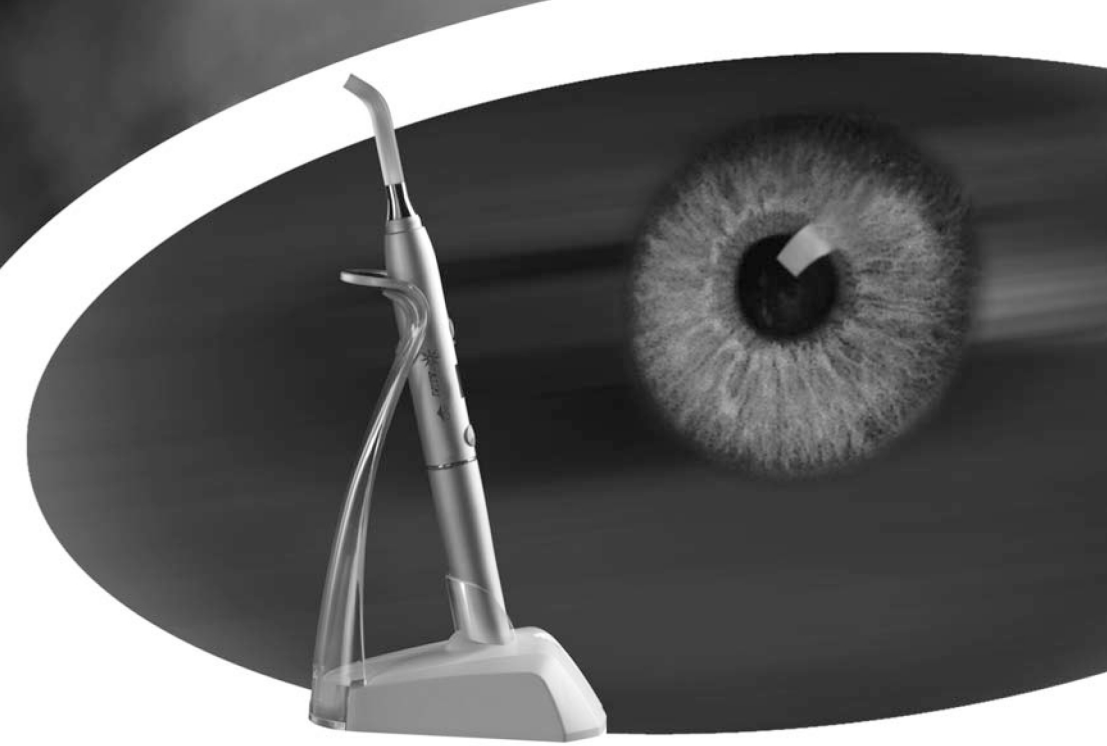


BLUE RAY 3
MICROFLASH LED

User's manual

AMERICAN ORTHODONTICS

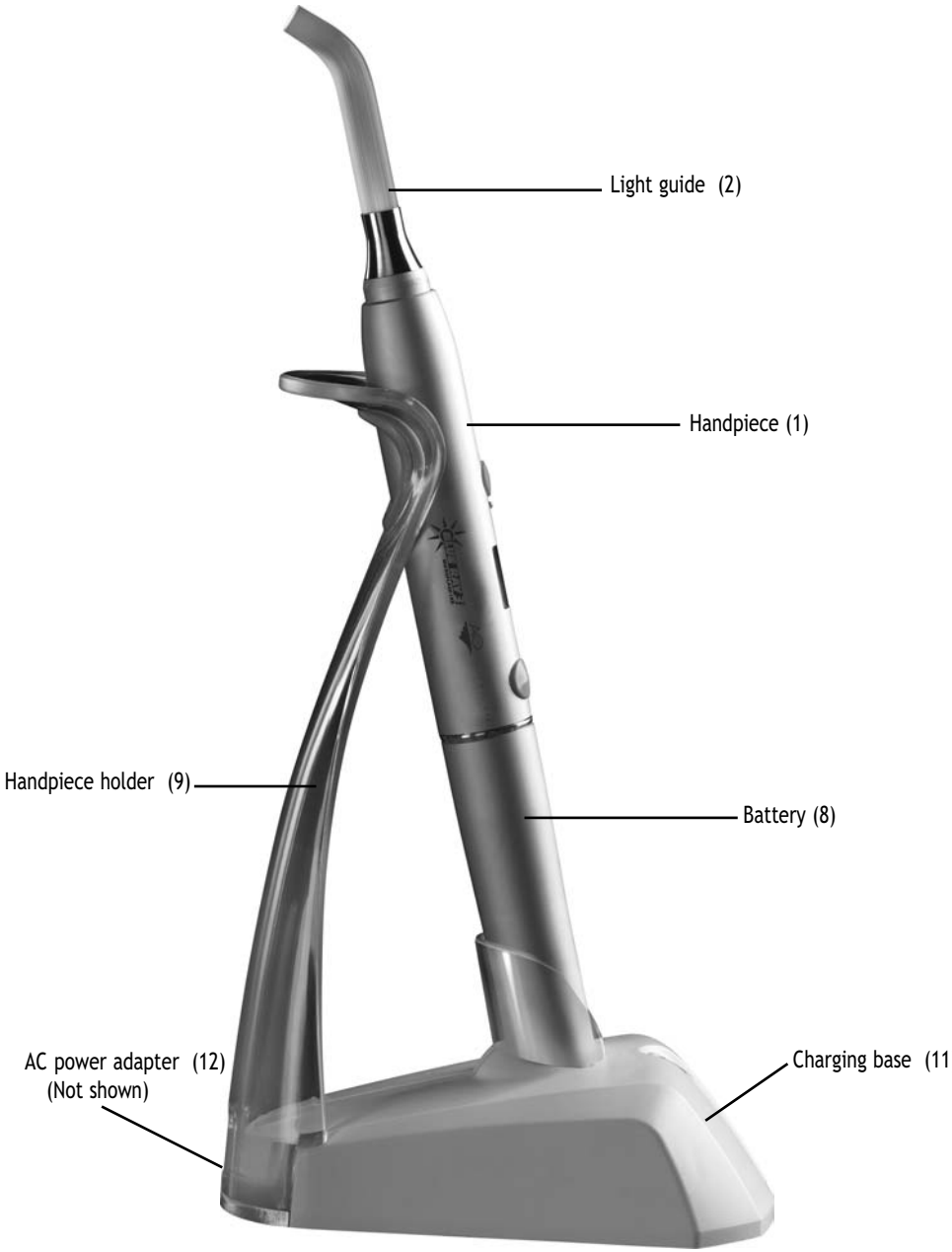

Light guide (2)
Handpiece (1)
Handpiece holder (9)
Battery (8)
AC power adapter (12)
(Not shown)
Charging base (11)

Fig. 1

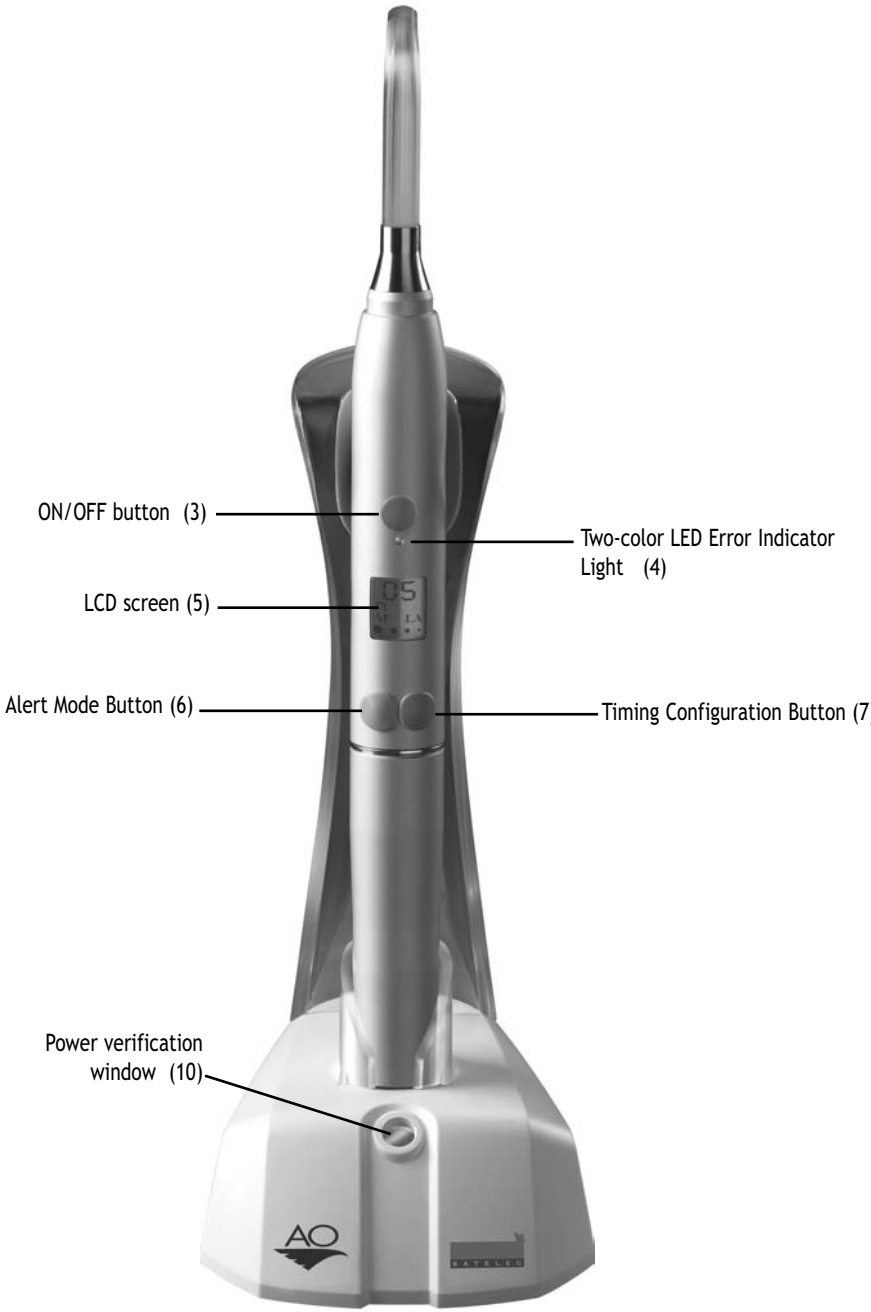

ON/OFF button (3)
Two-color LED Error Indicator Light (4)
LCD screen (5)
Alert Mode Button (6)
Timing Configuration Button (7)
Power verification window (10)

Fig. 2

ENGLISH
SUMMARY

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 chlortetracycline).
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.

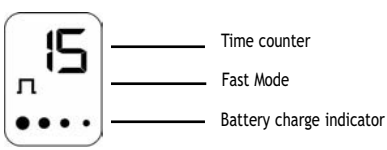
Optional :
- Multi-fiber light guide, 45° curve, Ø 7.5mm, sterilizable

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:	
Category:	Type B
Protection:	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.

Press and release the Right button to cycle through available timing in each mode.

Available timing in 3 sec. interval mode:
3 seconds (shows 03)
6 seconds (shows 06)
30 seconds (shows 30)
60 seconds (shows 60)

Available timing in 5 sec. interval mode:
5 seconds (shows 05);
10 seconds (shows 10);
30 seconds (shows 30);
100 seconds (shows 99).

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

(low consumption). The green indicator light and the LCD screen backlighting switch off. The unit can be taken out of standby mode by simply pressing one of the three buttons (which will not activate that function when coming out of 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

re-using them.
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.

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

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

Ray 3. The recommended separation distances in this paragraph must therefore be complied with.

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 the Blue Ray 3 is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emission - CISPR 11.	Group 1 Class B	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.

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 the Blue Ray 3 is used in such an electromagnetic environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Magnetic field at 50Hz. IEC61000-4-8	3A/m	3A/m	The intensity of the magnetic field should be equivalent to that of a typical commercial or hospital environment (hospital, clinic).
Electrostatic discharge (ESD) IEC 61000-4-2.	± 6KV contact ± 8KV air	± 6KV contact ± 8KV air	Floors must be wood, concrete, cement or tiled. If floors are covered with synthetic material (carpet, etc.), the relative humidity must be at least 30%.
Electrical fast transients IEC 61000-4-4.	± 2KV for power supply lines	± 2KV for power supply lines	Power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5.	± 1KV differential mode ± 2KV common mode	± 1KV differential mode ± 2KV common mode	Power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11.	<5% U_T (>95% dip in U_T) for 0.5 cycles. 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 250 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycles. 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 250 cycles	Power quality should be that of a typical commercial or hospital environment. If the use of the Blue Ray 3 requires continued operation during a power cut, it is recommended that the product be powered from a separate power supply (generator, etc.).

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile radiofrequency communications devices must not be used near the Blue Ray 3 (including its cables) at a distance less than that recommended and calculated according to the frequency and power of the emitter.			
Conducted disturbance, radiofrequency fields. IEC61000-4-6	3 V/m 150 KHz to 80 MHz	3 V/m	Recommended separation distance: $d = 1.2 \sqrt{P}$
Radiated radiofrequency electromagnetic field. IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80MHz to 800MHz. $d = 2.3 \sqrt{P}$ 800MHz to 2.5GHz. Where P is the maximum power rating of the emitter in watts (W) according to the manufacturer's specifications and d is the recommended minimum separation distance in meters (m).
The electromagnetic field strengths of fixed radiofrequency emitters, as determined by an electromagnetic environment measurement (a), must be less than the compliance level in each frequency range (b). Interference may occur near equipment marked with the symbol at right :			

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.

(a): The electromagnetic field strengths of fixed radiofrequency emitters, such as base stations for mobile telephones (cellular/cordless), mobile radios, amateur radios, AM/FM radio broadcasts and TV broadcasts cannot be determined exactly by theory. To assess the electromagnetic environment due to fixed radiofrequency emitters, an electromagnetic environment measurement must be made. If the measured radiofrequency field strength in the immediate environment where the product is used exceeds the compliance level specified above, the performance of the product must be tested to verify whether it conforms to the specifications. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

(b): In the 150 kHz to 80 MHz frequency range, the electromagnetic field strengths must be less than 3 V/m.

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.

Rated max. power of the emitter (W)	Separation distance in meters (m) according to emitter frequency		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m
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 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

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

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 IIa 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

SYMBOL	DEFINITION
	Alternating current
	Direct current
	Follow operating instructions
	“ON”/“OFF” (pushbutton)
	Type B
	Class II
	CE marking

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

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16. 2 SUBSIDIARIES

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