

MEND Wellness™ (IS02LCDs) User's Manual



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Introduction

Congratulations on your purchase of the MEND Wellness[™] (IS02LCDs) device. The MEND Wellness[™] is the most advanced two channel programmable transcutaneous electrical nerve stimulator or "TENS" device currently available. MEND Technology is a leading innovator and distributor of state-of-the-art medical devices.

The MEND WellnessTM is a high-end precision medical device used for the relief of pain. This device generates low intensity current pulses at microampere levels and frequency of pulses. The unit can hold multiple therapy protocols. Each protocol includes multiple frequency pairs. Your licensed health care practitioner can program frequency pairs with a variety of parameters including current intensity, frequency, time, modulated wave period, wave slope, and polarity. The micro-ampere level current is applied by electrodes.

The MEND WellnessTM is a small, portable device that is designed for use in a doctor's office, clinic or hospital as well as self-administered treatment at home under your practitioner's supervision.





Please read this entire manual thoroughly before using it the device

Indications

The MEND WellnessTM is intended for the symptomatic relief of chronic intractable pain. The degree of efficiency will vary with patient selection.

Warnings and Contraindications

- Microcurrent stimulation should not be used on patients whose pain syndromes are not diagnosed and etiology is not established. If another electrode is used as a dispersive electrode, placement of the dispersive electrode should ensure transthoracic stimulation is not possible.
- Safety of microcurrent stimulation has not been established during pregnancy or birth. Microcurrent stimulation is not effective for pain of central origin including headache.
- Microcurrent stimulation should be used only under the continued supervision of a licensed physician. Microcurrent stimulation has no curative value. Microcurrent stimulation is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- The stimulation and electrodes should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, especially over the carotid sinus (upper side of neck), or from electrodes placed on the chest and the upper back or crossing over the heart. Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Don't use microcurrent stimulation on patients who have a demand type pacemaker. A patient with an implanted electronic device (for example a cardiac

- pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained.
- Do not allow children to use or handle this device. Keep the device and lead wires away from children when not in use. Strangulation could result from baby or child entanglement in the wire leads.
- Do not operate vehicles or potentially dangerous machinery during periods of stimulation.
- Electronic monitoring equipment such as ECG monitors and ECG alarms may not operate properly when Inspirstar IS02 PMS is in use.
- Simultaneous connection of a patient to a high frequency surgical medical equipment may result in burns at the site of the IS02 PMS electrodes and possible damage to the IS02 PMS.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy medical equipment may produce instability in the ISO2 PMS output.

Adverse Effects

Please consult your doctor about possible adverse effects which may arise from the therapy protocols your doctor is using. A common issue is about skin reaction at the electrode sites. Skin irritation and electrode burns are potential adverse reactions. Cleaning and hydrating the skin are usually valid methods to reduce the skin irritation or electrode burns. If gloves or cloth or garment are used as electrodes, these gloves or cloth or garment should be wet or damp. If electrode pads are used, sometimes conductive gel on pads can be helpful to increase the conductivity and reduce the skin reaction.

Precautions

Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.



CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a licensed health care practitioner.



The following are precautions for the safety of the users and the device.

- The device is to be applied with electrodes to the skin of the human body.
- The device has micro amperage current output. The plugs must be inserted completely into the jacks. The patient may experience prickling sensation if the skin contact is too dry. Moisture the skin before use.
- Only use the recommended accessories. It can be unsafe to use accessories not in the instructions for use.
- Use alkaline batteries only. It cannot be connected to external power source. Any

- attempt to do so would cause damage of the device and possibly cause harm to the patient.
- Water into the device could affect the safety and performance. Do not use the
 device when the device has got water inside. Do not let water flowing on the
 surface of the device. Do not immerse the device into water. Do not use the device
 close to flammable mixtures or concentrated flammable fumes such as gasoline.
- The device can only be opened and repaired by the manufacturer or licensed service personnel. Do not modify the device as it can be unsafe.
- The device is for indoor use where a patient would comfortably stay. Consult your physician for use in unusual environment conditions e.g. strong magnetic fields or electromagnetic fields, external electrical influences, electrostatic discharge. Do not exposure the device in a high dust environment for long period of time.

Warranty and Service

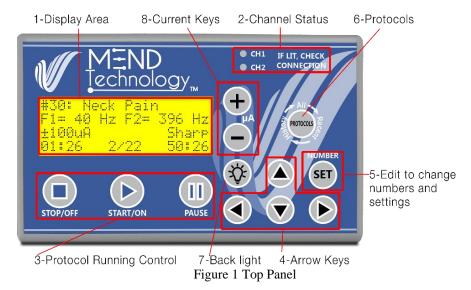
The MEND WellnessTM has a limited one-year warranty. MEND Technology warrants that the Product is manufactured by Inspirstar Inc in accordance with the specifications. There is no warranty of merchantability nor of fitness for a particular use. The Product is marketed under section 510(K) of the Federal Food, Drug and Cosmetic Act as a device substantially equivalent to a device in commerce. Inspirstar Inc. and MEND Technology expressly disclaim any claim that the Product can treat or cure any medical condition or illness. The user must consult with his or her healthcare practitioner as to the recommended use. The Product may only be used under the direct supervision of a licensed health care provider. There are no other warranties, expressed or implied. MEND Technology sole liability hereunder is to replace the Product with the same or a substitute product. In no event shall Inspirstar Inc. and/or MEND Technology be liable for personal injury or death of any person using or misusing the Product.

The MEND WellnessTM unit may be repaired or replaced with the same or a substitute product within one year of purchase based on the determination of the manufacturer. Lead wires have a limited warranty of 3 months. To replace products or obtain service, first call your doctor or MEND Technology. If necessary, send the entire unit with the carrying case and accessories, insured, postage prepaid, and well packaged, along with the Return Merchandise Authorization number obtained from MEND Technology. Please remove the batteries before returning your device.

 $Contact\ \underline{support@mendtechnology.com}\ for\ RMA\ and\ shipping\ information.$

MEND Wellness Device and Accessories

Top Panel and Keypad



- 1. Display Area: Menu selection, protocol information, running information and status, etc. are displayed on LCD screen.
- 2. Channel Status: LED CH1 and CH2 indicate if the output current can reach their peak current value in the protocol for channel 1 and channel2, respectively. If the LED is flashing or ON, check the connection of the electrode to the body.
- 3. Protocol Running Control:
 - Key START/ON to turn on the device, or to start the selected protocol.
 - Key PAUSE to pause the running of the current protocol. Use key START to resume the running.
 - Key STOP to stop the protocol in running, or to turn off the device.

4. Arrow Keys:

- Left Arrow: Back to previous menu level or move cursor to left.
- Right Arrow: Enter menu selection or move cursor to right.
- Up Arrow: Move cursor up or increase number
- Down Arrow: Move cursor down or decrease number

5. Set Number key:

• Press this key to go into and finish the number editing mode. In Number Editing mode, use arrow keys to change the digits of the number. Press this key again to move to next number or to finish editing numbers.

- In the Main Menu->Settings, use the SET key to jump to the next field and SET new value.
- 6. Protocols: Press this key to cycle between "All Protocols", "Recent Protocols", "History Protocols" and "Batch Protocols".
- 7. Back Light: turn on or off the back light of the LCD display.
- 8. Current Keys: to increase or decrease the output current intensity. Your practitioner should have these set at a typical default setting for you. Range is $20 \, \mu A$ to $400 \, \mu A$.

Rear Panel



Positive Jack +: Positive leads of CH1 and CH2 Negative Jack -: Negative leads of CH1 and CH2

Device is Body Floating (BF) Type.

Figure 2 MEND WellnessTM Output Jacks and USB port

USB Port

The micro USB port is for communication with the computer only, not to supply power to the MEND Wellness device. The MEND Wellness only operates with battery power supply.



Equipment that is connected to the Micro USB port interfaces must be certified according to the respective EN/IEC/UL standards.

Certified computer has one or more of the following markings on the power supply unit:

IEC 60950-1 IEC 60950-22 CAN/CSA-C22.2 No. 60950-1 CAN/CSA-C22.2 No. 60950-22 UL 60950-1 UL 60950-22 Information Technology Equipment Power Supply I.T.E. Power Supply ITE Power Supply QQGQ7 Power Supply

Microcurrent Output Ports

Output Jacks		Plugs	Connection	Connector
Combined Channel Output Jacks	Positive Jack (+)	Tip	CH2+	Red
CH2		Ring	CH1+	Yellow
×	Negative	Tip	CH2-	Blue
Jack(-)	Jack(-)	Ring	CH1-	Green

Table 1 Color Mapping of Output Ports to Wire Connectors

Accessories

The MEND device can be used with various accessories that can be purchased individually. For example, gloves, electrodes, push pin leads, conductive strips and conductive material. To purchase additional accessories visit www.mendtechnology.com



Operations

Prepare for Operations

The MEND WellnessTM device can be used inside the carrying case. If you have the soft carrying case, there are two Velcro strips attached inside. Use them to attach to the back panel of the MEND WellnessTM device.

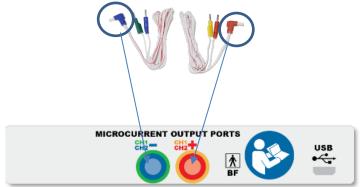
Install Batteries

The MEND WellnessTM device uses two alkaline batteries in size "AA". Remove the batteries when the device is not going to be used for more than one month.



Connect Wires to the MEND Wellness™ device

Insert the plugs into the jacks on the rear panel of the MEND Wellness $^{\text{TM}}$ device. Match the color of the plug with the color on the rear panel.



Connect Wires to Gloves, Strips or Electrodes



Snap the button or insert the pins on gloves, strips or electrodes.

Please follow your health care practitioner's instructions on where to place the electrodes, gloves, towels or strips on the body. Gloves, towels, and strips need to be wet to provide conduction.

It is recommended to leave the wires and buttons connected to the gloves and leave the plugs inserted in the MEND WellnessTM after use. If you want to unbutton the electrode wires from the gloves, hold the button base on the gloves instead of holding the fiber part of the gloves to avoid damage to the gloves.



DO NOT WEAR THE GLOVES ON BARE HANDS UNLESS YOU ARE TREATING YOUR OWN HANDS.

To isolate the conductive gloves from bare hands, wear latex or nitrile gloves first then put on the conductive Electrode Gloves. The gloves must be wet during treatment.



The electrodes and the wire leads may wear and lose conductivity over time. Check to ensure the CH1/CH2 LEDs are not flashing for any connectivity issue when a protocol is running.

Basic Operations

Power ON

Press START/ON to power on the unit. The Power-On Initial Screen displays the last protocol number previously run. Press START to run this last used protocol.



PROTOCOLS BUTTON - All, Recent, History and Batch Protocols

All Protocols lists all protocols in the profile.

Recent Protocols lists the protocols that were recently used. Use Recent Protocols to quickly select a protocol that is frequently used.

History Protocols lists the actual protocol running history. The latest used protocol is displayed on the top of the list. Use History Protocols to check the therapy history and also to select a protocol to run again. Note: the history will show the exact usage, so you may see the same protocol multiple times in the history.

Batch Protocols lists the protocols to run in a batch.



To switch between All Protocols, Recent Protocols, History Protocols or Batch Protocols: press Protocols key to cycle between the four protocol list screens.

Select a Protocol

There are a number of stored therapy protocols in the MEND WellnessTM IS02LCDs. Please follow your health care practitioner's instruction regarding the protocols to be used for your pain complaints.

To browse for a protocol: Press the PROTOCOLS key to get to the All Protocols screen.



Use the arrow keys UP and DOWN to browse through the protocol list.

To quickly jump to a protocol number: When the "All Protocols" screen is displayed, press the SET key and look to the top right corner of the display. The edit cursor will flash on either the ones or tens digit of the protocol number. Use the UP and DOWN keys to change the value. Use the LEFT arrow to move to the tens digit and use UP and DOWN to change the value. Use the RIGHT arrow to move to the ones digit. Press SET again when done. Alternatively, press and hold the up or down arrow to scroll quickly.



To see details of a protocol: Press the RIGHT arrow key to see the details. Use keys UP and DOWN to scroll through the screen to see details.



Run a Therapy Protocol

Press the START key to run a protocol. The protocol will start to run and there will be microcurrent from the output jacks. The protocol will stop after the programmed run time. If you do not start another protocol, the unit will automatically turn off.



Pause the Therapy Protocol

While a protocol is running, press the PAUSE key if you need to temporarily stop a protocol, press START to continue running. While paused, no current is running. The maximum time for a PAUSE is 30 minutes.



Stop the Therapy Protocol

At any time during a protocol, you can press the STOP key to stop running a therapy protocol.



Turn on the Back Light



To turn on the LCD back light: quickly press the Back Light key to turn on the LCD back light. The back light will turn off when there is no keypad operations within 10 seconds.

To turn on the LCD back light for 30 seconds: press and hold the Back Light key for 3 seconds, the light will remain on for 30 seconds. To keep the backlight on for 8 hours, press and hold the Back Light key again until the LCD backlight flashes once.

Turn power off

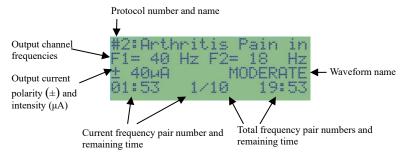
Depending on which screen you are on, continue to press the STOP/OFF key to turn off the MEND WellnessTM. The unit will power off automatically if the unit is not in use for 60 seconds.



Advanced Operations and Display Information

Protocol Run Information and Status

When a protocol is running, the screen will display the protocol information and status.



During the running of the protocol, the MEND WellnessTM uses two LED lights to indicate the output connection. If the channel status LED CH1 or CH2 turns on or flashes, check that your leads are inserted firmly into the jacks and your pins are plugged into the conductive material. The common problems are loose plugs, plugs are not inserted, the button or push pin is not inserted into gloves or electrodes, dry skin contact needs moisture or broken leadwires.



Note: During a treatment you may experience a mild tingling sensation as a result of the stimulating current flow.

Make Run Time Changes

To change output current intensity μA: Press the '+' key to increase the current

intensity value or press the '-' key to decrease the current intensity value. Or press the Number SET key multiple times until the edit cursor has moved to the output current position, then use the

#2:Arthritis Pain in F1=970 Hz F2= 52.9Hz ± 504A MODERATE 00:02 3/10 14:02

arrow keys to change the value. Changes made are only applied to the active pair. Range: $20\text{-}400\mu\text{A}$

To HOLD the current frequency pair, press and hold the START key for 2 seconds to hold the timer. Press the START key to resume the timer.

#2:Arthritis Pain in F1= 91 Hz F2= 18 Hz + 40µA MODERATE | HOLD 6/10 10:39

To SKIP the current frequency pair, press and hold the PAUSE key for 2 seconds to skip the current frequency pair and move to the next frequency pair.

To LOCK the keypad when running a protocol to avoid accidental change or

#1 Body Pain F1= 40 Hz F2= 45 Hz + 40µA MODERATE 00:40 <mark>2</mark>/8 12:40

stop of the protocol, press both the LEFT and RIGHT keys simultaneously. A lock icon will appear to indicate the keypad is locked. Press the LEFT and RIGHT keys simultaneously to unlock.

The new values will be applied on the microcurrent output in 3 seconds after changed. The change of Current Intensity will be carried into the next frequency pair in the protocol if the next frequency pair has the same parameters as the current frequency pair. All Run Time changes are dismissed when the protocol is finished or stopped.

Batch Protocols

Batch Protocols allows you to add up to 9 protocols and run as a batch. Protocols will run in order.

To go into Batch Protocols: press the Back (left arrow) key to Main Menu and use UP/DOWN to select Batch Protocols and press RIGHT arrow to enter. Main Menu 3.History Protocols >4.Batch Protocols 5.Manual Run Mode

Select a slot: There are 9 protocol slots in the batch. Each slot can be assigned to any protocol in the IS02. Use UP/DOWN to move the selection symbol ">" up and down.

```
Batch Protocols:1/9

Empty slot
Empty slot
Empty slot
Empty slot
```

Select a protocol for the slot: Press RIGHT key to enter to the protocol selection menu.

Select from other protocols: Press Protocols key to rotate between All Protocols, Recent Protocols and History Protocols. Use UP/DOWN arrows to select a protocol. See Select a Protocol on page 13.

Assign a protocol to the slot: press START key to assign the protocol to the slot. The assigned protocol will be shown in the slot in the batch.

Select protocols for other slots: repeat the above steps for other slots.

Remove a protocol from batch: select the batch slot and press and hold STOP key for 2 seconds until the slot is changed to empty. You can have empty slot between protocols in the batch. The empty slot will be skipped during runtime.

Run a batch of protocols: move the selection cursor ">" to the protocol to start with in the batch, and press START key to start running the protocols. The slot number in the batch is shown in front of protocol number.

```
<mark>2</mark>#4:Pain with Inflam
F1= 40 Hz F2=103 Hz
t 40µA MODERATE
01:48 1/16 31:48
```

Skip a protocol in batch: press **STOP** key to skip the current protocol. The next protocol in the batch will start.

Stop the batch: press and hold **STOP** key for 2 seconds to stop running the batch of protocols.

```
Batch (- All: #1/5

>1:Body Pain

2:Arthritis Pain in

3:Overall Activitie

Batch (- Recent: 0

Batch Protocols:1/9

>1:Body Pain

2 Empty slot

3 Empty slot
```

```
Batch Protocols:2/9
11:Body Pain
>4:Pain with Inflamm
3 Empty slot
```

Batch Protocols:1/9 >1:Body Pain 24:Pain with Inflamm 35:Tension

Batch Protocols:1/9 > Empty slot 24:Pain with Inflamm 35:Tension

Settings – MAIN MENU

To change Settings: press the BACK arrow to go to Main Menu and use the UP/DOWN arrows to select Settings, then press the RIGHT arrow to enter into the Settings screen. Press the SET key multiple times until the edit cursor has moved to the desired setting; use UP/DOWN to change the value; Press SET key again when the new value is set.

To turn ON/OFF Kev beeping: press the Number SET key until the edit cursor has moved to the ON/OFF of key beeping, use UP/DOWN to change the value. Press SET again when the new value is set.

To turn ON/OFF Protocol end beeping: press the SET key until the edit cursor has moved to the Protocol end beeping field, use UP/DOWN to change the value. Press SET to enter the new value.

To change the Output Drive: press the SET key a couple of times to go to "3. Output Drive". Use UP/DOWN arrows to change the value between HIGH. MEDIUM AND LOW. Press SET.

```
Main Menu
4.Batch Protocols
25.Settings
6.About
```

Settings: 1.Kew beering: 2.Protocol end beering:OFF

Settings: (3 items) 1.Kew hopping: OFF 2.Protocol end beering: OFF

Settin9s: (3 items) beering:OFF 3.Output Drive voltage: MEDIUM

If the user is sensitive to current, use "Low". If the user has high skin resistance, use "High". The recommendation is to hydrate the patient and especially the skin.

To change ON/OFF alert sound when the output connections is lost: use the UP/DOWN arrows to change the value.

```
Settings: (4 items)
   voltage: HIGH
4.Alert on loss of
   connection
```

The new settings will take effect after you press BACK arrow key to the Main Menu.

About

To go to About: press the LEFT arrow to go to the Main Menu and use the DOWN arrow key to scroll down to About and press the RIGHT arrow key to enter into the About screen.

Version: shows the hardware and firmware information.

Battery Status: shows the battery voltage

```
Main Menu
 4.Batch Protocols
 5. Settings
>6.About
About
 1. Version
 2.Battery Status
>3.Disclaimer
```

and estimated time that the batteries could run for protocols. The battery run time

varies on the output current levels of the protocols. (Note for software users: If you update your firmware, always use NEW batteries.)

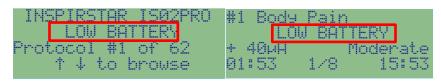
Battery Status 2.98V(98%) NORMAL 62 hours remaining

Low Battery Indication

"Low Battery" will be indicated either in the startup screen or protocol running screen. You can continue to use the device but it may shut down unexpectedly at any time. It is recommended that you change the batteries when you see the Low Battery message.

One startup screen

On protocol running screen



Disclaimer: shows the disclaimer for the device. Machine is approved for pain use only. Names & descriptions are solely to assist in most appropriate protocol selection. No claims can be made beyond use of pain. Use UP/DOWN key to scroll between screens. Use LEFT arrow to exit. You can also use STOP or START to skip the screens when the disclaimer is shown upon power up.



Maintenance & Troubleshooting



There are no serviceable parts inside the IS02 main unit. Do not open the units.

Pre-Use Inspection

To ensure **the** IS02 device and leadwires are in good working order, perform the following steps.

- Power on the unit, check the display and keypad are working normally.
- Plug the leadwires without electrodes into the output ports on the rear of the IS02 unit.
- Press START key to run a protocol. There should be no error on starting.
- Test the continuity for CH1. Use the YELLO pin to touch the GREEN pin. The CH1 LED on the unit should not flash. This is the indication of good continuity through the leadwires. Separate the touch of the two pins. The CH1 LED should start to flash to indicate that the continuity is broken.
- Repeat to test the continuity for CH2. Use the RED pin to touch the BLUE pin. The CH2 LED on the unit should not flash. This is the indication of good continuity through the leadwires. Separate the touch of the two pins. The CH2 LED should start to flash to indicate that the continuity is broken.

Stop using the IS02 device if the leadwires or unit failed the above inspection and contact MEND Technology for recommendations.

Sanitizing

To sanitize the IS02 main device, wipe the device with non-dripping cotton balls or sanitizing wipes with germicide or alcohol. It would be safe to wipe the faceplate (keypad), display (LCD screen) and the whole enclosure if the wiper does not drip. Wipe off extra liquid on unit surface immediately.

The IS02 main device is not waterproof. Excessive liquid could leak into the device especially through the surrounding of the LCD screen to cause the device to malfunction.

To sanitize leadwires, wipe the leads with cotton balls or sanitizing wipes with germicide or alcohol.

To sanitize the electrodes or gloves: Electrodes and gloves are single patient use and not to be shared between people.

Life of Service

All IS02 devices have been tested and calibrated at manufacturing. The device does not need re-calibration for general use in 10 years. The IS02 device can be re-calibrated within or after 10 years of manufacturing for assurance of the accuracy or to comply with certain requirements from user's application. Inspirstar provides such calibration service with a fee.

Disposal



Do not throw the device into trash bin for regular waste. Follow local law or regulation for the collection, recycling and recovery of electronic waste.

Troubleshooting

Troubleshooting		
Problem	Possible Reasons and Solutions	
No display when pressing ON.	Check whether the batteries are positioned	
	correctly or change to new batteries.	
No LCD display and	Check whether the batteries are positioned	
CH1/CH2 keeps flashing	correctly. Or change to new batteries.	
No LCD display and 3 short	Internal failure. Change with new batteries and	
beeping sound	try again. If problem persists, contact MEND	
	Technology for services.	
LCD displays "Low Battery"	Change to new batteries.	
CH1/CH2 LEDs flashing	The contact from MEND Wellness TM to the	
when running a protocol	skin may be lost. This is caused by poor	
	connection or dry skin.	
	You need to make the skin moist. If CH1/CH2	
	LEDs continue flashing, it means there is a	
	disconnection. Perform the Pre-Use	
	Inspection. Contact your health care	
	practitioner or MEND Technology if the	
	problem persists.	
No sensation of current	This is normal for the low current intensity.	
Treatment is not effective.	Please consult your health care practitioner.	
An error code appears on the	Write down or take a photo of the screen.	
screen.	Turn the unit off and try again. If the problem	
	persists, contact	
	support@mendtechnology.com for servicing.	

If a problem is not resolved, please check MEND Technology website FAQ page for additional troubleshooting and service information.

Technical Manual

Technical Specifications

Carrier Frequency

Frequency Range: 0.1 Hz to 999.9 Hz programmable Frequency Accuracy: 0.1 Hz to 99.9 Hz: +/-0.1%

100.0 Hz to 499.9 Hz: +/-0.3% 500.0 Hz to 999.9 Hz: +/-.5%

Frequency Waveform: Square pulses

Frequency Duty Cycle: 0.1 Hz to 99.9 Hz $49\% \sim 51\%$

100 Hz to 499.9 Hz $45\% \sim 55\%$ 500 Hz to 999.9 Hz $40\% \sim 60\%$

Modulation Envelope

Period: Programmable from 4 ms to 60000 ms

Modulation Waveform Programmable ramp up/down slopes

Programmable duty cycles

Current Intensity: 20 µA to 400 µA programmable,

in 10µA increment

Current Accuracy: $20 \mu A \sim 200 \mu A : +/-5 \mu A$

 $200 \mu A \sim 400 \mu A : +/- 10 \mu A$

Outputs

Output Polarity: Programmable alternating, always +, or always –

Output Load Resistance: 0 to 100K ohm

Output Indication: LED for poor connection

Output Channels: Two

Output Channel Dependency: Fully independent, or correlative with

programmable phase between two channels for the modulation

envelopes. Either one can be turned off by programming.

Output Connector: 2x 2.35mm jacks for combined ports

Timer

Timer: Up to 18 hours for each frequency pair

Timer Accuracy: +/- 0.2%

Protocols

Number of Protocols: Up to 99 programmable

Frequency Pairs: Up to 7000 frequency pairs, limited by memory size

and complexity of the protocols

General

Power Supply: 2x 1.5V Alkaline batteries (AA size)

Power Consumption: < 0.25 Watts Communication Port: micro USB

Dimensions: 5.12 x 3.15 x 1.1 inches
Weight: 4.8 ounces (without batteries)

Safety class: Type BF

The device is classified as type BF (Body Floating)

device. For example, the device has conductive contact with the patient and the device is electrically separated from earth.

Environmental Conditions

Ingress Protection rating: IP40

Protected against foreign objects larger than 1mm, ingress of dust is not

totally prevented. Device is not protected against water.

Glove Electrodes: hand washable

Condition	Operating	Non-Operating
		(Storage and transportation)
Temperature	+5°C to +40°C*	-30°C to +80°C
Relative Humidity	10% to 80%, non-condensing	0% to 90%, non-condensing
Maximum Altitude	3,048 meters (20,000 feet)	12,000 meters (40,000 feet)
Atmospheric Pressure	>69 kPa & <132 kPa	>23 kPa & <132 kPa

^{*} Wait for at least 10 minutes before use from the extreme non-operating temperature.

Protocols and Frequency pairs

MEND Wellness (IS02LCDs) can store up to 99 customized protocols. Each protocol can be programmed to have one or multiple frequency pairs. Each frequency pair includes output parameters of frequencies for two channels, current intensity, time, and all other parameters for one therapy sub-session. Each frequency pair includes parameters Frequency 1 "F1", Frequency 2 "F2", Current Intensity "I", Time "T", Waveform, etc. Please refer to "Waveform Description" of this document for detailed explanation of all parameters F1, F2, Current Intensity, Period, K0~K3, Polarity, Phase of a frequency pair. The multiple frequency pairs will run in sequence when a protocol is started.

Waveform Description

The output from Inspirstar IS02 unit is current pulses. The waveform and parameters are illustrated in Figure 3. Both channels have the parameters marked on the CH1 waveform (at the top).

- F: Frequency of the carrier, also called chopper frequency.
- T: Therapy time in minutes, programmable from 1 minute to 60 minutes for each frequency pair. The waveform will be repeated during the therapy time.
- I: Peak current intensity of the pulse, expressed in μA .

Polarity: the polarity of the pulse is programmable to be alternative, always positive, or always negative. In alternative mode, the output polarity will change the polarity.

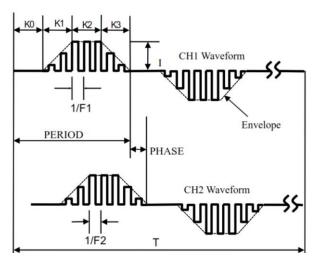


Figure 3 Waveform and Parameters

K: Duty cycle of the waveform. The pulse is composed of four segments for their nature in the waveform.
Each segment is programmable from 0% to 100% of the period of the envelope. When a period has 0% duty, the period will be eliminated.

K0: off period, there is no output current at this period, or i=0.

K1: current ramp up period, current ramps up to the peak current intensity I from 0 μA.

K2: peak current plateau period, the output current reaches the programmed peak value and maintains at the peak value for the period.

K3: current ramp down period, current ramps down from the peak current intensity I to $0 \mu A$.

Period: Period of the modulated pulse. The pulse can be modulated by the carrier frequency F. The period is programmable from 4 ms to 60000 ms. The outline of the waveform is often referred to as the envelope of the waveform, when the pulse is modulated, as shown in dotted lines in the figure.

Phase: is the relationship of the waveforms of the two channels. Channel 1 is used as the reference. A phase of 180 degrees equals to one period of channel 1. The phase of Channel 2 determines the time of the start point of the period of channel 2. When phase is 0 degree, the waveform of channel 2 is aligned with the waveform of channel 1. When the phase is 180 degrees, the waveform of CH2 starts one period later than CH1.



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