INSTRUCTION MANUAL FOR

Retinfix Vision Stimulator
Model: R-C101W

This manual is valid for the Retinfix Vision Stimulator
Please read this instruction manual completely
before operating the device and keep it in a safe place.
This user manual is published by the manufacturer.

The manufacturer does not guarantee the accuracy of this manual's contents and reserves the right to make improvements and amendments at any time without prior notice. Any amendments will be published in a new edition of this manual.

R-C101W Rev. V1.1©2025

Declaration of Conformity:

The manufacturer hereby declares that this device complies with the following standards:
IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-10, IEC 62304, ISO 10993-5, ISO 10993-10, ISO 10993-1, ISO 10993-23, ISO 14971

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1. Foreword

1.1 Introduction

The R-C101W is a dual-channel Microcurrent (MIC) stimulator. Before use, please read all the instructions in this manual carefully and keep it for future reference.

1.2 Medical Background

1.2.1 What is Microcurrent (MIC)?

Microcurrent stimulation is a therapy that involves sending very low currents into the body's cells. These currents are so faint that they are measured in microamps (millionths of an amp). Human cells generate a microcurrent which operates in the microamp range, so low that you can't feel it because it doesn't stimulate sensory nerves. Microcurrent is a physiological electrical modality that enhances ATP (energy) production in your cells, significantly accelerating tissue healing. The immediate response to the appropriate microcurrent frequency indicates other mechanisms might be at play. Noticeable effects include the softening of scars and reduced pain at trigger points within minutes when the correct

frequency is applied. These changes are often long-lasting and sometimes permanent.

2. Safety Information

2.1 Intended use

Intended purpose: The device is designed to be used for temporary relief of pain, including the acute and chronic pain relief.
Target population: The device using the object (patient) must be 18 years or older of adults.
Intended user: Medical staff or lay persons.
Intended condition: Intended for use in the home, hospital and health care facilities.
Indications:
- It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, joint, hip, hand, abdomen, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.
- Increasing local blood circulation.

2.2 Important Safety Precautions and Warnings

Please read all warnings and precautions in this manual. They are designed to ensure your safety, prevent injury, and avoid damage to the device.

Safety Symbols Used in This Manual

2.2.1 ⚠ Contraindications

1) Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic devices. This could cause electric shock, burns, electrical interference or death.

2) Do not use the device on cancerous lesions or other lesions in the treatment area.

3) Avoid applying stimulation over swollen, infected, inflamed areas, or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).

4) Avoid placing electrodes in the carotid sinus area (front of the neck) or transcranially (through the head).

5) Do not use if you have an inguinal hernia.

6) Do not use on scarred areas for at least 10 months post-surgery.

7) Avoid use if you have serious arterial circulation problems in the lower limbs.

2.2.2 ⚠ WARNING

1) Consult your physician before using if you have received medical or physical treatment.

2) Stop using the device and consult your physician if you feel pain.

3) Avoid applying stimulation to your neck to prevent severe muscle spasms, airway closure, breathing difficulty, or adverse effects on heart rhythm or blood pressure.

4) Do not apply stimulation across your chest as it may cause dangerous heart rhythm disturbances.

5) Avoid applying stimulation over or near cancerous lesions.

6) Do not use the device near electronic monitoring equipment (e.g., cardiac monitors, ECG alarms) as it may cause malfunctions.

7) Do not use while bathing or showering.

8) Do not use while sleeping.

9) Do not use the stimulator while driving, operating machinery, or during any activity that could pose a risk of injury due to electrical stimulation.

10) Apply stimulation only to normal, intact, clean, and healthy skin.

11) The long-term effects of microelectrical stimulation are unknown. This device cannot replace medication.

12) Do not use the stimulator while connected to high-frequency surgical equipment, as it may cause burns on the skin under the electrodes and interfere with the device.

13) Avoid using the stimulator near shortwave or microwave therapy equipment, as this may affect its output.

14) Never use the stimulator near the heart. Do not place electrodes on the front of the chest, especially over the pectoral muscles, as this can increase the risk of ventricular fibrillation and lead to cardiac arrest.

15) Never use the stimulator near the genitals.

16) Do not apply stimulation to areas of the skin that lack normal sensation.

17) Keep the stimulator out of reach of children.

18) Consult your doctor if you have any doubts.

19) Discontinue use and do not increase the intensity level if you experience discomfort.

2.2.3 ⚠ Precautions

1) You may experience skin irritation or hypersensitivity from micro electrical stimulation.

2) Follow your physician's precautions if you have heart disease or epilepsy.

3) Be cautious if you tend to bleed internally, such as after an injury or fracture.

4) Consult your physician before using the device after surgery, as it may interfere with healing.

5) For single-patient use only.

6) Do not use this stimulator if you are non-compliant or emotionally disturbed, including those with dementia or low IQ.

7) Follow the listed instructions to avoid danger.

8) Long-term use may cause skin irritation at the electrode site.

9) Avoid using this device near other electrical pulse equipment.

10) Do not use sharp objects to press buttons on the control panel.

11) Check electrode connections before each use.

12) Use only with the provided vision stim mask.

13) Users should consult a healthcare professional before using the device.

2.2.4 Adverse Reactions

1) Skin irritation or electrode burns under the electrodes may occur.

2) If symptoms of tachycardia or extrasystole (rapid heartbeat or extra stimulation) appear during treatment, stop the treatment and seek medical attention immediately.

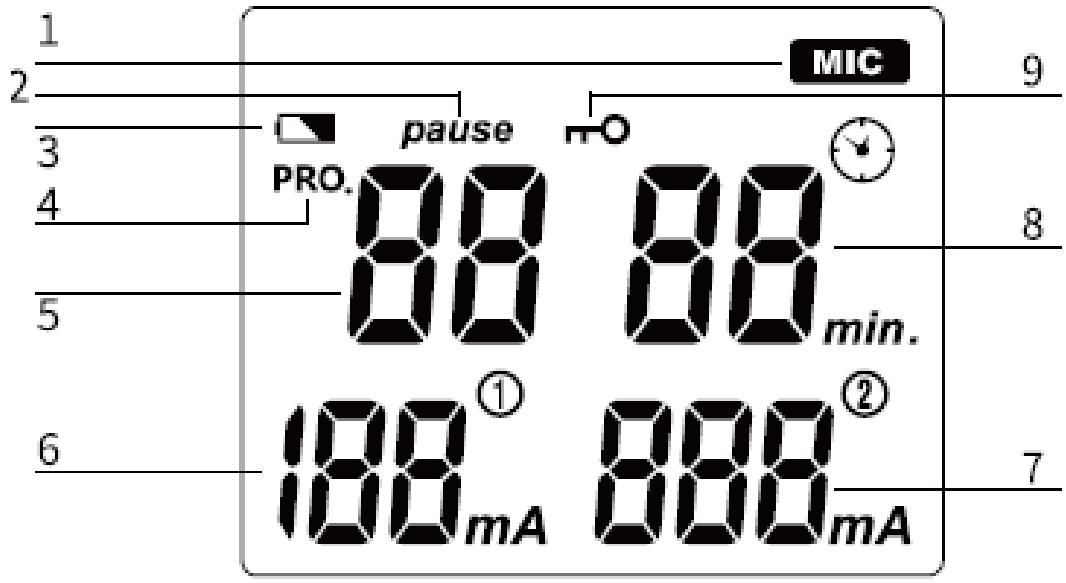
3) If the stimulation makes you uncomfortable, reduce the intensity to a comfortable level and contact your physician if the problems persist.

3.0 Getting to know your device

3.1 Package Includes

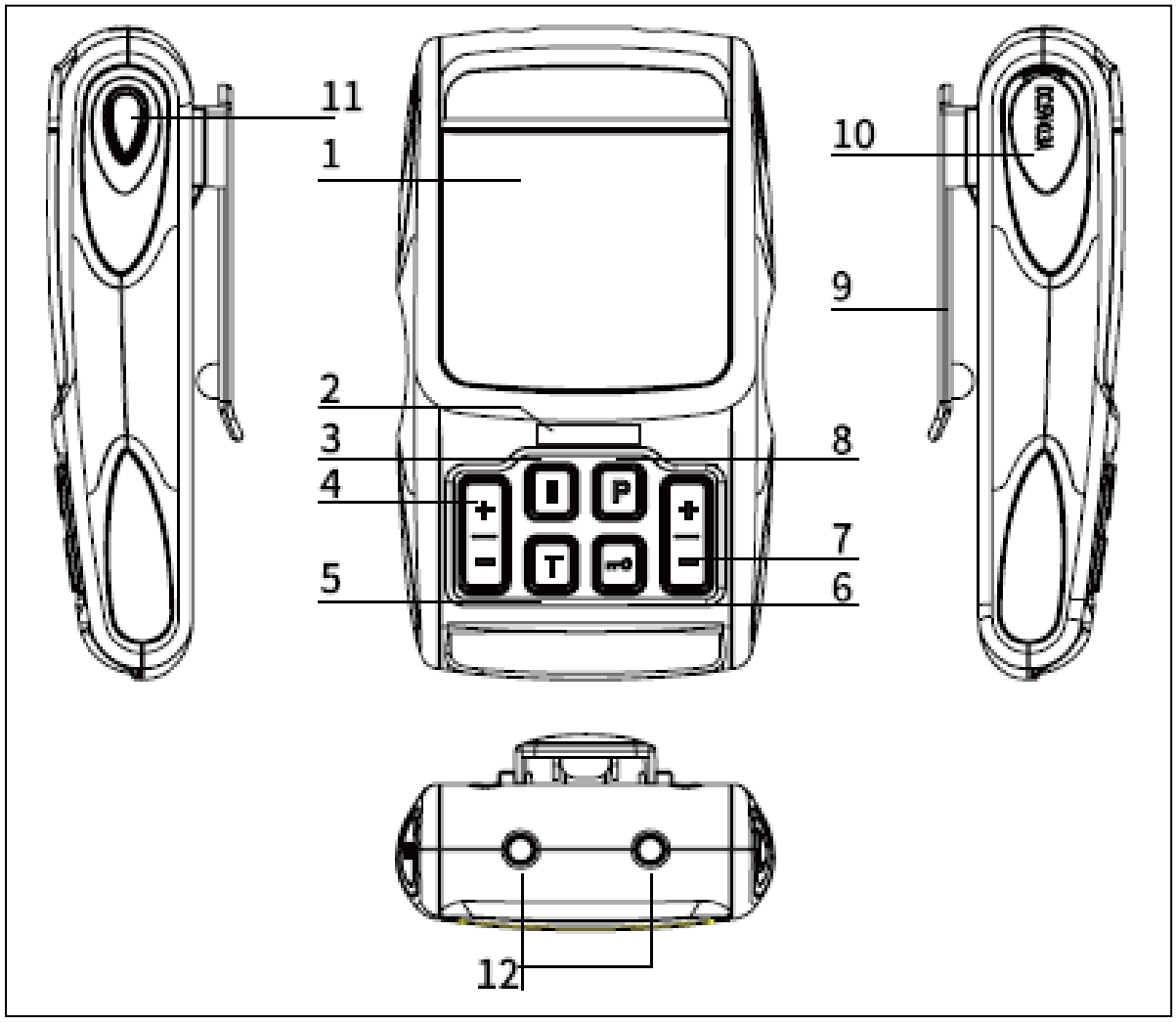
No.	Description	QTY
1	Retinfix Vision Stimulator	1 Pc.
2	Vision Stim Mask (VSM) *	1 Pc.
3	Electrode Wires	2 Pcs.
4	USB Cable	1 Pc.

3.2 LCD Display



No.	Function Description	No.	Function Description
1	Treatment Mode	6	Pulse Rate and Intensity for Channel 1
2	Pause Symbol	7	Pulse Width and Intensity for Channel 2
3	Low Battery Symbol	8	Treatment Time
4	Program Symbol	9	Key Locking Symbol
5	Program Number		

3.3 Device illustration



No.	Description
1	LCD Display
2	Charger Indicator: When the device is charging, the indicator light will be **yellow**. When charging is complete, the indicator light will be **green**.
3	[||] Button: In treatment mode, press the [||] button to pause or resume treatment.

4	Channel 1 Intensity Adjustment: In standby mode, press the [+]/[-] button to increase or decrease the output intensity of Channel 1.
5	Treatment Time Adjustment: In standby mode, press the [T] button to increase the treatment time.
6	Buzzer and Key Lock Control: In standby mode, press and hold the [⊣O] button to toggle the buzzer reminder sound. In treatment mode, press the [⊣O] button briefly to enable or disable the key lock function.
7	Channel 2 Intensity Adjustment: In standby mode, press the [+]/[-] button to increase or decrease the output intensity of Channel 2.
8	Program Selection: In standby mode, press the [P] button to select one of the 18 different treatment programs.

Additional Features:

9	Belt Clip
10	USB Socket

Power Control:

11	[ON/OFF] button: In power-saving mode, press the [ON/OFF] button to turn on the device. In treatment mode, press the [ON/OFF] button to stop the treatment.
12	Output Socket: Channel 1 Channel 2

4.0 Specification

4.1 Technical information

Device Name	Retinfix Vision Stimulator
Model/Type	R-C101W
Power Sources	3.7 V Li-ion battery
Power Supply	Input: 100-240V AC, 50/60Hz, 0.2A Output: 5V DC, 300mA
Output Channel	Dual channel
Waveform	Mono-phase square pulse wave
Output Current	0-0.7mA (at 1000 ohm load)
Output Intensity	0-700mVp (at 1000 ohm load)
Treatment Type	MIC mode
Operating Conditions	Temperature: 5°C to 40°C Humidity: 15%-93%
Storage Conditions	Temperature: -10°C to 55°C Humidity: 10%-95%
Dimensions	120.5 mm (L) x 69.5 mm (W) x 27 mm (H)
Weight	About 155 grams
Classification	BF type applied part, internal power equipment
Output Precision	±20% error for all output parameters
Pulse Width (P.W.)	1ms - 200ms
Pulse Rate (P.R.)	0.1Hz - 150Hz
Time Adjustment	5 to 20 minutes
Automatic Shut Off	1 minute
Low Battery Indication	A low battery indicator will appear on the LCD when the battery is low

5.0 Operating Instructions

5.1 Connecting the Vision Stim Mask to the Electrode Wires

Insert the electrode wire connectors (red/black) into the connectors of the Vision Stim Mask. Ensure they are properly connected for optimal performance.

5.2 Connect Electrode Wire connector to the Device

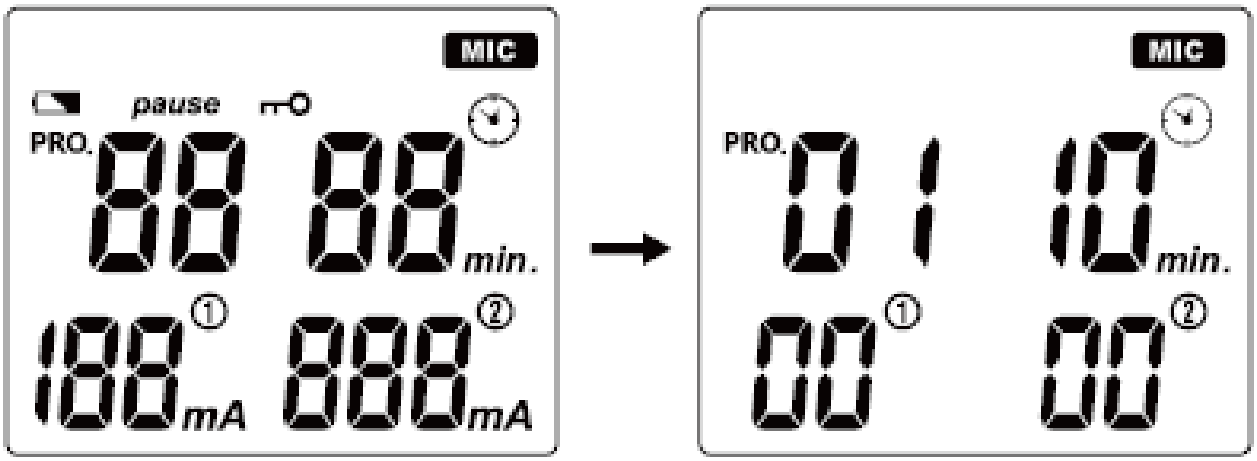
Before proceeding, ensure the device is completely switched off. The device has two output sockets controlled by Channel 1 and Channel 2 at the top. You may choose to use one channel. Hold the insulated portion of the electrode wire connector and insert the plug into the socket on top of the main device. Make sure the electrode wire are inserted correctly.

⚠ Caution
Do not insert the plug of the electrode wires into any AC power supply socket.

6.0 Instructions for use

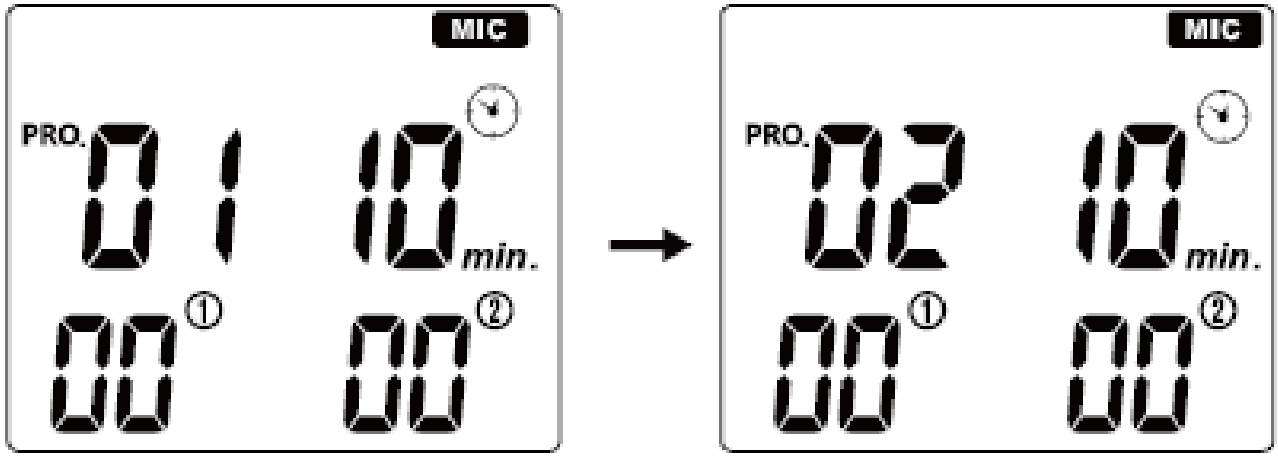
6.1 Turn on

Press the [ON/OFF] button to turn on the device. The LCD will light up and then enter standby mode, as shown below.



6.2 Selecting a Treatment Program

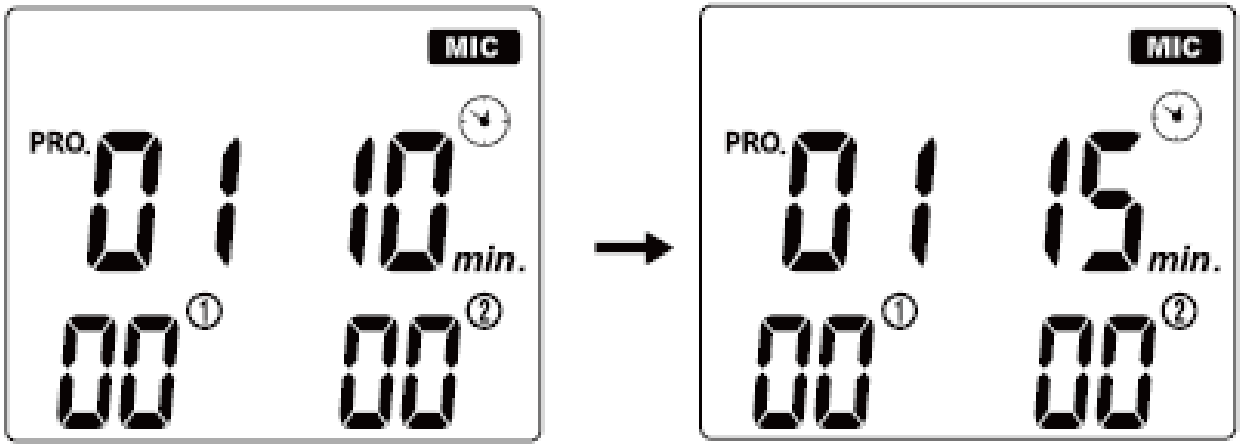
To select a treatment program, press the [P] button according to your needs. The LCD will display the following:



Program #	Frequency (Hz)	Pulse Width (mS)	Duration (Min)	Type
1	120-60	1	10	Modulation
2	4	50-25	10	Modulation
3	0.1	200	10	Continue
4	10	20-10	10	Modulation
5	60-30	2	10	Modulation
6	2	100	10	Continue
7	100	1	10	Continue
8	4-2	10	10	Modulation
9	20-10	5	10	Modulation
10	120	1	10	Continue
11	100 / 2	1 / 50	10	Hans
12	40-20	2	10	Modulation
13	60	2	10	Continue
14	80-40	2	10	Modulation
15	0.5	200	10	Modulation
16	100 / 33	2	10	Hans
17	150	1	10	Continue

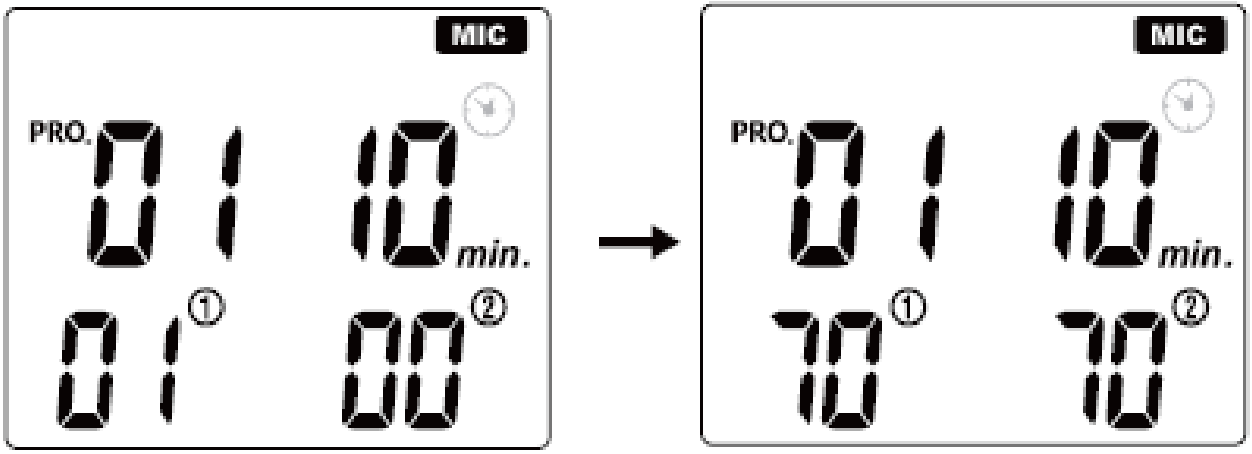
6.3 Setting the Treatment Time

To adjust the treatment time according to your needs, press the [T] button. The LCD will display the following:

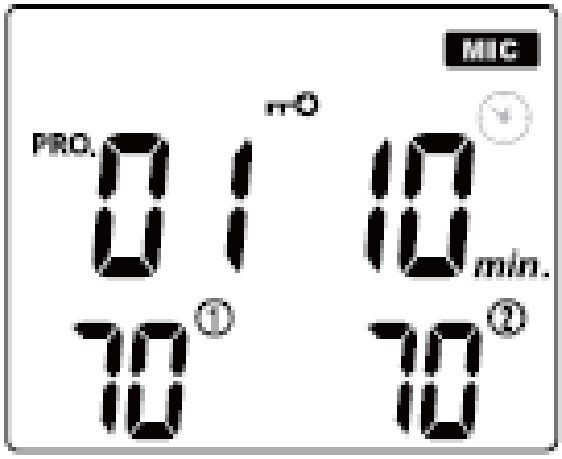


6.4 Start Treatment

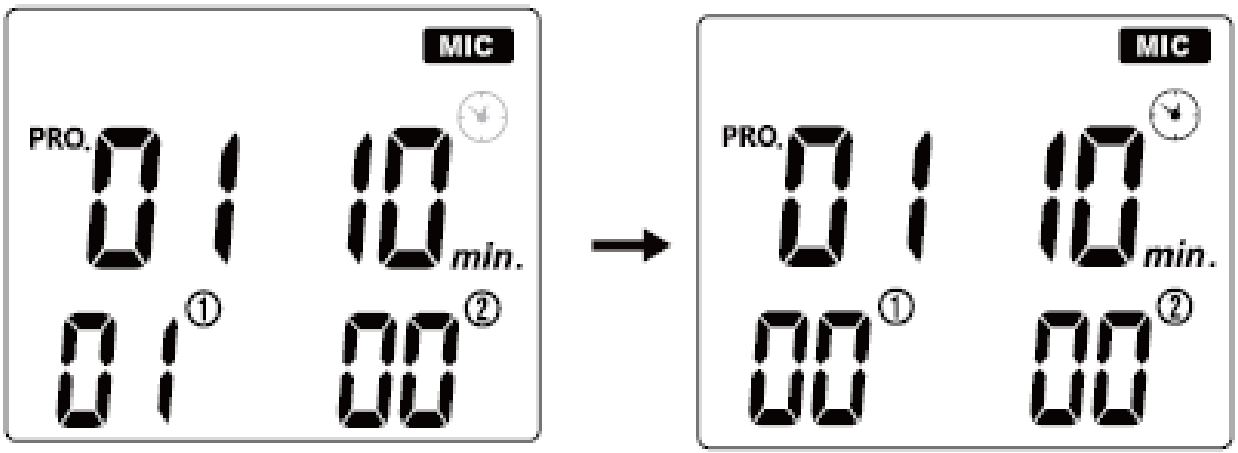
Press the [+] button to increase the intensity of the selected treatment channel. The LCD will display the following information:



During the treatment process, the user can briefly press the [⊸] button to activate the key lock function. This will render all other buttons inactive except for the [⊸] button and the [ON/OFF] button. If the user wishes to adjust the device afterward, they can unlock the keys by briefly pressing the [⊸] button again. The buttons will then function normally.



If the intensity feels too strong, press the [-] button to lower it. When the output intensity of both channels drops to zero, the stimulator will switch to standby mode. The LCD will display the following:

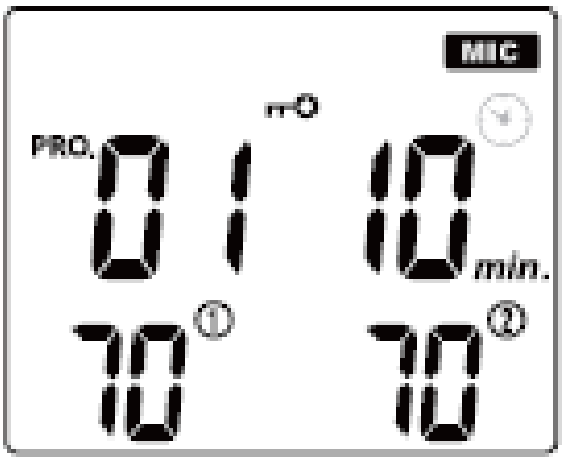


⚠ Caution:

If you experience discomfort, lower the stimulation intensity to a comfortable level. If the issue continues, seek advice from your medical practitioner.

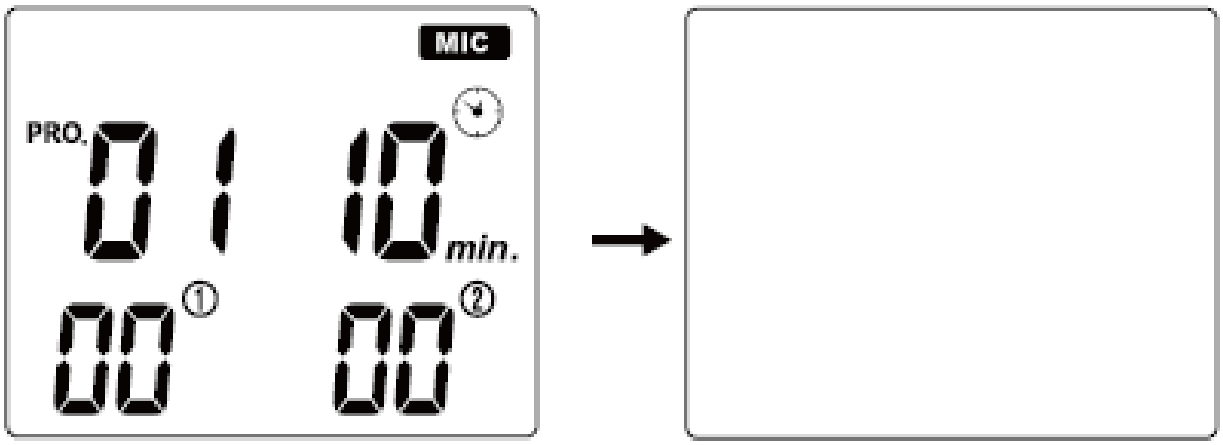
6.6 Pause Function

While in treatment mode, press the [||] button to pause. The LCD will show the pause icon. To continue the treatment, press the [||] button again.



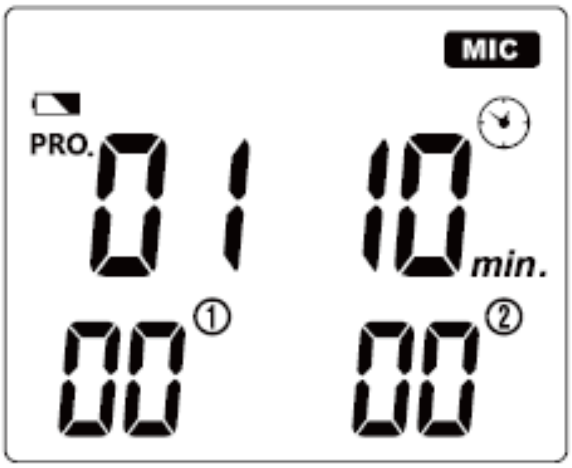
6.7 Stopping Treatment and Turning Off the Device

To stop the treatment during operation, press the [ON/OFF] button. To turn off the stimulator completely, press the [ON/OFF] button again. The LCD screen will then go blank.



Section 6.8: Low Battery Detection

When the battery is low, the '▭' icon will blink. Please stop the device and charge the battery.



Charging the Battery:

To recharge the battery, follow these steps:

1. This device cannot be used while charging.
2. Ensure the device is disconnected from the patient (unplug the output cables and electrodes).
3. Connect the USB cable to the device's charging port.
4. Plug the USB cable into the charger.
5. The indicator light will turn yellow while charging.
6. A full charge may take up to 2 hours.
7. Once charging is complete, the indicator light will turn green.

Battery Maintenance:

The lifespan of a rechargeable battery depends on the number of charging and discharging cycles and the manner in which these cycles are conducted. Follow these tips to extend battery life:

- If the device is not used frequently, charge the battery once a month.

- To extend battery life, discharge the battery as much as possible before recharging.

6.9 Sound Prompt Function

a. To disable the sound prompt, press and hold the [S] button in the waiting state. The device will emit a long “DI” sound.

b. To enable the sound prompt, press and hold the [S] button in the waiting state. The device will emit two short “DI” sounds.

Note: Reinstalling the battery will automatically turn on the sound prompt function.

7. Cleaning and maintenance

To ensure the device remains intact and maintains optimal performance and safety, adhere to the following daily maintenance requirements.

7.1 Cleaning and Care for the Device

7.1.1 Remove the electrodes from the vision enhancer and clean the device with a soft, slightly damp cloth. For heavier dirt build-up, use a mild detergent.

7.1.2 Avoid exposing the device to moisture or dampness. Do not hold it under running water or submerge it in water or any other liquids.

7.1.3 The device is sensitive to heat and should not be exposed to direct sunlight or placed on hot surfaces.

7.1.4 For hygiene reasons, each user should use their own vision stim mask.

7.1.5 Do not use chemical cleaners or abrasive agents for cleaning.

7.1.6 Ensure no water penetrates the machine. If water does enter, use the device only when it is completely dry.

7.1.7 Do not clean the device during operation. Ensure the device is turned off before cleaning.

7.2 Maintenance

7.2.1 The manufacturer has not authorized any maintenance agencies abroad. If your device has issues, contact us directly. The manufacturer is not

responsible for maintenance or repairs by unauthorized persons.

7.2.2 Users must not attempt to repair the device or its accessories. Contact us for repairs.

7.2.3 Unauthorized opening of the equipment is prohibited and will void any warranty claims.

Each product undergoes systematic validation to ensure stable performance without needing additional calibration. If your product does not meet expected performance or its basic function changes during normal use, please contact us.

8. Troubleshooting

If any malfunctions occur while using the device, check that the parameters are set correctly for therapy and adjust the controls as needed. Refer to the following table for guidance:

Malfunction	Common Causes	Solution
No display	The battery is depleted.	Recharge the battery.
No sensation of stimulation	1. Poor connection between the electrode and stimulator.	1. Ensure the connection is secure.
	2. The battery is depleted.	2. Recharge the battery.
	3. The skin is too dry.	3. Clean the electrode and the skin with a damp cotton cloth.
Automatic halt in the treatment	1. The vision stim mask has lost connection with the skin.	1. Reapply the vision stim mask properly to the skin.
	2. The battery is depleted.	2. Recharge the battery.

Rash or tickling sensation on the skin occurs during treatment	1. The treatment duration is too long.	1. Perform the treatment once a day and reduce the treatment time.
	2. The vision stim mask does not adhere well to the skin.	2. Ensure the vision stim mask is properly attached to the skin.
	3. The vision stim mask interface is dirty or dry.	3. Clean the vision stim mask with a damp cotton cloth before each use.
	4. The skin is sensitive to the vision stim mask.	4. Check your allergy history. Adjust the vision stim mask placement or reduce the treatment time. If your skin is highly sensitive, discontinue the treatment and consult a doctor.

9.0 Storage

9.1 Storing the Vision Stim Mask and Lead Wires

1. Remove the vision stim mask from your face and disconnect the lead wires.

2. Place the vision stim mask back into the box in its designated slot.

3. Wrap the lead wires and store them in the box.

9.2 Storing the Unit

1. Place the unit, vision stim mask, lead wires, and manual back into the box. Store the box in a cool, dry place with a temperature range of -10°C to 55°C and relative humidity between 10% and 95%.

2. Keep the unit out of reach of children.

10. Disposal

Used batteries do not belong in household waste. Dispose of the battery according to current regulations. As a consumer, you are obligated to dispose of batteries correctly. Consult your municipal authority or your dealer for information about disposal.

At the end of the product's life cycle, do not throw this product into normal household garbage. Instead, bring it to a collection point for recycling electronic equipment. Obsolete electrical and electronic equipment may have potentially harmful effects on the environment. Incorrect disposal can cause toxins to build up in the air, water, and soil, jeopardizing human health.

11. Electromagnetic compatibility (EMC) tables

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device is designed for use in the electromagnetic environment described below. The customer or user must ensure it is operated within this environment.

Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR11	Group 1	The device uses RF energy solely for its internal function. Consequently, its RF emissions are very low and are unlikely to interfere with nearby electronic equipment.
RF Emissions CISPR11	Class B	The device is suitable for use in all establishments, including those connected directly to the public low-voltage power supply network that provides power for domestic purposes in buildings.
Harmonic Emissions IEC61000-3-2	Not applicable	
Voltage Fluctuations/Flicker Emissions IEC61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration — Electromagnetic Immunity

This device is designed for use in the electromagnetic environment described below. The customer or user must ensure it is operated within this environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC61000-4-2	±8kV direct & indirect contact; ±15kV air discharge	±8kV direct & indirect contact; ±15kV air discharge	Floors should be wood, concrete, or ceramic tile. If covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst IEC61000-4-4	±2kV for power supply lines	Not applicable	Not applicable (for INTERNALLY POWERED ME EQUIPMENT)
Surge IEC61000-4-5	±1kV line(s) to line(s)	Not applicable	Not applicable (for INTERNALLY POWERED ME EQUIPMENT)

Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	Not applicable	Not applicable (for INTERNALLY POWERED ME EQUIPMENT)
	40% U_T (60% dip in U_T) for 5 cycles		
	70% U_T (30% dip in U_T) for 25 cycles		
	<5% U_T (>95% dip in U_T) for 5 sec		
Power Frequency (50Hz/60Hz) Magnetic Field IEC 61000-4-8	10V/m	10V/m	Power frequency mag-netic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration — Electromagnetic Immunity

This device is designed for use in the electromagnetic environment described below. The customer or user must ensure it is operated within this environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10V/m & Table 9	10V/m & Table 9	Portable and mobile RF communications equipment should not be used closer to any part of the device, including cables, than the recommended separation distance calculated based on the frequency of the transmitter. Recommended separation distance: $d = 1.167\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m).

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [Vi] V/m.

Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment (Table 9)

Test Frequency (MHz)	**Band (MHz)** [a)]	**Service** [a)]	**Modulation** [b)]	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						

810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
1720	1700-1990	GSM1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

NOTE: If it is necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because it does not represent actual modulation. It would be worst case.

12. Normalized symbols

	WEEE Symbol		Applied part of type BF
	Refer to instruction manual	IP22	IP classification
	Batch code		Authorized representative in the European Community
	Manufacturer		Date of manufacture
	Fragile, handle with care		Keep away from sunlight
	Keep dry		Temperature limit
	Use-by date		Serial number
	Humidity limitation		Atmospheric pressure limitation
	Caution		Green Dot
	Users of the artificial pacemaker are prohibited from using the device	CE 2460	CE mark
	Packaging material cycle mark	UDI	Unique device identifier
MD	Medical device	CH REP	Swiss Authorised Representative

13. Warranty

For warranty claims, please contact your dealer or the device center. If you need to return the unit, include a copy of your receipt and a clear description of the defect.

The warranty terms are as follows:

1. The warranty period for this device is 1 year from the date of purchase. For warranty claims, proof of purchase is required via the sales receipt or invoice.

2. Repairs covered by the warranty must occur within the warranty period for the device or its replacement parts.

3. The warranty does not cover the following cases:

    - Damages resulting from improper operation, such as not following user instructions.
    - Damages caused by repairs or tampering by the customer or unauthorized third parties.

- Damages incurred during transport from the manufacturer to the consumer or service center.
- Accessories subject to normal wear and tear.
- Damages from privately disassembling the device.

4. Liability for direct or indirect consequential losses caused by the unit is excluded, even if the damage to the unit is accepted as a warranty claim.

Shenzhen Roundwhale Technology Co.,Ltd.
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