

Patient User Guide



OsseoPulse™ Bone Regeneration System
Model AR300

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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 in a manner other than which it was designed for. Use of the Osseopulse™ equipment is entirely the responsibility of the operator. Information in this manual does not substitute for medical consultation. Please consult the appropriate health care practitioner if you have any concerns about the use of this product.

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.

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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 your dentist. Use the OsseoPulse™ at the times indicated by your 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 your dentist for replacement. 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. Do not use this device if you have an implanted cardiac pacemaker, defibrillator, or an equivalent cardiac device.

▲ 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 PHOTSENSITIVE.** Do not use the OsseoPulse™ if your skin is overly sensitive to light; note that some medications can increase sensitivity. Consult your dentist or physician to determine if this applies to you. Discontinue use if any adverse reactions to the treatments are noticed. Inform your dentist if you are subject to seizures triggered by flashing lights (photosensitive seizures) so your dentist can prescribe an appropriate safe protocol.

Safety Information: CAUTIONS

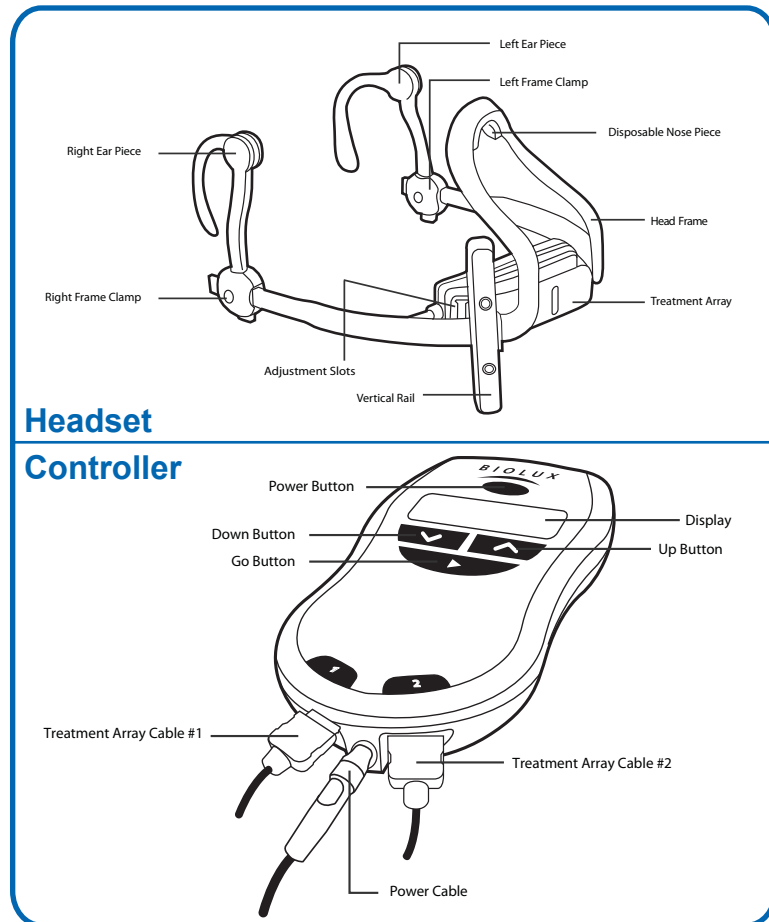
- To ensure that the Treatment Array remains in the correct position, always keep your mouth and teeth closed during treatment.
- Prior to removing the Headset, turn off the Osseopulse reducing the chance of shining the bright light directly in your eyes.
- The Treatment Array will be warm to touch during and after treatment, this is normal. If it becomes hot or uncomfortable to touch, discontinue treatment and contact your dental office.
- Do not cover the back or sides of the Treatment Array. If it is obstructed the Treatment Array could overheat. (An obstruction could be caused by an improperly positioned pillow, 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 you experience pain, discontinue the treatment and contact your dentist immediately.
- Do not wear any make-up or cosmetics while using the device.
- Do not eat or drink while operating the device. Spilt liquid could result in an electrical shock.
- Never leave the device unattended, especially if there are children around.
- Ensure that the OsseoPulse™ cables are placed where they will not create a tripping hazard.
- At the beginning of every treatment session OsseoPulse™ automatically runs a self-check to verify that no performance degradation has occurred. If a warning message such as the following is displayed:

“Fault Detected – Return to Dentist”

Immediately DISCONTINUE using the device and return the unit to your dentist in exchange for a new system.

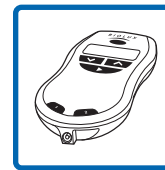
About OsseoPulse™

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.

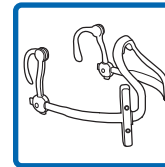


Before Using Your OsseoPulse™

Please check package contents to ensure that all parts are enclosed and that there is no damage. Your OsseoPulse™ comes with the following components:

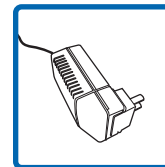


Controller

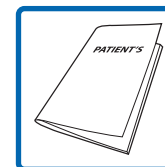


Headset with Vertical Track and Earpieces

Treatment Array should already be attached and positioned by your dentist.



Power Adaptor



Patient User Guide

Your OsseoPulse™ Treatment

Always operate the unit while seated in a comfortable position, with a table nearby for the controller. Make sure you are close to a household electrical outlet and that the power cords do not obstruct pathways. You should plan for uninterrupted time and remain still during your treatment. You may watch television, read, or listen to music if you wish. Before commencing treatment, ensure your hands are clean and dry. Do not adjust the Headset.

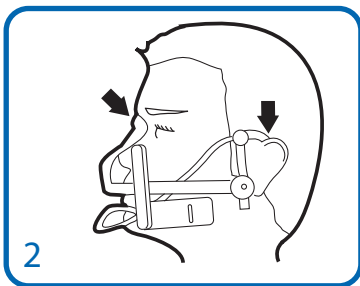


IMPORTANT: At any time you may stop treatment by pressing the on/off button at the top of the Controller, or by unplugging the Power Adaptor, or by unplugging the Treatment Array from Controller. To avoid looking into the bright light, do not remove the Headset until the power is off. If the Headset is removed during treatment, a safety mechanism places the OsseoPulse™ into standby mode, where the Treatment Array turns off automatically. Once the Headset is replaced the treatment will resume (provided the interval is less than 15 minutes).

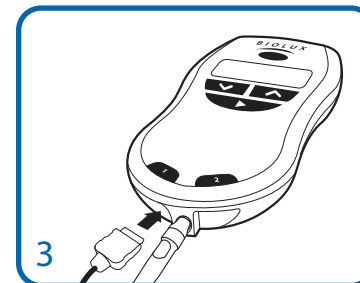
1. Connect the Power Adaptor to the Controller and plug the Power Adaptor into the wall. The unit turns on automatically.



2. Place the Headset on with the nose and the earpieces firmly in contact with the bridge of the nose and the top of the ears. Make sure that the Headset fits as it did at the dental office and that it feels secure.



3. Plug the Treatment Array cable into the #1 socket on the bottom left of the Controller.



4. If two Treatment Arrays are to be used, plug the second Treatment Array cable into the #2 socket.
5. The screen should display the number of sessions left and a prompt to press ► to start.

If **“No Prescriptions - Return to Dentist”** appears on the screen, the unit has not been configured, and must be returned to the dentist for programming.

If **“Treatments Completed - Return to Dentist”** appears on the screen, treatment has been completed and the unit is to be returned to the dentist.

6. Press the ► Button to start the session.

During the treatment session, the Controller displays the remaining treatment time. Pause the treatment at any time by pressing the “►” button.

If the treatment session pauses, one of the following messages may appear on the screen. Please follow the instructions.

- **“Check Headset Connection.”** Please check that the plugs are connected to the correct sockets.
- **“Temperature is __C Pausing to cool off!”** Once the Treatment Array has cooled, the session will resume automatically.
- **“It seems that the Headset is not being worn. Please ensure it is correctly positioned”** Reposition the headset and session will resume automatically.
- **“Headset position may be wrong. Check its position - or - press “►” to continue anyway”** Reposition headset and session will resume automatically - or - press “►” if you are sure the headset is positioned correctly.

Normally the treatment will continue automatically after a problem is corrected. If the pause is too long, this message will be seen:

“Pause was too long. Please power-off and restart the session.”

In this case, the session timer will begin again from the start.

7. Upon completion of the required treatment, the Controller will display a message that the session is complete. Press the power button at the top of the Controller to turn the unit off.
8. Remove the headset, and store all the OsseoPulse™ equipment in the protective carrying case. For convenience, keep all the cables connected between treatments. To reduce energy consumption when the Treatment Array is not in use, unplug the power adaptor from the wall socket.
9. Once all treatments have been completed, unplug all accessories, repack the OsseoPulse™ into the carrying case and return the OsseoPulse™ equipment to your dentist. When unplugging cables, remember to pull directly on the plug.

For more information or assistance with using the OsseoPulse™, please consult your dentist.

Notes:



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