## Contents

1 Documentation ........................................................................................................... 5
   1.1 Associated documentation ................................................................................. 5
   1.2 Electronic documentation ................................................................................. 5

2 Required information ................................................................................................ 7
   2.1 Indication for use ................................................................................................ 7
   2.2 Operating principle ............................................................................................ 7
   2.3 Date of inclusion of EC marking ........................................................................ 7
   2.4 Latest document update ..................................................................................... 7
   2.5 Repairing or modifying the device ...................................................................... 7
   2.6 Warranty ............................................................................................................. 8
   2.7 Accessory usage conditions .............................................................................. 8

3 Removal from packaging, installation, connections .................................................. 9
   3.1 Unpacking your medical device ......................................................................... 9
   3.2 Positioning the medical device ......................................................................... 9
   3.3 Installing cords .................................................................................................. 9
   3.4 Connecting the medical device to the electrical network .................................... 9
   3.5 Installing the control pedal .............................................................................. 10
   3.6 Fix the medical device to a non-removable support .......................................... 10

4 Description of the medical device ............................................................................. 11
   4.1 Control unit ....................................................................................................... 11
   4.2 Power configuration button .............................................................................. 11
       4.2.1 Remote configuration via Bluetooth (depending on option) ...................... 11
   4.3 Adjusting ultrasound power ............................................................................. 11
   4.4 SLIM handpiece .................................................................................................. 11
   4.5 Attach a tip or a file ......................................................................................... 11
   4.6 Connecting and disconnecting accessories during use ....................................... 12
   4.7 Connecting the handpiece .................................................................................. 12
   4.8 Handpiece support ............................................................................................. 12
   4.9 Handpiece cord ................................................................................................... 12
   4.10 Light indicator .................................................................................................. 12
   4.11 Irrigation flow configuration button .................................................................. 12
   4.12 Adjusting the irrigation .................................................................................... 12
   4.13 Initiating irrigation ........................................................................................... 13
   4.14 Air inlets .......................................................................................................... 13
   4.15 Control pedal .................................................................................................... 13
   4.16 Activating ultrasounds using the pedal .............................................................. 13
   4.17 Mains Connector ............................................................................................... 13
   4.18 Switch ............................................................................................................... 13
   4.19 Fuse recess ....................................................................................................... 13
   4.20 Irrigation solution tank ..................................................................................... 13
Foreword

The medical device SATELEC® that you are about to install and use in your practice is a medical device designed for professional use. It comprises the chosen tool with which you will provide treatment within the context of your work. To ensure optimum safety for yourself and your patients, comfort in your daily practice and to benefit fully from the technology of your medical device, please read the documentation provided carefully.
If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.

Please refer to the instructions relating to the comprehensive range of dental ultrasonic generators SATELEC® for information about the following:
- documentation format;
- the documentation archiving period;
- warnings concerning user and patient populations;
- the treatment area;
- the medical device usage interactions, contraindications and prohibitions;
- electromagnetic compatibility;
- disposal and recycling of the medical device;
- manufacturer responsibility.

Please refer to the accessory cleaning, disinfection and sterilization protocols and the hand-piece predisinfection, cleaning and sterilisation protocols for information about the following:
- preparation of parts for sterilization;
- detailed manual and automatic protocols;
- information concerning conditioning for sterilization;
- recommendations for the inspection of parts.
1 Documentation

This document contains the following information:
- indications for use;
- description of the medical device;
- installation of the medical device;
- use of the medical device;
- 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:

<table>
<thead>
<tr>
<th>Document title</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning, disinfection and sterilization protocols for Wrenches SATELEC®</td>
<td>J81001</td>
</tr>
<tr>
<td>Cleaning, disinfection and sterilization protocols for Tips SATELEC®</td>
<td>J02001</td>
</tr>
<tr>
<td>Cleaning, disinfection and sterilization protocols for Handpieces SATELEC®</td>
<td>J12911</td>
</tr>
<tr>
<td>General instructions relating to the complete range of SATELEC® dental ultrasonic generators</td>
<td>J00011</td>
</tr>
<tr>
<td>Method for consulting electronic user instructions</td>
<td>J00000</td>
</tr>
<tr>
<td>Quick Clean Newton® P5XS</td>
<td>J62101</td>
</tr>
<tr>
<td>Quick Start Newton® P5XS</td>
<td>J62100</td>
</tr>
<tr>
<td>User Manual for Newton® P5XS</td>
<td>J62151</td>
</tr>
<tr>
<td>Software User Manual Newton® P5XS</td>
<td>J62111</td>
</tr>
<tr>
<td>User Manual for SLIM handpiece</td>
<td>J12921</td>
</tr>
</tbody>
</table>

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

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
This medical device is used in association with a dental ultrasound handpiece to which an ultrasound instrument is attached. It is designed for the treatment of prophylaxis, periodontics, endodontics and preservation and restoration dentistry.

2.2 Operating principle
An electrical signal emitted by the medical device is supplied to the dental 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 tip or a dental file attached to the end of the ultrasonic handpiece.

The Newtron® SLIM B.LED fitted with its Blue LED ring and used in conjunction with the F.L.A.G.™ disclosing liquid, shows up dental plaque during the scale removal or dental prophylaxis phase. Fitted with a white LED ring, the handpiece emits a white light providing the user with optimum visibility of the treatment area.

2.3 Date of inclusion of EC marking
2013

2.4 Latest document update
04/2013

2.5 Repairing or modifying the 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 SATELEC® without seeking the prior permission of .
If the device is modified or repaired, specific checks and tests must be carried out to ensure that the 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 screws marked A, B and C must not under any circumstances be unscrewed by the user as this may void the warranty for the medical device.

2.7 Accessory usage conditions

Accessories and SLIM handpiece must be cleaned, disinfected and sterilized prior to use.
3 Removal from packaging, installation, connections

3.1 Unpacking your 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 Newtron® P5XS includes the following items:
- a Newtron® P5XS unit with non-detachable pedal cord, a non-detachable SLIM cord, a 300 or 500ml tank and a SLIM handpiece support;
- a Newtron® SLIM handpiece, a Quick Start [J12900] and a Quick Clean [J12930];
- tips and wrenches depending on selected options;
- an attachment kit;
- a box containing FLAG disclosing liquid;
- a Quick Start Newtron® P5XS [J62100];
- a Quick Clean Newtron® P5XS [J62101].

3.2 Positioning 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 you can access your medical device quickly.

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

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
Set the medical device to OFF position 0 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/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.
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.

### 3.5 Installing the control pedal

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

### 3.6 Fix the medical device to a non-removable support

The medical device that you have just acquired is not designed for mobile use. To avoid accidentally dropping the device, we recommend that you fix it in a precise place in your treatment room, using the screw and clamp [F61001] supplied in the packaging box, to ensure that it cannot be dismantled or moved without needing a tool.
4 Description of the medical device

4.1 Control unit
The control unit incorporates technology Newtron® patented by SATELEC®. The patented technology Newtron® controls the tips by Cruise Control®, an automatic system for setting the frequency and power in real time. This ensures that Satelec® tip vibration is gentle, regular and controlled.

4.2 Power configuration button
To ensure a quality treatment, you will need to use the tips at the power and irrigation flow settings recommended by SATELEC®.

The ultrasound power configuration button ensures:
- Configuration of the operating power: 1 to 20.

The configuration button has 4 colour sectors, each with 5 positions.
- Green: 1 to 6: very low to low power, used mainly for periodontics.
- Yellow: 6 to 11: medium power, used mainly for endodontics.
- Blue: 11 to 16: high power, used mainly for scale removal.
- Orange: 16 to 20: very high power, used mainly for implant loosening.

The ultrasound power configuration button can be removed by the user to facilitate the cleaning and disinfection of the control unit. The button cannot be sterilised.

The removal of the button inhibits the activation of ultrasounds. The top surface of the control unit lights up white and the control pedal can be pressed to activate the purge function. The purge function can be stopped at any time by pressing the control pedal again.

4.2.1 Remote configuration via Bluetooth (depending on option)
The Newtron® P5XS, depending on the option, allows you to use a tablet or a smartphone to remotely pre-configure the power and irrigation settings.

Refer to the P5XS application instructions [J62111] for more information.

Only the Newtron® P5XS with Bluetooth option is compatible with remote configuration.

4.3 Adjusting ultrasound power
Adjust the ultrasound power using the ultrasound power configuration button. The ultrasound power must be adjusted in accordance with the tip used and the required treatment. The operating power of the tips must be selected in compliance with the Satelec tips color coding system (CCS tips). Details of these indications are given in the adjustment table available at the address www.satelec.com/documents and on the treatment sheets.

4.4 SLIM handpiece
Only handpieces with SLIM connector SATELEC® can be connected to the medical device. There is a handpiece with SLIM connector without LED, and a handpiece with SLIM connector B.LED with white or blue LED. Refer to the handpiece user manual Newtron® [J12921] for more information.

4.5 Attach a tip or a file
A tip or a file vibrates correctly when it is perfectly tightened without being forced beyond its stop point. Tighten it moderately using the wrench provided to ensure optimum ultrasound operation. Over-tightening of the tip or file can result in breakage of the tip, file or handpiece.

To prevent self-locking of the tip or the file, the latter must be removed after each use.
4.6 Connecting and disconnecting accessories during use

Do not connect/disconnect the cord(s) or the handpiece when the medical device is switched on and your foot is on the pedal.

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

4.7 Connecting the handpiece

Check for the absence of signs of humidity at the SLIM handpiece connections, and eliminate them if necessary (wipe and blow using a multipurpose syringe).

Lubricate the irrigation system seal located behind the SLIM handpiece with dental instrument lubricant to extend its effectiveness and prevent leaks.

Connect the SLIM handpiece to the sleeve, by aligning the indexing points and by avoiding rotation movement. Install the SLIM handpiece on the support.

4.8 Handpiece support

Le support permet de poser la pièce à main ou la douille du cordon.

The handpiece support can be fixed to the front face or the right side face of the medical device. To change the position of this support, unscrew the two screws located under the support, position the support over the two holes located on the right side face and insert and tighten the two fastening screws.

The two silicone supports can be removed by sliding them along the metal rod. They can be sterilised.

4.9 handpiece cord

The SLIM cord is only compatible with handpieces SATELEC® with SLIM connector.

The SLIM cord ensures irrigation circulation and electrical connection between the medical device and the SLIM handpiece.

4.10 Light indicator

The light indicator is designed to provide information about the status of the device.

When the light indicator is illuminated, the medical device is on and ready to use. The indicator's colour corresponds to the power level.

4.11 Irrigation flow configuration button

The irrigation flow configuration button stops the irrigation function at the minimum stop marked by "0" and sets the irrigation flow from mark "I" to "+":

The irrigation flow configuration button can be removed to clean the medical device. The button cannot be sterilised.

The purge function is activated by pressing the pedal for 4 minutes; it can be stopped by pressing the pedal again.

The pump operates at its maximum flow rate ⏩ in purge position.

4.12 Adjusting the irrigation

Adjust the irrigation flow using the irrigation flow configuration button. This adjustment depends on the tip and the treatment.

As work habits, feedback and professional training differ from one professional to another, the user must make sure that the irrigation flow is perfectly adapted to the treatment to be carried out to avoid burning the treatment area.
4.13 Initiating irrigation
The medical device must be set to minimum power depending on the required irrigation flow rate. Press the pedal until a spray appears.

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

4.15 Control pedal
The ON/OFF type pedal is used by the practitioner to operate the medical device. 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 cannot be disconnected. Its weight and antislip pad ensure good stability.
The light function remains active for approx. 9 seconds after the pedal is released.

4.16 Activating ultrasounds using the pedal
To activate the ultrasounds on your medical device, press the control pedal.

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

4.18 Switch
The mains switch is used to switch on (position 1) or to stop (position 0) the medical device.

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

4.20 Irrigation solution tank
The medical device is equipped with a tank designed to hold 300ml or 500ml of irrigation solution depending on the option chosen. The maximum capacity is shown by the MAX mark on the tank.
The irrigation solution tank is fitted with a cover. Neither the tank nor the cover can be sterilised.

4.21 Filling the tank
Remove the tank from the medical device by pulling it upwards. Fill the irrigation solution tank up to the MAX mark with an irrigation solution that is approved for the medical device.
The following solutions are approved for use:
- Hydrogen peroxide < 3%;
- Chlorexidine < 3%;
- EDTA Ethylenediaminetetraacetic acid < 15%;
- Sodium Hypochlorite < 0.9%;
- Sterile water, distilled water, deionised water, dimineralised water;
- Saline solution at 0.9%
The following solutions must not be used:
- Hextril® Hexedrin;
- Bleach.

4.22 Pump
The medical device is fitted with a peristaltic pump. This pump must be replaced yearly by the practitioner using the F62202 kit or by the After-Sales Department SATELEC®.
4.23 Cleaning the irrigation system
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.

1. fill the tank with hypochlorite diluted at less than 3%;
2. position the irrigation flow configuration button on purge;
3. operate the irrigation spray for two minutes to rinse the medical device’s internal water system;
4. refill the tank with demineralised or distilled water, or even drinking water;
5. rinse the system for two minutes.

When the irrigation system has been cleaned, perform the following operations:
1. disconnect the handpiece and refer to handpiece predisinfection, cleaning and sterilisation protocols SATELEC® [J12910];
2. clean and disinfect the medical device as indicated in the chapitre medical device cleaning and disinfection page 15
3. follow the instructions for accessory cleaning, disinfection and sterilization protocols SATELEC® [J81000] and [J02000].
5 Cleaning, disinfecting and sterilizing

The instructions relating to accessory cleaning, disinfection and sterilization protocols provided by SATELEC® have been approved for each medical device and accessory. The applicable guides are listed in 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 accessory cleaning, disinfection and sterilization protocols take precedence over the information provided by SATELEC®.

5.1 Medical device cleaning and disinfection

The medical device must be in OFF or O stop position during cleaning and disinfecting procedures. Refer to the instructions detailed in the chapter Cleaning the irrigation system page 14. Avoid using cleaning and disinfection products that contain flammable agents. Otherwise, ensure that the product has completely evaporated from or that there is not fuel left on the medical device and its accessories before switching it on.

- Do not use 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 medical device control unit, handpiece cord and control pedal must be cleaned and disinfected daily. The following cleaning and disinfection products can be used:

- Unowipes wipes by Unodent;
- Alcohol-free hard surface disinfectant wipes by Classic;
- Spray alcohol-free hard surface disinfectant by Classic;
- Hard surface disinfectant wipes by Classic;
- Microzid wipes by Schülke;
- Cyberclean by Cybertech;
- SEPTOL wipes by Anios;
- SEPTOL spray by Anios;
- Dentasept spray 41 by Anios;
- Anionyxspray WS by Anios.
To prepare for cleaning, remove the various parts of Newtron® P5XS as shown here.

5.2 Cleaning and disinfecting accessories
Refer to the accessory cleaning, disinfection and sterilization protocols listed in the chapter Associated documentation page 5.
6 Monitoring and maintenance of the medical device

Before and after each use, check that the device and its accessories are not faulty in any way. This is necessary to detect any isolation fault or damage. If necessary, replace damaged parts.

Monitor the cleanliness of the air inlets on the control unit to prevent any heating.
7 Maintenance
The only preventive maintenance the medical device requires is:
- checking of accessories;
- everyday cleaning, disinfection and sterilisation procedures;
- cleaning;

7.1 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 After-Sales 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.

7.1.1 No operation
Symptoms: the indicator light on the medical device is off and the medical device is not working.

<table>
<thead>
<tr>
<th>Possible causes</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>No electrical current</td>
<td>Contact your electrician</td>
</tr>
<tr>
<td>Internal fuse not working</td>
<td>Return to After-Sales team SATELEC®</td>
</tr>
<tr>
<td>Mains switch in position O</td>
<td>Set the mains switch to position I</td>
</tr>
<tr>
<td>Faulty connection between the mains cord and the mains connector</td>
<td>Connect the mains cord to the mains connector.</td>
</tr>
<tr>
<td>Faulty connection between the mains cord and the electrical wall socket</td>
<td>Connect the mains cord to the electrical wall socket.</td>
</tr>
<tr>
<td>Mains fuses in the mains connector not working</td>
<td>Replace the mains fuses with fuses of the same type and rating</td>
</tr>
</tbody>
</table>

The medical device also has an internal fuse (ref. F1 on the printed circuit board) that cannot be accessed by the user.

7.1.2 No spray
Symptoms: There is no water spray at the tip.

<table>
<thead>
<tr>
<th>Possible causes</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow configuration button on minimum</td>
<td>Adjust the flow configuration button</td>
</tr>
<tr>
<td>Tip or file blocked</td>
<td>Unblock the tip or file</td>
</tr>
<tr>
<td>Incorrect choice of tip</td>
<td>Check the tip</td>
</tr>
<tr>
<td>Inadequate amount of spray</td>
<td>Adjust the spray</td>
</tr>
<tr>
<td>No irrigation solution in the tank</td>
<td>Fill the irrigation solution tank</td>
</tr>
</tbody>
</table>

7.1.3 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 at a standstill.
### Possible causes | Solutions
--- | ---
Worn or distorted tip | Replace the tip
Incorrect use: incorrect approach angle or inadequate pressure on the tooth | Refer to the configuration table available at [www.satelec.com/documents](http://www.satelec.com/documents)
Presence of liquid or humidity between the handpiece and cord | Thoroughly dry the electrical contacts

#### 7.1.4 Ultrasounds not working
Symptoms: the tip does not vibrate, vibration cannot be heard.

| Possible causes                  | Solutions                          |
--- | ---                            |
Tip loose | Tighten the tip using the wrench
Faulty connector contact | Clean the cord contacts
Handpiece cord wire(s) cut | Return to After-Sales Department SATELEC® to replace the cord

#### 7.1.5 Water leakage
Symptoms: Water is leaking from one of the following places:
- between the base of the SLIM handpiece and its cord;
- under the tank;
- under the medical device.

| Possible causes                          | Solutions                                          |
--- | ---                                |
Wear of 1.15mm x1mm SLIM handpiece seal | Replace the seal using F12304 kit. Refer to the instructions in document J12921
Wear of the tank seal                    | Contact the After-Sales Department SATELEC® to replace the tank
Worn irrigation cassette                 | Replace the irrigation cassette using kit F62202 as detailed in the chapitre *Replacing the irrigation cassette page 21*

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

#### 7.2.1 Replacing the fuses
The medical device is protected by two fuses in the mains connector.
To replace the fuses, perform the following operations:
- 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;

The medical device also has an internal fuse (P/N FU1 on the printed circuit board) that cannot be accessed by the user.

7.2.2 Replacing the irrigation cassette
8 Technical specifications for the medical device

8.1 Identification

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>SATELEC®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nom du medical device</td>
<td>NEWTRON® PSXS</td>
</tr>
</tbody>
</table>

8.2 Control unit

| Width (in mm) | 260 |
| Height (in mm) | 110, 145 with 300ml tank, 182 with 500ml tank |
| Depth (in mm)  | 155 |
| Weight (in g)  | SLIM cord 1674 with pedal, SLIM cord and 300ml tank; 1712 with pedal, and 500 ml tank |

Ingress protection rating: IPX0

8.3 Ultrasonic generator

| Supply voltage | 100 VAC - 240 VAC |
| Power consumption | 60 VA |
| Voltage supplied to handpiece | 150 VAC |
| Output frequency | Minimum 28 kHz |
| Power setting range | 1 to 20 |
| Operating mode | Intermittent: 10 minutes ON / 5 minutes OFF |
| Type of leakage currents | BF |
| Electrical rating | 1 |
| Internal fuse not accessible to the user | Ref: FU1 / 1.5 AT - 125 V - SMD - Breaking capacity: 50 A |
| Fuse (mains connector) | 2 x 1 AT / 230 VAC fuses - 5mm x 20mm - Breaking capacity: 35 A |

8.4 Length of cords

| Scaler handpiece cord (in mm) | >2040 |
| Control pedal cord (in mm)    | >2000 |

8.5 Irrigation

| Tank capacity (in ml) | 300 or 500 |
| Nominal water output flow at the end of the handpiece (in ml/min) | 5 to 40 |
| Nominal water output flow at purge (in ml/min) | 80 |

8.6 Control pedal

| Width (in mm) | 70 |
| Height (in mm) | 30 |
| Depth (in mm)  | 95 |
| Weight (in g)  | 150 |
8.7 Environmental characteristics

<table>
<thead>
<tr>
<th>Environmental characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating temperature</td>
<td>+10°C to +30°C</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>-20°C to +70°C</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>10 % à 100 %</td>
</tr>
<tr>
<td>Maximum storage humidity</td>
<td>70 %</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>Between 800 hPa and 1060 hPa</td>
</tr>
<tr>
<td>Altitude</td>
<td>Less than or equal to 2000 metres</td>
</tr>
</tbody>
</table>

8.8 Environmental restrictions

<table>
<thead>
<tr>
<th>Usage premises</th>
<th>Can be used at all medical premises. The medical device must not be used in an operating theatre, or outside.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use in gas-filled atmosphere</td>
<td>The medical device is not designed for use in a type AP or APG gas-filled atmosphere or in the presence of anaesthetic gases.</td>
</tr>
<tr>
<td>Immersion</td>
<td>The SLIM handpiece must not be immersed.</td>
</tr>
</tbody>
</table>

8.9 Main performance characteristics

Ultrasonic vibrations of the tip or file fitted to the end of the conventional dental ultrasonic handpiece.

- Vibration frequency ≥ 28 kHz.
- Tip amplitude ≤ 200 µm.
9 Regulations and standards

9.1 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 Electrical Safety standard IEC60601-1 in force. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.

9.2 Medical class of the device
This medical device is a class IIa device according to European Directive 93/42/EEC.
9.3 Standardised Symbols

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Information Icon" /></td>
<td>Refer to the accompanying documentation</td>
</tr>
<tr>
<td><img src="image" alt="Information Icon" /></td>
<td>Consult the User Manual</td>
</tr>
<tr>
<td><img src="image" alt="Information Icon" /></td>
<td>Accompanying documentation in electronic format</td>
</tr>
<tr>
<td><img src="image" alt="Person Holding Book Icon" /></td>
<td>LF type</td>
</tr>
<tr>
<td><img src="image" alt="Person Holding Book Icon" /></td>
<td>Class 1</td>
</tr>
<tr>
<td><img src="image" alt="Alternating Voltage Icon" /></td>
<td>Alternating voltage</td>
</tr>
<tr>
<td><img src="image" alt="134°C Icon" /></td>
<td>Sterilisation at 134°C in an autoclave</td>
</tr>
<tr>
<td><img src="image" alt="132°C Icon" /></td>
<td>Sterilisation at 132°C in an autoclave</td>
</tr>
<tr>
<td><img src="image" alt="Washing Machine Icon" /></td>
<td>Washer disinfector for thermal disinfection</td>
</tr>
<tr>
<td><img src="image" alt="EC Mark Icon" /></td>
<td>EC marking</td>
</tr>
<tr>
<td><img src="image" alt="Do Not Dispose Icon" /></td>
<td>Do not dispose of as household waste</td>
</tr>
<tr>
<td><img src="image" alt="Year Icon" /></td>
<td>Year of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Control Pedal Icon" /></td>
<td>Control pedal</td>
</tr>
<tr>
<td>O</td>
<td>Device OFF</td>
</tr>
<tr>
<td>I</td>
<td>Device ON</td>
</tr>
<tr>
<td>IPX1</td>
<td>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</td>
</tr>
</tbody>
</table>

9.4 Manufacturer identification
SATELEC
9.5 Branch addresses

FRANCE
SATELEC ACTEON GROUP
17 av. Gustave Eiffel
Zone industrielle du phare - B.P. 30216
33708 MERIGNAC cedex - France
Tel. +33 (0) 556 34 06 07
Fax. +33 (0) 556 34 92 92
e-mail: satelec@acteongroup.com.

U.S.A.
ACTEON Inc.
124 Gaither Drive, Suite 140
Mount Laurel, NJ 08054 - USA
Tel. +1 856 222 9988
Fax. +1 856 222 4726
e-mail: info@us.acteongroup.com

GERMANY
ACTEON GERMANY GmbH
Industriestrasse 9 - 40822 METTMANN - GERMANY
Tel. +49 21 04 95 65 10
Fax. +49 21 04 95 65 11
e-mail: info@de.acteongroup.com

SPAIN
ACTEON MEDICO-DENTAL IBERICA, S.A.U.
Avda Principal n°11 H
Poligono Industrial Can Clapers
08181 SENTMENAT (BARCELONA) - SPAIN
Tel. +34 93 715 45 20
Fax. +34 93,715 32 29
e-mail: info@es.acteongroup.com

U.K.
ACTEON UK
Unit 1B - Steel Close - Eaton Socon, St Neots
CAMBS PE19 8TT - UK
Tel. +44 1480 477 307
Fax. +44 1480 477 381
e-mail: info@uk.acteongroup.com

MIDDLE EAST
ACTEON MIDDLE EAST
Numan Center - 2nd Floor N° 205 - Gardens Street
PO Box 5746 - 11953 AMMAN - JORDAN
Tel. +962 6 553 4401
Fax. +962 6 553 7833
e-mail: info@me.acteongroup.com

CHINA
ACTEON CHINA
9.6 Disposal and recycling

As an item of Electrical and Electronic Equipment, the medical device disposed of via a specialist collection, removal, recycling or destruction channel. This applies in particular to the European market, in reference to Directive 2002/96/EC dated 27/01/2003.

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or ACTEON GROUP head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapitre Branch addresses page 30.
Index

A

After installation 14
air circulation 13
air inlets 17
Air inlets 13
Altitude 26
Amplitude 26
approved dealers 7
attachments 9

B

B.LED 11
Bleach 13
Bluetooth 11

C

Chlorexidine 13
clean and disinfect the device 14
clean irrigation system 14
cleaned 8
color coding system 11
control pedal 10, 13
control unit 11
cover 13

damage 17
dedionised water 13
demineralised water 14
dental file 7
dental ultrasonic generators 5
dimineralised water 13
disinfected 8
disposal 32
distilled water 13
drinking water 14

earting pin 13
EDTA Ethylenediaminetetraacetic acid 13
Electrical Safety 27
electronic user instructions 5
end of the day 14
endodontics 7
European Directive 27

F

F61001 10
fall risk 10
fault 17
first inclusion of EC marking 7
first use 14
fuse 19
fuses 20

gas-filled atmosphere 26

Newtron® P5XS • J62151 • V1 • (13) • 04/2013 • NBADEN040B - Page 33/36
Handpiece support 12
Handpieces 5
Hextril® Hexedrin 13
humidity 12
Hydrogen peroxide 13
hypochlorite 14

incorrect operation 19
indexing points 12
indicator light 19
instructions relating to the comprehensive range of
dental ultrasonic generators 3
irrigation flow 12
irrigation flow settings 11

kit F12304 20
kit F62202 13, 20

LED 11
light function 13
light indicator 12

mains connector 13, 20
mains fuses 13
mains switch 13
Mains switch 19
Manufacturer 25
Medical class 27

non-use 14

pedal 13
periodontics 7
peristaltic pump 13
power settings 11
preservation and restoration dentistry 7
Pressure 26
printed copy 5
prophylaxis 7
purge function 11-12

Quick Clean 5
Quick Start 5

recycling 32
removal of the button 11
repair 7
repairer 7

Saline solution 13
seal 20
silicone supports 12
SLIM cord 12, 25
smartphone 11
Sodium Hypochlorite 13
Software User Manual 5
spray 13, 19
Spray 15
Sterile water 13
sterilized 8

tablet 11
tank 13
Temperature 26
tip 7, 20
Tip 19
Tips 5
treatment 11-12

U
ultrasonic vibrations 7
ultrasound instrument 7
ultrasound power 11
update 7
user instructions 5
User Manual 5

V
Vibration frequency 26

W
water leak 20
Wipes 15
Wrenches 5