

User Manual for iTENS device



FOREWORD

Read this manual carefully before using your iTENS device.

iTENS strongly recommends carefully reading the “Warnings and Cautions”, and subsequent chapters of this manual.

WARNINGS AND CAUTIONS

Contraindications:

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

WARNINGS

1. If you are in the care of a physician, consult with your physician before using this device;
2. If you have had medical or physical treatment for your pain, consult with your physician before using this device;
3. If your pain does not improve, becomes more than mild, or continues for more than five days, stop using the device and consult with your physician;
4. Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
5. Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to

your heart, which could be lethal;

6. Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
7. Do not apply stimulation over, or in proximity to, cancerous lesions;
8. Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
9. Do not apply stimulation when in the bath or shower;
10. Do not apply stimulation while sleeping;
11. Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury;
12. Do not use the device on children, if it has not been evaluated for pediatric use.

13. Apply stimulation only to normal, intact, clean, healthy skin.
14. No modification of this equipment is allowed.

PRECAUTIONS

1. TENS is not effective for pain of central origin, including headache;
2. TENS devices have no curative value;
3. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
4. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head
5. The safety of electrical stimulation during pregnancy has not been established;
6. You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);

7. If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician;
8. If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
9. Use caution if you have a tendency to bleed internally, such as following an injury or fracture;
10. Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;
11. Use caution if stimulation is applied over the menstruating or pregnant uterus;
12. Use caution if stimulation is applied over areas of skin that lack normal sensation.
13. Keep this device out of the reach of children;
14. Use this device only with the electrodes, and accessories recommended by the manufacturer.

ADVERSE REACTIONS

1. You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin;
2. You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face;
3. You should stop using the device and should consult with your physician if you experience any adverse reactions from the device.

GENERAL WARNINGS

1. Do not immerse the iTENS in water.
2. Do not place the iTENS unit close to excessive heat.
3. To replace batteries, contract iTENS for instructions.
4. Environmental Condition:
 - Operating Temperature: +0°C to +40°C

- Operating Humidity: 10%RH to 93%RH
- Operating Atmospheric Pressure: 700 hPa to 1060 hPa
- Storage/Transport Temperature: -25°C to +70°C
- Storage/Transport Humidity: 8% to 93% R.H

INTENDED USE

iTENS is intended for the relief of pain associated with sore or aching muscles of body due to strain from exercise or normal household and work activities; and relief spasm of your muscles, relax muscles to achieve a resting effect and rehabilitate musculature in relation to injury.

INSTRUCTIONS FOR USE

Your iTENS is simple to use, but offers a robust selection of settings to learn and test if desired.

CONTENT IN THE PACK

Your iTENS pack should contain the following:

- 1 × iTENS device

- 2 × peel-n-stick Adhesive electrodes
- 1 × Resealable poly bag for storing device
- 1 × iTENS electrode wings
- 1 × iTENS charging station
- 1 × iTENS USB charging cable
- 1 × quick start guide

Having checked all the contents are correct please proceed to assemble the unit.

HOW TO ASSEMBLE YOUR UNIT

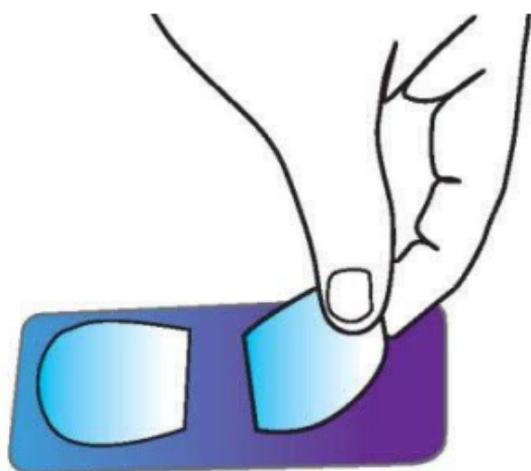
See the quick start guide for instructions on installing the app. Once the app is installed, proceed with these steps.

STEP 1 Remove the small circle iTENS device from electrode wing by twisting it firmly. It should unsnap from the "wing holder". Place the device in the docking station and plug in the charging cord to a USB port. Charge for 2.5 hours of use.

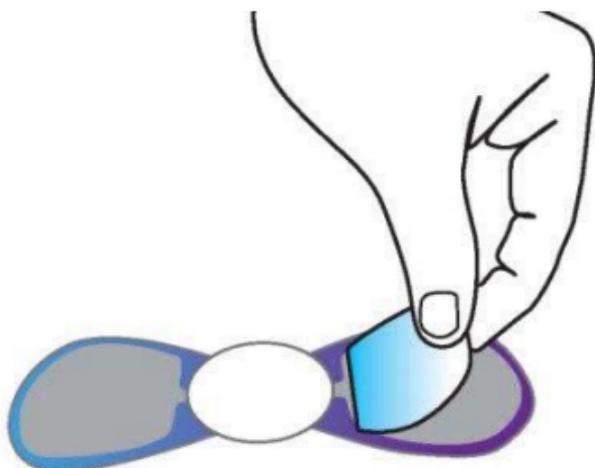
STEP 2 *Once the device is charged. Remove it from the charging station and snap it into the electrode wings.*

STEP 3 *Peel-n-stick electrodes*

Remove pads from the pouch and peel the first layer of film away from the gel.



Place the gel face down into the silver underside area of the wing so that the gel is flush and stuck to the wing.



Step 4 Install the iTENS app on your smartphone or tablet.

The iTENS app is available from the Apple App Store and Google Play Store. Visit www.iTENS.com for download links and device compatibility information.

As well as updates to device compatibility

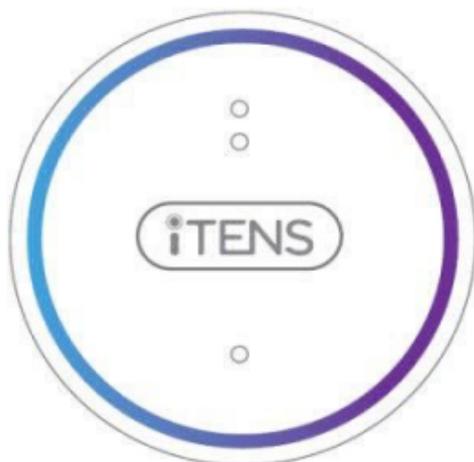
Step 5 Once the app is installed, you are ready to use the device. Press and hold the center button until it turns on. The LED light will start to blink, and attempt to pair with the app.

Make sure your Bluetooth is enabled on your phone however most phones auto adjust.

Step 6 Once pairing is complete, peel off the remaining film and stick the electrode wings onto your treatment site.

Ensure wherever you intend to place the iTENS the skin is clean and thoroughly dry. The electrode gel is for single patient use.

OPERATION OF THE iTENS



On-device settings:

- 1) Center button acts as an ON/OFF button
 - Press and hold it for more than 3 seconds to turn the iTENS on or off;

- 2) The area above and below the center button is used for intensity increase/decrease. The area above increases the intensity and the area below decreases the intensity. However, the intensity is mainly adjusted via the app;
- 3) LED light on the center button.
- a. The LED light will begin blinking fast which means the device is pairing;
 - b. A solid light means pairing is complete and the device is active;
 - c. The LED light also begins blinking slowly when the batteries are running low.

Button description on the App



- to switch current device off or on, grey indicates that it shuts down, and blue indicates that it is on work.



- to stop the output of current device



- the current device power



- to lock or unlock all devices and app screen settings, orange indicates that the screen is locked, and blue indicates that it is unlocked.



- to link to device list; grey indicates that device is disconnected to the app, and blue indicates that it is connected and ready for treatment.



- to add programs to your favorites



- to adjust intensity



- figure icons 1 to four, to tap the connected device for control; purple indicates that current device you control, green indicates that it is connected and grey indicates that it is disconnected.



- to pause/start current device



- main control screen



- program settings



- documents folder



- settings folder

Operation of the App:

When first accessing the app, you need to enter device located screen to select your device by pressing disconnect icon (). Press "Reset " on device list to search the available bluetooth devices that are ready to be connected and  disconnect all devices. Press disconnect icon () on devices list screen to disconnect the connected device.

Once select first device successfully, pressing link icon () on home screen to connect another device, if you need to use two devices simultaneously. Repeat it if you need more devices for use. No more than four devices can be used on one app simultaneously. Press the figure icon (e.g. ) to  the connected devices for control.

Access the treatment programs in your app by pressing

program settings icon () at the bottom of the screen. From there, you can either select a setting from the "Body Diagram" (for specific body part treatments), "Conditions" (to treat based on a current ailment), or "Manual mode" (to create a custom setting). After parameters are selected, you need to click "SELECT PROGRAM" to confirm and start your treatment. It is highly recommended to experiment with the different settings to find the optimal program.

Once you have chosen and selected a program setting, you will next need to adjust the intensity. As you adjust the intensity, you will feel a mild tingling sensation. Adjust the intensity to a level that is comfortable but not overpowering.

Initial treatments should last for around 30 minutes, and for some people it may take 3-4 therapy sessions over the first couple days of use, for the body to acclimate to electrotherapy. So do experiment with you settings and placement of the wings.

Note: The iTENS device will automatically shut off if the

treatment is finished for over 30 minutes or if no button used over 30 minutes. Also, at anytime, if the electrode wings lost contact with skin, the output will be set to zero.

For favorite function, at first you need to add parameters to favorite list by pressing star icon () , then pressing program settings icon () at the bottom of the screen, you can quickly access saved programs on favorite program.

Delete your parameters of your favorite list: Access the Favorite mode program, left the selected file to delete.

Accessing documents screen by pressing documents folder icon () you will find iTENS information for use, including Quick Start, Instructions, Privacy Statement, EULA, Electrode Placement.

Operation of settings screen

Accessing settings screen by pressing setting folder icon () , you will find other function of iTENS, including Rename, Track cumulative usage time , Track your results and Chart your results.

For rename function:

Accessing rename function by pressing setting folder icon (). Once the device is renamed successfully, it will disconnect current program and return to the devices list.

For Track cumulative usage time function:

It is used to survey total treatment time and the rest of current treatment time automatically when the intensity is set to above zero.



- to pause/start current device



- to reset total time

For track your result function:

You need to begin tracking your results slide the bar to "enable" on Track your results screen, which shut down for default. Then it will pop a pain scale automatically either the treatment intensity is set to above zero or the treatment is finished. Select your pain level by sliding purple ball on horizontal line and press "SAVE" icon () to save pain information before and after use.

For chart your result: (information compared with your treatment situation before use and after, including pain level, treatment time and so on. It only surveys your treatment when the Track your result setting enable. The initial chart will be covered when the memory is full. 100 memories are available for your use.



- to tap different charts

Caution: It is normal to get some skin reddening after a session. This fades quickly. You should always take rests between therapy sessions and check your skin underneath the electrode wings periodically. If the reddening does not disappear after a couple hours, discontinue use of the system, and contact www.iTENS.com. There is a small percentage of people that may have allergic reactions to gel and will need special hypo allergic gels.

SPECIFICATION

Model: iTENS

Channel: Single channel with capabilities to link multiple devices to one app program

Pulse Amplitude: 0-130ma= 0-65 volts, adjustable at 500ohm load

Pulse frequency (Hz): 1-150

Pulse width (us): 50-250

Waveform: Asymmetrical Biphasic Alternate Square,
Symmetrical Biphasic Alternate Square,
Monophasic Alternate Square

Timer control: (mins) 15, 30, 45, 60, Continuous

Power supply: Polymer lithium ion battery

Mode: Body Diagram
Conditions
Manual mode

Body Diagram, one default mode, is used for body specific area treatments. Body part program has 11 different types of treatment parameters as follow:

NO.	Program	Total time (min)
0	Wrist pain	30
1	Elbow pain	25
2	Shoulder pain	30
3	Quadriceps pain	40
4	Mid/upper back pain	40
5	Lower back pain	40
6	Abdominal cramping	25
7	Hip pain	30
8	Knee pain	25
9	Ankle pain	30
10	Hand/foot pain	30

Condition program is used to treat based on a current ailment, one of the default mode which the parameters is not adjustable except intensity. Depending on the different symptoms, Condition program has 13 different

types of treatment parameters as follows:

NO.	Program	Total time (min)
11	Acute pain	30
12	Chronic pain	35
13	Muscle spasm relief	30
14	Muscle massage	30
15	Muscle relaxation	35
16	Sciatica	20
17	Epicondylitis	25
18	Post surgical pain	20
19	Neuropathy pain	30
20	Bursitis	60
21	Osteoarthritis	60
22	Rheumatoid Arthritis	60
23	Carpel Tunnel	20
24	Fibromyalgia	40
25	Tendonitis	25

Manual mode is used to create a custom setting at the available area, including pulse width, waveforms, pulse rate, treatment time.

Manual mode settings

B - stands for burst mode (the impulses are delivered at a rate of 2 pulse train per second (2Hz))

C - stands for continuous mode (the impulses are steady; the interval rate and length of the impulses are fixed.)

M stands for modulation mode (the pulse rate modulated from 50Hz to 100Hz, while the pulse width changes from 200us to 60us within 6 seconds, then automatically modulated from 100Hz to 50Hz and 60us to 200us within the next 6 seconds. The cycle will be repeated automatically.

Pulse width - increases the space between each wave.

Pulse rate - increases the frequency in which the waves travel through the skin. Typically the higher, the more comfortable stimuli.

Wave form - addresses different main conditions in more effective manners, i.e. monophasic wave is best for pain in the extremities.

Explanations of the pain level:

The darker color you select, the severer pain you feel.

No.	Color	Pain level
1 		No pain
2 		Mild pain
3 		Moderate pain
4 		Moderate pain
5 		Severe pain
6 		Severe pain
7 		Very Severe pain
8 		Very severe pain
9 		Worst possible pain
10 		Worst possible pain

OTHER FEATURES

1. Intelligent pop-up tips for operation to help your use.
2. 20 intensity levels are available for selecting your

comfortable stimulate.

3. The iTENS device will automatically shut off if the treatment is finished for over 30 minutes or if no button used over 30 minutes .
4. The output of iTENS will down to zero and pop an alarm “Alarm: reconnect gel pads” if the wings lose contact with skin.
5. The app will pop a tip when the treatment is completed.
6. Once the device is connected to your app , device name will display on the top of the home screen, on the top right of the other screens. And the background of connected devices will turn purple from grey on devices list.

About the power:

1. It is recommended to charge your device when the power is low ().
2. The LED light also begins blinking slowly when the batteries are running low.

About charge

1. When charging the device, please ensure locate the device into the charging connectors correctly. (The two charging contacts on the device should be placed against the charging pins of the charging cradle.)
2. The LED light will blink during charging.
3. The LED light wil turn off with a beep sound when device fully charged.

About Body diagram

1. The selected body part turns blue () from grey () body diagram, which point to vividly the placement of the electrode.

About Conditions screen:

1. The last use parameter will display when you access the condition program screen.
2. For the program, the characters turn blue and the background turns grey, when you choose it. And selected program will display on the top of the all conditions' programs.
3. After B/C/M mode was chosen ,the output will down to zero.

4. Only tip “OK”, when you choose the same program as before.

About Manual mode screen:

1. The selected mode icon turns orange from green.
2. The selected wave form icon turns orange from white.
3. The Manual mode screen will display the last parameters that when you accessed it.
4. The default treatment time is continuous for initial use.
5. It is recommended to try the constant mode. It is a smooth comfortable stimulation.

About favorite mode:

1. The name of the favorite list is demanded greater than 1 character and less than 14 characters). Same filename is not allowed to cover the initial parameter.

About the rename function:

1. The name is demand greater than 1 character and less than 14 characters.

2. After input name successfully, it will return to the device located screen and disconnect current program.

About the other screens

1. "Back" icon: click it to turn back to the last step.
2. "Skip" icon:click it to back to the last page.
3. The screen name is on the top of the screen.

Other

1. When the program changes, the output level will go down to zero immediately .The app will display the last intensity if your selected program as the same as the last program.
2. The selected program will only run when the intensity is set above zero.
3. Only one device you can control each time, while you can use multiple simultaneously with a tap icon  ().
4. When the treatment timer is set, it will begin to count down one minute by one minute and display the remaining time on the Home screen; once it

counts down to zero, the device will automatically shut off.

Detailed information regarding the Waveform, Pulse width, Pulse frequency and Output voltage range.

A. Waveform

There are 3 types of waveforms - adjustable in manual modes.

(1). Symmetrical Biphasic Alternate Square waveform



(2). Asymmetrical Biphasic Alternate Square waveform



(3). Monophasic Alternate Square waveform



B. Pulse width - adjustable in manual modes

By pressing **+** or **-** in the app, the pulse width can be adjusted from $50\mu\text{S}$ to $250\mu\text{S}$ in step of $10\mu\text{S}$.

C. Pulse frequency - adjustable in manual modes

By pressing **+** or **-** in the app, the pulse frequency can be adjusted to one of the following values (Hz):

- 1, 2, 3, 4, 5, 10, 12, 14, 16, 18, 20, 25,
30, 35, 40, 45, 50, 60, 70, 75, 80, 90,

100, 110, 120, 130, 140, 150.

D. Output voltage range - adjustable in all modes

E. The adjust range of 3 modes about manual mode.

Mode	Pulse width	Wave form	Pulse rate
Burst	50~250 μ S	3 types	4~150 Hz
Constant	50~250 μ S	3 types	1~150Hz
Modulation	200 μ S (defaulted)	3 types	50Hz (defaulted)

ELECTRODES PLACEMENT

Accessing electrode placement of app by pressing documents folder icon () see correct positioning of the electrode wings.

PADS

The pads that are supplied with your iTENS device are self-adhesive and can be used several times. Skin must be

allowed to breathe, so the wings should be removed from the body periodically. When not in use, the pads can stay on the wings, but the wings should be placed onto the clear plastic poly bag and kept closed.

The condition of the pads does affect the conductivity and, therefore, the performance of the unit. When the pads initially lose their adhesive quality, it is possible to reactivate their adhesiveness by applying a dab of water. Once the pads have finally lost their adhesive quality, new pads should be purchased.

NOTE: AFTER USE

Always ensure that the device is turned OFF and place the iTENS with wings into the resealable poly bag provided.

WARNINGS

Allergic reactions to the self-adhesive pads can occur. If a red rash occurs that does not go away soon after treatment, discontinue use altogether and contact iTENS.

- Do not apply to broken skin.
- Do not apply pads to skin that do not have normal sensation .If the skin is numb, stimulation will not be felt and too great an intensity might then be used accidentally.

Manufactured for iTENS, LLC