Premier Premier Plus
Ultrasonic Piezo Scaler

[ Place Disk ]

EN Owner’s Guide
Important!

Alternate options for accessing Instructions for Use:
Email: info@coltenewhaledent.com or info@coltenewhaledent.ch or info@coltenewhaledent.de
to request a printed copy or visit www.coltene.com

This manual covers the following products:

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<th>Description</th>
<th>Voltage</th>
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<tr>
<td>BioSonic Suvi Premier (tap water) USA Plug Type B</td>
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<td>60014237</td>
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<tr>
<td>BioSonic Suvi Premier Plus (Medicament feeder) USA Plug Type B</td>
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<td>BioSonic Suvi Premier Plus (Medicament feeder) AUS Plug Type I</td>
<td>230</td>
<td>60014254</td>
</tr>
</tbody>
</table>

Important!
Read this manual carefully before using the product.

Rx ONLY

Caution: Federal (USA) law restricts these units to sale on or by the order of a dentist.

How to read this manual
Each chapter starts with a section with general instructions, which is followed by sections with additional information. First read the general section and then proceed to the section that applies to your product.
If there are any questions regarding the contents of this manual, please contact Coltène/Whaledent Inc.

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Safety

Indications for Use
The BioSonic Suvi Premier/Premier Plus Ultrasonic Scaler is intended for use in dental applications such as supra and subgingival scaling, periodontal therapy, endodontic procedures, cavity preparation and restorative dentistry.

General Requirements
Service of the product is only to be performed by authorized service personnel.
The product must be connected to an electrical and water supply meeting the requirements specified in the Technical data section 7.

The product needs special precautions regarding EMC (Electro-Magnetic Compatibility) and needs to be installed and put into service according to the EMC information provided in section 8.2. Portable and mobile RF (Radio Frequency) communications equipment can affect the product.

Contraindications
Do not use the scaler on patients with cardiac pacemakers. The scaler may disturb the function of the pacemaker.

General Precautions
• The product is not suitable for use in the presence of flammable gases.
• Only use the product in combination with BioSonic Suvi scaler tips.
• If the handpiece tubing is damaged or worn-out, it must immediately be replaced to avoid exposing the user or the patient to electric hazard.
• Use the original packaging when returning equipment for service.

Warnings
The product should not be used adjacent to or stacked with other equipment.
If adjacent or stacked use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.
Safety notices in this manual

*Warning* indicates a potentially dangerous situation. Non-observance may lead to death or injury.

*Caution* indicates a potentially harmful situation. Non-observance may damage the equipment.

*Note* indicates a situation where special notice should be observed.
Carefully unpack your BioSonic Suvi Premier / Premier Plus unit and verify that all accessories and components are included according to the content lists below:

### 1.1 General Content of Delivery

1. BioSonic Suvi Premier/Premier Plus unit
2. Scaler handpiece connected to unit (1 O-ring on handpiece)
3. Scaler introkit (see section 1.2)
4. 500 ml medicament bottle (Premier Plus) or water hose 6 mm (1/4”)
5. Foot control pedal
6. Foot pedal cable
7. Power cord

### 1.2 Contents of Introkit

- 2 x Scaler tips
- 2 x Grips
- 2 x Torque Wrenches
- 2 x Tip Check Cards
2 Equipment Description

2.1 General Description

BioSonic Suvi Premier / Premier Plus is an effective piezoelectric scaler in a versatile and ergonomic appliance.

The device’s LED lights, advanced electronics, quality, and the BioSonic Suvi tips made from high-durability DuraGradeMAX™ steel enhances the execution of procedures which require great precision.

Ergonomically designed grip handpieces with soft silicone removable grips give the user a comfortable, relaxed grip as well as an excellent feel.

BioSonic Suvi Premier / Premier Plus is highly adaptable to any procedure or user approach. It is not only an outstanding scaling and cleaning device, but it also brings power and versatility to endodontics, implantology, restorative treatments, minimally invasive treatments and apical procedures.

1. Premier / Premier Plus Handpiece (with a grip and a tip mounted)
2. Water flow control ring
3. Handpiece tubing
4. Control panel
5. Foot control pedal
6. Medicament bottle
7. Depressurization button
1. AC power input
2. Fuse holder
3. Water hose coupling (optional)
4. Foot control pedal connection
5. Decal serial label

2.2 Control Panel

1. Cleaning key
2. POWER ON key
3. POWER OFF key
4. Working mode 1 key = 0 to 40% power
5. Working mode 2 key = 0 to 70% power
6. Working mode 3 key = 0 to 100% power
7. StandBy indicator
8. POWER ON indicator
9. Dry mode indicator
10. Irrigation mode indicator
11. Working mode 1 indicator
12. Working mode 2 indicator
13. Working mode 3 indicator
14. Cleaning mode indicator
2.3 Foot Control Pedal

1. Connection for foot control pedal cable
2. OFF position
3. ON position
4. Diagnostic function, turn LED light ON or OFF by a single-click on the pedal
5. Irrigation position
6. Zero power position
7. Maximum power position
8. Power regulation
BioSonic Suvi Premier Plus has a medicament dispenser system, making the device independent of a fixed water supply connection. The medicament bottle can be used for either medicament solutions or ordinary clean water.

The unit contains an electrically driven air compressor. When operating the unit the compressed air forces the fluid from the bottle through the hose to the handpiece and the tip/nozzle.

1. Medicament bottle
2. Bottle connector
3. Depressurization button
4. O-rings (3)
2.5 Symbols on the equipment

Working mode 1 = 0 to 40% power

Working mode 2 = 0 to 70% power

Working mode 3 = 0 to 100% power

Irrigation mode

Dry mode

Automatic cleaning function

Power ON

Power OFF

Example of decal serial label. The product serial label is placed on the back side of the scaler unit.

Medical electrical equipment classified by ETL with respect to electric shock, fire, mechanical, and other specified hazards in accordance with the Safety Standards ANSI/AAMI ES 60601-1 and CAN/CSA C22.2 No 60601-1:08

Caution

Consult accompanying documents.

Compliance label indicating compliance with the Medical Device Directive 93/42/EEC.

Type B applied part according to the degree of protection against electrical shock.

Fuse

Input

Output

This appliance is labeled in accordance with European directive 2002/96/EC concerning used electrical and electronic appliances (waste electrical and electronic equipment - WEEE). This guideline determines the framework for the return and recycling of used appliances as applicable throughout the EU. The symbol on the product, or on the documents accompanying the product, indicates that this appliance may not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment.
Manufacturer

Date of Manufacture

European Union Authorized Representative

IPX1 Ingress Protection Rating, Device has dripping water protection

Autoclave at 132° C

Caution: Federal (United States) laws restricts this device to sale by or on the order of a physician or dentist.
3 Installation

3.1 General Installation Instructions

Checklist

- Position the unit horizontally with the handpiece in the holder and the hose hanging free.
- Position the unit where air is free to circulate on all sides and beneath it. Do not position the unit on a wall or next to a heat source.
- Avoid placing the unit in the immediate vicinity of sources of electromagnetic radiation, for example the Perfect TCS II or other electrosurgery equipment.
- Connect the foot pedal cable to the foot control pedal and at the rear side of the unit.
- Mount the scaler tubing in the groove underneath the unit, as indicated in picture.

3.2 Version for Tap Water (Premier)

Connecting to the water supply

1. Verify that the water supply can be turned off.
2. Verify that the water pressure conforms to the data in the Technical data section 7.
3. Verify that the water supply fulfills the medical demands of hygiene.
4. Push the hose onto the quick connect coupling.
5. Connect the other end of the hose to the water supply.
3.3 General Installation Instructions, continued

- Verify that the voltage rating on the rear side matches the voltage of the AC power outlet.
- Verify that the AC power outlet is provided with a protective ground.
- Connect the power cord to the unit and the AC power outlet. All indicator lights will illuminate for a short period during a self check of the unit.
- The unit is in standby mode when the green indicator light is illuminated.
4 Operating Instructions

Preparations (Premier Plus)

1. Fill the medicament bottle with water or medicament solution according to the Medicaments that can be used, listed on page 26.

2. Screw the bottle connector onto the bottle and push it onto the connector. See picture in section 2.4

3. Check that the power cord is connected and the unit is in stand-by mode, the green indicator light is illuminated.

4.1 Scaler

1a. Attach handpiece cord onto the scaler handpiece.

1b. Gently slide the grip onto the scaler handpiece.

2. Carefully place the tip in the torque wrench.

3. Use the torque wrench and screw the tip clockwise onto the scaler handpiece. Tighten until resistance and the torque wrench slides. The torque wrench prevents the tip from being overtightened.

WARNING

A tip that is bent, altered, or worn more than 2 mm will lose performance and must be exchanged. Prolonged use may cause tip breakage and injury to the patient.

The operator should be aware that ultrasonic instruments with small diameters are subject to breakage at any time. If not used correctly or with too much power or force the instrument WILL break.

Caution

Do not use nickel-titanium files, since they easily break at high frequencies.
4. Turn on the Premier / Premier Plus scaler by pressing the ON key on the control panel. The blue indicator light illuminates and the scaler is activated.

5. The indicator lights next to the working modes are flashing to remind that a working mode has to be selected. If several blue indicator lights are flashing instead, check that the scaler handpiece is connected. If the problem remains, check the troubleshooting section. Check the recommended working mode that is marked on the tip and choose the working mode by pressing the corresponding working mode key on the keyboard.

6. A second press of the “ON” button activates the dry mode for scaling without water/medicament.

7. A third press of the “ON” button activates the irrigation mode. The irrigation mode can also be activated in the scaling mode by pressing down the foot control pedal in the leftmost position.

8. By pressing the “ON” button repeatedly, it will toggle between normal scaling, dry and irrigation mode.

9. Keep the handpiece over the cuspidor bowl or sink and depress the foot control pedal in the leftmost position and adjust the water flow with the ring on the handpiece until the water is dripping from handpiece as in picture below. Recommended flow: 20 ml/min.

10. Keep the patient’s lips, cheeks and tongue out of the way of the activated tip, since contact may cause burns because of friction heat.

Caution
Without cooling fluid, the maximum operating time, for the scaler handpiece, is 2 minutes followed by a cooling-down period of 8 minutes. Operating without cooling fluid for more than 2 minutes may cause overheating of the scaler handpiece. After above cycle has been repeated 2 times, the scaler handpiece has to cool down for at least 60 minutes.

WARNING
Remember to choose the right working mode when changing scaler tip during the treatment.
New tips are not sterile upon delivery. Sterilize before use according to the Instructions in Section 5.1.
Keep the patient’s lips, cheeks, and tongue out of the way of the activated tip, since contact may cause burns because of friction heat.

Note
At low power settings there will be no spray.
Increase the water flow if the handpiece feels too warm.

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Note
At low power settings there will be no spray.
Increase the water flow if the handpiece feels too warm.
4.2 How to use the Premier / Premier Plus Scaler

The side of the tip-end shall be applied to the tooth so that the movement of the tip is parallel to the surface of the tooth. The first 2 mm of the tip are the most efficient. Place the tip on the tooth surface before activating the foot control pedal. The power is regulated with the foot control pedal from 0 to 100% within each working mode. Normal scaling rarely requires more than 50% power level of each working mode. However, hard to remove calculus might require a higher power setting.

Ensure that contact between the tip and the tooth surface is maintained during scaling. Keep moving the tip slowly back and forth and let the instrument do the work. Use short and long strokes so that the whole surface of each tooth is scaled. The tip is normally aimed towards the toothpocket.

To keep the tip working parallel to the surface of each tooth, it is important to follow the anatomy of the tooth. With the correct power setting, appropriate pressure against the tooth (approximately 20 grams but not exceeding 50) and the tip operating parallel to the surface, treatment will be gentle, quiet and efficient. If, during the treatment, a squeaking sound is heard (loud and dominating), the pressure against the tooth might be too low or the tip is not parallel to the surface of the tooth.

4.3 After Treatment

**Automatic cleaning function**

1. Make sure the water control is fully open. Place the scaler handpiece over the cuspidor bowl or sink and start the cleaning cycle by pressing the cleaning key “C”.
2. The cleaning cycle starts and stops automatically after 80 seconds.
3. After the cleaning cycle is finished, screw off the tip, counter clockwise, with the torque wrench.
4. Squeeze the grip gently at the top and at the same time slide it off the handpiece. Do not squeeze the grip too hard as this can make the removal difficult.

5. Press the depressurization button (Premier Plus).

6. Pull the medicament bottle from the unit (Premier Plus).

7. Clean, disinfect and sterilize the components according to the Cleaning and maintenance section below.

5 Cleaning and Maintenance

5.1 Cleaning of the equipment/components

Cleaning:
1. Initial cleaning of the Piezo tips must begin immediately after use to prevent drying of soil and contaminants in and on the device.
2. All exterior surfaces may be soaked in surface disinfectant to remove gross soil. Examine the Piezo tip for damage and discard if excessive wear, broken tip or distortion is noted.
3. Clean thoroughly using an ultrasonic cleaner such as the Coltène/Whaledent BioSonic® Ultrasonic Cleaning System with BioSonic® UC32 Solution Concentrate.

Disinfecting:
1. All exterior surfaces should be disinfected using a cloth soaked with a surface disinfectant or wipes such as CaviWipes®.
2. Do not allow the disinfectant to invade the interior of the unit or components since this may adversely affect the electronics (in the case of the handpiece).
3. Allow the surface disinfectant to reside on the surface for a minimum of three minutes. Do not allow the disinfectant to dry on the surface.
4. Using clean tap water on a clean cloth, wipe away residual disinfectant.

Drying:
1. Use a clean dry cloth to dry exterior surfaces. Do not allow fluids to accumulate (in the case of the handpiece) as this may adversely affect the electronics.

* CaviWipes® is not a registered trademark of Coltène/Whaledent.
Sterilizing:
Package in an FDA approved wrap prior to sterilization. Sterilization can be performed with either of the following cycles:

1. In a gravity autoclave at 132°C/270°F (≥30psig) for 15 minutes with a 15-30 minute drying time.
2. In a pre-vacuum sterilizer at 132°C/270°F for 4 minutes with a 20-30 minute drying time.

Sterilizable Components:

<table>
<thead>
<tr>
<th>Scaler tips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torque wrenches</td>
</tr>
<tr>
<td>Grip for handpiece</td>
</tr>
<tr>
<td>BioSonic Suvi Handpiece</td>
</tr>
</tbody>
</table>

5.2 Routine Cleaning Procedures

Beginning of the day
Run the automatic cleaning cycle with clean water. See instructions in section 4.3.

After each treatment
- Run the automatic cleaning cycle with clean water. See instructions in section 4.3.
- Wipe off the cover, control panel, handpiece and the hose with a soft cloth. Use a surface disinfectant suitable for hard plastics.
- Wash the grip, wrench, handpiece, and the tip.
- Sterilize according to the instructions above.

End of the day
- Run the automatic cleaning cycle with clean water. See instructions in section 4.3.
- Remove and wash medicament bottle and bottle cap at a maximum temperature of 65°C/149°F (Premier Plus).

Weekly (Premier Plus)
- With an antimicrobial cleaning agent solution in the bottle, run the automatic cleaning cycle. See instructions in section 4.3. We recommend to use a separate bottle for the cleaning agent solution. Concerning exposure times of cleaning agent, follow instructions given by manufacturer.
- Before patient treatment, to rinse the lines from cleaning agent solution, put clean water in the bottle and run the automatic cleaning cycle until clean water comes out of the handpieces.
5.3 Maintenance

Power cord
Inspect the power cord, cables and the handpiece hose daily to insure that the equipment is in good condition without mechanical damage.

O-rings (bottle connector)
Lubricate the O-rings regularly with a glycerine based, water soluble lubricant. Vaseline® may also be used, but it may shorten the durability time of the O-rings.

Tips
When a tip is bent, altered, or worn more than 2 mm it will lose performance and must be exchanged. Check the tip length routinely by comparing the tip to the tip check card.

Exchanging fuses
1. Disconnect the power cord from the AC power outlet and the unit.
2. Open the fuse holder on the rear side of the unit.
3. Inspect the fuses for damage. Replace damaged fuses with new ones. Verify the fuse specifications according to the Technical data section 7.
4. Close the fuse holder.

* Vaseline® is not a trademark of Coltène/Whaledent.
## 6 Troubleshooting Premier / Premier Plus

<table>
<thead>
<tr>
<th>Type of problem</th>
<th>Please see</th>
</tr>
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<tbody>
<tr>
<td>A. Unit is not responding and no lights are lit on the control panel</td>
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<tr>
<td>B. Lights are flashing on the control panel</td>
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<td>C. No tip vibration</td>
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<td>D. Weak tip vibration</td>
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<tr>
<td>E. Insufficient or no water flow</td>
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<td>F. Tip does not fit smoothly onto the handpiece</td>
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<tr>
<td>G. Difficult to remove the grip</td>
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</tr>
<tr>
<td>H. Handpiece is overheated</td>
<td>Page 24</td>
</tr>
<tr>
<td>I. Weak or no LED light</td>
<td>Page 24</td>
</tr>
</tbody>
</table>

### A. Unit is not responding and no lights are lit on the control panel

1. Check that the power cord is connected properly and double check the voltage (100/115/230V).
2. Check the fuse and replace if necessary. See section 5.3.
3. Check that the wall outlet and the fuse panel are OK.
4. If the problem still remains contact your dealer for support and indicate "Error Code E-X02".
B. Lights are flashing on the control panel

<table>
<thead>
<tr>
<th>Four blue lights on the control panel are flashing simultaneously.</th>
<th>Check that the foot pedal cable is connected at both ends and is not damaged.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The blue light next to the ON-button is flashing alternately with three other blue lights on the control panel.</td>
<td>Check that the scaler handpiece is properly connected.</td>
</tr>
<tr>
<td>Three yellow lights are flashing in sequence.</td>
<td>The Working Mode has not been selected. Select the working mode by pressing one of the keys next to the yellow lights.</td>
</tr>
<tr>
<td>The light next to the C-button is flashing.</td>
<td>The cleaning function has been activated. Wait until the cleaning process has finished and the light stops flashing.</td>
</tr>
</tbody>
</table>

C. No tip vibration

1. Check that the tip is firmly tightened. Preferably use a torque wrench and tighten clockwise until the torque wrench slides. (The torque wrench prevents the tip from being overtightened.)
2. Check that the green light below the keys on the control panel is lit. If it is not lit, please see Section A on page 22.
3. Check that the device has been turned on by pressing the ON-button and that the blue light next to the ON-button is lit.
4. Check that the Working Mode has been selected by pressing one of the Working Mode buttons and that one of the yellow lights on the control panel is lit.
5. If you have an additional handpiece, try replacing the handpiece.
6. If you have an additional foot pedal cable, try replacing the foot pedal cable.
7. If you have an additional foot control pedal, try replacing the foot control pedal.
8. If the problem still remains contact your dealer for support and indicate "Error Code E-S01".

D. Weak tip vibration

1. Check that the tip is firmly tightened. Preferably use a torque wrench and tighten clockwise until the torque wrench slides. (The torque wrench prevents the tip from being overtightened.)
2. Check that the tip is not worn out. Use a tip check card to evaluate wearing or try an unused tip. Use original BioSonic Suvi tips for reliable performance.
3. If you have an additional handpiece, try replacing the handpiece.
4. If the problem still remains – contact your dealer for support and indicate "Error Code E-S02".
E. Insufficient or no water flow when foot control pedal is activated

1. If the unit is equipped with a medicament bottle: Check that the medicament bottle is properly connected (i.e. the cap is tightened and pushed in all the way onto the connector). Check that the o-rings on cap and connector are in good condition. Replace o-rings if worn. O-rings can be lubricated with a glycerine based lubricant (or Vaseline®*).
2. If the unit is connected to tap water: Check that the tap water hose is properly connected to the back of the device and that the tap water system is OK (tap/valve is open and the filter is OK).
3. Check that dry mode is not activated i.e. that the blue light next to the crossed-out water drop is not lit. If it is lit, press the ON-button.
4. Adjust the water control ring on the handpiece to fully open (dots aligned).
5. Try another tip.
6. If the problem still remains contact your dealer for support and indicate "Error Code E-S04”.

F. Tip does not fit smoothly onto the handpiece

1. Clean handpiece threads with compressed air and try a new tip.
2. If the problem still remains, the threads of the handpiece may be damaged and the handpiece needs to be replaced. Contact your dealer and indicate "Error Code E-S06”.

G. Difficult to remove the grip from the handpiece

1. Grab the grip gently near the lens and at the same time twist and slide it off the handpiece.
2. If the problem still remains, replace the grip.

H. Handpiece is overheated during use

1. Check that the fluid flow is sufficient (at least 20 ml/min).
2. If the problem still remains, replace the handpiece and contact your dealer.

I. Weak or no LED light.

1. Check that lens in the grip is clear and clean. Clean or replace if necessary.
2. If you have an additional handpiece, try replacing the handpiece.
3. If the problem still remains contact your dealer for support and indicate "Error Code E-S03”.

* Vaseline® is not a trademark of Coltène/Whaledent.
# 7 Technical Data

| Manufactured for:       | Coltène/Whaledent Inc.  
|                        | 235 Ascot Parkway  
|                        | Cuyahoga Falls, OH 44223 / USA |
| Model                  | Premier / Premier Plus |
| Classification         | EN60601-1: Class 1, Type B  
|                        | 93/42 EU: Medical products, class IIa |
| L x W x H              | 270 x 110 x 165 mm (without bottle) |
| Weight                 | 2900 g |
| Voltage                | 100 Vac, 50-60 Hz  
|                        | 115 Vac, 50-60 Hz  
|                        | 230 Vac, 50-60 Hz |
| Primary fuse           | T500 mAh, 250 V, Ø5x20 mm (100 Vac)  
|                        | T400 mAh, 250 V, Ø5x20 mm (115 Vac)  
|                        | T200 mAh, 250 V, Ø5x20 mm (230 Vac) |
| Power cord             | Separate with protective ground plug |
| Power consumption      | Max. 40 VA |
| Scaler power consumption | Max. 24 VA |
| Scaler power output    | Max. 10 W (24 kHz - 28 kHz, automatic tuning) |

## Ambient Temperature
- **Operation:** 10°C (50°F) to +70°C (158°F)
- **Transport and storage:** -40°C (-40°F) to +70°C (158°F)

## Relative Humidity
- **Operation:** 10% to 95%
- **Transport and storage:** 10% to 95%
Medicaments that can be used - Premier Plus Unit

- Clean water
- Cetylpyridinium chloride
- Chlorhexidine (Canal Pro™ CHX)
- Essential oils
- Hydrogen peroxide, 3% USP
- Povidine iodine, 10% solution
- Saline solution
- Sangurinara extract
- Sodium hypochlorite, 1% solution

WARNING
Immediately after using any kind of medicament in the medicament bottle, run the automatic cleaning cycle with clean water in the medicament bottle for both the scaler and the polisher until clean water comes out of the handpieces.

| Water supply pressure (version conn. to tap water) | 1 - 10 bar (0.1–1.0 MPa, 14.5–145 PSI) |
| Water consumption | 10 - 50 ml/min |
| Bottle volume (bottle version) | 500 ml |
8 Warranty and Declaration of Conformity

8.1 Warranty Terms

All items are manufactured to impeccable standards and have been developed specifically for use in dentistry and are intended to be operated only by dental professionals in accordance with the instructions contained in this guide. However, notwithstanding anything contained herein, the user shall at all times be solely responsible for determining the suitability of the product for the intended purpose and the method of its use. Any guidance on application technology offered by or on behalf of the manufacturer, whether written, verbal or by demonstration, shall not relieve the dental professional of his/her obligation to control the product and to make all professional judgments regarding its use.

Coltène/Whaledent products are manufactured from new parts or new and serviceable used parts. Regardless, our warranty terms apply. The products are guaranteed in accordance with the terms of the written Certificate of Limited Warranty.

Coltène/Whaledent Inc. provides no warranties or guarantees covering this product, expressed or implied, including, without limitation, any warranties as to merchantability or fitness for use. Coltène/Whaledent Inc. assumes no responsibility for any inconvenience, loss, injury, or direct, indirect, or consequential damage arising from the possession or use of the product.

Tampering with any of the components, misuse, negligence, alteration, water damage, accident, or lack of reasonable or proper maintenance and care will void the warranty. Any claim for damage or breakage in transit should be made at once against the carrier. If factory service is required, be certain to properly pack your equipment and return prepaid and insured to the factory. Please refer to the Certificate of Limited Warranty for warranty terms and conditions.
### 8.2 EMC - Guidance and Manufacturer’s Declaration

#### Guidance and manufacturer’s declaration - electromagnetic emissions

The BioSonic Suvi is intended for use in the electromagnetic environment specified below. The customer or the user of the BioSonic Suvi should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The BioSonic Suvi uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The BioSonic Suvi is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

#### Guidance and manufacturer’s declaration - electromagnetic immunity

The BioSonic Suvi is intended for use in the electromagnetic environment specified below. The customer or the user of the BioSonic Suvi should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact</td>
<td>±6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>±8 kV air</td>
<td>±8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1 kV for input/output lines</td>
<td>±1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV differential mode</td>
<td>±1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±2 kV common mode</td>
<td>±2 kV common mode</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5 % ( U_T ) (&gt;95 % dip in ( U_T )) for 0,5 cycle</td>
<td>&lt;5 % ( U_T ) (&gt;95 % dip in ( U_T )) for 0,5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>40 % ( U_T ) (60 % dip in ( U_T )) for 5 cycles</td>
<td>40 % ( U_T ) (60 % dip in ( U_T )) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70 % ( U_T ) (30 % dip in ( U_T )) for 25 cycles</td>
<td>70 % ( U_T ) (30 % dip in ( U_T )) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5 % ( U_T ) (&gt;95 % dip in ( U_T )) for 5 sec</td>
<td>&lt;5 % ( U_T ) (&gt;95 % dip in ( U_T )) for 5 sec</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**NOTE** \( U_T \) is the a.c. mains voltage prior to application of the test level.
Warranty and Declaration

Guidance and manufacturer’s declaration - electromagnetic immunity

The BioSonic Suvi is intended for use in the electromagnetic environment specified below. The customer or the user of the BioSonic Suvi should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the BioSonic Suvi including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 kHz to 80 MHz</td>
<td></td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td>3 V/m</td>
<td>d = 1,2√P</td>
</tr>
<tr>
<td>IEC 81000-4-3</td>
<td>80 MHz to 2,5 GHz</td>
<td></td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 2,3√P 800 MHz to 2,5 GHz</td>
</tr>
</tbody>
</table>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BioSonic Suvi is used exceeds the applicable RF compliance level above, the BioSonic Suvi should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the BioSonic Suvi.

Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
The BioSonic Suvi is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BioSonic Suvi as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
<th>150 kHz to 80 MHz</th>
<th>80 MHz to 800 MHz</th>
<th>800 MHz to 2,5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>d = 1,2√P</td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>0.1</td>
<td>d = 1,2√P</td>
<td>0.38</td>
<td>0.38</td>
<td>0.73</td>
</tr>
<tr>
<td>1</td>
<td>d = 1,2√P</td>
<td>1.2</td>
<td>1.2</td>
<td>2.3</td>
</tr>
<tr>
<td>10</td>
<td>d = 1,2√P</td>
<td>3.8</td>
<td>3.8</td>
<td>7.3</td>
</tr>
<tr>
<td>100</td>
<td>d = 1,2√P</td>
<td>12</td>
<td>12</td>
<td>23</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.