User Manual

OPERATING ROOM CERTIFIED

Piezotome Solo M+

SATELEC ACTEON

Contents

Foreword

The SATELEC® medical device that you are about use is designed for professional use only. It is therefore a key tool with which you will provide treatment within the context of your work.

These medical devices are designed to be used exclusively within a hospital or private clinic operating theatre. Patients will be under general anaesthesia unless the procedure only requires local anaesthesia.

To ensure optimum safety for yourself and your patients, comfort in your daily practice and to benefit fully from your medical device's technology, 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 instructions for the entire range of SATELEC® M+ ultrasonic medical generators for information about the following:

- documentation format;
- documentation archiving period;
- warnings concerning user and patient populations;
- treatment area;
- medical device usage interactions, contraindications and prohibitions;
- electromagnetic compatibility;
- disposal and recycling of the medical device;
- manufacturer responsibility.

Please refer to the various cleaning, disinfection and sterilisation protocols for information about the following:

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

1 Documentation

This document contains the following information:

- indications for use
- medical device description
- installation of the medical device
- medical device use
- preparation prior to cleaning and disinfecting 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 M+ medical ultrasonic generators	J57821
General instructions relating to all M+ medical handpieces	J12861
Method for consulting electronic user instructions	J00000
Cleaning, disinfection and sterilisation protocols for SATELEC® tips	J02001
Cleaning, disinfection and sterilisation protocols for the Piezotome® M+ handpiece	J12801
Piezotome Solo ® M+ Quick Start	J57860
Piezotome Solo ® M+ Quick Clean	J57861
Piezotome Solo ® M+ user manual	J57851
Piezotome® M+ handpiece user manual	J57521
Pack M+ Quick Start	J57870
Pack M+ Quick Clean	J57871
Pack M+ user manual	J57841
User manual for sterile M+ bone surgery tips	J87601
User manual for non sterile M+ bone surgery tips	J87611
M+ bone surgery tips Quick Reference	J87621
User manual for the sterile CMF kit	J57831
User manual for the non-sterile CMF kit	J57881

1.2 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.

2 Required information

2.1 Indication for use

The Piezotome Solo ® M+ is an ultrasonic surgical device that uses a handpiece combine with M+ tips for cutting into bone, metal and bone substitutes.

The device's Piezotome® M+ surgical piezoelectric part can be used for osteotomy, osteoplasty, decortication, drilling, shaping and smoothing of teeth and bone in various surgical procedures, including but not limited to general, orthopaedic, otolaryngological, maxillofacial, oral, hand and foot, neurosurgery, spinal and plastic/reconstructive surgery.

The device can be used on patients of all ages, including paediatric patients.

2.2 Operating principle

An electrical signal emitted by the medical device is supplied to the dental piezo-ultrasonic handpiece. It comprises a piezoelectric ceramic transducer, which converts the electrical signal into ultrasonic vibrations. Mechanical vibrations are transmitted to a tip attached to the end of the ultrasonic handpiece.

The vibrations, applied with a very gentle pressure, cut the bone with ultrasounds. They act distinctively on the bone, minimising the risks of damaging the soft tissue, thereby guaranteeing a more precise and safe procedure with less strain on the surgeon's hand. This ultrasonic piezoelectric surgical procedure also improves bone healing.

2.3 Date of first inclusion of EC marking

2013

2.4 Latest document update

09/2013

2.5 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®.

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.

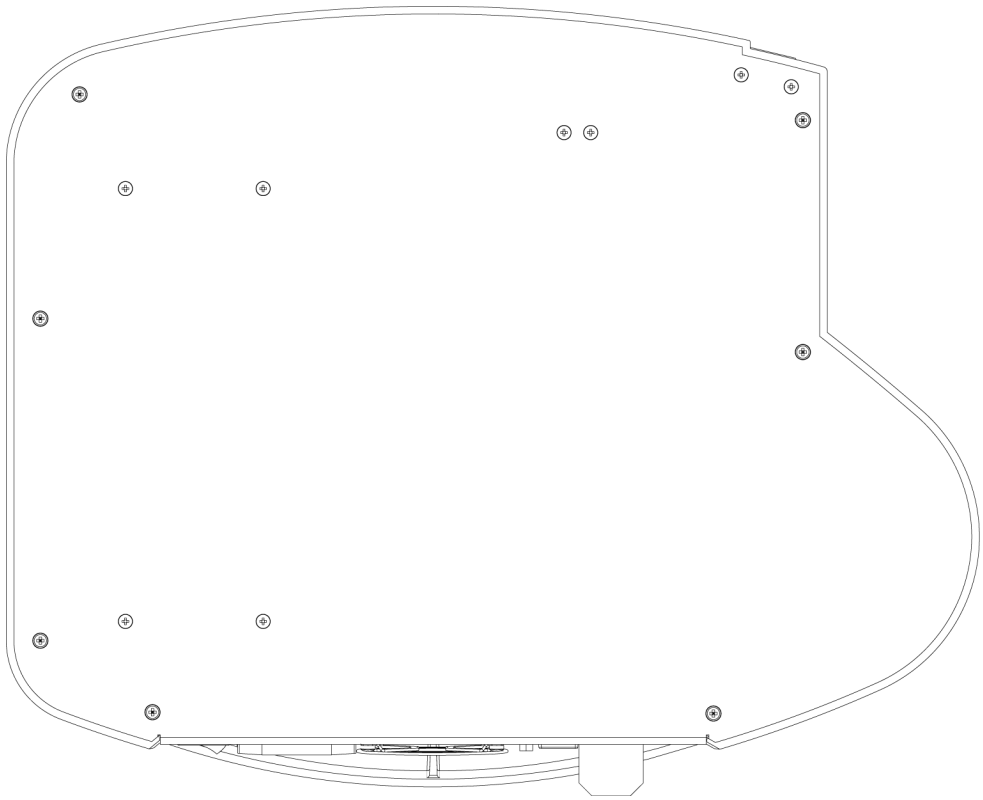
In the event of doubt, contact an approved dealer or the SATELEC® customer service team:

`www.acteongroup.com`

`satelec@acteongroup.com`

> SATELEC® at the request of technical personnel working for the network of dealers approved by SATELEC®, provide all information required to repair the faulty parts on which they may perform repairs.

2.6 Warranty



The user may not remove any of the screws shown on this view, as this would invalidate the medical device's warranty.

2.7 Accessory usage conditions

Accessories, handpieces must be cleaned, disinfected and sterilised prior to use.

3 Removal from packaging, installation, connections

3.1 Removing the medical device from its packaging

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 Solo ® M+ includes the following items:

- a Piezotome Solo ® M+ unit
- a multifunction footswitch
- one peristaltic pump recess
- one Irrigation solution bracket
- five irrigation lines with 10 single-use sterile clips
- one handpiece support
- 15 single-use, sterile irrigation line perforators
- a power cord
- a [J57860] Quick Start guide, a [J57861] Quick Clean guide
- an attachment kit.

3.2 Installing the medical device

Place the control unit in the position that is suitable for your activity. Check that the cords do not hinder the movement or free circulation of anyone. The medical device must be placed on a secure and flat surface or a surface with a maximum slope of 5 degrees.

Fix your medical device using the attachments provided to ensure that the device cannot be removed without the use of a tool.

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.

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

3.3 Installing cords

Check that the cords do not hinder the movement or free circulation of anyone. Make sure that it is not possible to wheel over or walk on the different cords. Cords attached to their I-Surge LED micromotor must be readily accessible. Make sure that the cord is slack during use.

Never rotate the handpiece connector on its cord as this can damage your medical device.

> Never wrap the handpiece cord around the medical device. Do not put the medical device cords in a cable cover or a cable tray.

3.4 Connecting the medical device to the electrical network

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

The medical device is equipped with a protective ground connection and must be connected to a mains power supply with a protective ground.

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

A different voltage would cause damage to the medical device and could injure the patient and/or 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.

> 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.

3.5 Fixing the medical device to a non-removable support

Your medical device is not designed to be moved. To avoid accidentally dropping the device, we recommend that you find a suitable place to install it in your practice and attach it with the kit [F57811] supplied with it, to ensure that it cannot be dismantled or moved without using a tool.

4 Medical device description

4.1 Control unit

The piezo-ultrasonic technology common to both piezoelectric handpieces, called Newtron®, is a patented system that automatically controls the frequency and power of tips in real time: the Cruise Control® system. Ultrasonic tips therefore maintain an even efficiency on the work area, regardless of the environment. Ultrasonic tips are active on hard tissue only, with minimal risks for soft tissues.

The piezo-ultrasonic technology of the piezoelectric handpiece, called Newtron®, is a patented system that automatically controls the frequency and power of tips in real time: the Cruise Control® system. Ultrasonic tips therefore maintain an even efficiency on the work area, regardless of the environment. Ultrasonic tips are active on hard tissue only, with minimal risks for soft tissues.

The touch-sensitive interface calls up all programmes stored in the memory and adjusts them before and after use.

4.2 I-Surge LED micromotor

Only SATELEC® handpieces can be connected to the medical device. For further information, refer to the documentation listed in chapter chapter *Associated documentation* page *5*.

4.3 Cords

The Piezotome® M+ cord is only compatible with the Piezotome® M+ handpiece. It ensures circulation and is used to connect the medical device to the Piezotome® M+ handpiece.

4.4 Inlets

The inlets at the back of the medical device provide suitable ventilation of the control unit and must be kept clear.

4.5 Switch

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

4.6 Mains connector

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

4.7 Fuse recess

The mains cord connector holds the recess for two mains fuses designed to protect the medical device in the event of overvoltage or an internal fault.

4.8 Pump

The medical device is fitted with a peristaltic pump. A single-use pump is connected to the irrigation line.

5 User interface

Buttons	Meaning	Power
	Programme D1	Very powerful
	Programme D2	Powerful
	Programme D3	Average power
	Programme D4	Low power
	Plus	
	Minus	
	Save	

Programme	Irrigation
D1	60 ml/min
D2	60 ml/min
D3	60 ml/min
D4	60 ml/min

Fine setting adjusts the power level for each programme between 1 and 5. The power value is a percentage of the maximum power at D1-5.

Programme	D1
Frequency modulation	60 Hz

Programme	D2
Frequency modulation	60 Hz

Programme	D3
Frequency modulation	60 Hz

Programme	D4
Frequency modulation	30 Hz

6 Medical device use

6.1 Preparing the medical device

6.1.1 Connecting the medical device to the electrical network

- Set the ON/OFF switch to O position (off).
- Connect the power cord to the device's mains connector.
- Connect the mains power cord to the mains socket equipped with an earthing pin.
- If necessary, connect the potential equalisation cable to the medical device's potential equalisation terminal marked with  .

6.1.2 Footswitch

The practitioner can start up the medical device using the footswitch. Press the footswitch to automatically start the ultrasounds on Piezotome® M+.

The footswitch equipped with its cord cannot be disconnected. Its weight and antislip pad ensure good stability.

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

6.1.3 Installing the footswitch

The footswitch must be positioned near the operator's feet and must always be within reach.

6.1.4 Connecting the Piezotome® M+ handpiece

Check for any traces of humidity on the handpiece cord connector. Wipe them off if there are any.

Connect the cord connector to the socket, by aligning the red indexing points and by avoiding rotation movement. Place the handpiece on the support.

6.1.5 Installing the irrigation system

Equipment: one sterile M+ irrigation line, 10 single-use sterile clips, one sterile perforator with cap, one bracket, one solution bag.

1. Insert the bracket into its holder
2. Open an irrigation line with its cassette
3. Slide the cassette into its support on the side of the medical device
4. Install the clips on the handpiece cord
5. Attach the irrigation line
6. Connect the end of the irrigation line to the water inlet on the handpiece
7. Install a bag on the bracket
8. Remove the cap from the perforator and insert the perforator into the solution bag.

> The medical device must always be used with SATELEC® M+ irrigation lines.

The medical device is not designed to administer medication and must only be used with bottles or bags containing no more than 1 litre of physiological saline solution or sterile water.

6.1.6 Purging the medical device

The medical device must be purged before and after use.

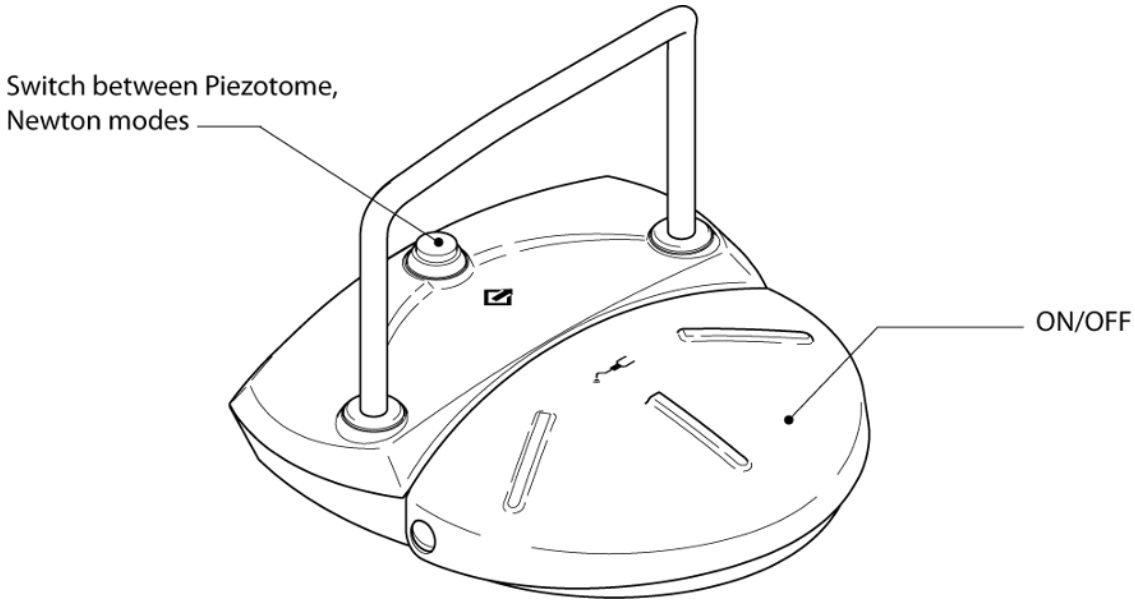
1. Immerse the irrigation line perforator in a container with distilled water.
2. Press  to rinse the irrigation line and handpiece.
3. Minimum purge time is 1 minute.

6.2 Switching on the medical device

Place the I/O switch to I. indicates that the device is switched on by an audible signal.

6.2.1 Common operations using the footswitch

The footswitch is used for common operations.



6.3 Connecting and disconnecting M+ accessories during use

> Do not connect/disconnect the cords when the medical device is switched ON and the footswitch is pressed.

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

6.4 Switching off the medical device

1. Remove the bag from the bracket.
2. Remove the irrigation line perforator from the bag.
3. Immerse the irrigation line perforator in a container with distilled water.
4. Press  and run the purge cycle for one minute to rinse the handpiece.
5. Remove the perforator from the container and purge the system until the medical device's irrigation line is completely empty.
6. Switch off the medical device (O/I switch to O).
7. Disconnect the medical device's handpiece cord.
8. Remove the irrigation line clips and dispose of them in a special container for soiled medical equipment.
9. Disconnect the handpiece and dispose of it in a special container for soiled medical equipment.
10. Detach the tip from the handpiece using the wrench and dispose of it in a special container for soiled medical equipment.
11. Remove the nozzle, optical guide and LED ring from the handpiece and place them in the appropriate sterilisation box.

> This procedure is applicable for single-use sterile M+ tips. Non sterile M+ tips that can be used up to 5 times should be placed in the appropriate sterilisation box.

Refer to the cleaning, disinfection and sterilisation protocols for I-Surge LED micromotors, handpieces and tips for further information about the detailed sequence of pre-disinfection, cleaning, sterilisation operations for these types of medical device.

7 Configuring the medical device

In addition to normal use of the medical device, the following parameters can be configured:

- screen brightness
- factory settings

7.1 Adjusting the screen brightness

1. To open the menu, press  and  simultaneously.
2. Switch on the medical device.
3. Select  by pressing  until the cross is underneath the pictogram.
4. Adjust the brightness using  and  .
5. Press  to save your settings.
6. Press  for 3 seconds to start the Piezotome Solo ® M+.

7.2 Reading the timer

1. To open the menu, press  and  simultaneously.
2. Switch on the medical device;
3. Check the value displayed under the pictogram  .
4. Press  for 3 seconds to start the Piezotome Solo ® M+.

7.3 Recovering the medical device's factory settings

1. To open the menu, press  and  simultaneously.
2. Switch on the medical device.
3. Select  by pressing  until the cross is underneath the pictogram.
4. Press  for 3 seconds to start the Piezotome Solo ® M+.

7.3.1 Piezotome mode factory settings

	Programme	Power	Irrigation
Very powerful	D1	3	60 ml/min
Powerful	D2	3	60 ml/min
Average power	D3	3	60 ml/min
Low power	D4	3	60 ml/min

8 Cleaning, disinfecting and sterilising

The instructions relating to cleaning, disinfection and sterilisation protocols for accessories provided by SATELEC® have been approved for each medical device and accessory. The applicable protocols are listed in the chapter *Associated documentation* page *5*.

They can be downloaded at the following address:

`www.satelec.com/documents`

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®.

> Do not use antiseptic products containing flammable substances.

8.1 Cleaning and disinfecting the medical device

The medical device must be OFF (switch on O) during cleaning and disinfecting procedures.

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.

Clean and disinfect the medical device's control unit and footswitch before and after use.

8.2 Cleaning, disinfecting and sterilising accessories

Refer to the cleaning, disinfection and sterilisation protocols for accessories listed in chapter *Associated documentation* page *5*.

9 Monitoring and general maintenance of the medical device

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

Check that the air inlets on the control unit are clean to prevent any overheating.

> The clips holding the irrigation lines may cause wear of the handpiece cords. Check each handpiece cord individually before and after use.

10 Maintenance

Maintenance of the medical device essentially involves preventive maintenance operations, covering the following aspects:

- checking of accessories;
- everyday cleaning, disinfection and sterilisation ;
- cleaning.

10.1 Touch-sensitive screen messages

Use the touch-sensitive screen to configure the medical device. Depending on your actions, one or more of the following elements will be displayed.

10.1.1 Problem at start up

Symptom: the medical device beeps and displays the following pictogram:

Possible causes	Solutions
Internal error during start up: there is no communication between mother board and screen	- Switch off the medical device (I/O switch to O). - Wait 5 seconds before switching it back on. - Switch the device on (I/O switch to I) and don't touch any of the buttons while it is starting up.

10.1.2 Missing handpiece

Symptom: the medical device beeps when the user presses the footswitch and displays the following pictogram:

Possible causes	Solutions
Faulty connection between the handpiece cord and the medical device	- Connect the handpiece cord to the medical device. - Switch off the medical device (I/O switch to O). - Wait 5 seconds before switching it back on. - Switch the device on (I/O switch to I) and don't touch any of the buttons while it is starting up.

10.1.3 Finding the software version

If you experience any problems with your medical device, the SATELEC® customer service team may ask you for the resident software version of your medical device.

To view the software version, proceed as follows:

1. To open the menu, press  and  simultaneously.
2. Switch on the medical device.

3. Note down the value displayed on the bottom of the screen.
4. Press  for 3 seconds to start the medical device.

10.2 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®.

> 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.

10.2.1 Not working

Symptoms: the screen is off, the medical device failed to start

Possible causes	Solutions
Faulty connection between the mains cord and the medical device	Connect the mains cord to the medical device
Faulty connection between the mains cord and the electrical wall socket	Connect the mains cord to the electrical wall socket
Switch in position O	Set the switch to position I
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 the device to the SATELEC® customer service team
No electrical current	Contact your electrician
Transmission fault	Switch off the medical device then switch it on again Return the medical device to the SATELEC® customer service team

> The medical device also has an internal fuse that cannot be accessed by the user.

10.2.2 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 at a standstill.

Possible causes	Solutions
Worn or bent tip	Replace the tip
Power setting incorrect	Adjusts the power
Angle of approach incorrect or inadequate pressure on the clinical site	Refer to the tip user manual indicated chapter *Associated documentation* page *5*
Moisture on the handpiece cord connector	Dry the electrical contacts

10.2.3 No spray or very little amount of spray

Symptoms: when the device is in use, irrigation is not working and no spray comes out the tip

Possible causes	Solutions
Irrigation solution bag empty	Replace the irrigation bag with a new one
Irrigation deactivated	Start irrigation using the footswitch or touch-sensitive screen
Irrigation line blocked	Replace the irrigation line
Irrigation line pinched	Check the length of the irrigation line
Incorrect irrigation adjustment	Adjust the irrigation flow rate

10.2.4 Light not working or too dim

Symptoms: the handpiece is not lighting up the clinical site

Possible causes	Solutions
LED ring missing in the handpiece nozzle	Install the LED ring
Faulty LED ring	Replace the LED ring
Cracks or fine cracks on the LED ring	Replace the LED ring
LED ring contacts faulty	Replace the LED ring
LED ring poles reversed	Install the LED ring with the correct polarity
Optical guide damaged	Replace the optical guide
Handpiece cord connector faulty	Dry the cord and medical device connectors Replace the handpiece and cord
Other	Return the medical device to the SATELEC® customer service team

10.2.5 Water leakage

Symptoms: water is leaking from one of the following places:

- irrigation cassette
- handpiece

Possible causes	Solutions
The handpiece irrigation inlet is damaged	Replace the handpiece and cord Return the handpiece to the SATELEC® customer service team
Pipe ruptured in the irrigation line cassette	Replace the irrigation line
Irrigation cassette not working	Replace the irrigation line

10.2.6 Ultrasounds not working

Symptoms: the tip does not vibrate, vibration cannot be heard.

Possible causes	Solutions
Tip loose	Fasten the tip using the wrench
Connector with the medical device faulty	Clean the cord contacts
Handpiece cord wire(s) cut	Return the handpiece and cord to the SATELEC® customer service team to have them replaced

10.3 Corrective maintenance

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

10.3.1 Replacing the fuses

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

To replace the fuses, perform the following operations:

- stop the medical device (position O);
- disconnect the mains cord from the electrical network;
- disconnect the mains cord from the mains connector;
- insert the tip of a flathead screwdriver into the notch on top of the fuse holder to release it;
- remove the used fuses;
- replace the used fuses with fuses of the same type and same rating;
- place the fuse holder in its recess by pushing it until you hear a click that confirms it is in the correct position;
- connect the mains cord to the connector;
- connect the mains cord to the electrical network;

11 Technical specifications of the medical device

11.1 Identification

Manufacturer	SATELEC®
Name of the medical device	PIEZOTOME SOLO ® M+

11.2 Control unit

Width (in mm)	378
Height (in mm)	136, with bracket 460
Depth (in mm)	306
Weight (in g)	3700

Ingress protection rating: IPX0

11.3 Generator

Supply voltage	100 - 230 VAC
Power supply frequency	50 Hz / 60 Hz
Power consumption	250 VA to 230 VAC
No-load voltage	250 V
Minimum output frequency	28 kHz
Ultrasonic operating mode: Piezotome® and Newtron®	Intermittent operation 10 minutes ON / 5 minutes OFF
Electrical rating	1
Electrical safety class, leakage current types	LF
Internal fuse not accessible to the user	1 fuse - F1: 5 mm x 20 mm - 10 AT / 250 VAC
Fuse (mains connector)	2 fuses - 5 mm x 20 mm - 2 AT for 100 to 230 VAC

11.4 Screen

Width (in mm)	115
Height (in mm)	86

11.5 Length of cords

Piezotome® M+ handpiece cord (in mm)	2900
Footswitch cord (in mm)	2900

11.6 Irrigation

Nominal water output flow at the handpiece tip of the Piezotome Solo ® M+ (in ml/min)	0 to 120 ml
Nominal water output flow at purge (in ml/min)	120 ml per min

11.7 Footswitch

Width (in mm)	173

Height including arch (in mm)	140
Depth (in mm)	176
Maximum weight (in g)	1000

Ingress protection rating: IPX6

11.8 Environmental characteristics

Operating temperature	10 to 30°C
Storage temperature	0 to 50°C
Operating humidity	30 to 75%
Maximum storage humidity	100%, including condensation
Atmospheric pressure	500 hPa to 1060 hPa
Altitude	2000 metres maximum

11.9 Environmental restrictions

Usage premises	The medical device is designed to be used in an operating theatre or in premises suitable for the procedure involved.
Use in gas-filled atmosphere	The medical device is not designed to be used in an AP or APG gas-filled atmosphere.
Immersion	The medical device must not be immersed.

11.10 Main performance characteristics

- Ultrasonic vibrations of the surgical tip fitted to the end of the surgical handpiece.
- Vibration frequency 28 kHz or greater.
- Modulation frequency

12 Regulations and standards

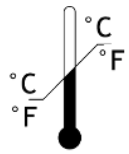
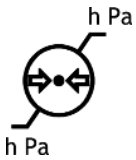
12.1 Official texts

This medical device complies with the essential requirements of European Directive 93/42/EEC. This equipment is designed and developed in compliance with the Electrical Safety standard IEC60601-1 in force. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.
This documentation complies with European regulation No.207/2012.

12.2 Medical class of the device

Class of medical device: IIb according to 92/42/EEC directive

12.3 Standardised symbols

Symbols	Meaning
	Authorised humidity range
	Authorised temperature range
	Authorised pressure range
	Quantity (1)
	Keep away from humidity
	Fragile
	Not to be used on patients with implantable medical devices
	Refer to the accompanying documentation
	Consult the User Manual

Symbols	Meaning
 Electronic user informations	Accompanying documentation in electronic format
	LF type
I	Class 1
	Alternating voltage
	Sterilisation at 134°C in an autoclave
	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
	Footswitch
O	Device OFF
I	Device ON
IPX6	**IP**: ingress protection ratings procured by a range **X**: no ingress of protection rating claim against the penetration of solids **6**: protected against powerful water jets

12.4 Manufacturer identification

SATELEC
A Company of ACTEON Group
17, avenue Gustave Eiffel
BP 30216
33708 MERIGNAC cedex
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13 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 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 chapter page 29.

14 Index

15 Glossary

A

accessory

includes micromotors, cords, handpieces, nozzles, LED rings, optical guides, tips, sterilisation boxes, and silicone supports used in conjunction with the control units

B

bag

container filled with physiological saline solution or sterile water. Can designate either a flexible container or rigid container like a bottle.

F

fixed installed medical devices

devices and their accessories which are intended to be installed, fastened or otherwise secured at a special location in a healthcare facility so that they cannot be moved from this location or detached without using tools or apparatus, and which are not specifically intended to be used within a mobile healthcare facility [European regulation No.207/2012]

I

Instructions for use

information provided by the manufacturer to inform the user of the device of its safe and proper use, of its intended performances and of any precautions to be taken [European regulation No.207/2012]

instructions for use in electronic form

instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together with the device, or instructions for use available through a website [European regulation No.207/2012]

P

professional users

persons using the medical device in the course of their work and in the framework of a professional healthcare activity [European regulation No.207/2012]

CE 0459 Ref - J57851 • V1 • 09/2013 • NO27EN010A

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