General Instructions

Range of dental ultrasonic generators

ACTEON

This document is an English translation of the original French version.
Reference J00050 version V12 and drawing number RBABFR070L

Contents

1 Documentation

This document contains the following information:

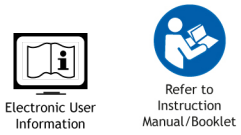
- Patient, practitioner and environment safety
- Installing your medical device in optimum conditions
- Identifying the manufacturer or the latter's representatives if necessary

1.1 Associated documentation

This document must be used in association with the following documents:

Document title	References
Consulting electronic user instructions	J00007
Newtron Booster User Manual	J60111
Quick Clean Newtron Booster	J60101
Quick Start Newtron Booster	J60100
Suprasson P5 Booster User Manual	I58801
Newtron P5 User Manual	J61101
P5 NEWTRON User Manual	I58370
Quick Clean Newtron P5	J61001
Quick Start Newtron P5	J61000
Newtron P5 XS B.LED User Manual	J62151
Quick Clean Newtron P5 XS B.LED	J62101
Quick Start Newtron P5 XS B.LED	J62100
P5 NEWTRON XS User Manual	I58220
Piezotome Cube User Manual	J50101
Piezotome Cube Quick Clean guide	J50151
Piezotome Cube Quick Start guide	J50150
Piezotome Solo LED user manual	I57520
Implant Center 2 user manual	J27171EN

1.2 Electronic documentation



The user instructions for your device are available in electronic format on the specified website and not in printed format. If the website is unavailable, try again later. You can also request a free printed copy of the user instructions within seven days via our website, by telephone or in writing.

The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file reader installed to read the electronic user instructions. It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories.

> Never use your device without first reading the user instructions.

The device user instructions can be consulted at `www.satelec.com/documents`

When you receive your device, you are asked to print and/or to download all documents or sections of documents that you may need to refer to in the event of an emergency, if you are unable to connect to the internet or if your electronic display tool is not working (computer, tablet, etc.). We recommend that you visit the website regularly to consult and to download the latest version of your device's user instructions. Users are asked to keep documentation close at hand for reference when necessary.

All paper or electronic documentation relating to your medical device must be kept for the device’s entire service life.

Keep the original documentation for your medical device and its accessories for future reference. When loaning out or selling the medical device, the documentation must be provided with it.

2 Warnings

2.1 Federal Law

> The indication below applies to the United States of America only.

The United States Federal Law restricts the use of this medical device in its territory to qualified, fit and certified dental health professionals (either directly or under their supervision).

2.2 Warning applicable to all countries in which the device is sold

> The information below is based on the requirements of standards to which the manufacturers of medical devices must adhere (as stated in standard IEC62366).

2.3 User population

This medical device must only be used by qualified dental health practitioners, fit and certified to perform their professional duties.

Users must know and comply with the rules of dental practice in compliance with knowledge acquired in the field and the key medical hygiene principles including cleaning, disinfection and sterilisation of medical devices.

The medical device can be used by any adult dental practitioner of any weight, age, height, gender or nationality.

The user must wear gloves.

The user is not the patient.

The user must not be prone to any of the following:

- visual impairments: any vision problems must be corrected by glasses or lenses.
- arm disability that may prevent the user from holding a handpiece;
- leg disability that may prevent use of a footswitch;
- hearing difficulties that could prevent the user hearing audible alarms depending on medical devices;
- difficulty memorizing or concentrating that could affect the setting of sequences or the performance of treatment protocols.

2.4 Specific user training

No specific training other than initial professional training is required to use this medical device.

The practitioner is responsible for performing clinical treatments and for dangers that may arise due to a lack of skill and/or training.

2.5 Patient population

This medical device is designed to be used with the following patient populations:

- children;
- Teenagers,
- Adults,
- Old Age Pensioners.

This medical device can be used on any patient of any weight (except children), age, height, gender or nationality.

2.6 Patient population restriction

This medical device must not be used on the following patient populations:

- infants
- pregnant or breastfeeding women due to restrictions associated with the possible use of medical solutions such as anaesthetics;
- patients with medical issues,
- Patients allergic to some of the medical device components,
- patients with a clinical site not suitable for treatment,

The patient must be calm, relaxed, still, ideally lying flat on a dental chair.

The user is the only person who can decide whether or not to treat his/her patients.

2.7 Parts of the body or types of tissues treated

Treatment must only be performed on the patient's oral environment.

2.8 Applied parts

Elements in direct contact with the patient For standard dentistry ultrasonic generators	Tip File

Elements in direct contact with the patient For intra-oral surgery dentistry ultrasonic generators	Tip Contra-angle Rotary instrument
Part in indirect contact with the patient	Handpiece nose Handpiece

2.9 Essential performance

As stated in the applicable safety standard pertaining to electrical medical devices, The manufacturer has determined that the medical device did not manage essential performances.

2.10 Basic safety in normal use

The active part, the handpiece is held by the practitioner throughout the treatment.
As a highly skilled medical expert, the practitioner can immediately detect any problems at the treatment area and react accordingly.
It is advisable to have a spare medical device or an alternative means with which to perform the medical treatment in the event of device failure.

2.11 Normal usage conditions

The normal usage conditions are as follows:

- storage;
- installation;
- use;
- maintenance;
- disposal.

2.12 Irrigation spray

The irrigation spray is required to cool down or rinse the treatment area.
In some specific applications, irrigation-free tips can be used.
In special treatment applications, e.g. endodontics, it is possible not to use irrigation, only if the following conditions are adhered to:

- use a visual aid, e.g. microscope or magnifying glass
- work with an assistant
- continually monitor the clinical site to immediately identify any heating risk
- continual work on the clinical site must remain under one minute
- apply an irrigant locally;
- dry with medical air.

> The practitioner must permanently check that lack of irrigation does not put the patient at risk.

Tips must be used with the irrigation recommended by the manufacturer.

2.13 Service life

Tip and file shape and weight are the key characteristics for guaranteeing maximum efficiency of the ultrasonic medical generator. The medical device will perform best if the user pays attention to these two characteristics. Therefore, we strongly advise against the modification of the structure of the tips and files by filing, twisting or by performing any other types of modification.

Also, the features of tips or files can be modified due to ageing, which induces normal wear. Tips or files that are damaged due to wear or accidental impact, such as a fall or distortion, etc., should always be replaced.
Because it is impossible to determine the maximum number of uses (may depend on a number of parameters such as operating time, enamel hardness, force exerted, wear, etc.), we recommend that you routinely replace used tips and files at least once a year. Replace the medical device if the tip does not vibrate at the expected frequency, the treatment is not progressing as normal and is taking longer or is at a standstill.
The ultrasonic force generated by the dental handpiece is adequate to carry out dental treatments. The practitioner does not need to apply force to the clinical site as extra and excessive mechanical force may cause the tips or files to break.
The tips and files have been developed to ensure safe use in association with SATELEC (a company of the Acteon group) handpieces, in accordance with the set power levels.
However, the tips may break depending on frequency of use, force exerted or by being dropped.

> To mitigate the risks, however minimal, use a suction device such as a saliva ejector. You should also encourage your patient to breathe through the nose.

3 Interactions, contraindications, prohibitions

This includes information relating to the interactions, contraindications and prohibited operations known by the manufacturer on the date on which this document was written.

3.1 Interference with other medical devices

The medical device presents potential risks due to the emission of electromagnetic fields. Interference may occur when the system is used on patients with implantable medical devices, such as a pacemakers, cochlear implants, deep brain stimulators or vagus nerve stimulators.

It may in particular cause malfunction of all types of active implanted device:

- before using this medical device, check whether patients and practitioners are fitted with a device of this type (active or inactive);
- explain the situation;
- weigh up the benefits versus the risks and contact your patient's cardiologist or another qualified health professional prior to starting treatment;
- keep this system away from implantable devices;
- apply suitable emergency measures and act fast if the patient shows signs of being unwell.

> Symptoms such as an increased heart beat, irregular pulse or dizziness may indicate a malfunction of a pacemaker or an implantable defibrillator.

The medical device is not designed to withstand electrical defibrillation shocks.

3.2 Using accessories not supplied by the manufacturer

The medical device was designed and developed with its accessories to guarantee maximum safety and performance. The use of accessories from another source could put you and your patients at risk and could damage your medical device.

Do not try to connect accessories not supplied by SATELEC, a company of Acteon group to your medical device connector (s) or to the handpiece.

SATELEC, a company of Acteon group tips and files are only compatible with SATELEC, a company of Acteon group handpieces.

Even if the manufacturer or dealer of your accessory claims full compatibility with SATELEC, a company of Acteon group equipment, it is advisable to exercise caution with regards to the origin and safety of the product offered. Look out in particular for lack of information, information in a foreign language, very attractive prices, suspect appearance, mediocre quality or premature wear. If necessary, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team.

3.3 Prohibited uses

- Never cover the medical device and/or obstruct the air inlets.
- Do not immerse or use outdoors.
- Do not place the medical device next to a source of heat or in direct sunlight.
- Do not expose the medical device to water spray or mist.
- Do not use the medical device in an AP or APG gas-filled atmosphere.

The medical device is not designed to operate near a source of ionising radiation.

A hot/cold temperature contrast can cause condensation to form in the medical device, which may be dangerous. If the medical device needs to be moved from a cold place to a warm place, do not use the device immediately. Wait until it reaches room temperature.

The medical device may not be stored or used outside the temperature, atmospheric pressure and humidity ranges recommended in the User Manual supplied with your medical device.

Do not touch accessible electrical connections. Do not use the medical device without irrigation.

Only use the medical device for the purpose for which it has been designed.

3.4 Moving the medical device

> The indication below only applies to the member countries of the European Union.

After its initial installation, the medical device is not designed to be moved. The medical device must be fixed to ensure that it cannot be removed or moved without the use of a tool.

3.5 Irrigation

> This concerns medical devices that use tanks, bottles or bags.

- Never fill an irrigation solution tank or bottle when they are installed on the medical device.
- Always remove the irrigation tanks or bottles from the medical device before filling them.
- Never fill an irrigation solution tank or bottle over the maximum level mark.
- Irrigation tank covers must always be closed when the medical device is in use.
- Use the medical device with bottles or bags that do not exceed the maximum levels recommended for the medical device (depending on option).
- To prevent any interaction such as crystallisation or precipitate between the different irrigation solutions used, rinse through the irrigation circuit and clean the tank in accordance with the instructions provided in the medical device User Manual.

3.6 Assembly and disassembly

Unless otherwise indicated in the instructions specific to your medical device:

- Control devices are not designed to be removed or disassembled.
- Access doors and/or flaps are not designed to be removed or disassembled.

4 Electromagnetic compatibility

> All the information below is based on the requirements of standards to which the manufacturers of electrical medical devices must adhere (as stated in standard IEC60601-1-2).

The medical device complies with the electromagnetic compatibility standards in force. However, the user must make sure that any electromagnetic interference does not create an additional risk, such as those created by radiofrequency transmitters, or other electronic devices.

This chapter contains the information required for you to install and use your medical device in optimum conditions in terms of electromagnetic compatibility.

The different medical device cords must be kept away from each other.

Some types of mobile telecommunication devices such as mobile phones may interfere with the medical device. The separation distances recommended in this chapter MUST be complied with.

The medical device must not be used near another device or placed on top of it. If this cannot be avoided, correct operation of the device in operating conditions must be checked prior to use.

The use of accessories other than those specified or sold by SATELEC, a company of Acteon group as replacement parts, may increase the transmission or reduce the immunity of the medical device.

4.1 Cable length

Cables and accessories	Maximum length	Test type	In compliance with:
Cables/Cords	< 3 m	RF emission	CISPR 11, Class B
		Harmonic current emission	IEC61000-3-2
		Voltage fluctuation and flickers	IEC61000-3-3
		Electrostatic discharge immunity	IEC61000-4-2
		Radiated immunity – Electromagnetic fields	IEC61000-4-3
		Electrical fast transient/burst immunity	IEC61000-4-4
		Surge immunity	IEC61000-4-5
		Immunity to conducted disturbances, induced by radiofrequency fields	IEC61000-4-6
		Radiated immunity - Magnetic fields	IEC61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11

4.2 Recommended separation distances

The medical device is designed to be used in an electromagnetic environment in which interferences caused by radiofrequency radiation are controlled.

Do not use handheld radiofrequency communication devices within 30 cm (12 inches) of any part of the medical device, including its cables.

Aerial cables and external aerials of handheld radiofrequency communication devices must not be positioned or used within 30 cm (12 inches) of any part of the medical device.

If the minimum distance is not adhered to when using handheld radiofrequency communication devices, this may impact the performance of the medical device.

4.3 Electromagnetic emissions

The medical device is designed for use in the electromagnetic environment described in the table below. The user and/or installer must ensure that the medical device is used in the environment described below.

Emission test	Conformity	Electromagnetic environment - comments
Electromagnetic radiation disturbance, radiated emissions (CISPR 11)	Group 1	The medical device uses radiofrequency energy for its internal operation. Consequently, its radiofrequency emissions are very low and are not likely to create any interference with other nearby equipment.
Radiofrequency emission (CISPR 11)	Class A	The emission characteristics of this medical device make it suitable for use in industrial and hospital areas [Class A defined in CISPR 11]. When used in a residential environment, for which class B defined in CISPR 11 is normally required, this medical device may not provide adequate protection for radio frequency communications services. The user may need to take corrective measures such as the re-installation or reorientation of the medical device.
Radiofrequency emission (CISPR 11)	Class B	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Harmonic current emission (IEC61000-3-2)	Class A	
Voltage fluctuation and flickers (IEC61000-3-3)	Compliant	

The following medical devices are categorised as Class B radio-frequency equipment according to CISPR 11:

- Suprasson P5 Booster
- P5 NEWTRON, P5 NEWTRON LED
- P5 NEWTRON XS, P5 NEWTRON XS LED
- Piezotome Solo LED
- Newtron Booster
- Newtron P5, Newtron P5 LED
- Newtron P5 XS B.LED
- Piezotome Cube
- Piezotome Solo M+

The following medical devices are categorised as Class A radio-frequency equipment according to CISPR 11:

- Implant Center 2

4.4 Magnetic and electromagnetic immunity

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level in accordance with IEC60601	Conformity level	Electromagnetic environment / comments
Electrostatic discharge (ESD) (IEC61000-4-2)	± 8 kV on contact ± 15 kV in the air	± 8 kV on contact ± 15 kV in the air	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Electrical fast transient/burst immunity (IEC61000-4-4)	± 2 kV for electricity supply lines ± 1 kV for signal ports Valid for medical devices with signal ports	± 2 kV for electricity supply lines ± 1 kV for signal ports	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Surge (IEC61000-4-5)	±0.5 kV, ±1 kV between phases ±0.5 kV, ±1 kV, ±2 kV between phase and earth Valid for earthed medical devices	±0.5 kV, ±1 kV between phases ±0.5 kV, ±1 kV, ±2 kV between phase and earth	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.

Immunity test	Test level in accordance with IEC60601	Conformity level	Electromagnetic environment / comments
Magnetic field at the assigned industrial frequency (IEC61000-4-8)	30A/m	30A/m	The magnetic field intensity must be equal to the level found in a home-based health care setting and in a professional health care establishment setting.
Voltage dip (IEC 61000-4-11)	0% UT for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25 cycles at 50 Hz for 30 cycles at 60 Hz Single phase at 0°	0% UT for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25 cycles at 50 Hz for 30 cycles at 60 Hz Single phase at 0°	The quality of the network supply must be equal to that of a home-based health care setting and a professional health care establishment setting. If the use of the system requires continuous operation during mains power outages, it is advisable to supply the medical device using a separate current source (UPS, etc.).
Voltage interruptions (IEC61000-4-11)	0% UT for 250 cycles at 50 Hz for 300 cycles at 60 Hz	0% UT for 250 cycles at 50 Hz for 300 cycles at 60 Hz	The quality of the network supply must be equal to that of a home-based health care setting and a professional health care establishment setting. If the use of the system requires continuous operation during mains power outages, it is advisable to supply the medical device using a separate current source (UPS, etc.).

4.5 Electromagnetic immunity, handheld radiofrequency equipment

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level	Conformity level	Electromagnetic environment - comments
Do not use handheld radiofrequency communication devices within 30 cm (12 inches) of any part of the medical device, including its cables. Aerial cables and external aerials of handheld radiofrequency communication devices must not be positioned or used within 30 cm (12 inches) of any part of the medical device. If the minimum distance is not adhered to when using handheld radiofrequency communication devices, this may impact the performance of the medical device.			
Radiated, radiofrequency, electromagnetic fields (IEC61000-4-3)	10 V/m 80 MHz to 2.7 GHz 80% MA at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% MA at 1 kHz	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.

Immunity test	Test level	Conformity level	Electromagnetic environment - comments
Proximity fields transmitted by wireless radiofrequency communication devices (IEC 61000-4-3, temporary method)	9 V/m 710 MHz, 745 MHz, 780 MHz, 5 240 MHz, 5 550 MHz, 5 785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930MHz, 1 720 MHz, 1 845 MHz, 1 970 MHz, 2 450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5 240 MHz, 5 550 MHz, 5 785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930MHz, 1 720 MHz, 1 845 MHz, 1 970 MHz, 2 450 MHz	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.
Conducted disturbances, induced by radiofrequency fields (IEC61000-4-6)	3 V/m 0.15 MHz to 80 MHz 6 V in ISM band and bands between 0.15 MHz and 80 MHz, amateur radio bands included 80% MA at 1 kHz	3 V/m 0.15 MHz to 80 MHz 6 V in ISM band and bands between 0.15 MHz and 80 MHz, amateur radio bands included 80% MA at 1 kHz	The medical device is suitable for use in a home-based health care setting or in a professional health care setting.

These specifications may not be applicable in all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

The electromagnetic field intensity of fixed radiofrequency transmitters, such as base stations for portable phones (mobiles / wireless), mobile radios, radio amateurs, AM/FM radio transmissions and TV transmissions cannot be determined accurately by the theory.

To assess the electromagnetic environment caused by fixed radiofrequency transmitters, an electromagnetic environment measurement must be taken. If the measured intensity of the radiofrequency field in the product's immediate use environment exceeds the radiofrequency conformity level specified above, it is necessary to test product performance to check this complies with specifications. If abnormal performance is observed, additional measures may be necessary, such as changing the direction of or moving the product.

In the 150 kHz to 80 MHz frequency range, the electromagnetic fields must be less than 3 V/m.

5 Disinfection and sterilising

The instructions relating to the accessory cleaning, disinfection and sterilisation protocols provided by SATELEC, a company of Acteon group have been approved for each medical device and accessory. The applicable guides are listed in the chapter *Associated documentation page 1*.
They can be downloaded at the following address: `www.satelec.com/documents`.

Download

Instructions For Use

In all cases, the local regulations in force relating to the cleaning, disinfection and sterilisation protocols for accessories take precedence over the information provided by SATELEC, a company of Acteon group.

6 Regulations and standards

6.1 Latest document update

01/2023

6.2 Manufacturer identification

SATELEC
A Company of the ACTEON Group
17, avenue Gustave Eiffel
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33700 MERIGNAC
France

CE 0459

6.3 Manufacturer responsibility

The manufacturer shall under no circumstances be liable in the following cases:

- Non-compliance with manufacturer recommendations during installation, whether this is the network voltage or the electromagnetic environment
- Maintenance or repair procedures performed by people who are unauthorised by the manufacturer.
- Use on an electrical fixture that is not compliant with regulations in force.
- Use of the device for purposes other than those specified in this manual.
- The use of accessories or handpieces other than those supplied by SATELEC, a company of Acteon group.
- Non-compliance with the instructions contained in this document.

> Note: the manufacturer reserves the right to modify the medical device and any documentation without notice.

6.4 Branch addresses

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6.5 Disposal and recycling

As an item of Electrical and Electronic Equipment, the medical device must be disposed of via a specialist collection, removal, recycling or destruction channel. This applies in particular to the European market, with reference to Directive no. 2012/19/EC of July 2012.

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or the Acteon head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapter *Branch addresses page 13*.

Do not dispose of as household waste

The indication below applies to France only.

In compliance with the provisions of the French Environment Code relating to the disposal of electronic and electrical equipment waste or WEEE (Decree no. 2012-617 dated 2 May 2012), our Company fulfils its obligations to reclaim and dispose of its electrical and electronic equipment through the means established by the approved organisation Récylum, NOR approval: DEVP1427651A.

As a manufacturer, our Company is listed in the National Register of Producers kept by the ADEME (French Environment and Energy Management Agency). Professionals buying our products directly from the distribution chain are responsible for passing on this information about our established recycling methods to the end user.

In addition, the buyer agrees to take back our brand's devices at the end of their service life and to transfer them to one of the collection centres set up by Récylum for recycling (see list of collection centres on the site `http://www.recylum.com/`.

If necessary, Récylum can come and collect these devices from you free of charge once the quantity of devices has reached a certain level in the pallets-containers with which you are provided to store this waste.

An accessory that has reached the end of its service life must be disposed of in infectious clinical waste containers.

6.6 Applicable standards and regulations

This medical device complies with the essential requirements of European Directive 93/42/EEC. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.

6.7 Symbols

Symbol	Meaning
	Always wear safety goggles
	Always wear protective gloves
	Refer to the supporting documentation
 Consult Instructions for Use	Consult the User Manual

Symbol	Meaning
	The accompanying documentation is available in electronic format
	Do not use the medical device if the patient or practitioner are fitted with an implantable device
	Do not use the medical device if the patient is wearing a medical device for deep brain stimulation
	Do not use the medical device if the patient is wearing a medical device for vagus nerve stimulation
	Biohazard
	Sterilisation at 134°C in an autoclave
	Sterilisation at 132°C in an autoclave
	Washer-disinfector for thermal disinfection
	CE marking
YYYY 	Year of manufacture
	Manufacturer
	Do not dispose of as household waste
	Recycle your lamps and professional electrical equipment with Récylum
Rx Only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.

7 Index

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