**English** 

# Owner's Manual





Jet Sonic Fit Cód. 300053881 Rev. 00 **GNATUS** 

#### PRESENTATION OF MANUAL

#### INSTRUCTIONS FOR USE

**Technical Name:** Equipment for Dental Prophylaxis by Sodium Bicarbonate/Scaler.

**Brand: GNATUS** 

Models: Jet Sonic Fit

Brand Name: Equipment for Gnatus Bicarbonate Jet/Scaler

Prophylaxis.

#### Manufacturer/ Distribuitor:

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#### **ATTENTION**

#### For greater safety:

Read and understand all the instructions contained in these Instructions for Use before installing or operating this Equipment.

Note: These Instructions for Use must be read by all the operators

of this Equipment.



#### **INDEX**

PRESENTATION OF MANUAL	.02
IDENTIFICATION OF EQUIPMENT	.04
MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION	.06
TECHNICAL SPECIFICATIONS	
- Technical characteristics	.10
- Dimension	.15
- Symbologies of product. - Contents of the accessible and inaccessible markings	
INSTALLATION OF EQUIPMENT	.16
OPERATION OF EQUIPMENT	.18
- Turning on / Turning of the appliance - "Scaler" applications and techniques	.18
PRECAUTIONS, RESTRICTIONS AND WARNINGS  - Conditions of transport and storage - Environmental conditions of operation	.23 .23 .24 .24 .25 .25
CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION  - Additional procedures for reuse	. 27 . 28 . 28
UNFORESEEN EVENTS – SOLUTION OF PROBLEMS	.30
WARRANTY OF EQUIPMENT	.30
FINAL CONSIDERATIONS	.31

#### **DESCRIPTION OF THE EQUIPMENT**

#### **Dear Customer**

Congratulations. You have made a good choice when you decided to buy a GNATUS QUALITY product comparable to the best products available in the World. This manual is a general presentation of your product and it will give you important details to help you to solve possible problems.

Please, read it and keep this with you.

#### Identification

Technical Name: Equipment for Dental Prophylaxis by Sodium Bicarbonate/Scaler.

**Brand: GNATUS** 

Models: Jet Sonic Fit



#### **IDENTIFICATION OF THE EQUIPMENT**

#### **Description of Equipment**

Equipment for prophylaxis with scaler and Bicarbonate Jet, modern and bold design, assembled in a set composed of body and lid made out of ABS (Acrylonitrile, butadiene, styrene) and digital control panel made out of polycarbonate. Available in the cart and bench models.

Electric-pneumatic synchronized system, with valves that provide cuts and aspirations of the water instantly, avoiding like this the contact of the water with the bicarbonate in the point of the hand piece.

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

Removable bicarbonate jet pen, with concentric diffuser which mixes the air, water and bicarbonate at a small distance from the handpiece.

Cover of the transducer made out of rigid and autoclavable thermoplastic resin.

Potentiometer with a fine adjustment for precise adjustment of the ultrasonic power, suited to each type of procedure.

Internal depressurization through automatic sweep of the bicarbonate, of the valves up to the handpiece.

Container for bicarbonate easy to access, transparent and removable, which allows its removal without needing to turn all the equipment upside down in order to remove the remains of bicarbonate powder.

Bicarbonate jet interruption system with a module of anti-agglutination which avoids the obstruction of the valves.

#### WORKING APPLICATION

- Distartarization
- Endodonty
- Periodonty
- Micro-recto surgery

- Amalgam condensation
- Inlays onlays condensation
- Gutta Percha Condensation
- Pines and crown removal

## Physical principle used by the Jet Sonic and Ultrasonic equipment

The scaler is derived from physical vibrations of particles of material, similar to sound waves, with a frequency exceeding the level of human perception, which produce a frequency up to 30,000 vibrations per second.

The Bicarbonate Jet (Prophylaxis) comes from the release under pressure of particles of sodium bicarbonate, together with the water, mixing together in the nozzle of the handpiece forming jet in the form of a concentrated spray.

#### **Indication of Equipment**

This equipment is for dental use use only. It must be operated and utilized by specialized professional (certified professional, according to the legislation of the country) and following the instructions of the manual.

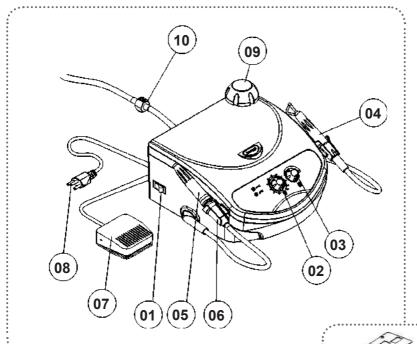
The operation of the equipment required, for the professional, the utilization of correct instruments and it should to be in perfect conditions of the use, and to protect the professional, the patients and others, in the eventual danger situation.

#### Purpose of the equipment

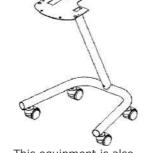
The Jet Sonic is an item of equipment for prophylaxis with scaler and bicarbonate jet, which was developed to be used in several dental practices such as: periodontics, endodontics, prosthesis, surgery, etc.

# MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION

#### **JET SONIC FIT**



- 01 Switch with 3 positions:
  - Turns on the Bicarbonate Jet;
  - Turns off the equipment;
  - Turns on the Scaler.
- 02 Regulator of sonic variation
- 03 Water flux regulator
- 04 Jet of bicarbonate hand pieces
- 05 Ultrasound hand piece
- 06 Support of the points
- 07 Actuation pedal
- 08 Electrical cable
- 09 Recipient of bicarbonate
- 10 Air flux regulator



This equipment is also available

in the Cart version.



# MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION



# MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION



#### General

Model

Jet Sonic Fit

Classification of Equipment as per ANVISA:

Class II

Classification of Equipment as per standard IEC 60601-1:

Protection against Electric Shock - Type B and Class I Equipment (IEC 60601-1)

Protection against harmful water penetration

IPX 0

**Mode of Operation** 

Continuous operation with intermittent load - 10min. work and 10min. rest.

Frequency of scaler

30.000Hz

**Transducer system** 

Piezoelectric ceramic

#### **Power Supply**

#### **Power Supply Voltage (Selectable)**

 $127V \sim \pm 20\% / 220V \sim + 20\%$ 

**Frequency** 

50/60 Hz

**Fuse** 

1A - (127/220V~)

**Power** 

60\/A

Consumed

0.43A

Net Weight Jet Sonic Fit 3,70kg

Gross Weight Jet Sonic Fit: 4,50kg

Water inlet pressure

Maximum = 40PSI

Minimum = 20PSI



The materials used to produce the equipment are Biocompatible.

#### Standards applied

This product was tested and approved in compliance with the following standards:

IEC 60601-1:2005 – Electromedical Equipment - Part 1: General prescriptions for safety; EN ISO 980:2008 (Ed. 2) - Graphical symbols for use in the labelling of medical devices; EN ISO 14971:2007 - Medical devices - application of risk management medical devices;

NBR ISO 9687: 2005 - Dental equipment - graphical symbols;

ISO 7494:2004 - Norma dental units;

EN ISO 13485-2003 - Quality systems - medical devices;

ISO 780:1997 - Packaging - pictorial marking for handling goods;

ISO 11144:1995 - Normal dental equipment - connections for supply and waste lines;

IEC 60601-1:2007 - Electromagnetic Compatibility.

Electromagnetic emissions			
The equipment for dental prophylaxis by sodium bicarbonate /scaler is intended to be used in the			
electromagnetic environments specified below. The customer or the user of the equipment for denta			
prophylaxis by sodium bicarbonate / scaler shall ensure that it is used in such an environment.			
Emission test	Compliance Electromagnetic environment - guide		
RF Emissions	Group 1	The equipment for dental prophylaxis by sodium	
ABNT NBR IEC CISPR 11		bicarbonate / scaler only uses RF energy for its	
		internal function. However, its RF emissions are	
		very low and are not likely to cause any	
		Interference in electronic equipment nearby.	
RF Emissions	Class B	The equipment for dental prophylaxis by sodium	
ABNT NBR IEC CISPR 11		bicarbonate / scaler is suitable for use in all	
Emissions of Harmonics	Class A	establishments, including domestic	
IEC 61000-3-2		establishments and those directly connected to a	
Fluctuations of Voltage /	As per	public network of supply of electricity of low	
Emissions of Flicker		voltage which supplies buildings used for	
IEC 61000-3-3		domestic purposes.	



#### Electromagnetic emissions

The equipment for dental prophylaxis by sodium bicarbonate /scaler is intended to be used in the electromagnetic environments specified below. The customer or the user of the equipment for dental prophylaxis by sodium bicarbonate / scaler shall ensure that it is used in such an environment.

Immunity Test	ABNT Test Level NBR IEC 60601	Level of Compliance	Electromagnetic Environment – directives	
Electrostatic	± 6 KV Contact	± 6 KV Contact	Floors should be wooden, concrete or ceramic. If the	
Discharge (ESD)			floor is covered with synthetic material, the relative	
IEC 61000-4-2	± 8 KV	± 8 KV	humidity should be at least 30%.	
Quick electric	± 2 KV in power supply	± 2 KV in power	It is advisable that the quality of the power supply	
transitory phases /	lines	supply lines	should be that of hospital or typical commercial	
	lines	supply lines	environment.	
train of pulses (Burst)	. 4 101/:- :	1.4.1677:	environment.	
IEC 6100-4-4	± 1 KV in input/output	± 1 KV in		
	lines	input/output lines		
Surges	± 1 KV line(s) to line(s)	± 1 KV line(s) to	It is advisable that the quality of the power supply	
		line(s)	should be that of hospital or typical commercial	
IEC 61000-4-5	± 2 KV line(s) to ground		environment.	
		± 2 KV line(s) to		
		ground		
Reduction, interruption	<5% U <sub>T</sub>	<5% U <sub>T</sub>	It is advisable that the quality of the power supply	
and variance of	(> 95% drop in U <sub>T</sub> )	(> 95% drop in U <sub>T</sub> )	should be that of hospital or typical commercial	
voltage in power	for 0.5 cycle	for 0.5 cycle	environment.	
supply input lines	40% U⊤	40% U⊤	If the user of the equipment requires continuous	
	(60% drop in U <sub>T</sub> )	(60% drop in U <sub>T</sub> )	operation during interruptions of power, it sis	
IEC 61000-4-11	for 5 cycles	for 5 cycles	advisable that the equipment is supplied by an	
120 01000 1 11	70% U <sub>T</sub>	70% U <sub>T</sub>	uninterrupted power supply source or a battery.	
	(30% drop in U <sub>T</sub> )	(30% drop in U <sub>T</sub> )	difficer upled power supply source of a battery.	
	for 25 cycles	for 25 cycles		
	<5% U <sub>⊤</sub>	<5% U <sub>⊤</sub>		
		(<95% drop in U <sub>T</sub> )		
	(<95% drop in U <sub>T</sub> )			
	for 5 s	for 5 seconds		
Magnetic field in	3 A/m	0.3 A/m	If there is distortion of image, it may be necessary to	
frequency of power			position the equipment away from sources of	
supply (50/60Hz)			magnetic field of power supply frequency or install a	
			magnetic screen. The magnetic field of frequency	
IEC 61000-4-8			must be measured at the place of installation to	
			ensure that it is sufficiently low.	
NOTE U <sub>T</sub> is t	NOTE $U_T$ is the a.c. power supply voltage before the application of the test level			

11

#### **Electromagnetic emissions**

The equipment for dental prophylaxis by sodium bicarbonate / scaler is intended to be used in the electromagnetic environments specified below. The customer or the user of the equipment for dental prophylaxis by sodium bicarbonate / scaler shall ensure that it is used in such an environment.

Immunity Test	ABNT Test Level NBR IEC 60601	Level of Compliance	Electromagnetic Environment – directives
			It is advisable that portable and mobile RF communication equipment is not used near any part of the equipment, including cables, with a separation distance less than the one recommended, calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance:
RF conducted	3 Vrms	3 Vrms	d=1.2 √P
IEC 61000-4-6 RF radiated IEC 61000-4-3	150 kHz up to 80 MHz 3 V/m 80 MHz up to 2.5 GHz	3 V/m	d = 1.2√P 80 MHz thru 800 MHz d = 2.3√P 800 MHz thru 2.5 GHz where P is the nominal maximum power of output of the transmitter in watts (W), as per the manufacturer of the transmitter, and d is the recommended separation distance in meters (m)  It is advisable that the field intensity from the RF, transmitter as determined by means of electric inspection on-site, *is less than the level of compliance in each frequency range. *b  There may be interference near the equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the highest frequency range applies.

NOTE 2 These directives may not be applicable in every situation. The electromagnetic transmission is affected by the absorption and reflection of structures, objects and people. The field intensities established by the fixed transmitters, such as base radio stations, telephone (cellular/wireless), land

The field intensities established by the fixed transmitters, such as base radio stations, telephone (cellular/wireless), land mobile radios, amateur radio, AM and FM radio transmission and TV transmission cannot be foreseen theoretically with great accuracy. In order to evaluate the electromagnetic environment due to fixed RF transmitters, it is advisable to consider an electromagnetic inspection of the place. If the measure of the field intensity in the place in which the equipment is used exceeds the aforementioned applicable level of compliance it is advisable to observe if the equipment is operating normally. If abnormal performance is observed, additional procedures may be required, such as re-orientating of repositioning the equipment.

equipment. Above the frequency range from 150 kHz up to 80 MHz, it is advisable that the field intensity is less than 3 V/m.

#### Recommended Separation Distances

#### Recommended distances between portable and mobile RF communication equipments and the Model 006.

This equipment is aimed to be used in an electromagnetic environment in which RF disturbances are controlled. The client or user may prevent the electromagnetic inferference by keeping a minimal distance between the portable and mobile RF communications equipments (transmitters) and the equipment as follow recommended, according to the maximum output potency.

Transmitter Maximum	Separation distance according to transmitter frequency (M)			
Output (W)	150KHz to 80MHz d = 1,2 √ P	80MHz to 800MHz d = 1,2 √ P	800MHz to 2.5GHz d = 2,3 √ 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 nominal output power not listed above, the recommended diseparation distance in meters (M) can be determined using an equation applicable to the frequency of the transmitter, where P is the transmitter maximum nominal output in watts (W) according to the transmitter manufacturer.

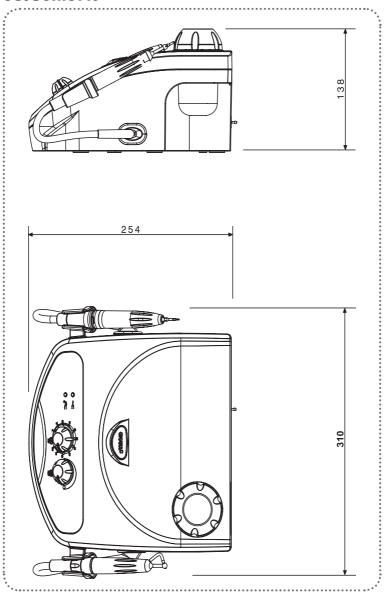
NOTE 1 At 80 MHz and 800 MHz, is applied the separation distance for the higher frequency range.

NOTE 2 These guidelines may not apply to all situations. The absorption and reflection from structures, objects and people affect the electromagnetic propagation.



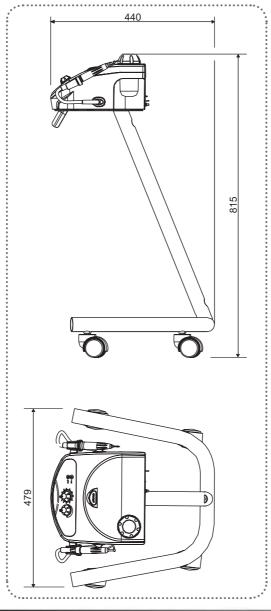
#### **Dimensions (mm)**

#### **Jet Sonic Fit**



#### **Dimensions (mm)**

#### Jet Sonic Fit (Cart)





#### **Packing symbols**



It determines the maximum quantity of boxes which can be stacked during transportation and storage "as per packaging".



Packing to be transported and / or stored avoiding humidity, rains and wet floor.



Packing to be transported and / or stored with the harrows up.



The packing must be stored and transported away from direct sun light exposure.



Packing to be transported and / or stored with care (should not suffer drop and neither receive impact).



Temperature limit for the packing to be stored or transported.

#### **Product symbols**



Indicated key of ultrasound function.



Indicated key of function jet of bicarbonate.



Warning - see the manual



Grounding (at several points of the equipment) indicates the condition of being grounded.



B type equipment



Water flow adjustment button.



Ultrasonic power adjustment button.



**Careful:** It indicates an important instruction for the operation of the product. Not following it can cause dangerous malfunctioning.



**Note:** It indi cates useful information for operation of the product.



**Important:** It indicates an instruction of safety for operation of the product. Not following it, can lead to serious danger to the patient.



Position of Off.



Position of On

#### Content of accessible and non-accessible demarcations



#### Atenção:

Para assegurar a vedação do sistema, manter as roscas da tampa e do reservatório devidamente limpas.

#### Attention:

To assure system insulation, keep the threads of the lid and the reservoir property clean.

#### Atención:

Para asegurar la vedeción del sistema, manter las roscas de la tapa y del reservatório propiamente limpas.



#### **INSTALLATION OF EQUIPMENT**



The installation of this equipment requires specialized technical assistance (Gnatus).



OBS: These information also make part of the Manual of Installation and Maintenance of the equipment that can be found with the authorized Gnatus technician.



Appropriated conditions of water feed for perfect operation of the Jet Sonic Fit.

- 1 To have/Have water filter of 30 micron in the consulting office network.
- 2 Use reservoir's filtered water of the consulting office for Jet Sonic Fit's feeding.
- 3 Acquire a sintered water filter in the GNATUS technical assistance network.

CAUTION: For the perfect operation of the Jet Sonic Fit is obliged that its feeding network has a water filter of 30 micron.

- This equipment shall only be able to be unpacked and installed by a Gnatus authorized technician, under penalty of losing the warranty, as only (s)he has the information, suitable tools and training required to execute this task.
  - This is equipment with RF communication and it may affect other equipment.



#### **INSTALLATION OF EQUIPMENT**

- Gnatus bears no responsibility for damages or accidents caused by poor installation executed by a technician not authorized by Gnatus.
- Only after the equipment has been installed and duly tested by the authorized technician representing Gnatus, will it be ready to start work operations.

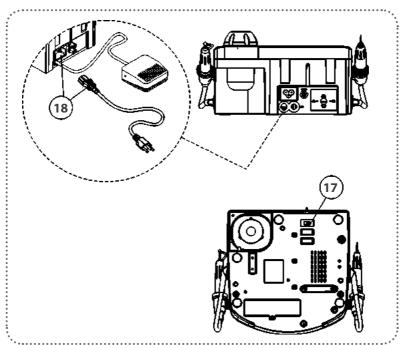
#### 1 - Procedures for hydraulic and pneumatic installation:

- a) Connect the air hose (blue) in the air network (80PSI Maximum) preferably next to the air input in the junction box, using the tee for connection.
- d) Connect the water hose (green) inside of the junction box in the water input hose of the consulting office or connect in the pressurized water hose that comes from the reservoir next to the same, using tee (do not accompany the product) to connect.
  - e) Connect the cable for the power input (18).

#### 2 - Procedures for electrical installation:

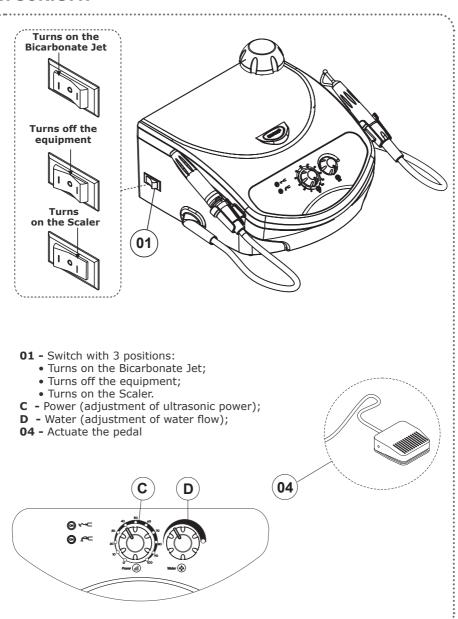
- a) For your safety, the equipment leaves the factory with the voltage selector switch (17) positioned at 220V, so ensure that your network is compatible before turning it on. If it is 127V, invert the position.
- b) Turn the equipment into the plug and proceed according to the following operations.

**ATTENTION:** Do not invert the voltage when the appliance is turned on.



The equipment must be installed by a Gnatus authorized technician, under penalty of loss of the warranty.

#### **JET SONIC FIT**





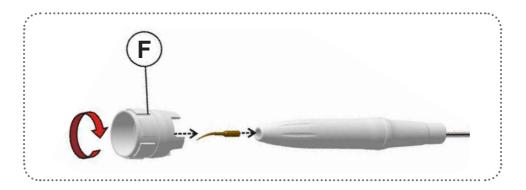
#### Use of the Scaler

After choosing the function desired, proceed according to the instructions below:

- Take out the hand piece ultrasound of the support
- Choose the insert right to the wished operation according to ("Technical and Applications").
- Coil the chosen insert into the hand piece with the help of the fixation key (F) and give a little pressure.
- Actuate the pedal and position the power selector (C) according to the sensibility of the operation.
  - Regulate the water flux in the selector water (D) according to the necessity.



It is recommended that after use, the insert being taken out to avoid damages.



#### **Technical and applications**

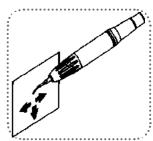
All the inserts of the scaler have the particularity of vibrating in an only plane (front vibrations to back, and in the axis of the insert).

The lateral vibrations common to other destartarizators don't exit, the rectilinear displacement favors more precise approach of the tooth and of the gum.

The enamel and the cement are protected of the inutile shocks.

Inside of this main plane of vibration, the end of each insert is driven by small vibratory movements.

To abtain the maximum performance of the scaler the operator should pay attention to the specific vibrations regulations of each insert.



#### **Periodontics**

#### Insert No 1 "Removal of supragengival calculus"

Tip  $N^{\circ}1$  is used for lingual, buccal and approximal supragingival scaling. Recommended for the removal of gross calculus.

Recommended power setting: 10-50%.

#### Insert No 2 "Removal of supragengival calculus"

Tip  $N^{\circ}2$  is used for lingual and buccal supragingival scaling. Recommended for the removal of gross calculus.

Recommended power setting: 10-100%.

#### Insert No 10-P "Universal"

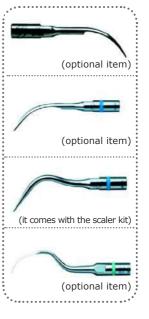
Tip 10-P is used for lingual and buccal supragingival scaling. It's one of the most popular Tips and is recommended for the removal of heavy calculus.

Recommended power setting: 10-70%.

#### Insert No H-3 "Universal"

Tip H-3 was designed for subgingival scaling and can also be used on furcations.

Recommended power setting: 10-70%.



#### **Endodontics**

#### Insert No ET-20 "Preparation of canal"

Tip ET-20 is used in the pulp chamber for removing pulp stones, dentin and old fillings. Length: 17 mm.

Recommended power setting: 10-25%.

#### Insert No ET-40 "Preparation of canal"

Tip ET-40 is used in the coronal and apical part of root canals. Among other things the tip can be used to remove posts, widen calcified canals and remove hard fillings. Length: 24 mm.

Recommended power setting: 10-15%.

#### Insert No S-04 "Preparation of canal"

Tip S-04 is made of titanium and has no diamond coating. Its primary area of use is the isolation and removal of broken instruments. Length: 24 mm.

Recommended power setting: 10-15%.





#### **Endodontics**

#### Insert No S12-90 "Apical surgery"

Tip S12-90 is angled at 110° and is used in combination with the instrument holders A-120 and A-90 With the aid of the instrument holder, the S12-90 can be precisely positioned at the angle needed for the treatment.

Recommended power setting: 10-50%.

#### Insert No P-14 "Apical surgery"

Tip P-14 is angled at  $100^{\circ}$  and it's also used in combination with the instrument holders A-120 and A-90. It has a slimmer design and is therefore better suited for small roots.

Recommended power setting: 10-50%.

#### Insert No A-120 "Removal of broken instruments"

Tip A-120 is a holder for files and instruments with a diameter of 0.8 mm. It can be used with implant tips and AP tips. A-120 has an angle of 120°.

Recommended power setting: 10-50%.

#### Insert No A-90 "Removal of broken instruments"

Tip A-90 is a holder for files and instruments with a diameter of 8 mm. It can be used with implant tips and AP tips. It has an angle of  $90^{\circ}$ .

Recommended power setting: 10-50%.

# (optional item) (optional item) (optional item) (optional item)

#### **Dentistry and Prosthesis**

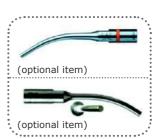
#### Insert No 5-AE "Removal of posts and crowns"

Tip 5-AE is used for removing crowns and inlays. Its small diameter enables access to difficult-to-reach areas.

Recommended power setting: 10-100%.

#### Insert No 6-A "Amalgam condensation"

Tip 6-A is used for amalgam condensation. Recommended power setting: 10-50%.



#### **Important recommendation**

The form and weight of each insert are determining factors for obtaining a maximum performance from the generator of scalers. The operator should pay all due attention to these two features to ensure the maintenance of the best performances of the unit. However, we recommend that the structure of the insert is not altered (filing it or twisting it), just as the aging of an insert leads to its original features being altered, making it inefficacious. Any insert which has been damaged by use or by accidental impact must be replaced.

#### Use of the bicarbonate jet

Bicarbonate jet removes dar $\vec{k}$  stains from teeth, caused by tobacco, coffee, tea, etc, related to plaque.

In order to obtain better results of its use, we recommend a distance of 5mm between the handpiece and the teeth, with an angle from 30 to 45°, describing circular movements over the teeth.

The bicarbonate jet must be directed to the occlusal edge and not to the gingival edge in order to avoid an unpleasant sensation to the patient.

This equipment shall not be used with patients suffering from respiratory or renal diseases, or under hemodialysis treatment. These cases must be surveyed by a physician.

We recommend the use of safety goggles and mask when using the bicarbonate jet. Proceed according to the instructions below:

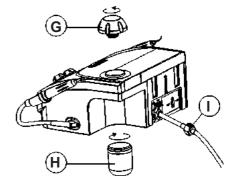
- Activate the option "Bicarbonate jet" by the side key of the equipment.
- Remove the upper cover (G) by unscrewing it (in accordance with the picture) and add a sufficient amount of sodium bicarbonate to a prophylaxis section, that is, from 20 to 40g (do not exceed the level indicated on the container). The bicarbonate level is visible through the transparent container (H). In order to remove the bicarbonate powder remains, unscrew the container (H) (according to the picture) and clean it.



Don't add over 40g of bicarbonate in the recipient (07) not to provoke blockage in the exit of the powder.



The efficiency depends of the perfect dose of the water and quantity of powder.



The water volume and air flow will be able to be adjusted as required, as follows:

- Address the hand piece of the bicarbonate jet to a recipient (ex: water unit, bowl, etc).
- Activate the command pedal and set the water volume in the regulator "selector water (D)" and with the help of a screwdriver the air flow in the regulator (I). The water quantity when in excess provoke the diminution of the powder effect, because of the washing. To decrease the water too much will provoke larger aggressiveness of the powder.



#### **Supply of the Bicarbonate Jet**

To clean your equipment, we advise using sodium bicarbonate "Clean Okta" (exempt

of registration by the Ministry of Health) or another product with similar features:

Composition of the product: Bicarbonate of Sodium (99,6%), Anidro Silícico, Essence - 105 spherical standard microns.

Larger information on the product, consult the manufacturer's instructions in the product.

NOTE: The registration in the Ministry of Health of the Sodium Bicarbonate product (Clean Okta) is performed separately from the Jet Sonic Fit, product is not manufactured by Gnatus.

#### PRECAUTIONS, RESTRICTIONS AND WARNINGS

#### **Transportation and storage**

This equipment must be transported and stored observing the following directions:

- Avoid falls and impacts:
- Keep it dry, do not expose it to rain, water drops or wet floor;
- Keep it away from water and direct sunlight, and in it original wrapping;
- Don't move it over irregular surfaces, protect it from rain and observe the maximum stack quantity specified in the packaging;
  - Transportation and storage temperature range: -12°C to 50°C;
  - Transportation and storage relative humidity range: 0°C to 90°C;
  - Atmospheric pressure range: 500hPa to 1060hPa (375 mmHg to 795 mmHg).



The Equipment maintains its condition of safety and efficacy, provided that it is maintained (stored) as mentioned in this instruction of use. Thus, the equipment will not lose or alter its physical and dimensional features.

**ATTENTION:** The equipment should only be used with power input cable supplied by Gnatus. Otherwise, it may cause an increase in the emissions of reduction in the immunity of the equipment.

#### **Operation ambient conditions**

- Ambient temperature range: +5°C to +45°C;
- Operation relative humidity range: 30% to 75% (non condensing);
- Atmospheric pressure range: 700 hPa to 1060 hPa (525 mmHg to 795 mmHg).

### Sensitivity to environmental conditions in normal situations of use

- The equipment has been planned not to be sensitive to interference such as magnetic fields, external electrical factors, electrostatic discharge, pressure or variance of pressure, provided that the equipment is installed, maintained, clean, preserved, transported and operated as per this instruction for use.

#### PRECAUTIONS, RESTRICTIONS AND WARNINGS

#### Recommendations for the dental equipment maintenance.

Your Gnatus equipment has been designed and developed according to the standards of modern techology. Similarly to other kinds of equipment, it requires special care, which is many times neglected due to several reasons and circunstances. Therefore, here are some important reminders for your daily routine. Try to follow these simple rules, which will save you a lot of time and will avoid unnecessary expenses once they start making part of your working procedure.

#### Precautions and warnings "during the installation" of quipment

- The equipment should only be installed by Gnatus authorized technical assistance or technicians.
- Check that the socket in which the device will be connected has a ground connection. According to the ABNT standard, this is essential for the safe operation of the system;
  - Position the equipment in a place where it will not get wet.
- Install the equipment in a place where it will not be damaged by pressure, temperature, humidity, direct sunlight, dust, salts, or sulfur compounds.
- This equipment was not planned for use in an environment where vapors, anesthetic mixtures inflammable with air, or oxygen and nitrous oxide can be detected.
- Check the voltage of the equipment at the moment of executing the electrical installation.
  - The equipment must be grounded correctly.
- Before the first use and/or after long interruptions from work such as vacations, clean and disinfect the equipment; eliminate air and water deposited in the internal hoses.
  - For the perfect operation of the Jet Sonic Fit is obliged that its feeding network has a water filter of 30 micron.

#### Precautions and warnings "during the use" of equipment

- The equipment should only be operated by duly enabled and trained technicians (Dental Surgeons, Capacitated Professionals)
- If any maintenance should be required, only use services of the Gnatus Authorized Technical Assistance.
- The equipment has been manufactured to handle both continuous and intermittent operation; so follow the cycles described in these Instructions for Use.
- Although this equipment has been planned in accordance with the standards of electromagnetic compatibility, it can, in very extreme conditions, cause interference with other equipment. Do not use this equipment together with other devices very sensitive to interference or with devices which create high electromagnetic disturbance.
- Do not expose the plastic parts to contact with chemical substances, use in the routines of dental treatment, such as: acids, mercury, acrylic liquids, amalgams, etc.

Avoid let sodium bicarbonate in the recipient for long time without being used. The residual air humidity effect will be able to change the properties of the powder and to provoke blockages.



**Ultrasound:** The use of the Ultrasound is not advisable for patients and dental surgeons using pacemakers.



#### PRECAUTIONS, RESTRICTIONS AND WARNINGS

#### **Gnatus shall not be responsible for:**

- Use of the equipment differing from that for which it is intended.

- Damages caused to the equipment, the professional and/or the patient by the incorrect installation and erroneous procedures of maintenance, differing from those described in these Instructions for use which come with the equipment or by the incorrect operation of it.

#### Precautions and warnings "after" the use of equipment

- Turn off the main switch of the dental set when it is not in use for an extended period of time.
  - Always maintain the equipment clean for the next operation.
- Do not modify any part of the equipment. Do not disconnect the cable or other connections without need.
- After using the equipment, clean and disinfect all the parts which may be in contact with the patient.

# Precautions and warnings during the "cleaning and disinfection" of equipment

- Before cleaning the equipment, turn off the main switch.
- Avoid spilling water, even accidentally, or other liquids inside the equipment, which could cause short circuits.
- Do not use microabrasive material or steel wool when cleaning, or employ organic solvents or detergents which contain solvents such as ether, stain remover, gasoline etc.

#### Ultra-som:

- After use, remove the insert to avoid damage.
- The part should be packaged duly clean.
- Do not sterilize the transducer in contact with other types of material.
- The inserts should be cleaned beforehand eliminating all the resin residue.
- After removing the insert from the transducer, it should be disinfected with surgical spirit and taken to be sterilized in autoclave.
- Before placing or removing the cover of the transducer, it is advisable first to remove the insert from the transducer, in order to avoid any damage to the cover.
- Never expose the covers of the transducer to any type of oil, as this may modify the structure of the material, jeopardizing its useful life.

#### **Bicarbonate Jet:**

- Before the sterilization procedure, the part should be packed duly clean.
- Do not sterilize the part in contact with other types of material.
- Before the sterilization procedure, remove the hose from the nozzle of the sodium bicarbonate jet handpiece, as it is not autoclavable.

#### PRECAUTIONS, RESTRICTIONS AND WARNINGS

# Precautions in case of alteration in the functioning of equipment

- If the equipment has any abnormality, check if the problem is related to any item listed in the topic of unforeseen events (failures, causes and solutions). If it is not possible to resolve the problem, turn off the equipment, remove the power supply cable from the socket and contact your representative (Gnatus).

# Precautions to be adopted against foreseeable or uncommon risks, related to the deactivation and abandoning of equipment

In order to avoid environmental contamination or undue use of the Equipment after it has become useless, it should be discarded in the suitable place (as per the local legislation of the country).

- Pay attention to the local legislation of the country for the conditions of installation and disposal of residue.



# CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

#### Additional procedures for reuse

The equipment can be reused in undetermined, i.e. unlimited, quantities, only needing to be cleaned and disinfected.

#### **Cleaning**

**Important:** In order to execute cleaning or any type of maintenance, ensure that the equipment is disconnected from the electrical network.

#### • RECIPIENT OF BICARBONATE

Locate the recipient of bicarbonate throw the lateral access, take it out rotating anticlockwise and make the cleaning with a dried cloth. Pay attention if the thread is covered with powder and put it again anticlockwise.

#### **BODY OF THE EQUIPMENT, CABLE OF TRANSDUCTOR AND HOSES**

To clean the equipment, we recommend the use of "BactSpray" (Reg no MS:

3.2079.0041.001-5) or any other similar product: Active component: Benzalkonium chloride (tri-quaternary ammonium)

**Chemical composition:** Butyl Glycol, Decyl polyglucose, Sodium Benzoate, Sodium Nitrate, Essence, Deodorized Propane / Butane, demineralized Water.

For more information concerning cleaning procedures, see manufacturer's instructions.

**NOTE:** The registration at the Ministry of Health of the "BactSpray" is executed separately from the product described in this manual, as the "BactSpray" is not manufactured by Gnatus.

#### **WARNING:**

- In order to prevent risks and damages to equipment, make sure that the liquid does not enter into the unit.
- The application of other solvent-based cleaning products or sodium hypochloride isn't recommended, because they may damage the equipment.



The cleaning procedure should be executed at the start of the working day and after each patient. Always turn the main switch off before executing the procedures of daily maintenance.

# CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

#### Disinfection

Use clean and soft cloth dampened in alcohol 70% to disinfection of the equipment. Never use corrosive disinfectants or solvents.



Note: Use gloves and other systems of protection, during the disinfection.

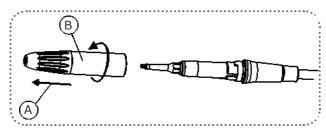


Attention: Do not use any disinfectant spray, as the vapor may be inflammable, or it may cause injury.

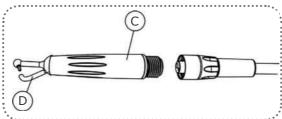
#### **Sterilization**

Transducer cover, bicarbonate jet handpiece (without the hose), inserts and insert tightening wrench are autoclavable at a maximum temperature of 134°C.

**Scaler:** Remove the insert of the transducer, and then turn the cover (B) in a clockwise pull it forwards (A) and take it for sterilization in autoclave (packed).



**Bicarbonate Jet:** Unthread the handpiece of the bicarbonate jet (C) and then remove the hose (D), as it **cannot be autoclavable** and take it for sterilization in an autoclave (packed).



#### **Preventive Maintenance**

The equipment should be calibrated routinely, as per the legislation in force in the country.

But never with a period exceeding 3 years. In order to protect your equipment, seek Gnatus technical assistance for periodic revisions of preventive maintenance.

**WARNING:** Never expose the transducer's cover to any kind of oil, because it may modify the material's structure, affecting its useful life.



# CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

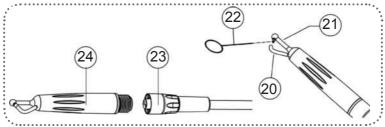
#### **Corrective Maintenance**

#### BICARBONATE JET HANDPIECE

The "Bicarbonate Jet" handpiece has an automatic system of depressurization and internal cleaning of the hoses and the handpiece.

The Jet sonic is doted of automatic system of depressurization and internal cleaning of the hoses and hand pieces. Being positioned the function key in jet of bicarbonate, when we stop the actuation of the command pedal, will be a jet of air of internal swept of the whole system, however if there is blockage in the system, proceed in the following way:

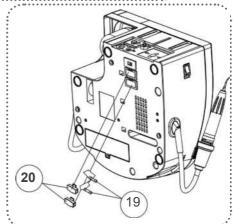
- a) Take the hose out (20) from the beak (21), direct the end to a right place (water unit, bowl etc) and actuate the pedal to certify that the blockage is in the beak (21).
- b) Clean the hole with the plunger (22), introducing it until that is across totally for many times.
  - c) Assemble the hose (20) in the nozzle (21). Replace the hose, if necessary.
- d) In case there is need for sterilization, remove the adapter (23) from the bicarbonate jet end (24) unscrewing it anticlockwise and take the bicarbonate jet end to sterilization in autoclave (packed) without the end's hose.



#### • REPLACEMENT OF FUSES

With the aid of a screwdriver, loosen the lid (20) of the fuse holder, and then replace the fuse (1A) item (19).

**WARNING:** After replacing the fuses for the first time, we recommend to reserve some fuses for future replacements.



If the equipment has any abnormality, check if the problem is related to any of the items listed in the item Unforeseen Events (situation, cause and solution). If it is not possible to solve the problem, turn off the equipment, and request Gnatus technical assistance.

#### **UNFORESEEN EVENTS - SOLUTION OF PROBLEMS**

 $\underline{\Lambda}$  Upon coming across any problem in operation, follow the instructions below to check and repair the problem, and/or get in touch with your representative.

Problem	Probable cause	Solution
-The equipment doesn't work.	- Burned fuse. - Plug desconected.	- Change the fuse. - Change the cable in wall plug.
-Lack of power to the ultra- sound.	- Deformed insert. - Loosen insert. - Bad utilization (incorrect attack angle).	- Change the insert. - Hold the insert with the key - See item "Technical and applications"
-There is no water in the hand piece.	- Inadequate alimentacion pressure water. - Bad regulating of the water flux.	- Correct the water filter. - Adjust the water flux throu- gh the actuator.
- Insufficient bicarbonate in the jet.	- Lack of bicarbonate in the recipient Obstruction in the exit of the recipient or in the beak Excess of bicarbonate in the recipient Inadequate position of the jet.	- Add bicarbonate into the recipient (maximun. of 40g) Remove the blocked parts with a plunger Take out the exceed See "Technical and Applications".
- Lack of pressure in the jet.	- Bad regulating of the air flux. - Pressure of air alimentation under the specified.	- Adjust the air flux in the regulator. - Adjust the alimentation pressure of the equipment (maximum 80 PSI).



#### **WARRANTY OF EQUIPMENT**

This equipment is covered by the warranty terms counting from the date of installation, as specified below; provided that the defect has occurred in normal conditions of use and that the equipment has not remained stored for more than 06 months counting from the issue date of the sales document until the date of the actual installation.

- WARRANTY TERMS: Verify the guarantee certificate;
- LOSS OF THE WARRANTY:
- A) Attempt to repair using an inadequate tool or by unauthorized technicians;
- B) Installation of the equipment by an unauthorized technician;
- C) Damage arising from inappropriate storage or signs of infringement;
- D) Incorrect use of the equipment;
- E) Use of a cleaning product not indicated by the factory;
- F) Falls or blows which the equipment may undergo or lack of observation of an compliance with the guidelines of the Owner's Manual, which was delivered with the present document, together with the equipment. Repair or replacement of parts during the warranty period shall not extend the validity term of their warranty.
- This warranty doe snot exempt the customer from paying the service charge for the visit and the travel expenses of the technician, except when the customer sends the equipment to execute the maintenance inside the establishment of the technical assistance.
  - "Consumer Defense Code art. 50, unique paragraph".
- The Warranty Certificate comes with the product and must be filled in upon the date of installation by the Gnatus Authorized Technician.
  - Queries and information: GNATUS Help Desk (+55) 16 2102-5000.
  - Check the warranty term attached to this manual.

#### FINAL CONSIDERATIONS

The most important aspect related to equipment care is that concerning spare parts. To guarantee the life span of your equipment, use only original Gnatus spare parts. They

are sure to follow the technical specifications and standards required by Gnatus.

We must also point out to you our chain of authorized dealers. Only dealers that make part of this chain will be able to keep your equipment constantly new for they count on technical assistants who have been trained and on spedific tools for the correct maintenance of your equipment.

Doubts and information: GNATUS Call center (55-16) 2102-5000.

EC REP

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NUM, REG. ANVISA: 10229030040



#### Manufacturer/ Distribuitor:



Technical Duties:
Gilberto Henrique Canesin Nomelini – CREA-SP: 0600891412



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