

6 MODE WIRELESS TENS AND EMS UNIT

RHB3052BLK

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OWNER'S MANUAL

6 MODE WIRELESS TENS AND EMS UNIT

WHAT'S INCLUDED



- 1x Digital TENS Device
- 2x Electrode Pads
- 1x USB Charging Cable
- 1x Instruction Manual
- 1x Quickstart Insert

INTENDED USE

This medical device is designed to provide transcutaneous electrical nerve stimulation (TENS) for pain management. It delivers controlled micro-electrical currents through electrode pads to provide temporary relief of muscle and joint pain. The device may be used under healthcare professional guidance for pain management and rehabilitation.

USER PROFILE

Primary users are adults ages 18+, healthcare professionals, including physicians, pain management specialists, physical therapists, and qualified practitioners. Secondary users include patients or caregivers under healthcare professional guidance.

ENVIRONMENT OF USE

Suitable for both indoor and outdoor use within typical residential and clinical settings. The device is portable and designed for daily use scenarios.

ILLUSTRATIONS OF THE DEVICE

Button	Description
	Hold on for 3s to turn on the device. Short press to change the mode.
	Decrease the intensity
	Increase the intensity
	Increase the intensity
	Increase the intensity

APPLICATION INSTRUCTIONS



IMPORTANT:

Clean skin surface before applying electrodes

1. PREPARE

Ensure device is fully charged, Clean application area with alcohol wipe. Remove protective film from electrode pads.



NOTE:

Any excessive body hair may need to be shaved for better contact with skin and electrode pad.

2. PLACEMENT

Position electrodes on the pain area. Ensure full contact with skin.

3. OPERATION

Power on the device, select the desired program. Adjust intensity gradually as needed. Monitor the skin response.

4. MONITORING Normal Use Signs:

Gentle tingling sensations are normal, along with mild muscle contractions.

STOP USE IF:

- Sharp pain occurs
- Skin irritation develops
- Numbness appears

CONTRAINDICATIONS

DO NOT USE IF YOU HAVE:

- Cardiac pacemaker/implanted defibrillator
- Pregnancy
- Epilepsy
- Active cancer
- Open wounds in application area
- Metal implants in application area

TECHNICAL SPECIFICATIONS

- Model Number: SM9116
- Type: Wireless TENS and EMS Unit
- 6 Modes, 19 Intensities

Electrical Parameters

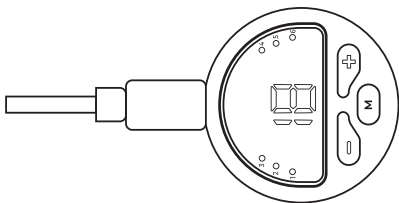
- Input Voltage: 100-240V, 50/60Hz
- Input Current: 0.4A
- Output: DC 5V, 300mA
- Pulse Width Range: 50 - 495 μ s
- Frequency Range: 1 - 142Hz

Power Supply

- Battery Type: Lithium-ion polymer
- Battery Capacity: 110mAh
- Battery Voltage: 3.7V

BATTERY CHARGING, AND BATTERY STATUS

1. Insert the USB-C charging cable to the charging port on the device.
2. Connect the USB cable to a suitable adapter. (DC 5V, 300mAh)
3. When charging, the mode lights will flash in a sequence.
4. It takes about 2 hours to fully charge the device, when the battery is fully charged, all 6 mode lights will turn on.



CLEANING THE DEVICE

1. Shut down your device and detach the electrode pads from the main device.
2. Clean the device with a soft cloth.
3. If the pads lose their stickiness, they may need to be replaced or cleaned with a few drops of water to remove any debris.

SAFETY CLASSIFICATIONS

- Type BF Applied Part
- Class II Medical Device
- Software Safety Class A
- Mode of Operation: Continuous

ELECTROMAGNETIC COMPATIBILITY

This device complies with IEC 60601-1-2 for EMC requirements.

WARNINGS AND PRECAUTIONS

- Do not use while driving or operating machinery
- Keep away from water
- Do not apply over carotid sinus nerves
- Stop use if skin irritation occurs
- Do not modify device
- Use only supplied accessories
- Keep away from children
- Do not use on neck, face, or sensitive areas.

MAINTENANCE

- Clean electrode pads after each use.
- Replace pads when adhesive weakens.
- Charge battery when indicated.
- Store in protective case.
- Regular safety checks recommended.

SYMBOLS GLOSSARY

	Manufacturer ISO 7000-3082 To identify the manufacturer of the Medical Device.
	Authorized representative in the European Community/European Union
	Date of manufacture ISO 7000-2497 To indicate the date on which the Medical Device was manufactured.
	Batch Number
	Serial Number
	Unique Device Identifier
	Importer To identify the importer of the Medical Device.
	Caution ISO 15223-1, Clause 5.4.4 To indicate the need for the user to consult the Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the Medical Device itself.
	RHB3052BLK
	Indicates a medical device that has not been subjected to a sterilization process.
	Indicates a medical device that needs to be protected from moisture.
	Consult instructions for use ISO 7000-1641 Indicates the need for the user to consult the Instructions for Use.
	Indicates a medical device that needs protection from light sources.
	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.
	Medical device indication ISO/DIS 15223- 1:2020 Reference no. 5.7.7 Indicates the item is a Medical Device.
	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information

	Athmospheric Pressure Limitations
	Humidity limitations

TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
Can't feel any stimulation.	The intensity level is too low.	Press the  button until stimulation is felt.
	The electrode pad is not firmly secured to the skin.	Press down the electrode gel pad against the skin to ensure uniform contact.
	The adhesive surface of the gel pad is damaged.	Replace it with a new electrode pad.
	The adhesive surface of the gel pad is dirty.	Refer to the cleaning section above to see how to properly clean the electrode pad.
Electrical stimulation is too weak.	The Battery is very low.	Charge device.
	The adhesive surface of the electrode pad is damaged.	Replace with a new electrode pad.
	The adhesive surface of the gel pad is dirty.	Refer to the cleaning section above to see how to properly clean the electrode pad.
Electrical stimulation is too strong.	The intensity level is too high or the electrode pad is not attached correctly.	Press the  button to decrease intensity or attach the electrode pad correctly.
Stimulation stopped unexpectedly.	The battery is low.	Charge device.

The electrode pad won't firmly attach to the skin.	The adhesive surface of the electrode pad is dirty.	Refer to the cleaning section above to see how to properly clean the electrode pad.
	The adhesive surface of the electrode pad is damaged.	Replace with a new electrode pad.
The skin turns red or becomes irritated.	The electrode pad is not firmly attached to the skin.	Make sure the skin is clean and attach the electrode pad firmly to the skin. (No lotions/oils).
	The adhesive surface of the electrode pad is dirty or dried out.	Refer to the cleaning section above to see how to properly clean the electrode pad.
	The adhesive surface of the gel pad is damaged.	Replace with a new electrode pad.

MANUFACTURE INFORMATION

Manufacturer



Vive Health

8955 Fontana Del Sol Way
Naples FL 34109

service@vivehealth.com
1-800-487-3808
vivehealth.com

Compliance Management Solutions Europe

2 Bulgaria Str, 2850 Petrich,
Bulgaria.

IMPORTANT SAFETY NOTICE!!

If you experience any serious incident related to the use of this device, immediately discontinue use and report it to:

1. The manufacturer: Vive Health (8955 Fontana Del Sol Way, Naples FL 34109)
2. Contact your national health authority or medical device regulator
3. Your healthcare provider

A serious incident is any incident that directly or indirectly led, might have led, or might lead to:

- Death of a patient, user, or other person
- Temporary or permanent serious deterioration of a patient's, user's, or other person's state of health
- A serious public health threat

For any questions or concerns that are not serious incidents, please contact Vive Health customer service at: service@vivehealth.com 1-800-487-3808 vivehealth.com

WARRANTY

Your Vive Wireless TENS and EMS Unit includes a one-year limited warranty against manufacturing defects with proof of purchase. Contact Vive Health (1-800-487-3808 or service@vivehealth.com) for warranty service. Consumable items like electrode pads are not covered under warranty.



HAVE MORE QUESTIONS?

Check out our list of Frequently Asked Questions at vhealth.link/h1h for helpful answers.



And if that doesn't answer your question, our customer service team would love to help! Feel free to connect with them by phone, e-mail, or chat on our website

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