

Dentist User Guide



OsseoPulse™ Bone Regeneration System
Model AR300

BIOLUX
Accelerating Regeneration

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Disclaimer and Limitation of Responsibility

Biolux Research Ltd. assumes no responsibility for any damage, loss, or claims which may result from: failure to follow the instructions contained in this Manual; malfunction due to unauthorized repairs or modifications; or use of the OsseoPulse™ equipment is entirely the responsibility of the operator.

Radio-frequency Interference

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Canadian ICES 03 and part 15 of the USA FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the antenna
- Increase the separation between the equipment and the receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the manufacturer or an experienced radio/TV technician for help.

Any changes or modifications to this equipment not expressly approved by the manufacturer will void the Dental Practitioner's authority to operate and/or prescribe this equipment for use.

OsseoPulse™ is a trademark of Biolux Research Ltd.
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Safety Information: WARNINGS

United States Federal law and other national regulations require that this device be purchased only by a dentist or a person acting on behalf of a dentist. Biolux Research Ltd. cannot be held responsible for any damage or injury which results from a failure to follow the directions in this user guide. Please ensure that you are entirely familiar with the correct procedures for operating the instrument before use.

▲ USE ONLY AS DIRECTED. The OsseoPulse™ must be used under the direction or supervision of a dentist.

▲ DO NOT STARE DIRECTLY AT THE LIGHT SOURCE. The OsseoPulse™ emits an intense beam of red and/or invisible infrared light.

▲ DO NOT USE OR PLACE THE DEVICE IN OR NEAR WATER OR HEAT PRODUCING APPLIANCES. As with any electrical equipment, contact with liquids or heat may damage the device and may pose fire hazards.

▲ DO NOT OPEN OR TAMPER WITH THE CASING. If the OsseoPulse™ becomes damaged, return it to the manufacturer for repair. Any changes or modifications to this equipment not expressly approved by the manufacturer will void the Dental Practitioner's authority to operate and/or prescribe this equipment for use.

▲ DO NOT USE WITH HIGH FREQUENCY (HF) SURGICAL EQUIPMENT. OsseoPulse™ has not been tested in conjunction with High Frequency (HF) surgical equipment (e.g., electrocautery)

▲ DO NOT USE ON MULTIPLE PATIENTS SIMULTANEOUSLY. The two Treatment Array connections are electrically connected and do not provide isolation between two patients. If both Treatment Arrays are used, they must be used on a single patient only.

▲ KEEP AWAY FROM ITEMS AFFECTED BY MAGNETIC FIELDS. OsseoPulse™ contains magnetic components and may affect computer discs, credit cards, magnetic strips, etc. This device is not recommended for use by those who have an implanted cardiac pacemaker, defibrillator, or an equivalent cardiac device unless the cardiac device is known to not be affected by magnetic fields.

▲ **KEEP AWAY FROM CHILDREN AND PETS.** OsseoPulse™ is a medical device and misuse could be harmful. It must be used only by the intended patient.

▲ **HANDLE WITH CARE.** Excessive force should never be applied when setting up or storing the device. When not in use, store the OsseoPulse™ in its protective carrying case. The OsseoPulse™ power cord has a detachable plug, but this plug is normally firmly fastened to the power cord and should not be removed. When unplugging the power, pull directly on the plug to release it from the socket and without using any bending or twisting motions.

▲ **DO NOT USE WHEN IMPAIRED.** Do not use this device after taking sedatives or alcohol.

▲ **DO NOT USE IF YOU ARE PHOTOSENSITIVE.** The OsseoPulse™ should not be used by patients whose skin is overly sensitive to light; note that some medications can increase sensitivity. Discontinue use if any adverse reactions to the treatments are noticed. If a patient is susceptible to seizures triggered by flashing lights (photosensitive epilepsy), ensure that only the non-flashing protocols are used with that patient.

Safety Information: CAUTIONS

- To ensure that the Treatment Array remains in the correct position, the patient should always keep their mouth closed and their teeth together during treatment.
- Prior to removing the Headset, turn off the OsseoPulse™ reducing the chance of shining the bright light directly in the patient's eyes.
- The Treatment Array will be warm to touch during and after treatment, this is normal. If it becomes hot or uncomfortable to touch, discontinue treatment and contact Biolux or your distributor.
- The Treatment Array should not be covered. If it is covered, the Treatment Array could overheat. (An obstruction could be caused by an improperly positioned pillow or by long hair, for example).
- A small degree of tingling, warm feeling and pulsing is normal in the tissue and jaw during and after an OsseoPulse™ treatment session. Most patients find this comforting and soothing. If a patient experiences pain, discontinue

the treatment.

- The OsseoPulse™ is programmed with self-diagnostic software that runs automatically at the beginning of every treatment session to verify that no system performance degradation has occurred. When the system detects a fault, the following warning message is displayed:

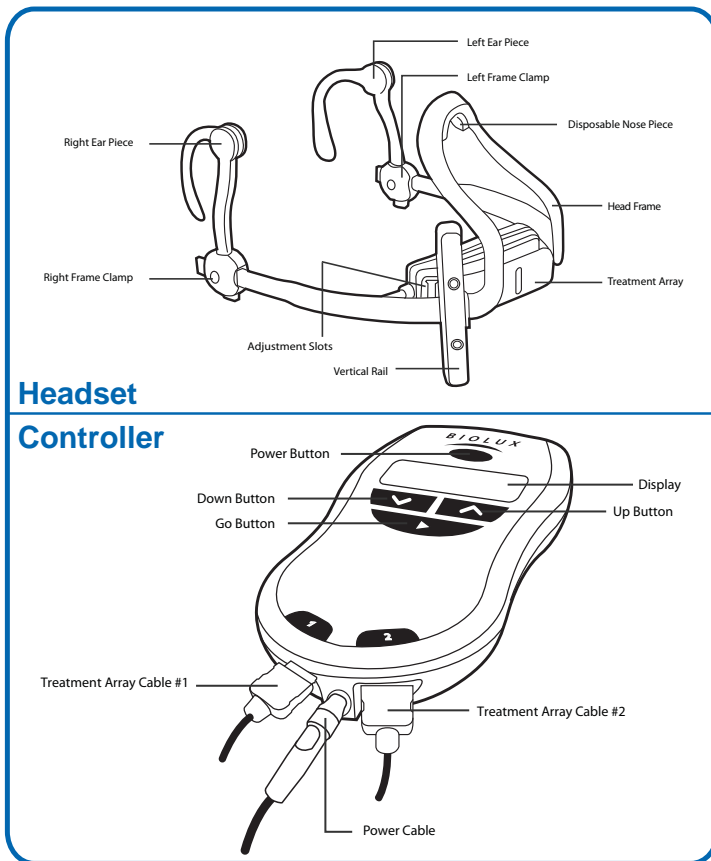
“Fault detected – Return to Dentist”

- In the case of a fault, discontinue the use of the unit immediately. Please contact your distributor or Biolux Research Ltd. for customer service.
- Ensure that the system is thoroughly cleaned and disposable parts are replaced between patients to prevent cross-contamination.

For instructions on correct assembly and use of the OsseoPulse™ device, please read this guide in its entirety. For more information on light therapy, visit our Web site at www.bioluxresearch.com

About OsseoPulse™

The OsseoPulse™ is an extra-oral, Light Emitting Diode (LED) based, photobiomodulation device for the stimulation and acceleration of implant-bone interface healing in dental implant placement. The device uses safe, high-power LEDs to produce photons at therapeutic wavelengths in the near-infrared and visible red spectrums. OsseoPulse™ is intended to be operated under dentist prescription and to be used by eligible patients in a home setting according to preset combinations of frequency and intensity.



Before Prescribing the OsseoPulse™ Treatment

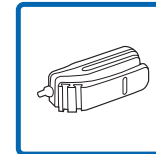
Please review both the Dentist User Guide and the Patient User Guide.

Before Using the OsseoPulse™

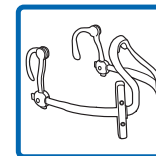
Please check package contents to ensure that all parts are enclosed and in good condition. Your OsseoPulse™ comes with the following components:



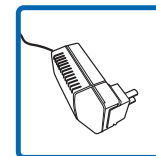
Controller



Treatment Array with cable
Mounts on Headset



Headset with Vertical Track and Earpieces



DC Power Adaptor



Hygienic Disposables: nose piece, ear covers, alignment tool and lens film



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Patient User Guide

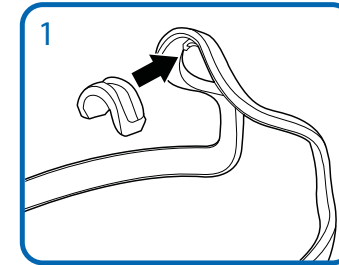


Accessories

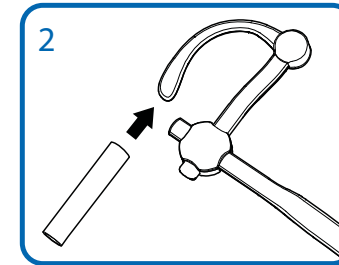
- Adjustment tool

Setting Up the OsseoPulse™ (prior to the patient visit)

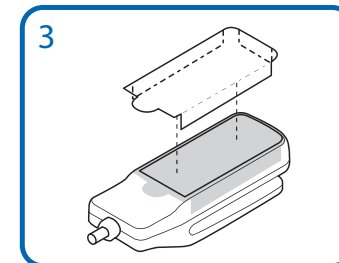
Fitting the Hygienic Disposables



1 Attach a disposable nose piece to the Headset. The parts will snap together.



2 Slip disposable ear cover completely onto each ear piece.



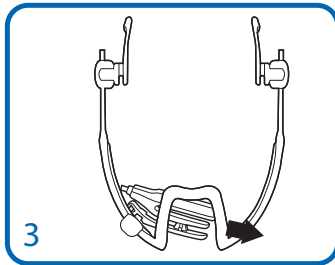
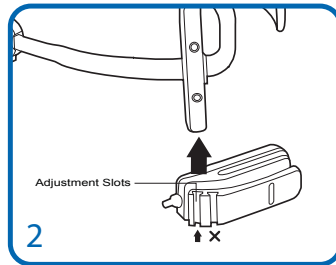
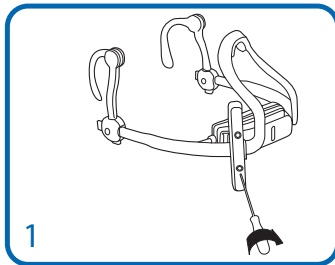
3 Place a disposable film onto the Treatment Array lens. Ensure film edges wrap around the array sides for a secure fit.

One Treatment Area

One Treatment Array is necessary if you are treating a single implant site, or multiple implants within two to four adjacent teeth.

Anterior teeth

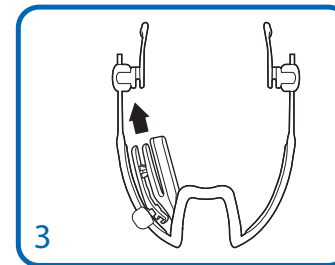
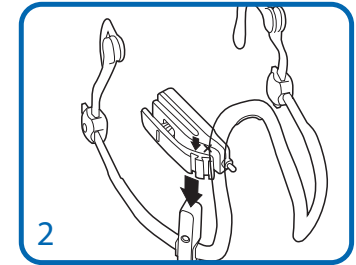
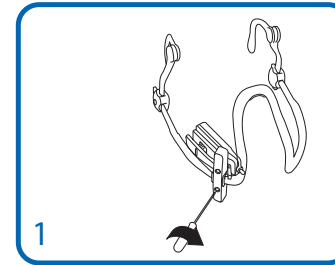
1. Using the adjustment tool, slightly loosen the 2 screws on the vertical rail.
2. Position array so that its adjustment slots are towards the posterior.
3. Gently slide the array onto the rear most adjustment slot.



Posterior teeth

1. Using the adjustment tool, slightly loosen the 2 screws on the vertical rail.
2. Position array so that its adjustment slots are towards the anterior.
3. Gently slide the array onto the vertical rail using the inner most adjustment slot.
4. Snug or loosen the 2 screws on the vertical rail to roughly position the array in the middle of the vertical rail in the approximately correct position.

You are now ready to try on the Headset.



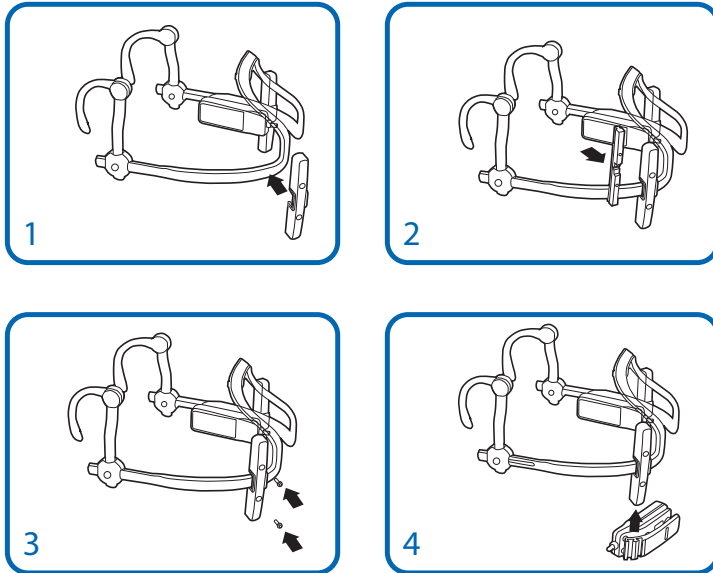
Two Treatment Areas

Two Treatment Arrays are necessary if you are treating two implant sites which are not within two to four adjacent teeth.

NOTE: You may need to add a second vertical adjustment bar if the 2nd treatment area is NOT directly above or below the first treatment area.

To add a second vertical adjustment bar:

1. Remove the 2 screws present.
2. Place the plastic portion of the bar on the outside of the Headset's horizontal track.
3. Place the metal slider bar on the inside against the outer portion.
4. Insert the 2 screws and gently tighten.
5. Insert array from bottom or top of vertical rail as per instructions above.



Fitting the OsseoPulse™ Headset

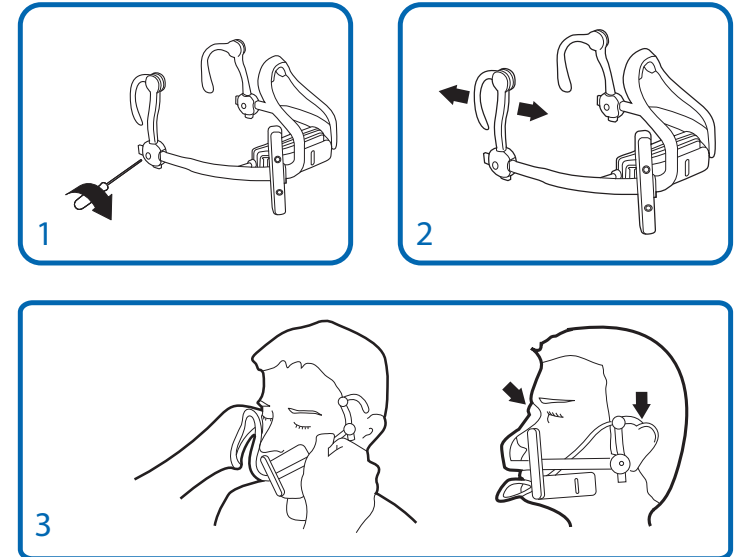


IMPORTANT: Have the patients close their eyes whenever placing the Headset assembly on to reduce the chance of accidentally touching their eyes.

1. Loosen the earpiece screw on each earpiece, so that earpiece is positioned roughly in the centre of the track.
2. Gently tighten the screw so that the earpiece will not move.
3. Ask the patient to close their eyes and gently place the Headset on the patient placing the earpieces over and behind the ears and sliding the nose piece onto the bridge of the nose.
4. If the Headset will not seat properly, you will need to loosen the earpiece screws and slide the earpieces back to make the frame larger.
5. Once the Headset has seated and the earpieces and nose piece are in the proper position, you will need to tighten up the earpieces so that the Headset is very stable front to back. The nose piece should always remain on the

bridge of the nose.

6. Loosen and tighten the earpiece screws and bring the earpieces forward as required to create a snug fit. Try to keep right (R) and left (L) earpieces at a similar position.



Positioning the Array (after adjusting the Headset)

In order to position the array directly over the desired treatment area it is important to use the alignment tool.

1. Gently retract the cheeks with a mouth mirror and separate the 2 forks of the alignment tool placing the internal bullseye directly centered horizontally over the treatment area.
2. Adjust the locator vertically:
 - Maxillary: lower edge of bullseye is aligned on the gingival margin or crest of the edentulous ridge
 - Mandibular: upper edge of the bullseye is aligned on the gingival margin or crest of the edentulous ridge

- Once the alignment tool is positioned correctly, gently allow the cheek to reposition over the teeth maintaining intraoral position of tool. Make sure the cheek and lips are in relaxed position.
- Release the extra-oral arm and place mark on cheek through perforation. Remove and discard the alignment tool.
- Place the headset on the patient. Adjust the position of the array so that the center (vertical notch on front of array is center) is over the mark and tighten the 2 vertical adjustment screws.

Tips for best positioning

- The Treatment Array cable should be tucked in and around the earpiece.
- Tighten the earpieces sufficiently to ensure adequate anterior tissue pressure.
- Earpieces should be even on both sides.
- Patients should remove any large earrings before use.

Programming the OsseoPulse™

Prior to patient use, the practitioner needs to prescribe the treatment protocol on the OsseoPulse™ by taking 2 actions.

1 – Enter Prescription Mode

- Turn on the unit by plugging the power cord in. A splash screen will display the OsseoPulse™ copyright notice.
- While the copyright notice is being displayed, press and hold the ▼ and ▲ keys simultaneously.
- Keep both keys pressed a few seconds, until the menu with 3 options appears **“Prescribe Treatment / Clear Prescription / Exit.”**
- Use the ▼ and ▲ keys until the arrow cursor → points at Prescribe Treatment. Press ►.

2 – Select a Treatment Protocol

The treatment option and its number of sessions need to be programmed.

NOTE: The controller has been pre-programmed with treatment protocols. Please refer to the OsseoPulse™ Clinical and Treatment Guidelines Document. Choose the appropriate treatment as follows:

- Scroll down the list of Treatments using the ▲ and ▼ keys. Select a Treatment choice from the list. Press ►.
- The screen will display **“How many Sessions?”** Use the ▲ and ▼ keys to increase or decrease the number of Sessions from the default number. (this should be left at 21 unless protocols change) After this number of sessions the patient will receive a message telling them to return to their dentist. Press ► to save the prescription and number of sessions.
- The screen will display the treatment protocol and number of sessions. Press ► to save and continue.
- The screen will display **“Ready to Test”**. Ensure the headset is fitted and positioned properly. Press ► and the Treatment Array will turn on twice for a few seconds.
- When the test is complete, the screen will display **“Prescription Ready, Disconnect Power.”**
- The unit is now configured; press the power button at the top of the Controller to turn the unit off.

Demonstrating the Treatment Process to the Patient

Note: It is important to guide the patient through each step. This establishes a routine for the patient to follow during home treatments.

- Plug the power adaptor into the wall socket. Plug the power adaptor cable into the socket at the bottom of the Controller. The unit turns on automatically.

- Plug the cable attached to the Treatment Array into the marked 1 Socket on the bottom left side of Treatment Array Controller; you are now ready to commence treatment.
- Start the unit by pressing the ► button.



IMPORTANT: At any time you may stop treatment by pressing the power button at the top of the Controller, or by unplugging the Power Adaptor, or by unplugging the Treatment Array from Controller. To avoid eye exposure to the bright light, DO NOT remove the Headset from the patient until the power is off. If the Headset is removed from the patient's face during treatment, a safety mechanism places the Treatment Array into standby mode. Once the Headset is replaced the treatment will resume (provided the interval is less than 15 minutes).

During the treatment, if the Controller continues to indicate that the headset is removed but you are sure that it is correctly positioned, this feature can be temporarily disabled by pressing and holding the ► button for four seconds during the message indicating the headset is removed. Only instruct the patient about this feature if necessary.

- During the treatment session, the Controller screen will display the remaining treatment time. Upon completion of the required treatment, the Treatment Array will turn off automatically.

Unless the full treatment session is completed, the Treatment Counter will not count down to the next session.

Note: For demonstration purposes during setup, stop the treatment after 1 or 2 minutes.

- Once the treatment session is complete and the Treatment Array is turned off, remove the Headset from the patient. Turn the unit off, store the Headset, Controller and Power Adaptor in the carrying case to be given to the patient together with the OsseoPulse™ Patient User Guide.

After the Patient returns the OsseoPulse™ to the Dentist

- Check that the treatment has been completed. When you turn the unit on, the screen should display “*Treatment Complete.*”
- Check that all parts are in working order and that the unit has not been damaged.
- Remove the nose piece and Treatment Array membrane and replace.
- Clean the device. Wipe with a mild surface disinfectant or alcohol. Do not immerse in liquid.

Specifications

Power Requirement: 100 to 240 VAC; 50 to 60 Hz; 0.4 amps

Temperature: In Use: 10 to 35°C; In Storage: 0 to 50° C

Humidity: 5 to 95%

Package Dimensions: 380 x 360 x 175mm

Package Weight: 2.5kg

Complies with:

IEC 60601-1

CAN/CSA c22.2 No. 601.1-M90 (Am. 2)

UL 60601-1 (1st Ed.)

IEC 60601-1-2 (3rd Ed.:2007)

IEC CISPR 11 (Ed 4.1: 2004)

IEC 61000-6-1 (2nd Ed.: 2005)

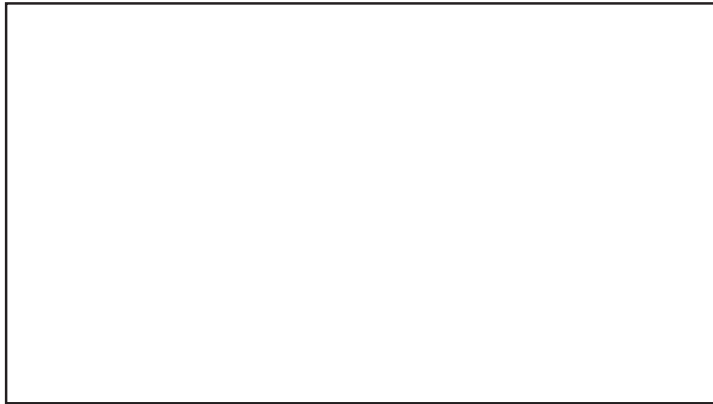
IC ICES-003

FCC CFR47 Part 15/B



Customer Service

For customer service regarding OsseoPulse™ please contact your distributor representative at:



For further information on Biolux or OsseoPulse™ please contact:

Biolux Research Ltd.
825 Powell Street Suite 220
Vancouver, BC, Canada V6A 1H7
North American Toll Free: +1 888 669 0674
Telephone: +1 604 669 0674
Website: www.bioluxresearch.com

Product Manufacturing

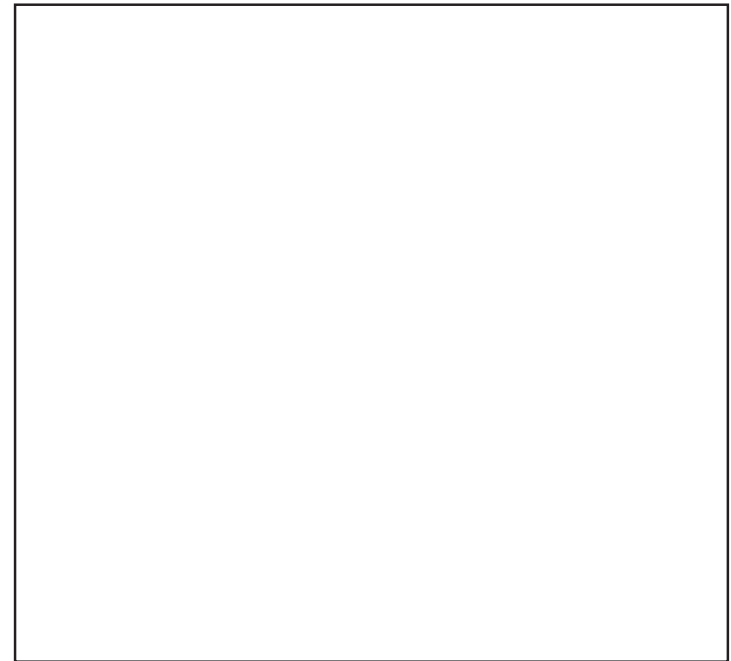
This product has been manufactured for Biolux Research by:

Starfish Product Engineering
#5-555 Ardersier Road
Victoria, BC, Canada V8Z 1C8
Telephone: + 1 250 388 3537
Website: www.starfishmedical.com

Device Disposal

As with all electrical equipment, the OsseoPulse™ should be disposed of in an environmentally responsible manner or be returned to the manufacturer.

Notes:





www.bioluxresearch.com