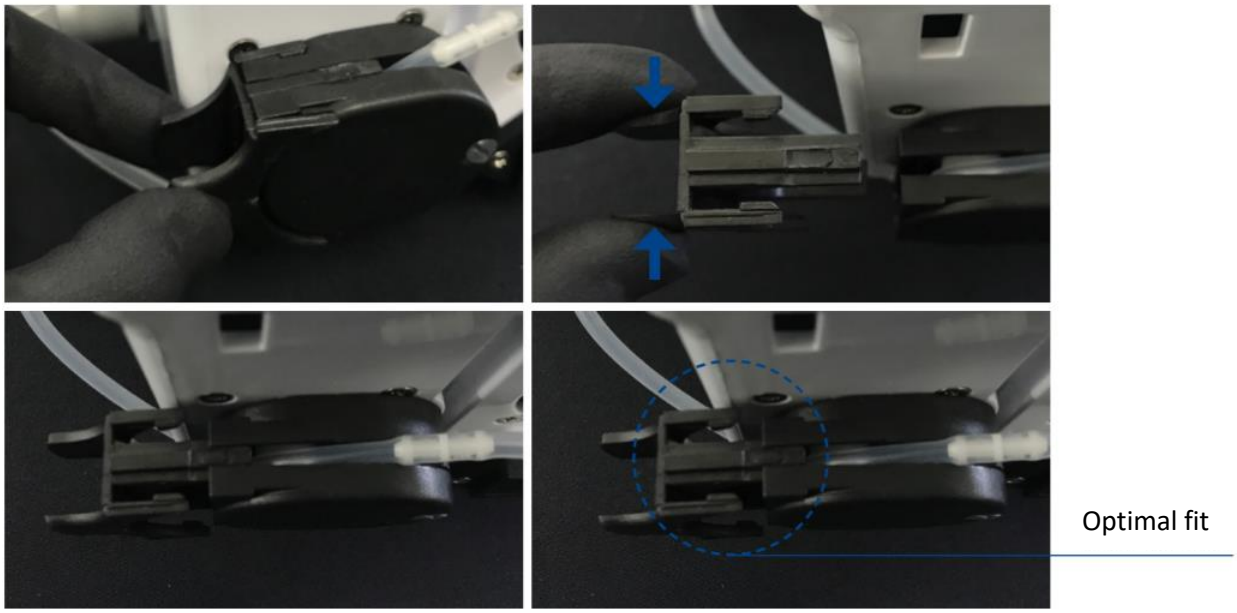


Figure 8: Replace the silicone tube, press the drawer fins and push it towards the main body until it snaps into place.

IMPORTANT CONSIDERATIONS:

- When first turning on your device on the day of or after cleaning (autoclave) the cooling system, run the cleaning mode as instructed in the “Installation” item of this manual;
- Wait for the coolant to reach the end of the handpiece and after the cycle, connect the insert and tighten with the ratchet wrench. As soon as it starts operating, adjust the flow according to the intended use of each tip and/or procedure.
- If the pump does not rotate at first, remove the drawer and check if the silicone tube is properly cleaned and unobstructed. Then, reassemble the system and proceed with the normal use.
- Make sure the tip of the handpiece to be used is tightly coupled with the proper torque provided by the ratchet wrench.
- Make sure your equipment’s water flow is not off.
- Always follow the instructions of CLINICAL PLUS User Manual.
- Do not make any changes or replacements with any other product that is not supplied by the manufacturer.
- **The autoclave temperature must not exceed 135ºC.**

D – Foot Switch

The foot switch's function is to easily turn on the **CLINICAL PLUS** equipment without interrupting the treatment in progress. Turning on the foot switch provides:

(a) The handpiece power-up, making the insert vibrate;
(b) Activation of the peristaltic pump providing cooling flow to the handpiece and the insert;
(c) It works with wireless technology or detachable cable;
(d) Indication of low battery charge level by means of acoustic signaling.

Figure 9: Foot switch with detachable cable.

E – Bottle

CLINICAL PLUS comes with a high-quality, fully non-toxic and autoclavable polypropylene bottle.

Figure 10: Polypropylene bottle.

Control panel and main unit connectors

The functions of the touch display on the main unit are detailed here, according to the figures below. The function of each key or button on the main unit is detailed here according to the figures below.

1- Touch Display:

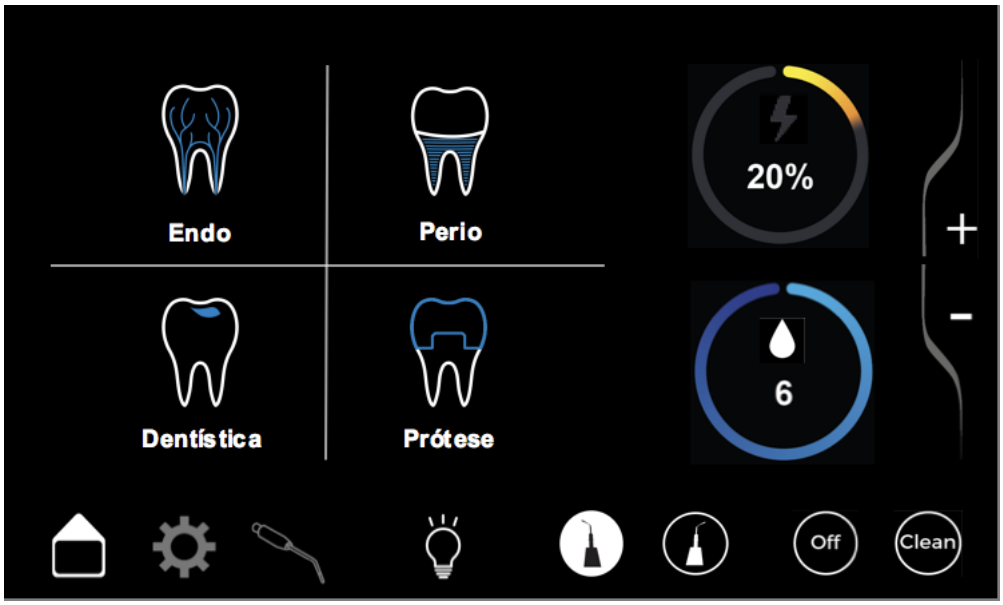
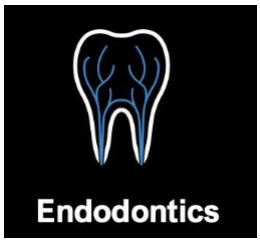
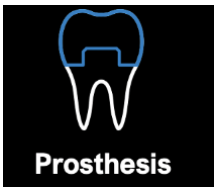
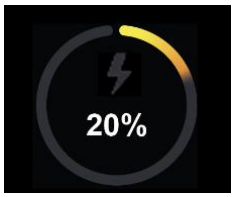


Figure 11. Main screen of **CLINICAL PLUS** ultrasound equipment

	A. ENDODONTICS specialty selection key
	B. PERIODONTICS specialty selection key

	C. DENTISTRY specialty selection key
	D. PRÓTESE (Prosthesis) specialty selection key
	E. Indicator of power adjustment
	F. Indicator of irrigation level adjustment
	G. Power and irrigation intensity selector
	H. Left or right pen selector

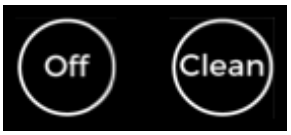
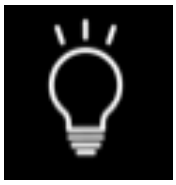
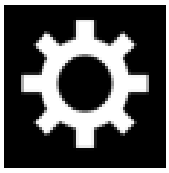
	I. Selectors for non-irrigation mode (“OFF”) and cleaning mode (“CLEAN”)
	J. Button to adjust the handpiece brightness. There are 4 levels of brightness – 0%, 30%, 50% and 100%.
	K. Button to go to the home screen “HOME”.
	L. Button to go to the language-setting screen.
	M. Button to go to the information leaflet about the tips.

Figure 12. Legend of icons on **CLINICAL PLUS** panel

The ***Indicator of power adjustment*** key (Item E of figure 12) selects the power setting ranging from 0% to 100% in units of 10%. The ***Indicator of irrigation level adjustment*** key (Item F of figure 12) selects the irrigation setting, ranging from 0 to 6. By selecting any of the keys, a LED indicator lights up in the center of the respective power or irrigation function circle.

The ***Power and Irrigation intensity selector*** keys (Item G of figure 12) allow increasing and decreasing the desired power and irrigation levels, respectively. The ***Button to adjust the handpiece brightness*** (Item J of figure 12) allows turning on/off the handpiece LED lighting.

When selecting the ***"CLEAN" mode*** (Item I of figure 12), CLINICAL PLUS device starts the "CLEAN" mode function. When selecting the ***non-irrigation mode ("OFF")*** (Item I of figure 12), CLINICAL PLUS goes into the "PUMP OFF" mode, i.e. irrigation function is disabled.

There is a "POWER ON" LED in the bottom left corner. Green LED indicates the equipment is on.

WARNING

- Do not use the equipment if the display is "snowy" or shows confusing characters. In this case, the equipment must be sent to technical assistance.

2- Front Panel

Figure 13. Connecting the handpiece to **CLINICAL PLUS** ultrasound equipment

3- Back Panel

Figure 14 shows the back panel of the main unit. It contains the on-off power button  , the power connector, the foot switch connector and the USB port.

Figure 14. Back of **CLINICAL PLUS** ultrasound equipment, place of the on-off power button.

WARNING

Before turning on the main unit, make sure that all other components are connected, the power plug is plugged into a powered outlet and the foot switch is not pressed.

Installation Guide

1. Removing from Package

When unpacking, check the unit for damage. If damaged, contact your dealer or the manufacturer immediately. When sending the product to the authorized service center, send a copy of the invoice with it.

2. Storage

The unit must be stored in a clean and dry environment. The following environmental limitations apply to storage and transportation:

- Temperature: +10ºC to +40ºC;
- Humidity: 10% to 90% non-condensing;
- Atmospheric Pressure: 860 to 1060 hPa.

SAFETY INSTRUCTION: Before any connection is made to the equipment (main unit), make sure the local grid is properly grounded. The power plug can only be plugged into a wall outlet if it is possible to connect the ground pin.

3. List of Materials and Accessories

Inside the package, you will find:

- 01 Main Unit **(Clinical Plus)**
- 02 Peristaltic pumps (fixed on the back panel) (CVDentus – BP1 Model)
- 02 Handpieces (Clinical) (CVDentus – PM2 handpiece model)
- 01 Wireless foot switch
- 01 Foot switch connection cable (2m)
- 02 Bottle holders
- 02 Bottles (Nalgon – G05 Model)
- 04 Silicone tubes
- 02 Connection spigots (Connected to silicone tube)
- 04 Silicone tubes (spare)
- 01 Power cable
- 01 Quick Installation Guide
- 01 Transport case (Optional)

Other accessories:

- **CVDentus** tips (refer to our website, www.cvdentus.com.br, call our consultants at +55 (12) 3944-1126 and request a catalog to get to know all **CVDentus** tips available for use with **CLINICAL PLUS**);

4. Installation:

Once unpacked, check that the handpiece is disconnected from the main unit, and the peristaltic pumps are placed in their positions, but disconnected from the water circuit. Follow these steps to install:

a. Place the main unit in the position that is most convenient for you. Its small size allows easy integration into your office, and installation is in the closest possible position for you to use, remaining firmly supported or fixed;
b. Check that the “on-off” power button () is off (switch lever facing the () the position;
c. Install the handpiece in its respective connector (H);
d. Install the irrigation tube (silicone tubing), connecting the peristaltic pump outlet to the handpiece irrigation connector. Connect the peristaltic pump irrigation inlet to the bottle outlet connector.
e. Position the foot switch conveniently to use and turn it on while using **CLINICAL PLUS**;
f. Unroll the power cord and connect the plug. Check for a grounded outlet within reach for the length of the power cord. Note that the power supply is automatic dual voltage;
g. Turn on the main unit by moving the on-off power button lever  to the (**I**) position and check if the LED indicator () lights up;
h. Before activating the “*CLEAN*” mode, face the handpiece to a sink or spittoon;
i. Run the “*CLEAN*” mode by selecting it through the SELECTION key (*CLEAN*) located on the home display;
j. After performing the cleaning mode (“CLEAN”), attach a **CVDentus** tip to the handpiece;
k. Using the ratchet wrench, tighten to secure the chosen **CVDentus** tip;
l. Adjust the ultrasound power according to the recommended power for the **CVDentus** tip in use;
m. After coupling and adjusting the power, turn the foot switch on so that the **CVDentus** tip vibrates at the ultrasound frequency;
n. Adjust the irrigation flow. Turn on the foot switch again and watch the flow. Repeat this procedure until reaching the desired flow;
o. You’re all set! The equipment is up and running.

5. Special Installation Recommendations

As patients may experience some tissue trauma during treatment. We suggest the operator to use purified or distilled water. This will significantly reduce the potential for infection. In some procedures, it may be convenient to use a sterile liquid, such as saline solution.

Install the main unit in an accessible place. Its reduced dimensions and weight allow it to be positioned around the work area without interfering with the handling of other instruments.

After installation, the entire extra length of the power cord must be neatly arranged to avoid accidents.

The foot switch must be placed in a position where users can easily reach it.

Prior to First Use

To better use all functions and maximize the performance of **CLINICAL PLUS**, users/doctors are recommended to practice on models/plates before treating patients in order to be familiar with the system. For traditional tartar removal tips, use an aluminum plate (for example, a soda can may be used). As for **CVDentus** tips, the purpose is to test the cut of the active tip diamond, therefore, it is necessary to use a hard material, which can be a piece of ceramic floor. In either case, gently maneuver the tip on the test material. Get familiar with and watch the subtleties of applying pressure under the different angles of the tips, the main working positions, etc. Closely examine the scratches left on the aluminum plate after each session and try, in practice, to match each scratch to the angles and positions that originated it. Search for more learning details in the respective instruction manual for the use of **CVDentus** tips.

Additionally, adjust the ultrasound power intensity using the respective keys. Get familiar with the differences by changing the ultrasound power intensity. Finally, adjust the irrigation flow through the increasing (**+**) and decreasing (**-**) keys. Get familiar with and watch the subtleties between different irrigation flow situations. Watch the temperature of the handpiece when changing the irrigation flow. Do not overheat the handpiece. Perform the training steps above several times in order to prepare for patient treatment.

Expected Operator Distance

CLINICAL PLUS equipment has moving parts and accessories on the main unit, as well as some symbols and important information. The distance from the operator is important for the markings readability. Among all the markings, the readability of the symbols marked on the handpiece depends on the position of the operator according to the images below:

Figure 15: Marking of symbols on the handpiece.

Instructions for use and operation

FREQUENTLY USED FUNCTIONS

- Connect the equipment to the power grid;
- Turn on the equipment on/off power button;
- Empty and fill the bottle with coolant;
- Place and remove the CVDentus tip (applied part);
- Cleaning of irrigation system;
- Wield/hold the handpiece;
- Turn off the equipment.

PRODUCT SAFETY RELATED FUNCTIONS

- Selecting the right power for the CVDentus tip (applied part);
- Correct attachment of the CVDentus tip (applied part);
- Cleaning and disinfection of the parts that come in contact with the patient;
- Cleaning of the equipment;
- Always keeping the bottle filled with coolant. Ensuring irrigation.

Identification of the applied part

Figure 16: The CVDentus ultrasound tip comes into physical contact with the patient so that the equipment performs its function. The handpiece triggers this tip's ultrasonic vibration.
The CVDentus ultrasound tip is considered an applied part.

ATTENTION: In case of emergency to isolate the equipment from the power grid, remove the plug from the outlet. Removing the plug from the outlet is considered a means of total isolation from the power grid. Do not block the access to the outlet. In case of emergency, this procedure should be easy and quick.

Figure 17 - (a) and (b): Putting the liquid inside the bottle:

a

b

Hold the bottle and remove the cap, turning counterclockwise (a). Remove the cap (b) and pour the liquid into the bottle. Close the bottle by turning the cap clockwise.
Note: Sanitize the bottle prior to using. Never leave liquid inside the bottle if the equipment is not in use.

Figure 18 - (a) and (b): Connecting and disconnecting the tube to/from the bottle:

a

b

Image (a): The operator must hold the bottle with the cap attached and place the tube of the peristaltic pump into the connector located on the bottle cap. Slightly force the tube until the end as shown in image (b).

To remove: Hold the tube in the same position as shown in image (a) and pull the tube applying a light force.

Figure 19: Connecting and disconnecting the tube to/from the handpiece cable:

Figure 19: Hold the handpiece cable connector and fit the tube end of the peristaltic pump into it. Slightly force the tube until the end.

To remove: Hold the tube in the same position and pull it applying a light force.

Figure 20 (a) and (b):Connecting and disconnecting the handpiece cable to/from the main unit:

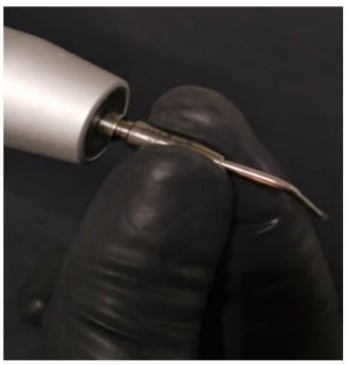
A

B

Image (a): Hold the connector area of the handpiece cable to support the connection on the main unit. In the image (b), the connector is fully attached to the main unit.

Figure 21 (a), (b) and (c): Connecting and disconnecting the CVDentus diamond tip to/from the end of the handpiece:

a



b

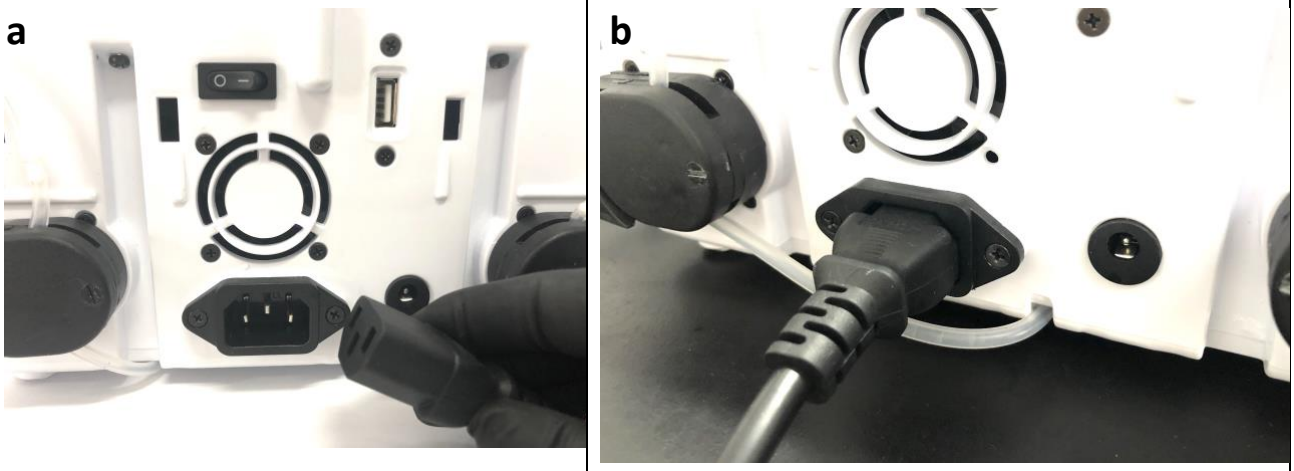
c

Image (a): Hold the handpiece and with your other hand, screw the CVDentus tip clockwise (model defined by the operator) until there is resistance to tightening. To finish tightening, use the ratchet wrench (b) and insert the tip into the internal hole until it touches the stop, as shown in image (c).

Finish tightening by turning the ratchet wrench clockwise. When you hear a ratchet sound and the ratchet wrench start spinning endlessly, it means the tip is fully tight. Remove the ratchet wrench carefully.

To remove the tip, repeat the procedure from (c) to (a) but turning counterclockwise.

Figure 22 - (a) and (b): Connecting and disconnecting the power cable to/from the main unit:



Hold the power cable connector as shown in image (a) and plug it into the back of the main unit. Use your other hand to support the main unit. Make sure the cable is fully connected as shown in picture (b). The other end of the cable must be plugged into the outlet.

To unplug the cable, make sure the equipment is turned off and the other end of the cable is unplugged from the outlet. Hold the connector close to its end as shown in picture (a) and pull it out to disconnect it from the main unit. Use your other hand to support the main unit.

Details of the insert ultrasonic movement

A piezoelectric handpiece, such as **CLINICAL PLUS**, provides an anteroposterior vibration motion at the end of the insert. This motion, despite the low amplitude, has high speed, which causes a strong impact on the front, back and top of the insert. Due to the high-precision motion, the impact on the sides of the insert is much lower. This typical motion is what defines the insert application.

For **CVDentus** tips, the strong impact is very useful, because that is what provides the dental structure cutting during a cavity preparation (more details on this application are available in **CVDentus** tips documentation). However, for other applications, with tartar removal inserts, periodontics inserts and endodontics inserts, great care must be taken to avoid direct impact of the insert against the dental structure, to avoid cracks and fissures.

This care defines two ways of application for removing tartar:

- **Tangential application** – touch the side of the insert to the tooth, letting the impact of the anterior and posterior parts occur directly on the tartar and not on the tooth. Apply the tip firmly but without pressure. Let the handpiece follow a “forward” and “backward”, slow and regular movement;

- **Front application** – lean the front or back of the insert directly against the tartar, but never directly against the tooth. This is only recommended when the tartar layer is thick and resistant, so that there is no risk of acting directly on the tooth. Whenever the thicker and more resistant tartar is removed, proceed to the tangential application. Slightly press and use a “forward” and “backward”, slow and regular movement.

When applying in periodontics and endodontics, besides these precautions, low, safe, recommended powers should be used for the technique.

Operating Procedures

ATTENTION: To avoid breaking the tip or releasing it from the handpiece, avoid the following:

- Leveraging (incorrect use);
- Excessive pressure;
- Incorrect assembly;
- Accidental mechanical shock (falling).

This damage can cause intraoral or bodily injury, with the risk of the patient swallowing the loose part.

1. PREPARING TO TREAT A PATIENT

a) Turn on the main unit by moving the on-off power button lever  to the (**I**) position and check if the LED indicator () lights up;
b) Before activating the “*CLEAN*” mode, face the handpiece to a sink or spittoon;
c) Run the “*CLEAN*” mode by selecting it through the SELECTION key (*CLEAN*) located on the home display;
d) After performing the cleaning mode (“CLEAN”), attach a **CVDentus** tip to the handpiece;
e) Using the ratchet wrench, tighten to secure the chosen **CVDentus** tip;
f) Adjust the ultrasound power according to the recommended power for the **CVDentus** tip in use;

g) Turn the FOOT SWITCH on and allow the coolant to circulate through the handpiece for a few seconds until it flows without interruption.

h) Place the tip in the patient’s mouth and press the FOOT SWITCH to turn on the handpiece and the irrigation flow.

2. WHEN TREATING A PATIENT

The handpiece must be approximately 10cm away from the patient's ear.

Other distances must be considered for the operator's safety (distance considered until the operator's ear):

- Minimum distance between the equipment and the operator (>= 30cm);
- Minimum distance between the handpiece and the operator (>= 30cm).

a) Position the patient comfortably on the chair. Adjust the angle of the chair and/or position it so that you can easily reach the patient's oral cavity.

b) Position the saliva sucker into the patient's mouth to evacuate saliva and debris.

c) Gently rotate the patient's head so that the oral cavity can be easily reached with good direct vision.

3. TIP APPLICATION AND PATIENT SENSITIVITY

During treatment, keep the angle between the patient's tooth surface and the tip of the handpiece as close as possible to 15 degrees. If the patient does not feel comfortable during treatment, try the following steps:

a) When treating places where the patient is highly sensitive, try to increase the speed of the handpiece movement on the tooth surface.

b) Treat less sensitive places first, returning to more sensitive areas later.

c) If these problems persist, reduce the intensity of the handpiece ultrasound power.

4. HANDPIECE CONTROL WITH THE FOOT SWITCH

The FOOT SWITCH is designed to control the functions of the handpiece in two ways:

1 - When pressing the FOOT SWITCH, the handpiece and the irrigation flow are turned on.

2 - When releasing the FOOT SWITCH, the handpiece and the irrigation flow are turned off.

5. CONTROL OF IRRIGATION FLOW AND TEMPERATURE

The increasing (**+**) and decreasing (**-**) keys control the irrigation flowing into the handpiece when the IRRIGATION function is selected by the SELECTION key (**S**). There are six defined flow positions, equivalent to 16.6%, 33.3%, 49.9%, 66.5%, 83% and 100%. When selecting the operating power, a minimum irrigation flow is automatically set.

NOTE: The higher the irrigation flow, the lower the temperature of the handpiece, and vice versa.

WARNING
Avoid using the handpiece with the irrigation flow off. This is only possible with some specific procedures of ENDO specialty.

6. PROCEDURE CONTROL AND POWER ADJUSTMENT

Before turning the foot switch on, check the operating power (Value recorded on the insert body). Adjust the power with the increasing (**+**) and decreasing (**-**) keys in the ***Indicator of power adjustment*** icon (Item E in figure 12).

There are ten defined power positions, equivalent to 10%, 20%, 30%, 80%, 90% and 100%. Depending on the tip model applied, the appropriate power level is defined.

Preventive Maintenance and Inspection

CLINICAL PLUS does not require special maintenance routines, but it needs to be regularly and fully cleaned and sterilized (as described in the following section), and the integrity of its components must be verified.

1. DAILY BOOT

a. Make sure that the equipment and its parts are all intact, properly placed and connected.

b. Check the integrity of the power cable.

c. Plug the power plug into the outlet.

d. Press the on-off power button () to turn on the equipment and light the LED indicator (⏻).

e. Check if the irrigation container has enough liquid.

f. Before activating the "*CLEAN*" mode, face the handpiece to a sink or spittoon;

g. Run the "*CLEAN*" mode by selecting it through the SELECTION key (*CLEAN*) located on the home display;

NOTE -1: Wait a few seconds until the coolant flows through the handpiece.

NOTE -2: **If the LED indicator (⏻) does not light, check that the power plug is correctly connected.**

2. DAILY SHUTDOWN

a. Disconnect the silicone tube from the bottle;

b. Before activating the "*CLEAN*" mode, face the handpiece to a sink or spittoon;

c. Run the "*CLEAN*" mode by selecting it through the SELECTION key (*CLEAN*) located on the home display Take these steps until all residual water from the pen is removed;

After performing the cleaning mode ("CLEAN"), activate the "on-off" power button () to turn the unit and the LED indicator () off.

d. Unplug the power plug from the outlet;

e. Remove the pens, bottles, and silicone tubing for cleaning and/or autoclaving

WARNING

Unplug the power plug from the outlet at each end of workday in order to avoid damage and to extend the life of the equipment.

3. PREPARING TO TREAT A PATIENT

Make sure that all parts requiring sterilization are autoclaved and available for use. **CVDentus** tips need to be autoclaved with each use. In some cases, it is absolutely necessary to autoclave the entire handpiece, including its handle, the entire irrigation circuit, and the coolant container. At the discretion of the dentist, in case of low invasive treatments, it is possible to autoclave only the tip to be inserted into the handpiece.

4. MAINTENANCE OF THE IRRIGATION CIRCUIT AND THE PERISTALTIC PUMP

The external irrigation circuit, composed by the bottle, peristaltic pump drawer and respective tube is fully autoclavable at a maximum of **135ºC**. These items suffer wear and tear from use and autoclaving, and must be replaced when wear and tear compromises operation. It is always recommended to have spare silicone tubing for replacement.

Extending Equipment Life

Place the main unit in an open area where air can flow freely around it.

If you need to move the main unit, hold it carefully.

Before leaving the office, make sure the power plug is disconnected.

After six months or if you notice the handpiece ultrasound power is not enough to perform the treatment, the insert is very likely to be worn out. In this case, replace it with a new one, or ask your authorized agent to service the system.

Customer Service: If service is required, please contact your local authorized agent or the manufacturer.

Cleaning and Sterilization

It is important to follow these procedures prior to using the equipment, as patients and/or doctors may get an infection. It is imperative that clinicians wear sterile gloves throughout ALL these procedures to avoid any possibility of incomplete sterilization and/or infection. Below, infection control procedures are detailed for the care of the handpiece, the tips and the main unit, respectively.

ATTENTION: Only the use of cleaning and sterilization methods authorized by current legislation is recommended.

The use of acids in the cleaning process is not allowed.

1. HANDPIECE

Before cleaning, remove the tip from the handpiece. Use the “CLEAN” (Cleaning Mode) by selecting the “CLEAN” button in the lower right corner of the display.

Clean and disinfect the outer surface of the handpiece, using 70% alcohol*, which must be rubbed for 60 seconds. The application of 70% alcohol must be repeated three times. Do this procedure on the entire exposed part of the handpiece, including the handle. Attention should be paid to the removal of potentially contaminating debris from the handpiece. Never subject the handpiece to ultrasound bath cleaning.

After each use, there will be saliva and/or blood or other debris left on the handpiece. Therefore, it is necessary to first clean it with a cleaning liquid. This can be done manually by scrubbing with a brush or by using ultrasonic cleaning equipment, with a neutral detergent solution in water. After scrubbing, rinse it thoroughly with water to remove all detergent and then dry it.

Dry the handpiece, put it in a sterilization pouch and then into an autoclave, and sterilize it at 127ºC for 30 minutes, or as recommended by the autoclave manufacturer, always respecting the maximum temperature of 135ºC.

After disinfecting the handpiece, insert the sterile tip into it, when preparing for the next patient.

NOTES: The parts inside the handpiece are highly sensitive, therefore do not try to open or hit it. This can shorten its life or damage it. Never subject the handpiece to

ultrasound bath cleaning. We recommend the handpiece is replaced every six months or when the operator notices a reduction in cutting speed.

2. PERISTALTIC PUMP AND IRRIGATION CIRCUIT

Whenever necessary, disassemble the cooling circuit and sterilize its parts in autoclave. The bottles, their caps, the silicone tubes and their connectors must be packed in sterilization pouches, together or separately. Autoclave at 127ºC for 30 minutes, or as recommended by the autoclave manufacturer, always respecting the maximum temperature of 135ºC.

WARNINGS

- The handpiece is autoclavable at a maximum temperature of 135ºC.
- The bottle and its cap, as well as the entire irrigation system, are autoclavable at a maximum temperature of 135ºC.
- Autoclaving is always recommended to minimize cross-infection issues.
- It is always recommended to have spare sterile silicone tubes available.
- Autoclaving the handpiece is suggested after use on each patient.

3. TIPS

After each use, there will be saliva and/or blood or other debris left on the tip. Therefore, it is necessary to clean the tip first with a cleaning liquid. This can be done manually by scrubbing with a brush or by using ultrasonic cleaning equipment, with a detergent solution in water. After scrubbing, rinse the tip thoroughly with water to remove all detergent and then dry it. Dry the tip, put it in a sterilization pouch and then into an autoclave, and sterilize it at 127ºC for 30 minutes, or as recommended by the autoclave manufacturer.

Entirely-made-of-metal tips can be sterilized in an autoclave up to 200ºC. However, in many cases, these pieces are also built with elastomeric parts; therefore, it is not recommended to use this kind of autoclave.

WARNINGS

- High room temperature conditions, improper dilutions, or excessive immersion time in a chemical sterilant can result in damage to plastic and elastomeric materials.
- The use of a dry oven, an incompatible type of chemical steam sterilizer, or quaternary ammonium compound must be avoided, as it can result in damage to plastic and elastomeric materials.
- Do not attempt to change the shape or weight of the tip, as this may decrease the power of ultrasound generated.

4. MAIN UNIT

Since the main unit has no direct contact with patients, cleaning is simple. Simply clean the main unit carefully with a 70% alcohol disinfectant, and keep it free of dust. If another disinfectant is used, choose one that has no chemical effect on the surface of the main unit's ABS plastic. If you are not sure of this, test it before use or consult your supplier.

Essential Performance

Essential performance is considered: Prime performance where its lack or degradation results in an unacceptable risk. Thus:

- The equipment must always operate cooled, i.e., with a constant flow of liquid throughout the cooling circuit (bottle, peristaltic pump, handpiece and CVDentus ultrasound tip, "applied part").

Electromagnetic Compatibility

WARNING: The facilities in the room where CLINICAL PLUS will operate must comply with the guidelines mentioned here.

The use of accessories other than those specified by the manufacturer may result in increased emissions and decreased immunity regarding the EMC (Electromagnetic Compatibility).

STATEMENT

RF (radio frequency) communication equipment can affect the correct operation of CLINICAL PLUS ultrasound.

IMPORTANT: Completely turn off cell phones or personal communication system, radio transceivers and cordless phones in the dental office area.

STATEMENT

The CLINICAL PLUS dental ultrasound equipment is suitable for use in public power supply (127 to 220 Vac ~ 50/60Hz).

The power cable, the handpiece, the peristaltic pump and the tips comply with electromagnetic compatibility.

1. ELECTROMAGNETIC EMISSIONS

CLINICAL PLUS dental ultrasound is intended for use in the electromagnetic environment specified below. The owner or user of CLINICAL PLUS dental ultrasound may want to ensure that it is used in such environment.

Table 1 - Guidelines and Statement: Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic Environment - Guidelines
RF emissions CISPR 11	Group 1	CLINICAL PLUS dental equipment does not use RF energy for its internal functions.
RF emissions CISPR 11	Class B	CLINICAL PLUS dental equipment is suitable for use in all establishments, including households and those directly connected to the public low-voltage power supply grid that feeds the buildings used as households.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliant	
 **WARNING:** CLINICAL PLUS ultrasound equipment must not be used stacked or too close to other equipment.		

2. ELECTROMAGNETIC IMMUNITY

CLINICAL PLUS dental ultrasound is intended for use in the electromagnetic environment specified below. The owner or user of CLINICAL PLUS dental ultrasound may want to ensure that it is used in such environment.

Table 2 - Guidelines and Statement: Electromagnetic Immunity

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air In no situation is there loss of essential performance, only the information on the display corrupts.	The floors must be made of wood, concrete or ceramic. If they are covered with synthetic material, the relative humidity should be at least 30%. In the rare event of electrical fast transients that corrupt the information shown on the display, just release the foot switch to update the information. If the foot switch is not turned on, the information is updated periodically.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	In no situation is there loss of essential performance, only the	The quality of the power supply must be typical of a hospital or commercial environment. In the rare event of electrical fast transients that corrupt the information shown on the display, just

		information on the display corrupts.	release the foot switch to update the information. If the foot switch is not turned on, the information is updated periodically.
Surges IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 1 kV differential mode ± 2 kV common mode	The quality of the power supply must be typical of a hospital or commercial environment.
Voltage drop, short breaks and voltage changes in the power supply input lines. IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for 0.5 cycle 40% U_T (60% drop in U_T) for 5 cycles 70% U_T (30% drop in U_T) for 25 cycles	< 5% U_T (> 95% drop in U_T) for 0.5 cycle 40% U_T (60% drop in U_T) for 5 cycles 70% U_T (30% drop in U_T) for 25 cycles	The quality of the power supply must be typical of a hospital or commercial environment.
	< 5% U_T (> 95% drop in U_T) for 5 seconds	This condition shuts down the equipment, which cannot be reconnected by turning the switch foot on.	In this case, human intervention is necessary to release the foot switch and reconnect the equipment, returning to the previous conditions of use. If the user of CLINICAL PLUS ultrasound needs continuous operation during power supply breaks, CLINICAL PLUS ultrasound should be powered by an Uninterruptable Power Supply.
Magnetic field generated by power grid frequency (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	The quality of CLINICAL PLUS ultrasound installation room must provide levels below the tested level in order to ensure its correct operation.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 3 - Guidelines and Statement: Electromagnetic Immunity

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidelines
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Mobile or portable RF communication equipment should not be used at shorter distances from any part of the CLINICAL PLUS dental ultrasound, including cables, than the recommended separation distance calculated by the formula applicable to the transmitter frequency. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum level of the transmitter's output power in watts (W), according to the transmitter

			manufacturer and *d* is the recommended separation distance in meters (m). The field strength from RF transmitters, as determined by an electromagnetic field survey[a], should be less than the compliance level for each frequency range.[b] Interference may occur in the vicinity of equipment, which is marked with the following symbol: 

NOTE 1: At 80MHz and 800MHz, the highest frequency range is applicable.

NOTE 2: These guidelines may not be applicable to all situations. Electromagnetic propagation is affected by the absorption and reflection of structures.

a	Field strength from stationary transmitters, such as radio base stations for telephones (cellular or wireless) and ground mobile radios, amateur radio, AM and FM radio broadcasting and TV broadcasting, cannot be accurately predicted in theory. To assess the electromagnetic environment generated by stationary RF transmitters, an electromagnetic field survey should be considered. If the field strength measured at the location where CLINICAL PLUS dental ultrasound will be used exceeds the applicable RF COMPLIANCE LEVEL defined above, we recommend to watch and check if CLINICAL PLUS dental ultrasound is working normally. If abnormal performance is detected, additional measures may be required, such as redirecting or relocating CLINICAL PLUS dental ultrasound.
b	Above the frequency range of 150kHz to 80MHz, the field strength should be less than 3V/m.

Table 4 – Recommended separation distances

Recommended separation distances between mobile or portable RF communication equipment and CLINICAL PLUS dental ultrasound			
CLINICAL PLUS dental ultrasound is intended for use in an electromagnetic environment where RF radiation disturbances are controlled. The owner or user of CLINICAL PLUS dental ultrasound can help to prevent electromagnetic interference by keeping the minimum distance between mobile or portable RF communication equipment (transmitters) and CLINICAL PLUS dental ultrasound, as recommended below, as per the maximum output power of the communication equipment.			
Maximum level of the transmitter's output power W	**Recommended separation distance as per transmitter frequency** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum output power level not listed above, the recommended separation distance *d* in meters (m) can be determined through the formula applicable to the transmitter frequency, where *P* is the transmitter's maximum output power declared in watts (W), according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the highest frequency range is applicable.
NOTE 2: These guidelines may not be applicable to all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

STATEMENT

It is not required to use CLINICAL PLUS dental ultrasound equipment in a shielded environment.

Identification of defects

Table 5: To identify a potential issue.

Issue	Cause	Test	Solution
The equipment does not work	The power plug is not plugged into the power outlet	Visual	Plug the power supply into a 127 or 220Vac outlet
	The on-off power button ( ) lever is in the ( ) position	Visual	Set the "on-off" power button ( ) lever to ON ( ) position
	The foot switch is not turned on	Visual	Press the foot switch until you turn it on
	The tip is loose or partially loose from the handpiece	Tightening	Tighten the tip with the spanner wrench so as to attach firmly to the handpiece.
No water comes out of the insert	The bottle is below the minimum water level	Visual	Fill the bottle with coolant;
	The peristaltic pump is not pumping	Hearing (the difference in the pumping sound is evident)	Reassemble the peristaltic pump, cleaning it if necessary. If wear is noticed, contact Customer Service to replace the peristaltic pump with a new one.

	The motor does not rotate	Listen to whether the axis of the respective motor rotates when the foot switch is turned on.	Test it under many flow adjustment conditions from the front panel.

If the failure persists after performing the solution suggested by the table above, the equipment must be sent to the authorized service center to diagnose the cause of the failure and proceed with the necessary repair.

CORRECTIVE MAINTENANCE

If the equipment does not work again after the defect identification procedure or when any damage occurs to one of the parts of the equipment compromising safety, follow the steps below:

- Set aside the equipment and the purchase invoice;
- Contact the service center to formalize the call;
- Send all the parts, copy of the invoice and a letter in your own hand reporting the problem;
- Securely pack all parts in an appropriate package and write the call number on the outside of the box as instructed by the Customer Service.

WARNING: DO NOT modify this equipment without the manufacturer's authorization.

PREVENTIVE MAINTENANCE

Table 6: Indication for preventive maintenance.

Description	Frequency
Inspection of power cables and handpieces. Check that they are not broken or with exposed wiring.	Daily
Inspection of the cooling system hoses. Check that they are not broken, cracked or constricted.	Daily
Inspection of peristaltic pump and cooling hose. It is likely that after a long period of use, some powder will form from the wear of the silicone tube. We recommend cleaning and replacing it if necessary.	After each cycle of sterilization in the autoclave.

Inspection of CVDentus ultrasound tip (applied part). Verification of the correct attachment of the tip to the handpiece. The tip must be firmly attached and tightened with the ratchet wrench.	Before each procedure.

Warranty

Pursuant to the Law, any and all MANUFACTURING DEFECTS may be claimed within 90 (ninety) days from the date of delivery of the device. As we trust its quality, besides the legal warranty, we grant the buyer of the product a supplementary coverage, totaling a 01 (ONE) YEAR warranty (90-day legal warranty, plus 9-month factory supplementary) against manufacturing defects, as of the date of purchase in the invoice.
For handpieces, a total of 06 (SIX) MONTHS warranty is granted (90 days of legal warranty, plus a complementary 03 months factory warranty) against manufacturing defects, also counting from the purchase date on the invoice.

In the event of a defect, the customer can count on TECHNICAL ASSISTANCE from the factory and possible authorized ones. The shipment of equipment and handpieces for evaluation must be notified and properly identified.

LOSS OF WARRANTY

This warranty shall be voided if any of the following situations is found:

1. The equipment or parts thereof have been damaged due to falls, natural phenomena, improper installation and/or use;

2. The equipment or parts thereof have been serviced by non-authorized persons by the manufacturer and/or non-original parts;

3. Malpractice, recklessness, violation and/or negligence in handling or operation;

4. Improper power grid installation;

5. Use for purposes other than those for which it is intended;

6. Failure to submit the Invoice.

Should any of the above situations be found, the buyer (CUSTOMER) shall bear ALL expenses arising from transport and repair of the product.

WARNING

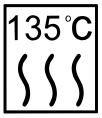
Any replacement or repair must be performed by authorized service center.

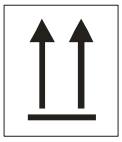
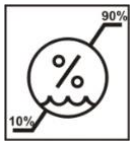
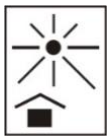
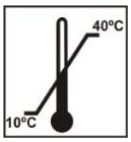
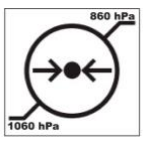
Technical, maintenance problems within and outside the warranty period, please contact:

Clorovale Diamantes Ind. E Com. LTDA
Estrada José Augusto Teixeira, 500 – Torrão de Ouro II
São José dos Campos, SP – ZIP CODE: 12.229-840
Phone: +55 (12) 3944-1126
e-mail: sac@cvdentus.com.br

List of Symbols

Table 7: Legend of Symbols

	Attention. Read the operating instructions
	Operation instructions.
	Type B. Equipment with type-B applied part.
IP21	Protected against foreign solid objects with a diameter greater than and equal to 12.5mm. Protected against drops of water falling vertically.
~	AC supply voltage. The power supply is automatic dual voltage and can be connected to any outlet between 127 and 220 VAC. The power outlet must have a grounding terminal.
O	Off (power supply). On-off power button facing this position. In this situation, only the main unit is turned off. To completely shut down the equipment, it is necessary to remove the plug from the power outlet.
|	On (power supply). On-off power button facing this position.
	On/powered equipment. The lit green LED on the main unit panel indicates this condition, which is obtained with the equipment plugged into a powered outlet and with the on-off power button in the “on” position.
	Autoclave maximum temperature symbol.
	Serial number symbol.
	Manufacturing date symbol

	Manufacturer’s data symbol.
	Symbol of authorized representative in the European Community.
	Do not dispose of the equipment in household waste. Use the appropriate disposal system as per your country’s law.
	Follow the instructions of the manual for use.
	Transport and storage positioning (upward direction).
	Caution in transport and storage. Handle with care (fragile).
	Need for protection against humidity in transport and storage.
	Humidity limits for transportation and storage in percentage.
	Keep protected from sunlight.
	Storage temperature limits.
	Atmospheric pressure limits.