User Manual

Piezotome Cube

ACTEON

This document is an English translation of the original French version.
Reference J50100 version V5 and plan number NO37FR010E

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1 Documentation

This document contains the following information:

- Indications for use
- Intended use
- Medical device description
- Installation of the medical device
- Medical device use
- Preparation for cleaning and disinfection of the medical device
- Monitoring and general maintenance of the medical device
- Maintenance to be performed by the user

1.1 Associated documentation

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

Document title	References
Cleaning, disinfection and sterilization instructions for wrenches	J81009
Cleaning, disinfection, and sterilization instructions for tips	J02009
Cleaning, disinfection and sterilization instructions for Piezotome handpiece-cord assembly	J12801
Method for consulting electronic user instructions	J00007
Piezotome Cube User Manual	J50109
Ultrasonic generator power settings table for intraoral surgery	J58010
Cube LED handpiece user manual	J28821

1.2 Electronic documentation

The user instructions for your device are available electronically at the URL provided. The instructions are not automatically provided in paper format. If the website is not available, please 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.

> Do not use your device without first reading the user instructions.

The device user instructions can be consulted at the following addresses: `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 Required information

2.1 Intended use

The Piezotome Cube SATELEC intended use is to supply utilities and to serve as a base for dental tools and accessories for use by qualified dental practitioners.

2.2 Indication for use

The Piezotome Cube is an ultrasonic surgical system that supply utilities to and serve as a base for dental tips. The Piezotome Cube consists of a control unit and handpiece designed for use in intraoral surgery procedures including osteotomy, osteoplasty, periodontics and implantology.

2.3 Operating principle

An electrical signal emitted by the medical device is supplied to the ultrasonic handpiece. This is connected to the medical device via a cord. The handpiece comprises a piezoelectric ceramic transducer, which transforms the electrical signal into ultrasonic vibrations.

Mechanical vibrations are transmitted to a intra-oral surgery tip screwed on the end of the ultrasonic handpiece.

The medical device must be used with a Cube LED handpiece. Refer to the Cube LED handpiece user manual [J28821] for more information.

The Piezotome Cube is an intra-oral dental surgery medical device used with an intra-oral dental surgery ultrasonic handpiece. An ultrasonic instrument attached to the handpiece allows to cut intra-oral bone. The medical devices working together are designed for use in various intra-oral dental surgery procedures .

2.4 Using accessories not supplied by the manufacturer

The handpiece is designed to operate with SATELEC, a company of Acteon group tips. The use of other manufacturer tips or files will damage the handpiece and break tips.

2.5 Connecting and disconnecting accessories during use

Do not tighten or loosen the tips when the handpiece is activated.

2.6 Repairing or modifying the medical device

Contact the supplier of your device. Using the services of an unapproved repairer could render your device dangerous for you and your patients.

Do not repair or modify the device without seeking the prior permission of SATELEC, a company of Acteon group.

If the device is modified or repaired, specific checks and tests must be carried out to ensure that the medical device is still safe to use.

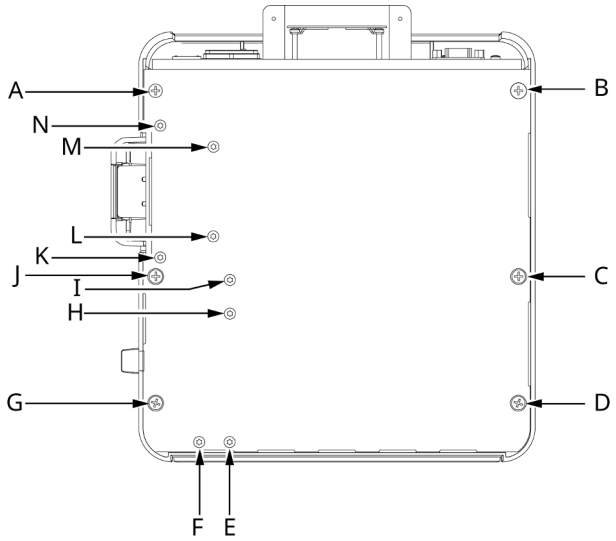
In the event of doubt, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team:

`www.acteongroup.com`

`satelec@acteongroup.com`

> SATELEC, a company of Acteon group, at the request of technical personnel working for the network of approved dealers, will provide any information required to repair defective parts on which they may perform repairs.

2.7 Warranty



The screws marked A to N must never be unscrewed by the user. Unscrewing these screws will void the warranty for the medical device.

2.8 Latest document update

05/2018

2.9 Date of first CE marking

2017

3 Unpacking the medical device

When you receive your medical device, check for any damage that may have occurred during transportation.
If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.
If you have any questions or requirements, contact your supplier.

4 Connect the medical device

4.1 Connecting the medical device to the electrical network

> Have your medical device connected to the AC power by an approved dental installation technician.

Switch the medical device OFF (position O) and check that the AC voltage is compatible with that indicated on the medical device or its AC adapter. Next, connect the cord to the wall socket in compliance with the standards in force in the country of use.

A different voltage would cause damage to the medical device and could injure the patient and the user. Any variation in the electrical network voltage or electromagnetic field that is non-compliant with the limits in force, could interfere with the medical device's operation.

Medical devices equipped with a protective grounding must be connected to a supply network equipped with a protective earth.

> Do not plug the medical device into an extension cord and do not put the AC cord in a cable cover or cable tray.

> If when using the medical device, a power outage can create an unacceptable risk, the user and the installer must ensure that the medical device is connected to an appropriate power source such as an uninterruptable power supply.

4.2 Connecting the medical device to the electrical network

1. Set the medical device's AC switch to "O" OFF position.
2. Connect the AC cord to the control unit's AC connector.
3. Connect the AC cord to the AC socket.

5 Installing the medical device

Place the medical device in the position that is suitable for your activity.

The medical device must be placed on a secure and flat surface or a surface with a maximum slope of five degrees.

Check that the cords do not hinder the movement or free circulation of anyone.

Adjust the position of your medical device to correspond to your angle of vision and the characteristics of your workstation, e.g. lighting or distance between the user and the medical device.

Ensure that your medical device is readily accessible. The disconnecting devices that are the switch and the power plug are located there and must be easy to locate and access.

Do not install your medical device near or on another device.

5.1 Install cords

Never wrap the handpiece cord around the medical device.

Make sure that it is not possible to wheel over or walk on the different cords.

The cord attached to its handpiece must be easily accessible. Make sure that the cord is slack during use.

5.2 Installing the control pedal

Connect the pedal cord to the rear of the medical device.

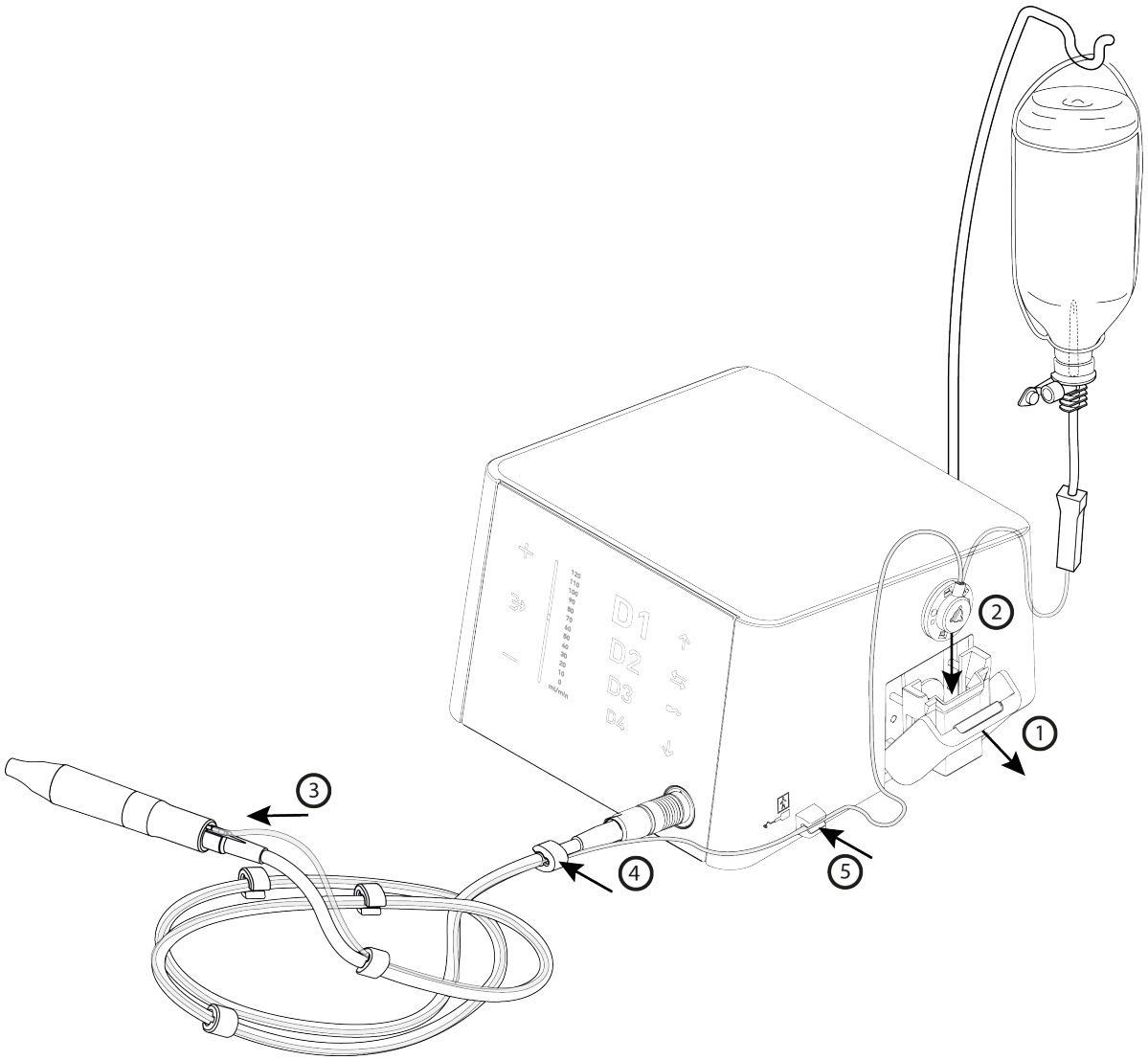
The control pedal must be positioned near the feet of the operator and must be readily accessible.

5.3 Connecting the handpiece

Connect the cord and handpiece assembly to the connector on the front of the control unit.

5.4 Install an irrigation line

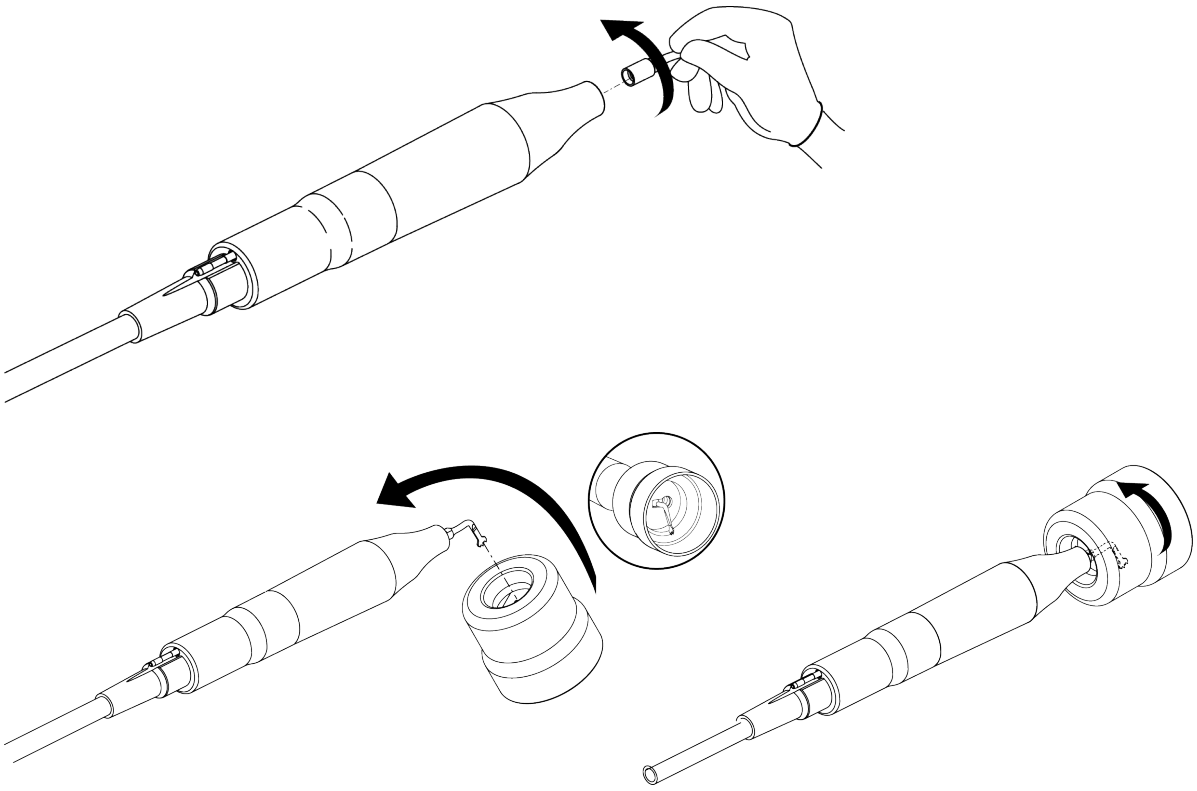
1. Remove the irrigation line from the sterilization bag.
2. Remove the clips from the bag.
3. Open the cassette drawer on the right-hand side of the medical device.
4. Put the cassette in the drawer and close it.
5. Connect the end of the irrigation line (the long tube) to the handpiece.
6. Moving up along the handpiece cord, clip the irrigation line with the handpiece cord.
   Any excess length of the irrigation line will be by the medical device unit and will not interfere with the use of the handpiece.
7. On the short tube side, pierce the bag of irrigation solution with the perforator.
8. With the medical device switched on, open the seal of the perforator and purge the irrigation system.



5.5 Screw in a tip

The intraoral surgery tips designed to operate with this medical device are called “second generation”. Their base is engraved with II. They are not compatible with tips for Implant Center and Piezotome first generation.
The reverse is also true, old generation tips are not compatible with , Piezotome Cube, Implant Center 2 LED, Piezotome 2 and Piezotome Solo LED.
A tip vibrates correctly when it is perfectly tightened without being forced beyond its stop point. Tighten it moderately using the wrench supplied to ensure optimum ultrasonic function. Over-tightening of the tip can result in breakage of the tip or handpiece.

> To prevent self-locking of the tip, the latter must be removed and sterilized after each use.



The wrench is a slip type torque wrench. After a few turns, the wrench appears to slip or to stop tightening, which means that the tightening torque has been reached.

6 Dispensing a treatment

6.1 accessory usage conditions

The accessories of the Piezotome Cube must be cleaned, disinfected and sterilized prior to each use.

Refer to the cleaning, disinfection and sterilization instructions for accessories listed in the chapter *Associated documentation page 3*.

> This medical device is designed to be used with a SATELEC, a company of Acteon group handpiece and second-generation intraoral dental surgery tips.

6.2 Preparation for use

To prepare your medical device, follow the steps below:

1. Wear safety goggles and protective gloves.
2. Put the handpiece support in position.
3. Clean the unit with an alcohol disinfectant wipe.

1. Put the bracket in position.
2. Connect the handpiece cord to the connector on the front of the medical device.
3. Remove the handpiece support from its sterilization bag.
4. Remove the handpiece and the cord from their sterilization bag.
5. Remove the wrench from its sterilization bag.
6. Remove the tip from its sterilization bag.
7. Screw the tip onto the handpiece, first manually and finishing with the wrench.
8. Place the handpiece on its support.
9. Put an irrigation solution bag in position on the bracket.
10. Remove the irrigation line from its sterile bag.
11. Put the irrigation line and its cassette in position, as far as the irrigation bag.
12. Switch on the medical device.
13. Check the irrigation parameters depending on the tip chosen, and adjust the flow using the touch-sensitive areas.

    + and − .
14. Check the mode depending on the tip chosen, and adjust the mode using the touch-sensitive areas

    ↑ and ↓ .
15. After water drainage, check that the handpiece spray works correctly.

Your medical device is now ready to use.

6.3 Switching off the medical device

After installation and before first use, at the end of the day and following a period of prolonged non-use of the medical device, it is important to clean the irrigation system.

When irrigation bags are used to irrigate your medical device:

1. Disconnect the irrigation bag from the perforator of the irrigation line.
2. Discard the irrigation bag.
3. Soak the short end of the irrigation line in a recipient containing a hypochlorite solution diluted to less than 3%.

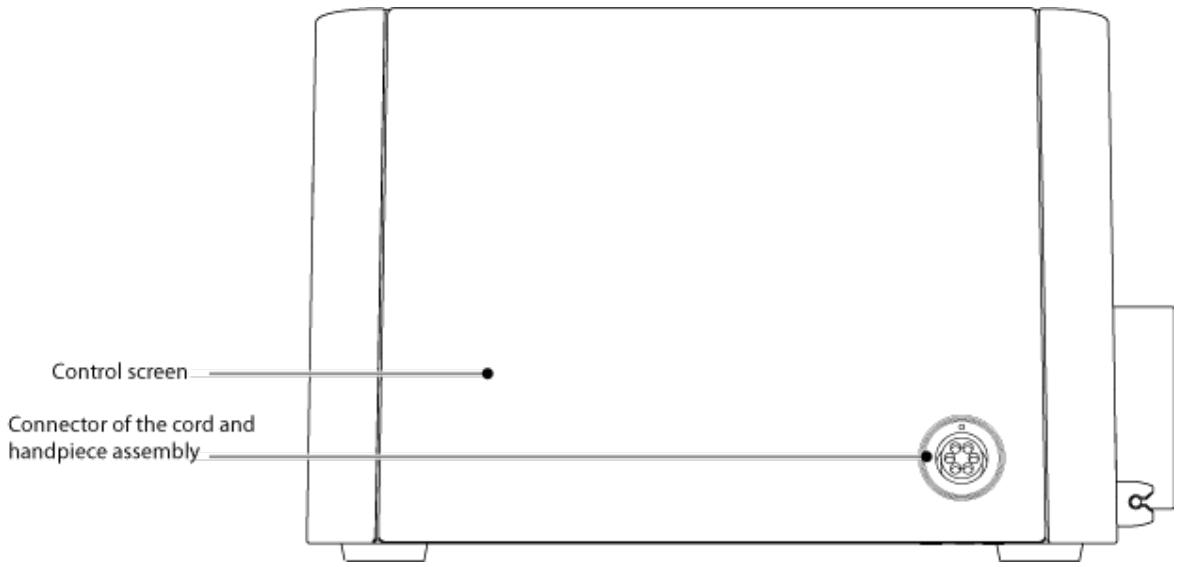
4. Press the Purge icon.
5. Operate the irrigation spray for 2 minutes to rinse the medical device's water system.
6. Refill the recipient with demineralized or distilled water.
7. Rinse the irrigation system for 2 minutes.

When the irrigation system has been cleaned, perform the following operations:

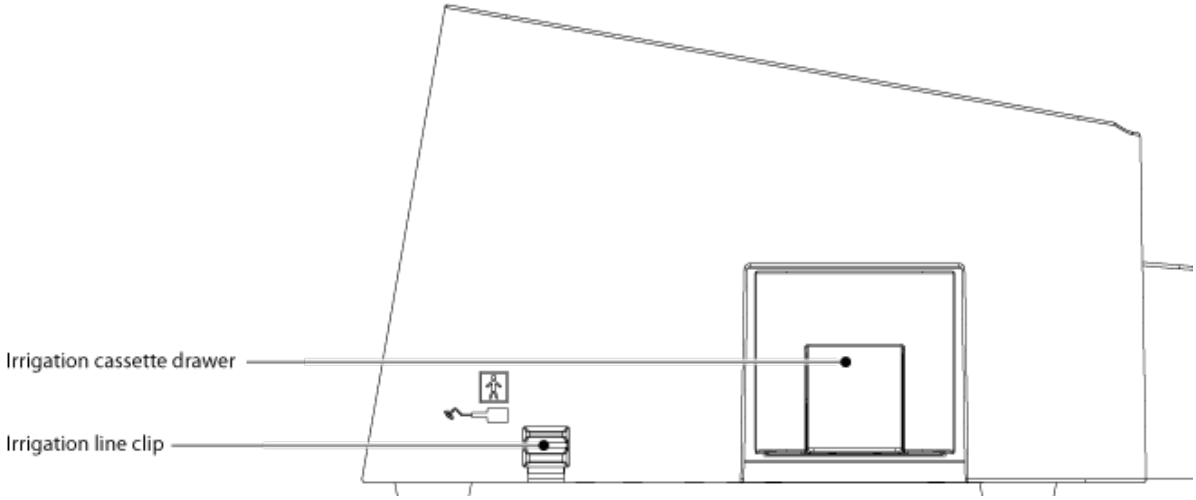
1. Disconnect the handpiece and cord assembly and refer to the cleaning, disinfection and sterilization instructions for the J12801 handpiece assembly
2. Clean the medical device as indicated in the chapter *Clean and disinfect the medical device page 23*.
3. Refer to the cleaning, disinfection and sterilization instructions for SATELEC, a company of Acteon group accessories listed in the chapter *Associated documentation page 3*.

7 Medical device description

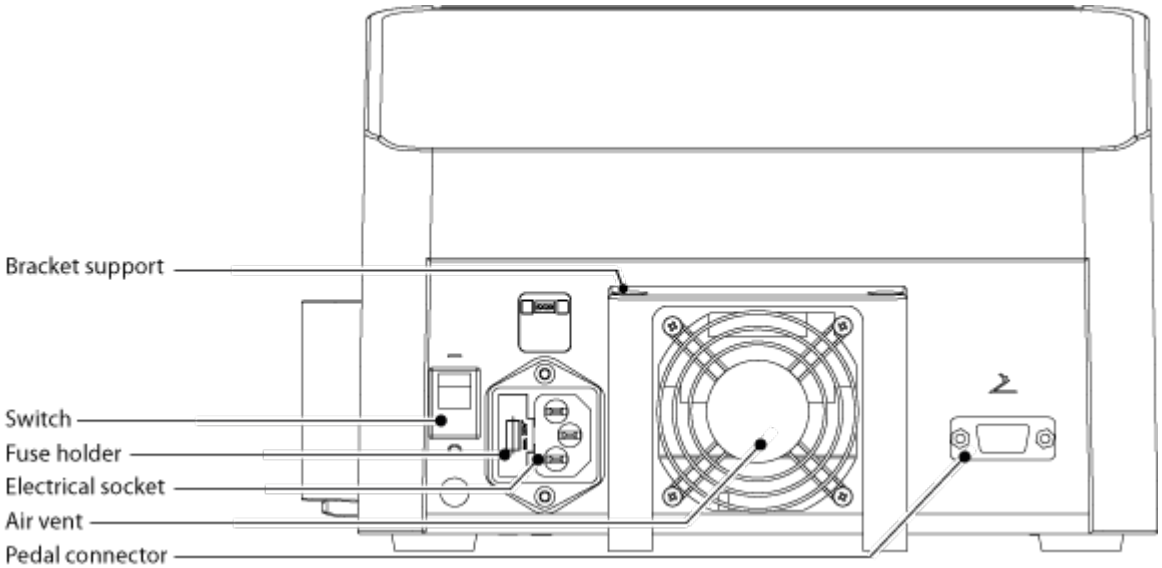
7.1 Front view of the medical device



7.2 View of the right-hand side of the medical device

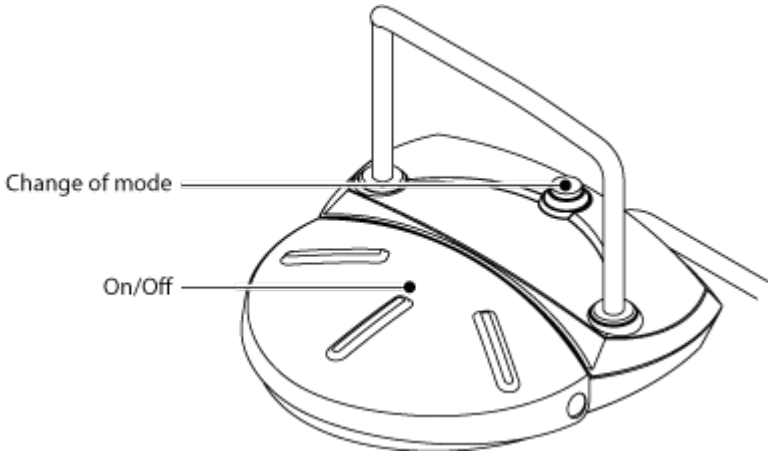


7.3 Rear view of the medical device



7.4 Recap of the interface

D1	D1 mode. The active mode is illuminated.
D2	D2 mode. An inactive mode is not illuminated.
D3	D3 mode
D4	D4 mode
↑	Touch-sensitive area. Press to change the mode.
↓	Touch-sensitive area. Press to change the mode.
+	Touch-sensitive area. Press to increase irrigation in steps of 10 ml/min.
−	Touch-sensitive area. Press to decrease irrigation in steps of 10 ml/min.
	Touch-sensitive area. Press and hold while purging.
	Indicator light. Comes on when the handpiece and cord assembly is not connected to the unit.
	Indicator light. Comes on when communications are not established between the mother board and the front face board. The touch-sensitive areas on the front and the pedal buttons are inactive.
	Press to switch from one mode to the other.
	Press to activate the ultrasounds.



7.5 Control unit

The control unit incorporates Newtron® technology patented by SATELEC, a company of Acteon group S.A. N°US6,765,333B1.

Newtron® technology emits ultrasonic vibrations in a controlled way. Relayed by SATELEC, a company of Acteon group tips, these vibrations are used to deliver effective treatments and to ensure patient safety.

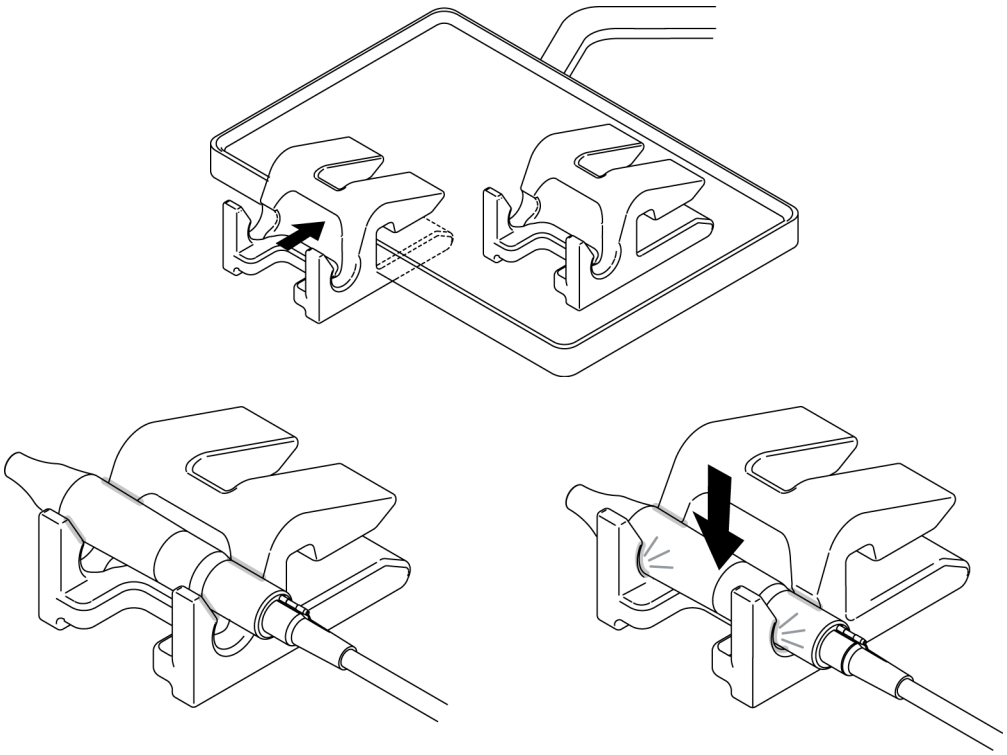
The control unit incorporates a dental ultrasonic generator equipped with a piezoelectric command.

7.6 Handpiece

Refer to the Cube LED handpiece user manual J28821 as well as to the handpiece and cord assembly cleaning, disinfecting and sterilizing protocol J12801 for more information.

The support holds the handpiece.

The handpiece support must be clipped as close to the working field as possible. Make sure that, once fitted with a tip, the handpiece is positioned so that it cannot become tangled up in clothing or cords.



7.7 The screen of the medical device

The screen displays the interface of the medical device.

Practitioners can use the touch-sensitive screen to make adjustments by pressing the active areas.

> Always make adjustments with a finger. Never use stylets or instruments, which could damage the screen.

> The touch-sensitive areas are capacitive and extremely sensitive. Therefore the screen must always be clean and dry in order to avoid any disturbance to the user settings.

The touch-sensitive areas that you can use to interact with the medical device are circled in black.

Adjust the irrigation flow by pressing the touch-sensitive areas + and −

Select the required mode by pressing the touch-sensitive areas ↑ and ↓

Press the touch-sensitive area to activate the purge

7.8 Adjusts the power

The ultrasound power must be adjusted in accordance with the tip used and the required treatment.

Select the required mode by pressing the touch-sensitive areas ↑ and ↓

Each tip must be used in accordance with the settings defined in the ultrasonic generator power settings table for intraoral surgery [J58010].

7.9 Setting the irrigation flow

The medical device must be set to minimum power in order to adjust the irrigation flow rate. Press the footswitch until a spray appears.

Because work habits, feedback, and professional training differ from one professional to another, the user must ensure that the irrigation flow is compatible with the procedure to be carried out to prevent burns to the clinical site.

Adjust the irrigation flow using the irrigation flow configuration arrows. This setting depends on the tip used and on the procedure to be carried out.

Adjust the irrigation flow by pressing the touch-sensitive areas + and −

7.9.1 Start the purge / start the irrigation

Press the purge icon and hold for as long as necessary.

Press the touch-sensitive area to activate the purge

7.10 Air inlets

Air inlets ensure correct ventilation of the control unit. Leave them uncovered to allow air to circulate.

7.11 Control pedal

The pedal may be set either to ON/OF operation or to progressive operation.

Pressing the pedal automatically activates the handpiece ultrasounds, and the irrigation function if it is not in 0 position.

The control pedal, equipped with its cord, must be disconnected for daily cleaning with a disinfecting alcohol wipe.

The light function remains active for approx. 9 seconds after the pedal is released.

For more information, refer to the *Control Pedal* chapter page 1.

7.12 Power Input

The AC connector is used to connect the device to the electrical network via a disconnectable AC cord.

7.13 Switch

The AC switch is used to switch on (position I) or to stop (position O) the medical device.

7.14 Fuse recess

The recess holds two fuses designed to protect the medical device in the event of overvoltage or an internal fault.
Refer to instructions on chapter *Replacing the fuses page 25*

7.15 Irrigation lines

Sterile irrigation lines must be discarded in a biomedical waste receptacle after use.
The irrigation bottles or bags must not exceed one kilogram. Heavier containers will cause the medical device to tip over.
The medical device is not designed to deliver medicamental substances.
The medical device is solely designed to be used with bottles of saline or sterile water.

8 Cleaning and sterilizing

The instructions relating to cleaning, disinfection and sterilization protocols for accessories 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 3*.

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 sterilization protocols for accessories take precedence over the information provided by SATELEC, a company of Acteon group.

8.1 Clean and disinfect the medical device

The medical device control unit must be cleaned and disinfected daily.

The control pedal must be cleaned and disinfected daily.

The handpiece cord must be cleaned, disinfected and sterilized after each use.

The medical device must be in OFF or O stop position during cleaning and disinfecting procedures.

Refer to the instructions in the chapter *Cleaning the irrigation system page 25*

Use alcohol disinfectant wipes.

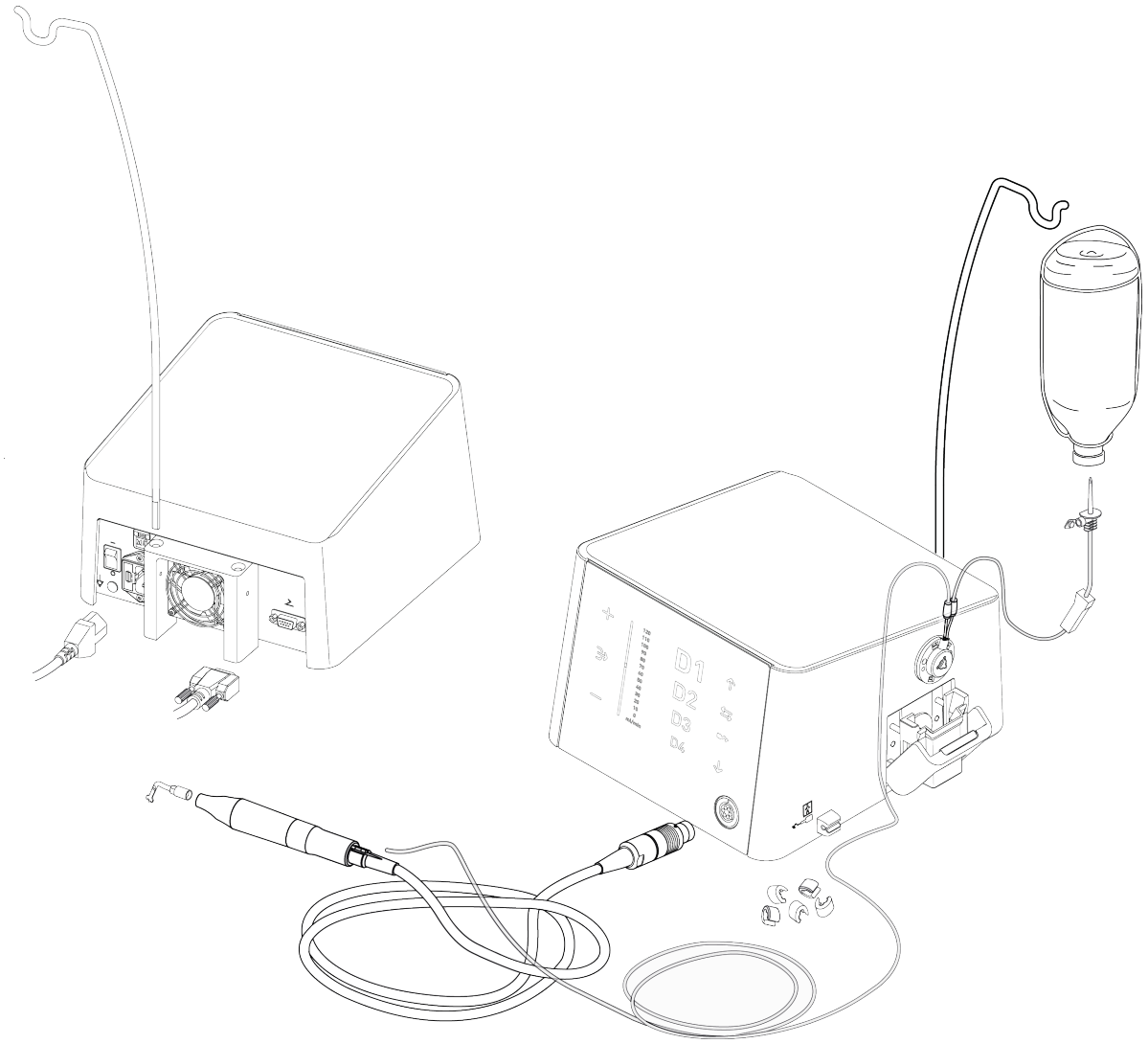
Avoid using cleaning and disinfection products that contain flammable agents.

Otherwise, ensure that the product has completely evaporated or that there is no fuel left on the medical device and its accessories before switching it on.

> Do not use an abrasive product to clean the medical device.

> Never apply sprays directly to the medical device to clean it. Always spray the product onto a wipe, then clean the medical device.

To prepare for cleaning, remove the various parts of the Piezotome Cube as shown here.



8.2 Cleaning, disinfecting and sterilizing accessories

Refer to the cleaning, disinfection and sterilization instructions for accessories listed in the chapter *Associated documentation page 3*.

8.3 Diamond coated tips

> Diamond coated tips are for single use only.

The diamond coated tips cannot be reprocessed since they cannot be cleaned properly. Bone and soil residues might remain adhered to the diamond coating even after cleaning and sterilization and enter into the oral cavity of another patient.

9 Monitoring and routine maintenance

The only preventive maintenance the medical device requires is:

- Monitoring of accessories
- Routine cleaning, disinfection, and sterilization
- Cleaning

Check the cleanliness of the air inlets on the control unit to prevent any heating.

Check the condition of the handpiece-cord assembly and the cord connectors.

Check the cleanliness of the handpiece nosepiece. It must be clean, smooth and corrosion-free. The handpiece must screw easily and firmly inside it.

Before and after use, check the medical device and its accessories thoroughly for any problems. This is necessary to detect any electrical isolation fault or damage. If necessary, replace damaged parts.

9.1 Cleaning the irrigation system

Operate the device at minimum power, at maximum irrigation flow rate for 2 minutes.

When irrigation bags are used to irrigate your medical device:

1. Disconnect the irrigation bag from the perforator of the irrigation line.
2. Discard the irrigation bag.
3. Soak the short end of the irrigation line in a recipient containing a hypochlorite solution diluted to less than 3%.
4. Press the Purge icon.
5. Operate the irrigation spray for 2 minutes to rinse the medical device's water system.
6. Refill the recipient with demineralized or distilled water.
7. Rinse the irrigation system for 2 minutes.

When the irrigation system has been cleaned, perform the following operations:

1. Disconnect the handpiece and cord assembly and refer to the cleaning, disinfection and sterilization instructions J12801 for the handpiece assembly
2. Clean and disinfect the medical device as indicated in the chapter *Clean and disinfect the medical device page 23*.
3. Follow the instructions for cleaning, disinfecting and sterilizing SATELEC, a company of Acteon group accessories [J81009] and [J02009].

9.2 Corrective Maintenance

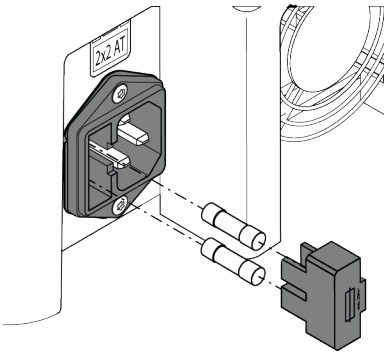
In the event of faulty operation, the following corrective maintenance actions may be performed by the user.

9.2.1 Replacing the fuses

The medical device is protected by two fuses in the AC connector.

To replace the fuses, perform the following operations:

1. Stop the medical device (position O).
2. Disconnect the AC cord from the electrical network.
3. Disconnect the AC cord from the AC connector.
4. Insert the tip of a flathead screwdriver into the notch on top of the fuse holder to release it.
5. Remove the used fuses.



6. Replace the used fuses with fuses of the same type and same rating.
7. Place the fuse holder in its recess by pushing it until you hear a click that confirms it is in the correct position.
8. Connect the AC cord to the AC connector.
9. Connect the AC cord to the electrical network.

10 Identifying incorrect operation

In the event of incorrect operation, refer to the tables below to quickly identify and repair the non-complex parts of the medical device.

If the incorrect operation is not described in the tables below, please contact your supplier or the customer service team at SATELEC, a company of Acteon group.

Do not use the medical device if it appears to be damaged or faulty. Isolate the medical device and make sure that it cannot be used.

10.1 Not working

Symptoms: the screen of the medical device is off and the medical device is not working.

Possible causes	Solutions
No electrical current	Contact your electrician
AC switch in position O	Set the AC switch to position I
Faulty connection between the AC cord and the electrical wall socket	Connect the mains cord to the electrical wall socket
Faulty connection between the AC cord and the AC connector	Connect the AC cord to the AC connector
AC fuses in the mains connector not working	Replace the AC fuses with fuses of the same type and rating
Internal fuse not working	Return to Acteon Customer Service team
If the screen is on, transmission fault	Switch off the medical device, wait for a few seconds, then switch it on again Return to the Acteon Customer Service team

10.2 No spray

Symptom: There is no water spray at the tip.

Possible causes	Solutions
Tip clogged	Unblock the tip using an ultrasonic tank
Incorrect choice of tip	Check the tip
Inadequate amount of spray	Adjust the spray
Irrigation solution bag or bottle empty	Install a full container
Irrigation deactivated	Activate the irrigation flow
Irrigation line pinched, blocked or faulty	Install a new irrigation line.

10.3 The power is not as expected

Symptoms: 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.

Possible causes	Solutions
Worn or bent tip	Replace the tip
Incorrect use: incorrect approach angle or inadequate pressure	Refer to the user instructions available at www.acteongroup.com

10.4 Ultrasounds not working

Symptoms: the tip does not vibrate.

Possible causes	Solutions
Tip loose	Fasten the tip using the wrench Renew your torque wrench once a year.
Faulty connector contact	Clean the cord contacts
Handpiece cord is cut	Return to the Acteon Customer Service team to replace the handpiece and cord
Adjust the power	Please read the *Setting the power* chapter

10.5 Water leakage

Symptoms: There is a water leak from the irrigation line or from the handpiece and cord assembly.

Possible causes	Solutions
The irrigation line is disfunctional	Replace the irrigation line with a new one

10.6 Disturbance of user settings

Symptoms: The medical device suddenly changes from one mode to another, the irrigation speed increases/decreases, or the purge suddenly turns on.

Possible causes	Solutions
Liquid on the medical device screen.	Turn off the medical device and wipe with a clean and dry cloth.

11 Technical specifications of the medical device

11.1 Identification

Manufacturer	SATELEC, a company of Acteon group
Name of the medical device	Piezotome Cube

11.2 Generator

Supply voltage	100 - 240 VAC
Power supply frequency	50 / 60 Hz
Power consumption	150 - 150 VA
Voltage supplied to handpiece	150 VAC
Power setting range	D1 - D4
Output frequency	28 kHz - 36 kHz
Type of leakage currents	LF
Operating mode	Intermittent: 10 minutes ON / 5 minutes OFF
Electrical rating	I
Fuse (AC connector)	2 T2AL fuses, 250 VAC
Width	251 mm
Height	160 mm, 481 mm with the bracket
Depth	271 mm
Weight	3 500 g without accessories
Ingress protection rating	IPX0

11.3 Length of cords

Handpiece cord	2000 mm +/- 50 mm
Control pedal cord	2000 mm +/- 50 mm

11.4 Irrigation

The irrigation bottles or bags must not exceed one kilogram. Heavier containers will cause the medical device to tip over.

Maximum volume of the irrigation solution bags	1,000 ml
Maximum weight of the irrigation solution bags	1 000 g
Nominal water output flow at the end of the handpiece Cube LED	0 ml/min to 120 ml/min
Maximum water output flow at purge	120 ml/min

11.5 Control pedal

Width	173 mm
Height	140 mm with arch
Depth	176 mm
Weight	1 060 g
Ingress protection rating	IPX1

11.6 Environmental characteristics

Ambient operating temperature	+10°C to +30°C
Operating RH	30% to 75 %
Atmospheric operating pressure	Between 800 hPa and 1060 hPa
Maximum altitude for operation	Equal to or less than 2000 meters
Storage temperature	0 to +50°C
Storage RH	10 % to 100 %, including condensation
Atmospheric pressure for storage	Between 500 hPa and 1060 hPa
Transportation RH	10 % to 100 %, including condensation
Atmospheric transportation pressure	Between 500 hPa and 1060 hPa

11.7 Environmental restrictions

Usage premises	Usable in all medical premises. The medical device must not be used in an operating theater or outdoors.
Use in gas-filled atmosphere	The medical device is not designed for use in a type AP or APG gas-filled atmosphere or in the presence of anesthetic gases.
Immersion	The unit must not be immersed.
Immersion	The ultrasound handpiece must not be immersed.

11.8 Main performance characteristics

Ultrasonic vibrations of the tip fitted to the end of the ultrasonic intraoral dental surgery handpiece.

12 Regulations and standards

12.1 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.

12.2 Medical class of the device

The medical device is a class II device according to the Code of Federal Regulations 21 CFR 872.4580.

12.3 Symbols

Symbol	Meaning
	Control pedal
O	Switching off (OFF)
I	Switching on (ON)
	Always wear protective eyewear
	Always wear protective gloves
	Refer to the supporting documentation
	Consult the user manual
	The accompanying documentation is available in electronic format
	Pressure limit
	Temperature limit
	Humidity limit

Symbol	Meaning
	Packaging unit
	Fragile. Handle with care
	Keep in a dry place
	Biohazard
	Sterilization at 132°C in an autoclave
	Washer-disinfector for thermal disinfection
	Ultrasonic bath
	LF type part in contact
	Alternating current
	Purge
	Electromagnetic interference
	CE marking
	CE marking
YYYY 	Year of manufacture
	Manufacturer

Symbol	Meaning
	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.
IPX1	**IP**: ingress protection rating 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

12.4 Manufacturer identification

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12.6 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 2012/19/EU, 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 33*.

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 May 2, 2012), our Company fulfils its obligations to reclaim and dispose of its electrical and electronic equipment through the means established by the approved organization 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 centers set up by Récylum for recycling (see list of collection centers 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.

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