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User Manual



Piezotome Cube

ACTEON

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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
General instructions relating to the complete range of dental ultrasonic generators	J00051
Cleaning, disinfection and sterilisation instructions for keys	J81001
Cleaning, disinfection and sterilisation instructions for tips	J02001
Cleaning, disinfection and sterilisation instructions for the Handpiece-piezotome cord assembly	J12801
Consulting electronic user instructions	J00007
Piezotome Cube Quick Start guide	J50150
Piezotome Cube Quick Clean guide	J50151
Piezotome Cube User Manual	J50101
Dental surgery ultrasonic generator power settings table	J58010
Installation flyer for handpiece support	J50152
Cube LED handpiece user manual	J28821

> The Quick Start and Quick Clean documents are summaries created for your approval. The only binding instructions are the user manuals and regulatory documentation associated with the medical device.

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 the following addresses:www.ultradent.com and www.satelec.com.
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.

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2 Required information

2.1 Intended use

The intended use of the Piezotome Cube SATELEC is to provide utilities and to act as a base for various dental instruments and accessories. This device is intended to be used by qualified professional dentists.

2.2 Indication for use

The Piezotome Cube is a command unit used in combination with the following items.
An intraoral surgery ultrasonic handpiece and an intraoral surgery tip. This combination is intended for use in intraoral surgery procedures, including osteotomy osteoplasty, syndesmotomy, membrane detachment and bone expansion.

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 an intraoral surgery dental tip attached to the end of the ultrasonic handpiece.
The medical device must be used with a Cube LED handpiece. Refer to the Cube LED [J28821] handpiece user manual for further information.

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 makes of tips will damage the handpiece and break the tips.

2.5 Connecting and disconnecting accessories during use

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

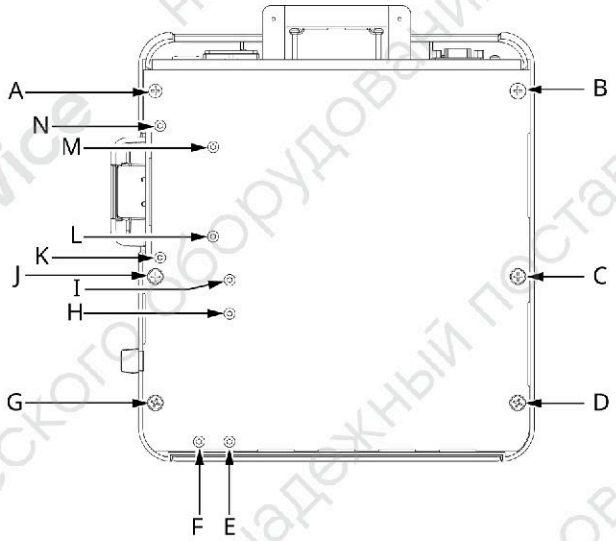
2.6 Repairing or modifying the medical device

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.

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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

03/2018

2.9 Date of first CE marking

2017

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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.
The Piezotome Cube features the items listed in the document J50154. The article codes of the items for restocking are indicated in the same document.

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4 Connect the medical device

4.1 Connecting the medical device to the electrical network

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

Switch the medical device OFF (position O) and check that the mains voltage is compatible with that indicated on the medical device or its mains 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 earth must be connected to a supply network equipped with a protective earth.

> Do not plug the medical device into an extension lead and do not put the mains 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 mains switch to "O" OFF position.
2. Connect the mains cord to the control unit's mains connector.
3. Connect the power lead to the mains socket.

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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 - the switch and the power plug - 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 footswitch cord to the back of the medical device.
The control pedal must be positioned near the feet of the operator and must be readily accessible.

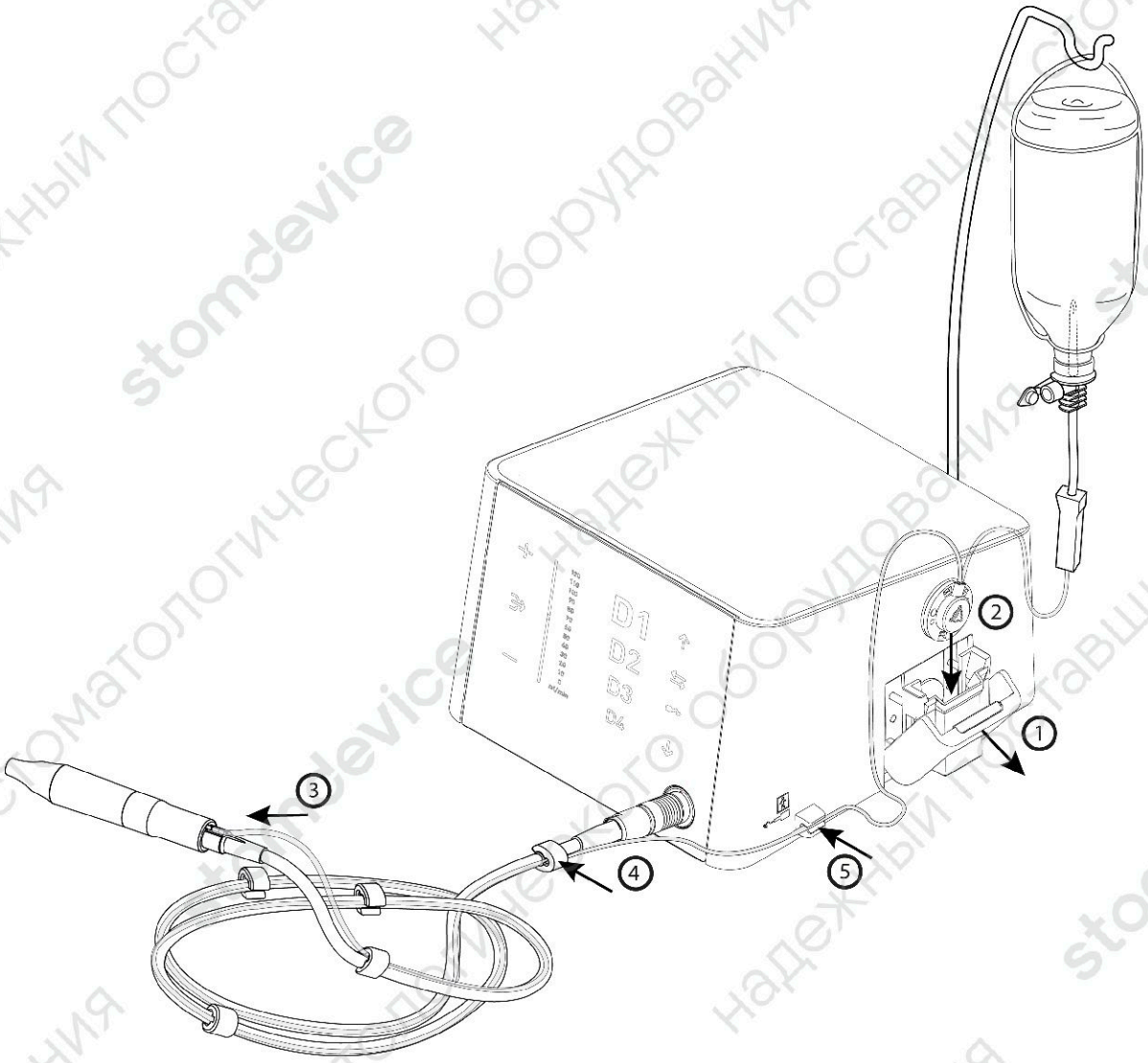
5.3 Connecting the handpiece

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

5.4 Installing an irrigation line

1. Remove the irrigation line from its sterilisation bag.
2. Remove the clips from their bag.
3. Open the cassette holder on the right side of the medical device.
4. Insert the cassette and close the holder.
5. Connect the end of the irrigation line, the long infusion line, to the handpiece
6. Working your hands along the handpiece cord, attach the irrigation line to the handpiece cord using the clips.
   Any excess irrigation line will be at the medical device unit and will not hamper use of the handpiece.
7. On the short infusion line side, pierce the irrigation solution bag with the perforator.
8. When the medical device is switched ON, open the perforator cap and purge the irrigation system.

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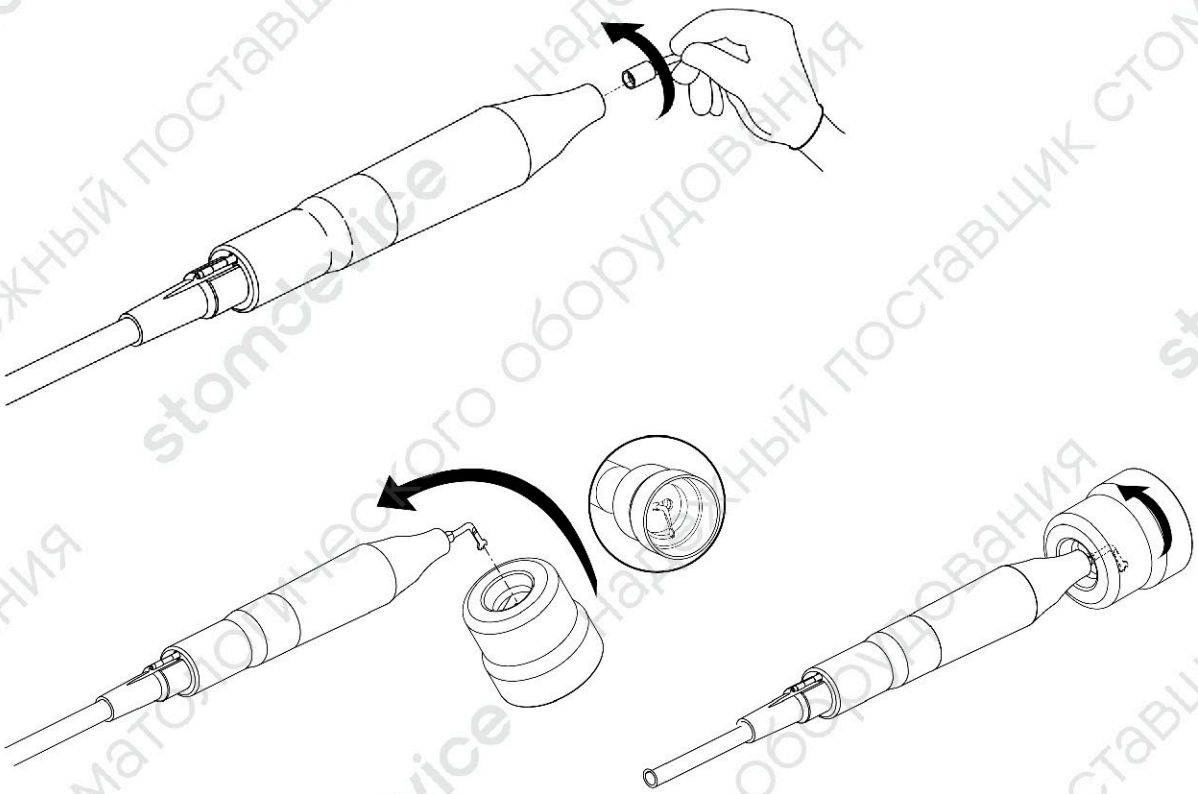


5.5 Attaching a tip

The tips that can be used on this medical device are referred to as "second generation". They are recognizable by the engraving II on the base. They are incompatible with first-generation Implant Center and Piezotome tips.
Conversely, older-generation tips are incompatible with Piezotome Cube, Implant Center 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 sterilised after each use.

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The wrench is a sliding torque wrench. After a few turns, the wrench will seem to slide or turn without resistance. This means the tightening torque is reached.

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6 Dispensing a treatment

6.1 Accessory usage conditions

The accessories of the Piezotome Cube must be cleaned, disinfected and sterilised before use.



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

> This medical device is designed to be used in conjunction 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 place.
3. Clean the unit with an alcohol disinfectant wipe.



1. Put the bracket in place.
2. Connect the handpiece cord to the connector on the front of the medical device.
3. Remove the handpiece support from its sterilisation pouch.
4. Remove the handpiece and its cord out of its sterilisation pouch.
5. Remove the wrench from its sterilisation bag.
6. Remove the tip from its sterilisation 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 place on the bracket.
10. Remove the irrigation line and its cassette from its sterilisation bag or packaging if sterile.
11. Put in place the irrigation line and its cassette, up to the irrigation bag.
12. Switch on the medical device.
13. Check the irrigation settings according to the chosen tip and adjust the flow via the touch zones.

    + and − .
14. Check the mode according to the chosen tip and adjust the active mode via the touch zones

    ↑ and ↓ .
15. Above a water drain, check that the spray of the handpiece is working properly.

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.

This allows the autoclavable irrigation line to be cleaned prior to being disinfected, cleaned and sterilised.

When using irrigation solution bags to irrigate your medical device:

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

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4. Press the Purge icon .
5. Operate the irrigation spray for two minutes to rinse the medical device's internal water system.
6. Refill the tank with demineralised or distilled water.
7. Rinse the irrigation system for two minutes.

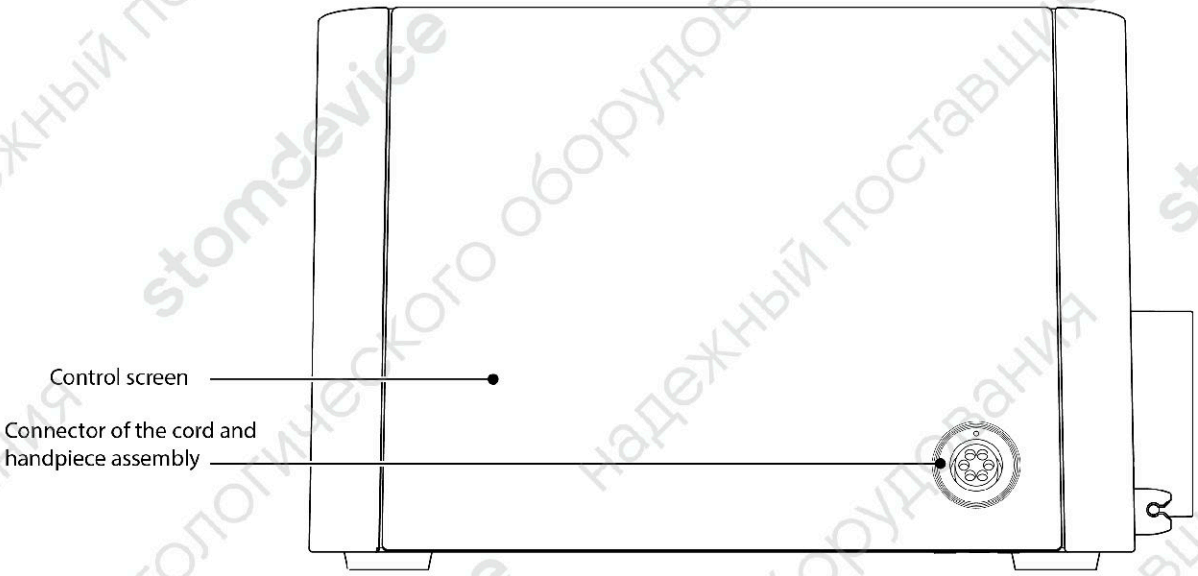
When the irrigation system has been cleaned, perform the following operations:

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

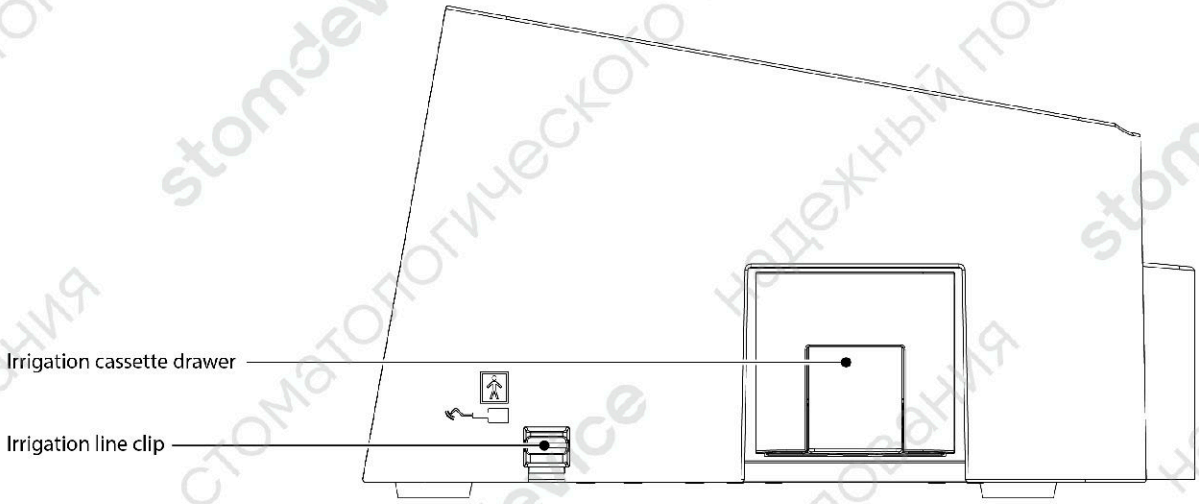
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7 Medical device description

7.1 Front view of the medical device

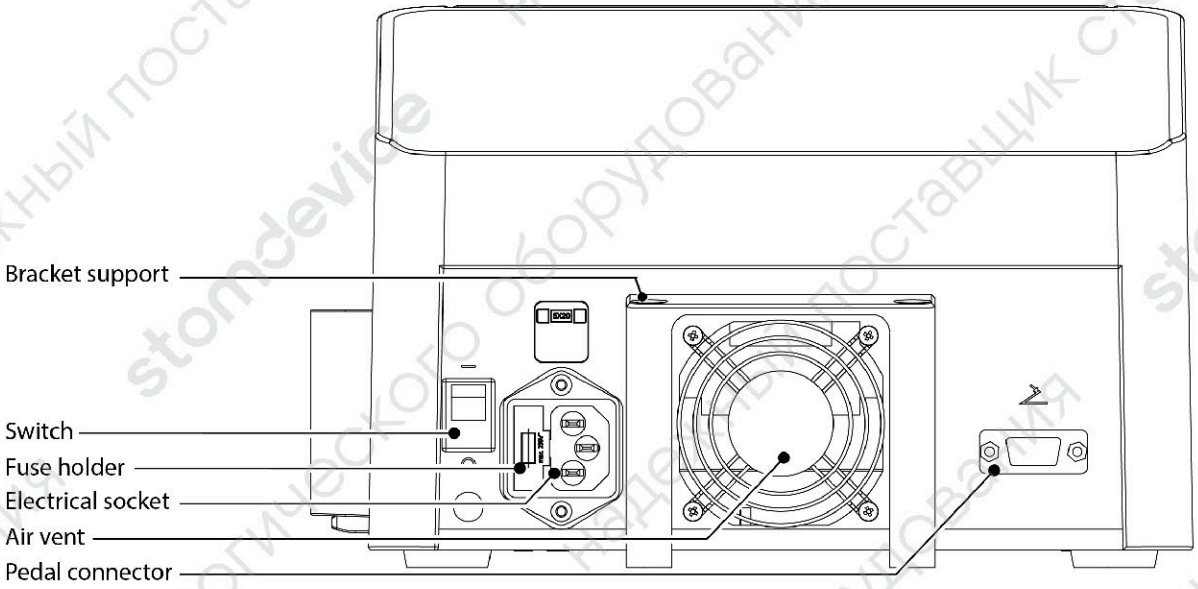


7.2 View of the right-hand side of the medical device



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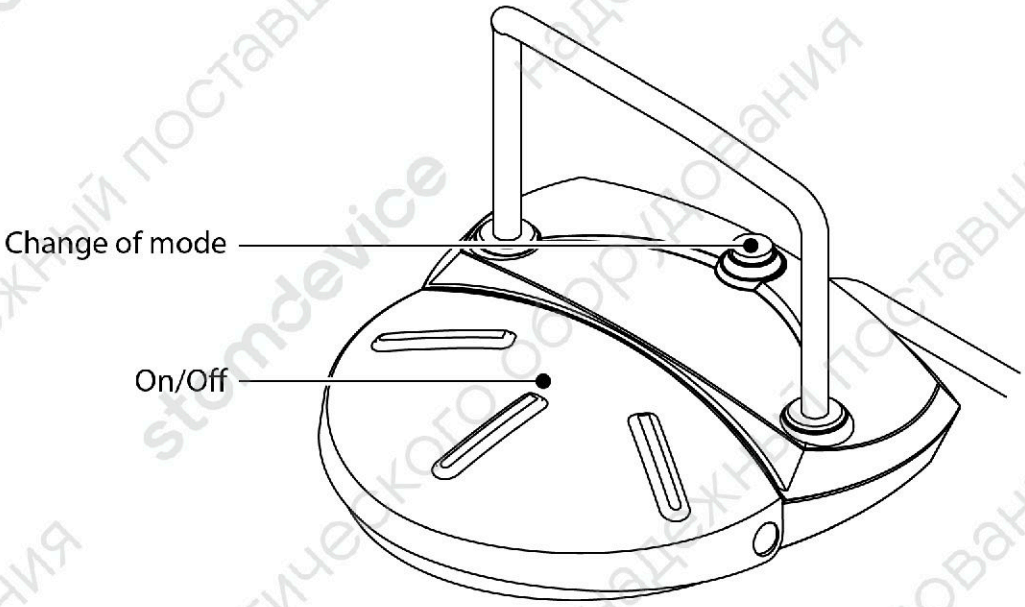
7.3 Rear view of the medical device



7.4 Overview of the interface

D1	D1 mode. The active mode is the illuminated mode.
D2	D2 mode. An inactive mode is not lit.
D3	D3 mode
D4	D4 mode
↑	Tactile zone. Press to change the mode.
↓	Tactile zone. Press to change the mode.
+	Tactile zone. Press to increase irrigation in steps of 10 ml/min.
−	Tactile zone. Press to decrease irrigation in steps of 10 ml/min.
	Tactile zone. Press and hold the purge time.
	Indicator. Lights on when the handpiece-cord assembly is not connected to the unit.
	Indicator. Lights on when communication between the motherboard and the front-panel board is not established. The tactile zones of the front face and the buttons of the pedal are inactive.
	Press to switch from one mode to another:
	Press to activate the ultrasound.

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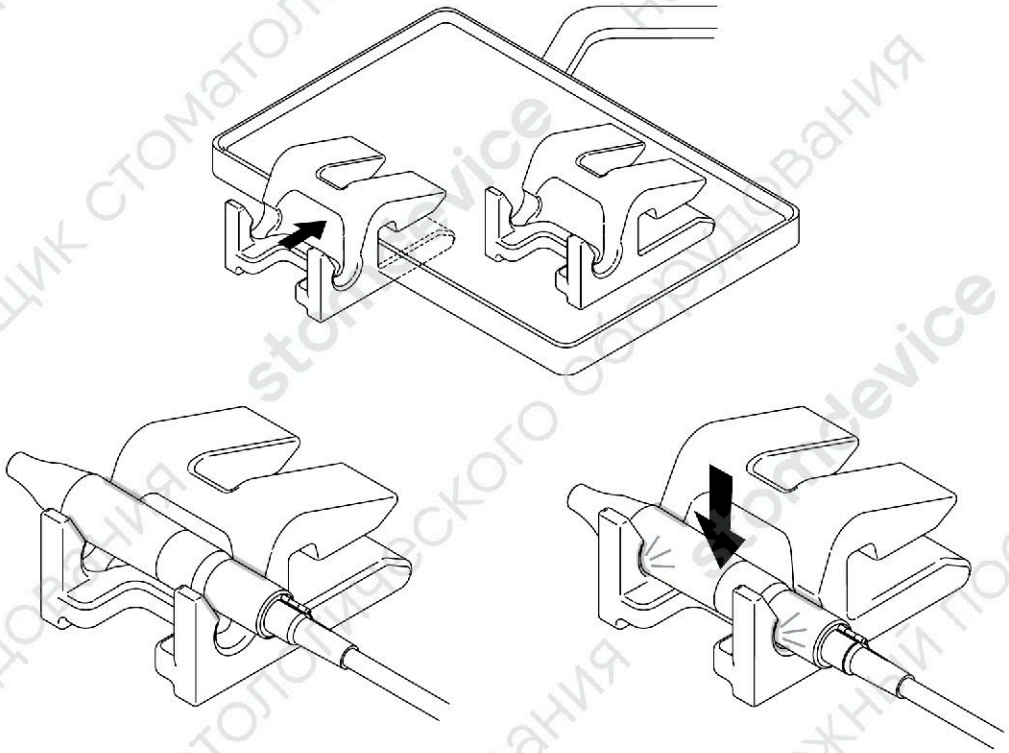


7.5 Control unit

The control unit incorporates Newtron® technology patented by SATELEC, a company of Acteon group .
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 an dental ultrasonic generator equipped with a piezoelectric command.

7.6 Handpiece

Refer to the user manual of the Cube LED J28821 handpiece, and to the protocol for cleaning, disinfecting and sterilising the J12801 handpieces and cord for further information.
The support holds the handpiece.
The handpiece support should be clipped as close as possible to the work area. Be sure to position it so that the handpiece, once fitted with a tip, cannot get caught in clothes or cords.



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7.7 Screen of the medical device

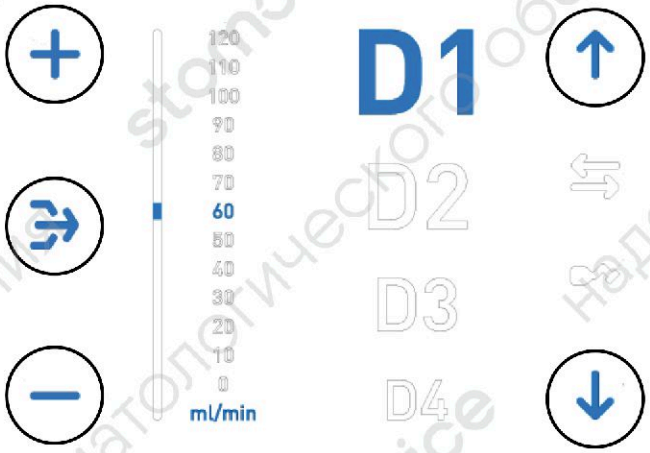
The screen of the medical device serves as the interface display.

It is tactile such that practitioners can make adjustments by pressing the active areas.

> Always make adjustments with your finger. Never use stylets or instruments, as these may damage the screen.

> The touch zones are capacitive and extremely sensitive. The screen must therefore be constantly clean and dry to avoid disturbing user-defined settings.

The tactile areas, those with which you can interact with the medical device, are as shown below.



Set the irrigation flow by pressing the tactile zones + and −

Select the requisite mode by pressing the tactile zones ↑ and ↓

Activate the purge by pressing the tactile zone ⇉

7.8 Setting the power

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

Select the requisite mode by pressing the tactile zones ↑ and ↓

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

7.9 Setting the irrigation flow

The medical device must be set to minimum power 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.

Set the irrigation flow by pressing the tactile zones + and −

7.9.1 Activating the purge function/starting irrigation

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

Activate the purge by pressing the tactile zone ⇉

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 can be set either in ON/OFF mode or in progressive operation.

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Pressing the foot-switch automatically activates the handpiece ultrasounds and the irrigation function.
The control footswitch fitted with its cord must be disconnected for daily cleaning using an alcohol disinfectant wipe.
The light function remains active for approx. 9 seconds after the pedal is released.
For further information, refer to the chapter entitled *Pedal Overview page 1*.

7.12 Mains Connector

The mains connector with its earthing pin is used to connect the device to the electrical network via a disconnectable mains cord.

7.13 Switch

The mains 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.
Please read the instructions listed in the chapter *Replacing the fuses page 25*

7.15 Irrigation lines

The autoclavable irrigation lines can be reused after cleaning, disinfection and sterilisation.
After use, sterile irrigation lines should be discarded in a biomedical waste container.
Bottles or irrigation bags should not weigh more than one kilogram. A heavier container will make the medical device tip over.
The medical device is not designed to deliver medicinal substances.
The medical device may only be used with bags or bottles of saline solution or sterile water.

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8 Disinfection and sterilising

The instructions relating to cleaning, disinfection and sterilisation protocols for accessories supplied 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 sterilisation 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's control unit must be cleaned and disinfected daily.

The medical device's control pedal must be cleaned and disinfected daily.

The handpiece and its cord must be cleaned, disinfected and sterilised after use.

The autoclavable irrigation lines must be cleaned, disinfected and sterilised 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.

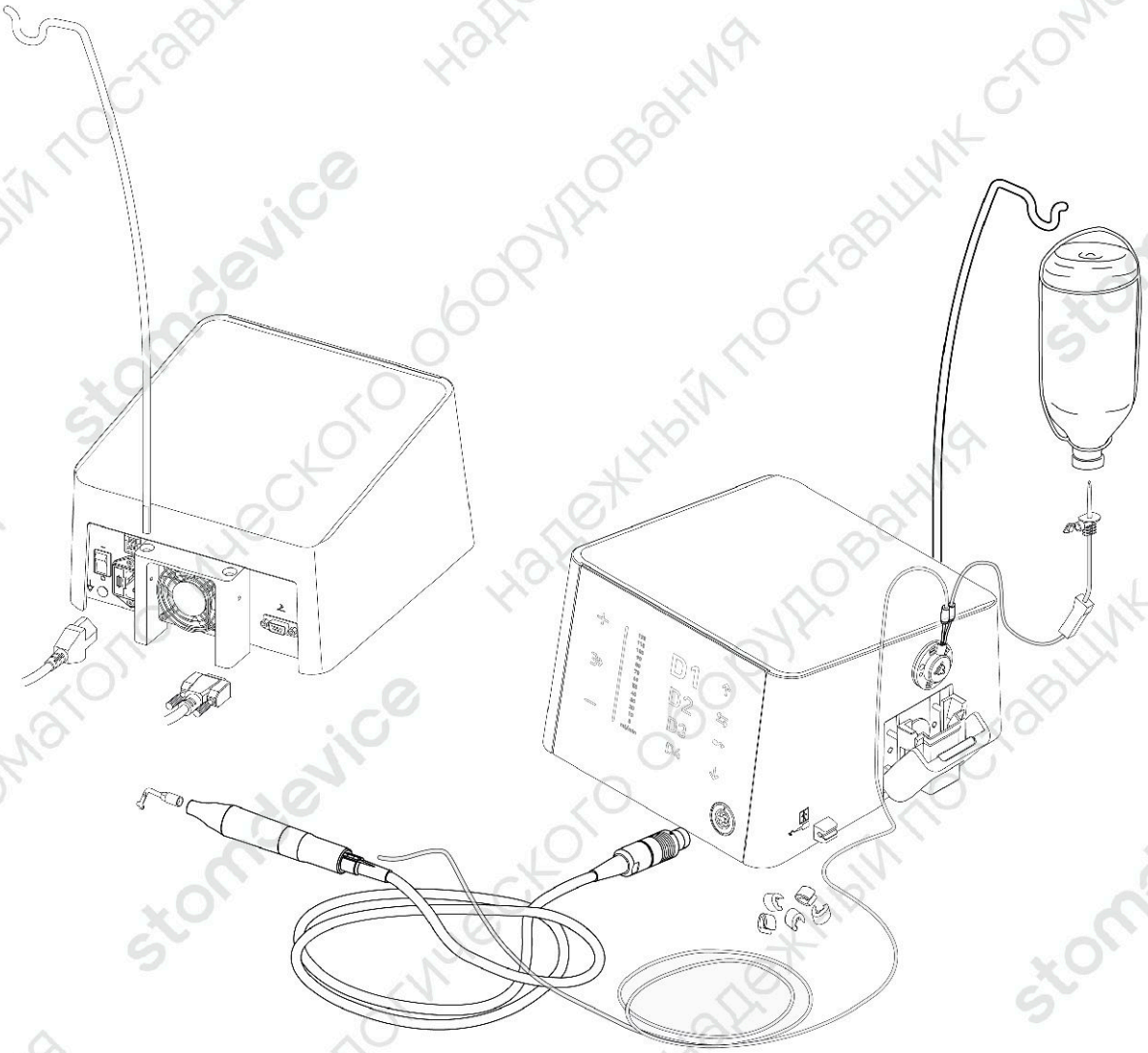
> Never apply sprays directly to the medical device to clean it. Always spray the product onto a wipe, then clean the medical device.

The autoclavable irrigation lines must be cleaned, disinfected and sterilised after each use.

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

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8.2 Cleaning, disinfecting and sterilising accessories

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

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9 Monitoring and routine maintenance

The only preventive maintenance the medical device requires is:

- Monitoring of accessories
- Routine cleaning, disinfection and sterilisation
- 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 entirely 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 two minutes.

This allows the autoclavable irrigation line to be cleaned prior to being disinfected, cleaned and sterilised.

When using irrigation solution bags to irrigate your medical device:

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

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

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

9.2 Corrective Maintenance

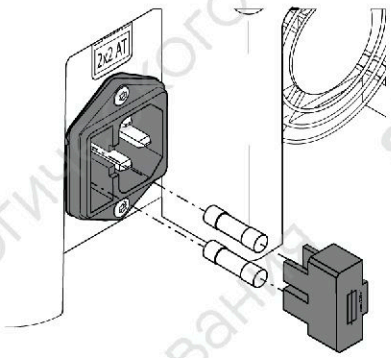
In the event of faulty operation, the following corrective maintenance actions may be performed by the user.

9.2.1 Replacing the fuses

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

To replace the fuses, perform the following operations:

1. Stop the medical device (position O).
2. Disconnect the mains cord from the electrical network.
3. Disconnect the mains cord from the mains 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.



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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 mains cord to the connector.
9. Connect the mains cord to the electrical network.

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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
Mains switch in position O	Set the mains switch to position I
Faulty connection between the mains cord and the electrical wall socket	Connect the mains cord to the electrical wall socket
Faulty connection between the mains cord and the mains connector	Connect the mains cord to the mains connector
Mains fuses in the mains connector not working	Replace the mains fuses with fuses of the same type and rating
Internal fuse not working	Return to the Acteon Customer Service team
If the display is on, transmission failure	Turn off the medical device, wait a few seconds, then turn it back on Return to the Acteon Customer Service team

10.2 No spray

Symptom: There is no water spray at the tip.

Possible causes	Solutions
Blocked tip	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 angle of incidence or inadequate pressure	Refer to the user instructions available at www.acteongroup.com

10.4 Ultrasounds not working

Symptoms: the tip does not vibrate.

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Possible causes	Solutions
The tip is incorrectly tightened	Fasten the tip using the wrench Replace your torque wrench once a year
Faulty connector contact	Clean the cord contacts
Cut handpiece cord	Return the handpiece and cord to the Acteon Customer Service team to have them replaced
Adjust the power	Please read the *Setting the power* chapter

10.5 Water leakage

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

Possible causes	Solutions
Dysfunctional irrigation line	Replace the irrigation line with a new one.

10.6 Disturbance of settings defined by the practitioner

Symptoms: the medical device suddenly switches from one mode to another, the irrigation flow increases/decreases or the purge function suddenly starts up.

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

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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	BF
Operating mode	Intermittent: 10 minutes ON / 5 minutes OFF
Electrical rating	I
Fuse (mains connector)	2 fuses T2AL, 250 VAC
Width	251 mm
Height	160 mm, 481 mm with bracket
Depth	271 mm
Weight	3,500 g without accessories
Ingress protection rating	IPX0

11.3 Length of cords

Handpiece cord	2 500 mm +/- 50 mm
Control pedal cord	2 500 mm +/- 50 mm

11.4 Irrigation

Bottles or irrigation bags should not weigh more than one kilogram. A heavier container will make the medical device tip over.

Maximum volume of irrigation solution bags	1,000 ml
Maximum weight of 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 Footswitch

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

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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 operating altitude	Equal to or less than 2000 metres
Storage temperature	0°C to +50°C
Storage RH	10% to 100 %, including condensation
Atmospheric storage pressure	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 theatre 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 anaesthetic gases.
Immersion	The console must not be immersed.
Immersion	The handpiece must not be immersed.

11.8 Main performance characteristics

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

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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

Class of medical device: IIa according to 93/42/EEC directive

12.3 Symbols

Symbol	Meaning
	Footswitch
O	Switching off (OFF)
I	Switching on (ON)
	Always wear safety goggles
	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

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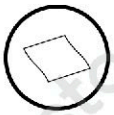
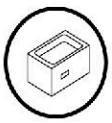
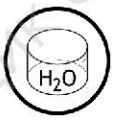
Symbol	Meaning
	Packaging unit
	Fragile, handle with care
	Store in a dry place
	Biohazard
	Sterilisation at 134°C in an autoclave
	Sterilisation at 132°C in an autoclave
	Washer-disinfector for thermal disinfection
	Ultrasonic bath
	Type BF part in contact
	Alternating current
	Purge
	Electromagnetic interference
	CE marking
	CE marking
	Year of manufacture
	Manufacturer

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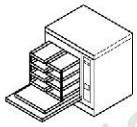
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Symbol	Meaning
	Do not dispose of as household waste
recylum	Recycle your lamps and professional electrical equipment with Récylum
Rx Only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.
IPX1	**IP**: ingress protection 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

12.4 Quick Start and Quick Clean symbols

	Use a dipping tank for cleaning
	Use a soft brush for cleaning
	Use a lint-free cloth for cleaning
	Use an ultrasonic tank for cleaning.
	Use a swab for cleaning
	Use deionised or osmosis-purified water for cleaning
	Use an alcohol disinfectant wipe for pre-disinfection and cleaning.
	Do not use the ultrasonic tank for cleaning.
	Clean under running water

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	Use a syringe for cleaning
	Use a washer-disinfector for cleaning and disinfection
	Use a pre-vacuum air autoclave for sterilisation

12.5 Manufacturer identification

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CE 0459
CE Marking

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12.7 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 35*.



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.

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