i-Pulz

User Manual

USER MANUAL

Read this manual carefully before using the i-Pulz TENS device and keep to the instructions of your doctor or specialist.

Table of contents

1 Safety information, maintenance and defects

1.1 Use of the device
The i-Pulz is an external stimulator used for pain treatment among people suffering from chronic and acute pain. Do not use the nerve stimulator for other purposes. Use it only with permission from a medical specialist.

1.2 Precautions

- Make sure the nerve stimulator does not get hit, falls or is used inappropriately to avoid it getting damaged.
- Check the nerve stimulator and cables for any inconsistencies before using it.
- Do not use the nerve stimulator when driving or controlling heavy machinery.
- Always check if the nerve stimulator is switched off before removing or placing electrodes.

1.3 Indications

TENS can be used for many purposes. Both acute and chronic pains can be treated with TENS. In general, TENS can be used with:
- Neurological pain, like neuralgia, blunt pain and phantom pain
- Muscle- and joint pain, like rheumatic, lower-back pain, neck- and shoulder pain, etc.
- Postsurgeon and posttraumatic pain
- Angina Pectoris
- Facial pain
- Circulationdisorders
- Delivery pain
- Complex Regional Pain Syndrome, CRPS type I and II
- Scar tissue pain
- Certain bone fractures

1.4 Contra-indications

At this moment there are no contra-indications, either short term, or long term. Caution: Electrodes, gel or patches can cause an allergic reaction.

1.5 Warnings

- Patients with a pacemaker: the nerve stimulator can influence the workings of the pacemaker.
- Never stimulate the nerves of the jugular vein (the area of the sinus caroticus), on the eyes or in the mouth.
- Simultaneous use of the nerve stimulator and surgical devices operating on a high frequency can cause burns where the electrodes are placed on the skin.
- Use of the nerve stimulator in the range of shortwave or microwave equipment (cellular phone or microwave) can cause fluctuations in the output of the nerve stimulator.
- The functioning of electronic monitors, like ECG equipment, can be disrupted when the nerve stimulator is activated.
- Never use the nerve stimulator for purposes not described in this manual.
- Keep the nerve stimulator out of reach from children.
- Only use the nerve stimulator on account of a medical prescription; never lend out your TENS device.
- Do not place electrodes on damaged or irritated skin.
- Do not use electrodes with a smaller surface than 5 cm².
- Irritation of the skin can be caused by "lengthy" use of small electrodes and/or an electric current that is too high.
- Do not use on the skull area.

1.6 Maintenance

The i-Pulz stimulator requires little to no maintenance. If needed, clean the device with a damp cloth. Never use aggressive detergents like ether, alcohol or abrasives.

Never submerge the device in water or in any other liquid. In case it does get submerged, get the device checked by the manufacturer or distributor before you use the i-Pulz again.

The manufacturer advises a technical check up of the device every 5 years.

You can clean the cables with a damp cloth. The use of aggressive detergents is not advised, because the cables can get damaged or rigid, which increases the likelihood of the cables breaking.

Store the nerve stimulator and its accessories in the original casing.

1.7 Maintenance of the batteries
Remove the batteries from the device if you do not intend to use it for an extended period of time. This will improve the longevity of the batteries.

1.8 Battery charger
The supplied charger can charge rechargeable AA batteries and rechargeable AAA batteries. Place 2 or 4 batteries in the charger and plug it into the wall socket. The lights on the charger will illuminate as follows:

LED	Description
Light burns red	Batteries are being charged
Light blinks red	Batteries are defect or not placed in charger correctly
Light burns green	Batteries are fully charged

i-Pulz batteries will be charged within 2 hours.
When the batteries are fully charged, you must remove the charger from the wall socket before removing the batteries.

Warning: do not place non-rechargeable batteries in the charger - this may cause leakage in those batteries which may release dangerous chemicals.

When using rechargeable batteries, keep in mind the following points:
- Rechargeable batteries are sensitive to over-charging. Remove the batteries from the charger after the incidated time has passed.
- Rechargeable batteries have an electric discharge that strongly depends on the temperature of the environment.
- New rechargeable batteries need a few charging-cycles in order to reach their nominal capacity.
- Rechargeable batteries (NiMH) must be charged at least once per 6 months.

- The average life expectancy of rechargeable batteries is usually 500 charging-cycles, though this strongly depends on its use. The total capacity of the battery will slowly decrease after multiple charging-cycles.

1.9 What to do in case of a defect

Repairs, expansions or alterations to your nerve stimulator should only be done by the manufacturer or distributor.

Manufacturer	Distributor
Rehan Electronics Aughrim Road Carnew Co-Wicklow Ierland Tel: 00353-53-9426742 Fax: 00353-53-9426051	

2. The i-Pulz nerve stimulator

2.1 General

The i-Pulz is a two-channel nerve stimulator. There is a channel on the left- and right side of the device. Both channels work independently from each other and do not influence each other – two different forms of stimulation can therefore be used simultaneously. You can also use just one channel.

The i-Pulz has 10 standard stimulation programs (indicated by P1 to P10). It is also possible to adapt special user programs and to mask them (render invisible). The i-Pulz will always start with the last used preset and, if set, the timer function as well.

2.2 Controls

When you flip open the i-Pulz nerve stimulator, the buttons and the display will become visible. All presets or settings are selectable and controllable by pressing these buttons. Presets, intensities and other settings are visible on the display.

channel

screen

clip

screen

left channel

right channel

up, left

up, right

down, left

down, right

battery compartment

on/off

mode

timer
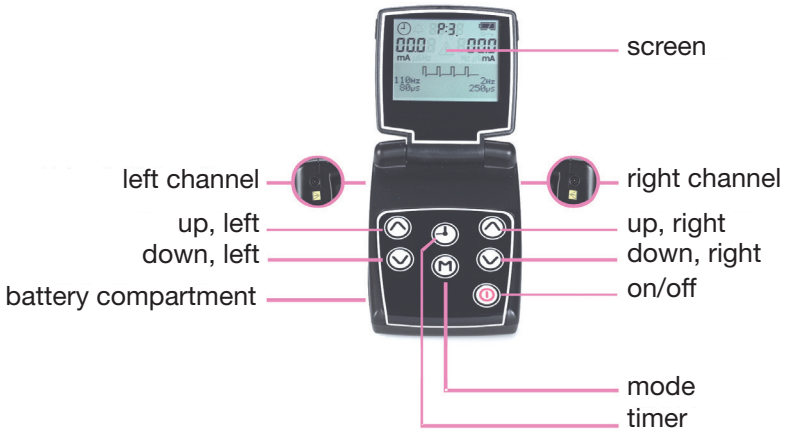
2.3 Buttons

2.3.1 On/off
Press this button to switch the stimulator on or off.

2.3.2 Mode
Pressing this button (multiple times) will select a program. In case of an active program (output currents > 0mA), it is possible to reduce the current to 0 immediate by pressing this button.

2.3.3 Timer
Pressing this button enables you to set a timer for the program. Press the timer button (multiple times) to set up the desired time (ranging from 0 to 90 minutes). The timer is switched off when 4 horizontal lines are visible on the display. The timer logo in the upper left corner of the screen, which usually indicates that the timer is activated, will disappear as well. Timer adjustments can only be done if both channels are set to 0mA.

2.3.4 Up / down
Pressing these buttons allows you to control the intensity. The buttons on the right-hand side of the device control the right-hand side channel and vice versa. These buttons can also be used to set other parameters of the device (see chapter 4).

2.4 The display
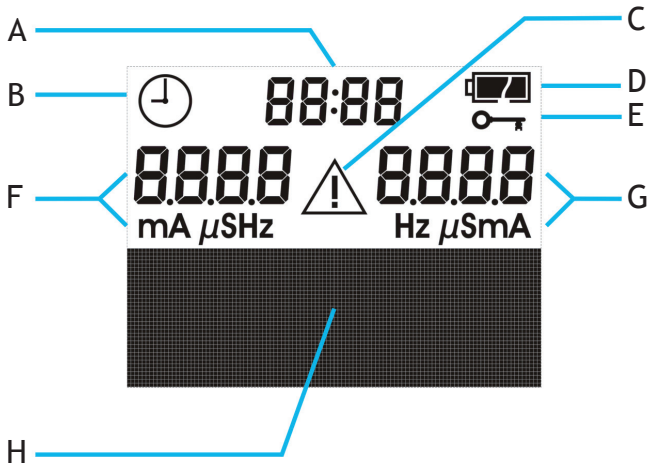
A - Preset number / (remaining) time
B - Timer
C - Check the user manual
D - Battery indicator
E - Keypad lock
F - Intensity display left channel
G - Intensity display right channel
H - Graphic section

A - Preset number / (remaining) time
The program number will be displayed here. After setting the intensity, the timer will countdown to 0 minutes (if activated). The semi colon between the "P" and the program number will blink each second.

During the therapy it is possible to show the remaining minutes of the therapy by pressing the Timer button.

B - Timer
When the clock-icon is visible, the timer is active.

C - Check the user manual
When this icon is displayed please read the manual for further instructions (see chapter 3.3).

D - Battery indicator
This icon indicates the capacity of the battery and is displayed in 3 steps (full, half full and empty).

E - Keypad lock
If the buttons aren't pressed after setting up the intensity, the keypad lock will activate after 15 seconds. This is to prevent any accidental increase in the current. The key-icon indicates that the lock is active.

Press the intensity-down button once (of the channel in use) to cancel the keypad lock.

F - Intensity display left channel
The display shows the set intensity.

G - Intensity display right channel
The display shows the set intensity.

H - Graphic section
This section is used to clarify the presets used. Every preset has a graphic representation of the TENS waves being used. See chapter 4 for device options and other display menus.

2.5 Clip
On the rear side of the device you can find an attachment clip. With this clip you can easily attach the device to your trousers, skirt or belt. The hole in the clip can be used to attach the device to a key-chord or something similar.

2.6 Battery compartment

The left hand side of the device contains a compartment where the batteries can be inserted into the device. Be careful that during insertion of the batteries their polarity is consistent with the + and – sign on the compartment. When sliding the compartment into the device, a clicking sound will indicate that the compartment is closed.

release

The latch to release the battery compartment can be found on the rear side of the device. Press your finger on the latch until the compartment is ejected.

3. Starting the treatment

For the daily use of the device there are the following steps:
- Cleansing of the skin
- Placing of the electrodes
- Setting up the stimulator
- Treatment period
- Stopping the daily treatment period
- Removing the electrodes
- Skin care

3.1 Cleansing of the skin

It is important that you give the proper care to your skin. Cleaning your skin properly will ensure good contact with the electrodes and will help you to prevent irritation to the skin. It is advised that you remove all body hair on the location where the electrodes are to be placed, as they may cause irritation. To ensure that the electrodes stick to your skin properly, please make sure that your skin is not oily or greasy. Furthermore, the electrodes and patches will be easier to remove.

3.2 Placing of the electrodes

Keep to the instructions of your doctor or specialist when placing the electrodes.

Follow the instructions on the packaging of the electrodes or on its user manual.

3.3 Setting up the stimulator
After the electrodes are placed properly, you can activate the device. The device starts up with the program you used last. During the trial period you and your doctor/specialist have decided which program(s) is best suited for you.
In the back of this manual you will find a summary of the standard programs.

Every time you press the MODE button the next program will appear (it is an ongoing list, you will reach your starting position eventually).

Check if the timer is set properly. By default, the timer is set to 30 minutes per program, unless your doctor or specialist has altered this. The timer you set for a program will be saved and used automatically when you select that program again.

After you have selected the desired program, you can set up its intensity. Pressing the Up-button briefly will increase the intensity in small steps of 0,5mA. When you keep the up-button pressed, the intensity will increase faster.

Caution: for safety regulations it is not possible to increase the intensity beyond 20mA when keeping the Up-button pressed. Only when you release the button briefly you can increase the intensity again, but only 10mA per time.

If there is no or limited connectivity between the device and your skin, you are able to set up the intensity to a maximum of 7.5mA. If you try to go beyond the 7.5mA, the device will produce a beeping sound and the intensity will be reduced to 00,0 mA. You will also see a warning sign on the display. This problem is caused by the cables or electrodes. Check that the cables and electrodes are properly connected and if necessary replace them.

> If you are only using 1 channel, e.g. the left channel, you should use the left Up / Down button.

If you have finished setting up the intensity, the automatic key lock will activate after 15 seconds. The keypad will be activated again by pressing the Down-button once.

An overview of all available programs can be found in the back of the manual at the technical specifications.

3.4 Treatment period
Regarding the treatment period you must strictly adhere to the instructions from your doctor or specialist. If you need a longer treatment period, you should discuss this with your doctor or specialist before changing your stimulation patterns.

Close the flip of the device during treatment to prevent any damage to the display.

3.5 Stopping your daily treatment
If you have activated the timer, the i-Pulz stimulator will switch off automatically after the treatment has run its course. You can also stop the program manually by pressing the MODE button or by tuning down the stimulation until it reaches 00,0mA. When the current reaches 00,0mA the device will switch off after a few minutes in order to pre-

serve the batteries. The device can also be switched off by pressing the On / Off button.

3.6 Removing the electrodes

Pay attention: Always switch the device off before removing electrodes!

When removing the electrodes, follow the instructions on the packaging of the electrodes.

3.7 Taking care of your skin

After you have removed the electrodes you can carefully clean your skin with a mild soap. Never use aggressive substances like ether or alcohol to remove any adhesive residues.

After the skin is cleaned, a red mark from the patches and/or electrodes may be visible on the skin. This reaction usually disappears quickly.

3.7.1 Irritation of the skin

Despite all the precautions, it is possible that you experience irritation of the skin. Many skin creams take good care of your skin but are, unfortunately, not compatible with nerve stimulation therapy. Most skin creams are oily or greasy, which may impair the flow of the current onto your skin. We advise you to use a special TENS cream that does not contain any oils or perfumes. This cream is especially designed for this kind of stimulation and does not impair it in any way.

Irritation of the skin can only be solved temporarily by using a cream. However, the cause of this irritation, being overly sensitive for a specific type of material, is not changing. If you experience persistent irritation of your skin when using the nerve stimulator, please contact your distributor.

4. Advanced options and setup possibilities
4.1 General

Pressing the MODE button when starting up will activate the advanced options and setup possiblities.

The advanced mode has been activated when you the device information is visible on the screen (such as the serial number).

Using the right Up / Down button it is possible to select different items in the menu. Pressing the Mode button will (de)activate an item in the menu. With the left Up / Down button you can change the set up which are immediately stored in memory.
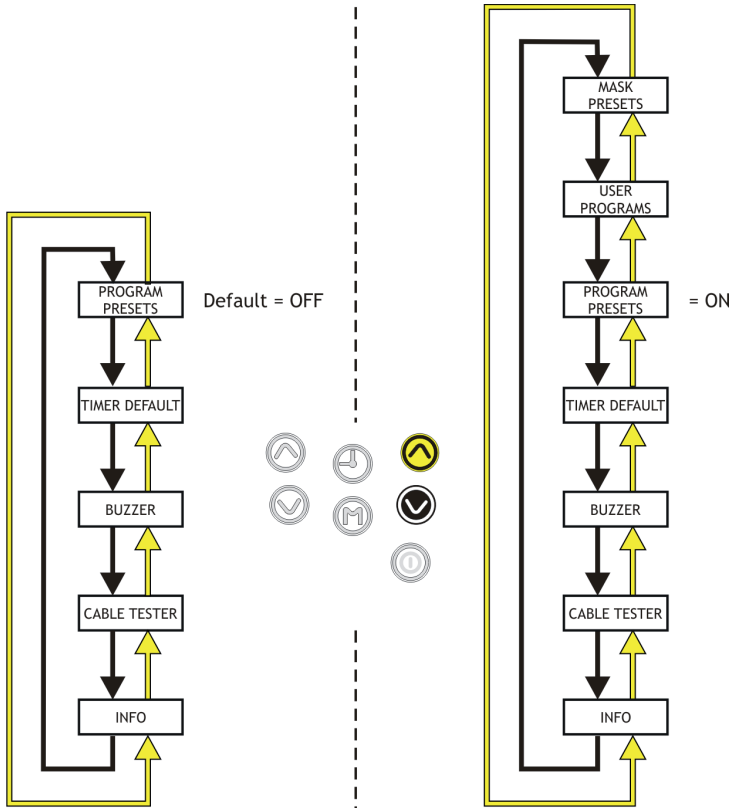
Switch off the device to exit the advanced mode.

4.2 Menu Options
4.2.1 Device information
This data may be requested by the manufacturer or distributor if you report a defect or problem.

4.2.2 Cable tester
Connect the supplied cable(s) to the device without connecting the electrodes. For both channels, the text OPEN will be displayed on the screen. You can now test the cable by pressing the 2mm pins together. The text on the display will change from "OPEN" to "CLOSED" on the side of the device where you are testing the cables. You will hear a beeping sound when the cable is functioning. This means that the cables are functioning properly.

If this is not the case, and the text OPEN remains on the screen, this indicates that the cable is defect and must be replaced. Please contact your distributor for a new set of cables.

4.2.3 Buzzer
This option allows you to switch the sound on or off that is heard when the i-Pulz is switched on.

4.2.4 Default timer
The interval size with which you can set the timer is 10 minutes by default. This interval size can be changed to 1, 5, 10, or 15 minutes.

4.2.5 Program presets
The program presets are generally switched off. After activating this option, 2 extra menu items will be added to the menu: User Programs and Mask Presets. These menu options allow you to modify and mask the programs.

To activate program presets, make sure you see the text PROGRAM PRESETS on your display. Select it with the Mode button. You will now see the text OFF on your display. Use the left up / down button to change this to ON. De-select the option with the Mode button.

Program presets is now activated and you can access the user programs and mask presets options.

4.3 User Programs

This mode allows you to adapt the user programs. These are saved under U1 – U10, which correspond to the default programs P1 - P10.
It is also possible to combine these presets with the standard conventional TENS wave.

> With combined TENS programs, the standard TENS pulse (conventional TENS) always flows from the right channel.

The right hand side Up / Down button are used to select the preset.
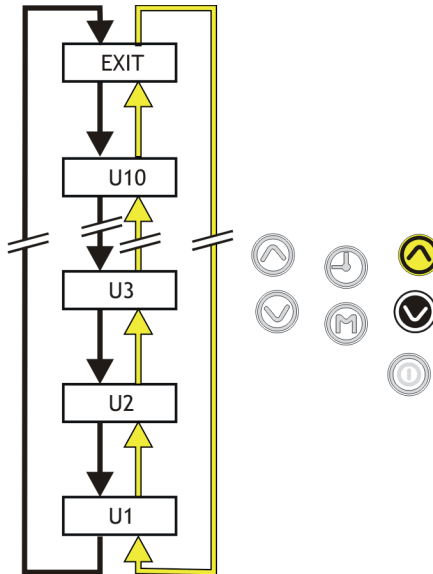
> Use the right hand side Up / Down button to select "EXIT" in the menu to return to the main menu.

The left hand side Up / Down buttons are used to change the settings and parameters.
Pressing the Mode button allows you to select the parameter.

> User programs (U1-U10) are hidden by default, so you need to "unmask" them first before use. See chapter 4.4 for details.

On the following pages you can find several ways to set up your User Programs (U1-U10).

User Program U1			
Step	Parameter	Adjustments	Description
1	Pulsewidth	30..300 µS	
2	Frequency	1..175 Hz	

User Program U2			
Step	Parameter	Adjustments	Description
1	Pulsewidth	30..300 µS	
2	Frequency	1..175 Hz	

User Program U3			
Step	Parameter	Adjustments	Description
1	Pulsewidth	30..300 µS	left channel
2	Frequency	1..175 Hz	"
3	Pulsewidth	30..300 µS	right channel
4	Frequency	1..175 Hz	"

User Program U4			
Step	Parameter	Adjustments	Description
1	Pulsewidth	30..300 µS	phase 1
2	Frequency	60..175 Hz	"
3	Duration	1..10 sec.	"
4	Pulsewidth	30..300 µS	phase 2
5	Frequency	1..20 Hz	"
6	Duration	1..10 Sec.	"

User Program U5			
Step	Parameter	Adjustments	Description
1	Pulsewidth	30..300 µS	phase 1 (left channel)
2	Frequency	60..175 Hz	"
3	Duration	1..10 sec.	"
4	Pulsewidth	30..300 µS	phase 2 (left channel)
5	Frequency	1..20 Hz	"
6	Duration	1..10 sec.	"
7	Pulsewidth	30..300 µS	right channel
8	Frequency	1..175 Hz	"

User Program U6			
Step	Parameter	Adjustments	Description
1	Pulsewidth	30..300 µS	
2	Amount of pulses	2..25	
3	Select combi-TENS	yes/no	If yes, go to step 4, 5
4	Pulsewidth	30..300 µS	right channel
5	Frequency	1..175 Hz	"

User Program U7			
Step	Parameter	Adjustments	Description
1	Frequency	1..175 Hz	
2	Select combi-TENS	yes/no	If yes, go to step 3, 4
3	Pulsewidth	30..300 µS	right channel
4	Frequency	1..175 Hz	"

User Program U8			
Step	Parameter	Adjustments	Description
1	Pulsbreedte	30..300 µS	
2	Select combi-TENS	yes/no	If yes, go to step 3, 4
3	Pulsewidth	30..300 µS	right channel
4	Frequency	1..175 Hz	"

User Program U9			
Step	Parameter	Adjustments	Description
1	Amount of pulses	2..10	
2	Select combi-TENS	yes/no	If yes, go to step 3, 4
3	Pulsewidth	30..300 µS	right channel
4	Frequency	1..175 Hz	"

User Program U10			
Step	Parameter	Adjustments	Description
1	Pulsewidth	30..300 µS	
2	Frequency	60..175 Hz	
3	Upward phase	0,5..2,5 sec.	
4	Stimulation duration	0..10 sec.	
5	Downward phase	0,5..2,5 sec.	
6	Break	0..10 sec.	
7	Select combi-TENS	yes/no	If yes, go to step 8, 9
8	Pulsewidth	30..300 µS	right channel
9	Frequency	1..175 Hz	"

4.4 Mask presets

Using this menu option you can (un)mask every program. This option can be activated to simplify the use of the device if desired.

With the right hand side Up / Down button you can select the program. Using the left hand side Up / Down button the mask can be applied or removed.

On = program is visible
Off = program is masked (invisible)

> If all presets are masked, P1 will remain visible during normal use.

5. Accessories

5.1 Cables
2 cables will be supplied with the device. Please contact your distributor if the cables need replacing.

5.2 Batteries and charger
The i-Pulz uses 2 rechargeable AAA batteries. Use an appropriate charger to charge your batteries. See your charger's instructions for the required charging time for the batteries.

5.3 Removing adhesive residues
Sometimes it may be difficult to remove the adhesive residues from your skin from the patches or electrode gel. Using a special cream you can remove these residues. This cream is especially designed for this purpose and does not contain aggressive substances like acetone or alcohol.

5.4 Treating the irritated skin

Should any skin irritation appear when using the nerve stimulation therapies, it can be treated effectively with a special TENS cream. This cream helps to reduce irritation and allows the skin to recover quickly. This cream does not harm the electrodes and does not interact with the flow of the currents through the skin.

5.5 Disposable electrodes

Disposable electrodes are ready-to-use, adhesive, disposable electrodes that consist of a patch and an electrode that comes with a layer of gel. Due to this ready-to-use system, these electrodes are easy to place. They are meant for single use and to be disposed afterwards.

5.6 Reusable electrodes

Reusable electrodes are ready-to-use, adhesive electrodes that can be used multiple times. There are a several types of reusable electrodes, each with different sizes and gels. Depending on the circumstances and the type of allergy, a specific kind of electrode can be selected. Because these electrodes do not contain any patches, they are remarkably mild to the skin. However, the effectiveness of the adhesive is less than with disposable electrodes.

6. Contents of package

The i-Pulz stimulator is supplied with the following accessories:
- i-Pulz nerve stimulator
- Set of cables
- Charger
- Batteries
- User manual

7. Technical information

Number of channels: two, independent, adjustable intensity
Pulstype: Asymmetric block, square wave-form two phased without a direct-current component.
Intensity: 0-70mA, current source, continuously inter-changeable (<15% tolerance with an intensity between 500 and 1k ohm)
Frequency: 1-175Hz <10% tolerance
Pulsewidth: 30µS - 300µS <10% tolerance
Feed: 2 rechargeable batteries, type AAA, 900mAh Ni-MH
Dimensions: 78x59x28mm
Weight: 91 grams   (without battery)
115 grams   (including battery)

Conditions of use:
Temperature: +5°C to +35°C
Air humidity: <70%, no condensation
Storage and transport conditions:
Temperature: +0°C to +50°C
Air humidity: <90%, no condensation

$C \epsilon$ **0120** This product adheres to Directive 93/42/EEG of the Council of 14 June 1993 concerning medical supplies. Part of type BF.

The device offers, under permitted leakage current, protec tion against electric shocks.

The serial number of the device consists of 6 numbers. The first 2 numbers represent the year of production, and the other 4 numbers represent the device's number.

Manufacturer
Rehan Electronics Aughrim Road Carnew Co-Wicklow Ierland Tel: 00353 53 9426 742 Fax: 00353 53 9426 051
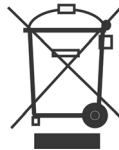
Do not throw this product into the bin. Please ask your city council's environmental department about the proper ways to dispose of this product.

8. Program overview

	Stimulation	Frequency (Hz)	Pulse duration (µS)	Extra information
P1	Conventional TENS	110	80	
P2	Low frequency TENS	2	250	
P3	Combination conventional and low frequency TENS	110	80	left channel (P1)
		2	250	right channel (P2)
P4	HAN	100	150	phase 1 / 3 seconds
		2	200	phase 2 / 3 seconds
P5	HAN combination	100/2	150/200	left channel (P4)
		110	80	right channel (P1)
P6	Burst	100	180	8 pulses, 2x per sec.
P7	Pulsewidth modulation	110	60 tot 100	1 sec. from min. to max.
P8	Frequency modulation	2 tot 100	80	5 sec. from min. to max.
P9	Depth TENS	3.636k	75	4 pulses, 100x per sec.
P10	Muscle stimuation	100	150	ramp up: 1 sec.
		100	150	stimulation: 4 sec.
		100	150	ramp down: 1 sec.
				pause: 3 sec.

9. Important information regarding EMC

9.1 General

Electronic devices such as portable and mobile RF-communication devices and medical devices can be sensitive for electromagnetic interference of similar devices. This malfunction may lead to faulty functioning of the medical device, causing a potential unsafe situation. Also pay attention that the medical device may not cause interference with other devices.

Keeping an eye on the requirements to regulate EMC with the purpose of preventing unsafe product situations, the EN50501-1-2 norm has been implemented. This standard defines the rate of immunity for electromagnetic interferences and the maximum electromagnetic radiations for medical equipment.

The i-Pulz is manufactured by Rehan Electronics Ltd and adheres to the EN60601-1-2 norm, for both immunity and emission.
Nonetheless certain precautions must be taken:

The 2 cables of 1,2 meter (Rehan part number 200-01-0044) that are supplied with the device ensure the connection between the i-Pulz and the electrodes. The use of cables other than those supplied can lead to a larger emission or decreased immunity of the device.
The i-Pulz contains no parts that can be replaced by the user, and unauthorized repairs can lead to increased emission or reduction of immunity of the device.
The medical device may not be used alongside of or toghether with other devices. Should this be necessary, it must be confirmed that the i-Pulz is functioning normally in the configuration that the device is being used in.
There are no known cases where the device creates an unacceptable risk for the patient/user when an error should occur in the device.
For further directions regarding the EMC-environment in which the device should be, you can find more information in tables 1 to 4 below.

9.2 Emissions Guidance for Users

Guidance and Manufacturer's declaration-electromagnetic emissions		
The i-Pulz (ES-2) is intended for use in the electromagnetic environment specified below. The customer or the user of i-Pulz (ES-2) should assure that it is used in the following environment:		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR11	Group 1	The i-Pulz (ES-2) 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 CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	The device is battery powered
Voltage Fluctuations / Flicker emissions IEC 61000-3-3	Not applicable	The device is battery powered

9.3 Immunity Guidance for Users

Guidance and Manufacturer's declaration-electromagnetic immunity			
The i-Pulz (ES-2) is intended for use in the electromagnetic environment specified below. The customer or the user of i-Pulz (ES-2) should assure that it is used in the following environment:			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be made of 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	Not applicable	The device is battery powered
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	The device is battery powered
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% Un (>95% drop in Un) for 0,5 cycle 40% Un (60% drop in Un) for 5 cycles 70% Un (30% drop in Un) for 25 cycles <5% Un (>95% drop in Un) for 5 seconds	Not applicable	The device is battery powered
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

9.4 Conducted and Radiated Immunity Guidance

Guidance and Manufacturer's declaration-electromagnetic immunity			
The i-Pulz (ES-2) is intended for use in the electromagnetic environment specified below. The customer or the user of i-Pulz (ES-2) should assure that it is used in the following environment:			
Immunity Test	IEC 60601-1-2 Test Level	Complian-ce Level	Electromagnetic Environment - guidance
RF Common mode/ Conducted Suscepti-bility IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communica-tions equipment should be used no closer to any part of the i-Pulz (ES-2), including cables than the recommen-ded separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$
Radiated RF Electromag-netic Field IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,4 \sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output po-wer rating of the transmitter in watts (W) according to the transmitter ma-nufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF trans-mitters, as determined by an electro-magnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the fol-lowing symbol:
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propaga-tion is affected by absorption and reflection from structures, objects and people.		

	Guidance and Manufacturer's declaration-electromagnetic immunity continued
a	Field strengths from fixed 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 the i-Pulz (ES-2) is used exceeds the applicable the applicable RF compliance level above, the i-Pulz (ES-2) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or elocating the i-Pulz (ES-2).
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9.5 Recommended separation distance

Recommended separation distance between portable and mobile RF communications equipment and the i-Pulz (ES-2)		
The i-Pulz (ES-2) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the i-Pulz (ES-2) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the i-Pulz (ES-2) as recommended below.		

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,4 \sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.76
1	1.2	1.2	2.4
10	3.8	3.8	7.6
100	12	12	24

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 watt (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

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