Fig. 1

- Handpiece (1)
- Light guide (2)
- Handpiece holder (9)
- Battery (8)
- AC power adapter (12) (Not shown)
- Charging base (11)
ON/OFF button (3)

LCD screen (5)

Power verification window (10)

Two-color LED Error Indicator Light (4)

Alert Mode Button (6)

Timing Configuration Button (7)

Fig. 2
I - INTRODUCTION

You have just taken possession of your Blue Ray 3 unit, congratulations.

Created by SATELEC®, the Blue Ray 3 is a photopolymerizer allowing dental care to be given using the suitable light guide supplied with the unit.

To take full advantage of the technology of this product, we request that you read carefully the chapter covering all safety recommendations.

The manufacturer's warranty is applicable only if these indications relating to the unit's operation and safety have been correctly applied. All of these safety measures require a sound knowledge of dentistry, photopolymerization and of the specific instructions regarding the operation of the Blue Ray 3 given in this operating manual.

Sections with the symbol ⚠ are points to which we would like to attract your attention.

II - WARNINGS

⚠ United States Federal Law restricts on its territory the use of this unit exclusively to trained, capable and qualified dental healthcare professionals, or under their control.

To reduce the risk of accidents, it is imperative to comply with the following precautions:

Users of the unit

Use of the Blue Ray 3 is limited exclusively to trained dental healthcare professionals, apt and qualified in the usual context of their activity.

If you have received this unit in error, contact the unit's supplier to arrange for its return.

Interactions/contraindications

Do not use on persons currently suffering from, or that have suffered from in the past, photo-biological reactions (including solar urticaria or erythropoietic protoporphyria) or on persons undergoing treatment using photosensitizing medications (including methoxsalen or chlorotetracycline).

Any person, practitioners or patients who have previously suffered from a retina or lens condition or who have undergone eye surgery, in particular cataract surgery, must consult their ophthalmologist before using this unit.

Even in the event of agreement, it is strongly recommended to be prudent as the light intensity may cause accidents.

It is particularly recommended to continuously wear protective glasses suited to the use of equipment emitting radiation of wavelengths less than 500 nm.

The light radiation produced by this type of equipment can be dangerous and must never be directed towards the eyes, even if the practitioner or the patient is wearing protective glasses suited to the use of equipment emitting radiation of wavelengths less than 500 nm.

The light produced by this unit must be directed only at the part to be treated in the oral cavity.

The equipment must not be used if the patient and/or the operator has a pacemaker or any other active implant (cochlear implant...).

The equipment has not been designed to withstand shocks from an electrical defibrillator.

The unit complies with current electromagnetic compatibility standards, nevertheless, the user shall ensure that any electromagnetic interference does not create an additional risk (presence of radiofrequency emitters, electronic equipment...).

⚠ Overexposure to light radiation of the pulp and soft tissues can result in the release of heat and can result in injury to the patient.

To use your equipment in the best possible conditions, it is important to comply with the specifications given in sections II - WARNINGS Equipment users and V - ROUTINE USE.

As far as possible, avoid the accumulation of heat due to a dental dam.

The use of 30 seconds, 60 sec. and 100 sec. on the same tooth segment is forbidden.

To prevent a feeling of heat, it is recommended to carry out polymerization in intermittent intervals of 10 sec. for the 5 sec. menu, 30 sec. for the 10 sec. menu, 2 minutes for the 30 sec. menu and 10 minutes for the 100 sec. menu.

For the orthodontic clinical menus, 30 sec., 60 sec. and 100 sec. menus can remain on at the condition of not staying on the same tooth segment. This condition complies with the state of the orthodontic dental art (the medical device must be exclusively settled and used by qualified and graduated dental health professionals).
Connection to AC power supply
Ensure that your equipment is connected to the AC power supply by an authorized dentistry installation technician.
Before connecting the unit, check that the AC voltage is compatible with that indicated on the AC power adapter allowing unit charging.
A different voltage would result in damage to the unit and could injure the patient and/or the user.
The AC power supply used to power the unit must comply with the applicable standards of your country.
Any fluctuation of the voltage of the AC power supply or electromagnetic field, noncompliant with the applicable limits, may affect the unit’s operation.

Unit operation
Do not use the unit if it appears to be damaged or defective.
Do not use the unit if the light guide is damaged (injury hazard...).
Before each use, check that light intensity is compliant (see section 3.2 TECHNICAL DESCRIPTION) using the power verification window on the charging base.
When handling the AC power adapter and/or the battery disconnected from the handpiece, avoid contact with the patients or other persons.
Do not touch the accessible battery and charging base connectors (spring loaded contacts).
To disconnect the AC power supply adapter, grip the AC adapter plug and hold the wall socket.
During dental care, the Blue Ray 3 must not be connected to its charging base.
In the event that the unit is not in use or stored, or in the case of a prolonged absence, disconnect the AC adapter from the AC power supply and remove the battery from the body of the unit to protect it from a slow and detrimental discharge.
Do not exert excessive pressure on the unit’s LCD screen.
Do not change the battery during use.
Do not short-circuit the battery.
Do not short-circuit the charging spring loaded contacts on the charging base.
Do not incinerate the battery (risk of explosion).

Environment
Do not immerse and do not use outside.
Place the charging base on a level surface.
Do not place the unit close to a heat source.
The use of solvents, detergents or flammable substances can result in damage or even short-circuits.
Ensure that the power cord connecting the AC adapter to the charging base does not prevent persons from moving freely.
The unit must be stored in its original packaging, in an appropriate place, without danger for persons.
For unit transportation, unscrew the battery and protect the light guide from any unexpected shocks.
Any condensation inside electrical equipment can be dangerous.
If the unit must be transported from a cold place to a warm place, it must not be used immediately, but only after reaching the ambient temperature.
To avoid an electric shock or short-circuit hazard, never insert or try to insert metallic objects into the equipment.
The unit is not designed for operation in the presence of anesthetic gas or any other flammable gas.
Do not expose the unit to water mist or water splashing.
The unit is not designed for operation close to ionizing radiation.

Maintenance
Before and after each use, it is essential that the unit be disinfected with the products recommended by SATELEC.
Before each use, it is essential that a cleaned and disinfected rigid eye shield be used.
Before each use, it is essential that a cleaned, disinfected and sterilized light guide be used.
Before each use, check the integrity of the unit and its accessories.

Accessories
Do not use accessories other than those supplied by SATELEC or American Orthodontics.
The manufacturer refuses to accept any responsibility if damaged parts or accessories are not replaced exclusively by those supplied by the manufacturer. In particular, the use of light guides, AC adapters or batteries other than those supplied by the manufacturer may be dangerous for the patient and the user.
Repair:
Do not perform equipment repairs or modifications without the prior authorization of SATELEC.
In the event of an anomaly, immediately disconnect the unit’s base and ensure that nobody can use the unit before verification by the manufacturer or the supplier.
This anomaly may be due to noncompliance with safety rules or because of technical damage to the unit.
In the event of an anomaly, contact the supplier of the unit rather than just any repairer, which may return
your unit in a hazardous state for both you and your patients.

www.acteongroup.com
Email: satelec@acteongroup.com

or American Orthodontics :
www.americanortho.com
Email : info@americanortho.com

III - DESCRIPTION

3.1 PHYSICAL DESCRIPTION
The Blue Ray 3 includes the following components:
- Handpiece (fig. 1-1).
- Lithium-ion battery (fig. 1-8).
- Opalescent light guide, 45° curve, Ø 5.5mm, sterilizable (fig. 1-2).
- Charging base with handpiece holder (fig. 1-9 and 11).
- AC adapter (fig. 1-12 - not shown).
- Thow rigid eye shields.
- Accompanying documentation.

Optional :
- Multi-fiber light guide, 45° curve, Ø 7.5mm, sterilizable

3.2 TECHNICAL DESCRIPTION
The Blue Ray 3 is equipped with a Light-Emitting Diode (LED) that emits blue visible light of a wavelength between 420 and 480 nm for the photopolymerization of dental materials.

- LCD (Liquid Crystal Display) screen (fig. 2–5)
The LCD screen is backlit and allows the display of the different pieces of information required by the user.

The LCD comprises, from top to bottom:
- Display of time counter for polymerization light emission time, expressed in seconds.
- A pictogram indicating the Fast mode.
- Display of the battery charge level status (battery being most charged when all of the pictogram’s round symbols are displayed and the least charged when all of the round symbols have disappeared from the LCD screen).

- Control buttons (fig. 2 - 3/6/7)
The handpiece comprises three buttons:
- On/Off button (fig. 2-3) Press to start or stop the polymerization cycle
- Left button (fig. 2-6) Press to select alert mode (see Types of alerts below)
- Right button (fig. 2-7) Press and hold to toggle between 3 and 5 second curing interval modes. Press and release to cycle through the timing options available in each curing interval mode. (see Curing intervals below)

- Types of alerts
Blue Ray 3 offers two alert signals to mark each 3 or 5 sec. curing interval. Press the left button (fig 2-6) to select the following alert combinations:
- Beep only
- Microflash only
- Beep and microflash
- No alert/continuous On

- Curing intervals
Blue Ray 3 offers either a 3 second or 5 second curing interval mode, depending on your needs and preferences.
Press and hold the Right button (fig 2-7) to toggle between 3 and 5 sec. modes.
Press and release the Right button repeatedly to cycle through the timing options in each mode:
Available timing in 3 sec interval mode: 3, 6, 30, 60 sec.
Available timing in 5 sec interval mode: 5, 10, 30, 100 sec. (Note: 100 sec. cycle will read 99 on LCD screen).

- Charge time
Battery charge time is about 3 hours.

- Battery charge level indicator
When only one element of the pictogram remains (the one farthest to the right on the LCD screen), two beeps warn you that there are about 500 seconds of polymerization remaining.
The Blue Ray 3 should then be returned to the charging base.
When the battery is completely discharged, the LCD screen displays the message “Lb” (Low battery) and no round symbols are shown, the handpiece then beeps 4 times and the error indicator light becomes red.

- Error Indicator light
An error indicator light (fig. 2-4) is located below the On/Off button. The indicator light shines red when the
unit detects an error and shines green when the unit is in good working condition. The indicator light is unlit when the handpiece is in standby mode.

- Charging base
The charging base is used to recharge the battery and also includes a translucent handpiece holder (fig. 1-9) and a power level verification window (fig. 2-10). The translucent handpiece holder holds the unit in the charging base and also lights up to indicate charging status. The power level verification window is located on the front of the charging base and serves to verify the power output of the light curing unit.
Place the charging base on a hard, level, stable surface with an inclination of no more than 5°.
When the charging base’s AC power is plugged in, the translucent handpiece holder beeps and flashes red, green, and blue.
Place the curing light on the holder ensuring that there is good contact between the spring loaded contacts on the charging base and the copper contacts on the bottom of the battery. Two beeps confirm that the unit is correctly positioned on the charging base and the translucent holder flashes blue, indicating that the battery is charging.
When the battery is completely charged, the translucent holder will shine steady blue.

- Power level verification window
The procedure for using the power level verification window is as follows: Check that the power level verification window is intact and clean.
Ensure that the light guide is intact and clean and insert it into the handpiece.
Place the tip of the light guide flat against the power level verification window and activate the curing light.
The translucent handpiece holder will shine green if compliant power level is detected or red if the power is insufficient.
If the power level is low, please refer to chapter IX TROUBLESHOOTING.

- Technical specifications
Model name: Blue Ray 3
Medical category: IIa
Dimensions without light guide:
Weight: 160 g
Dimensions: Ø24 x 201 mm

Operation: Continuous operation
Protection: Type B
Protection (Category): 5 A T fuse (non accessible) 125 V
Protection index: IPX0

AC power adapter:
Input voltage: 100 V AC to 240 V AC
Frequency: 50 Hz to 60 Hz
Output voltage: 12 V DC
Output current: 0.8 A
Category: II
Protection index: IP 41

Charging base:
Input voltage: 12 V DC
Protection: 3 A T fuse (non accessible) 125 V
Category: Continuous operation
Protection index: IPX0
Battery:
Type: Lithium-Ion
Dimensions: Ø24 x 88 mm
Capacity: 2500 mAh

Optical specifications:
- LED for polymerization:
Wavelength range: 420 - 480 nm
Peak wavelength: 455 - 465 nm
Intensity: 3000 mW/cm² ± 10% for opalescent light guide diameter of 5.5 mm
Class: IIa according to European directive 93/42/CEE
Maximum exposure time: 100 seconds (Mode Fast 99)

Temperatures:
Operation: +10°C to +40°C
Storage: -20°C to +70°C

Humidity:
Operation: 30% to 75%
Storage: 10% to 100% condensation included
IV - INSTALLATION/STARTUP

4.1 UNPACKING THE UNIT
On reception of the unit, look for any damage that may have occurred during transportation. If necessary, contact your supplier.

4.2 RECOMMENDATIONS
Check that the environmental conditions have been complied with (ambient temperature between 10°C and 40°C and humidity between 30% and 75%).

4.3 INSTALLATION
Ensure that the unit is not installed adjacent to or on top of any other equipment.
Do not place the power cord in a cable feedthrough or cable cover.
Remove the protective caps from the handpiece, screw the battery onto the handpiece and insert the sterilized light guide into the handpiece.
Ensure that the light guide is properly inserted, confirmed by a click.
Ensure that all sections of the LCD screen are illuminated once the battery has been properly screwed on.
Place the base on a hard and stable surface that is not inclined by more than 5°.
Connect the AC adapter after ensuring that the voltage indicated corresponds to the electrical installation available in the dental practice.
Two audible beeps confirm that the unit has been correctly placed on its holder.
The translucent holder base lights up blue and starts flashing, indicating that the battery is charging.
As soon as the battery is charged, the translucent holder base stops flashing and the blue light remains illuminated continuously.

4.4 OPERATING FOR THE FIRST TIME
Before operating, it is essential that the sterilizable accessories (light guide) be sterilized and that the Blue Ray 3 be disinfected (see chapter VIII - MAINTENANCE).

4.5 EXPOSURE TIMES AVAILABLE
Blue Ray 3 offers either a 3 second or 5 second curing interval mode, depending on your needs and preferences. Press and hold the Right button to toggle between 3 and 5 sec. modes.

4.6 ALERTS OFFERED
Blue Ray 3 offers two alert signals to mark each 3 or 5 sec. curing interval. Press the left button (fig 2-6) to select the following alert combinations:
- Beep only (shows b)
- Microflash only (shows F)
- Beep and microflash (shows Fb)
- No alert/continuous On (shows --)

V - ROUTINE OPERATION
Blue Ray 3 is normally placed on its holder. The first time you plug it into the battery it will default to the 3 sec. fast curing mode and the beep alert. Your Blue Ray 3 is ready to operate once the curing time and the kind of alert have been selected. Place the light guide as close as possible to the surface of the material to be polymerized, without touching it as this may adversely affect the quality of the polymerization. The polymerization starts by pushing the ON/OFF button. The setting will be confirmed by an audible signal (beep). A countdown on the LCD screen shows you how much time remains, and the selected alert method signals each timing interval; either every 3 or 5 sec. depending on mode chosen. When the polymerization cycle is completed, the time that was applied is displayed. You can press the ON/OFF button at any time to interrupt the current polymerization cycle. After 3 minutes without use, the unit goes into standby mode.
VI - CONFIGURATION

6.1 START UP
On start up, the unit performs an automatic test sequence (auto-check).
The device automatically recalls the settings used for the previous dental treatment.

6.2 EXPOSURE TIMES
Select 3 or 5 second mode by pressing and holding the Right button (fig 2-7) on the handpiece. Then select the desired exposure time by pressing and releasing the Right button repeatedly to cycle through the available timing options within each mode.

6.3 ALERTS
Combinations are chosen by pushing the left button (fig. 2-6). Then, this selection is validated by waiting 3 sec., by pushing the ON / OFF button (fig. 2-3), or by pushing the button on the right (fig. 2-7).

VII - INTERLOCKS

Blue Ray 3 is equipped with a system for the detection of possible unit operation anomalies.

7.1 EXCESSIVE TEMPERATURE
During intensive use, an excessive temperature may be detected and the screen then displays the letters “OH” (Over Heat), the audible alert (beep) sounds 4 times and the error indicator light (two-color LED) becomes red. It is then recommended that the user leave the handpiece to cool for a few minutes, until the indicator light becomes green again and the screen once again displays the selected time cycle.

7.2 BATTERY CHARGE LEVEL
When the LCD screen displays the last remaining round battery charge indicator, the audible alert (beep) sounds twice. You then have about 500 sec. remaining before the unit becomes completely discharged. It is then recommended, if possible, to charge the battery for further use. When the battery becomes completely discharged, the letters “Lb” (Low Battery) are displayed on the screen, the audible alert (beep) sounds 4 times and the indicator light (two-color LED) becomes red.

The user must return the handpiece to its charging base to recharge the unit’s battery (see chapter 4.3 INSTALLATION).

VIII - MAINTENANCE

Before conducting any maintenance on the Blue Ray 3, check that:
- The Blue Ray 3 is not on its charging base.
- The battery has been unscrewed from the handpiece.
- The charging base has been disconnected from the AC supply.

Before cleaning the handpiece, insert the protective cap in the place of the light guide, supplied to ensure that liquid does not enter the handpiece. Avoid using cleaning and disinfection products containing flammable agents (or other corrosive agents such as acetone, chlorine or bleach). Otherwise, ensure that the product completely evaporates and that there are no combustibles on the unit and its accessories before operation. Do not use abrasive products to clean the unit. Do not immerse the unit. Never use ultrasonic cleaning, whether for the Blue Ray 3 or its accessories. None of the accessories is delivered in a sterilized state. Only the light guide is sterilizable. Before sterilization, check the cleanliness of your autoclave and the quality of the water used. After each sterilization cycle, immediately remove the items from the autoclave to reduce the risk of corrosion of metallic parts. It is necessary to leave the sterilized items to cool down to the ambient temperature and dry before
It is recommended to sterilize the items identified as sterilizable individually in the sterilization bags foreseen for this purpose.

To maintain the sterile and aseptic state of accessories, make sure that they are kept in hermetically-sealed bags or containers suited for use in dentistry.

The maintenance and/or sterilization instructions that follow must be applied before each use of the unit.

**8.1 - Pre-disinfection/cleaning**
Clean and disinfect the body, light guide, eye shield and the charging base of the Blue Ray 3 using ready-to-use cleaning/disinfecting wipes based on alcohol, amphoteric disinfectant and biguanide (of the type SEPTOL™ WIPE, refer to the manufacturer's instructions) for at least two minutes.

Leave the product to act for at least 15 minutes.

Use wipes with CE marking, or compliant with any standard that may be required by national regulations.

**8.2 - Drying**
Dry using a clean, single-use, non-woven cloth to remove any liquid traces.

**8.3 - Packing**
Pack in single-use sterilization bags or sleeves compliant with the requirements defined in the EN ISO 11607-1 standard, or compliant with any standard that may be required by national regulations.

**8.4 - Sterilization**
The fiber optic light guide for the Blue Ray 3 must be sterilized in an autoclave according to the following parameters:
- **Autoclave:** Type B compliant with the EN 13060 standard.
- **Sterilization temperature:** 134°C.
- **Sterilization steady state:** 18 minutes.
- **Pressure:** 2 bar minimum.

**CAUTION:** Not all autoclaves can reach 134°C. Not all autoclaves perform a pre-depressurization. For further information on the applicable sterilization instructions, consult the autoclave manufacturer.

**8.5 - Storage**
After this, store the sterilized items in a dry, dust-free place.

Before re-use, in the event of nonconforming packaging integrity, re-package and re-sterilize according to the defined protocol.

**IX - TROUBLESHOOTING**

In the event of a problem, before contacting the after-sales service of SATELEC or the supplier:
- Ensure that the base is correctly connected to the AC supply to ensure that the battery is charged normally. If the Blue Ray 3 holder is not lit despite being correctly connected, contact the after-sales service of SATELEC or the supplier.
- Check that at least one of the four round battery charge level indicators is visible on the LCD screen before pressing the ON/OFF button. In the event of a faulty battery (see VII - INTERLOCKS) an automatic interlock system will prevent the unit from operating. If this is the case, recharge the battery by placing the curing light on its holder or by using a second fully-charged battery.
- Intensive use of the curing light can result in high temperatures inside the unit. If this happens, an automatic interlock system prevents the unit from operating (see VII - INTERLOCKS).

Leave the unit at rest for a few minutes to allow it to cool down. After each use, check that there is no composite residue adhering to the light guide. If this is the case, immediately remove the residues and check that the surface of the light guide has not been damaged. If damage is visible, replace the light guide as the unit's power could be significantly reduced.

- Under normal conditions of use, the unit’s power does not vary if the battery is properly charged. Consequently, it is not necessary to check power as with ordinary polymerization lamps. Nevertheless, in case of doubt, check its power using the verification window.
- The battery located at the bottom of the handpiece can be removed by unscrewing it. After removing the light guide, check that the LED is clean and undamaged. If necessary, clean it using a medical-quality dry air jet (free from compressor oil). During verification of the power level of the handpiece, if the translucent handpiece holder base is red, check if the LED, light guide and verification window are clean.
- In the event of dust being present, clean using a dry air jet. If the problem persists or if the light guide or the verification window is damaged, the unit must be returned to the after-sales service.

**In the event of an anomaly, contact the supplier of the unit rather than just any repairer, who may return your unit in a hazardous state for both you and...**
your patients. The technical service of your supplier is available for any technical problems encountered on your unit.

<table>
<thead>
<tr>
<th>Anomaly observed</th>
<th>Possible causes</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>No operation (LCD screen off)</td>
<td>Battery completely discharged</td>
<td>Recharge battery</td>
</tr>
<tr>
<td></td>
<td>Battery defective</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Blue Ray 3 defective</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td>No operation (LCD screen on)</td>
<td>Blue Ray 3 defective</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td>Light power defect, or no light power</td>
<td>LED defective and/or dirty</td>
<td>Check cleanliness of verification window and/or Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Blue Ray 3 defective</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Defective buttons</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Light guide defective and/or dirty</td>
<td>Clean light guide and/or Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Reflector defective or dirty</td>
<td>Clean reflector (dry air jet) and/or Return to SATELEC after-sales department</td>
</tr>
<tr>
<td>Charger does not operate</td>
<td>AC power wall outlet defective</td>
<td>Contact your electrician</td>
</tr>
<tr>
<td></td>
<td>AC power adaptor defective</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Light and/or audible alerts defective</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Contact failure on Jack connector socket</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Fuse defective</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td>Dysfunction of power level verification</td>
<td>Error indicator light defective</td>
<td>Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Light guide defective and/or dirty</td>
<td>Clean light guide and/or Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>LED defective and/or dirty</td>
<td>Clean LED (dry air jet) and/or Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Reflector defective and/or dirty</td>
<td>Clean reflector (dry air jet) and/or Return to SATELEC after-sales department</td>
</tr>
<tr>
<td></td>
<td>Window defective and/or dirty</td>
<td>Clean window and/or Return to SATELEC after-sales department</td>
</tr>
</tbody>
</table>

**X - ELECTROMAGNETIC COMPATIBILITY**

**Warning:** The charger power cord must be kept apart from those of any nearby devices.

Blue Ray 3 requires special precautions to be taken with regard to electromagnetic compatibility. It must be installed and prepared for use as described in chapter IV. Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the Blue
Blue Ray 3 must not be used near or on top of another device. If this cannot be avoided, its operation under the conditions of use must be checked beforehand. The use of accessories other than those specified or sold by SATELEC or American Orthodontics as replacement parts may have the consequence of increasing the emissions or decreasing the immunity of the Blue Ray 3.

10.1 - Electromagnetic emissions

Blue Ray 3 is intended for use in the electromagnetic environment specified in the table below. The user and/or installer must ensure that Blue Ray 3 is used in such an environment.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emission - CISPR 11.</td>
<td>Group 1 Class B</td>
<td>Blue Ray 3 uses RF energy for internal operation. Therefore, its radiofrequency emissions are very low and are not likely to cause any interference in nearby equipment. Blue Ray 3 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>
</tbody>
</table>

10.2 - Magnetic and electromagnetic immunity

Blue Ray 3 is intended for use in the electromagnetic environment specified in the table below. The user and/or installer must ensure that Blue Ray 3 is used in such an electromagnetic 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>Magnetic field at 50Hz.</td>
<td>±3A/m</td>
<td>±3A/m</td>
<td>The intensity of the magnetic field should be equivalent to that of a typical commercial or hospital environment (hospital, clinic).</td>
</tr>
<tr>
<td>Emission test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6KV contact</td>
<td>±6KV contact</td>
<td>Floors must be wood, concrete, cement or tilled. If floors are covered with synthetic material (carpet, etc.), the relative humidity must be at least 30%.</td>
</tr>
<tr>
<td>Emission test</td>
<td>±8KV air</td>
<td>±8KV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transients</td>
<td>±2KV for power supply lines</td>
<td>±2KV for power supply lines</td>
<td>Power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Emission test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1KV differential mode ±1KV common mode</td>
<td>±1KV differential mode ±1KV common mode</td>
<td>Power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations</td>
<td>-5% U(t) (&lt;95% dip in U(t)) for 0.5 cycles. 40% U(t) (&gt;60% dip in U(t)) for 5 cycles 70% U(t) (20% dip in U(t)) for 25 cycles -5% U(t) (&lt;95% dip in U(t)) for 0.5 cycles. 40% U(t) (&gt;60% dip in U(t)) for 5 cycles 70% U(t) (20% dip in U(t)) for 25 cycles -5% U(t) (&lt;95% dip in U(t)) for 0.5 cycles. 40% U(t) (&gt;60% dip in U(t)) for 5 cycles 70% U(t) (20% dip in U(t)) for 25 cycles</td>
<td>-5% U(t) (&lt;95% dip in U(t)) for 0.5 cycles. 40% U(t) (&gt;60% dip in U(t)) for 5 cycles 70% U(t) (20% dip in U(t)) for 25 cycles</td>
<td>Power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Emission test</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10.3 - Electromagnetic immunity / mobile radiofrequency equipment

Blue Ray 3 is intended for use in the electromagnetic environment specified in the table below. The user and/or installer must ensure that the device is used in such an electromagnetic environment.
10.4 - Recommended separation distances

Blue Ray 3 is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled. Blue Ray 3 user and/or installer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radiofrequency communications equipment (emitters) and the Blue Ray 3, according to the maximum output power of the equipment, as recommended in the table below.

<table>
<thead>
<tr>
<th>Rated max. power of the emitter (W)</th>
<th>Separation distance in meters (m) according to emitter frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 KHz to 80 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>0.1</td>
<td>0.12 m</td>
</tr>
<tr>
<td>1</td>
<td>0.38 m</td>
</tr>
<tr>
<td>10</td>
<td>3.8 m</td>
</tr>
<tr>
<td>100</td>
<td>12 m</td>
</tr>
</tbody>
</table>

For emitters rated at max. power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the emitter, where $P$ is the max. power rating of the emitter in watts (W) according to the manufacturer.

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

Note 2: These specifications may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and persons.
10.5 - Cable lengths

<table>
<thead>
<tr>
<th>Cables and accessories</th>
<th>Maximum length</th>
<th>Complies with:</th>
</tr>
</thead>
<tbody>
<tr>
<td>charger power cord</td>
<td>&gt;3m</td>
<td>RF emission, CISPR 1 - Class B</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immunity to magnetic fields: IEC61000-4-8,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immunity to electrostatic discharge: IEC61000-4-2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immunity to electrical fast transients/bursts: IEC61000-4-4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immunity to surges: IEC61000-4-5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immunity to voltage dips, short interruptions and voltage variations: IEC61000-4-11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immunity to conducted disturbances induced by radiofrequency fields: IEC61000-4-6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immunity to radiated radiofrequency electromagnetic fields: IEC61000-4-3</td>
</tr>
</tbody>
</table>

XI - DISPOSAL AND RECYCLING

As electrical and electronic equipment, the device must be disposed of according to a specialized procedure for collection, pick-up and recycling or destruction (in particular on the European market, with reference to Directive 2002/96/EC of 23/01/2003).

When your device reaches the end of its life, we consequently recommend that you contact your dental equipment dealer (or, failing this, the nearest ACTEON GROUP office, the list of which is given in chapter 16), for information on how to proceed.

XII - LIABILITY

The manufacturer is not liable if:
- the manufacturer's installation recommendations have not been followed (supply voltage, electromagnetic environment, etc.);
- repairs have been performed by persons not authorized by the manufacturer;
- the device has been used in an electrical installation which does not comply with current standards;
- the device has been used in a way which is not stipulated in this Manual;
- accessories other than those supplied by SATELEC have been used;
- the instructions in this document have not been followed.

The manufacturer reserves the right to modify the unit and/or the Operating Manual without notice.

XIII - ACCESSORIES

The following accessories are available from American Orthodontics for the Blue Ray 3:
- Opalescent light guide Ø 5.5 mm : Ref. 852-913F
- Opalescent light guide Ø 7.5 mm : Ref. 852-915F
- Molar shaped eye shield : Ref. 852-933
- Oval eye shield : Ref. 852-934
- Power cord : Ref. 852-936
- Battery : Ref. 852-932
XIV - REGULATIONS

This medical device is classified as class Ila according to European Directive 93/42/EEC.
This equipment is manufactured in compliance with the current IEC 60601-1 standard.
This equipment has been designed and manufactured according to an ISO 13485-certified quality assurance system.

XV - SYMBOLS AND ABBREVIATIONS

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>~</td>
<td>Alternating current</td>
</tr>
<tr>
<td></td>
<td>Direct current</td>
</tr>
<tr>
<td>⚠</td>
<td>Follow operating instructions</td>
</tr>
<tr>
<td></td>
<td>“ON”/“OFF” (pushbutton)</td>
</tr>
<tr>
<td>♂</td>
<td>Type B</td>
</tr>
<tr>
<td></td>
<td>Class II</td>
</tr>
<tr>
<td>CE</td>
<td>CE marking</td>
</tr>
</tbody>
</table>

Note: Technical personnel of the Satelec authorized dealer network can obtain from ACTEON Group on request all the information they need for repair of the parts of the curing light that Satelec has identified as repairable.
XVI - CUSTOMER RELATIONS

16. 1 MANUFACTURER IDENTIFICATION

SATELEC
17, avenue Gustave Eiffel - BP 30216
33708 MERIGNAC cedex - France
Tél. +33 (0) 556.34.06.07
Fax. +33 (0) 556.34.92.92
E.mail : satelec@acteongroup.com
www.acteongroup.com

16. 2 SUBSIDIARIES

FRANCE
SATELEC
A Company of ACTEON Group
17 av. Gustave Eiffel - BP 30216
33708 MERIGNAC cedex - France
Tél. +33 (0) 556.34.06.07
Fax. +33 (0) 556.34.92.92
E.mail : satelec@acteongroup.com
www.acteongroup.com

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

GERMANY
SATELEC GERMANY
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 IBERICA
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.
SATELEC (UK) LIMITED
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 - 1st Floor N’111 - Gardens Street
- PO Box 468 - AMMAN 11953 - JORDAN
Tel. +962 6 553 4401
Fax. +962 6 553 7833
E.mail : info@me.acteongroup.com

CHINA
ACTEON CHINA
Office 401 - 12 Xinyuanxili Zhong Street - Chaoyang
District - BEIJING 100027 - CHINA
Tel. +86 10 646 570 11/2/3
Fax. +86 10 646 580 15
E.mail : beijing@cn.acteongroup.com
PHILIPPINES
ACTEON PHILIPPINES
4th Floor Alco Building - No. 391 Sen. Gil Puyat Avenue - Makati City - 1200 - PHILIPPINES
Tel. +632 899 78 66 or 67
Fax. +632 899 78 43
E.mail : info@ph.acteongroup.com

THAILAND
ACTEON THAILAND
23/45 Sorachai Building 16th floor - Sukumvit 63 Road, Klongton Nua - Wattana, BANGKOK 10110 - THAILAND
Tel. +66 2 714 3295
Fax. +66 2 714 3296
E.mail : info@th.acteongroup.com

KOREA
ACTEON KOREA
8F Hanil B/D - 132-4 1Ga Bongrae-dong - JOONG-GU - SEOUL - KOREA
Tel. +82 2 753 41 91
Fax. +82 2 753 41 93
E.mail : info@kr.acteongroup.com

COSTA RICA
ACTEON LATIN AMERICA
Del Cristo Sabanilla 2,6 km arriba - 100 mts Este del Taller Autotransmisiones - Residencial "El Refugio" - San Ramón de Tres Ríos - COSTA RICA
Tel. +506 2273 4033
Fax. +506 2273 4033
E.mail : am.latina@es.acteongroup.com

RUSSIA
ACTEON RUSSIA
Valdajski Proezd 16 - Building 1 - office 253 - 125445 Moscow - RUSSIA
Tel./Fax. +7 495 451 80 50
E.mail : sergey.koblov@ru.acteongroup.com

AUSTRALIA/NEW ZEALAND
ACTEON AUSTRALIA/NEW ZEALAND
L3, Suite 23, 6-8 Crewe Place, 2018 Rosebery, NSW Australia
Tel. +612 966 24400
Fax. +612 966 24600
E.mail : sandy.junior@au.acteongroup.com

INDIA
ACTEON INDIA
B-94, G.I.D.C. Electronic Estate - Sector 25 - GANDHINAGAR 382044 (Gujarat) - INDIA
Tel. ++91 79 2328 7473
Fax. ++91 79 2328 7480
E.mail : info@in.acteongroup.com