

INSTRUCTION MANUAL FOR THE Smart Pain Reliever LT5019



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This manual is valid for the Smart Pain Reliever LT5019

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The device complies with all the standards relating to Class ll electrical medical devices and to devices which use electrical stimulation for use at home.

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Conformity to safety standards

Shenzhen Dongdixin Technology Co., LTD declares that the device complies with following normative documents:

IEC60601-1, IEC60601-1-2, I EC60601-2-10, IEC62366, ISO10993-5, ISO10993-10, ISO10993-1, ISO14971



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INTRODUCTION

Thank you for purchasing Dongdixin's Smart Pain Reliever LT5019 for pain relief solution.

In order to use the stimulator safely, read the complete manual carefully before using the device for the first time.

Keep this instruction manual in a convenient place or store with the device for future reference.

The Essential Performance of the device is free from the production of unwanted or excessive stimulation output.

Indications for use:

- ◆ TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities(arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.
- ♦ EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

It should be applied to normal, healthy, dry and clean skin of adult patients. It is design to be used at home.

The gift box contains the following components:

8 8 F						
Standard Parts:						
No.	DESCRIPTION	QUANTITY				
Α	LT5019	1PC				
В	Electrode pad (50mm×75mm)	2PCS				
С	Electrode wire	1PCS				
D	Instruction manual	1PC				
E	Adaptor	1PC				
F	Micro-USB cable	1PC				

SAFETY GUIDE

Who should not Use the device

Check the following list of 15 questions:

Questions		Yes/No
1	Are you equipped with a cardiac pacemaker, defibrillator, or other	
	implanted metallic or electronic device?	
2	Are you epileptic?	



3	Have you recently been victim of an acute trauma (less than 6 months)?
4	Have you recently been subject to a surgical procedure (less than 6 months)?
5	Do you have blood flow deficiency in your lower limbs?
6	Do you have an abdominal or inguinal hernia?
7	Do you suffer from cancer?
8	Are you pregnant?
9	Do you suffer from cardiac problems or diseases?
10	Do you have muscle spasms?
11	Do you have atrophied muscles?
12	Do you have skin that lack normal sensation?
13	Do you need muscle reeducation?
14	Do you have any joint showing a decrease in its range of motion?

If you answer "Yes", or "Maybe", or "I don't know" to one or more questions, don't use thedevice and contact your physician or medical practitioner for more information.

IMPORTANT SAFETY PRECAUTIONS AND WARNINGS



It is important that you read all the warning and precautions included in this manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the device.

SAFETY SYMBOLS USED IN THIS MANUAL				
↑ DANGER	Indicates a potentially hazardous situation which, if not avoided,			
DANGER	could result in death or serious injury.			
A WARNING	Indicates a potentially hazardous situation which, if not avoided,			
	could result in serious injury and equipment damage.			
A ▲ (A)	Indicates a potentially hazardous situation which, if not avoided,			
A CAUTION	may result in minor or moderate injury to the user or patient or			
	damage to the device or other property.			



This stimulator must not be used in combination with the following medical devices:



- Internally transplanted electronic medical devices, such as a pacemaker.
- Electronic life support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs.

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





- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances in certain susceptible individuals.
- On open wounds or rashes, or over swollen, red, infected, or 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 opposite sides of your head since the effects of stimulation of the brain are unknown.
- Stimulation should not take place while the user is connected to high-frequency surgical equipment, it may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
- Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.

DO NOT USE ON THESE INDIVIDUALS

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

DO NOT USE THIS DEVICE DURING THESE ACTIVITIES

- When in the bath or shower;
- While sleeping;
- While driving, operating machinery, or during any activity in which electrical stimulation can put you at risk for injury.

PAIN MANAGEMENT WARNINGS

- If you have had medical or physical treatment for your 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 the device and consult with your physician.
- The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this TENS Stimulator.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

- Apply pads to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
- If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.
- Pads should not touch each other when placed onto your skin.

NEVER APPLY THE PADS TO:

• The head or any area of the face.



The neck or any area of the throat because this could cause severe muscle spasms



resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure. Do not use the device on your neck. This could cause severe muscle spasms that may result in closure of your airway, breathing difficulties, 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.



\triangle CAUTION

WARNINGS AND PRECAUTIONS REGARDING THE PADS

- Do not bend or fold because the pad may not function properly. Place the pads onto the plastic film and then store into the sealed package when not in use.
- Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.
- The pads are already pre-gelled and will adhere to your skin.
- To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic film provided.
- Place the pads at least 1 inch apart on your skin. The pads should never touch each other.
- Always place the electrodes in accordance with illustrations provided (Refer to the Pad Placement illustrations).
- Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY

- Pads should not touch each other when placed onto your skin.
- Do not place on your spine or backbone.
- Pad should not touch any metal object, such as a belt buckle or necklace.
- Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
- Always turn the power off before removing or changing the pad location.
- Do not leave pads attached to the skin after treatment.

CAUTION WHILE USING THE STIMULATOR

• If the stimulator is not functioning properly or you feel discomfort, immediately stop using the device.



- Do not use for any other purpose except for what it is intended for.
- Do not pull on the electrode cord during treatment.
- Do not use the device while wearing electronic devices such as watches as this may damage the device.
- Do not use near a cell phone as this may cause the stimulator to malfunction.
- Do not bend or pull the end of the electrode wire.
- When pulling out the electrode wire from the device, hold the plug of electrode wire and pull.
- Replace the electrode wire when broken or damaged.
- Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
- The electrical performance characteristics of pads may affect the safety and effectiveness of electrical stimulation.
- Using pads that are too small or incorrectly applied, could result in discomfort or skin burns.
- FCC

Caution: The user is cautioned that changes or modi-cations 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 two conditions:

- (1) this device may not cause harmful interference, and
- (2) 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 canradiate 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 o 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 co-located or operating in conjunction with any other antenna or transmitter.

GENERAL PRECAUTIONS

- The patient is intend operator.
- The long-term effects of electrical stimulation are unknown.
- Apply stimulation to only normal, intact, clean, dry, and healthy skin.
- TENS is not effective in treating the original source or cause of the pain, including headache.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices do not cure disease or injuries.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Do not apply stimulation over painful areas. If you have painful areas, you should consult with your physician before using this device;
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- 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.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- This stimulation should not be applied over the menstruating or pregnant uterus.
- This stimulation should not be applied over areas of skin that lack normal sensation.
- ÆKeep unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your physician.
- Use this device only with the electrode wire, electrodes, adaptor and Micro-USB cable recommended by the manufacturer.
- **A**Keep unit out of the reach of young children. The electrode cord can cause strangulation.
- Please report to your agency if any unexpected operation or events occur.
- If you have any problems with this device, such as setting up, maintaining or using, please contact with SERVICE PERSONNEL of SDT.

Possible Adverse Reactions

- Do not use to treat one region for extended periods of time (more than 30 minutes a session, up to 3 times/day) or muscles in that region may become exhausted and sore.
- You may experience skin irritation and burns beneath the stimulation electrodes



applied to your skin.

- You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face.
- You should stop using the device and consult with your physician if you experience adverse reactions from the device.
- The materials (e.g. ABS) of expect contact with patient had passed the ISO 10993-5 and ISO10993-10 standards test, no toxicity, allergy and irritation reaction. However, based on the current science and technology, other potential allergic reactions are unknown. If you have allergic reaction to materials, please stop treatment immediately and consult your physician.

HOW TENS STIMULATOR WORK FOR PAIN RELIEF

What is it?

Smart Pain Reliever LT5019 is one output channel TENS machine and highly effective in relieving pain. TENS is now regularly recommended by doctors, physiotherapists and pharmacists throughout the world.

Transcutaneous Electrical Nerve Stimulation (TENS) is a noninvasive, drug free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

How TENS works?

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

- 1) The gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from ever reaching the brain from the source of the pain.
- 2) The gentle electrical pulses increase the production of the body's natural pain killer, such as endorphins.

HOW EMS STIMULATOR FOR MUSLCE STIMLATION

What is it?

EMS works by sending electronic pulses to the muscle needing treatment; this causes the muscle to exercise passively. It is a product derived from the square waveform (ladder-shaped). Through the square wave pattern it is able to work directly on muscle motor neurons. This device has low frequency and this in conjunction with the square wave pattern allows direct work on muscle groupings.

How EMS works?

The EMS units send comfortable impulses through the skin that stimulate the nerves in the treatment area. When the muscle receives this signal it contracts as if the brain has sent the signal itself. As the signal strength increases, the muscle flexes as in physical exercise. Then when the pulse ceases, the muscle relaxes and the cycle is repeated. The goal of electrical muscle stimulation is to achieve contractions or vibrations in the muscles. Normal muscular activity is controlled by the central and peripheral nervous systems, which transmit electrical signals to the muscles. EMS



works similarly but uses an external source (the stimulator) with electrodes attached to the skin for transmitting electrical impulses into the body. The impulses stimulate the nerves to send signals to a specifically targeted muscle, which reacts by contracting, just as it does with normal muscular activity.

PACKAGE CONTENTS



LT5019 Unit



Electrode pad (50mm×75mm)





Instruction manual



Electrode wire



Adaptor and Micro-USB cable

KNOW YOURS DEVICE

Features

Channels: One channel

Treatment modes TENS: 11 programs

EMS: 8 programs

MASSAGE: 1program

Output Amplitude: 0-60mA (1000Ω Load)

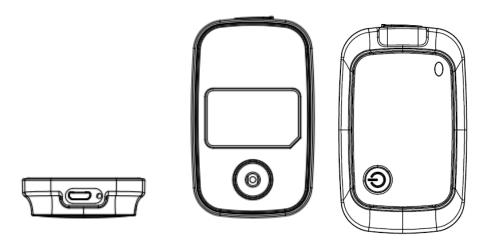
Waveform type: Symmetrical Biphasic square pulse

Output characteristics: Constant Current(CC)



Control platform APP control (ISO or Android)

Front and Rear Panel



- 1). On/off button [$^{\circ}$]: Press this button to turn on the device or turn off the device.
- Indicator light: Green flashing: It means that the device is in standby mode;
 Continuous green: It means it has connected with APP or the battery is full when charging;

Continuous orange: It means in treating mode or the battery is being charging;

Orange flashing: It means that the device is in paused mode;

3). Socket of the device: connect the Micro-USB cable and the adaptor to charge; Connect the electrode wire and the electrode to treat;

Charging

Disconnect the electrode wire from the Micro-USB plug from the device (if you insert the electrode wire to the Micro-USB socket of the device).

Insert the Standard USB plug of the Micro-USB cable to the socket for standard USB plug of the adaptor. And then insert the Micro-USB plug of the Micro-USB cable to the Micro-USB socket of the LT5019 device, you should insert the adaptor to the SUPPLY MAINS.

When the battery light goes into continuous orange (which means that the battery is being charged) to a continuous green (the battery is full), remove the micro-USB plug from the micro-USB socket of the device.



NOTES:

- 1) Please use the adaptor and the Micro-USB cable which proved by the manufacturer.
- 2) Firstly charge the device before use. In normal times (ambient temperature), it takes 5 hours to charge the device. A full charge allows a battery life of about 8 hours continuously when functioning in normal conditions.
- 3) Please charge the device fully before beginning a session. If the charge is not complete at the beginning of a program, the battery may become deplete before the end of the session. You cannot use the device when it is on charge.



- 4) Warning: If batteries leak and come into contact with the skin or eyes, wash immediately with copious amounts of water.
- 5) Dispose the used batteries safely according to the local regulations.
- 6) The life of a rechargeable battery depends on the number of recharging/rundown cycles it undergoes and how these cycles are performed. The service life of rechargeable battery is more than 300 recharging/rundown cycles. We provide the following suggestions for the longer life of the battery:
 - 1) Whenever the device is not used frequently, we recommend recharging the battery once a month.
 - 2) The device can only be used safely with the original recharger, DO NOT re-assemble or change the specification of the recharger. So please always use the recharger which supply by manufacturer or distributor.

EASY STEPS TO GET STARTED WITH YOUR THERAPY WITH ELECTRODE PADS

Step 1 Downloading the APP

Download the application to your smart phone or table:

-By the APP store or Google Play



-Then search 'LT5019', and click the Smart Pain Reliever LT5019

The app operates on IOS and Android platforms (At least IOS 8.0, Android 5.0)

Step 2- Attach electrode pads to the electrode button

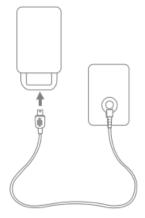
Remove the electrodes from the bag, ensure they are not damaged or worn. If the expiry limit is exceeded, do not use these electrodes. And then pressure the electrodes respectively into the snaps of the electrode wire and the back of the main device.

As shown in the picture on the right:

Step 3- Insert electrode wire to the socket of the device

Insert the Micro-USB plug of the electrode wire to the Micro-USB socked of the device.

As shown in the picture on the right:



Step 4–Electrodes Placement

Remove the clear plastic film from the back of the pad. Place electrodes on clean, dry and healthy skin near, and do not let them touch. Make sure there is a linear path between the two electrodes.

(See the following illustrations).

Note: Replace the electrodes when they are damaged or dirty, when they have lost their adhesive power or when stimulation becomes uncomfortable, i.e. when you experience an unpleasant stinging or biting sensation.

Note: Always connect the device before you place the electrodes on the skin.

Note: Do not place the electrodes on top of each other or so close to each other that they touch each other.



Note: It is possible that you may need external assistance for placing the electrodes in certain areas. Replace the electrodes if:

- -they are damaged or torn.
- -they are past the use-by date indicated on the re-sealable bag.
- -they have lost their adhesive power. Never use plaster or tape to attach them to your skin.
- -stimulation feels less strong.
- -when stimulation is uncomfortable, i.e. when you experience an unpleasant stinging or biting sensation.

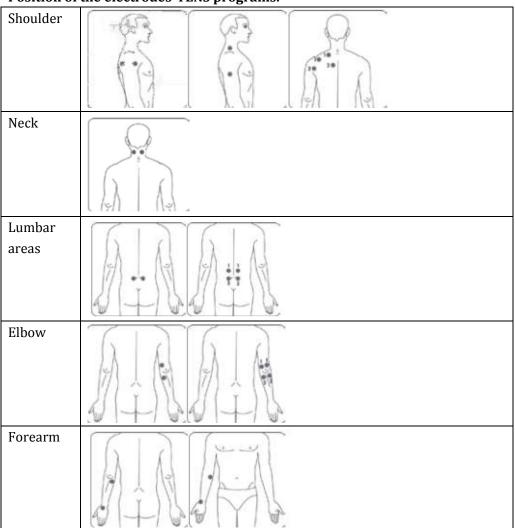
Note: Always replace the electrodes with electrodes recommended for this device by the manufacturer.

AWARNING: Make sure the device is turned off before place electrodes.

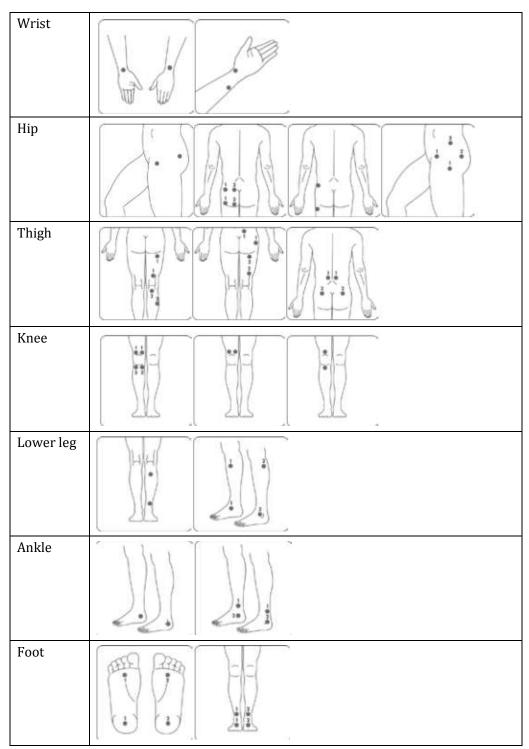
WARNING: Place the electrode pads according to the electrode Pad placement illustrations, as follows.

Pad Placement illustrations (The pad placement of the massage program includes all the following sites (TENS and EMS))

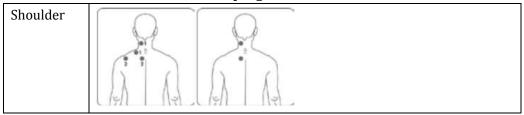
Position of the electrodes-TENS programs:







Position of the electrode-EMS programs



Abdominal	
Lumbar areas	10 02
Forearm	
Hip	
Thigh	
Lower leg	
Foot	



Step 5- Turn on the device

Press the $[\mathfrak{U}]$ button to turn the device on, the indicator light is in green flashing.

Step6- Turn on the APP on your smart phone or table

Ensure that the Bluetooth (4.0) connection is activated on your smart phone or tablet, and then open the APP which you had already downloaded.

Step7- The operation of APP and the LT5019 device

1. Connect the APP and the LT5019 device

Scan the Bluetooth device automatically after you ensure that the Bluetooth (4.0) connection is activated on your smart phone or tablet and then open the LT5019 device, if you use the LT5019 device for the first device, there will show the searching result, as shown in the picture on the right:

And at the bottom of the interface, there has three function modules: Treat, Plans, Setting

2. And you can select the device in the scanning Bluetooth device list or automatically added to the already binding manually by click " equipment list to complete the binding operation, and the status will be change after connect successfully. When the APP is good connection with device, the interface of the APP, as shown in the picture on the right:

After connect the LT5019 device to the APP, click the binding equipment to the main interface of treatment.

And the indicator light of the device from green flashing into continuous green.

3: Delete device: delete device in the binding equipment list through left slip operation. As shown in the picture on the right:



- 4. Treatment site and program selection
- 4.1 Modify device name button: modify user-defined device name

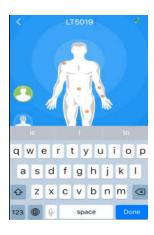
In the main operation interface, you can click the " " to change the name of the LT5019 device. As shown in the picture on the right:



Free from pain to enjoy life

Added device







4.2 Human posture adjusting button: the front and back of posture will be able to switch



e " utton to switch freely

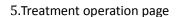
direction of front and back of the human body site.
As shown in the picture on the right:





4.3 Click the site of human body, it will display the information about the site which you choose: human body site icon, name of human body site icon and treatment type (TENS, EMS and massage) switch. Some site of human body only has TENS or EMS mode and unable to be switched. And the massage mode is suitable for all the site of human body. Click the information bar to enter treatment working interface.

As shown in the picture on the right:



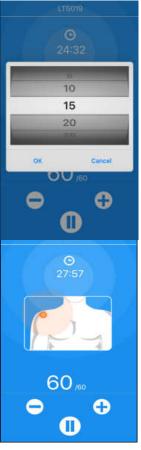
- 5.1 The operation page has setting time, electrical stimulation level display, electrical stimulation level adjustment button (+ or -), start/pause button.
- 5.2 There will show the treatment time in the top of the interface, you can click the time fence toset the user-defined treatment time, click "OK" button to complete the time setting.

As shown in the picture on the right:

5.3 Click "+" or "-" button to adjust the electrical stimulation intensity level, Maximum intensity is 60. When you click '+' button, the device start output, and after the device works, the indicator light of the device is continues orange, and start the countdown timer. At the meantime, the center of treatment site show the animation of radar signal spread.

As shown in the picture on the right:







5.4 Click the "start/pause" button to enter a state of pause. The countdown to stop, pop-up prompt box of operation, the indicator light of the device is orange flashing, at this interface, you can click "End" button to over this treatment, or click the "Continue" button to continue treatment.

As shown in the picture on the right:



5.5:When the status is in treating, the device detect the load is in abnormal, it will stop the output of electrical stimulationand enter the standby condition, the indicator light of the device from continues orange to continues green. At the same time, popupwarning prompt dialog box and both of the treatment time and intensity of electrical stimulation restore to the initial values. At this moment, you should check whether both of the electrodes in good connection status.

As shown in the picture on the right:

5.6: The end of the treatment

When the device is in treatment, the only way to terminate the treatment is the user clicks the "start/pause" button, and then click "End" button; or you can press the "On/Off" button to turn off the device.

6. The record of treatment result

After you click the "End" button after you click the "start/pause" button, there will display the treatment result confirmed page, and it will display the current site of treatment, treatment date and time, treatment type ,treatment time ,intensity.

At this interface:

- -Click "Retain" button to return the page of treatment operation.
- -Click "New Start" button to return initial treatment site selection interface.

If treatment time is 0, the results will not be recorded history list.

Note: The MASSAGE program not record in the history.

7. The treatment history record

Click "History" button at the main operation interface, can check all the validtreatment record. The app contains a history function that shows the details of over 200 past treatments. The information of display of treatment records are as following:

- 1: The line number of record
- 2: Detail of treatment date /time
- 3: The name of the device, which you setting



0





- 4: The site of treatment
- 5: The intensity of electrical stimulation
- 6: Treatment type
- 7: Treatment time
- 8. Click the top right corner "delete" button, and then select the history records which you want to delete, and then click the "OK" button to delete the treatment history.

07/26/2016 19:29:52 LT5019 107/26/2016 15:03:32 LT5019 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15:03:00 15

9. Plans page

Whenyou bindingthe LT5019 device, and you can obtain the information of the plans if you have made. Without binding equipment, there will show "Haven't a plan, add one".

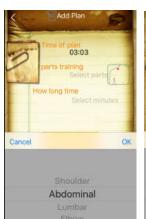
9.1 Add plan

Click the "button in the top right corner to enter the editingplans page, set up relevant options and click add button "+"to complete a new adding plans, Max 8 training plans can be add.



At the "Add Plan" interface, you can click the "Treatment of plan", "parts of training", "How long time",







After you set these information, click the " Add " button to add the plan.





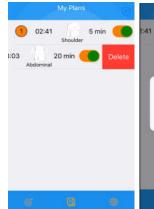
In the plans page, there will display the number of plan, the plan treat time you set, the site of treatment of plan, plan the training time, the switch of notice.

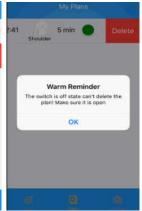
The switch of the new plan's notification is opened by default. When the time and the "Time of plan" reach consensus, there will have a remind notice to push. If the switch of new plan's notification is closed, the push notification will be cancel.



9.2 Delete plan

Delete training plans: delete plans through Left slip operation, and only can be delete in the condition that the switch of new plan notify is open ,if not , prompt dialog box will be pop to remind user.



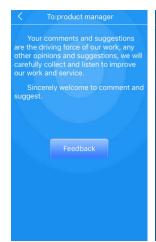


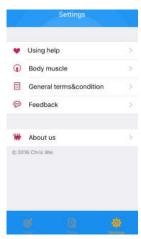
Setting page

The interface of setting information has the following option: using help, encyclopedias of human body, protocol license, suggestion feedback, about us.

- 1: using help: the operation instruction of APP and the using guidance of the Bluetooth device.
- 2: encyclopedias of human body: Display the structure of human body muscle, exchange the front and back through sliding the right and left.
- 3:protocol license: introduce agreement license of use of product.
- 4: suggestion feedback: when the user uses this product, you can give the comment and the advice by the way of Email.
- 5: About us: introduce the version of the system software and the device information.

Send E-mail: Click the 'Feedback' button in the feedback interface, but send E-mail must through the mailbox on your smart phone, if there has no mailbox on your smart phone, there will remind you to configure mailbox.









ACAUTION:

- 1) If the electrodes are not placed firmly on skin or the device has not connected with the electrodes and the output intensity level over 1, the intensity will stop automatically.
- 2) If the stimulation levels are uncomfortable or becomeuncomfortable, reduce the stimulation intensity to acomfortable level and contact your medical practitionerif problems persist.
- 3) If your pain does not improve and become sore from over-use, refrain from treating those areas for 2 days. If this issue reoccurs, reduce the treatment time and intensity settings for future treatment.
- 4) If you feel pain, dizziness, discomfort or nausea, call your physician or medical practitioner.
- 5) You should therefore take care to work with maximum intensities, i.e., always at the limit of what you can support.Do not exceed your comfort level.

Step 8-EASY STEPS TO TURN OFF THE DEVICE

To turn off the device by press the "On/Off" button of the device;

If there is not any button to press, the device will automatically turn off after three minutes when the device in standby mode.

Caution: Always end the treatment in the app or by pressing the on/o button before you remove thedevice or the electrodes. If you fail to do this, you may get an unpleasant sensation in your fingers when you touch the connectors. This sensation is not harmful, but it can be unpleasant.

OTHER IMPORTANT FUNCTIONS IN THIS STIMULATOR

Low battery indicator

When the low power indication pushed, you should charge in time.



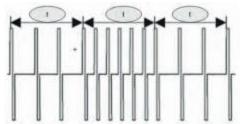
Presentation of the program

Forms of waves:

Cont: form of continuous wave



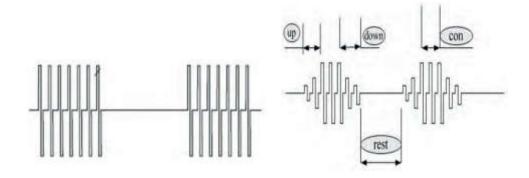
Burst: Wave from deviation



Hans: Form of alternating wave

EMS: Wave form





PROGRAM LIST

TENS PROGRAMMES LIST

Traditional transcutaneous neurostimulation program:

A common transcutaneous neurostimulation program is performed with a high frequency stimulation. This stimulation is intended to block the transmission of the pain signal to the nervous system. Generally, people use traditional transcutaneous neurostimulation for a session of about 30 minutes. It is possible to use these programs for a variable period and frequency according to what you want. It is normal to feel the effects of this program more intensely during the stimulation and to experience it's decay after the end of the session. To gain in efficiency, it is necessary to adjust the intensity of the program, avoiding any painful or unpleasant sensation.

Burst transcutaneous neurostimulation program:

A burst programme (Burst TENS) allows high frequency stimulation in the form of series of impulses. It enables the release of endorphins. It is possible to use the transcutaneous neurostimulation in bursts for 30 minutes. The frequency can be up to several times per day, 3 times for example. For a sensation of strong stimulation, it is advisable to adjust the intensity of the burst program. An unpleasant feeling may then appear. You can also adjust the intensity of the program at a level leading to perceptible muscle contractions in the stimulation area.

These contractions are not dangerous. However, if you experience discomfort, it is advisable to decrease the intensity of the program, change or move the electrodes. The burst transcutaneous electrical neurostimulation (Burst TENS) can trigger a muscle contraction in the area of stimulation. We therefore ask you to perform this program at rest.

TENS Impulses						
Treatment	Treatment	Treatment	Frequency	Width (us)	Wave form	Description
area	time	phases	(time)			
Shoulder	30min	Phase 1	2Hz (10s)	250	CONT	Continuous
		Phase 2	4Hz (8s)	250		output
		Phase 3	6Hz (6s)	250		
Lumbar	30min	Phase 1	80Hz (20s)	250	CONT	Continuous
		Phase 2	80Hz (20s)	250		output



		Phase 3	75Hz (4s)	250		
		Phase 4	10Hz (20s)	250		
		Phase 5	70Hz (4s)	250		
		Phase 6	65Hz (4s)	250		
Elbow	30min	Phase 1	2Hz (3s)	200	HANS	Altemating
		Phase 2	100Hz (3s)	150		output
Forearm	30min	Phase 1	2Hz (3s)	200	HANS	Altemating
		Phase 2	100Hz (3s)	150		output
Wrist	30min	Phase 1	2Hz	250	CONT	Continuous
						output
Hip	30min	Phase 1	6Hz (30s)	250	CONT	Continuous
		Phase 2	6Hz (30s)	250		output
		Phase 3	8Hz (20s)	250		
		Phase 4	8Hz (20s)	250		
		Phase 5	10Hz (20s)	250		
		Phase 6	10Hz (20s)	250		
Thigh	30min	Phase 1	100Hz	200	EMS	Up : 0,5s
						Con:7s
						Down : 0,5s
						Rest : 7s
Knee	30min	Phase 1	100Hz	150	BURST	On: 0.25s
						OFF : 0.25s
Lower leg	30min	Phase 1	100Hz	150	BURST	On: 0.25s
						OFF: 0.25s
Ankle	30min	Phase 1	100Hz	200	CONT	Continuous
						output
Foot	30min	Phase 1	40Hz (5s)	250	CONT	Continuous
		Phase 2	6Hz (10s)	250		output
		Phase 3	50Hz (5s)	250		

Electrical muscle stimulation (EMS) programs

These programs, commonly called "neuromuscular electrical stimulation" (NMES) or "electromyostimulation", emit impulses to cause a muscle contraction. They are especially used forstrengthening the muscle mass. Only perform the electrical muscle stimulation programon intact and healthy muscles. Because they involve muscle contraction, they need to be performed at rest (lying or sitting).

When using for the first time, the electrical stimulation can lead to a atypical and strange sensation. It is advisable to begin the programme on low intensity and change to a higher one to become used to it. The stimulation must remain comfortable and muscle contractions must not be harsh or painful. If your program is part of intensive physical exercise or after effort, you are advised to choose a low intensity to limit muscular fatigue.

EMS			Impulses			
Treatment	Treatment	Treatment	Frequency Width (us) Wave form Description			Description



area	time	phases	(time)			
Shoulder	28min	Phase 1	5Hz (5min)	280	EMS	Preparation
		Phase 2	55Hz (10s)	280		Intensity:50%
						Up:1.5s
						Down:0.75s
		Phase 3	6Hz (8s)	280		Intensity:25%
		Phase 4	3Hz (10min)	280		Intensity:40%
Abdominal	22min	Phase 1	30Hz	200	EMS	Up : 10s
			(23min)			Con:5s
						Down: 10s
						Rest : 5s
		Phase 2	45Hz (9min)	200		Up : 5s
						Con:5s
						Down:5s
						Rest : 5s
		Phase 3	60Hz (9min)	200		Up : 6s
						Con : 8s
						Down:6s
						Rest : 5s
		Phase 4	30Hz (2min)	200		Up : 10s
						Con:5s
						Down: 10s
						Rest : 5s
Lumbar	28min	Phase 1	5Hz (5min)	300	EMS	Preparation
		Phase 2	55Hz (10s)	300		Intensity:50%
						Up:1.5s
						Down:0.75s
		Phase 3	6Hz (8s)	300		Intensity:25%
		Phase 4	3Hz (10min)	300		Intensity:40%
Forearm	28min	Phase 1	5Hz (5min)	200	EMS	Preparation
		Phase 2	55Hz (10s)	200		Intensity:50%
						Up:1.5s
						Down:0.75s
		Phase 3	6Hz (8s)	200		Intensity:25%
		Phase 4	3Hz (10min)	200		Intensity:40%
Hip	32min	Phase 1	5Hz (5min)	300	EMS	Preparation
		Phase 2	75Hz (6.3s)	300		Intensity:50%
						Up:1.5s
						Down:0.75s
		Phase 3	4Hz (8s)	300		Intensity:25%
		Phase 4	3Hz (10min)	300		Intensity:40%
Thigh	28min	Phase 1	5Hz (5min)	370	EMS	Preparation
		Phase 2	55Hz (10s)	370		Intensity:50%



						Up:1.5s
						Down:0.75s
		Phase 3	6Hz (8s)	370		Intensity:25%
		Phase 4	3Hz (10min)	370		Intensity:40%
Lower leg	28min	Phase 1	5Hz (5min)	370	EMS	Preparation
		Phase 2	55Hz (10s)	370		Intensity:50%
						Up:1.5s
						Down:0.75s
		Phase 3	6Hz (8s)	370		Intensity:25%
		Phase 4	3Hz (10min)	370		Intensity:40%
Foot	30min	Phase 1	50Hz	200	EMS	Up : 2s
						Con:8s
						Down : 2s
						Rest : 4s

MASSAGE program

For Massage, the electrodes placed on the skin close to the area of fatigue. The Massage program produces gentle muscle twitches, like a massage, to facilitate recovery from muscle fatigue and to help recover muscle strength after training sessions and competitions. There only have one massage program, and the intensity of the pulse can be adjusted.

	0 1 0 7	,		,	
MAS	SAGE		Imp	ulses	
Treatment	Treatment	Frequency	Width (us)	Wave form	Description
time	phases	(time)			
30min	Phase 1	80Hz (20s)	250	CONT	Continuous
	Phase 2	75Hz (20s)	250		output
	Phase 3	10Hz (20s)	250		
	Phase 4	70Hz (20s)	250		
	Phase 5	65Hz (20s)	250		

SPECIFICATIONS

Power Sources: 3.7V /500mAh Li-ion

Frequency: 2Hz~100HzPulse Width: 150us~370us

• Wave form: Biphasic square wave (net current 0dc)

• Output Voltage: 0~60V (at 1000 ohm load)

• Output Intensity Level: 0~60 levels

• Operating Conditions: 5° C \sim 40 $^{\circ}$ C; 30%RH \sim 75%RH; 700hPa \sim 1060hPa

• Storage Conditions (main device): -10 $^{\circ}$ C ~55 $^{\circ}$ C; 10%RH~90%RH; 700hPa ~1060hPa

• Storage Conditions (electrodes): 0° C to 40° C; 10° RH~90%RH; 700° hPa ~1060hPa

• Size: 13x41x67mm(main device)

• Weight: 28g (main device)

Service life of the device: 2 years

• Service life of electrode pads: 10times



• Electrode impedance: $\leq 500\Omega$

Applied part: ElectrodeSize of electrode: 50 x75mm

Adaptor: Input:100-240V AC 50/60Hz
 Output: 5V DC 300mA

• IP classification system: IP22

HOW TO CONTROL AND REDUCE YOUR PAIN

When should the device be used?

Use as soon as your pain begins. Start with one session (unit automatically turns off at 30 minutes). If you get to your pain early, it may prevent the pain frombecoming worse, or even chronic. It's better for you to get it undercontrol sooner so that it does not reach a high pain threshold whereit limits your daily activities.

Setting the intensity

Intensity is based upon your level of comfort. Begin the first session with a low intensity and a short duration while learninghow to operate. You should therefore take care to work with maximum intensities, i.e., always at the limit of what you can support. Do not exceed your comfort level.

How long should you use the device?

Start with one 30 minute session. Always turn unit off with padsstill on. Rate your pain to check your progress, 1 low to 60 high. Intensity is based upon your level of comfort. Begin the first session with a low intensity and a short duration while learninghow to operate.

Stop therapy session if pain has reduced or stopped. If your pain does not improve and become sore from over-use, refrain from treating those areas for 2 days. If this issue reoccurs, reduce the treatment time and intensity settings for future treatment.

Recommended treatment session as following:

1 session	Max session	Max times/day
30 minute section	2 Sections	3 Sections per day
shut-off		

When to stop using the device?

- 1) If you experienced an adverse reaction (skin irritation/redness/burns, headache or other painful sensation, or if youfeel any unusual discomfort).
- 2) If your pain does not improve, becomes seriously chronicand severe, or continues for more than five days.

NOTE:

If you feel pain, dizziness, discomfort or nausea, call your physician or medical practitioner.

What type of pain is it best for?



This therapy works best on acute pain because it is localized. Acute pain is pain in one area for less than 3 months. If you havechronic pain, you may have pain in more than one area and forlonger than 6 months. Chronic pain may be compounded by otherissues that this device cannot address.

Rememberthis device does not cure your pain or the original cause of the pain. It provides temporary relief or reduction of painso that you can control your life and activities better.

CLEANING AND STORAGE

Cleaning the unit

- 1) Turn unit off and disconnect theelectrode wire from the unit.
- 2) Clean the device after use with a soft, slightly moistened cloth and wipe gently.
 - Do not use chemicals (like thinner, benzene).
 - Do not let water get into the internal area.

Note:

• This device and accessories does not require sterilization.

Cleaning the electrode pads

- 1) Turn the power off and remove theelectrode wire from the pads.
- 2) Wash the pads when the adhesive surface becomes dirty and/orthe pads are difficult to attach.
 - Wash the pad softly with your fingertips under slowrunning cold water for several seconds (do not use asponge/cloth/sharp object like a nail on adhesive side, do not use detergents, chemicals or soap).
- 3) Dry the pads and let the adhesive surface air-dry completely(do not wipe with a tissue paper or cloth).

ACAUTION:

- 1) The life of pads may vary by the frequency of washing, skincondition, and storage state.
- 2) If the pad no longer sticks to your skin or the pad is broken, you should replace new pads.
- 3) Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
- 4) Do not turn on the device when the electrodes are not positioned on the body.
- 5) Never remove the self-adhesive electrodes from the skin while the device is still turned on.
- 6) If replacement electrodes are necessary, use only electrodes that are the same size (50*75mm) as the electrodes provided with the LT5019.
- 7) Use of electrodes that are larger may reduce the effect of the stimulation. Use of electrodes that are much smaller than the electrodes provided with the LT5019 may increase the chance of skin irritation or electrode burns occurring under the electrodes.
- 8) Always use electrodes that have been cleared for marketing in the US by the FDA.
- 9) Always clean the electrodes after your treatment every time.



- 1) Turn the device off and remove the electrode wire from the unit.
- 2) Remove the pad from your body and pull out electrode wire from the pads.
- 3) Place the pads onto the plastic film and then store into the sealed package.
- 4) Wrap the electrode wire and store into the sealed package.

Storing the unit

- Place the unit, electrodes, electrode wire and manual back to gift box. Store the box in a cool, dry place, -10° C \sim 55°C; $10\% \sim$ 90% relative humidity.
- Do not keep at places that can be easily reached by children
- When not in use for a long period, remove the batteries beforestorage, to avoid liquid discharge from batteries.

TROUBLESHOOTING

Problem	Possible causes	Possible solution	
The device cannot			
power on, or the			
indicator light on the	Are the batteries exhausted?	Recharge the batteries.	
device is displayed in			
orange continuously		_	
	Electrodes dried out or	Replace new electrodes	
Stimulation	contaminated	Replace new electrodes	
weak or cannot	Electrodes cannot stick skin	Reconnect the electrodes	
feel any	well	Reconnect the electrodes	
stimulation	Electrode wire	Replace new electrode wire	
	old/worn/damaged		
	Intensity is too high	Decrease intensity in the APP.	
	Electrodes aretoo close		
Stimulation is	together; or placed in the	Reposition the electrodes.	
uncomfortable	correct location;		
	May not be operate thedevice	Please check the	
	accordingto the manual.	manualbefore use	
		Verify connection issecure.	
		Insure firmly.	
		Turn down the intensity.	
		Rotateelectrode wire in	
Intermittent	Electrode wire	socket90°. If still	
output	Electrode wire	intermittent,replace lead wire.	
		If still intermittent	
		afterreplacing lead wire,	
		acomponent may have failed.	
		Call the repair department.	
Stimulationis	Improper electrode	Reposition electrode	



ineffective.	placement		
	Unknown	Contact clinician.	
	Use the electrodeson the same	Re-position the electrodes. Ifat any time you feel pain	
	siteevery time.	ordiscomfort stop useimmediately.	
The skinbecomesred and/or youfeel a	The electrodesaren't stuck onto the skin properly	Ensure the electrode is stucksecurely on the skin.	
stabbingpain	The electrodes aredirty.	Clean the electrodesaccording to description in this manual orreplace new electrodes.	
	The surface of theelectrode wasscratched.	Replace new electrode.	
Output gurrent	The electrodes come off the skin.	Turn off the device and place the electrodes again.	
Output current stops during	Theelectrode wire isdisconnected	Turn off the device and connect the electrode wire.	
therapy	The power of thebatteries has beenexhausted.	Replace newbatteries.	

DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly.



Please dispose of the device in accordance with the legal obligation.

GLOSSARY OF SYMBOLS



Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.



Equipment capable of delivering output values in excess of 10mA r.m.s. or 10V r.m.s. averaged over any period of 5s



Type BF Applied Part



Refer to instruction manual

IP 22

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 titled up to 15° . Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15° , on either side of the vertical.

SN

From left to right, the first digits represent area code and the next six digits represent the the order number which include last two numbers of manufacture year and month, the last 6 digits represent serial number.

SN:		
Area number	Order number	Serial number



This symbol means that this device emits non-ionizing radiation. All devices with RF transmitters or that use RF electromagnetic energy must have a label with this symbol.

WARRANTY

Please contact your dealer or the device center in case of aclaim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

- 1) The warranty period for device is one year from date of purchase. In case of a warranty claim, the date of purchase to be proven by means of the sales receipt or invoice.
- 2) Repairs under warranty do not extend the warranty periodeither for the device or for the replacement parts.
- 3) The following is excluded under the warranty:
 - All damage which has arisen due to improper treatment, e.g.nonobservance of the user instruction.
 - All damage which is due to repairs or tampering by thecustomer or unauthorized third parties.
 - Damage which has arisen during transport from themanufacturer to the consumer or during transport to theservice center.
 - Accessories which are subject to normal wear and tear.
- 1) Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit isaccepted as a warranty claim.

IMPORTANT INFORMATION REGARDING ELECTRO MAGNETIC COMPATIBILITY (EMC)

With the increased number of electronic devices such as computers and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices. In order to regulate the requirements for EMC (Electromagnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601- 1-2 standard has been implemented. This standard defines the levels of



immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices. The devices conform to this IEC60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The use of accessories other than those provided by manufacturer, may result in increased emission or decreased immunity of the device.
- Refer to EMC table guidance regarding the EMC environment in which the device should be used.

Table 1

Guidance and manufacture's declaration - electromagnetic emission

The DEVICE *is* intended for use in the electromagnetic environment specified below. The customer of the user of the DEVICEshould assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device use 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 emission CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly
Harmonic emissions IEC 61000-3-2	Class A	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacture's declaration - electromagnetic immunity

The DEVICEis intended for use in the electromagnetic environment specified below. The customer or the user of DEVICEshould assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic	±6 kV contact	±6 kV contact	Floors should be wood, concrete or
discharge (ESD)	±8 kV air	±8 kV air	ceramic tile. If floor are covered
IEC 61000-4-2	20 KV dii	20 KV un	with synthetic material, the
12001000 1 2			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	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode	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	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec	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 DEVICEbe powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m ains voltage prior to applica	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 4

Guidance and manufacture's declaration - electromagnetic immunity

The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the DEVICE should assure that it is used in such an environment.



Immunity test	IEC 60601 test	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V _{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DEVICE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 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 metres (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. 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 in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 DEVICE is used exceeds the applicable RF compliance level above, the DEVICE shouldbe observed to verify normal operation. If abnormal performance is observed, additional measures may benecessary, such as re-orienting or relocating the DEVICE.



b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 800 MHz to 2,5 GHz column of Table 6 of IEC 60601-1-2:2007, as appropriate.

Table 6

Recommended separation distances between

portable and mobile RF communications equipment and the DEVICE.

The DEVICE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DEVICE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DEVICE as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter			
Rated maximum output	(m)			
power of transmitter	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
(W)	$d = 1.2\sqrt{p}$	d = 1.2√ p	$d = 2.3 \sqrt{\mathbf{p}}$	
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 inmetres (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 separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption andreflection from structures, objects and people.



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