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iTENS User Manual



body clock

Body Diagram Parameters - used to treat specific areas of the body. All parameters are pre-programmed, except for the intensity. The Body Part program has 11 different types of treatment parameters as follow:

NO.	Program	Frequency (Hz)	Pulse width (µS)	Total time (min)
1	Wrist pain	100	50	30
2	Elbow pain	1-100	50-300	25
3	Shoulder pain	4	200	30
4	Quadriceps	2-150	50-250	40
5	Mid/upper back pain	2-120	100-250	40
6	Low back pain	2-100	75-250	40
7	Abdominal cramping	2-30	100	25
8	Hip pain	2-80	100-150	30
9	Knee pain	5-150	50-150	25
10	Ankle pain	5-150	50-200	30
11	Hand/foot pain	2-150	200	30

FAQ's:

- Q Are there any side effects?**
A No, it is totally drug free. There are no known side effects.
- Q Can I use it with other medications?**
A Yes. TENS is drug-free so you can use it with any other medication including paracetamol and ibuprofen.

Troubleshooting

- Q Why does the pulse sensation not appear to be as strong after you have used the iTENS for a while?**
A Increase the intensity, you may have become acclimatised to a lower setting.
- Q Why does the pulse sensation feel strong but ineffective?**
A You may need to reposition the gel pads (don't forget to switch the iTENS off before doing so).
- Q What should I do if I can not feel any or little sensation even on a high intensity setting?**
A Check that the gel pads are fixed to the skin and also check that the unit is charged. Check if the gel pads need replacing.
- Q There appears to be a small amount of discolouration on my electrode wing. Is there something wrong?**
A No, this is perfectly normal. You may notice some small brown specks appearing on your electrode wing over time. It is a reaction which may occur between the electrode wing, the sticky pads and the natural oils found in your body. This will not diminish the effectiveness of the TENS stimulation. However, please be aware that the electrode wing is a consumable item and should be replaced up to every six months if used regularly.

Other Features

- When the intensity is set to zero or the iTENS has not been used 30+ minutes, the device will automatically shut down.
- When the unit is turned on, it will automatically remember the mode which was previously used.
- When switching between programs, the output level will automatically drop to zero.
- When the treatment timer is set, it will begin to count down one minute at a time. Once it counts down to zero, the unit will automatically shut down.
- When one or both electrodes are not placed firmly on skin, or they become loose from the skin, the output level will automatically drop to zero.
- The selected program will only run when the intensity is set above zero.
- The iTENS App can operate in the background of your phone or tablet enabling you to use it normally during treatment
- The treatment time will be accumulatively recorded when the output level is above zero. Other track and chart features need to be enabled in the settings section of the App.

Gel Pads

The pads that are supplied with your iTENS device are self-adhesive and can be used several times. Properly maintained gel pads can last up to 15 times. Your 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, covered with the protective liners and should be placed into the clear plastic poly bag, which should be resealed and kept closed afterwards.

After Use

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

iv) Favourite Mode

At any time you can save your favourite treatment via the home page, by pressing the 'STAR' button. Once pressed you can type and save the name of this program, which can be accessed at any time from the 'Favourite' Mode as found in the Programs section of the app (see page 8).

Once you have selected your 'Favourite' program, follow 'Commencing Treatment' section as found on page 9.

N.B 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 acclimatise to electrotherapy. You should experiment with your settings and placement of the wings to find the optimal treatment settings.

THE DOCUMENTS FOLDER

This can be accessed by pressing the 'book' symbol at the bottom of the App. This contains the Quick Start Guide, Full Instructions, Privacy Statement, EULA (End User License Agreement) and Electrode Placement Chart.

It is recommended that you view these to obtain the most out of your iTENS device.

Condition Program Parameters - used to treat based a specific pain condition with a pre-set modes except for the intensity level which is adjustable. The Conditions program has 15 different types of treatment parameters as follows:

NO.	Program	Frequency (Hz)	Pulse width (µS)	Total time (min)
1	Acute pain	3-100	50	30
2	Chronic pain	2-70	100-250	35
3	Muscle spasm relief	3-25	200	30
4	Muscle rehabilitation	1-25	200	35
5	Muscle stimulation	3-60	340	30
6	Sciatica	2-150	50-250	20
7	Epicondylitis	1-100	50-300	25
8	Post surgical pain	50-150	50-250	20
9	Neuropathy pain	1-120	50-100	30
10	Bursitis	70	150	60
11	Osteoarthritis	100	200	60
12	Rheumatoid Arthritis	70	200	60
13	Carpel Tunnel	5-100	50-200	20
14	Fibromyalgia	2-100	75-250	40
15	Tendonitis	1-100	50-300	25

THE SETTINGS FOLDER

This can be accessed by pressing the 'Cog' symbol at the bottom of the App.

- Rename**
 - Rename** - This is where you can personalise the name of your iTENS device. Select 'Rename' and type the required name then press 'OK'.
- Track cumulative usage time**
 - Track cumulative usage time** - You can view the length of time you have used your device in this section. To reset, press the 'Reset' button.
- Track your result**
 - Track your result** - Here you can enable or disable the "track your results" settings. By enabling this function, you will be prompted to enter your pain level before and after your treatment. You can select this by sliding the purple ball back and forth to determine your pain level for before and after treatment.

- Chart your results**
 - Chart your results** - Here you can chart and record your results and measure the benefit of using the iTENS device.

Other data points regarding your therapy sessions will begin to be tracked as well. Tracking can be disabled whenever needed.

N.B There will be no data initially.

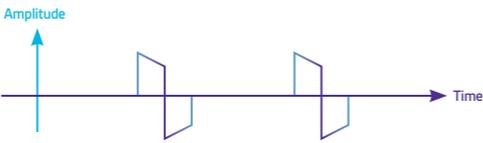
Specifications

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

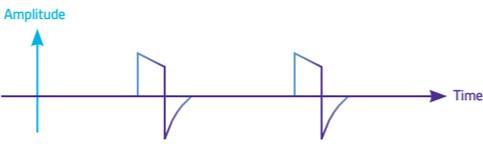
A. Waveform

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

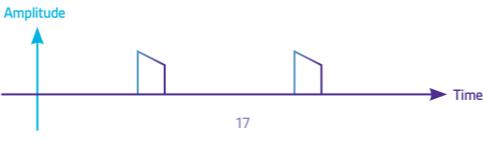
- Symmetrical Bi-Phasic rectangular waveform**



- Asymmetrical Bi-Phasic rectangular waveform**



- Mono-Phasic waveform**



- Pulse Width** - adjustable in manual mode.

By clicking area above and below the center button, or +/- in the app, the pulse width can be adjusted from 50µS to 250µS in step of 10µS.

- Pulse Frequency** - adjustable in manual mode.

By clicking area above and below the center button, 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.

- Output Voltage Range** - adjustable in all modes.

Model:	iTENS
Channel:	Single
Output:	Max 130 mA (peak value) across 500 Ohm load
Pulse Width:	From 50µS to 250µS adjustable
Pulse rate:	From 1Hz to 150Hz adjustable
Waveform:	Symmetrical Bi-phasic rectangular Asymmetrical Bi-phasic rectangular Monophasic rectangular
Treatment timer:	15, 30, 45, 60min, unlimited
Mode:	Body Diagram Conditions Manual mode

Information related to Electro-Magnetic Compatibility (EMC)

The iTENS unit is designed to be used in typical domestic or clinical environments and approved according to the EMC standard of EN 60601-1-2.

The iTENS unit emits very low levels in the radio frequency (RF) interval. Therefore it is not likely to cause any interference to your nearby electronic equipment such as a radio, computer or telephone etc. A small distance of approx. 3.3 meters is recommended to avoid any such interference.

The iTENS unit is designed to withstand foreseeable disturbances originating from electrostatic discharges, mains supply magnetic fields and radio frequency transmitters (such as mobile telephones).

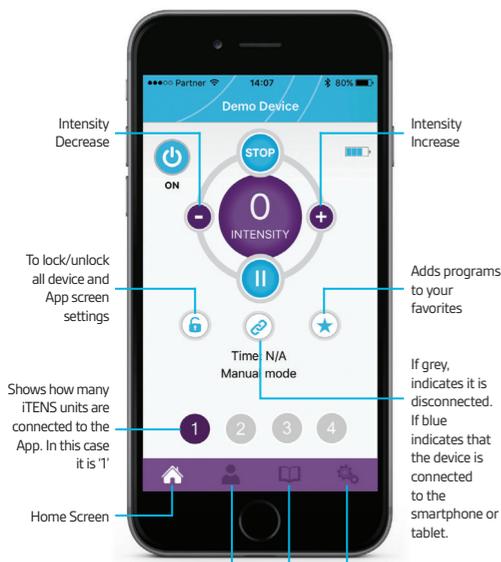


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Button Description on the App



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Explanation of Symbols on Unit



Equipment providing a particular degree of protection against electric shock particularly regarding allowable leakage currents having an F type (floating) applied part.



Warning - refer to page 3 of these instructions.



Please keep device away from sprays of water or rain.

IP22

The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12mmø, 80mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5mmø and greater.
The second number 2: 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.



Denotes a product which must be disposed of safely.



This symbol indicates the serial number of the device and includes the year of manufacture.
The serial number can be found on the base of the charging station.



EMC information can be found on page 19.

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Foreword

Read this manual before using your iTENS device. Body Clock strongly recommends carefully reading the Contraindications, Precautions and Warnings and subsequent chapters of this manual before use.



Contraindications:

- Do NOT use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device.
- 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.
- Do NOT use the iTENS device during pregnancy unless under medical supervision.
- Since the effects of stimulation of the brain are unknown, do NOT apply stimulation across your head, and electrodes should not be placed on opposite sides of your head.
- Do NOT place electrodes on the front or side of the 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.
- If you are in the care of a physician, consult your physician before using this device.
- If your pain does not improve, becomes more than mild, or continues for more than five days, stop using the device and consult your physician.
- If you suffer from any undiagnosed pain, have any metal implants or any doubts whatsoever do NOT use the iTENS and consult your medical adviser.
- Never use iTENS to mask undiagnosed pain as this could require urgent treatment.

General Precautions & Adverse Reactions

- Do NOT use this unit without first reading these instructions.
- Do NOT immerse the iTENS in any liquid and do NOT apply stimulation when in the bath or shower.
- Do NOT place it close to any source of excessive heat or operate it in the presence of flammable gas.

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- Do NOT drop this unit onto a hard surface.
- Do NOT attempt to dismantle the iTENS.
- Only use the specified charger unit and gel electrodes.
- If damaged, do not use. Return to supplier.
- Switch off the unit when not in use.
- Do NOT apply stimulation while sleeping.
- Do NOT use while driving or operating potentially dangerous machinery or during any activity in which electrical stimulation can put you at risk of injury.
- Do NOT use in close proximity (e.g. 1m) to shortwave or microwave therapy equipment to avoid instability in the stimulator output.
- Do NOT apply stimulation in the presence of electronic monitoring equipment (such as ECG monitors and ECG alarms), which may not operate properly when iTENS is in use. Portable and mobile RF communications equipment can affect medical electrical equipment. Operation of the equipment or system below this amplitude or value may cause inaccurate results.
- Do NOT use adjacent to or stacked with other equipment.
- Do NOT use the device on children, if it has not been evaluated for paediatric use.
- Do NOT place electrodes across the head, directly or near the eyes, covering the mouth, on the front or sides of the neck (especially the carotid sinus), on the chest and upper back so as to cross over the heart, directly over your heart or an area of broken, inflamed, infected or numb skin.
- The gel electrodes should only be applied to skin with normal sensation unless under medical supervision since skin irritation could occur following long term application.
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

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THE PROGRAMS FOLDER

Access the treatment programs in your App by pressing the 'head and shoulders' symbol at the bottom of the Home Screen. All unused symbols are dark purple. When in use they become white. From here you can select one of the following four settings:

- 'Body Part' - for specific body part treatments
- 'Condition' - select treatment based on your specific pain condition
- 'Manual Mode' - to create a custom setting
- 'Favourite' - saves your favourite setting(s), which you can name and access from the 'star' symbol on the Home Screen (see page 11 for more details)

It is highly recommended to experiment with the different settings to find your optimal program.

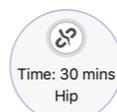
i) Body Part

Once selected, this mode enables you to choose a TENS treatment program associated with 11 different body parts (see page 15 for a list of these).

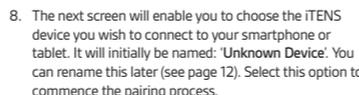
Simply scroll to your preferred body part by using the arrows on the screen and press 'Select Program'. This will return you to the Home Screen where you can commence treatment.

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is indicated by the small 'HOUSE' sign at the bottom of the screen.



Press the 'broken' chain link icon on the Home Screen to search and pair with all available iTENS devices. Initially this icon link will be greyed out.



You should now see a solid blue light on the button of the iTENS device.

You will automatically be returned to the Home Screen of the App which will now show a 'complete' chain icon and it will be coloured blue.

The 'ON' button will also be highlighted in blue.

N.B the iTENS device is capable of connecting up to 4 devices at one time. Each number at the bottom of the Home Screen represents how many devices are connected to your smartphone or tablet (see page 5).

10. Your device is now ready to use. Before removing the remaining layer of film on the electrodes from the electrode wing, you will need to choose your desired treatment and pad placement. This can be done in four ways on your iTENS device. The 'THE PROGRAMS FOLDER' section will describe how to do this (see page 8).

11. After using the iTENS for the first time (or any time), in order for it to stay paired to your device, you should switch the iTENS off via the app.

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- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- This is an internally powered medical electrical equipment. Do not use power sources other than those specified in these instructions.
- Warnings**
 - Mild temporary skin irritation can occur following long term application. Simultaneous connection by the user to a high frequency surgical medical electrical equipment may result in burns at the site of the electrodes and equipment. Users should seek advice from their medical advisors when use of this equipment is required.
 - Ensure that the device and all accessories are stored away safely out of the reach of children and babies at all times. Keep out of the reach of children and babies.
 - It is unsafe to use accessories, detachable parts and materials not described in these instructions for use. Please see www.bodyclock.co.uk for suitable accessories or contact us if you require any spare parts on +44 (0)20 8532 9595.
- Do NOT interconnect this device with any other equipment not described in these instructions for use.
- Do not modify this equipment in any way.
- The iTENS is not user repairable and must be returned to the manufacturer if it requires repair.
- This unit needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided on page 20.



Warnings

- Mild temporary skin irritation can occur following long term application. Simultaneous connection by the user to a high frequency surgical medical electrical equipment may result in burns at the site of the electrodes and equipment. Users should seek advice from their medical advisors when use of this equipment is required.
- Ensure that the device and all accessories are stored away safely out of the reach of children and babies at all times. Keep out of the reach of children and babies.
- It is unsafe to use accessories, detachable parts and materials not described in these instructions for use. Please see www.bodyclock.co.uk for suitable accessories or contact us if you require any spare parts on +44 (0)20 8532 9595.



Environmental Conditions

- 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% RH

If you have any concerns please do not hesitate to contact Body Clock Health Care Ltd on +44 (0)20 8532 9595 or at sales@bodyclock.co.uk

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Instructions for Use

Your iTENS is simple to use and offers a wide variety of settings ideal for acute and chronic pain relief.

Pack Contents

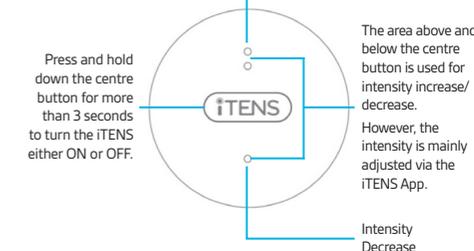
Your iTENS pack should contain the following:

- 1 x iTENS device
- 2 x Peel-n-Stick Adhesive Gel Pads
- 1 x Resealable poly bag for storing electrode wings
- 1 x Set of iTENS electrode wings
- 1 x iTENS charging station
- 1 x iTENS USB charging cable
- Quick Start Guide
- User Manual

Having checked that all of the contents are present and correct, please proceed to assembling the unit.

Operating the iTENS

On-device settings:



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Commencing Treatment

Now remove the extra layer of film on the sticky pads of your iTENS device and attach it to the desired body part. Retain the film for storage.

Commence your treatment by increasing the intensity + button. Decrease the intensity by pressing the - button.

As you increase the intensity, you will feel a mild tingling sensation. Adjust intensity to a level that is comfortable but not overpowering.

N.B Each of the 11 'Body Part' programs have different treatment times. Please refer to page 15 for a list of these.

ii) Condition Mode

Once selected, this mode enables you to choose a TENS treatment program associated with 15 different pain conditions (see page 13 for a list of conditions and treatment times).

Now follow the 'Commencing Treatment' section as above.



iii) Manual Mode

This mode enables you to create a specific TENS setting where you can adjust the Pulse Rate, Pulse Width, the Waveforms and Treatment Time according to your requirements.

Manual mode settings

- B - stands for Burst Mode (a rise and fall of impulses. Typically used for short term therapy sessions)
- C - stands for Continuous Mode (a constant level of impulses. Typically used for short or long term therapy sessions)
- M - stands for Modulation Mode (a ratio of impulses such that your body doesn't adjust to the stimuli. Typically used for long term therapy sessions)

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 the stimuli.

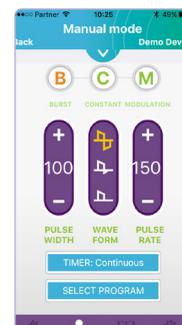
Wave Form - addresses different main conditions in more effective manners, e.g. mono-phasic wave is best for pain in the extremities.

Timer: Chooses between 15, 30, 45, 60 and continuous minutes.

Once you have selected your parameters by choosing them on the screen press 'Select Program'. You will now return the Home Screen.

N.B Review page 17 for a more detailed explanation of these parameters.

Now follow the 'Commencing Treatment' section as found on page 11.



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