General Instructions

Range of dental ultrasonic generators

SATELEC ACTEON

Contents

Foreword

The medical device SATELEC® that you are about to install and use in your practice is a medical device designed for professional use. It comprises the chosen tool with which you will provide treatment within the context of your work.

To ensure optimum safety for yourself and your patients, comfort in your daily practice and to benefit fully from the technology of your medical device, please read the documentation provided carefully.

If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.

Please refer to the accessory cleaning, disinfection and sterilization protocols and the handpiece predisinfection, cleaning and sterilisation protocols for information about the following:

- preparation of parts for sterilization;
- detailed manual and automatic protocols;
- information concerning the sterilization;
- recommendations for the inspection of parts.

Please refer to the User Manuals, Quick Start Guides and Quick Clean Guides for each medical device for information about the following:

- unpacking and installing the medical device;
- using the medical device;
- monitoring and maintaining the medical device;
- technical specifications for the medical device.

1 Documentation

This document contains the following information:

- relating to patient, practitioner and environmental safety;
- required to install your medical device in optimum conditions;
- required to contact the manufacturer or the latter's representatives if necessary;

1.1 Electronic documentation

The user instructions for your device are provided in electronic format and not in printed format. However, you can request a free printed copy of the user instructions within 7 days via our website, by telephone or in writing.

The electronic user instructions are available in PDF format (Portable Document Format) and you will need to have a PDF file read software installed to read the instructions.

The device user instructions can be consulted at the following address:

www.satelec.com/documents

Electronic user informations

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 prior to use.

We recommend that you visit the website regularly to consult and/or to download the latest version of your device's user instructions.

1.2 Archiving duration

Users are asked to keep documentation to hand so that it can be consulted when necessary. You are asked to print and/or to download all documents or sections of documents that you may need to consult 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.). All printed and electronic format documentation relating to your medical device must be kept for the device's entire service life. When loaning out or selling the medical device, the documentation must be provided with it. Users are asked to keep documentation to hand so that it can be consulted when necessary.

2 Required information

2.1 Latest document update

11/2013

2.2 Official Texts

This medical device complies with the essential requirements of European Directive 93/42/EEC. This equipment is designed and developed in compliance with Electrical Safety standard IEC60601-1 in force. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.

2.3 Standardised Symbols

Symbols	Meaning
	Refer to the accompanying documentation
	Consult the User Manual
 Electronic user informations	Accompanying documentation in electronic format
	BF type
	Alternating voltage
	Sterilisation at 132°C in an autoclave
	Washer disinfector for thermal disinfection
	EC marking
	Do not dispose of as household waste
YYYY 	Year of manufacture
	Control pedal
O	Device OFF
I	Device ON
IPX1	**IP** : ingress protection ratings procured by a range **X** : no ingress of protection rating claim against the penetration of solids **1**: protects against the vertical falls of drops of water
Rx Only	Caution: US Federal law restricts this device to sale by or on the order of a Physician

2.4 Manufacturer identification

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2.5 Manufacturer responsibility

The manufacturer shall under no circumstances be liable for:

- 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,
- uses other than those specified in this manual,
- use of accessories (tips, handpieces, etc.) other than those supplied by SATELEC,
- non-compliance with the instructions contained in this document.

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

3 Warnings

3.1 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 dental health professionals, fit and certified to perform and manage their professional duties.

3.2 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).

3.3 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 sterilization of medical devices.

The medical device can be used by any adult dental practitioner of any weight, age, height, gender and 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.
- disability of arms that may prevent the user from holding a handpiece, or legs that may prevent use of a control pedal;
- 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.

3.4 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.

3.5 Patient population restriction

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

- Infants,
- pregnant or breastfeeding women due to restrictions associated with the possible use of medical solutions such as anaesthetics;
- patients with medical issues,
- patients with allergies,
- 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.

3.6 Parts of the body or types of tissues treated

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

3.7 Essential performance

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

3.8 Basic safety in normal use

The active part, the is held by the practitioner throughout the treatment. Being medically qualified, the practitioner is qualified to immediately detect any problem at the treatment site and to react accordingly.

The force applied to the fitted with its tip must be managed by the practitioner in compliance with good dental practices. Basic safety is ensured by the practitioner.

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.

3.9 Normal usage conditions

The normal usage conditions are as follows:

- Storage;
- Installation;
- Use;
- Maintenance;
- Disposal.

3.10 Irrigation spray

The irrigation spray is required to cool down or rinse the treatment area.

Tips must be used with the irrigation function in accordance with manufacturer recommendations.

3.11 Tip service life

The shape and weight of the tips are determined to obtain maximum performance of the ultrasonic 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 by filing, twisting or by performing other types of modification.

In addition, tip ageing leading to normal wear can modify the tip characteristics. Systematically replace a tip that is damaged due to wear or accidental impact (drop, distortion, etc.).

As it is not possible to establish a maximum number of uses (that may be determined by many parameters such as duration of use, hardness of enamel, the force applied, wear, etc.), we recommend that tips being used are replaced at least once a year.

3.12 Broken tips

A tip is a medical device to which a mechanical force is applied to perform dental treatments. The mechanical force of the user is combined with the ultrasonic force generated by the dental handpiece.

The tips have been developed to ensure safe use in association with SATELEC® handpieces in accordance with the power levels defined.

However, the tips may break depending on frequency of use, force exerted or by being dropped.

To reduce all risk, however minimal, we recommend the use of a suction device such as a saliva suction cannula. You should also encourage your patient to breathe through their nose.

4 Interactions, contraindications, prohibitions

This includes information relating to the interactions, contraindications and prohibitions known by SATELEC® on the date on which this document was written.

4.1 Interferences with other medical devices

Interferences may occur when the system is used on patients fitted with a pacemaker.

The medical device presents potential risks due to the emission of electromagnetic fields.

It may in particular cause malfunction of implanted devices such as a pacemaker or implantable defibrillator and, generally, of any type of active implant:

- before using this product, check whether patients and practitioners are fitted with a device of this type;
- 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.

4.2 Using accessories not supplied by SATELEC®

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 provided by SATELEC® to your medical device connector(s) or to the handpiece.

Even if the manufacturer or dealer of your accessory claims full compatibility with SATELEC® 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® customer services department.

4.3 Prohibited uses

- Never cover the medical device and/or obstruct the air inlets.
- Do not immerse or use outside.
- 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.

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 but wait until it reaches room temperature.

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

Do not touch accessible electrical connections.

4.4 Irrigation systems of the medical devices

> 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.

4.5 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.

5 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 will make sure that any electromagnetic interference does not create an additional risk, such as 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 as replacement parts, may increase the transmission or reduce the immunity of the medical device.

5.1 Cable length

Cables and accessories	Maximum length	Test type	In compliance with:
Cables/Cords	< 3m	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 radio-frequency fields	IEC61000-4-6
		Radiated immunity - Magnetic fields	IEC61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11

5.2 Recommended separation distances

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

The user or installer of the medical device may help to prevent electromagnetic interference by maintaining a minimum distance, depending on the maximum power of the handheld and mobile radiofrequency transmission equipment (transmitters), between the medical device and the equipment as recommended in the table below.

	Separation distance in metres (m) determined by transmitter frequency		
Max. nominal power of the transmitter in Watts	From 150 kHz to 80 Mhz d = √P 1.2	From 80 MHz to 800 MHz d = √P 1.2	From 800 MHz to 2.5 GHz d = √P 2.3
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m
With regards to transmitters for which the maximum power is not listed above, the recommended separation distance (d) in metres (m) can be estimated by using the equation applicable to the transmitter frequency where (P) is the maximum power of the transmitter in watts (W) according to the manufacturer.			

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

Note 2: These specifications cannot be applied to all situations.

The electromagnetic propagation is reduced by the absorption and reflection of structures, objects and people.

5.3 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
RF emission (CISPR 11)	Group 1	The medical device uses RF energy for its internal operation. Consequently, its radiofrequency emissions are very low and are not likely to create any interference with other nearby equipment.
RF emission (CISPR 11)	Class B	The medical device is suitable for use in all establishments, including domestic and those directly connected to the low voltage energy supply public network supplying buildings used for domestic purposes.
Harmonic current emission (IEC61000-3-2)	Class A	
Voltage fluctuation and flickers (IEC61000-3-3)	Conforming	

5.4 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)	± 6 kV in contact ± 8 kV in the air	± 6 kV in contact ± 8 kV in the air	Floors must be wood, concrete, cement or tiled. If floors are covered with synthetic materials (carpet, etc.), the relative humidity must be 30% minimum.
Electrical fast transient (IEC61000-4-4)	± 2 kV for electricity supply lines	± 2 kV for electricity supply lines	The quality of the electricity supply must be equivalent to that of a typical commercial environment or hospital establishment (hospital, clinic).
Surge (IEC61000-4-5)	± 1 kV in differential mode ± 2 kV in common mode	± 1 kV in differential mode ± 2 kV in common mode	The quality of the electricity supply must be equivalent to that of a typical commercial environment or a hospital.
Magnetic field at 50 hz/60 hz (IEC61000-4-8)	3A/m	3A/m	The magnetic field intensity must be equal to the level found in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variation (IEC 61000-4-11)	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250 cycles	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250 cycles	The quality of the network supply must be equal to that of a typical commercial or hospital environment. If the use of the system requires continuous operation during mains power outages, it is advisable to supply the medical device using an separate current source (UPS, etc.).

5.5 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
Handheld and mobile radiofrequency communication devices must not be used near the device (including cables) atmedical device a distance below that recommended and calculated according to the frequency and power of the transmitter.			
Radiated radiofrequency electromagnetic field (IEC61000-4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 √ P 80 MHz to 800 MHz d = 2.3 √ P 800 MHz to 2.5 GHz Where (P) is the maximum nominal power of the transmitter in Watts (W) according to the manufacturer specifications and (d) is the minimum recommended separation distance in metres (m).
Radiofrequency conducted disturbance (IEC61000-4-6)	3 V/m 150KHz to 80MHz	3 V/m	Recommended separation distance: d = 1.2 √P
The electromagnetic field intensity of fixed radiofrequency transmitters, as determined by an electromagnetic environment measurement (a), must be less than the conformity level for each frequency range (b). Interferences may occur near the equipment identified by the following symbol: 			

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

Note 2: These specifications cannot be applied to all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

(a) 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 immediate product 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.

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

6 Cleaning, disinfecting and sterilizing

The instructions relating to accessory cleaning, disinfection and sterilization protocols provided by SATELEC® have been approved for each medical device and accessory.

They can be downloaded at the following address:

www.satelec.com/documents

In all cases, the local regulations in force relating to the accessory cleaning, disinfection and sterilization protocols take precedence over the information provided by SATELEC®.

7 Branch addresses

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7.1 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, in reference to Directive 2002/96/EC dated 27/01/2003.

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or ACTEON GROUP 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 16*.

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 DEEE (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 Recydent (NOR approval: DEVP1229534A) .

As a producer, 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 Recydent for recycling (see list of collection centres on the site `Recydent.fr`).

If necessary, Recydent 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.

7.2 Disposing of accessories

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

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