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 Accessory usage conditions ..................................... 7
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 water system .......... 9
  3.5 Connecting the medical device to the electrical network .... 10
  3.6 Plugging the medical device to the electrical network ...... 10
  3.7 Installing the control pedal ..................................... 10
  3.8 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
  4.3 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 ......... 11
  4.7 Connecting the handpiece ........................................ 11
  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 .............................................. 12
  4.14 Air inlets .......................................................... 12
  4.15 Connection to water system .................................... 12
  4.16 Control pedal ...................................................... 12
  4.17 Activating ultrasounds using the pedal ......................... 13
  4.18 Electrical Adapter ............................................... 13
  4.19 Cleaning the irrigation system ................................ 13
5 Cleaning, disinfecting and sterilizing ............................... 15
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 handpiece 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 Newtron® Booster</td>
<td>J60101</td>
</tr>
<tr>
<td>Quick Start Newtron® Booster</td>
<td>J60100</td>
</tr>
<tr>
<td>User Manual for Newtron® Booster</td>
<td>J60111</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.

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 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® Booster includes the following items: 
• a Newtron® Booster unit with non-detachable pedal cord, a non-detachable SLIM cord and a SLIM hand-piece support; 
• a Newtron® SLIM handpiece, a Quick Start [J12900] and a Quick Clean [J12930]; 
• tips and wrenches depending on selected options; 
• a mains adapter and its cord; 
• an attachment kit; 
• a Quick Start Newtron® Booster [J60100]; 
• a Quick Clean Newtron® Booster [J60101].

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 water system
The information below only applies to medical device that need to be connected to the water system to 
operate. 
Ask an approved dental installation technician to connect your medical device to the water system. 
The water supply system pressure may vary throughout the day. The water supply system pressure must be adap-
ted to the values recommended for your medical device. It is very important to make sure that the maximum 
pressure permitted for the medical device is never reached or exceeded. If in doubt, you are strongly advised 
to install or arrange for installation of a water pressure limiting system.
The water supply system must comply with the quality criteria compatible with the practice of dental treatments.

3.5 Connecting the medical device to the electrical network
Set the medical device to 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/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.

3.6 Plugging the medical device to the electrical network
1. Move the power configuration button to position O;
2. Connect the mains adapter to the medical device connector;
3. Connect the mains adapter cord to the mains adapter;
4. Connect the mains adapter cord to the electrical fixture wall socket;

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

3.8 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:
- Switching On/Switching off of the device (Ol symbol).
- 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 is not designed to be removed.

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. The medical device must be used with a SLIM handpiece Newtron®. 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 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.

4.11 Irrigation flow configuration button
The irrigation flow configuration button stops the irrigation function at the stop at least and sets the irrigation flow: from “min” to “max”.
The irrigation flow configuration button is not designed to be removed.
The purge function is activated by pressing the pedal for 4 minutes; it can be stopped by pressing the pedal again.

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 Connection to water system
The supply pipe connector is used to connect the medical device device to the domestic water distribution system. The connector is extended by a pipe to which a filter is attached. The filter needs to be cleaned and/or replaced regularly as specified in the chapitre Replacing the water filter page 19.
The water quality must meet the criteria required to perform dental treatments.

4.16 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.

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

4.18 Electrical Adapter
The medical device is designed to be connected to a mains adapter, which is considered as being an integral part of the medical device device. The mains adapter helps to make the medical device device electrically safe. The medical device device’s mains adapter serves as a disconnecting device, the socket outlet must be installed near the medical device device and must be easily accessible.

The mains cord connects the mains adapter to the control unit.

| Only use the mains adapter supplied with your medical device 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, demineralised water;
- Saline solution at 0.9%.

The following solutions must not be used:
- Hextril® Hexedrin;
- Bleach.

4.19 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.

Operate the device at minimum power, at maximum irrigation flow rate 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 chapitre 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 chapitre Cleaning the irrigation system page 13.

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® Booster as shown here.

5.2 Cleaning and disinfecting accessories

Refer to the accessory cleaning, disinfection and sterilization protocols listed in the chapitre 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;
- replacement of the water filter cartridge.

7.1 Replacing the water filter

The water filter must be cleaned regularly and must be replaced every 6 months.

Proceed as follows:
- shut off the water supply;
- stop the medical device (position O);
- unplug the network plug;
- unscrew the two filter sections;
- using the two 10mm open-ended wrenches, remove the filter cartridge to be replaced [kit F10389] or clean it with water spray;
- repeat the same process for the seal;
- perform the same operations in the reverse order for reassembly;
- check that the spray works correctly and that there is no leakage.

A damaged or blocked cartridge must be replaced.

7.2 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 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.

7.2.1 No operation

Symptoms: the indicator light on the mains adapter is off, 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>Faulty connection between the mains cord and the mains adapter</td>
<td>Connect the mains cord to the mains adapter</td>
</tr>
<tr>
<td>Faulty connection between the control unit and the mains adapter</td>
<td>Connect the mains adapter to the control unit</td>
</tr>
<tr>
<td>No electrical current</td>
<td>Contact your electrician</td>
</tr>
<tr>
<td>Power configuration button in position O</td>
<td>Set the power configuration button to I</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>
</tbody>
</table>

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

7.2.2 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>Dental cabinet water inlet in shut-off position</td>
<td>Open the water inlet</td>
</tr>
<tr>
<td>Flow configuration button on minimum</td>
<td>Adjust the flow configuration button</td>
</tr>
<tr>
<td>Faulty water pipe connection</td>
<td>Check the water inlet</td>
</tr>
<tr>
<td>Low water pressure</td>
<td>Check the water system pressure</td>
</tr>
<tr>
<td>Blocked filter</td>
<td>Clean or change the filter</td>
</tr>
<tr>
<td>Faulty solenoid valve</td>
<td>Return to After-Sales Department SATELEC®</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>
</tbody>
</table>

### 7.2.3 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.

<table>
<thead>
<tr>
<th>Possible causes</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worn or distorted tip</td>
<td>Replace the tip</td>
</tr>
<tr>
<td>Incorrect use: incorrect approach angle or inadequate pressure on the tooth</td>
<td>Refer to the configuration table available at <a href="http://www.satelec.com/documents">www.satelec.com/documents</a></td>
</tr>
<tr>
<td>Presence of liquid or humidity between the handpiece and cord</td>
<td>Thoroughly dry the electrical contacts</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Possible causes</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tip loose</td>
<td>Tighten the tip using the wrench</td>
</tr>
<tr>
<td>Faulty connector contact</td>
<td>Clean the cord contacts</td>
</tr>
<tr>
<td>Handpiece cord wire(s) cut</td>
<td>Return to After-Sales Department SATELEC® to replace the cord</td>
</tr>
</tbody>
</table>

### 7.2.5 Water leakage
Symptoms: Water is leaking from one of the following places:
- between the base of the SLIM handpiece and its cord.

<table>
<thead>
<tr>
<th>Possible causes</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear of 1.15mm x1mm SLIM handpiece seal</td>
<td>Replace the seal using F12304 kit. Refer to the instructions in document J12921</td>
</tr>
</tbody>
</table>
# 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® BOOSTER</td>
</tr>
</tbody>
</table>

## 8.2 Mains Adapter

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>CINCON ELECTRONICS CO.LTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>TR60M36</td>
</tr>
<tr>
<td>Supply voltage</td>
<td>100 VAC - 240VAC</td>
</tr>
<tr>
<td>Power supply frequency</td>
<td>47Hz - 63Hz</td>
</tr>
<tr>
<td>Power consumption</td>
<td>60 W</td>
</tr>
<tr>
<td>Output voltage</td>
<td>36 VDC</td>
</tr>
<tr>
<td>Output current</td>
<td>1.66A</td>
</tr>
<tr>
<td>Width (in mm)</td>
<td>58</td>
</tr>
<tr>
<td>Height (in mm)</td>
<td>30.5</td>
</tr>
<tr>
<td>Depth (in mm)</td>
<td>132</td>
</tr>
<tr>
<td>Weight (in g)</td>
<td>1620 with mains cord</td>
</tr>
</tbody>
</table>

## 8.3 Control unit

| Width (in mm) | 130 |
| Height (in mm) | 88 |
| Depth (in mm) | 161 |
| Weight (in g) | 1110SLIM cord 1674 with pedal, SLIM cord and 300ml tank; 1712 with pedal, |

Ingress protection rating: IPX0

## 8.4 Ultrasonic generator

| Supply voltage | 36 VDC |
| Power consumption | 25 W |
| 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 | 2 |
| Internal fuse not accessible to the user | Ref: F1 / 750 mAT - 125 V - SMD - Breaking capacity: 50 A |
8.5 Length of cords

<table>
<thead>
<tr>
<th>Description</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scaler handpiece cord (in mm)</td>
<td>2040</td>
</tr>
<tr>
<td>Control pedal cord (in mm)</td>
<td>2000</td>
</tr>
</tbody>
</table>

8.6 Irrigation

<table>
<thead>
<tr>
<th>Description</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water pressure at inlet</td>
<td>1 to 5 bars</td>
</tr>
<tr>
<td>Maximum water output flow at the end of the handpiece</td>
<td>80ml/min to 100ml/min at 5 input bars</td>
</tr>
</tbody>
</table>

8.7 Control pedal

<table>
<thead>
<tr>
<th>Description</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width (in mm)</td>
<td>70</td>
</tr>
<tr>
<td>Height (in mm)</td>
<td>30</td>
</tr>
<tr>
<td>Depth (in mm)</td>
<td>95</td>
</tr>
<tr>
<td>Weight (in g)</td>
<td>150</td>
</tr>
</tbody>
</table>

Ingress protection rating: IPX1

8.8 Environmental characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>Measurement</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>

8.9 Environmental restrictions

<table>
<thead>
<tr>
<th>Description</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usage premises</td>
<td>Can be used at all medical premises. The medical device must not be used in an operating theatre, or outside.</td>
</tr>
<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>

8.10 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="Refer to the accompanying documentation" /></td>
<td>Refer to the accompanying documentation</td>
</tr>
<tr>
<td><img src="image" alt="Consult the User Manual" /></td>
<td>Consult the User Manual</td>
</tr>
<tr>
<td><img src="image" alt="Accompanying documentation in electronic format" /></td>
<td>Accompanying documentation in electronic format</td>
</tr>
<tr>
<td><img src="image" alt="LF type" /></td>
<td>LF type</td>
</tr>
<tr>
<td><img src="image" alt="Class 2" /></td>
<td>Class 2</td>
</tr>
<tr>
<td><img src="image" alt="Alternating voltage" /></td>
<td>Alternating voltage</td>
</tr>
<tr>
<td><img src="image" alt="Sterilisation at 134°C in an autoclave" /></td>
<td>Sterilisation at 134°C in an autoclave</td>
</tr>
<tr>
<td><img src="image" alt="Sterilisation at 132°C in an autoclave" /></td>
<td>Sterilisation at 132°C in an autoclave</td>
</tr>
<tr>
<td><img src="image" alt="Washer disinfector for thermal disinfection" /></td>
<td>Washer disinfector for thermal disinfection</td>
</tr>
<tr>
<td><img src="image" alt="EC marking" /></td>
<td>EC marking</td>
</tr>
<tr>
<td><img src="image" alt="Do not dispose of as household waste" /></td>
<td>Do not dispose of as household waste</td>
</tr>
<tr>
<td><img src="image" alt="Year of manufacture" /></td>
<td>Year of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Control pedal" /></td>
<td>Control pedal</td>
</tr>
<tr>
<td><img src="image" alt="Device OFF" /></td>
<td>Device OFF</td>
</tr>
<tr>
<td><img src="image" alt="Device ON" /></td>
<td>Device ON</td>
</tr>
<tr>
<td><img src="image" alt="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

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Fax. +962 6 553 7833
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CHINA
ACTEON CHINA
TAIWAN

User Manual • Newtron® Booster • J60111 • V1 • (13) • 04/2013 • NBABEN030B - Page 27/31
9.6 Disposal and recycling

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

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or ACTEON GROUP head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapter Branch addresses page 26.
10 Index

A

After installation 13
air circulation 12
air inlets 17
Air inlets 12
Altitude 22
Amplitude 22
approved dealers 7
attachments 9

B

Bleach 13

C

Chlorexidine 13
clean and disinfect the device 13
clean irrigation system 13
cleaned 7
color coding system 11
control pedal 10, 13
control unit 11
Cruise Control® 11

data

damage 17
deonised water 13
dental file 7
dental ultrasonic generators 5
diminerlised water 13
disinfecte 7
disposal 28
distilled water 13

D

EDTA Ethylenediaminetetraacetic acid 13
Electrical Safety 23
electronic user instructions 5
end of the day 13
endodontics 7
European Directive 23

F

F61001 10
fall risk 10
fault 17
Filter 20
first inclusion of EC marking 7
first use 13
fuse 19

gas-filled atmosphere 22

H

Handpiece support 12
Handpieces 5
Hextril® Hexedrin 13
humidity 11
Hydrogen peroxide 13

I

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
Index: kit F10389 - Wrenches

K

kit F10389 19
kit F12304 20

L

light indicator 12

M

mains adapter 10, 13
Mains switch 19
Manufacturer 21
Medical class 23

N

non-use 13

P

pedal 12
periodontics 7
power configuration button 10
power settings 11
preservation and restoration dentistry 7
Pressure 22
printed copy 5
prophylaxis 7
purge function 12

Q

Quick Clean 5
Quick Start 5

R

recycling 28
repair 7
repairer 7

S

Saline solution 13
seal 20
silicone supports 12
SLIM cord 12, 21
Sodium Hypochlorite 13
spray 12, 19
Spray 15
Sterile water 13
sterilized 7
supply pipe 12

T

Temperature 22
tip 7, 20
Tip 20
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 22

W

water filter 19
water leak 20
water system 9
Wipes 15
Wrenches 5