OrthoPulse®

User Guide

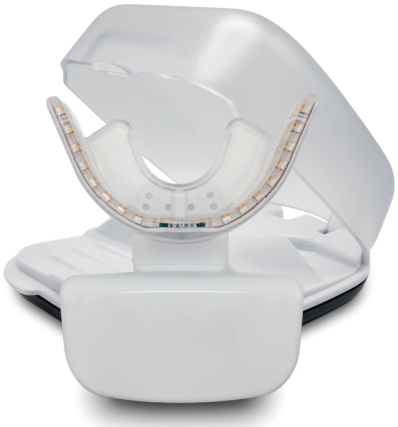
CE 1304

Contents

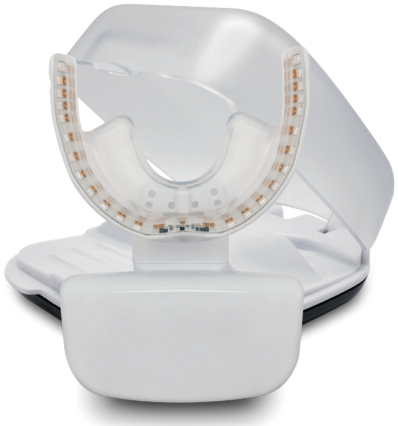
Inside Your OrthoPulse® Box

Ensure that all package contents are enclosed and that there is no visible damage

1 OrthoPulse® device with Charger case



OrthoPulse GEN2.0 Standard.
Model Number OPi2S-100



OrthoPulse GEN2.0 Extended.
Model Number OPi2E-100

Your doctor will prescribe one of the above two models for you.

2 Quick Start

1. Introduction

1.1 About OrthoPulse®

OrthoPulse® is an established device that uses low levels of light energy to stimulate the bone surrounding the roots of teeth and facilitate tooth movement which may reduce treatment time for braces or clear aligners.
There are two models available. Your Orthodontist will select the suitable model for you:
OrthoPulse® 2.0S – OrthoPulse® 2.0E

OrthoPulse® uses low intensity near infra-red light technology to gently facilitate orthodontic tooth movement.
For further information about the clinical benefits and supporting research, please visit orthopulse.com
OrthoPulse® therapeutic device has a Mouthpiece with treatment LEDs and a controller housing with battery and electronics. The OrthoPulse® device does not have an on/off switch. Wake the device by removing it from the charging case.

1.2 Intended Use /Indications for Use

The OrthoPulse® device is intended to accelerate orthodontic movement of teeth and reduce the overall treatment time for the patient. The device is intended to be used in conjunction with traditional orthodontic treatment with brackets and wires or aligners.
A patient shall use the OrthoPulse® device themself by following the orthodontist or dentist by the prescribed treatment plan. The OrthoPulse® device does not require any servicing or maintenance, the patient shall charge the device prior to the first use and after each daily treatment.

OrthoPulse® is operated under prescription by your orthodontist or dentist. Your prescribing orthodontist or dentist will provide instructions on how to use OrthoPulse® device.

Please direct questions regarding your orthodontic treatment plan toward your prescribing orthodontist or dentist. Biolux Technology is not authorized and unable to make representations related to patient-specific treatment and/or provide orthodontic treatment advice.

⚠ **WARNING:** OrthoPulse® is a single patient prescription device. Do not use the OrthoPulse® appliance on multiple patients. Use by an individual without the proper issuance from an orthodontist may result in unintended consequences, including the possible transmission of viral and bacterial infective agents.

The medical device can be used in any patients if not contraindicated to treat the indications mentioned in section 1.3.

Clinical performance claims:

- No increase of root resorption compared to standard orthodontic treatment
- Increased Cellular Metabolism in the Periodontium: PBM at 850 nm increases mitochondrial activity and enhances energy availability (ATP) in periodontal cells.
- Improved Orthodontic Treatment Predictability: PBM improves the predictability of planned orthodontic tooth movements.

Clinical Benefit:

- Patient satisfaction: comfortable treatment that can help reduce discomfort associated with orthodontic treatment

- Reduction of the orthodontic treatment time up to 50 %
- Pain reduction up to 70 %

Clinical Evaluations of OrthoPulse®

Clinical testing of the OrthoPulse® device with orthodontic treatment demonstrated that the device may accelerate tooth movement and may decrease treatment time. Two primary clinical studies of the intra-oral OrthoPulse® demonstrated device performance for its intended use; the device may accelerate orthodontic movement of teeth and may reduce the overall treatment time for the patient when used in conjunction with traditional orthodontic treatment with brackets and wires or aligners.

In a prospective, open-label, randomized cross-over study (TD3), the effect of daily OrthoPulse® use on the rate of orthodontic tooth movement during Invisalign® treatment in the mandibular arch was evaluated. The primary objective was to determine whether OrthoPulse accelerates tooth movement during the alignment phase. A total of 33 subjects were enrolled, with two later excluded due to unmet inclusion criteria, resulting in 31 participants in the safety population. Of these, 28 had evaluable data for the intent-to-treat (ITT) analysis. Subjects were randomized into two groups: Group A (n=15) began with OrthoPulse, and Group B (n=13) started without it.

The study's primary endpoint was the mean number of days each Invisalign aligner was worn during control and OrthoPulse periods. Results demonstrated that aligners were worn for an average of 7.56 days in the control phase and only 5.29 days with OrthoPulse, a statistically significant reduction of 2.27 days (27.08% decrease; p=0.00041). Median values similarly showed shorter wear times with OrthoPulse (5.50 days) compared to control (7.13 days). For all aligners except Aligner 7—used primarily during the washout phase—the wear time was consistently lower during OrthoPulse use.

Kaplan-Meier analysis confirmed a consistent leftward shift in aligner wear curves for the OrthoPulse phase, indicating faster progression through aligners. No serious adverse events were reported. Additionally, clinical monitoring revealed no cases of root resorption, gingival recession, or pathological tooth mobility throughout the six-month observation period. These findings support the safety and effectiveness of OrthoPulse in accelerating orthodontic tooth movement during aligner therapy.

OrthoPulse® was also evaluated in conjunction with brackets and wires in a controlled study of 33 subjects (mean age 25.0 years). Matched controls (based on subjects' age, initial crowding, eligibility criteria) were retrospectively selected before any data analysis of the OrthoPulse® subjects. Eligibility criteria included requiring that the subjects have permanent dentition, mild to moderate crowding with no labiolingually displaced teeth, Class I or Class II by 1/2 cusp or less, good oral hygiene, and be non-smoking. Subjects who were pregnant, enrolled in another study, had periodontally involved teeth, used bisphosphonates during the study or had spaces between anterior teeth were excluded. There were no differences between groups in terms of gender, ethnicity, age, and initial crowding. The rate of tooth movement was measured using the change in Little's Irregularity Index measurements in both groups to evaluate OrthoPulse® use with fixed orthodontic appliances. Root resorption was determined by use of panoramic dental X-rays collected before treatment and after 6 months of treatment. Results demonstrated that subjects treated with OrthoPulse® showed a statistically significantly faster rate of tooth movement ($p<0.001$) compared to the control group, achieving the primary effectiveness objective of the study. There were no serious adverse events, and no gingival recession or pathological tooth mobility reported throughout the study. Data demonstrated the absence of external apical root resorption with OrthoPulse® use, and that there is no device effect of accelerated tooth movement on tooth root integrity.

Several additional clinical studies were also conducted with prototype and final OrthoPulse® devices to supplement the clinical findings observed in the primary studies, and results consistently confirmed device performance for its indicated use.
Therefore, results from the clinical studies demonstrate that subjects treated with OrthoPulse® achieve statistically significantly faster rates of tooth movement than control. The amount of change in an individual's tooth movement rate during OrthoPulse® daily treatment may be dependent upon their specific biology and treatment plan. For clear aligners, only Invisalign brand aligners have been examined with daily OrthoPulse® use. Results with other brands of aligners may vary.

1.3 Contraindications for Use

- Poor oral hygiene
- Acute oral infection or periodontal disease or oral cancer
- Photosensitivity[1] and photosensitive epilepsy
- Use of drugs that may cause photosensitivity
- Known or suspected allergy or hypersensitivity to device materials

A dental professional should be consulted prior to use if any of these situations are suspected.

2. How to Use

2.1 Steps and Schedule for Use

An OrthoPulse® treatment takes five minutes per arch for a total of ten minutes daily.[2] It is recommended to select the same time everyday to do your treatment.

1 A condition in which the skin becomes very sensitive to sunlight or other forms of ultraviolet light and may burn easily.

2 there are no benefits of doing more than 2 sessions.

⚠ **Caution:** To maximize the life of your device and to avoid potential overheating of the device do not use the OrthoPulse® device for more than two 5-minute sessions subsequently.

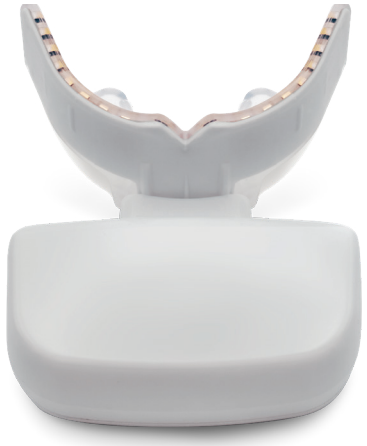
The status light guide is available on the bottom of the OrthoPulse® charging case.

Typically, it takes two to three weeks to develop a habit, so be patient. Some patients prefer to set up OrthoPulse® next to their bed, so they can do treatments first thing upon rising or prior to sleeping.

You may pause the treatment for up to 20 seconds by simply removing the device from your mouth. If you pause for more than 20 seconds, the treatment will abort and you will have to restart your OrthoPulse® treatment.

To use your OrthoPulse®, complete the six steps below:

1. Remove the OrthoPulse® from the charging case, this will wake the device from sleep mode. The status light will display green upon waking when the battery has sufficient charge to complete a treatment. If a yellow light appears, return it to the charging case. Refer to the LED indicator on the next page or on the charger case bottom label.



2. Place the OrthoPulse® device in your mouth, centering it between the front teeth.
3. Bite down gently to hold it in place. The device will beep twice and the status light will turn blue indicating that the treatment has started. A warm, pleasant sensation can be felt during treatment. The device has temperature management system, if the temperature exceeds 48 °C the treatment will be paused for cooling, the treatment will be auto resumed after several seconds.
4. Once the treatment is complete, the device will beep three times continuously and the blue status light will start pulsing.
5. Flip the device and repeat steps 2 through 4 to treat the other jaw.
6. Return the device to the plugged-in charging case to re-charge the device after treatment.

TIP: Avoid loud background noise during treatment to ensure you hear the aural indicators.

During the treatment, the device controller (box outside the mouth) could reach a temperature above 41 °C, patient's lip may contact the device controller during the treatment. In case the heat exceeds the patient's comfort level the device can be removed from the mouth to trigger the cooling mode by pausing the treatment.

⚠ **Warning:** Do not use the device under direct sunlight, or in an environment with ambient temp above 30 °C.

There is no clinical benefit or any additional risk to the patient in the case the device reaches 41 °C temperature. The device Firmware has safety features that pause the treatment or cease the device operation in the case of overheating.

2.2 Charging

Using the tethered USB cable to connect the charging case to a power adaptor and plug it into a power outlet to charge the device. You can use any USB power adapter, e.g. of your mobile phone.

Approximately three hours are needed to fully recharge the OrthoPulse® device. A green status light will indicate a sufficient battery charge to complete two treatment sessions. When the device is fully charged, the status light will turn off and the device will sleep automatically.

Two sessions can be completed on one full charge. The device must be recharged after each 10-minute treatment. If the status light is solid yellow, the device needs to be recharged prior to use.

⚠ **CAUTION:** Place the OrthoPulse® on a stable flat surface and out of the way to avoid tripping hazards.

2.3 Status Light Guide

Pick up the OrthoPulse® to check the status light before your treatment.

In hand

Ready for treatment
Low battery, not ready
Error, consult your dentist

In treatment

Treatment started
Treatment completed
Treatment paused

In charging case

Charging, ready
Charging, not ready
Fully charged, ready
Restarting
Ready for Bluetooth®
Syncing

Charger case status

Charging
Error
Charging completed

2.4 Optional OrthoPulse® Software

This software is no standalone SW and can only be used in connection with OrthoPulse®. It has no effect on safety or performance of OrthoPulse® but provides an increased scope of features versus the current app in order to digitalize the treatment. Furthermore, it can optionally be used but OrthoPulse® can further be used without the software as before.

The main high-level components of the software are the Patient mobile app, the Back-office, the Doctor portal (web) app and the Backend. Those are deployed/distributed through use of the following services:

Patient app: Apple App Store for iOS devices and Google Play Store for android devices

Back-office: Cloudfront distribution serving static content from S3 Buckets

Doctor portal: Cloudfront distribution serving static content from S3 Buckets

Backend: Hosted on an EC2 virtual machine: The "Backend System" provides the interfaces to manage the main entities of the software and their sub-entities.

It will be supplied with the following features:

Patient App

- Login (via Email or Phone number)
- Syncing to OrthoPulse hardware
- Treatment status overview
- Streak overview (weekly, monthly)
- Weekly treatment compliance score
- If not in treatment: searching for a doctor close by
- Reminders for weekly sync, daily treatment and aligners change

- Help section with FAQs
- Guides & Manuals on how to use the app and the hardware
- Profile settings
- Display of practice details
- Achievements, e.g. 1-Week streak

Doctor Portal

- Patient management
- adding new patients
- editing patient details
- archiving patients
- displaying patients compliance scores
- displaying communication sent to patient via patient app
- Profile section
- editing personal information
- adding/editing practice information
- adding treatment specifications
- editing reminder texts that are sent to patient via patient app

Backoffice

- Device management
- all device logs
- reporting
- Patient management
- adding new patients
- editing patient details
- archiving patients
- deleting patients
- Doctor management
- adding new doctors
- editing doctor details
- deleting doctor details
- Practice management
- adding new practice
- editing practice
- deleting practice
- Backoffice user management for admins of the backoffice
- Device model management
- Device error code management

The mobile application will be available for all iOS and Android users to be downloaded on the App Store and Play Store respectively for mobile phone usage. A smartphone with either iOS or Android as operating system will be required to be able to download the application from the App or Play Store.
It requires the following minimum operating system specifications:

- iOS minimal Version: 15.7
- Android minimal Version: 9.0 Pie

3. Care and Maintenance

3.1 Cleaning

It is not necessary to clean OrthoPulse® after every use. It is recommend that patients rinse the mouthpiece under warm water once a week and set it to air dry on the charging case. Hold the OrthoPulse® device by the white plastic housing – do not hold it by the silicone mouthpiece.

⚠ **CAUTION:** The OrthoPulse® device is NOT dishwasher safe.
⚠ **CAUTION:** Avoid rinsing the white plastic housing of the OrthoPulse® device.
⚠ **CAUTION:** The charging case is not water resistant and should not be rinsed or submerged in water. The charging case should be used in a dry environment, inside, and kept away from water.

3.2 Storage

Store your OrthoPulse® in its charging case when not in use. This will prevent damage.
The OrthoPulse® device should be stored in a cool, dry place away from direct sunlight. Avoid storing your OrthoPulse® in locations where it may be exposed to extreme temperatures.

⚠ **CAUTION:** The OrthoPulse® should be stored out of the reach of young children or pets; it is not a toy.

3.3 Service Life

OrthoPulse® should last for the duration of your orthodontic treatment. The device should last for up to two years of continuous use if used with care.

The OrthoPulse® device contains a lithium polymer battery that will lose charge over time if not re-charged. The OrthoPulse® device should be fully charged within three months of delivery and should be fully charged prior to first use. To maintain battery life, do not let the battery completely discharge.

3.4 Replacement

No component of the OrthoPulse® device is user- serviceable or -replaceable. During the course of treatment, no OrthoPulse® components should require replacement. Bite marks and other wear marks that become present in the mouthpiece over time are normal, and do not require replacement. However, they may be indications that you are biting or clenching too hard during your OrthoPulse® treatment. If there are punctures, or any of the internal surfaces of the mouthpiece become exposed, stop using the OrthoPulse® immediately and contact support@orthopulse.com.
In case of other damage or unforeseen wear and tear, please contact support@orthopulse.com.

⚠ **WARNING:** Do not tamper with or attempt to repair your OrthoPulse® or its charging case.

If your OrthoPulse® becomes damaged, contact support@orthopulse.com for replacement or repair. Prior to use, inspect OrthoPulse® for noticeable signs of damage or wear. Do not substitute any parts or materials in the device.

3.5 Environmental Protection Disposal

The user guide and packaging are recyclable and should be disposed of with other recyclable paper products. To preserve the environment and protect human health, the device should not be disposed of with normal household waste.
Dispose of your device and charging case with tethered USB cable by delivering them to a designated collection point for the recycling of waste electrical and electronic equipment.

⚠ **WARNING:** Never incinerate OrthoPulse®, expose to excessive heat, short circuit or cause any similar action to the battery. Mishandling the battery may cause burns, fire or explosion.

Contact your local waste authorities, your household waste disposal service or support@orthopulse.com if you require more information regarding disposal.

4. Support

4.1 Orthodontic Treatment

Please contact your orthodontist or dentist directly for all inquires regarding your treatment.

4.2 Device Inquiries

Please contact the OrthoPulse® Support Team:

- for assistance in setting up, using or maintaining your OrthoPulse®
- to report unexpected operation or events
- for technical assistance and any concerns specifically related to OrthoPulse® or its accessories

Manufacturer Contact Information:
Biolux Technology GmbH, Neubaugasse 31, 3462 Absdorf, Austria
Email: info@bioluxtec.com
Web: orthopulse.com

4.3 Troubleshooting

Visit the FAQ section on the OrthoPulse® website, available here: http://www.orthopulse.com/patients/support

4.4 Warranties

Limited Warranty: Biolux Technology (Biolux) warrants to the original purchaser that the OrthoPulse® device will be free from defects in material and workmanship for a period of two (2) years from the date of the original purchase from Biolux or its authorized resellers, provided the purchase occurs before the expiration date indicated on the packaging box label of the device. This limited warranty is non-transferable.

If the OrthoPulse® device is found to be defective during the warranty period, the purchaser's sole and exclusive remedy, and Biolux's sole obligation, will be, at Biolux's discretion, to either:

1. Repair the OrthoPulse® device to conform to its original specifications, or
2. Replace the OrthoPulse® device with a comparable product.

Repaired or replaced products or parts may be new or reconditioned and will be covered under this limited warranty for the remainder of the original warranty period.

To obtain warranty service, the purchaser must:

- Contact OrthoPulse® support via email at support@orthopulse.com.

This warranty does not cover:

- Defects or malfunctions caused by misuse, neglect, unauthorized attempts to open, repair, or modify the OrthoPulse® device.
- Use of the OrthoPulse® device with accessories or products not authorized by Biolux.

- Any issues arising from causes other than the intended normal use of the OrthoPulse® device.

Any presumption of lack of conformity is expressly excluded.

EXCLUSIONS: TO THE FULL EXTENT ALLOWED BY LAW, THIS LIMITED WARRANTY IS THE PURCHASER'S SOLE AND EXCLUSIVE REMEDY, AND NO OTHER WARRANTIES, CONDITIONS, OR GUARANTEES OF ANY KINDS SHALL APPLY, WHETHER STATUTORY, WRITTEN, ORALLY EXPRESSED OR IMPLIED; INCLUDING WITHOUT LIMITATION WARRANTIES, CONDITIONS OR GUARANTEES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, PERFORMANCE, QUALITY, OR DURABILITY, ALL OF WHICH ARE DISCLAIMED. IN NO EVENT WILL BIOLUX BE LIABLE FOR ANY SPECIAL, EXTRAORDINARY, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION DAMAGES FOR LOSS OF DATA, LOST PROFITS, LOSS OF OPPORTUNITY, BUSINESS INTERRUPTION, PERSONAL INJURY OR DEATH, OR ANY OTHER LOSS ARISING OUT OF, RELATING TO, OR IN CONNECTION WITH THE ORTHOPULSE®, EVEN IF BIOLUX IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

LIABILITY LIMITATIONS: IF, AS A RESULT OF OR IN CONNECTION WITH ANY USE OF THE ORTHOPULSE®, BIOLUX BECOMES LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY DAMAGES, LOSSES, COSTS, EXPENSES, OR OTHER LIABILITIES WHATSOEVER, AND REGARDLESS OF THE FORM OF ACTION (IN CONTRACT, TORT OR PURSUANT TO STATUTE), THEN BIOLUX'S AGGREGATE LIABILITY WILL BE LIMITED TO AN AMOUNT EQUAL TO THE PURCHASE PRICE PAID FOR THE ORTHOPULSE®.

The exclusion of certain conditions and warranties and time limitation of certain liability is prohibited in some jurisdiction, so these limitations and exclusions may not apply to some purchasers. This limited warranty is governed solely by the laws of the Republic of Austria, excluding any rules of private international law or the conflict of laws which would lead to the application of any other laws; the courts of Vienna, 1st district, Austria shall have exclusive jurisdiction over any claims relating to this limited warranty.

Biolux has US and international patents pending for OrthoPulse® and the accompanying technology. Patented orthopulse.com/patents

Manufacturers Liability

Biolux Technology 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. Use of the OrthoPulse® equipment is entirely the responsibility of the operator.

5. Safety

5.1 Technical Description and Classifications

The following is a technical description of OrthoPulse®. It is intended to provide all data essential for safe operation, transport and storage as well as permissible environmental conditions and electrical safety classifications.

⚠ **WARNING:** No modification or servicing of this equipment is allowed.

- OrthoPulse® is considered to be an applied part according to the IEC 60601-1 3rd Ed. OrthoPulse® is classified as a Type BF applied part.
- Protection Class: Class II equipment.
- OrthoPulse® LEDs operate at 850 nm wavelength, 61 mW/cm^2 output power, corresponding to 18.3 J/cm^2

Ingress Protection Class:

- OrthoPulse® is rated as IP37, is tool proof and submersible in water up to 1 m deep for up to 30 minutes.
- Charging case is rated as IP32, is tool proof and resistant to dripping water while tilted 15°.

5.2 Environmental Conditions

Environmental Operating Conditions:

- Ambient temperature range: 5°C to 30°C
- Relative humidity range: 15 to 93% non-condensing
- Atmospheric pressure range: 700 to 1060 hPa

It is normal that the OrthoPulse® device will warm up during the treatment or after charging and can reach up to 41°C. To prevent overheating and prolong its life let the device cool down to ambient temperature before use.

⚠ **CAUTION:** Do not use the OrthoPulse® device for more than two 5-minute sessions subsequently. It may cause the device to overheat.

⚠ **CAUTION:** Ensure the device is not warm after it is charged before starting treatment.

Transport and Storage Conditions:

- Minimum ambient temperature: -25°C
- Maximum ambient temperature: 70°C
- Maximum humidity: 93% non-condensing
- Storage pressure range 700 to 1060 hPa

⚠ **WARNING:** The device shall not be used in conditions beyond the listed above only! The patient shall check the device for any visual defects prior to performing the treatment.

5.3 EMC Compliance Statement

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential setting. This device 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 device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try one or more of the following measures:

- Reorient or relocate the device or the receiver
- Increase the distance between the device and the receiver
- Connect the device to an outlet on a circuit different from that to which the receiver is connected

- Consult the manufacturer or an experienced broadcast engineer/ technician for help

Be aware that portable and mobile radio-frequency communications equipment (for example, mobile phones, iPads) may affect the operation of this device; take appropriate precautions during operation.

Accessories

To maintain electromagnetic compatibility (EMC) within limits, the device must be used with the cables and accessories specified by Biolux. The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the device.

Radio-Frequency Transmitter

OrthoPulse® contains a Bluetooth LE transmitter module that operates at 2.4 GHz. This module is active only when the device is placed in the charging case and the Ready for Bluetooth indicator is on.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the 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 receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

Transmitter Module Certifications

CE: Complies with Radio Equipment Directive, RED 2014/53/EU
FCC Limited Modular Certification 15.212 FCC #2A6CA-OPi
Canada: IC #28421-OPi
Bluetooth SIG certified #D060368

USA – User Information

OrthoPulse® contains transmitter module FCC ID: 2A6CA-OPi.

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

⚠ **CAUTION:** Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Canada – User Information

OrthoPulse® contains transmitter module IC ID: 28421-OPi.
This device complies with Industry Canada licence- exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

5.4 Electromagnetic Compatibility

This device is intended for use in a HOME HEALTHCARE ENVIRONMENT.
This device emits energy in the infrared range for a predetermined duration.
This device has a tethered USB cable with a maximum length of 4' or 122 centimeters.

⚠ **WARNING:** Use of other accessories such as cables other than the ones provided by Biolux Technology for this device may result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

⚠ **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables provided by Biolux Technology. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Emissions

Test or Measurement	Standards	Test Method	Description	Results
Radiated Emissions	EN 60601-1-2:2015 Ed. 4 CISPR 11 EN 60601-1-11 EN 60601-2-57 EN 301 489-1 V2.1.1 ICES-003 Issue 6 CFR Title 47 FCC Part 15	ICES-003 Issu.6 Class B Limits	The radiated emissions are measured in the 30-1000MHz range or up to 5x the highest EUT frequency whichever is higher[1]	Complies
Conducted Emissions			The Conducted Emissions are measured on the phase and Neutral Power lines in the 0.15 - 30.0 MHz range.	

[1] Highest frequency generated by the device is 2.4GHz

Emission Test	Compliance	Comments
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal functions.
RF Emissions CISPR 11	Class B	This device is predominantly intended for use in a HOME HEALTHCARE ENVIROUNMNET and to be connected to the PUBLIC MAINS NETWORK
Harmonic Emissions EN 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions EN 61000-3-3	Class A	

Electromagnetic Immunity

Immunity Test	Standard/Test Method	Test Levels	Compliance
Electrostatic Discharge	IEC 61000-4-2	Air Discharge: ± 2, 4, 8, 15 kV Contact Discharge: ± 8 kV	Complies
Radiated RF	IEC 61000-4-3	10V/m, 80% AM @ 1kHz, 30MHz to 2.5GHz, Vertical and Horizontal Polarizations	Complies
Immunity to Proximity Fields from RF Wireless Communications Equipment	IEC 61000-4-3	9 V/m to 28 V/m @ 15 Frequencies 380 - 5800 MHz	Complies
Electrical Fast Transient/ Burst	IEC 61000-4-4	AC Power Lines: ± 2 kV @ 100 kHz Signal Lines: ± 1 kV @ 100 kHz	Complies
Surge	IEC 61000-4-5	±0.5, 1 kV line to line, 0°, 90°,180°, 270° ±0.5. 1, 2 kV line to earth, 0°, 90°,180°, 270°	Complies
Conducted RF	IEC 61000-4-6	3Vrms, 0.15-80MHz, 80% AM @ 1 kHz 6Vrms in ISM & Amateur radio bands, 0.15-80MHz, 80% AM @ 1 kHz	Complies
Power Frequency Magnetic Field	IEC 61000-4-8	30 A/m	Complies
Voltage Dips	IEC 61000-4-11	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles	Complies
Voltage Interruptions	IEC 61000-4-11	0 % UT; 250/300 cycles	Complies

NOTE: UT is the AC mains voltage prior to application of the test level.

5.5 Additional requirements for warning and safety notices

Side effects that are generally observed with therapeutic light in the near infrared wavelength and which are described in the literature. Even though this type of treatment is generally very safe, negative effects may occur. As a consequence of light therapy, patients can complain of irritability, headaches, eye strain, sleep disturbances and insomnia. Mild visual side effects are not unusual but remit promptly.
However, since light therapy is as safe as it is effective, there are no known long-term side effects of this form of light therapy. Other than averting your eyes from the laser's red or infrared light, the FDA has found no other red flags or adverse side effects. Because the light emitted does not cause your skin to burn, there is no risk of pain except under certain conditions.
This is why there are no side effects associated specifically with OrthoPulse®. Resulting from the risk analysis, we thus conclude that the OrthoPulse® does not contain foreseeable risks of unacceptable levels. The device is designed and manufactured such that, when used as intended, it will not compromise the conditions of safety of the patients and operator, and any remaining risk is managed with a high level of protection of health and safety.
Based on the individual/overall risk/benefit analysis carried out for all identified risks we thus conclude that the OrthoPulse® does not contain foreseeable risks of unacceptable levels. The device is designed and manufactured such that, when used as intended, it will not compromise the conditions of safety of the patients and operator, and any remaining risk is managed with a high level of protection of health and safety.
BIOLUX will continue to monitor the risks associated with the use of this product throughout the product lifecycle, including manufacturing, inspection and testing, complaint handling, non-conformance reports, post-market clinical follow-up, clinical evaluation, post market surveillance, product changes, and management reviews.

5.6 Power Adapter Specification

Standard power adapter with USB A outlet shall be used to power the charger case via USB cable; power supply output: Voltage - 5V, Current up to 2A.

5.7 Warnings and Safety Notices

United States Federal law and other national regulations restrict this device to sale by or on the order of a doctor. Biolux Technology cannot be held responsible for any damage or injury resulting from a failure to follow the directions in this user guide. Ensure that you are entirely familiar with the correct procedures for operating the appliance before use.

ATTENTION:

- Use only as directed. OrthoPulse® must be used under the direction or supervision of an orthodontist or dentist.
- Discontinue use if you have an allergic reaction to OrthoPulse® or its accessories and seek medical opinion.
- Chewing or clenching on the bite pad may damage the device, or lead to a choking hazard.
  During use, bite gently on the bite pad.
- Staring at the near-infrared light source may cause eye irritation. Do not stare directly at the mouthpiece.
- Avoid knocking, hitting or pulling your OrthoPulse® with force. Rough handling may cause damage. Discontinue use if damage is suspected.
- The charging case and cable may be a tripping hazard. Plug in near the wall outlet on a stable flat surface.

- Do not use the device while operating machinery or performing complex tasks.
- Do not use with high frequency (HF) surgical equipment.
- Patients with an implanted cardiac pacemaker, defibrillator, or an equivalent cardiac device should not use OrthoPulse® unless the cardiac device is known to not be affected by magnetic fields.

Mobile app and OrthoPulse® device privacy policy

This Privacy Policy describes the ways in which Biolux Technology ("we," "our," or "us"), collects, uses, and discloses information about you through the OrthoPulse® and the associated OrthoPulse® mobile application (the "OrthoPulse® App"). (We refer to the OrthoPulse® and the OrthoPulse® App collectively as the "OrthoPulse® System".) For using an OrthoPulse® or the OrthoPulse® App, you have to consent to the processing of your information as set forth in this Privacy Policy, now and as amended by us. Your use of www.orthopulse.com and io.bioluxresearch.com or OrthoPulse® Connect™ is governed by a separate privacy policy, which is available here: https://www.orthopulse.com/privacy-policy and here, for patients under the age of majority who require guardian/parental consent: https://io.bioluxresearch.com/admin/doctor/consent/exampleassent

What Information Do We Collect?

The information we collect from users is an essential component of the OrthoPulse® System: Information You or Your Dental Provider Share with Us: We and our service providers collect and store any information that you provide to us, as well as information that is provided to us by your dentist, orthodontist or other treatment provider. If you, your dentist, orthodontist or other treatment provider create a provider or patient account linked to your name or contact information (an "Account"), we collect the registration information that is shared with us. We collect information when you contact us via the OrthoPulse® App with a request, question, or comment. We collect information about patients when dental providers create patient Accounts, when patients access their Accounts via the OrthoPulse® App, and when an OrthoPulse® syncs with the OrthoPulse® App. The information provided to us may include, but is not limited to: (a) your name, contact information, email address, mobile phone number, password, OrthoPulse® device serial number, and other registration information; (b) your personal details such as your age and gender; (c) orthodontic treatment details such as your treatment start date or planned duration of treatment (d) information regarding your usage of the OrthoPulse®, such as the date, time, and duration of your use; and (e) information you provide us when you contact us with a request, question, or comment. Even if you, as a patient, do not use the OrthoPulse® App, your dental treatment provider may send us information regarding your usage of your OrthoPulse® by syncing your OrthoPulse® with his or her OrthoPulse® App.

Information Automatically Collected From You: We and our service providers collect and store certain types of technical information from your mobile device over time whenever you interact with us through the OrthoPulse® App, such as: your Internet Protocol address; your general geographic location (e.g., for purposes of determining your time zone); your mobile device's model, software version, IP address, and network status; information about how and when you use the OrthoPulse® App and/or your mobile device.

How Do We Use This Information?

We may use the information we collect for a number of purposes, including, but not limited to: providing you and your dental provider with information about your use of the OrthoPulse®; operating the OrthoPulse® System, including providing to you the features and services available through the OrthoPulse® App;

- providing you with information, services, or products you request and responding to your inquiries;
- customizing your experience when using the OrthoPulse® System, such as by providing personalized treatment options;
- monitoring the safety and efficacy of the OrthoPulse® System;
- generating and analyzing statistics about your use of the OrthoPulse® System;
- providing you with information about the OrthoPulse® System or required notices;
- delivering marketing communications, promotional materials, or advertisements that may be of interest to you;
- improving the OrthoPulse® System and the services we provide; and
- detecting, preventing, and responding to fraud, intellectual property infringement, violations of our Terms and Conditions, violations of law, or other misuse of the OrthoPulse® System.

Sharing your Information

We may disclose the information we collect from you through the OrthoPulse® System in the following circumstances:

Treatment Purposes: Information collected from patients, such as information about usage of the OrthoPulse® System, may be disclosed to your dental treatment provider.

Third-Party Service Providers: We may employ other companies and individuals to perform certain business functions on our behalf. Examples include providing data hosting services, application development services, and providing customer service support. These service providers may have access to information that we collect in order to perform services on our behalf.

As Required by Law: We may disclose information in order to comply with legal obligations or requests, such as to comply with a subpoena or other legal process, or to comply with government reporting obligations.

Protection of Rights: We may disclose the information we collect to enforce or apply our Terms and Conditions and other agreements; or protect the rights, property, or safety of the OrthoPulse® System, our users, or others. This includes exchanging information with other companies and organizations for fraud protection and credit-risk reduction. This does not include selling, renting, sharing, or otherwise disclosing information that reasonably identifies users for purposes other than those addressed in this Privacy Policy.

In Connection with a Transaction: we may disclose the information we collect to service providers, advisors, potential transactional partners, or other third parties in connection with the consideration, negotiation, or completion of a corporate transaction in which we are acquired by or merged with another company or we sell, liquidate, or transfer all or a portion of our assets.

Where Is This Information Processed?

We process information collected via the Online Services/OrthoPulse® App in and subject to the laws of the EUROPEAN UNION, which may not provide the same level protection for your information as your home country. In addition, we may transfer your information outside the European Union to our affiliates, business partners, and service providers located in other countries. By using the Online Services/ OrthoPulse® System, you consent to such transfer to, and processing in, the European Union, Canada, USA, Switzerland, and Hong Kong.

Information Security

We have administrative, technical, and physical safeguards designed to safeguard the information collected by the OrthoPulse® System. However, no information system can be 100% secure, so we cannot guarantee the absolute security of your information. Moreover, we are not responsible for the security of information you transmit to and from the OrthoPulse® System over networks that we do not control, including the Internet and wireless networks

Your Choices

The OrthoPulse® App allows you access to information about your Account for the limited purpose of viewing and, in certain cases, updating that information.

Children's Information

If you are a parent or legal guardian of a child that uses the OrthoPulse® App, you may be able to review or delete certain information that we have collected in association with your child's use of the OrthoPulse® App. If you would like to do so, please contact us at support@orthopulse.com.

Your California Privacy Rights

If you reside in California and have provided to us information that identifies you, you may be entitled to request information once per calendar year about our disclosures of certain categories of certain information to third parties for their direct marketing purposes. Such requests must be submitted to us in writing at the following email address: support@orthopulse.com.

Changes To This Privacy Policy

If we update this Privacy Policy, we will notify you by posting a new Privacy Policy on this page. If we make any revisions that materially change the ways in which we use or share the information previously collected from you through the OrthoPulse® System, we may give you the opportunity to consent to such changes before applying them to that information.

Your Rights

You have the fundamental rights to access to information, rectification, erasure, restriction, data portability and to object. If you believe that the processing of your data contravenes data- protection law or your legal claim to protection of your data has been violated in some other way, you can complain to the supervisory authorities.

For Customers in the European Union Reporting of incidents:

All serious incidents related to this product must be reported to the manufacturer and the Federal Office for Safety in Health Care (BASG) at +43 (0)664 831 28 43. A serious incident is defined as an incident which directly or indirectly caused, could have caused or could cause the death or serious permanent deterioration of the health of a patient, user or other person or a serious risk to public health.

The Data Protection Authority is the responsible authority in Austria.
Biolux Technology GmbH
Neubaugasse 31, 3462 Absdorf, Austria
Email: info@bioluxtec.com

Contact Us

If you have any questions about this Privacy Policy or our use of your information collected through the OrthoPulse® System, please contact us at support@orthopulse.com.

Manufactured by

Creanova doo – Kamenareva 34, 22300 Stara Pazova, Srbija

Manufactured for

Biolux Technology GmbH
Neubaugasse 31, 3462 Absdorf, Austria

Mailing Address

Biolux Technology GmbH
Simmeringer Hauptstraße 397/115, 1110 Vienna, Austria

Registered Address

Biolux Technology GmbH Neubaugasse 31, 3462 Absdorf, Austria

Australian Sponsor

Emergo Australia, Level 20 Tower II, Darling Park, 201 Sussex Street
Sydney, NSW 2000, Australia

Australian Distributor

Kerr Australia Pty. Ltd., Unit 6, 12 Mars Road, Lane Cove West,
NSW 2066, Australia

CH REP CH-REP

Freyr Life Sciences GmbH, Bahnhofplatz, CH-6300 Zug, Switzerland

UK Responsible Person

Freyr Life Sciences Ltd, 9 Greyfriars Road, Reading, Berkshire,
United Kingdom RG1 1NU

Imported and distributed in Europe by

Biolux Technology GmbH
Neubaugasse 31, 3462 Absdorf, Austria

Kerr Italia S.r.l., Via Passanti, 174
Scafati (SA), 84018 Italy
+39 081 850 8311

This Privacy Policy was last updated on 3 March 2021.

GLOSSARY OF APPLICABLE SYMBOLS

Manufacturer

Date of manufacture

Direct current

Class II Equipment

30 °C 86 °F
5 °C 41 °F
Environmental temperature limit for use

65 °C 149 °F
-20 °C -4 °F
Shipping and storage temperature range

Keep Dry

Fragile, handle with care

Expiration date

Federal law restricts this device to sale by or on the order of a doctor

SN
Serial number

REF
Catalog Number

General Caution Sign

Follow the instructions

Refer to instruction manual

Type BF Applied Part

93%
15%
Humidity Limitation

Separated collection for electrical and electronic equipment use

10 min
24 hours
Device has 10 minutes treatment time, 24 hours Off time

Single patient multiple use

MD
Medical device

CH REP
Swiss authorized representative

The label with the respective symbols is attached on the charging case.

C US

OrthoPulse 2.0S
Model Number OPi2S-100
UDI-Di: 91201180900018

OrthoPulse 2.0E
Model Number OPi2E-100
UDI-Di: 91201180900025

Complies with
EU MDR (Regulation (EU) 2017/745)

TD-IFU-EN_OrthoPulse_V2.3
Released on 9 APR 2026

Questions?

orthopulse.com

OrthoPulse®