

Lumident-Ortho™

User Guide / Instructions for Use

Version 1.0

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1. Introduction

1.1 About Lumident-Ortho™

Lumident-Ortho™ is a photobiomodulation device that uses low-intensity near-infrared light technology. Low-intensity near-infrared light is known to gently facilitate orthodontic tooth movement, helping to reduce treatment time and discomfort for patients undergoing orthodontic treatment with braces or clear aligners.

The light is absorbed by mitochondria in the cells of the alveolar bone that holds the teeth, which may increase cell metabolism and support faster tooth movement.

Lumident-Ortho™ is inspired by 60 years of research in photobiomodulation and has been developed under license from Biolux, the developer of OrthoPulse®, the first device to use this approach to make orthodontic treatment faster and more comfortable.

Lumident-Ortho™ is easy and comfortable to use — just 10 minutes a day (5 minutes per arch). Your orthodontist will explain how to use the device and its benefits as part of your treatment plan.

1.2 Intended Use

Lumident-Ortho™ is intended to be used in conjunction with traditional orthodontic treatment involving brackets and wires, or with clear aligners.

The device is used by the patient at home, following the treatment plan and instructions provided by their treating orthodontist or dentist.

This device should only be used under the guidance of a licensed dental or orthodontic professional, in accordance with applicable regulations in your market.

1.3 Contraindications for Use

A dental professional should be consulted prior to use if any of the following are suspected:

- Use of osteoporosis medication
- Use of medication that may cause photosensitivity
- Photosensitivity¹
- Poor oral hygiene
- Acute oral infection, active periodontal disease, or oral cancer
- Epilepsy

2. How to Use

2.1 How to Charge the Power Bank

Fully charge the Power Bank using the USB-C connector cable. The Power Bank has 4 LEDs indicating 25%, 50%, 75%, and 100% battery charge status.

2.2 Steps and Schedule for Use

A Lumident-Ortho™ treatment takes five (5) minutes per arch, for a total of ten (10) minutes daily.²

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

²There is no additional benefit to treatment sessions beyond the recommended two 5-minute sessions per day.

It is recommended to choose the same time each day for your treatment. It typically takes two to three weeks to develop a habit, so be patient. Some patients prefer to keep their device next to their bed, so they can complete treatment first thing in the morning or before sleep.

To use your Lumident-Ortho™, complete the following six steps:

1. Remove the mouthpiece from its case and connect it to the Power Bank via the magnetic connector.
2. Push the power button on the Power Bank. The Power Bank's LEDs will light up, and the mouthpiece will light up as well (not visible to the naked eye).
3. Place the mouthpiece in your mouth facing upward, for the upper jaw. A warm, pleasant sensation may be felt during treatment. After 5 minutes, the LEDs on the Power Bank turn off, indicating the upper-jaw treatment is complete.
4. Remove the mouthpiece, flip it 180 degrees to face downward, and place it back in your mouth for the lower jaw. Push the power button again and wait 5 minutes until the LEDs turn off. Treatment is now complete.
5. Remove the mouthpiece and disconnect it from the Power Bank. Gently rinse it with water and set it to air-dry on its case. Return it to the case once dry.
6. Recharge the Power Bank as needed so it is ready for the next day.

3. Care and Maintenance

3.1 Cleaning

Gently rinse the mouthpiece with water after each use and set it to air-dry on its case. Return it to the case once dry.

3.2 Storage

Store your Lumident-Ortho™ in its case when not in use to prevent damage. Keep the device in a cool, dry place away from direct sunlight, and avoid locations where it may be exposed to extreme temperatures.

3.3 Service Life

Lumident-Ortho™ is designed to last for the duration of your orthodontic treatment, and should last up to two years of continuous use if cared for properly.

The Power Bank contains a lithium polymer battery that will lose charge over time if not recharged. Fully charge the battery within three months of delivery, and before first use. To preserve battery life, avoid letting the battery fully discharge.

3.4 Replacement

No component of the Lumident-Ortho™ device, including the battery, is user-serviceable or replaceable. No components should require replacement during the course of treatment. Bite marks or wear on the mouthpiece over time are normal and do not require replacement, though they may indicate you are biting or clenching too hard during treatment.

If the mouthpiece becomes punctured, or if any internal surfaces become exposed, stop use immediately and contact your orthodontist or support@lumident-ortho.com.

3.5 Environmental Protection and Disposal

The user guide and packaging are recyclable and should be disposed of with other recyclable paper products. To protect the environment and human health, do not dispose of the device with normal household waste.

Dispose of the device and battery at a designated collection point for the recycling of waste electrical and electronic equipment.

Contact your local waste authority, household waste disposal service, or support@lumident-ortho.com for more information on disposal in your area.

4. Support

4.1 Orthodontic Treatment

For all questions regarding your treatment plan, please contact your orthodontist or dentist directly.

4.2 Device Inquiries

For assistance setting up, using, or maintaining your Lumident-Ortho™, or to report unexpected operation or an adverse event, please contact the Lumident-Ortho™ Support Team.

Manufacturer Contact Information:

Lumident (Hong Kong) Co., Ltd

2 Mercer Street (2/F), Sheung Wan, Hong Kong

Email: support@lumident-ortho.com

Web: www.lumident-ortho.com

4.3 Warranties

Limited Warranty: Lumident (Hong Kong) Co., Ltd ("Lumident") warrants to the original purchaser that the Lumident-Ortho™ device will be free from defects in material and workmanship for two (2) years from the date of original purchase from Lumident or its authorized resellers. This warranty does not apply if the defect or malfunction was caused by misuse, neglect, or unauthorized attempts to open, repair, or modify the device.

4.4 Manufacturer's Liability

Lumident (Hong Kong) Co., Ltd assumes no responsibility for any damage, loss, or claims resulting from failure to follow the instructions in this guide, or from malfunction due to unauthorized repairs or modifications. Use of the Lumident-Ortho™ device is entirely the responsibility of the user.

5. Safety

5.1 Precautions for Children

Keep this device away from children; it is not a toy.

If the device is to be used by a child, usage should be clearly demonstrated in advance, and sessions should be supervised by a parent or adult to ensure correct use.

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 for the Lumident-Ortho™ device to warm up during treatment or after charging, reaching up to 41°C. To prevent overheating and prolong the device's life, let it cool to ambient temperature before use.

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

5.3 Warnings and Safety Notices

ATTENTION:

- Use only as directed. This device should be used under the guidance of your orthodontist or dentist.
- Discontinue use if you experience an allergic reaction to Lumident-Ortho™ or its accessories, and seek medical advice.
- Biting or clenching on the mouthpiece may damage the device or create a choking hazard. Bite gently, just enough to hold the device in place.
- Staring directly at the near-infrared light source may cause eye irritation. Do not stare directly at the mouthpiece.
- Avoid knocking, hitting, or pulling on your Lumident-Ortho™ with force. Rough handling may cause damage. Discontinue use if damage is suspected.
- Do not use the device while operating machinery or performing tasks that require your full attention.
- Patients with an implanted cardiac pacemaker, defibrillator, or similar cardiac device should not use Lumident-Ortho™ unless it has been confirmed that the device is unaffected by magnetic fields.

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