EN

iHealth® Soothe

INSTRUCTION MANUAL

iHealth Soothe Dual-Channel TENS Unit

Model: AD-2126

Please read this instruction manual carefully before using the product

Thank you for purchasing the iHealth Soothe Dual-Channel TENS Unit. Please retain this Instruction Manual for reference.

TABLE OF CONTENTS

INTENDED USE

The iHealth Soothe Dual-Channel TENS Unit is a Transcutaneous Electrical Nerve Stimulation (TENS) unit that is intended to provide temporary relief from muscle soreness caused by exercise, household tasks, or work activities. It is also effective in alleviating chronic pain, intractable pain, and pain associated with arthritis. It is important to apply the electrode pads only on intact skin and avoid placing them directly on the head, neck, chest, near the thorax and private areas. The TENS device is suitable for adult users, including laypersons and professionals.

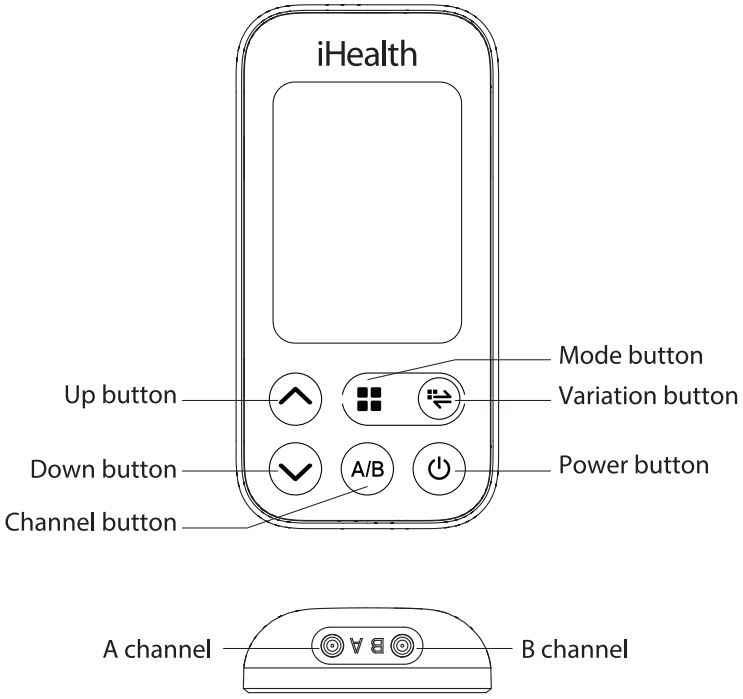
CONTRAINDICATION

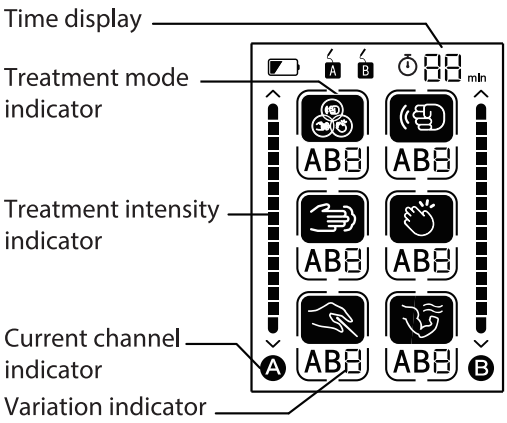
Patients with implanted electronic devices such as pacemakers, life-sustaining medical devices (e.g., artificial hearts or lungs), or electrocardiographs should not use this device.

OPERATION PRINCIPLE

The electrical impulses {Output pulse frequency: 0-100 Hertz (Hz); Output voltage: max. 120 peak-to-peak voltage (Vpp) (500 ohms); Output pulse width: 20-100 μs} generated by the TENS device are transmitted to the nerves under the skin to block or shut out the pain message from the source of pain to the brain. Additionally, these electrical impulses also increase the production of the body's natural painkillers, such as endorphins. Furthermore, low-frequency vibrations can promote blood circulation and relieve pain.

DISPLAY INDICATORS





low battery symbol

electrode A outputs symbol

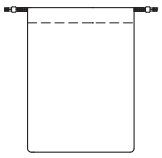
electrode B outputs symbol

A A-channel symbol

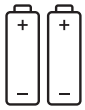
B B-channel symbol

BOX CONTENTS

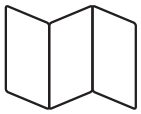
1 x Main Unit



1 x Storage bag



4 x AAA Batteries



1 x Instruction Manual

1 x Quick Start Guide

2 x Electrode cords

2 x Pad Holders

2 x Rectangle Electrode Pads

8 x Square Electrode Pads

SPECIFICATIONS

1.Product name: iHealth Soothe Dual-Channel TENS Unit
2.Model: AD-2126
3.Classification: Internally powered; Type BF applied part; IP22; No AP or APG; Continuous operation; not intended to be used in an oxygen-rich environment
4. Size:
Approx. 4.8″× 2.4″× 0.8″ (120.3mm×60.3mm×20.6mm)
5. Weight: Approx. 2.6 oz. (73g) (exclude batteries)

6.Electrode pads:
a.Square Electrode Pads: Approx. 2.0" x 2.0" (50mm×50mm); Model: EP505036N01
b.Rectangle Electrode Pads: Approx. 2.0" x 3.9" (50mm×100mm); Model: EP5010036N01
7.Electrode cords: Approx. 47.3" (1200 mm); Electrode Cords model: 23507-3.8-1201
8.Output channel: 2 (A and B)
9.Number of treatments: 24 treatments
10.Intensity levels: 15
11.Output pulse frequency: 0-100 Hz
12.Output voltage: max. 120 Vpp (500 ohms)
13.Output pulse width: 20-100μs
14.Large liquid crystal display (LCD) with blue backlight
15.15-minute countdown timer or self-select time periods
16.Batteries: 4×1.5V ⎓ SIZE AAA
17.Environmental temperature for operation: 41°F to 104°F (5°C to 40°C)
18.Environmental humidity for operation: ≤80%RH
19.Environmental temperature for storage and transport: -4 °F to 131°F (-20°C to 55°C)
20.Environmental humidity for storage and transport: ≤90%RH
21.Environmental pressure: 80 kPa to 105 kPa
22.Main unit life: Three (3) years
23.Battery life: Approx. Six (6) months with alkaline batteries (when used for two (2) times a day)
24.SKU: TENS-Soothe

IMPORTANT SAFETY INFORMATION

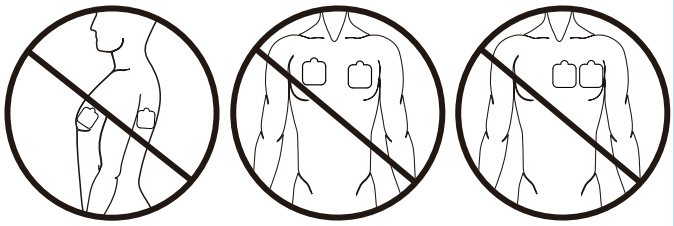
SAFETY SYMBOLS USED IN THIS INSTRUCTION MANUAL	
⚠ Warning	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ Caution	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user.

1. ⚠ Use alongside implanted electronic devices (e.g., pacemakers, intracardiac defibrillators, etc.) may result in electric shocks, burns, interference, or even be life-threatening.
2. ⚠ Simultaneous connection of a PATIENT to high-frequency surgical medical electrical (ME) equipment may result in burns at the site of the stimulator electrodes and possible damage to the device.
3. ⚠ For Hospitals and Clinics: In the presence of, or when attached to the body, electronic monitoring equipment (e.g., cardiac monitors, ECG alarms, etc.) may not operate properly when the electrical stimulation device is in use.
4. ⚠ Operation within proximity (e.g., 3 feet or 1 meter) to shortwave or microwave therapy equipment may produce instability in the stimulator output.
5. ⚠ Pregnant women should not use the device.
6. ⚠ This device is designed for adults and should **never** be used on infants or young children. Consult your physician or other health care professionals before use on older children.
7. ⚠ **Never** let children or persons who are incapable of expressing their own use the TENS device. Keep the device safely stored and inaccessible to children to prevent from swallowing the batteries or small parts.

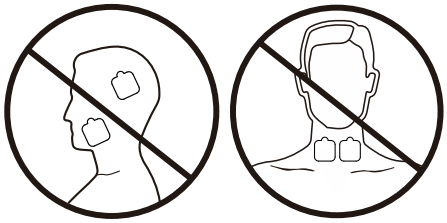
8. ⚠ **Never** use the device while sleeping or driving. **Never** use the device in humid environments (e.g., bathroom), as it may cause intense stimulation.

9. ⚠ **Never** apply the pads to these body areas:

a.Avoid placing the electrode pads near to the heart, or on both sides of the thorax simultaneously (lateral or front and back), or across your chest (especially on the two large pectoral muscles). Otherwise, it can increase the risk of ventricular fibrillation and may induce cardiac arrest.



b.Avoid placing the electrode pads on the following areas: head, eyes, mouth, any area of the face, neck (especially the carotid sinus), private parts, or affected skin. Once you feel unwell or your skin appears abnormal while using the device, please stop using it immediately and seek medical attention.



10. ⚠ If you are allergic to the device's material, please do not use it.

11. ⚠ See the section regarding ELECTROMAGNETIC COMPATIBILITY INFORMATION for information regarding potential electromagnetic interference (EMI), or other interference, between the TENS device and other devices. MR Please do not use the device within the environment of the following devices: Magnetic Resonance Imaging (MRI), computerized axial tomography (CT), diathermy, Radio Frequency Identification (RFID), active HF SURGICAL EQUIPMENT, and electromagnetic security systems such as metal detectors.

12. ⚠ Place the electrode pads on intact skin only. Do not place on cuts, wounds, or areas with skin conditions.

13. ⚠ Please do not share electrode pads to prevent the risk of infection and cross-contamination.
14. ⚠ Please do not use any other electrode pads and/or electrode cords other than those supplied by the original equipment manufacturer. Injury, discomfort, or equipment damage could result.
15. ⚠ Keep all electrode cords away from babies and children to prevent suffocation and death from winding cords around the neck.
16. ⚠ If the electrode pads are damaged or the adhesive starts to weaken, please replace them immediately to prevent potential skin injuries.
17. ⚠ The patients can operate the device by themselves. Ensure the battery cover is properly installed on the main unit; otherwise, the device will not work properly.
18. ⚠ Do not use this device for anything other than its intended purpose.
19. ⚠ Limit therapy time to no more than 30 minutes per session if using the electrode pads on the same part of the body.
20. ⚠ Power off the main unit before shifting or moving the position of the electrode pads.
21. ⚠ During stimulation and therapy, please do not let any metal (e.g., a part of a leather belt, wristwatch, jewelry, etc.) touch the electrode pads.
22. ⚠ The device might not meet its performance specifications or may cause safety hazards if stored or used outside the specified temperature and humidity ranges listed in the specifications section.
23. ⚠ The output wave parameters are not to be influenced by load resistance, except output voltage.
24. ⚠ 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 protect reasonably 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 the receiver.
- Connect the equipment to 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.

SETUP AND OPERATION

1.LOADING BATTERY

a.Open the battery cover at the back of the main unit.
b.Insert four "AAA" batteries. Make sure the batteries are inserted according to the positive and negative marks ("+" and "-") printed in the battery housing.
c.Insert the battery cover back on the main unit, see Figure 1.

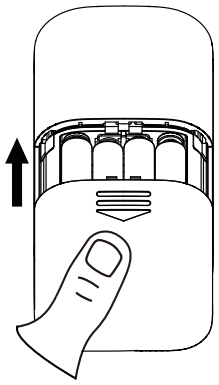


Figure 1

Note: Ensure the battery cover is properly installed before turning on the main unit, otherwise, the main unit will not power on.
When the LCD shows a battery symbol , replace all batteries.
Rechargeable batteries are not suitable for this main unit.
⚠ Avoid getting battery fluid in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.
⚠ The negative terminal of the battery needs to be compressed into the battery compartment properly after the horizontal compression of the negative electrode. The battery must contact the spring.
⚠ Make sure the battery cover is intact and not damaged before installing the battery.

The main unit, the batteries, the electrode pads, and the electrode cords must be disposed of according to local regulations at the end of their usage.

2.PREPARING THE ELECTRODE PADS

a.Attach the end of the electrode cord with two metal buttons to two electrode pads. Connect the other end of the electrode cord with one plug into Channel A/B on the top of the main unit.

b.Each electrode pad is protected by a layer of transparent film. Remove the layer of film before applying the pads to the skin.

Note:

1)Hold the plug when pulling it out. Do not pull on the electrode pad.

2)Never stick two adhesive electrode pads together. The electrode pads must fit precisely inside the conductive surface.

3)If the electrode pads are not stuck in the exact position, remove the electrode pads and attach them again.

4)The electrode pad has a service life and is generally not recommended to be used for a long time. It is recommended to use the electrode pads less than 20 times in total. The specific number of times depends on usage and storage conditions.

3.USING YOUR TENS DEVICE

The iHealth Soothe Dual-Channel TENS Unit can treat many different types of pain. For electrode pad placement for different forms of pain, please refer to the diagram in **section 5**.

a.Clean the areas of the skin where you will be placing the electrode pads.

b.Attach the electrode pads around the treatment areas.

c.Press the ⏻ button to power on the main unit.

d.Press the A/B button to switch between channels.

e.Press the ▦ button to choose your primary treatment mode.

f.Press the ⇄ button to select your variation.

Note: Each primary treatment mode has four variations for a total of 24 treatments. Please refer to **section 6** for detailed information.

g.After selecting your treatment, the default intensity is set to zero. Use the ^ or v button to adjust the intensity and start the treatment.

h.Treatment time will begin counting down with a flashing timer displayed on the LCD. The default treatment time is 15 minutes.

Note: During a treatment, the timer will not change, even if the program or intensity is modified.

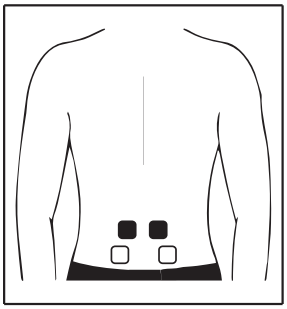
i.After treatment, or when the intensities of both Channel A and Channel B are set to 0, the main unit will automatically shut off after 20 seconds of inactivity.

j.Press the ⏻ button to power off the main unit at any time.

4.ADJUSTING TREATMENT TIME

a.Long press the ⏻ button to enter the treatment time setting when the main unit is powered on.
b.When treatment time is flashing on the LCD (the default value is 15 minutes), press the ^ or v button to adjust the treatment time. Short press the ⏻ button to complete the treatment time setting.

5.ELECTRODE PADS PLACEMENT GUIDE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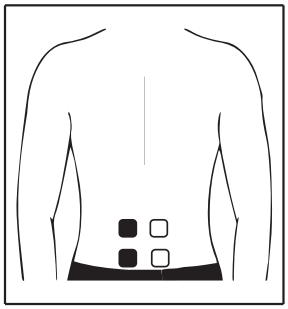
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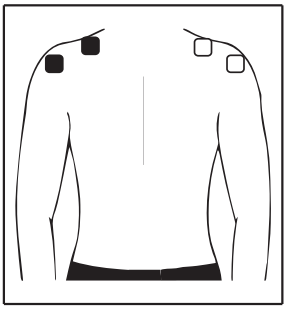
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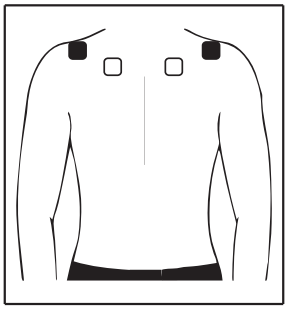
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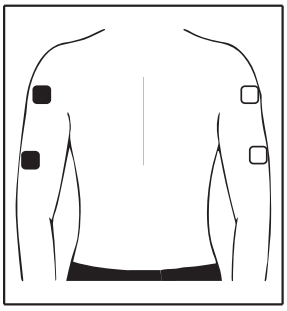
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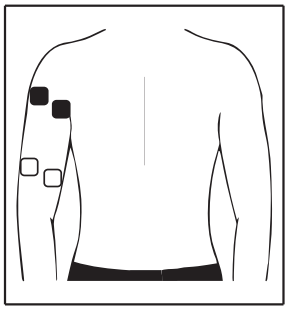
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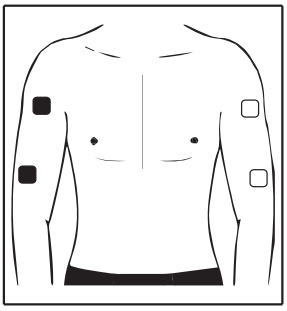
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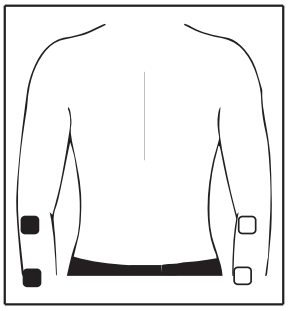
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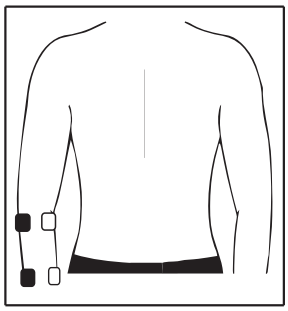

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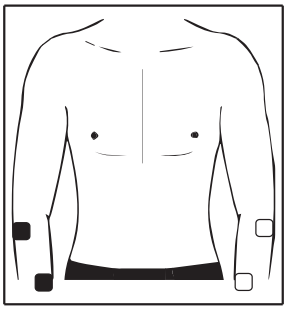

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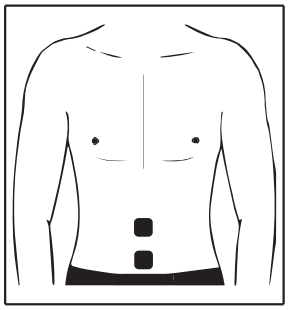

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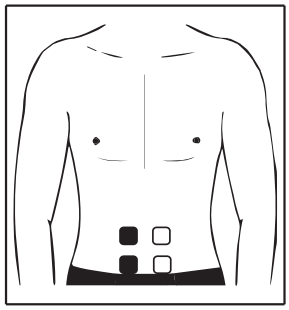

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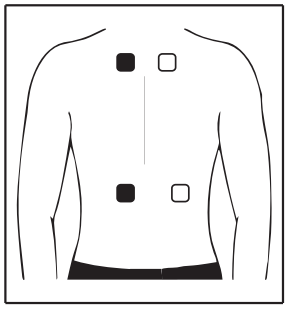

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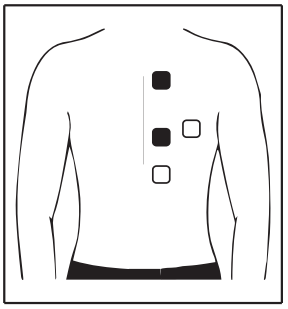

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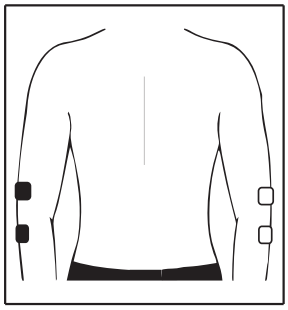

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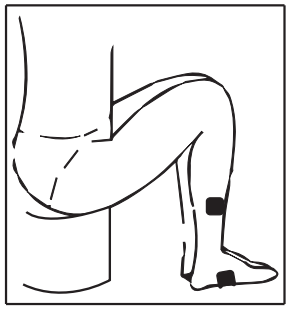

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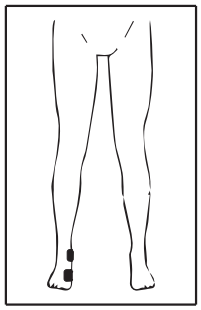

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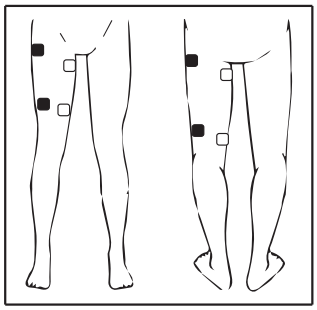

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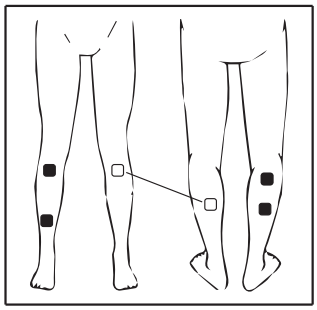


5.19

5.20

6.TREATMENT CHART

The device has 7 types of stimulations (see Table 6.1). The combinations of these stimulations make up a total of 24 treatments (6 modes and 4 variations each, see Table 6.2).

Table 6.1 Stimulation Descriptions

Stimulation	Sensation
Vibration	Less intense, numbing electrical stimulation
Slap	Slapping sensations that vary in duration, intensity, and interval
Knock	Knocking feeling that alternates from fast to slow and back to fast
Press	Simulates manual pressing, providing a repeated pressing sensation
Knead	A slight sense of kneading
Thump	A fast, high-strength hammering sensation
Deep press	More intense manual pressing sensation; the pressing time is longer and at higher strength

Table 6.2 24 Treatments (6 Modes, Each Containing 4 Variations)

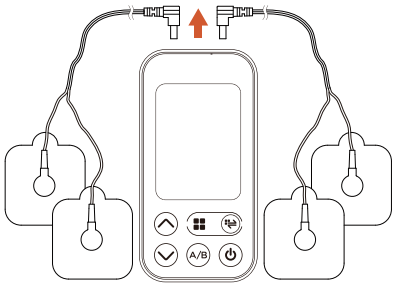
Mode	Display	Variation	Stimulation (Refer to Table 6.1 for description)	Electrode Pad Placement
Composite		1	Vibration, Slap, and Knock	Image 5.1-5.20
		2	Knock and Press	
		3	Press, Thump, and Knock	
		4	Deep press and its variations	Image 5.3, 5.4, 5.16
Knock		1	Knock: vary in frequency and pulse length	Image 5.1-5.20
		2		
		3		
		4		

Mode	Display	Variation	Stimulation (Refer to Table 6.1 for description)	Electrode Pad Placement
Press		1 2 3 4	Press: vary in frequency and pulse length	Image 5.1-5.4 Image 5.11-5.14 Image 5.20
Slap		1 2 3 4	Slap: vary in frequency and pulse length	Image 5.1-5.10 Image 5.13-5.15 Image 5.18-5.19

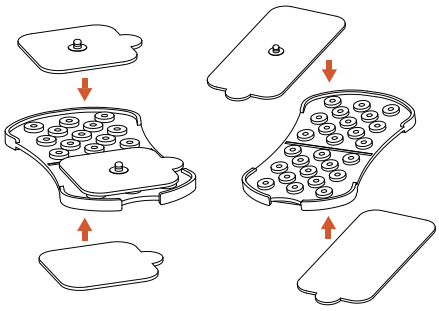
Mode	Display	Variation	Stimulation (Refer to Table 6.1 for description)	Electrode Pad Placement
Acupuncture		1	Press and Slap	Image 5.1-5.7 Image 5.13-5.18
		2	Press and Knead	
		3	Press and Knock	
		4	Knock and Press	
Muscle Relaxation		1	Knock: vary in frequency and pulse width	Image 5.3-5.7 Image 5.18-5.20
		2	Press and Knead	
		3	Knock and Knead	
		4	Press, Knead, and Knock	

7.STORING YOUR DEVICE

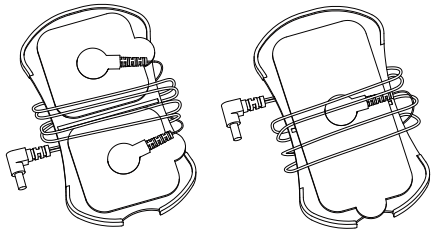
1.Power off the main unit and disconnect the plug end of the electrode cords from the main unit. Then, remove the electrode pads from your body.



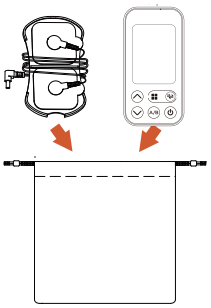
2.Attach the electrode pads to the pad holder.



3.Wrap the electrode cords around the pad holders.



4.Place the device and pad holders into the storage bag.



Note:
⚠ If the device will be stored for long periods without use, it is recommended to remove the batteries before storing.

8.TROUBLESHOOTING

Problem	Question	Answer
1.Main unit cannot be turned on properly.	Is the battery cover closed?	Ensure the battery cover is correctly installed.
	Are the batteries installed?	Correctly installed the batteries.
	Are the batteries exhausted?	Replace the batteries.
2.No stimulation feeling.	Is the electrode cord properly connected to the device and the electrode pads?	Ensure the electrode cord is firmly connected to both the device and the pads.
	Have the protective film been removed from the pads?	Remove the protective film from the pads before using.
	Is the intensity＞ 0?	Press the up button ^ to increase intensity.

Problem	Question	Answer
3.Weak stimulation.	Are the electrode pads firmly adhered to the skin?	Ensure the pads are firmly adhered to the skin for optimal performance.
	Are the electrode pads overlapped?	Separate the pads and ensure the pads individually attached to the skin.
	Is there any dirt on the electrode pads?	Gently clean the pads to maintain their effectiveness.
	Is the level of intensity too low?	Increase the intensity to a level that suits your personal comfort.
	Have the electrode pads been placed in the proper position?	Consult the **section6** in instruction manual for guidance on positioning the electrode pads correctly for maximum effectiveness.

Problem	Question	Answer
4.The skin becomes red or uncomfortable.	Is the therapeutic time too long?	Control it within 10~15 minutes a time.
	Are the electrode pads too dry?	Rinse with a small amount of running water, scrub gently with your fingers for a few seconds, and dry naturally before using.
	Do the electrode pads stick closely to the skin?	Stick the electrode pads closely to the skin.
	Are the electrode pads dirty?	Clean the electrode pads.
	Are the surface of the electrode pads scratched?	Replace the electrode pads with new ones
5.Power cut off during use	Are the electrode pads detached from the skin?	Turn off the power and stick the electrode pads firmly to the skin.
	Are the electrode cords disconnected?	Turn off the power and connect the electrode cords.
	Have the batteries been exhausted?	Replace the batteries with new ones.

MAINTENANCE

1. ⚠ Avoid dropping or subjecting the device to strong impacts.
2. ⚠ Avoid high temperatures and solarization. Do not immerse the device in water, as this will result in equipment damage.
3. ⚠ Changes or modifications not approved by the manufacturer will void the user's warranty. Do not disassemble or attempt to repair the device or components.
4. ⚠ Clean the main unit with a lightly moistened cloth (or a cloth soaked in a neutral cleaning solution) and wipe gently. Do not use chemicals (like thinner. benzene).
5.Wash the electrode pads when the adhesive surface becomes dirty, or they are difficult to attach. First, remove the electrode cord from the electrode pads. Then wash the electrode pads softly with your fingertips under slow-running cold water for several seconds (do not use a sponge/cloth/sharp object like a nail on the adhesive side, and do not use detergents, chemicals, or soap.) Dry the pads and let the adhesive surface air dry completely. Do not wipe with tissue paper or cloth.
6.If necessary, We can provide product circuit diagrams and repairable component data to the qualified maintenance service personnel.
7.Please wait for approximately 2 hours for the device to warm up or cool down before use when the device is transferred from the ultimate temperature of storage and transportation to the normal operating temperature environment.
8.The device shall not be serviced or maintained while in use with a patient.

EXPLANATION OF SYMBOLS


Symbol for "THE INSTRUCTION MANUAL MUST BE READ" (The sign background-color: blue. The sign graphical symbol: white)


Symbol for "TYPE BF APPLIED PARTS" (The electrode pads are type BF applied part)


Symbol for "ENVIRONMENT PROTECTION. Electrical products should not be disposed of as household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice."


Symbol for "MANUFACTURER"


Symbol for "DATE OF MANUFACTURE"

SN Symbol for "SERIAL NUMBER"

IP22 The first characteristic numeral symbol for "Degrees of protection against access to hazardous parts and against solid foreign objects. " The second characteristic numeral symbol for "Degrees of protection against ingress of water."

MR Unsafe

WARRANTY INFORMATION

iHealth Labs, Inc. ("iHealth") warrants the iHealth hardware (the "Product"), and only the Product, against defects in materials and artistry under regular use for one year from the date of purchase by the original purchaser ("Warranty Period"). Under this Limited Warranty, if a defect arises and a valid claim is received by iHealth within the Warranty Period regarding the Product, at its option and to the extent permitted by law, iHealth will either (1) repair the Product using new or refurbished replacement parts or (2) exchange the Product with a new or refurbished Product. In the event of a defect, to the extent permitted by law, these are the sole and exclusive remedies.

This warranty does not apply: (a) to consumable parts, such as the electrode pads or the battery, that diminish over time unless failure has occurred due to a defect in materials or quality; (b) to cosmetic damage, including but not limited to scratches, dents; (c) to damage caused by accident, abuse, misuse, contact with liquid; (d) to damage caused by operating the iHealth product outside the user manual, the technical specifications or other iHealth product published guidelines; (e) to damage caused by service performed by anyone who is not a representative of iHealth or one of its representatives.

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ELECTROMAGNETIC COMPATIBILITY INFORMATION

- The essential performance in normal working mode is output frequency 0Hz~100Hz, intensity max—120 Vpp (500 ohms) pulse waveform.
- When EMI affects the above performance, please stop using the device.
- Use of this equipment and accessories adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and improper operation.
- Equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AD-2126, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 1. Emission Limits Per Environment

Phenomenon	Compliance	Electromagnetic environment
Conducted and radiated RF emissions	CISPR 11 Group 1, Class B	The device is intended to be used in home healthcare environment
Harmonic distortion	IEC 61000-3-2 NA	The device is powered by battery
Voltage fluctuations and flicker	IEC 61000-3-3 NA	The device is powered by battery

Table 2. Enclosure Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3. Proximity Fields from RF Wireless Communications Equipment

Test Frequency (MHz)	Band (MHz)	Immunity Test Levels
		Professional Healthcare Facility Environment
385	380-390	Pulse modulation 18 Hz, 27 V/m
450	430-470	FM, ±5 kHz deviation, 1k Hz sine, 28 V/m
710	704-787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800-960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4. Patient Coupling Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Conducted disturbances induced by RF fields a)	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz

Table 5. Signal Input/Output Parts Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transients / bursts	IEC 61000-4-4 NA	The device is powered by battery
Surges Line-to-ground	IEC 61000-4-5 NA	The device is powered by battery
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz