iSoothe®

3-in-1 Wireless Electrotherapy

Drug-free Pain Relief Technology

Model iT300AB

User Manual

This manual is applicable to iSoothe® 3-in-1 Wireless Electrotherapy Device Model iT300AB.

This instruction manual is published by Innovo Medical.

Innovo Medical reserves the right to update this manual at any time without prior notice.

Amendments may however be published in new editions of this manual.

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INTRODUCTION

Thank you for purchasing the iSoothe® 3-in-1 Wireless Electrotherapy Device Model iT300AB for your pain relief solution.

In order to use this electrotherapy device safely, please read the user manual carefully before use.

Keep this user manual in a secure place or store with the device for future reference.

Indications for use:

- TENS: The device is designed to be used for the temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arms) and lower extremities (legs) due to strain from exercise or regular housework.
- EMS: The device is designed to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Device should be applied to normal, healthy, clean and dry skin of adult users. Device is designed to be used at home.

Package contains the following components:

Standard Parts:		
No.	**Description**	**Quantity**
A	iT300AB electrotherapy device	1PC
B	Electrode pads(110mm x 70mm, 190mm x 95mm)	2PCS
C	Instruction manual	1PC
D	Micro-USB cable	1PC
E	Quick start guide	1PC
F	Electrode placement guide	1PC

IMPORTANT SAFETY PRECAUTIONS AND WARNINGS

It is important that you read all warnings and precautions included in this user manual before using the product. They are intended to keep you safe, prevent injury and avoid a situation that can damage the device.

SAFETY SYMBOLS USED IN THIS MANUAL

DANGER
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

WARNING
Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and device damage.

CAUTION
Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury to the user, or damage to the device or other property.

DANGER

THIS ELECTROTHERAPY DEVICE MUST NOT BE USED IN COMBINATION WITH THE FOLLOWING MEDICAL DEVICES:

- Cardiac pacemaker, implanted defibrillator, or other implanted metallic, rods or electronic devices.
- Electronic life-support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs.

Using this electrotherapy device with other electronic medical devices may cause erroneous operation of those devices.

WARNING

DO NOT USE THIS DEVICE UNDER THESE CONDITIONS:

- Consult with your physician before use. Device may cause lethal rhythm disturbances in certain susceptible individuals.
- 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.
- If you are on a life-supporting medical electronic device such as an artificial heart, lung or respirator.
- In the presence of electronic monitoring equipment (e.g. cardiac monitors, ECG alarms), which may not operate properly when device is in use.
- While connected to high-frequency surgical equipment. It may cause burn injuries on skin under the electrodes, as well as problems with the device.
- In the vicinity of shortwave or microwave therapy equipment. This may affect the output power of device.
- On open wounds or rashes; over swollen, red, infected, inflamed areas; or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins); or on top of, or in proximity to, cancerous lesions.
- Over areas of skin that lack normal sensation.
- On the head since the effects of electrical stimulation on the brain are unknown.

DO NOT USE THIS DEVICE ON THESE INDIVIDUALS:

- Pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
- Children or infants, because device has not been evaluated for pediatric use.
- People incapable of expressing their thoughts or intentions.

DO NOT USE THIS DEVICE WHILE:

- Bathing, showering or swimming.
- Sleeping.
- Driving, operating machinery or in any activities where electrical stimulation can put you at risk for injury.

PAIN MANAGEMENT WARNINGS:

- If you have had prior medical or physical treatment for pain, consult with your physician before using this device.
- If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using device and consult with your physician.
- Pain may be an indicator of illness. If you are suffering from any serious illness, consult with your physician before using device.

WARNINGS REGARDING THE ELECTRODE PAD:

- Apply electrode pad only to normal, healthy,clean and dry skin (of adult users). It may otherwise disrupt the skin healing process.
- If you experience any skin irritation or redness after a session, do not continue electrotherapy in that area of the skin.

NEVER APPLY THE ELECTRODE PAD TO:

- The head or any area of the face.
- The front side of the neck or any area of the throat because this can cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances, which could be lethal.

CAUTION

PRECAUTIONS REGARDING THE ELECTRODE PAD:

- Do not bend or fold pad because it may prevent pad from functioning properly.
- Place pad onto plastic film provided and store in the sealed package when not in use.
- Pad is pre-gelled and ready to use. It will adhere to skin. No additional gel/formula is required.
- Do not apply ointment or any solvent to pad or your skin because it will prevent pad from functioning properly.
- To avoid damage to adhesive surface of pad, place pad only on clean and dry skin or on plastic film provided.
- Always place clean pad in accordance with illustrations provided (Refer to Electrode Pad Placement Illustrations on page 20).
- Make sure electrode pad is well connected to device. Pad should be properly placed on part of the body you wish to treat or the therapy will not be effective.

DO NOT USE THE ELECTRODE PAD THIS WAY:

- Do not place pad on your spine or backbone.
- Pad should not touch any metal object, such as a belt buckle, necklace or other jewelry made from metal.
- Do not share pad with another person. This may cause skin irritation or infection. The pad is intended for use by one person only.
- Do not place or relocate the pad while device is on.
- Always turn the power off before removing or changing location of the pad.
- Do not leave pad attached to skin after treatment.
- The life of pad may vary depending on the frequency of washing, skin condition and storage state.

CAUTION WHILE USING THE DEVICE:

- If device is not functioning properly or you feel discomfort, stop using device immediately.
- Do not use device while wearing electronic devices such as watches as this may damage the device.

- Do not use device in the vicinity of a cellphone as this may cause device to malfunction.
- Do not throw device into a fire. The batteries may explode.
- Dispose device and components according to applicable local laws and regulations. Unlawful disposal may cause environmental pollution.
- The size, shape and type of electrode pad may affect the safety and effectiveness of electrotherapy. Using pad that is too small or incorrectly applied could result in discomfort or skin burns.Use device only with the specially designed pad. Refills can be purchased separately (iSoothe® Wireless Electrode Pad Model iT300AG-S, iT300AG-L).

GENERAL PRECAUTIONS:

- The user is the intended operator.
- The long-term effects of electrical stimulation are unknown.
- Do not use the electrotherapy device for any other purpose not described in this manual.
- Apply the electrotherapy device only to normal, intact, clean, dry and healthy skin.
- TENS is not effective in treating the original source or cause of pain, including headache.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS does not cure diseases or injuries.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a warning mechanism.
- The effectiveness of electrotherapy is highly dependent upon the individual.
- You may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium (gel) on the electrode pad.
- If you are at risk or diagnosed with a heart condition or epilepsy, you should follow precautions recommended by your physician.
- Use caution if you are at risk of internal bleeding, such as after an injury or fracture.
- Consult with your physician prior to using device after a surgical procedure. Electrical stimulation may disrupt the healing process.
- The device should not be applied to the abdomen during pregnancy or menstruation.

- The device should not be applied to areas of skin that lack normal sensation.
- Use device only with electrode pad and Micro-USB cable recommended by manufacturer.
- Do not modify device without authorization from the manufacturer.
- Do not use device or electrode pad if it is damaged. The use of a damaged device may cause injury, improper results or serious danger.
- Store device and components in a clean and dry place.
- Do not expose device and components to any chemical solvent, water, lint, dust, direct sun or high temperature.

CAUTION
Keep device and components out of reach of young children. The cable may cause strangulation. Small pieces may be a choking hazard. Contact your physician immediately if ingested.

POSSIBLE ADVERSE REACTIONS:

- Do not use device to treat one region for an extended period of time (more than 30 minutes a session, up to 3 times/day). This may cause muscles in the treated region to become exhausted and sore.
- You may experience skin irritation, redness or burns in the treated region.
- You should stop using device and consult with your physician if you experience adverse reactions from using the device.

HOW TENS WORKS FOR PAIN RELIEF

What is TENS?

TENS stands for Transcutaneous Electrical Nerve Stimulation. TENS is a clinically tested, non-invasive drug-free method of managing pain. It uses tiny electrical impulses sent through the skin to the nerves to relief pain. TENS is highly recommended by medical professionals as a safe and effective means for pain management.

TENS does not cure any physiological problem. It only helps to manage pain. Please note that using TENS to manage pain may not work for all users.

How does TENS work?

Scientific theory suggests that electrical stimulation therapy may work in several ways:

- The gentle electrical pulses block “pain message” carried by the nerves from reaching the brain.
- The gentle electrical pulses induce an increase in the production of endorphins, the body’s natural pain killer.

HOW EMS WORKS FOR MUSCLE CONDITIONING

What is EMS?

EMS stands for Electrical Muscle Stimulation. EMS is widely utilized as a muscle conditioning tool. It uses gentle electrical impulses sent through the skin to the muscle, causing it to contract, mimicking physical exercise. This allows your muscles to exercise passively even when you are sedentary. EMS facilitates muscle performance, aids in strength training and recovery from minor muscle injuries and post exercise.

How does EMS work?

EMS device sends electrical impulses that mimic the action potential from the central nervous system. It uses square wave pattern (ladder-shaped) which is effective in targeting muscle motor neurons. When muscle receives electrical signal, it flexes. When electrical signal ceases, it relaxes. This cycle is repeated, mimicking normal muscular activity during physical exercise.

How does MASSAGE work?

The MASSAGE electrotherapy program is a type of low level EMS that provides relaxing vibration to loosen tight muscles. It mimics manual massage to promote relaxation and reduce muscle tension.

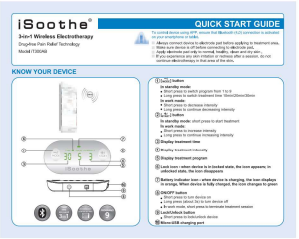
PACKAGE CONTENTS

iT300AB
electrotherapy device

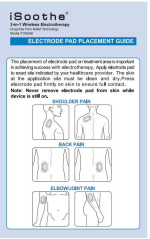
Electrode pads
(110mm x 70mm,190mm x 95mm)

Micro-USB cable

Instruction manual



Quick start guide

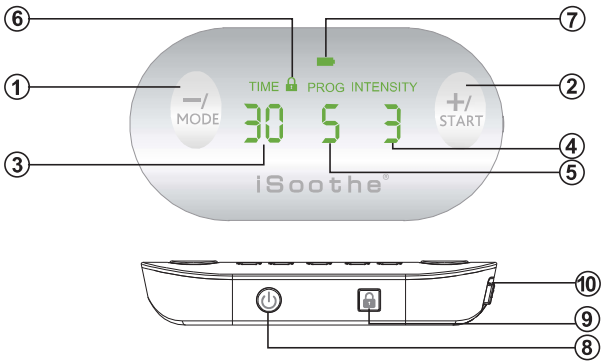


Electrode placement guide

KNOW YOUR DEVICE

Features

- Channels: One channel
- Treatment modes TENS: 5 programs
  EMS: 2 programs
  MASSAGE: 2 programs
- Output Amplitude: Max. 45V (at 500Ω load)
- Waveform type: Symmetrical Biphasic square pulse
- Control platform: App control (iOS or Android) and device control



① **[−/MODE] button**
In standby mode:
- Short press to switch program from 1 to 9
- Long press to switch treatment time 10min/20min/30min

In work mode:
- Short press to decrease intensity
- Long press to continue decreasing intensity

② **[+/START] button**
In standby mode:
- Short press to start treatment

In work mode:
- Short press to increase intensity
- Long press to continue increasing intensity

③ **Display treatment time**

④ **Display treatment intensity**

⑤ **Display treatment program**

⑥ **Lock icon - when device is in locked state, the icon appears; in unlocked state, the icon disappears**

⑦ **Battery indicator icon - when device is charging, the icon displays in orange. When device is fully charged, the icon changes to green**

⑧ **ON/OFF button**

- Short press to turn device on
- Long press (about 3s) to turn device off
- In work mode, short press to terminate treatment session

⑨ **Lock/Unlock button**

- Short press to lock/unlock device

⑩ **Micro-USB charging port**

CHARGING

Using Micro-USB cable, connect the Micro-USB plug to the Micro-USB charging port on device. Then, connect the Standard USB plug of cable to an appropriate power supply source that can output 5V d.c. 300mA.

While charging, the battery indicator light displays orange. When battery is fully charged, the indicator light turns green.

Note:

- Use only the Micro-USB cable that is included with the device.
- Device must be fully charged prior to first use. It takes about 2.5 hours to charge the device.
- A full battery charge typically allows up to 4 30-minute treatment sessions under normal conditions.
- Please charge device fully before starting each session. Otherwise, the battery may be depleted before session ends. Note: device cannot be used while it is charging.

WARNING

- If battery leaks and comes into contact with skin or eyes, wash immediately with large amount of water.
- Dispose used battery safely in accordance with local regulations.
- The life of a rechargeable battery depends on the number of recharging/rundown cycles. The service life of the rechargeable battery is about 300 recharging/rundown cycles.
- If device is not used frequently, please recharge battery at least once a month to exten d battery life.

EASY STEPS TO GET STARTED WITH ISOOTHE® ELECTROTHERAPY

The iSoothe® electrotherapy device can be used with or without the mobile application (App). To use with the App, start with Step 1. To use without the App, skip Step 1.

STEP 1 Download the mobile application.

Download the App to your smartphone or tablet.

- Go to App Store or Google Play.
- Search for 'Innovo iSoothe'.

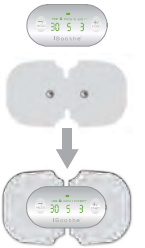
The App operates on iOS and Android platforms (At least iOS 8.0, Android 5.0).

STEP 2 Prep the skin.

Clip excess hair from treatment area. Remove any jewelry that may come in contact with device. Clean skin with soap and water, and dry completely.

STEP 3 Prepare the device.

Make sure device is off. Connect device to electrode pad by pressing male snaps of electrode pad to female snaps of device.



STEP 4 Apply device and electrode pad to treatment area.

Remove the clear plastic film from adhesive side of electrode pad by peeling from one end. Apply adhesive side of pad to treatment area by pressing down firmly to ensure full contact with skin. See page 20 for placement suggestions.

Note:

- Do not discard the plastic film. It will be used to protect adhesive surface of pad when not in use.

- The pad is designed to adhere well to clean, dry skin. Use of additional medium (such as electrode gel in a tube) is not recommended and may damage the device.
- You may need assistance when applying pad to certain treatment areas.

WARNING

Make sure device is off before connecting to electrode pad.

Always connect device to electrode pad before applying to treatment area.

Replace the electrode pad if:
- it is dirty, damaged or torn.
- it is past the expiration date.
- it has lost its adhesiveness. Never use bandage or tape to attach pad to your skin.
- when stimulation feels weak or uncomfortable, i.e. when you experience unpleasant stinging or biting sensation.

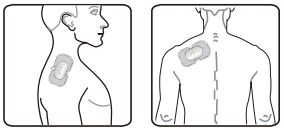
WARNING

Use only electrode pad recommended for this device by the manufacturer.

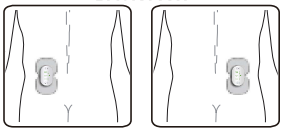
Apply device and pad to treatment area according to Electrode Pad Placement Illustrations on page 20.

Electrode Pad Placement Illustrations

SHOULDER PAIN



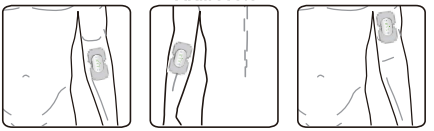
BACK PAIN



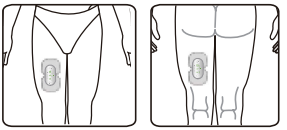
ELBOW/JOINT PAIN

Note: To treat areas of shoulder or back, please use large size electrode pad.

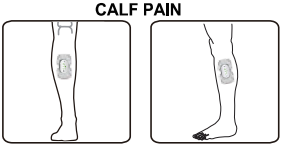
ARM PAIN



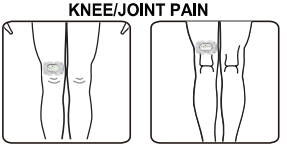
LEG/THIGH PAIN



CALF PAIN



KNEE/JOINT PAIN



Skip Steps 5-9 if using device without the App.

STEP 5 Connect device to App.

- Ensure that Bluetooth (4.0) connection is activated on your smartphone or tablet. Turn on the App.
- Turn device on by pressing the ON/OFF button. App will automatically detect the device. Select your iSoothe® device by pressing 'CONNECT' button. In case of inactivity (more than 3 min), device will switch off. Press the ON/OFF button again to continue.
- Device is now paired with the App - screen shows your iSoothe® as 'Connected'. Press arrow '>' on the right to continue.

STEP 6 Select treatment type and treatment area.

- Select treatment type by pressing TENS, EMS or MAS (Massage).
- Select treatment area accordingly. Note: 'FRONT' and 'BACK' show available treatment areas (tagged with bright circles).

Note:
You can select from your saved favorite treatment programs list by pressing the heart icon at the top right.

STEP 7 Select your pain level.

Estimate the intensity of pain you are currently experiencing in the treatment area.Select from a scale of 0 to 10 (0-no pain, 10-intense pain). Press 'START' to continue.

Note:
A recommended program for the treatment area is preselected. You can switch treatment program by pressing left or right arrow '< >'.

STEP 8 Start treatment session.

- Press '+' button to start treatment. Note that this increases intensity level to 1. Press '+' button again to increase intensity to desired level. Press ' – ' button to decrease intensity.
- You can pause treatment by pressing ' ⏸ ' button. The countdown timer will stop. Press again to resume treatment.
- Press ' 🔒 ' button to lock the intensity controls for safety during treatment. You can unlock at any time by pressing the button again.
- If you experience any discomfort, you can stop treatment session at any time by pressing 'STOP' button.

Note:

- The default treatment time is set to 20min. You can select other treatment time from 10min to 30min. Prior to starting treatment, press the '⏲' icon, then select accordingly. Press 'OK' to continue.
- In work mode, device will lock automatically after 15 seconds of no operational activity.
- Pressing '⏻' button shuts down device and ends treatment session.
- Prior to starting treatment, you can switch treatment program by pressing the program icon accordingly (top of page). Pressing the program icon during a treatment will end current session. To start another session, press '+' button.

–	Decrease intensity
+	Increase intensity
⏸	Pause treatment
STOP	Stop treatment
🔒	Lock/Unlock
⏻	Shut down device
⏲	Set treatment time

STEP 9 End treatment session.

- After treatment session is completed, you will be prompted to select your satisfaction level. Press the icon accordingly.
- You can also save treatment program to favorite by pressing 'ADD THIS PROGRAM TO FAVORITE' button.
- Press 'EXIT' button. Details of the treatment session is displayed. Treatment session is also stored in treatment history.
- Press 'Retry' to restart the same treatment program on the same treatment area or 'New Session' to start a new treatment session.

Note:
You can end treatment session at any time by pressing the 'STOP' button.

Continue to Step 12 to turn device off.

Follow Steps 10-11 if using device without the App.

STEP 10 Start treatment session using controls on the device.

Note: Please refer to pages 15-16.

- Turn device on by pressing the ON/OFF button.
- Press [-/MODE] button to switch treatment program from 1 to 9.
- Long press [-/MODE] button to switch treatment time from 10min to 20min to 30min.
- Press [+/START] button to start treatment session.
- During treatment, you can increase intensity level by pressing [+/START] button or decrease intensity level by pressing [-/MODE] button. There are 15 intensity levels.

Note:

- If you experience any discomfort, you can stop treatment session at any time by pressing the ON/OFF button.
- Press Lock/Unlock button to lock device. This inactivates the [-/MODE] and [+/START] buttons to prevent accidental press during

treatment session.

- In work mode, device will lock automatically after 15 seconds of no operational activity.

Treatment program list:

Program		Type
1	Continuous	TENS
2	Acupuncture	
3	Burst	
4	Hans	
5	Modulation	
6	Strengthening	EMS
7	Building	
8	Tap	Massage
9	Knead	

STEP 11 End treatment session using controls on the device.

- After treatment session is completed, device will turn off automatically.
- You can end treatment session at any time by pressing the ON/OFF button.

STEP 12 Turn the device off.

Press the ON/OFF button on the device until it turns off.

Note:

- To turn device off using App, go to the 'treatment operation' page, then press '⏻' button.
- Device will turn off automatically after 3 minutes of no activity.

STEP 13 Remove device and pad from treatment area and store.

- Remove electrode pad from skin by peeling gently from one edge.
- Remove device from electrode pad.
- Protect adhesive surface of electrode pad using the clear plastic film.
- Store device and electrode pad in cool and dry place away from direct sunlight.

Note:

You can charge the device if necessary. A full battery charge is advisable before starting a new treatment session.

CLEANING AND STORAGE

Cleaning the device

1) Turn device off. Remove Micro-USB cable if device has been charging.
2) Wipe device gently with slightly moistened, lint-free soft cloth.

- Do not use chemicals (such as thinner, benzene).
- Do not allow any water to seep into the device.

Note:

- Device and accessories do not require sterilization.

Cleaning the electrode pad

1) Turn device off. Remove pad from device.
2) Wash pad when adhesive surface becomes dirty and/or no longer adheres well to skin.

- Wash adhesive surface of pad softly with fingertips under slow running cold water for several seconds.
- Do not use sponge/cloth/sharp object like fingernail on adhesive surface.
- Do not use detergent, chemicals or soap.

3) Allow pad and adhesive surface to air-dry completely.

- Do not wipe with tissue paper or cloth.

4) Protect adhesive surface of pad using the clear plastic film.

CAUTION

- The life of pad may vary depending on frequency of washing, skin condition and storage state.
- If pad no longer adheres to skin or it is damaged/broken, discontinue use immediately. Refills can be purchased separately (iSoothe® Wireless Electrode Pad Model iT300AG-S, iT300AG-L).

Storage

- Store electrode pad in sealed bag.
- Store device and accessories in cool and dry place.
- Keep device and accessories out of reach of children.

CAUTION

If device is not used for a long period of time, it is recommended that you recharge the battery at least once a month.

SPECIFICATIONS

- Power Source: 3.7V Li-ion
- Power Supply: Input 100-240V AC, 50/60Hz, 0.2A; Output 5V DC, 300mA
- Frequency: 2Hz~132Hz
- Pulse Width: 30us~250us
- Wave form: Biphasic square wave
- Output Voltage: max. 45V (at 500 ohm load)
- Output Intensity Level: 0~15 levels
- Operating Conditions: 5°C~40°C; 30%RH~75%RH; 700hPa ~1060hPa
- Storage and transport conditions (device): 14°F~131°F (-10°C ~55°C); 10%RH~90%RH; 700hPa ~1060hPa
- Size: 71x36.7x12.3mm (device)
- Weigh t: 25g (device)
- Service life of device: 2 years
- Service life of electrode pads: up to 15 uses
- Applied part: Electrode
- Size of electrode: Large: 190mm x 95mm; Small: 110mmx70mm
- IP classification system: IP22
- Maximum separation distance: 10m (In open environment)
- The recommended separation distance: 3m

Description of the Wireless Functions and Technology:

RF frequency	2.4GHz-2.48GHz
Channel bandwidth	2 MHz (-20db)
Operation voltage	DC3.7 V
Types of spread spectrum	DSSS
Modulation type	GFSK
Number of channel	40
Chanel spacing	2 MHz
Channel frequency	0-39 Channel 2.402-2.480GHz
Antenna gain	2dBi
Bluetooth version	V4.0

The iT300AB device uses one-on-one connection of BLE4.0, and the device as a peripheral, responds to the App's connection request passively, establishing a one-on-one connection with the App. After iT300AB device connects to the App, it will not be connected to or controlled by other wireless devices. When the App connects to peripheral device, App will send command. When iT300AB device ensures this command is right, it will open the control command. You can then control the iT300AB device. Otherwise, the App cannot control the iT300AB device.

HOW TO MANAGE YOUR PAIN

When should the device be used?

It is recommended that you use the device as soon as you experience pain. Start with one treatment session and evaluate your pain level. Starting early may prevent your pain from becoming worse, or even chronic. It is advisable to start managing your pain early before it reaches a high threshold where it may limit your daily activities.

How often can the device be used?

It is recommended that you use the device once a day (up to 30 minutes) for each treatment area. Depending on your pain level, you may need to use it longer. Do not exceed 3 times a day (maximum 90 minutes total).

Start with one treatment session. Keep track of your progress by rating your pain level from 0 (no pain) to 10 (intense pain) before each treatment. Stop electrotherapy session if pain reduces or stops. If it does not improve and you experience soreness from over-use, refrain from treating the affected areas for 2 days. If this reoccurs, reduce treatment time and intensity for future treatment.

Setting the intensity level

Treatment intensity should be based on your level of comfort. Always start the first session with short treatment time and low intensity level. When you are familiar with the electrotherapy session, you can adjust treatment time and intensity accordingly. Please practice caution when using device with high intensity. Do not exceed your comfort level.

CAUTION

Stop using the device under these conditions:

- If you experience any adverse reaction, such as skin irritation/redness/burns, headache or other

painful sensation, or if you feel any unusual discomfort.

- If your condition does not improve, becomes chronic and severe, or continues for more than five days.

Note:
If you feel increasing pain, dizziness, discomfort or nausea, discontinue use and consult with your healthcare provider.

What type of pain is the device suitable for?

Electrotherapy works best on acute pain - pain in one local area less than 3 months. It is not suitable to address chronic pain - pain in more than one area lasting longer than 6 months. Chronic pain is usually caused by other issues that electrotherapy cannot address.

Note:
TENS does not cure any physiological problem. It only helps to manage pain. Using TENS to manage pain may not work for all users.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
The device does not power on.	The battery is exhausted.	Charge the device.
Electrical stimulation is weak or cannot feel any stimulation.	Electrode pad has dried out or is dirty.	Replace with new electrode pad.
	Electrode pad does not adhere to skin well.	Replace with new electrode pad.
Electrical stimulation is uncomfortable.	Intensity level is too high.	Decrease the intensity level.
	Device is not operated according to instructions.	Please read user manual before use.
Electrical stimulation is ineffective.	Improper electrode pad placement.	Reposition electrode pad.
	Unknown	Consult your healthcare provider.

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
The skin becomes red and/or you feel a stabbing pain.	Electrode pad is applied on the same site too often.	Reposition the electrode pad. If you feel pain or discomfort, discontinue use immediately.
	Electrode pad is not adhered to skin properly.	Ensure that electrode pad is securely adhered to skin.
	Electrode pad is dirty.	Clean electrode pad according to instructions in this manual or replace with new electrode pad.
	The surface of electrode pad is scratched.	Replace with new electrode pad.
Output current stops during electrotherapy.	Electrode pad detaches from skin.	Turn device off and reapply electrode pad. If necessary, replace with new electrode pad.
	The battery is exhausted.	Charge the device.

PRODUCT/BATTERY DISPOSAL

Used and fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electronic retailer. Please dispose of the device in accordance with local laws and regulations.

GLOSSARY OF SYMBOLS

Disposal in accordance with Directive 2012/19/EU (WEEE)

Type BF Applied Part (The applied part is the electrode)

Refer to Instruction Manual

SN Serial number

IP22 The first number 2: Protected against solid foreign objects of 12,5 mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.

Transportation and storage temperature from -10°C to 55°C

Transportation and storage humidity limits from 10% to 90%

Transportation and storage atmospheric pressure limits from 700 hPa to1060 hPa

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

- Use of accessories 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 result in improper operation.
- Use of this equipment 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.
- Portable RF communications 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 1

declaration - electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3

declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of device, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.7 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, [a] should be less than the compliance level in each frequency range.
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	

	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 to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast 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 in which device is used exceeds the applicable RF compliance level above, device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating device.

b Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and device, as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	0.15 MHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer

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.

FCC Compliance information

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with Part 15 of the FCC Rules. Operation is subject to the following 2 conditions:

- this device may not cause harmful interference, and
- this device must accept any interference received, including interference that may cause undesired operation.

NOTE: 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 provide reasonable protection 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 receiver.
- Connect the equipment into 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.

FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be colocated or operating in conjunction with any other antenna or transmitter.

WARRANTY

Please contact Innovo Medical in case of a claim under the warranty. The following warranty terms apply:

1) The warranty period for the device is 1 year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of a sales receipt or invoice.
2) Repairs under warranty do not extend the warranty period for the device or for the replacement parts.
3) The following is excluded under the warranty:
   - All damage due to improper use, e.g. nonobservance of the user instructions.
   - All damage due to repairs or tampering by customer or unauthorized third parties.
   - Accessories which are subject to normal wear and tear.
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.

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