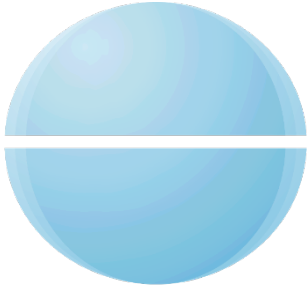
# VILIM ball (1.5)

Therapeutic device for tremor reduction



VILIM ball

Instructions for Use

Revision 9, English (EN)

# Contents

# 1. MEANING OF SYMBOLS

WARNING: You must read these warnings before using VILIM ball.

CAUTION: Contains important information about the operation and maintenance of the VILIM ball. Read it carefully in order to avoid any problems.

RECOMMENDATION: Contains recommended information for help with operation of the VILIM ball.

NOTICE: Takes a user notice.

Manufacturer


Serial number

Type BF applied part

WEEE – (Waste Electrical and Electronic Equipment)

Caution

Consult instructions for use

CE marking of conformity (Product conforms to the essential requirements of European MDD 93/42/EEC)


Medical device


Country of manufacture (Lithuania)

Date of manufacture


Unique device identifier

## 2. INTRODUCTION

The VILIM ball device is non-invasive portable physiotherapeutic remedy. It is intended to be used at home or in a professional environment as a mechanical vibration therapy device to temporary reduce hand tremor caused by Essential tremor.

The device is patented, certified, and corresponds with requirements of Europe Union. The effectiveness and safety have been proven by scientific research and clinical evaluation.

## 3. INTENDED APPLICATION OF THE DEVICE

The VILIM ball non-invasive device intended for temporary alleviation of upper limbs tremor caused by Essential tremor.

Patient target group - people with Essential tremor disorder.

## 4. CONTRAINDICATIONS AND PRECAUTIONS

- **Contraindications**
  - Pregnancy
  - Acute thrombotic process (myocardial infarction, (acute vascular constriction)
  - Implants in activated regions of the body (e.g. artificial joints)
  - Acute inflammation of the locomotor system active arthrosis or arthropathy e.g. acute inflammation or swelling of joints
  - Acute tendinopathy in activated regions of the body (acute tendon inflammation)
  - Acute desmopathy (acute problems at the intervertebral disc)
  - Fresh fractures in activated regions of the body
  - Post-surgery wounds and fresh wounds in activated regions of the body or incomplete wound healing
  - Rheumatoid arthritis
  - Epilepsy.

- **Precautions**
  - The VILIM ball is not intended for other uses: cranial application to treat headache (should not be placed anywhere to induce vibrations in the head area), head or neck tremor or other conditions. It is to only be used as a handheld device to produce local vibration in the upper limb.
  - The device is not created to be thrown or used in other unintended applications (e.g. heating in the microwave, chewing or gnawing). It is not intended to be a children's toy.
  - The device may induce or exacerbate Raynaud's syndrome. In such event device use should be discontinued. The device induces Raynaud's syndrome is a reversible condition. Consultation of a physician is to be sought in such case.
  - The device may induce or exacerbate Carpal tunnel syndrome. Carpal tunnel syndrome is a condition that causes pain and numbness in the fingers and hands, and sometimes the arms. It happens when a nerve in the wrist called the "median nerve" gets pinched or squeezed. In such case the device use should be discontinued. No irreversible damage should be expected.
  - Itching and redness of the skin. If such conditions develop and seem to be related with the device use, the use should be discontinued, and medical attention sought.

# 5. SERIAL NUMBER DESCRIPTION

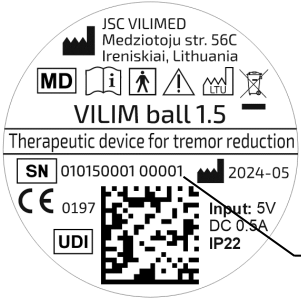



**Figure 1**. Device label

NOTICE: Any serious incident that has occurred in relation to the device should be reported to JSC Vilimed and the competent authority of the Member State in which you are established.

Electronic version of instructions for use can be accessed on the website vilimed.com/ifu.

# 6. DEVICE DESCRIPTION

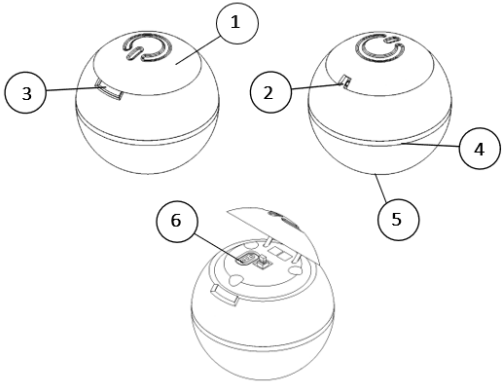



**Figure 2**. External view of the device

1. Button cap.
2. Hook for holding strap.
3. Opening cutout.
4. User Interface Window.
5. Label (bottom of the device).
6. Charging connector.

# 7. PREPARATION FOR USE

VILIM ball device should be held in palm and softly compressed with fingers (Figure 3). Relax your hand for the best therapy results. The device can be portable / body-worn if it is turned off.

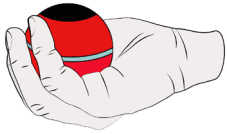


**Figure 3.** Holding instruction

Vibration therapy starts when Button cap (1) is pressed. Device can be stopped any time by pressing the same button cap (1). Therapy stops automatically after 10 minutes.

Before starting the procedure, it is necessary to consult Instruction for Use of the device.

CAUTION: VILIM ball should not be used on patients with implanted heart stimulator / No access for persons with pacemakers.

WARNING: Before charging the device, it is necessary to check the power supply cable for mechanical damage.

WARNING: Users with visual impairments shall have attention of caretaker for full duration of therapy.

RECOMMENDATION: If the device was in premises with temperature lower than 5°C, then it is necessary to keep it in the workplace for at least 15 minutes before connecting to the power supply.

RECOMMENDATION: Sounder for visually impaired can be installed to the device. For more information contact manufacturer.

## 8. OPERATING THE DEVICE

- The device is turned on by pressing the Button cap (1). A GREEN light on User Interface Window (4) indicates that therapy is in progress:
- After 10 minutes of therapy device will stop automatically. A BLUE light will appear on User Interface Window (4) to inform about end of therapy.
- After the therapy Button cap (1) must be pressed to turn the device off. If Button cap (1) is not pressed, the device turns off automatically 5 minutes after end of therapy.
- No light in User Interface Window (4) indicates that device is turned off.

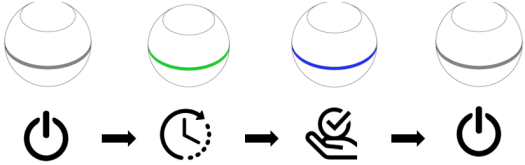


**Figure 4**. User Interface Window (4) instruction (off- therapy- completed- off)

- Low battery level is indicated by a blinking BLUE light in User Interface Window (4) before start of therapy.
- Cap (1) must be opened in order to access the Charging connector (6). This shall be done by putting finger in the Opening cutout (3) and softly lifting Cap (1) until it opens (figure 5).

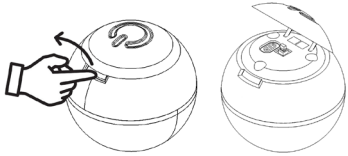


**Figure 5**. Opening the cap to access Charging connector (6)

- The device charging process is performed in such order:

1. Wall adapter is connected to the power supply (see figure 6).

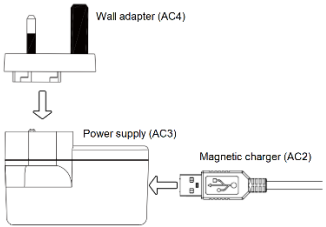



**Figure 6**. Preparation for charging (6)

2. USB connector of magnetic charger cable is connected to power supply's USB socket (see figure 6).
3. Power supply is connected to standard AC outlet.
4. Magnetic connector of magnetic charger cable is connected to VILIM ball's Charging connector (6).

- While the battery is charging, BLUE light is fading in User Interface Window (4).

- If the charging connector is connected and BLUE light in User Interface Window (4) is turned off- charging is completed.

- If the charging connector is connected and the BLUE light in User Interface Window (4) is not appearing- the battery is empty. In such case the charging connector shall be connected for at least hour.

- The Holding strap shall be fixed to a device using a simple knot on Hook for holding strap (3) as described in figure 5.

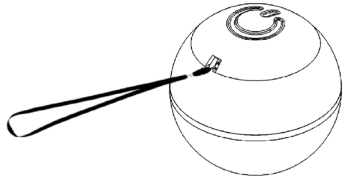


**Figure 7**. Holding strap.

NOTICE: A constantly blinking RED light in User Interface Window (4) means that possible error occurred. In this case, the therapy is discontinued, and the device should be switched off.

WARNING: After fixing the holding trap, check if fixation if strong before use. This can be done by softly pulling the strap with one hand while holding the turned off device in other hand.

## 9. PERSONALIZED THERAPY

Device implements system that measures individual patient's tremor. Depending on those measurements, device settings are adjusted to fit needs of each patient individually.

Take into consideration when using the VILIM ball:

- Minimum amount of two weeks of everyday use is needed for system to fully personalize the therapy.
- Sharing device with other patients corrupts personalization data. Time to fully personalize the therapy in such case may be prolonged drastically.

NOTICE: Therapy personalization may cause sudden change of device vibration.

## 10. SAFETY REQUIREMENTS

WARNING: Before plugging the device to charge it is necessary to check the power supply cable for mechanical damage.

WARNING: It is forbidden to roll up the hook near the plug in and charger.

WARNING: Before starting a procedure VILIM ball device must be held on the patient's palm and only then the Button Cap can be pressed.

WARNING: It is forbidden to use the device while battery is charging.

WARNING: The device must be kept out of the reach of children.

WARNING: The device is not recommended for children.

WARNING: The device shall not be held above the legs to prevent damage in case of accident fall.

WARNING: Holding strap accessory shall be used only with attention of caretaker for full therapy duration.

WARNING: Any modification of the device is forbidden.

WARNING: Unauthorized disassembly and any modification of the device is forbidden. In case of malfunction and failure of the device always contact equipment manufacturer.

CAUTION: Keep the device in a dry area, away from sun rays.

CAUTION: It is recommended to disinfect surface with 70 % spirit before every procedure.

CAUTION: The accessory cables may cause cord strangulation for children.

RECOMMENDATION: After continuous 1 hour work it is recommended to turn off the device for 15 minutes.

RECOMMENDATION: Use device only in 5°C…+40°C ambient temperature range.

NOTICE: Device must be periodically charged even if not used (every 3 weeks).

NOTICE: Battery lifetime is 2 years (300 cycles), based on datasheet of the battery. The battery of the device defines lifetime of the device due to lowest lifetime of the main component. Calculations assume that an average user recharges the VILIM ball after 2-3 days of usage. That is around 147 cycles per year. Battery can be replaced after two years of usage to ensure full battery capacity.

# 11. PACKAGE CONTENTS

The complete device set includes:

- VILIM ball device
- Instruction for Use
- Holding strap (Accessory marked “AC1”)
- Charger:
  - Magnetic charger cable (Accessory marked “AC2”)
  - Power supply (Accessory marked “AC3)
  - Wall adapter (Accessory marked “AC4”)
  - Power supply (AC3) specifications:

| | |
|---|---|
| Name: | UES06WNCPU-050100SPA |
| Manufacturer: | Dongguan Shilong Fuhua Electronics Co., Ltd |
| Type: | AC – DC switching power adaptor |
| Input voltage: | 100 Vac – 240 Vac |
| Output current: | 1 A |
| Input frequency: | 50 Hz – 60 Hz |
| Output voltage: | 4.75 Vdc – 5.25 Vdc |

CAUTION: It is forbidden to use other power supplies to charge VILIM ball.

CAUTION: It is forbidden to use or interconnect device with accessories, parts and materials that are not described in instructions for use.

## 12. RECOMMENDATIONS FOR APPLICATION

Proposed therapy time is 10 minutes per hand, three times daily, at intervals of 4 hours.

CAUTION: Do not use device for more than 30 minutes per a day for one hand.

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

## 13. TRANSPORTATION AND STORAGE

Storage and transportation environments for device and its accessories must be clean and dust-free.

CAUTION: The device can be transported in any means of covered transport, an ambient temperature range of -25 °C to + 72 °C, a relative humidity range of 10 % to 90 %.

CAUTION: Transporting the device in a stationary position must be guaranteed to avoid mechanical damage, vibration and sudden motions.

CAUTION: For storage the device must be packed in plastic bag, placed in carboard box and stored indoor at an ambient temperature range of + 5 °C to + 40 °C, a relative humidity range of 15 % to 90 %.

## 14. DISPOSAL OF THE DEVICE

Disposal of the VILIM ball non-invasive device must be performed in accordance with Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE). The device must be consigned to the companies engaged in recycle and utilization of electronic waste.

- Material specifications:
  - a) Steel
  - b) Stainless Steel
  - c) Copper
  - d) Aluminum
  - e) Carbon
  - f) Bronze
  - g) Brass
  - h) Composition of polycarbonate and ABS (PC+ABS)
  - i) Silicone rubber
  - j) Polyamide (PA)
  - k) Polyurethane
- Hazardous components to be separated at the end of lifecycle
  - a) Li- ion battery
  - b) Printed Circuit Board (PCB)
  - c) Electric cables

# 15. CLEANING

Device cleaning procedure shall be performed in this order:

1) Moisten a soft napkin with 1 % chloramine solution.
2) Take the device and close the Button cap.
3) Clean the device by carefully rubbing moistened napkin to its surface.
4) Open the Button cap.
5) Clean the device by carefully rubbing moistened napkin to its surface under the Button cap.
6) If holding strap is attached, clean it by carefully rubbing moistened napkin to its surface.
7) If device was being charged, take the charger and clean it by carefully rubbing moistened napkin to its surface.
8) Leave the device and accessories in dry place for 10 minutes.
9) Close the button cap.

If device and its accessories are used only by one individual, cleaning procedure shall be performed at least once in a month.
If device and its accessories are used by multiple individuals, cleaning procedures shall be performed after each use.

WARNING: It is forbidden to disassemble the device during cleaning.

WARNING: Device shall be kept away from dust and cleaned immediately if contaminated.

## 16. TROUBLEHOOTING

| Failure | Causes and actions |
|---|---|
| Battery does not charge | 1. No contact. Clean or reattach the cable.<br>2. Battery is out of order. Contact the manufacturer. |
| If the green LED is not illuminating when the device is turned on (the device is loaded) | Failure of the device, contact the manufacturer |
| RED LED is constantly blinking and/or audio signal is generated | Possible internal malfunction. Contact the manufacturer. |
| Device works unusually noisy or vibration is not “clean” | Possible device body failure or contamination (dust, hair or other material). Contact the manufacturer. |

## 17. GUARANTEE OF THE MANUFACTURER

A warranty period of the device and accessories in operation - 24 months from the date of realization, and a warranty period of storage - 48 months from the date of manufacturing.

The manufacturer eliminates free-of-charge all malfunctions of the device during a warranty period - 24 months at absence of mechanical damages and safeties of a seal of the manufacturer.

For assistance, if needed for using or maintaining the device or in case of the device going out of order and with suggestions or requests please contact:

JSC „Vilimed“
Vilimed.com
Medziotoju str. 56C, Ireniskiai, Lithuania (LT-53275)
Tel.: +370 646 22334
E-mail.: info@Vilimed.com

NOTICE: Service life of device and accessories is 24 months from the date of realization.

NOTICE: Device battery needs to be replaced after 24 months from the date of realization.

WARNING: It is strictly forbidden to repair the device yourself. In this case, the company is not liable for the consequences.

## 18. TECHNICAL SPECIFICATIONS

| | |
|---|---|
| Charging input voltage: | 5V DC |
| Charging input current: | 200 mA |
| Battery type | Li- ion |
| Battery capacity: | 430 mAh |
| Battery Voltage | 3.7V |
| Max. battery voltage: | 4.2 V |
| Battery compliance: | EN IEC 62133, UN 38.3 |
| Active battery lifetime | 1 – 5 hours |
| Stand by battery lifetime | 28 days |

| | |
|---|---|
| Charging time | 2 hours |
| Max power: | 2 W |
| Max current: | 0.7 A |
| Weight: | 120 g |
| Diameter: | 70mm |
| IP certified: | IP22* |
| Communication frequency: | 2.4 GHz (BLE) |
| Medical device class: | IIa |
| Vibration's type: | Mechanical |
| Vibration's frequency range: | 8Hz…18Hz |

Environmental conditions for normal device operation:

| | |
|---|---|
| Ambient temperature | 5°C…+40°C |
| Relative humidity | 15%…90% |
| Atmospheric pressure | 700hPa…1060hPa |

Environmental conditions for device transportation:

| | |
|---|---|
| Ambient temperature | -25°C…+70°C |
| Relative humidity | 10%…90% |
| Atmospheric pressure | 500…1060hPa |

Standards conformity:

EN IEC 60601-1
EN IEC 62133
EN IEC 62304
EN 62366-1
EN 300 328 v2.1.1
EN ISO 10993-1
WEEE

*Ingress protection (IP) rating describes the level of protection from solid objects and the level of protection from liquids. The VILIM ball device is certified IP22 level protection:
Protected against solid objects over 12 mm (fingers, sticks, etc.).
Protection against direct sprays of water up to 15 degrees from the vertical position (mist, vapor, etc.).

| Rev. | Date | Change description |
|---|---|---|
| 1 | 2019-06-13 | Initial version of document. |
| 2 | 2019-07-01 | Specified ambient temperature for normal operation in clause “Specifications”. Edited recommendation in clause "Safety requirements". Changed document history table column names. |
| 3 | 2019-07-15 | Removed cautions - duplicates. Clause “Contraindications” was supplemented with Precautions. Added release version. Updated specifications. |
| 4 | 2019-12-01 | Added Risk management and EN 60601-1-11 related information, corrected environmental conditions for transport, storage and normal use, added clause “Cleaning” and power supply specifications, explained Ingress protection level. |
| 5 | 2020-01-07 | Changed format to A5. Added warnings related to radio frequency (RF). |
| 6 | 2020-04-09 | Detailed cleaning procedure. Detailed requirements for storage and transportation environment added. |
| 7 | 2021-06-28 | Added target group, manufacturers symbol, language identifier. |
| 8 | 2022-08-01 | Added notice for incident reporting. Device version set to 1.4. |
| 9 | 2023-09-01 | Added website to access instructions for use electronic version. Added UDI symbol and additional used symbol explanations. |