English

OWNER´S MANUAL

Equipment for Prophylaxis by Ultrasound / Bicarbonate Jet

SAEVO

Cód.:77000000863 - Rev.:12

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MANUAL PRESENTATION

Technical Name: Equipment for Dental Prophylaxis Sodium Bicarbonate/Ultrasound
Trade Name: Equipment for Prophylaxis by Ultrasound / Bicarbonate Jet
Models: Sonic Duo / Sonic Duo LED / Sonic Duo Fit / Sonic Duo Fit LED / Sonic / Sonic LED / Sonic Fit / Sonic Fit LED
Brand: Saevo

Technical Responsible: Daniel R. de Camargo
CREA-SP: 5062199650

ANVISA Registration Nº: 10069210086

Alliage S/A Indústrias Médico Odontológica
Rodovia Abrão Assed, Km 53 + 450m - CEP 14097-500
Ribeirão Preto - SP - Brasil
Tel: +55 (16) 3512-1212

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Document originally written in Portuguese.

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The performance characteristics provided in this manual are for reference only and should not be considered as guaranteed specifications.

SUMMARY

SUMMARY

1

GENERAL INFORMATION

Alliage S/A Industrias Médico Odontológica
Telephone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brazil

1. GENERAL INFORMATION

1.1.DEAR CUSTOMER

Congratulations on your excellent choice. When you buy ALLIAGE quality equipment, you can be sure of purchasing products with technology compatible with the best in the world in their class. This manual provides you with a general presentation of your equipment, describing important details that can guide you in its correct use, as well as in solving small problems that may eventually occur. This manual must be read in full and kept for future reference.

1.2.INDICATIONS FOR USE

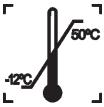
The Saevo Ultrasound / Bicarbonate Jet Prophylaxis Equipment is intended to assist in dental treatments such as removing plaque and residual stains; tartar removal; periodontal treatment; endodontic treatment; micro retro surgery; cavity preparations for restorations; amalgam condensation, inlays and on lays and gutta percha; removal of pins and crowns, among other procedures related to dental treatments.

1.3.CONTRAINDICATIONS

This equipment is contraindicated for use in patients who have serious respiratory, renal or hemodialysis changes, these cases must have medical monitoring. We recommend the use of a mask and glasses to apply the bicarbonate jet.

1.4.SYMBOLOGY

The following symbols are used both throughout this manual and on the product. Make sure you fully understand each symbol and follow the instructions that come with it.

	Fragile, handle with care		Maximum stacking
	Protect from rain		Temperature limit
	This side Up		Protect from direct sun
	Model number		Recyclable

	Catalog number		Sterilizable in a steam sterilizer (autoclave) at specified temperature
	Type B applied parts		Indicates that the product must be taken to a special waste collection site at the end of its useful life. Applies to both the device and accessories
	Attention		Electrostatic sensitive devices (ESD)
	Protective ground wire		General warning
	Alternating current		Serial number
	Turn Off (Power: Disconnects from the main switch)		Mandatory action
	Turn On (Power: Connects from the main switch)		Follow the instructions for use

	Manufacturer		Manufacturing date
MODEL	Model		Ultrasound
	Bicarbonate jet		Power – Ultrasonic power adjustment knob
	Air – Air flow regulation button		Water – Water flow regulation button
S	Scaling function (micro retro surgery)	P	Periodontal function (periodontics)
E	Endo function (endodontics)		

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WARNINGS, CAUTIONS AND RECOMMENDATIONS

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2.WARNINGS, CAUTIONS AND RECOMMENDATIONS

General warnings

	Read and understand all instructions contained in these instructions for use before installing or operating this equipment.
	Use only the equipment in perfect condition and protect yourself, patients and others against possible dangers.
	The Saevo Ultrasound / Bicarbonate Jet Prophylaxis Equipment has 4 different interactions with the user, they are: - Identification label: Located on the side of the equipment; - Safety symbols: Located at risk locations and on their identification tag; - Central panel; - Pedal.

During transportation

The equipment must be transported and stored, observing the following:
• Handle with care to avoid falls, excessive vibrations and impacts;
• The arrows on the packaging must be pointing upwards;
• To handle the package as a single unit, consider the center of gravity indicator;
• Do not stack above the quantity indicated on the packaging;
• Do not walk or stand above the package
• Protect against sunlight, moisture, water and dust;
• Observe the temperature, pressure and relative humidity limits.

During the installation of the equipment

	The installation procedure must be carried out by an authorized technician. Instructions for installing the equipment are found in this manual.
	To avoid the risk of electric shock, this equipment must only be connected to a mains supply with a protective ground.
	Before turning on the equipment, make sure that it is connected to the correct voltage.

• The equipment must be installed only by authorized technical assistants.
• The service manual's recommendations regarding the mandatory existence of protective earth must be followed.
• The recommendations in the service manual regarding the mandatory existence of a protective circuit breaker must be followed.
• Install the equipment in a place where it will not be in contact with moisture, water, plants and animals.
• Install the equipment in a location where it will not be damaged by pressure, temperature, humidity, direct sunlight, dust, salts or corrosive products.
• The equipment must be correctly attached according to the service manual and must not be subjected to an inclination greater than 5 °. Risk of tipping.
• This equipment is not designed for use in the presence of vapors from flammable anesthetic mixtures or nitrous oxide.
• Place any other external devices at least 1.5 meters away from the equipment, so that the patient cannot touch any other external devices while they are being attended to.
• The recommendations in this manual for EMC should be followed. Communications equipment and RF generating sources can affect the operation of the equipment.
• Equipment may cause radio interference or interrupt the operation of nearby equipment, making it necessary to take mitigating measures, such as reorientation, relocation of equipment or shielding the location.

Before using the equipment

To help ensure proper hygiene and protect against infectious diseases, before using for the first time, the equipment must be cleaned and disinfected according to the instructions contained in this manual.

While using the equipment

• Under no circumstances can the patient operate the equipment.
• The patient must not touch other parts than those specific to be treated.
• The equipment must be operated only by qualified health professionals.
• To operate the equipment, operating personnel must:
- Read and understand the user manual
- Be familiar with the basic structure and functions of this equipment.
- Be familiar with the emergency situation protocols for this equipment.
- Be able to recognize irregularities in the operation of the equipment and implement the appropriate measures, when necessary.
• The equipment has been designed according to the electromagnetic compatibility standards, but in very extreme conditions, it can cause interference with other equipment. Do not use this equipment in conjunction with other devices that are extremely sensitive to interference or with devices that create high electromagnetic disturbances.
• Do not position the patient on the equipment while starting it, as the patient may be injured if the equipment does not work properly. In the event of an error that requires turning the equipment off and on, remove the patient before turning it on again.
• In case of risk to the patient, press the emergency button immediately located on the side of the equipment.
• If this product is exposed to water, moisture or foreign substances, turn it off immediately and contact an Alliage Authorized Service Center.
• In case of damage or defect, do not use the equipment and contact an Authorized Alliage Service Center.
• Do not use the equipment if any of its compartments or parts are damaged, loose or have been removed. Contact an Alliage Authorized Service Center and request repair or replacement

of any damaged, loose or removed enclosures or parts of the equipment before using the equipment again.
• Do not touch the equipment or use it if it is being repaired or if the equipment's cabinets have been removed.
• Do not open or remove any of the equipment's cabinets. No internal parts can be repaired by the user.
• In case of falling or impact of moving parts causing it to break, be careful when handling them, there may be sharp parts.
• The operator cannot come into contact with the patient when in contact with accessible connectors.
• The operator cannot use tools to open the equipment.
• When using the product, the dental tip can reach the normal use temperature of 114.2 ° C. That if you are in contact for more than 1 min there may be a risk of slight superficial burns or irritation.
• If there are obstructions or blockages in the cooling system, the tip can reach a maximum rate of temperature increase of 63% (179.7 ° C). That if you are in contact for more than 1 min there may be a risk of slight superficial burns or irritation.

Cross contamination prevention

	Adequate cleaning and disinfection / sterilization measures should be taken to avoid cross-contamination between patients, users and others.

• For each new patient, perform cleaning, disinfection / sterilization procedures and according to the instructions contained in this manual.

After using / operating the equipment

• Turn off the equipment if it is not in use for a long time
• All parts that have been in contact with the patient must be cleaned and disinfected / sterilized with each new patient to prevent the transmission of infectious agents that can cause serious illness.
• Perform cleaning and disinfection / sterilization according to instructions contained in this manual.
• Do not unplug the cable or other connections unnecessarily.
• Do not modify any part of the equipment.

Precautions in case of alteration of the equipment operation

If the equipment shows any abnormality, check if the problem is listed in any item listed in the “Problem diagnosis” topic of this user manual.
If it is not possible to solve the problem, turn off the equipment, contact an Alliage Authorized Technical Assistance.

	The manufacturer is NOT responsible: • If the equipment is used for purposes other than those for which it was designed. • For damage caused to the equipment, the operator and / or the patient, as a result of incorrect installation and maintenance procedures that do not comply with the operating instructions that accompany the equipment.

Precautions for reducing environmental impact

Alliage S / A aims to achieve an environmental policy to promote the supply of environmentally conscious medical and dental products that continually minimize environmental impact and are more friendly to the environment and human health.
To maintain a minimal impact on the environment, observe the recommendations below:
• After installation, send recyclable materials for recycling process.
• During the life cycle of the equipment, turn it off when it is not in use.
• To prevent environmental contamination, the disposal of waste and consumables must follow the normal procedure for biomedical waste.
Biomedical waste includes non-acute materials that may cause disease or suspicion of harboring pathogenic organisms that must be stored in a yellow bag properly labeled with a biohazard symbol, stored in a puncture-resistant, watertight container until collection and incineration.

	The equipment packaging consists of cardboard and polyethylene that are 100% recyclable materials.

DIMENSIONS:
380 x 380 x 270mm /MASS: Approximately: 10 Kg

Precautions in case of unusable equipment

To avoid environmental contamination or improper use of the equipment, when it is unusable, it must be disposed of (in accordance with current legislation) in an appropriate place, as the materials inside can contaminate the environment.
For the European Economic Area (EEA), this product is subject to Directive 2012/19 / EU, as well as the corresponding national laws. This directive requires that the product must be taken to a special waste collection site at the end of its useful life. Applies to both device and accessories
Contact your dealer if final product placement is required.

	This equipment must not be disposed of as household waste

3

SYSTEM OVERVIEW

Alliage S/A Industrias Médico Odontológica
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Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brazil

3.SYSTEM OVERVIEW

3.1.SYSTEM DESCRIPTION

Equipment for prophylaxis by ultrasound and Bicarbonate Jet, modern and bold design, assembled together composed of body and cover made of ABS (Acrylonitrile, butadiene, styrene) and digital control panel in polycarbonate. Available in cart and bench models.
Synchronized electropneumatic system, with valves that provide cuts and aspirations of water instantly, thus avoiding water contact with bicarbonate at the tip of the handpiece.
It has Piezoelectric ultrasound activated through ceramic tablets in which it allows use in operations without the use of water.
Removable bicarbonate jet pen, with concentric diffuser that mixes air, water and bicarbonate a short distance from the tip.
Transducer cover made of rigid and self-cleaning thermoplastic resin.
Function selector key with 3 programmable options, P (periodontal), E (endo) and S (scaling).
Fine adjustment potentiometer for precise regulation of ultrasonic power, suitable for each type of procedure.
Internal depressurization through automatic scanning of the bicarbonate, from the valves to the handpiece.
Bicarbonate container with easy access, transparent and removable that allows its removal without the need to turn all the equipment to remove the leftover bicarbonate powder.
Bicarbonate jet interruption system with an anti-agglutination module that prevents clogging in the valves.
It has a contamination-free system for feeding the ultrasound pens and the bicarbonate jet, through the peristaltic pump with antiseptic liquid, water, serum or similar. The peristaltic system has the function of pulsating the liquid from the reservoir to the tips (ultrasound and bicarbonate jet).

3.2.APPLICATION SPECIFICATION

The Dental Prophylaxis by Sodium Bicarbonate / Ultrasound project is intended for prophylaxis with ultrasound and bicarbonate jet, which was developed to be used in various dental practices such as: periodontics, endodontics, prosthesis, surgery and others.

3.2.1.Principles of operation

Ultrasound is derived from physical vibrations of matter particles, similar to sound waves, with a frequency higher than the level of human perception, which produces a frequency of up to 30,000 vibrations per second.
The Bicarbonate Jet (Prophylaxis) comes from the release under pressure of sodium bicarbonate particles that, together with the water, mix in the tip of the tip forming a jet in the form of a concentrated spray.

3.2.2.Significant physical characteristics

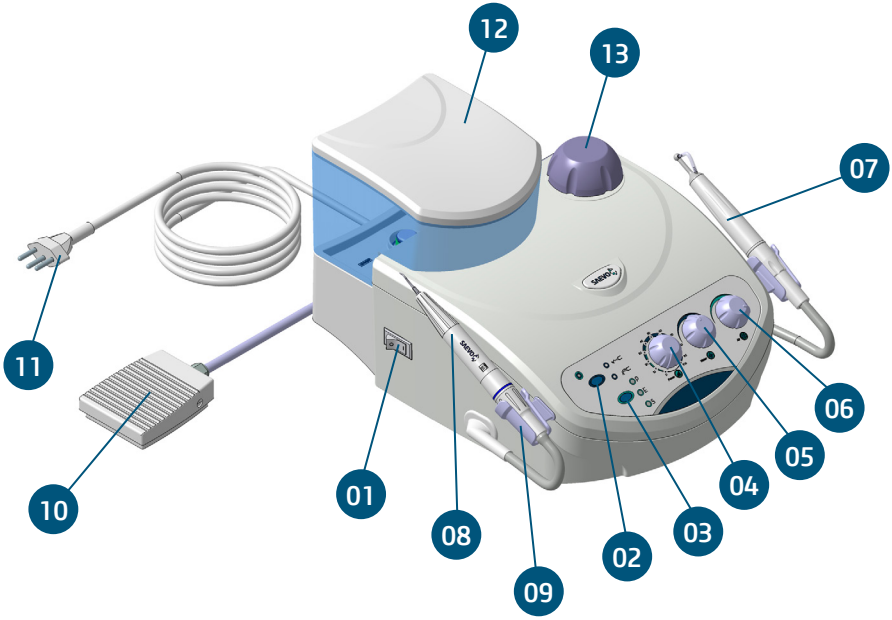
It has Piezoelectric ultrasound activated through ceramic inserts at a frequency of 30,000 Hz. The Piezoelectric system of the transducer allows use in operations without the use of water.

3.2.3.User profile

The user to operate and handle the Ultrasound and Bicarbonate Jet must be aged between 18 and 70 years old, both sexes, with the ability to read and understand images, symbols, icons, western Arabic characters (Arial font), alpha numeric characters, to know distinguish intraoral part of the human body, not being able to present a degree of visual imperfection for reading or seeing and an average degree of impairment of recent memory, not being clearly able to perform the activities and functions of the product in a correct manner to the profession.
The user needs to be a qualified health professional and trained to perform the activities, functions frequently used in the application of Dental Prophylaxis by Sodium Bicarbonate / Ultrasound and their primary operations functions.

3.3.MAIN PRODUCT COMPONENTS

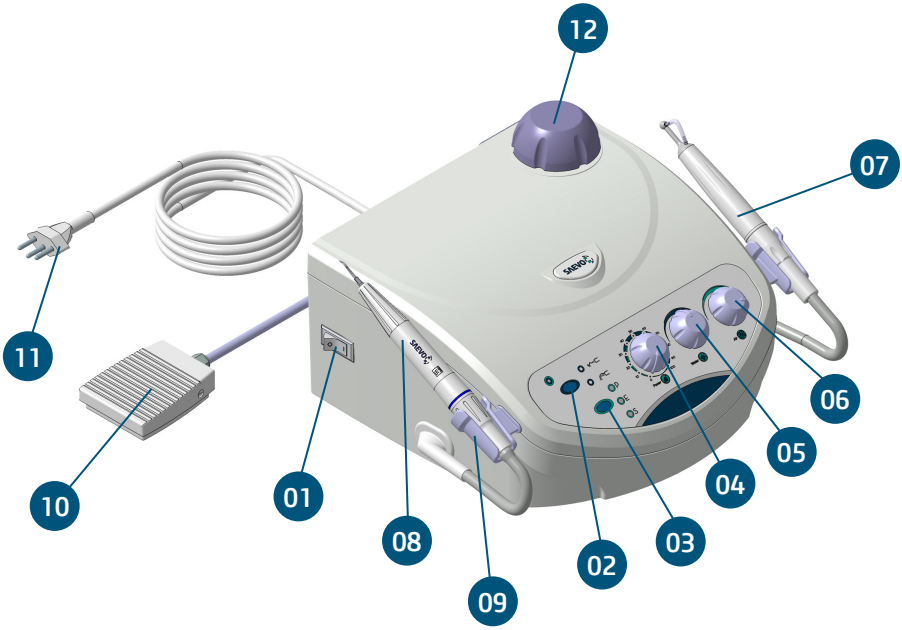
3.3.1.Sonic Duo / Sonic Duo LED



01. On/Off switch
02. Ultrasound selection button or bicarbonate jet
03. Ultrasound function selection key (PES)
04. Ultrasonic variation regulator
05. Water flow regulator
06. Air flow regulator
07. Bicarbonate jet pen
*08. Ultrasound pen
09. Tip support
10. Foot pedal
11. Power input cable
**12. Reservoir for peristaltic
13. Bicarbonate container

* Handpiece with exclusive LED lighting for the Sonic Duo LED model.
** Optional Reservoir Heater (Subject to commercial availability).

3.3.2.Sonic Duo Fit / Sonic Duo Fit LED



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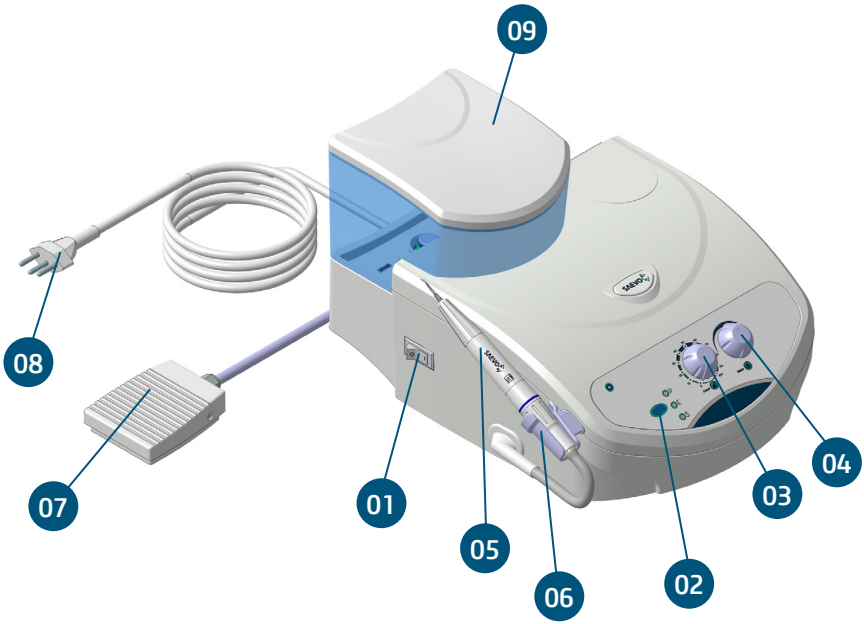
07. Bicarbonate jet pen
*08. Ultrasound pen
09. Tip support
10. Foot pedal
11. Power input cable
12. Bicarbonate container

* Handpiece with exclusive LED lighting for the Sonic Duo Fit LED model

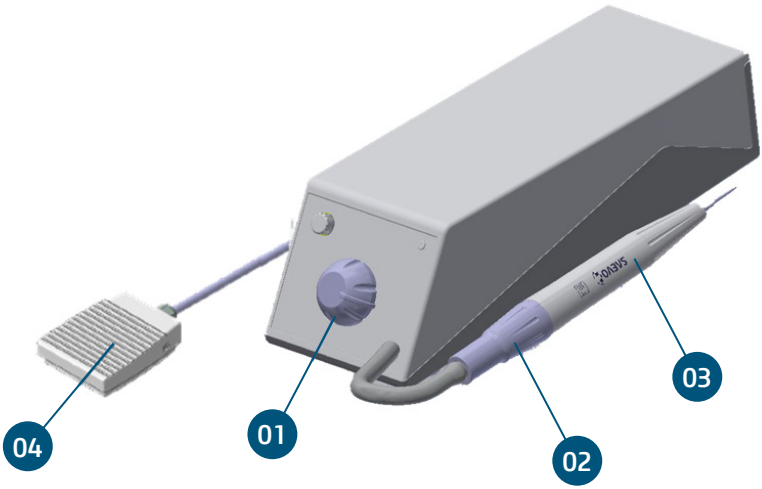
3.3.3.Sonic / Sonic LED



01. On/Off switch
02. Ultrasound function selection key (PES)
03. Ultrasonic variation regulator
04. Water flow regulator
*05. Ultrasound pen
06. Tip support
07. Activation pedal
08. Power input cable
09. Reservoir for peristaltic pump

* Handpiece with exclusive LED lighting for the Sonic LED model .
** Optional Reservoir Heater (Subject to commercial availability).

3.3.4.Sonic Fit / Sonic Fit LED



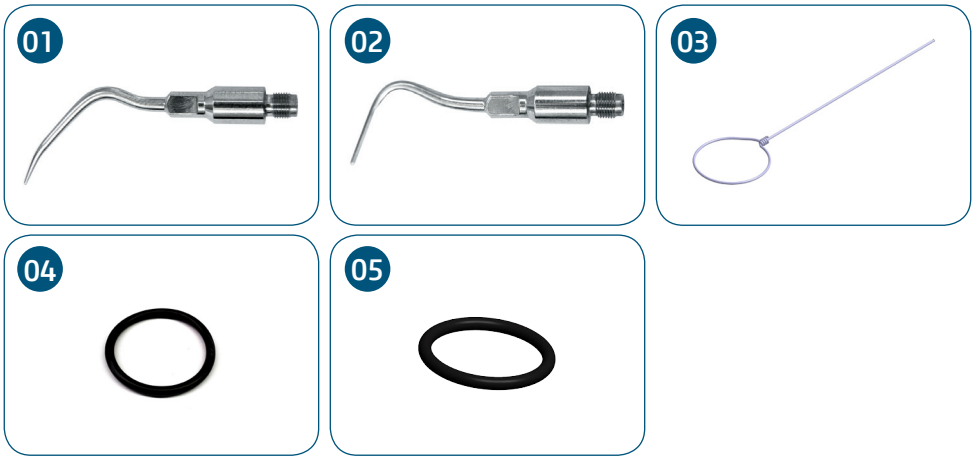
01. Ultrasonic variation regulator
02. Tip support
*03. Ultrasound pen
04. Activation pedal

* Handpiece with exclusive LED lighting for the Sonic Fit LED model

3.4.SETS AND ACCESSORIES

	All parts, accessories and options described in the owner's manual are for exclusive use. The use of any parts, accessories or materials not specified in this manual is the sole responsibility of the user.

Accessories that accompany the product



The Sonic Duo Kit consists of:
01. Tip Periodontal Supra (1 units)
02. Tip Periodontal Sub (2 units)
03. Nozzle cleaning needle (1 unit)
04. O-ring Int Ring 11,17 (1 unit)
05. O-ring Int Ring 12.49 (1 unit)

Accessories that do not accompany the product

01 

02 

03 

04 

05 

06 

07 

08 

09 

10 

11 

12 

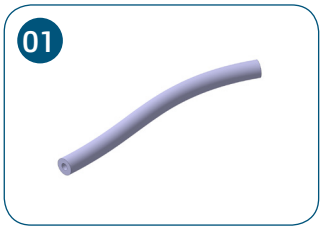
13 

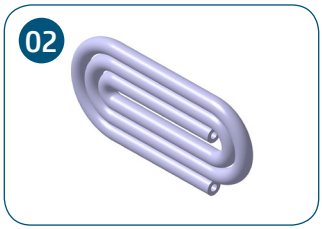
14 

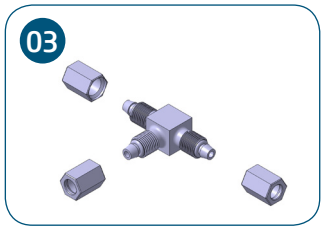
15 

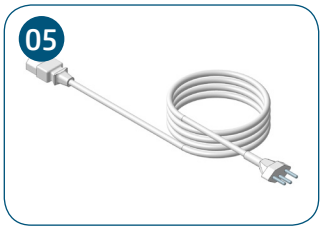
01. Tip Endo L
02. Tip Remo C
03. Tip Remo N
04. Tip Endo G
05. Tip Periodontal E
06. Tip Periodontal Sub
07. Tip Periodontal Supra
08. Tip Retro A3
09. Tip Retro A5
10. Tip Retro R3
11. Tip Retro R5
12. Tip Dent C1
13. Tip Dent C2
14. Tip Dent C4
15. Tip Dent C5
16. Tip Dent C6
17. Tip Dent A1

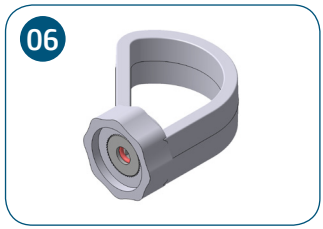
Parts and pieces accompanying the product











01 - Silicone hose
02 - AR hose
03 - Air tee for connection
04 - Transducer cover
05 - Power input cable
06 - Tips fixing key

Consumables

01. Sodium bicarbonate

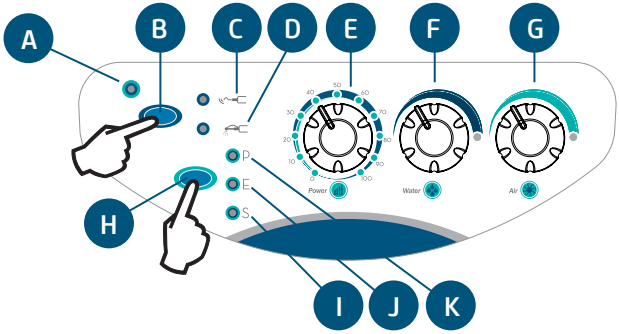
3.5.APPLIED PARTS

The following item is used in the treatment of the patient

Type of parts		Contact type	Contact duration	Classification
TIPs	Removable	Mucous membrane/ Bone structure	<60s	Type B
Transducer cover Bicarbonate Jet	Removable	Mucous membrane	<60s	Type B
Transducer cover Ultrasound	Removable	Mucous membrane	<60s	N/A
Plastic Covers	Fixed	Mucous membrane	<60s	N/A

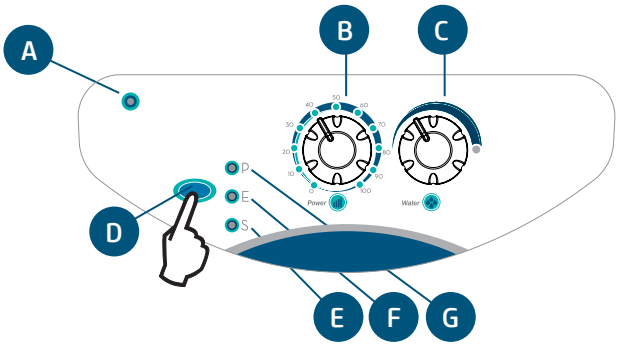
3.6.USER INTERFACE

3.6.1.Sonic Duo / Sonic Duo LED / Sonic Duo Fit / Sonic Duo Fit LED



Buttons / Indicators	Function
A On	Indicates that the machine is on
B Function Selection	Selects function (Ultrasound / Bicarbonate Jet)
C Ultrasound	Indicates selected Ultrasound function
D Bicarbonate Jet	Indicates selected Bicarbonate Jet function
E Power	Adjustment of ultrasonic power
F Water	Water flow regulation
G Air	Air flow regulation
H US Mode Selection	Selects ultrasound function (periodontics, endodontics and scaling)
K Periodontics	Indicates selected Periodontics mode
J Endodontics	Indicates selected Endodontics mode
I Scaling	Indicates selected Scaling mode

3.6.2.Sonic / Sonic LED



Buttons / Indicators	Function
A On	Indicates that the machine is on
B Power	Adjustment of ultrasonic power
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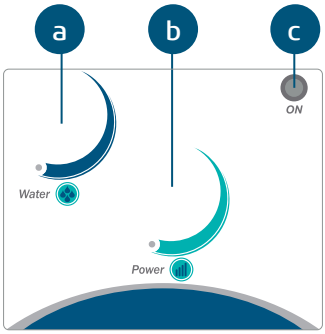
D US Mode Selection	Selects ultrasound function (periodontics, endodontics and scaling)
G Periodontics	Indicates selected Periodontics mode
F Endodontics	Indicates selected Endodontics mode
E Scaling	Indicates selected Scaling mode

3.6.3.Sonic Fit / Sonic Fit LED



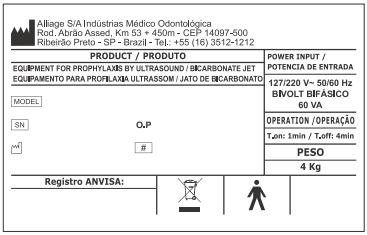
Buttons / Indicators	Function
A Water	Water flow regulation
B Power	Adjustment of ultrasonic power
C On	Indicates that the machine is on

3.7.LABEL POSITIONING

The following figure illustrates the location of the labels on the equipment components.

A. Identification label
B. Security label
C. Consultation instructions manual

a



Demonstrative image
Real dimensions 100 x 63 mm

b

Demonstrative image
Real dimensions 50 x 23 mm

c

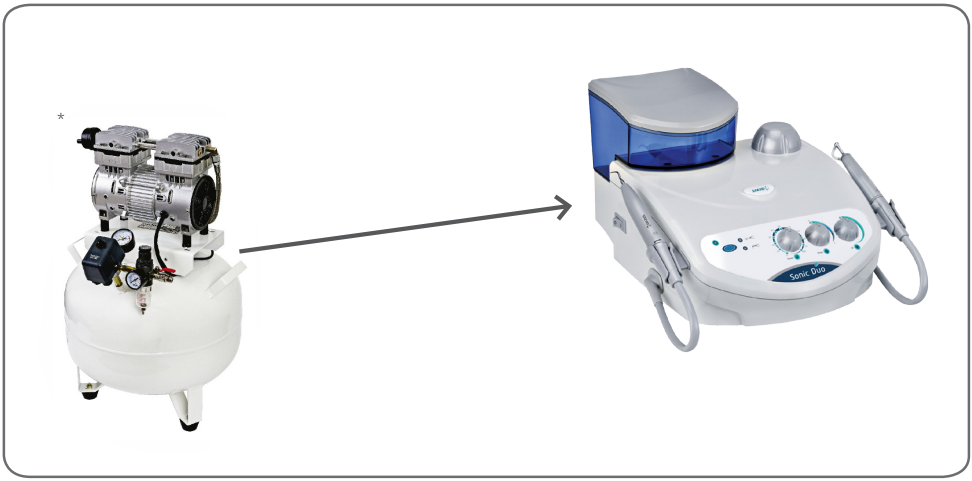
Demonstrative image
Real dimensions diameter. 10 mm

3.8.SYSTEM REQUIREMENTS

3.8.1.Compressor requirements

The compressor is required to provide compressed air for clinical and laboratory use, having stable performance and flow capacity in accordance with the minimum requirements for the installation of the Ultrasound / Bicarbonate Jet Prophylaxis Equipment, in addition to being oil and emission free. smoke, vapors or unpleasant odors.
It must have a safety system with a valve that goes into operation to release the pressure in case the pressure switch fails and also an overload protector in order to protect the equipment from overheating. The location of your installation should be an airy place, preferably outside the office and should not be installed in sanitary facilities such as bathrooms and toilets, in order to minimize the contamination of the air used in the offices.
For the safety of the patient, the operator and the perfect functioning of the product, the installation of the compressor must respect the following recommendations:
Install a pressure relief device next to the compressor;
Install an air filter with pressure regulator, thus preventing oil, moisture and solid particles from entering the office and subsequently reaching its vital parts, such as; valves, pen, etc.;
Install the compressor close to the supply point to avoid losses;
In installations, preferably use rigid copper tubes. The pipes can also be made with galvanized steel, stainless steel, nylon or polyethylene tubes.
Pressure limit of 80 psi;
Flow rate limit ≥ 47 Nl / min;
Humidity limit between 40 and 60%;
Oil contamination limit of 0.5 mg / m³;
Particle contamination limit <100 particles / m³ (particles between 1 and 5µm in size);
Air quality regulations are in accordance with the laws of each country.

3.8.2.System layout



* Do not accompany the product

	To meet safety standards, do not operate non-medical equipment within the patient's area. Outside the patient's area, the presence of non-medical equipment is acceptable, provided approved and certified equipment is used.

	It cannot be possible to connect any component of the system with other equipment not recommended by the manufacturer.

3.9.EQUIPMENT INSTALLATION

	Use only the equipment in perfect condition and protect yourself, patients and others against possible dangers.

	Before connecting the water hose to the appliance, let the water flow for approximately 5 minutes, for possible cleaning in the hydraulic pipes and check that the water in the local network does not contain impurities or contaminants.

3.9.1.Installation procedure

a. Procedures for hydraulic and pneumatic installation:

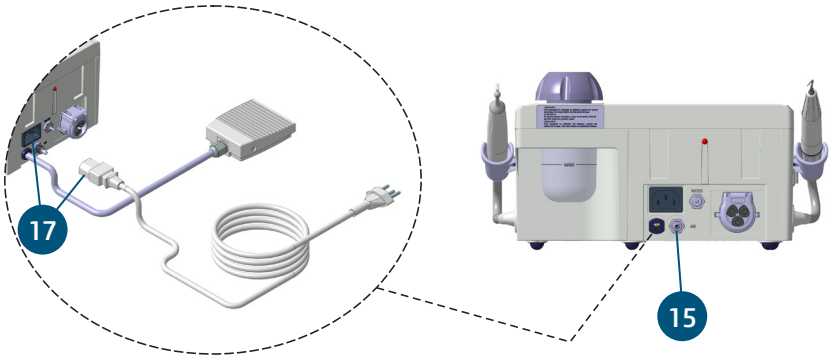
• Connect the hose to the air inlet (15) and tighten the nut[1]

• Connect the other end of the hose to your air network (80PSI-Maximum) preferably right after the air inlet in the connection box, using the tee for connection[1]

• Connect the power input cable (17).

b. Procedures for electrical installation:

Plug the equipment into the outlet and proceed according to the sequence of operations that follow.



[1]Only available for models:
onic Duo / Sonic Duo LED / Sonic Duo Fit / Sonic Duo Fit LED

4

OPERATION

Alliage S/A Industrias Médico Odontológica
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4.OPERATION

4.1.INITIAL PREPARATION

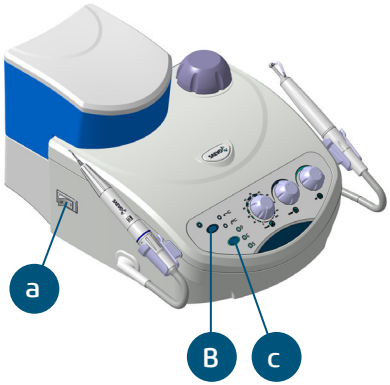
	The equipment must be cleaned and disinfected before use on a new patient, observing the instructions contained in this manual.

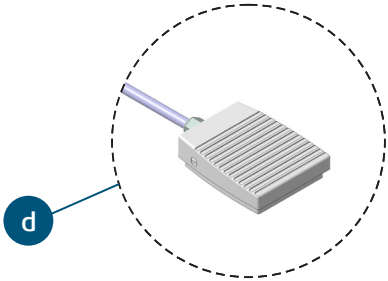
	To isolate the equipment from the mains, use the general switch.

To start operating the equipment, follow the instructions below.

4.1.1.Sonic Duo / Sonic Duo LED / Sonic Duo Fit / Sonic Duo Fit LED

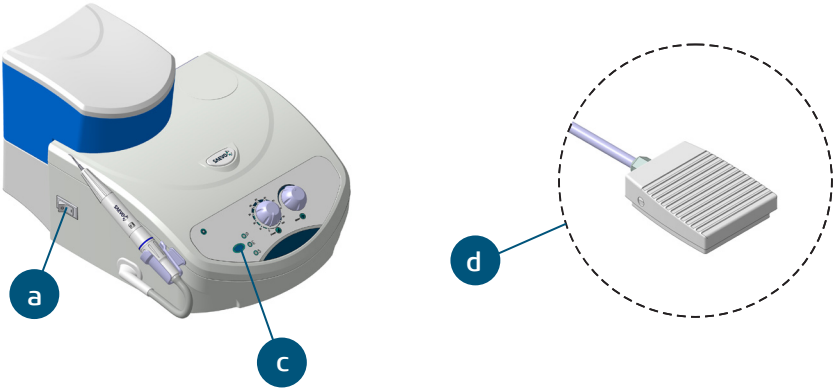
1. Switch on the device by pressing the on / off switch (a);
2. Select the function Ultrasound or Bicarbonate Jet (b);
3. If the ultrasound function is selected, select the operation mode - periodontics, endodontics and scaling (c);
4. Operate the pedal (d).





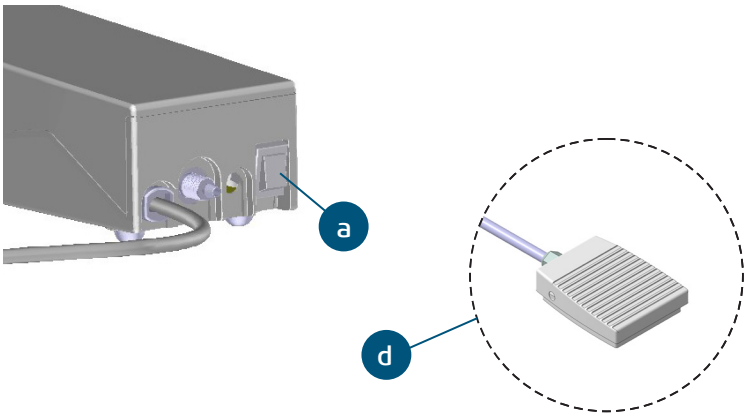
4.1.2.Sonic / Sonic LED

1. Switch on the device by pressing the on / off switch (a);
2. Select the operation mode - periodontics, endodontics and scaling (c);
3. Operate the pedal (d).



4.1.3.Sonic Fit / Sonic Fit LED

1. Switch on the device by pressing the on / off switch (a);
2. Operate the pedal (d).

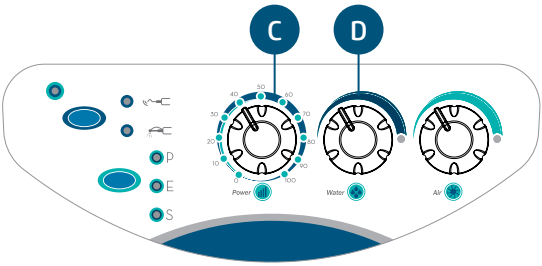


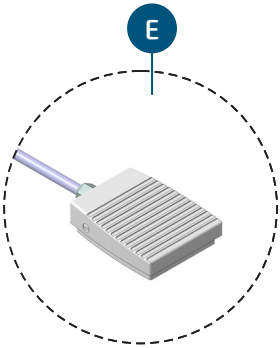
4.2.USING THE ULTRASOUND

4.2.1.Operation

After choosing the desired function, proceed according to the instructions below:
1. Fill the reservoir of the peristaltic pump (only for models with peristaltic pump).
2. Remove the ultrasound pen from the holder.
3. Choose the appropriate tip for the desired operation according to the techniques and application
4. Screw the selected tip onto the handpiece with the aid of the fixation key (F) and a small tightening.
5. Operate the pedal (E) and position the power selector (C) according to the sensitivity of the operation.
6. Adjust the water flow in the water selector (D) according to the need.

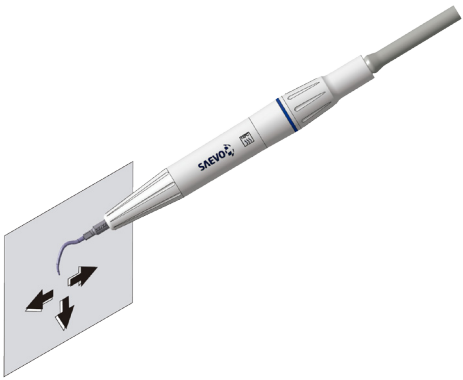
⚠	We recommend that after use, do not leave the handpiece with the Tip in the tip holder in order to avoid accidents.





4.2.2.Techniques and applications

All the tips of the ultrasound have the peculiarity of vibrating in a single plane (vibrations from front to back, and on the tip axis).
The lateral vibrations common to other scalers do not exist, the straight displacement favors a more precise approximation of the tooth and gum.
Enamel and cement are protected from useless shock.
Within this main plane of vibration, the tip of each tip is driven by small vibratory movements.
To obtain the maximum performance of the ultrasound, the operator must consider the vibration settings, specific to each Tip



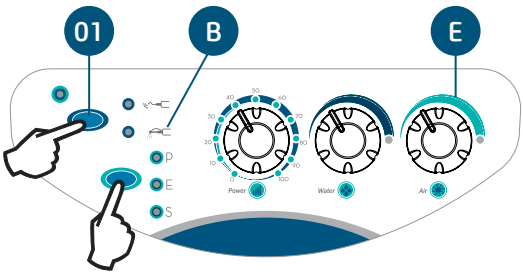
⚠	The shape and weight of each Tip are determining factors to obtain maximum performance of the ultrasound generator, the operator's attention to these two characteristics, will ensure the maintenance of the best performance of the unit, however, we recommend that the structure of the Tip is not altered (by filing or twisting it), in the same way the aging of a Tip leads to a change of its original characteristic, making it ineffective. Any Tip that has been damaged by use or by accidental impact must be replaced.

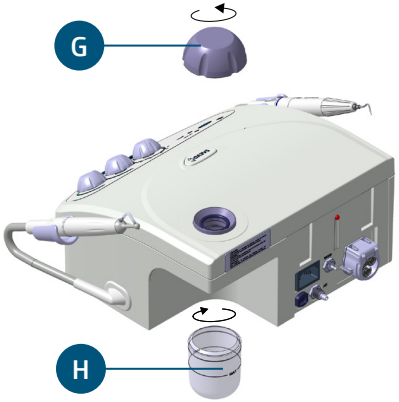
4.3.USE OF THE BICARBONATE JET

4.3.1.Operation

The bicarbonate jet removes dark stains from the teeth, caused by cigarettes, coffee, tea, etc., associated with bacterial plaques and not the stone.
To obtain the best result from the bicarbonate jet, we recommend respecting the distance of the handpiece in relation to the tooth (5mm), with an inclination of 30 ° to 45 ° describing small circular movements over the teeth.
To avoid unpleasant sensations in patients, the jet of bicarbonate should be directed to the occlusal edge and not to the gingival sulcus.
This equipment is contraindicated for use in patients who have serious respiratory or renal disorders or who are undergoing hemodialysis, these cases must have medical monitoring. We recommend the

use of a mask and glasses to apply the bicarbonate jet.
1. Pressing the (01) key a second time the Bicarbonate Jet function (B) will be activated. Proceed according to the instructions below.
2. Remove the top cap (G) by unscrewing it (according to the drawing) and add enough sodium bicarbonate for a section of prophylaxis, that is, from 20 to 40g (do not exceed the level indicated on the container). The bicarbonate level is visible through the transparent container (H). To remove the leftover bicarbonate powder, unscrew the container (H) (as shown) and clean.





⚠	Do not add more than 40g of bicarbonate to the container (H) as this will cause the powder to become blocked.

The volume of water and air flow can be regulated according to the need, as follows:
3. Direct the bicarbonate jet handpiece to a container (Ex: spit pan, sink bowl, etc.).
4. Operate the foot control and adjust the water volume “water selector (D)” and air flow “air selector (E)”. The amount of water in excess will cause a decrease in the effect of the powder due to washing. Decreasing the water too much will cause the powder to become more aggressive.

⚠	The effectiveness depends on the dosage of the water volume and the amount of powder.

4.3.2.Supply of the bicarbonate jet

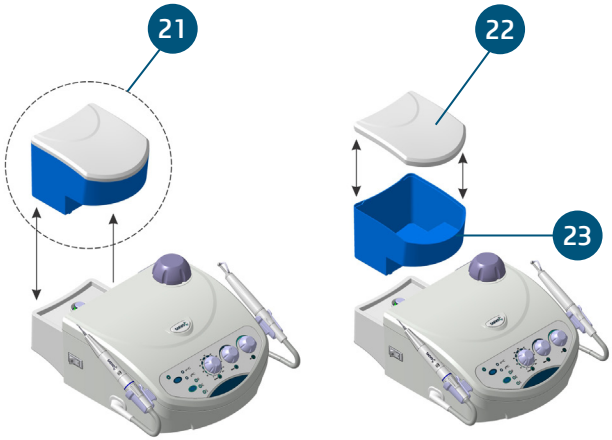
To supply your equipment, we recommend the use of “Clean Okta” sodium bicarbonate (Reg. ANVISA 80339810002) or one that has similar characteristics:
Product composition: Sodium Bicarbonate (99.6%), Silicic Anhydrous, Essence - 105 microns spherical pattern.
For more information about the product, see the manufacturer's instructions on the product.

⚠	Registration with the Ministry of Health for this product is carried out separately, as the product Sodium Bicarbonate (Clean Okta) is not manufactured by Alliage.

4.3.3.Filling the peristaltic pump reservoir

❗	Before filling the tank, check that the water to be used does not contain impurities or contaminants.

1. Remove the “reservoir and cover” assembly (21) by pulling it upwards.
2. Then remove the cap (22) and fill the reservoir (23) with water or antiseptic liquid in a maximum quantity of 1 liter. After filling, place the “reservoir and cover” assembly (21) in the initial position.



❗	After you finish using the product, turn it off using the main switch and remove it from the outlet.

5

CLEANING, DISINFECTION AND STERILIZATION

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5.CLEANING, DISINFECTION AND STERILIZATION

	Before starting the cleaning and disinfection procedure, turn off the main switch of the equipment to avoid permanent damage.

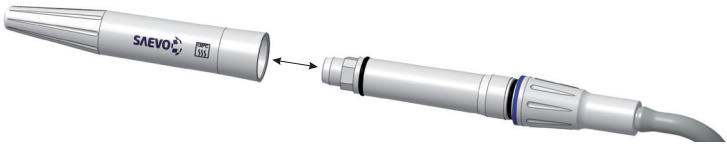
	For your protection, during the cleaning and disinfection process of the equipment use PPE such as disposable gloves and goggles.

5.1.EQUIPMENT

The cleaning and disinfection process must be performed at each patient change.
When starting the process, check for visible dirt, such as blood or saliva.
Thoroughly clean the patient's entire contact area.
For cleaning use a clean, soft cloth moistened with mild soap and then dry with a clean, soft cloth or paper towel.
For the disinfection process of the equipment, use foam disinfectant detergent that has active components based on didecyldimethylammonium chloride.
Apply the disinfectant detergent foam on the surface or on a clean cloth and spread it on the surface to be treated. Respect the antimicrobial contact time specified by the manufacturer.
After application, allow to dry. Do not rinse.
Some of the removable parts that come in contact with the patient can be autoclaved. These parts are: Ultrasound cover, Tips, Bicarbonate jet covers and Insert grip wrench.

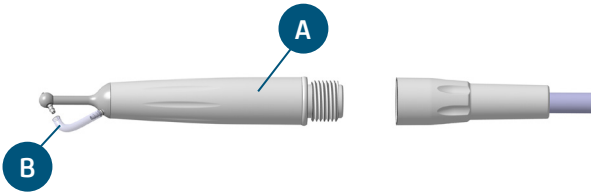
5.1.1.Ultrasound

Remove the Tip of the transducer, and then remove the cover by means of pressure, "do not try to rotate", then take it for autoclaving (packed).



5.1.2.Bicarbonate Jet

Unthread the handpiece of the bicarbonate jet (A) and then remove the hose (B), as it cannot be autoclavable and take it for sterilization in an autoclave (packed).



	Minimum sterilization time 30 minutes at 121°C or minimum 3 minutes at 135°C, and equivalent temperature and time parameters can be used within this range. Maximum sterilization temperature 135 °C.

If these items are autoclaved, disinfection by alternative methods is not necessary.
There is no limit on cycles or application time that the equipment and its parts can tolerate during the cleaning, disinfection and / or sterilization process, following the instructions in this manual.

	Do not spill liquid disinfectant on the equipment.

	Do not use organic solvents, for example, thinner, to clean the equipment. In the event that the developer solution is spilled on the panel, clean it immediately, as these solutions may compromise the equipment's paint.

	Sterilization parameters must always be followed. Accessories that are not properly sterilized can cause disease in patients.

5.2.BICARBONATE CONTAINER

Locate the bicarbonate container through the side access, remove it by turning it counterclockwise and clean it with a dry cloth.
Check that the thread is completely free of dust and replace it by turning it clockwise.

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TROUBLESHOOTING

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6.TROUBLESHOOTING

6.1.SOLUTION OF PROBLEMS

Occasionally, malfunctions may occur during use. In the event of an error, restart the equipment and resume operation. If the problem persists, follow the instructions below.

Failures	Probable causes	Solutions
- Inoperative Equipment.	- Plug disconnected.	- Connect the plug to the outlet.
- Lack of power in the ultrasound.	- Deformed tip. - Tip loose. - Misuse (incorrect angle of attack).	- Replace the Tip. - Tighten the Tip with the key. - See item “Techniques and applications”.
- There is no water in the pens.	- Inadequate water supply pressure. - Poor regulation of the water flow.	- Correct the water pressure. - Adjust the water flow through the water register for ultrasound.
- Insufficient bicarbonate in the jet.	- Bicarbonate is missing in the container. - Blockage at the outlet of the container or at the spout. - Excess bicarbonate in the container. - Inadequate jet position.	- Add bicarbonate in the container (max. 40g). - Remove the blocked parts with the plunger. - Remove the excess. - See item “Techniques and applications”.
- The jet lacks pressure.	- Poor regulation of the air flow. - Air supply pressure below specified.	- Adjust the air flow in the regulator. - Adjust the supply pressure of the device (max. 80 PSI).
- Peristaltic pump does not work.	- Lack of water or antiseptic liquid in the reservoir of the peristaltic pump. - Internal hose of the peristatic pump damaged due to friction of the rollers.	- Put water or antiseptic liquid in the reservoir of the peristaltic pump. - Carry out the replacement of the inner tube of the peristaltic pump (ask for the presence of an authorized technician Alliage).

If problems persist, contact the Alliage Service Department.

7

INSPECTION AND MAINTENANCE

Alliage S/A Industrias Médico Odontológica
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7.INSPECTION AND MAINTENANCE

Maintenance or service procedures may only be carried out by a technical service authorized by the manufacturer.

All instructions for using the equipment as intended are provided in this user guide.
If a problem is detected and cannot be corrected with the instructions in the problem diagnostics section, contact the Alliage Service Department.

7.1.PERIODIC INSPECTION

It is imperative that this equipment be regularly inspected to ensure operational safety and functional reliability. This inspection must be carried out by personnel familiar with the necessary precautions to avoid exposing the patient to risk.
Periodic inspection should be carried out at regular intervals (at least once a year) to ensure that the product is permanently safe and operational. All components subject to normal wear and tear should be checked and, if necessary, replaced.
The manufacturer and the assembler / installer are exempt from responsibility for the standard results not being compliant in cases where the user does not perform the maintenance recommended by the manufacturer.
Neither inspection nor service is part of the equipment warranty.
Maintenance performed must be documented and maintained with the equipment.
The table below gives a description of the main inspection items and recommended frequency.

Item	Inspection description	Recommended frequency
Operation / Security System	Foot pedal, tip power, water flow, dust flow, jet pressure (Auditory and visual).	Diary
Electrical parts	Overheating / Noise / Burning smell (Auditory and visual).	Monthly
Parts and pieces	Operation / Noise / Vibration (Auditory and visual).	Yearly
Pedal and Controls	Operation / Damage (Auditory and visual).	Yearly

If problems are detected during the inspection, contact the Alliage Service Department.

7.2.PREVENTIVE MAINTENANCE

In addition to the annual inspection, to ensure a long service life and smooth operation of your equipment, it is important to carry out preventive maintenance for a maximum period of three (3) years. Contact the Alliage Service Department about our periodic review and preventive maintenance program.

7.3.CORRECTIVE MAINTENANCE

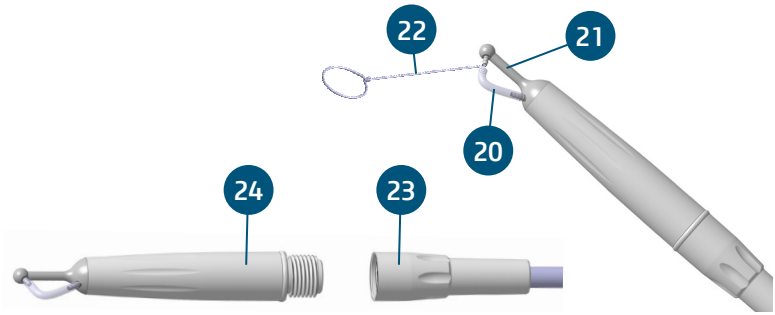
	The corrective maintenance that can be performed by the user Ultrasound / Bicarbonate Jet Prophylaxis equipment is limited to unblocking the bicarbonate jet pen.
	Do not open the equipment or attempt to repair it yourself or with the help of someone without training or authorization. This can aggravate the problem or produce a failure that can compromise the safety of the equipment.
	The power cables and electronic boards can be changed only by the authorized technician.
	The equipment or any of its parts cannot be maintained or serviced during use with a patient.
	The equipment contains parts under high voltage. Risk of electric shock. Turn off the main switch before servicing.
	The service manual is only available for Authorized Technical Assistance.

7.3.1.Equipment

Alliage declares that the provision of circuit diagrams, component lists or any other information that provides technical assistance on behalf of the user, can be requested as long as previously agreed between the user and Alliage.
The warranty will be void if the original parts are removed / replaced by unauthorized service technicians.

7.3.2.Bicarbonate Jet Pen

The “Jet of bicarbonate” pen is equipped with an automatic system for depressurization and internal cleaning of hoses and handpiece. With the function key positioned in Bicarbonate Jet, when the command pedal is stopped, there will be an internal sweeping air jet of the entire system, however, if there is blockage in the system, proceed as follows:
a. Remove the hose (20) from the spout (21), direct the tip to a suitable location (spit, sink bowl, etc.) and operate the pedal to make sure that the clog is in the spout (21).
b. Clean the hole with the plunger (22), inserting it until it crosses completely several times.
c. Replace the hose (20) nozzle (21). If necessary, replace the hose (20).
d. Remove the adapter (23) from the bicarbonate jet tip (24) by unscrewing it counterclockwise and take the bicarbonate jet tip for autoclaving (packaged).



7.4.ALLIAGE AUTHORIZED SERVICE NETWORK

All services performed on the Alliage equipment must be performed by an Authorized Technical Assistant, as otherwise they will not be covered by the warranty.
If you need to request electrical diagrams and or specification of components that is not stated in the user manual, use the Alliage Customer Service to make the request.

Telephone: +55 (16) 3512-1212
Address: Rodovia Abrão Assed, Km 53 - Recreio Anhanguera – Ribeirão Preto -SP/ Brazil ZIP CODE 14097-500

8

WARRANTY

Alliage S/A Industrias Médico Odontológica
Telephone: +55 (16) 3512-1212
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8.WARRANTY

This equipment is covered by the warranty periods, terms and conditions contained in the Warranty Certificate that comes with the product.

9

STANDARDS AND REGULATIONS

Alliage S/A Industrias Médico Odontológica
Telephone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brazil

9.STANDARDS AND REGULATIONS

This equipment has been designed and manufactured to meet the following rules:

ABNT NBR IEC 60601-1:2010 Amendment 1:2016	Medical Electrical Equipment - Part 1: General requirements for basic security and essential performance.
ABNT NBR IEC 60601-1-2:2017	Medical Electrical Equipment, Part 1-2: General basic safety requirements and essential performance - Collateral standard: Electromagnetic interference - Requirements and tests.
ABNT NBR IEC 80601-1-60:2015	General requirements for basic safety and essential performance of dental equipment.
ABNT NBR 60601-1-6:2011	Electromedical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
ABNT NBR IEC 62366:2010	Health products - Application of usability engineering to health products.
IEC 60601-1-9:2007+AMD1:2013	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design.
IEC 62304:2006	Medical device software - Software lifecycle processes.
ISO 10993-1:2018	Biological assessment of medical devices - Part 1: Assessment and testing.
ABNT NBR ISO 14971:2009	Medical devices - Application of risk management to medical devices.
ABNT NBR ISO 13485:2016	Quality management systems - Requirements for regulatory purposes.

10

TECHNICAL SPECIFICATIONS

Alliage S/A Industrias Médico Odontológica
Telephone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brazil

10.TECHNICAL SPECIFICATIONS

10.1.EQUIPMENT CLASSIFICATION

Class of classification according to ANVISA

Class I

Classification of equipment according to standard EN IEC 60601-1

Product classification for applied parts - Type B
Protection Against Electric Shock - Class I

Protection Against Harmful Water Penetration

Dental Prophylaxis by Sodium Bicarbonate / Ultrasound
IP00 - Product not protected against harmful penetration of water and particulate material
Pedal
IP01 - Product not protected against harmful penetration of drops in water and particulate material

Degree of safety of application in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide

Unsuitable equipment

Operation mode

Ultrasound
Non-continuous operation
Time on: 1 min. / Time off: 4 min.

Bicarbonate Jet
Continuous operation

	The pedal cannot be installed in an emergency room.

10.2.APPLIANCE INFORMATION (GENERAL)

Connection to suitable power supply

External power supply

Power supply voltage

127 / 220 V~ (Dual voltage)

Power supply frequency

50 / 60 Hz

Allowable fluctuation

+/- 10 %

Number of phases

Biphasic

Stand-by rated current

2.6 mA - 127 V~
1.5 mA - 220 V~

Rated current during load

3.5A (max) - 127 V~
2.5A (max) - 220 V~

Master key

Contact resistance: maximum of 20 milliohms with application of 1A in VCC;
Electrical characteristics: 10A / 120 VAC;
Insulation resistance: minimum of 1,000 megaohms;

Power consumption

60 VA - Momentary

Maximum grid impedance

0,2Ω

Net weight

Sonic Duo / Sonic Duo LED: 4 kg
Sonic / Sonic LED: 3,4 kg
Sonic Duo Fit / Sonic Duo Fit LED: 3,7 kg
Sonic Fit / Sonic Fit LED: 1,0 Kg

Gross weight

Sonic Duo / Sonic Duo LED: 5 kg
Sonic / Sonic LED: 4,4 kg
Sonic Duo Fit / Sonic Duo Fit LED: 4,5 kg
Sonic Fit / Sonic Fit LED: 1,8 Kg

10.3.SPECIFIC INFORMATION

Air pressure

80 PSI (5.52 BAR)

Maximum air consumption

80 l/min

Water tank capacity

1000 ml

10.4.ULTRASOUND SPECIFICATIONS

Ultrasound Vibration Frequency
30.000 Hz
Consumption of irrigating liquid
28 ml/min
Power consumed
15 VA
Transducer system
Electric piezo ceramic
Maximum tip temperature in normal use
114.2°C
Maximum rate of temperature rise of tip
179.7°C

10.5.ENVIRONMENTAL CONDITIONS

Environmental conditions of transport and storage

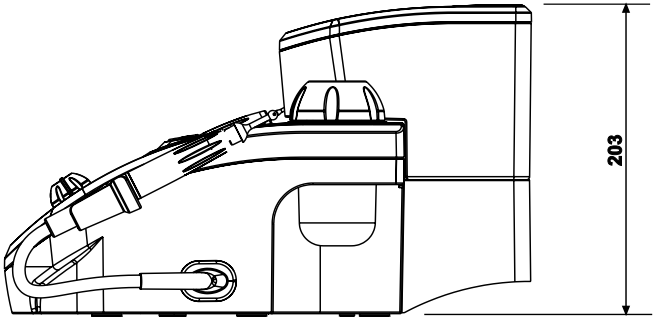
Transport or storage ambient temperature range
-29ºC to +60ºC
Transport and storage relative humidity range
20% to 90%
Atmospheric pressure range
500 hPa to 1060 hPa (375 mmHg to 795 mmHg)

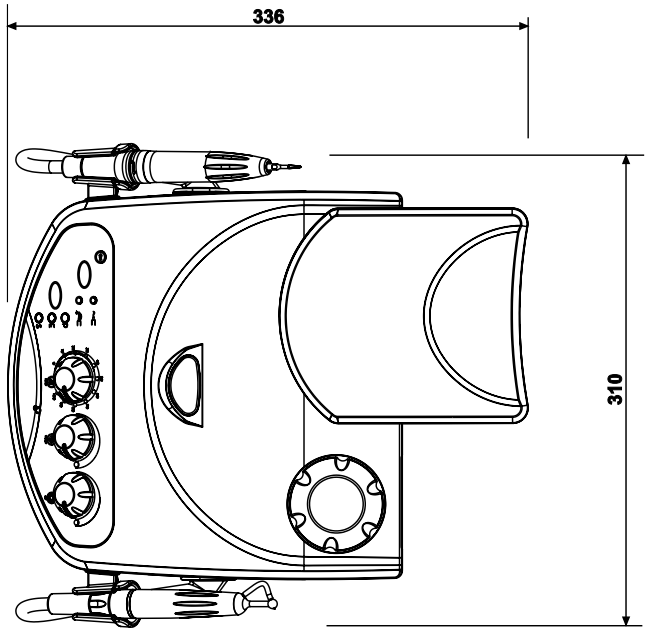
Environmental conditions of installation and operation

Ambient operating temperature range
+10ºC to +34ºC
Recommended ambient temperature range
+21ºC to +26ºC
Operating relative humidity range (non-condensing)
30% to 75%
Atmospheric pressure range
700 hPa to 1060 hPa (525 mmHg to 795 mmHg)
Operating altitude
≤ 2000 m

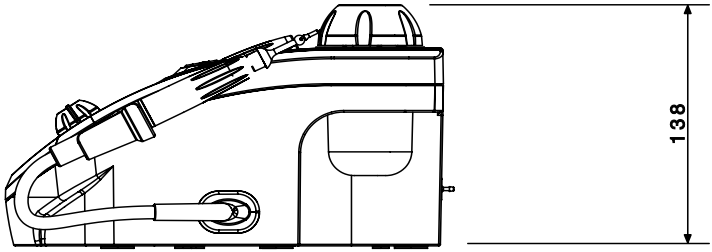
10.6.EQUIPMENT DIMENSIONS

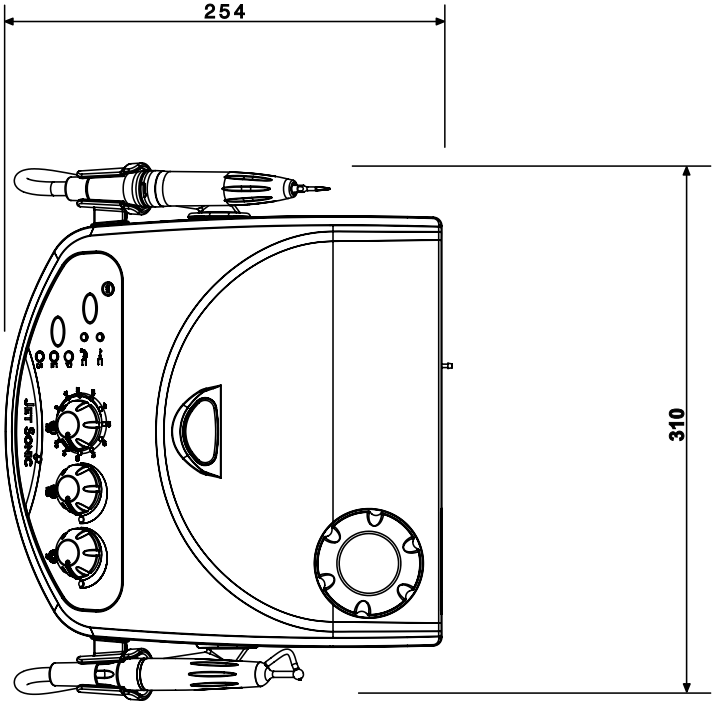
10.6.1. Sonic Duo / Sonic Duo LED



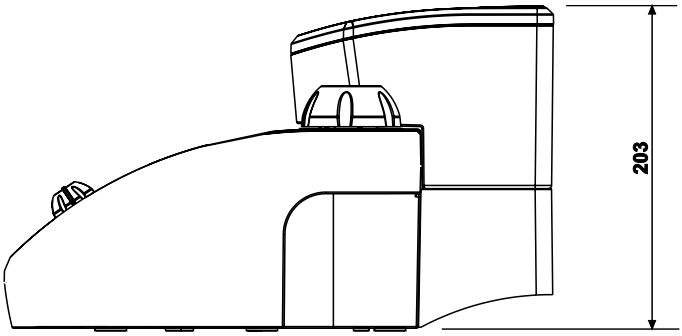


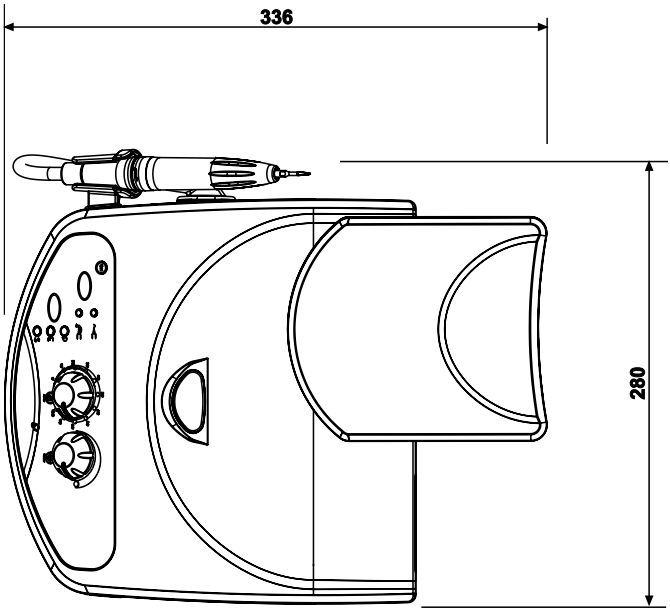
10.6.2.Sonic Duo Fit / Sonic Duo Fit LED



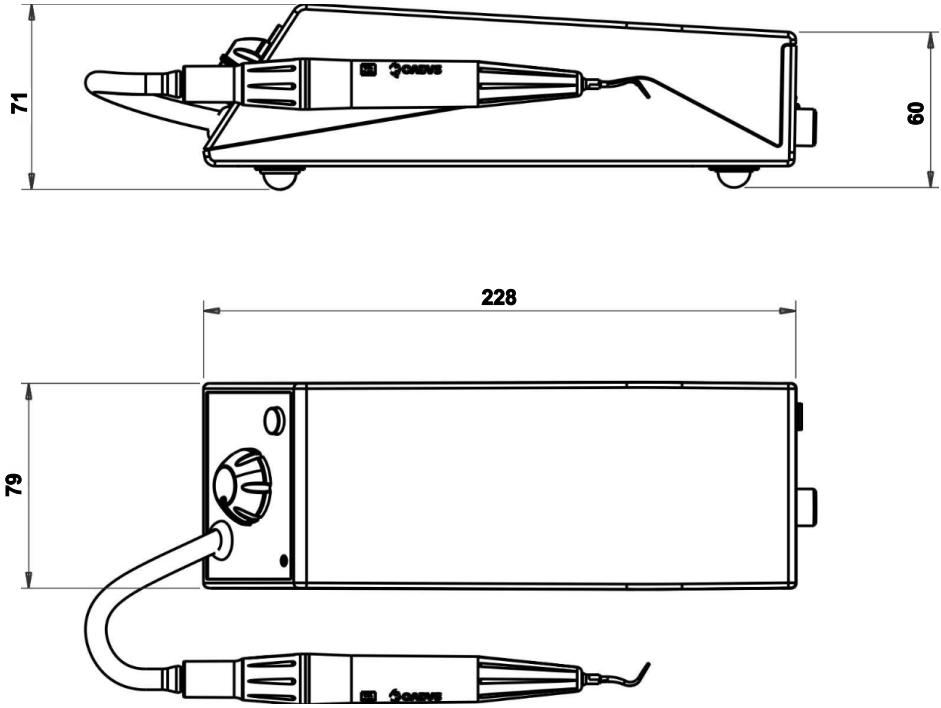


10.6.3.Sonic / Sonic LED





10.6.4.Sonic Fit / Sonic Fit LED



11

ELECTROMAGNETIC COMPATIBILITY

Alliage S/A Industrias Médico Odontológica
Telephone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brazil

11.ELECTROMAGNETIC COMPATIBILITY

The **Equipment for Prophylaxis by Ultrasound / Bicarbonate Jet** is intended for use in the electromagnetic environment specified below. The buyer or user should ensure that it is used in such an environment.

The **Equipment for Prophylaxis by Ultrasound / Bicarbonate Jet** is suitable for use in a professional health care environment, not including areas where sensitive equipment or sources of intense electromagnetic disturbances are present, such as the RF shielded room of a magnetic resonance imaging system. , in operating rooms close to active AF surgical equipment, electrophysiology laboratories, armored rooms or areas where short wave therapy equipment is used.

The following tables provide information on the equipment's compliance with the ABNT NBR IEC 60601-1-2: 2017 standard.

11.1.GUIDANCE AND DECLARATION FOR ELECTROMAGNETIC EMISSIONS

Emissions Tests	Compliance	Electromagnetic Environments - guidelines
RF emissions CISPR 11	Group 1	The **Equipment for Prophylaxis by Ultrasound / Bicarbonate Jet** uses RF energy only for its internal functions. Therefore, its RF emissions are extremely low and are unlikely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The **Equipment for Prophylaxis by Ultrasound / Bicarbonate Jet** is suitable for use in all establishments, except households and those directly connected to the public low voltage power supply network that powers buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation / Scintillation emissions IEC 61000-3-3	Compliant	

Note: The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (IEC / CISPR 11, Class A). If used in a residential environment (for which IEC / CISPR 11, Class B is normally required), this equipment may not provide adequate protection for radio frequency communication services. The user may need to take mitigation measures, such as relocating or redirecting equipment.

11.2.ORIENTATION AND DECLARATION FOR ELECTROMAGNETIC IMMUNITY

Phenomenon	Basic EMC standard or test method	Immunity test level	Compliance level
Electrostatic discharge	IEC 61000-4-2	±8 KV contact ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV air	±8 KV contact ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV air
EM fields of radiated RF	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Fields in the vicinity from RF wireless communications equipment	IEC 61000-4-3	See table	See table
Fast / saved electrical transients	IEC 61000-4-4 alternating current power input	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency
	IEC 61000-4-4 signal input / output	± 1 kV 100 kHz repetition frequency	± 1 kV 100 kHz repetition frequency
Outbreak Line by line	IEC 61000-4-5	± 0.5 kV, ± 1 kV	± 0.5 kV, ± 1 kV
Outbreak Ground line	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disorders induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Magnetic fields at the stated feed frequency	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
Voltage drops	IEC 61000-4-11	0% UT; 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0 °	0% UT; 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0 °
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycles	The device will shut down and / or reset if the power is interrupted for five seconds.

NOTE 1 At 80 MHz and 800MHz, the higher frequency range is applicable.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
NOTE 3 UT is the AC mains voltage before applying the test level.

Proximity fields from wireless RF communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	18 Hz pulse modulation	1.8	0.3	27
450	430-470	GMRS 460,FRS 460	FM deviation of ± 5 kHz 1kHz sinusoidal	2	0.3	28
710 745 7480	704-787	Band LTE 13, 17	217 Hz pulse modulation	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, Band LTE 5	18 Hz pulse modulation	2	0.3	28
1720 1845 1970	1700 -1990	GSM 1800; CDMA 1900; GSM 1900; DECT; Band LTE 1, 3, 4, 25; UMTS	217 Hz pulse modulation	2	0.3	28
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, Band LTE 7	217 Hz pulse modulation	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	217 Hz pulse modulation	0.2	0.3	9

List of used cables

Cables	Description	Length
Power	Tripolar Power Cable 3x Gauge 2.50 mm², 250V AC, Male Plug 20A NBR 14136 2P + T, with female plug, INMETRO.	3 m

	The **Equipment for Prophylaxis by Ultrasound / Bicarbonate Jet** is intended to assist the health professional, and it is for exclusive dental use. In the event of EMC disturbances, the operator may experience loss of communication between the equipment and controls.
	Compliance with EMC and EMI standards cannot be guaranteed by using cables that have been altered or that do not comply with the same standards as the equipment has been validated.
	Use of this equipment adjacent to other equipment should be avoided as it may result in improper operation. If this use is necessary, it is advisable that this and the other equipment be observed to verify that they are operating normally.
	Do not use accessories, transducers, internal parts of components and other cables other than those previously specified by the manufacturer. This can result in increased emission or decreased electromagnetic immunity and result in improper operation.
	Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any part of the Sonic Duo / Sonic Duo LED / Sonic Duo Fit / Sonic Duo Fit LED / Sonic / Sonic LED / Sonic Fit / Sonic Fit LED / Sonic Prophylaxis / Bicarbonate Jet Equipment Fit, including cables specified by the manufacturer. Otherwise, performance degradation of this equipment may occur.
	To maintain basic safety from electromagnetic disturbances during the expected life, always use the equipment in the specified electromagnetic environment and follow the maintenance recommendation described in this manual.
	The pins, connector sockets or elements that carry the ESD warning symbol must not be touched or connected without ESD protection measures.

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