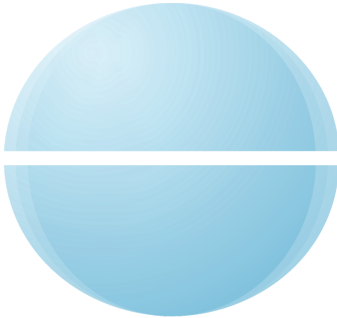
VILIM ball (1.6)

Therapeutic device for tremor reduction



VILIM ball

Instructions for Use

Revision 11, English

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1. MEANING OF SYMBOLS

	WARNING: You must read these warnings before using the 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: Take 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)
	Unique device identifier
	Country of manufacture (Lithuania)
	Date of manufacture

2. INTRODUCTION

The VILIM ball device is non-invasive portable physiotherapeutic remedy. The device 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 the requirements of Europe Union.

The effectiveness and safety have been proven by scientific research and clinical evaluation.

3. INTENDED APPLICATION OF THE DEVICE

VILIM ball is a 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 redness of skin. If such condition develops and seems to be related with the device use, the use should be discontinued, and medical attention sought.

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

5. DEVICE LABEL

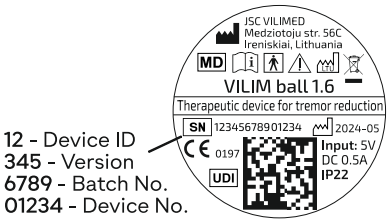

Figure 1. Device label

6. DEVICE DESCRIPTION

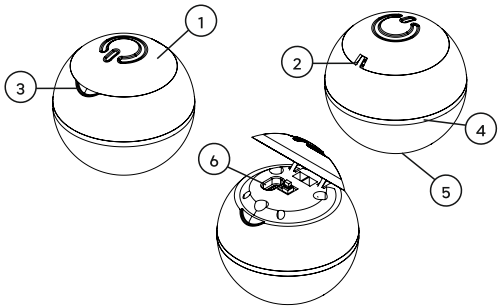

Figure 2. External view of the device

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. OPERATING THE DEVICE

The VILIM ball device should be held in palm. Default holding position is presented in figure 6.

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.

The suggested therapy duration is 10 minutes per hand, three times a day, with 4-hour intervals between sessions. This recommendation is particularly important during the initial 14-day personalization period.

	Before starting the procedure, it is necessary to consult Instruction for Use of the device.
	CAUTION: The 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 an environment below 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.
	RECOMMENDATION: It is recommended to perform therapy on each hand separately. However, if tremor between hands differ very significantly, we recommend using the device solely on the dominant hand. Alternatively, two devices may be used, one for each hand.
	RECOMMENDATION: You can take a VILIM ball with you during a flight. It is a standard electronic device, but please be aware that flight regulations may allow you to carry only one (or at most two) devices with lithium batteries in your luggage.

- The device is turned on by pressing the Button cap (1). 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 device turns off automatically 5 minutes after end of therapy.
- No light in User Interface Window (4) indicated that device is turned off.

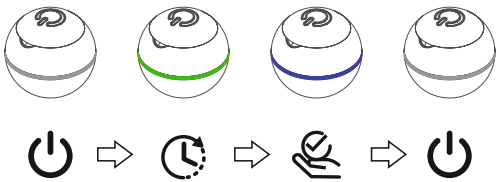

Figure 3. User Interface Window (4) instruction (off - therapy - completed - off)

8. CHARGING

- Low battery level is indicated by blinking BLUE light in User Interface Window (4) before start of therapy. This means you have enough charge for one more therapy session.
- 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 Button cap (1) until it opens (figure 4).

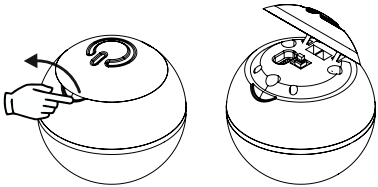

Figure 4. Opening the cap to access Charging connector (6)

- Device charging process is performed in such order:

1. Wall adapter is connected to the power supply (see figure 5).
2. USB connector of magnetic charger cable is connected to power supply's USB socket (see figure 5).

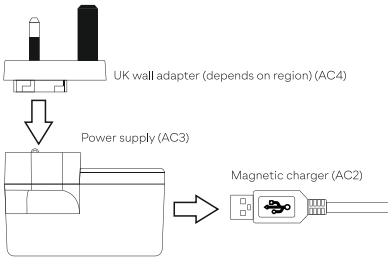

Figure 5. Preparation for charging (6)

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

	NOTICE: 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.
	RECOMMENDATION: Hold the device in hand while disconnecting the charging cable.
	NOTICE: Device must be periodically charged even if not used (every 3 weeks).
	NOTICE: Battery lifetime is 2 years (300 cycles). Calculations assume that an average user recharges the VILIM ball after 2-3 days of usage. That is approx. 147 cycles per year. Battery can be replaced after two years of usage to ensure full battery capacity.

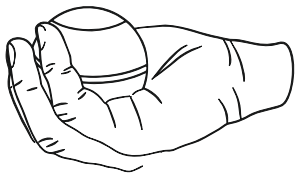

Figure 6. Default holding position

9. PREPARATION FOR USE

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

Achieving successful therapy depends on proper device setup. Pay attention to these details 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.
- Efficacy may be impacted by the way you hold the device during the therapy.

10. HOLDING GUIDELINES

Initially, the device in its default position (figure 6). It is advisable to sit comfortably throughout the therapy session. Keep your arm relaxed on your lap or another comfortable surface. Avoid making sudden movements while therapy is active. Ensure the device does not come into contact with any solid objects; only your hand should make contact.

If resting tremors* are not experienced or if the therapy seems insufficient enought, consider experimenting with alternative holding positions.

Some of the other holding position variants includes:

- Holding the device firmly, squeezing your fingers.
- Holding the device firmly with your fingertips.
- Rotating the device with fingers several times around the device axis during the therapy.
- Aligning the device with the most severe tremor axis. Use the Button cap (1) as a pointer to the tremor direction.
- Pointing the Button cap (1) to touch the bottom side of your palm.
- Your custom position that triggers the most severe tremor.

Another alternative is to adopt a posture that maximizes tremors during the first 30 seconds of the therapy session. In this case, the device will detect and measure tremors more easily.

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

If you find visual guidance more helpful, scan the QR code provided below.

Figure 7. QR code for visual guidance on holding positions.

	RECOMMENDATION: Use device only in 5°C...+40°C ambient temperature range.
	WARNING: When securing the holding strap, ensure it is firmly fixed before use. To test this, gently pull the strap with one hand while holding the turned-off device in the other hand.
	CAUTION: Do not use device for more than 30 minutes per a day for one hand.

11. 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 the 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 to use 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 disassemble and any modification of device is forbidden. In case of malfunction and failure of the device always contact equipment manufacturer.
	CAUTION: Keep the device in 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.

12. PACKAGE CONTENTS

The complete device set includes:

- VILIM ball device
- Instruction for Use
- Holding strap (Accessory marked “AC1”)
- Charger items :
  - Magnetic charger cable (Accessory marked “AC2”)
  - Power supply (Accessory marked “AC3)
  - UK wall adapter (depends on region) (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
Input current:	0.2A
Input frequency:	50 Hz – 60 Hz
Output voltage:	4.75 Vdc – 5.25 Vdc
Output current:	1A

	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.

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 covered transport mean, an ambient temperature range of -25 °C to + 72 °C, a relative humidity range of 10 % to 90 %.
	CAUTION: Transporting the device the 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 cardboard box and stored indoor at an ambient temperature range of + 5 °C to + 40 °C, a relative humidity range of 15 % to 90 %.
	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.

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 life cycle:
  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 rubbing moistened napkin to its surface.
4) Open the Button cap.
5) Rub moistened napkin to its surface under the Button cap.
6) If holding strap is attached, clean it with moistened napkin.
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 disassembly the device during cleaning.
	WARNING: Device shall be kept away from dusts and cleaned immediately if contaminated.
	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.

16. TROUBLESHOOTING

Failure	Causes and actions
Battery does not charge	1. No contact. Clean or reattach the cable. 2. Battery is out of order. Contact the manufacturer.
Green LED is not ON when the device is turned on	Failure of the device. Contact the manufacturer.
RED LED is constantly blinking	Possible internal malfunction. Contact the manufacturer.
Device is unusually noisy or vibrations are too loud	Possible device body failure or contamination (dust, hair or other material). Contact the manufacturer.
The device does not power on despite being fully charged. There are no light indications or vibrations.	Possible software error. Press the button with something heavy and hold it for at least 4 hours. Afterward, recharge the device.

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:

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

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
IP certified:	IP22*
Medical device class:	IIA
Vibrations 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

Conformity:	EN IEC 60601-1	EN IEC 62133
	EN IEC 62304	EN 62366-1
	EN ISO 10993-1	WEEE

**Ingress Protection (IP) rating indicates a device's protection against solids and liquids. IP22 means protection against solid objects over 12 mm (e.g., fingers, sticks). Also, protection against direct water sprays up to 15 degrees from the vertical position (e.g., mist, vapor).*

Portable and mobile RF communications equipment should be used no closer to any part of the VILIM ball, including cables, than the recommended separation distance d calculated from the equation appropriate to the frequency of the transmitter.

Recommended separation-distance equations:

- 150 kHz to 80 MHz: $d = 1.2 \sqrt{P}$
- 80 MHz to 800 MHz: $d = 1.2 \sqrt{P}$
- 800 MHz to 2.7 GHz: $d = 2.3 \sqrt{P}$

(P = maximum output power of the transmitter in watts, d = distance in meters))

At 80 MHz and 800 MHz, use the higher-frequency range. For transmitters not listed in the table, estimate distance d using the relevant equation.

P (W)	150 kHz – 80 Mhz ($d = 1.2 \sqrt{P}$)	80 MHz – 800 Mhz ($d = 1.2 \sqrt{P}$)	800 MHZ – 2.7 GHz ($d = 2.3 \sqrt{P}$)
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

Rev.	Date	Causes and actions
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	2019-12-15	Added Risk management and EN 60601-1-11 related information, corrected environmental conditions for transport, storage, and normal use, added clause “Cleaning”, power supply specifications, explained IP 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 incident reporting notice. Device version updated to 1.4.
9	2023-09-01	Added website to access instructions for use electronic version. Added UDI symbol and additional used symbol explanations.
10	2024-05-01	Device version set to 1.6. Added „Preparation for use“ and „Charging“. Removed clauses „Personalized therapy“ and „Recommendations for application“. Updated label.
11	2025-06-26	Added serious incident reporting notice. Improved guidance on electromagnetic immunity.

Document control (DO NOT PRINT THIS PAGE)

Responsability	Role	Role	Signature	Date
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Approved by	Mantas Venslauskas	CEO		2025-06-26

Mini-Reviewer checklist

Question	Rationnale	YES?
Identification & traceability – Does the label/IFU show device name, manufacturer, serial number, date?	MDR Annex I §23 2 (a-j), Article 27 + Annex VI Part C	Yes
Safety & performance - Are intended purpose, performance specs, warnings/contra-indications, side-effects and residual-risk information clearly stated?	MDR Annex I §23 4 (b-g), (s)	Yes
Regulatory & vigilance statements – Is the CE-mark with NB-ID (if class IIa via NB) present, and does the IFU contain the required serious-incident notice including manufacturer contact?	MDR Article 20; Annex I §23 4 (z)	Yes
Symbols & language – Are only harmonised ISO 15223-1 symbols used (or explained) and is the IFU in the correct languages for the target Member States?	ISO 15223-1:2021; MDR Art 10 (11)	Yes
Storage, handling, disposal & environmental info - Does the label/IFU specify storage, transport conditions and safe disposal measures if required?	MDR Annex I §23 2 (k), §23 4 (v)	Yes
Document control - Is the IFU revision/date shown up to dateand has this checklist been fully completed?	ISO 13485 §4.2.4	Yes

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