

Device name: SNM-FDC01 Transcutaneous Electrical Acustimulator (TEA)

Instructions for use

Manufacturing and after-sales service company: Ningbo MedKinetic Medical Device Co., Ltd.

Production Address: Lushan West Road, 167-8, Ningbo Free Trade Zone(South), 315806 Ningbo

Phone: +86 574 86808886

Fax: +86 574 86808885

Production License Number:

Registration Certificate No.:

Table of contents

Indications for Use

Safety warnings and precautions

Chapter 1: Product overview

1.1 List of included parts

1.2 TEA Device

1.3 USB charging cable

1.4 Lead cable

1.5 Electrode pads

1.6 Holding strap

1.7 Holding clip

1.8 TEA app

Chapter 2: Directions for Use

Chapter 3: Electromagnetic compatibility

3.1 Cable Information

3.2 Electromagnetic emission and immunity guidelines and manufacturer's statement

Chapter 4: Fault Analysis and Troubleshooting

Chapter 5: Product Maintenance

5.1 Maintenance and Maintenance

5.2 Waste Disposal

Chapter 6: Product Warranty

Chapter 7: Technical Specifications

Chapter 8: Applied Standards

Indications for Use

TEA Device is an Over-The-Counter Class II medical device intended to activate healthy nerves in order to improve or facilitate health. It is to be used by adults only.

TEA Device is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of TEA Device stimulation programs are designed for injured or disease afflicted skin. Its use on such skin is contraindicated.

TEA Device electrical impulses allow the triggering of action potentials of nerves (excitations). Depending on the parameters of the electrical impulses (pulse frequency, ON and OFF durations, total session duration), different types of nerve excitations can be produced. TEA Device may therefore be considered a technique of neuromodulation.

TEA Device is used for:

- symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

CONTRAINDICATIONS

A contraindication indicates a situation in which the device should not be used.






Never use TEA Device if you have ANY of the following:

- Atrophied muscles or need for muscle rehabilitation
- Muscles with spasms or persistent pain
- Cardiac stimulator (pacemaker)
- Epilepsy
- Cancer or cancerous lesions
- Any heart problem or condition
- Pregnancy (do not use on the abdominal area)
- Serious arterial circulation disorders in lower limbs
- Abdominal or inguinal hernia
- Mental disorders

Safety warnings and precautions


The warnings and precautions provided here are for intended and safe use of TEA Device in order to prevent harm or damage to users and others.

The following symbols will be used throughout the manual:

Symbol	Meaning
	High-level warning about a situation when if the device is used incorrectly it can result in death to the patient
	General warning about a situation when if the device is used incorrectly it can result in injury to the patient or user or damage to the equipment or other property
	Type BF application part
	two types of medical devices
	Attention! Consult documentation

Precautions for use

Please read this manual carefully first and always follow the instructions to operate.


<ul style="list-style-type: none">• Please keep out of reach of children and pets• Do not use in persons with contraindications to this product, as described on previous page• If pregnant or menstruating, do not place electrodes directly over the uterus or connect pairs of electrodes across the abdomen• Use only with the electrode pads supplied by manufacturer• Do not cut the electrode pads• Do not connect lead cable or electrode pads to the other objects• Do not allow any foreign material (soil, water, metal, etc.) to get into the device• Do not apply solvents of any kind to the electrode pads• Do not touch the pads from the conductive side• Do not attempt to place the pads on any part of the body which is not directly visible without assistance• When attaching the pads, please ensure that the entire surface is in contact with the skin• Do not apply over skin abrasions• Apply to dry skin only; for oily skin, clean of any oil and dry it before attaching the electrode pads• For hygienic reasons, each user must have his/her own set of pads. Do not use the same pads on different people• Never use a set of pads for more than 30 stimulation sessions as their bonding power deteriorates over time and optimal contact is very important for both user comfort and stimulation efficacy

- During a stimulation session, do not disconnect the lead cable and electrode pads during stimulation; stop the stimulation first
- For first time users, skin stimulation can produce an unusual sensation. We recommend that you begin in a seated position with low stimulation settings to familiarize yourself with the sensation before progressing to higher intensities
- Some people with very sensitive skin may experience redness under the pads after the stimulation session. Generally, this redness is completely harmless and disappears after 15 to 20 minutes. However, avoid starting a stimulation session on the same area until the redness is no longer visible
- Do not use in environment with strong electromagnetic radiation, such as portable communications equipment
- Do not use within 1.5 meters of short wave or unshielded microwave devices as this could alter the current generated by the stimulator.
- Do not apply stimulation near metal. Remove jewelry, body piercings, belt buckles or any other removable metallic product or device in the area of stimulation
- Do not apply stimulation near the area of an implant, such as cochlear implants, pacemakers, electrical or skeletal anchorage implants
- Do not use in water or in a humid atmosphere (sauna, hydrotherapy, etc.)
- Do not use in an oxygen-rich atmosphere
- Do not use at altitudes of over 3,000 meters
- Sudden temperature changes can cause condensation to build up inside the stimulator. Only use the device once it has reached ambient temperature
- Do not use while driving, operating machinery or cycling
- Do not apply stimulation while sleeping
- Do not recharge the device when unit is attached to an electrode and/or on your body
- Do not apply electrode pads to the head, face, genitals, neck, both sides of the chest or torso at the same time
- For long-term storage, batteries should be removed from the device and stored separately
- Replace the drained battery timely to ensure normal use



It is prohibited for users or non-professionals to disassemble or modify the device or accessories

Turn off the device before removing the lead cable or pads

Unplug the USB power adapter from the power socket before using the device

Use only the provided USB power adapter for device charging. Using a different power adapter can be dangerous

It is prohibited to use this device with accessories not supplied by manufacturer

Chapter 1: TEA Device and accessories

1.1 List of included parts

Part Name	Quantity
TEA Device	1
Lead cable	1
USB charging cable	1
USB power adapter	1
Electrode pads	2
Holding strap	1
Holding clip	1

1.2 TEA Device

As shown on Figure 1, the front of TEA Device has a display and buttons for viewing and setting the device operations. A magnetic snap connector is located on the back of TEA Device. The interface can be used to connect the lead cable or the charging cable.

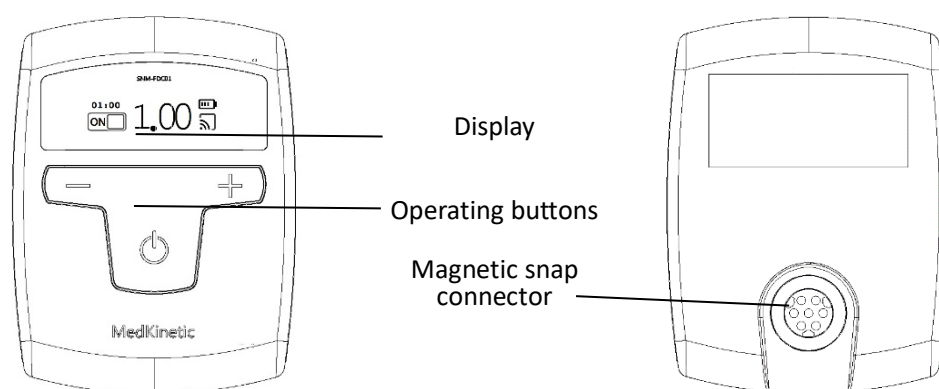


Fig. 1 TEA Device

1.3 USB charging cable

TEA Device is powered using an internal rechargeable lithium polymer battery. Once the device is turned on, the battery level indicator is located on upper-right corner of the display. When the battery is fully charged, treatment can be provided for up to 20 hours under normal operating conditions. When the battery is discharged, as can be seen on the battery level indicator, the USB charging cable should be connected for recharging the battery. For connecting the USB charging cable, its magnetic snap connector is connected to TEA Device, while its USB connector is connected to the USB jack of USB power adapter, as shown on Figure 2. Make sure to use the supplied USB power adapter that is approved for use with the US power lines (120 V, 60 Hz).

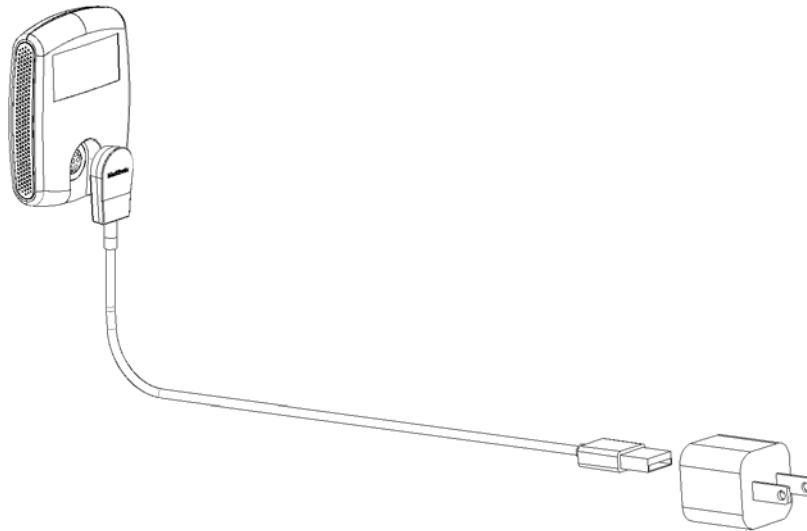


Fig. 2 USB charging cable

1.4 Lead cable

Connection of the lead cable and the electrode pads is shown on Figure 3: magnetic snap connector of the lead cable is connected to TEA Device, while two male connectors on the other side are connected to two electrode pads, which are placed on the skin to inject electrical current through the human body.

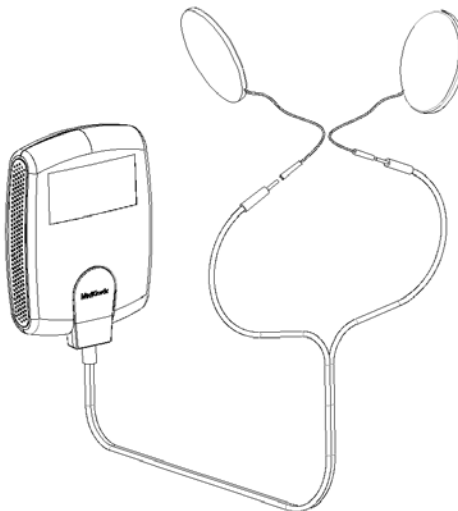
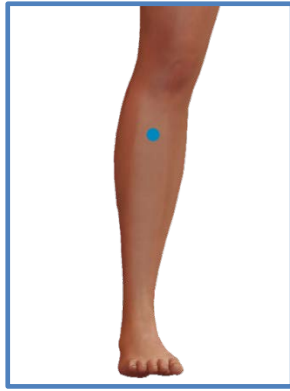


Fig. 3 Lead cable connection

1.5 Electrode pads

As shown on Figure 4, the electrode pads are commonly placed on the following acupuncture points (acupoints) to achieve the best treatment results: Zusanli (ST36), Guanyuan (CV4), Zhongwan (CV12), or Neiguan (PC6).



Zusanli (ST36)



lower Guanyuan (CV4), higher Zhongwan (CV12)



Neiguan (PC6)

Fig. 4 Common locations for electrode pad placement

1.6 Holding strap

Based on electrode pad placement, TEA Device can be attached to an arm or leg by using the holding strap. The strap is first passed through the slit on TEA Device. After connecting the lead cable with electrode pads and setting stimulation amplitude on the TEA Device, wrap the strap with TEA Device around the arm or leg and adjust the length of comfort.

1.7 Holding clip

TBD

1.8 TEA app


The keys on TEA Device allow users to perform only basic operations, including starting and stopping treatment and adjusting the stimulus strength. In order to perform advanced operations, users have to install and use the companion TEA app on the Android phone.

Chapter 2: Directions For Use

2.1 Preparing the device

Before using this product for treatment, connect the TEA Device to the lead cable with electrode pads and attach the pads to the skin, as described in 1.6 and confirm that the device is charged. The charging instructions are in 1.3.

2.2 Turning the device ON

To turn the device ON, press the Power button  and hold for 3 seconds. TEA Device goes into Standby mode.

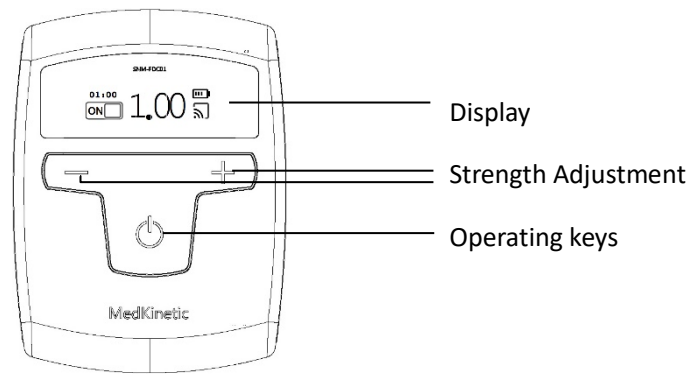


Fig 5. Operating the device

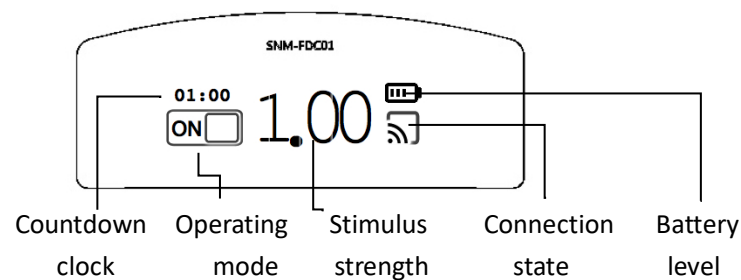



Fig. 6 Display indicators

2.2 Initiating treatment

Press the Power button  to start the treatment process. Once the treatment starts, countdown begins at the upper-left corner of the screen. Figure 7 illustrates two operating modes: Standby mode and Treatment mode. In order to avoid sudden unpleasant sensation of stimulation, the initial current should be set to 1.0 mA.

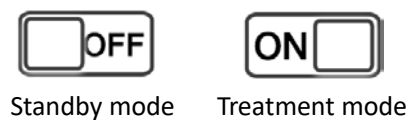




Fig. 7 Operating modes

2.3 Adjusting stimulation strength

Apply a short press to  and  keys to adjust the stimulation strength.

2.4 Terminating treatment

while in the Treatment mode, press the Power button  to terminate the treatment process and enter Standby mode.

2.5 Turning the device OFF

While in the Treatment or Standby modes, press the Power button  and hold for 3 seconds to power off the

device.

2.6 Using the TEA App

Install the TEA App on the Android smart phone, as shown on Figure 8.



Fig. 8 TEA Device control app icon

Once the TEA app is launched on the phone, TEA Device can establish wireless Bluetooth connection with the phone. Once the Bluetooth connection to the phone is established, the Connection State indicator on the bottom right corner of the display is changed from "Not Connected" to "Connected" state, as shown on Figure 9.

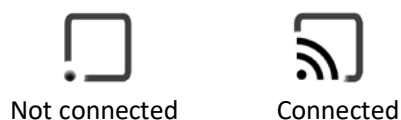


Fig. 9 Bluetooth connection state

After starting the TEA App, go to the Welcome screen, as shown on Figure 10:

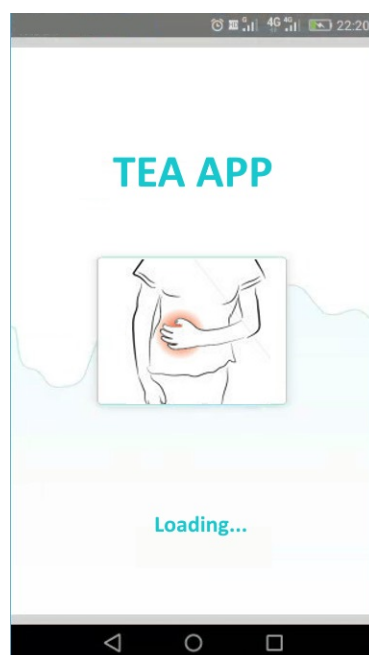


Fig. 10 Welcome screen

Registration: click on the Welcome screen to enter the login screen. If using the App for the first time, you need to register the user account: please click on the login page "no account number?" Create a new account name and password, as shown on Figure 11:



Fig. 11 New User Registration screen

Once completing the registration, please enter the login information on login screen, as shown on Figure 12:



Fig. 12 Login screen

If you forget the account password, please click on the "Forgot password" link, please go to the Forgot Password screen, please enter the registered mobile phone number or email number and click the "Submit" button. the TEA App will send the account password to your mobile phone or email, as shown on Figure 13.



Figure 13 Forgot password screen


Select the Treatment mode: Click on  icon on top left corner to activate pop-up menu and click “Therapy” to enter the treatment interface as shown on Figure 14.



Fig. 14 Treatment interface screen

Enter the site

Start the treatment



Initiate the Therapeutic function operation

1) device Search and connection

- Device Search
- Device connection

2) Stimulating function operation

- Start stimulating.
- Stop stimulating
- Adjust the output stimulation strength (+/-)



4. Device Info

4.1 Add a Device

On the left menu, click "Device Information", go to the Device Information page, the default device information is empty, as shown in the following figure:



You can go to the Add Device page by clicking the "Add Device" button, the pop-up menu "add Manually" (or you can add a device by sweeping the QR code), as shown in the following figure:



Enter TEA Device number and Bluetooth according to the indicator on the back of the device Mac, and select prescription information, etc., click the "Submit" button to add the device information to the TEA App, as shown in the following figure:



4.2 Delete devices and data downloads

On the Device Information page, You can swipe a row of device information from right to left, Can see The download and delete buttons are shown in the following figure:



- 1) Download: This feature provides users with information about the treatment in the download stimulation device;
- 2) Delete: This feature provides users with the ability to delete false or unwanted device information.

5. Prescription information

Prescription information is used to set the parameters of the stimulator output stimulation, which is generally the equipment factory or hospital doctors according to the subjects using the treatment of disease characteristics and input of the treatment parameters.

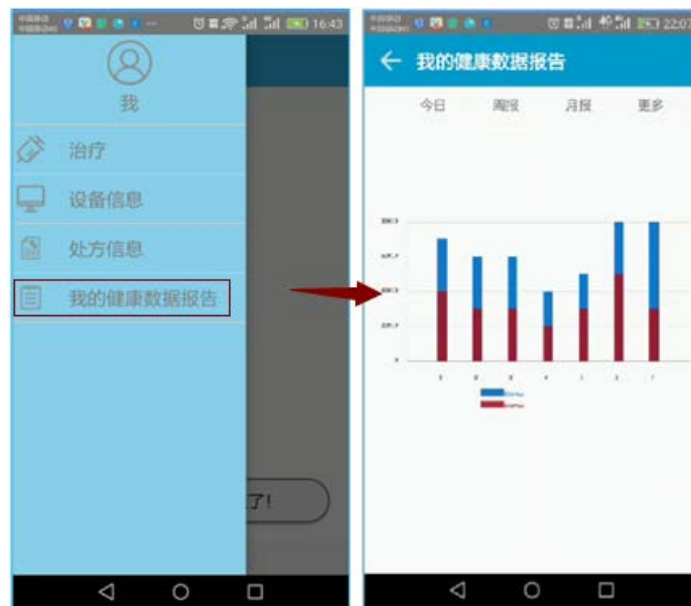
On the left menu, click "Prescription Information", go to the Prescription information page, the default prescription is empty, as shown in the following figure:



You can go to the Add Prescription page by clicking the "Add Prescription" button, the pop-up menu "add Manually" (or you can add a device by sweeping the QR code), as shown in the following figure:



6. My Health Data Report



Chapter 3: Electromagnetic compatibility

3.1 Cable Information

Number	Name	Cable length	whether to block	Manufacturers	Model
1	USB 2.0 AM to Magnetic snap connector(7p)	80Cm	是	Shenzhen Scs Fu Electronics	

3.2 Electromagnetic emission and immunity guidelines and manufacturer's statement

3.2.1 Guide and Manufacturer's statement-electromagnetic emission

Guide and manufacturer's statement-electromagnetic emission		
TEA Device is expected to be used in the following electromagnetic environments, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Launch test	Compliance	Electromagnetic Environment-Guide
RF emission GB 4824	1 组	TEA Device does not produce or use RF energy for material handling or inspection/analysis. TEA Device directly connected to residential low-voltage power grid facilities for use.
RF emission GB 4824	B 类	
Harmonic radiation GB 17625.1	Class A	

Voltage fluctuation/flash ing emission GB 17625.2	Meet	
--	------	--


3.2.2 Guide and manufacturer's statement-electromagnetic immunity-for all devices and systems

Guide and Manufacturer's statement— —Electromagnetic immunity			
TEA Device is expected to be used in the following electromagnetic environments, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Disturbance resistance test	IEC60601 Test level	Compatible with level	Electromagnetic Environment-Guide
Electrostatic Discharge (ESD) GB/T 17626.2	±6KV Contact Discharge ±8KV Air Discharge	±6KV Contact Discharge ±8KV Air Discharge	The ground should be woody, concrete or tile, and if the ground is covered with synthetic material, the relative humidity should be at least 30%.
Electric Rapid Transient pulse Group GB/T 17626.4	±2KV to the power cord ±1KV Input/Output 线	±2KV to the power cord ±1KV to input/output lines	The network power supply should have the quality used in a typical commercial or hospital environment.
Lang Chung GB/T 17626.5	±1KV Line Alignment ±2KV line to the ground	±1KV Line Alignment ±2KV line to the ground	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage drop, short time interrupt and voltage change on power input line GB/T 17626.11	<5% U_T For a period of 0.5 weeks (in U_T On, >95% 's temporary Drop) 40% U_T For a period of 5 weeks (in U_T On, >60% 's temporary Drop)	<5% U_T For a period of 0.5 weeks (in U_T On, >95% 's temporary Drop) 40% U_T For a period of 5 weeks (in U_T On, >60% 's temporary Drop) 70% U_T For a period of	The network power supply should have the quality used in a typical commercial or hospital environment. If the user needs to run continuously during a power outage, the recommended device is powered by an uninterruptible electricity supply or battery

	70% U _T For a period of 25 weeks (in U _T On, >30% 's temporary Drop) <5%u _T , continuous 5s (in U _T On, >95% 's temporary Drop)	25 weeks (in U _T On, >30% 's temporary Drop) <5%u _T , continuous 5s (in U _T On, >95% 's temporary Drop)	
Working frequency magnetic field (50/60Hz) GB/T 17626.8	3 a/m	3 a/m	The frequency magnetic field should have the characteristics of the frequency magnetic field in typical places in a typical commercial or medical environment.

3.2.3 Guide and Manufacturer's statement-electromagnetic immunity-for non-life support equipment and systems

Guide and Manufacturer's statement— —Electromagnetic immunity			
TEA Device is expected to be used in the following electromagnetic environments, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Disturbance resistance test	IEC60601 Test level	Compatible with level	Electromagnetic Environment-Guide
RF conduction GB/T 17626.6	3V (valid value) 150KHz~80mhz	3V (valid value) 150KHz~80mhz	Portable and mobile RF communication devices should not be used closer to any part of the device than the recommended isolation distance, including cables. The distance is calculated by a formula corresponding to the transmitter frequency Recommended Isolation Distance $D = 1.2 \sqrt{(P)}$ 150KHz-80MHz $D = 1.2 \sqrt{(P)}$ 80MHz-800MHz
RF radiation	3V/m 80MHz~2.5GHz	3V/m	

GB/T 17626.3		80MHz~2.5GHz	<p>$D = 2.3 \sqrt{(P)}$ 800MHz-2.5GHz</p> <p>In the formula:</p> <p>p--according to the transmitter manufacturer to provide the maximum rated output power, in Watts (W);</p> <p>d-Is the recommended isolation distance, in meters (m).</p> <p>The field strength of a stationary RF transmitter is determined by the electromagnetic site survey and should be lower than the compliance level in each frequency range.</p> <p>Interference may occur near devices that mark the following symbols</p> 
	<p>注 1:在 80MHz 和 On the 800MHz frequency, the formula of higher frequency band is used.</p> <p>Note 2: In these guidelines may not be suitable for all cases, electromagnetic transmission is affected by the absorption and reflection of buildings, objects and the human body.</p>		
	<p>A fixed-type transmitters, such as base stations for wireless (cellular/cordless) telephones and ground mobile radios, amateur radios, amplitude modulation and FM radio broadcasts, and television broadcasts, are theoretically not accurately predictable in their field strength. In order to evaluate the electromagnetic environment of fixed RF transmitter, the survey of electromagnetic site should be considered. If the measured field strength near TEA Device is higher than the above applicable RF compliance level, you should observe TEA Device to verify that it is functioning properly. If abnormal performance is observed, additional measures may be necessary, such as resizing or position the device.</p> <p>b in 150khz~80mhz the entire frequency range, the field strength should be lower than 3v/m.</p>		

Recommended isolation distances between 3.2.4 portable and mobile RF communication devices and devices or systems-for non-life support devices and systems

Recommended isolation distance between portable and mobile RF communication devices and devices or systems			
TEA Device is expected to be used in the controlled electromagnetic environment of radiofrequency radiation harassment. According to the maximum rated output of communication equipment Rate TEA Device users can maintain portable and mobile RF communication equipment (transmitters) and TEA Device to prevent electromagnetic interference by the minimum distance between			
Maximum Transmitter Amount Fixed output power W	Isolation distance of different frequencies of the corresponding transmitter/m		
	150KHz-80MHz $D = 1.2 \sqrt{(P)}$	80MHz-800MHz $D = 1.2 \sqrt{(P)}$	800MHz-2.5GHz $D = 2.3 \sqrt{(P)}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the maximum rated output power of the transmitter not listed in the table above, the isolation distance d, in meters (m), is recommended and can be determined by the formula in the corresponding transmitter frequency bar.			
Note 1:from 80MHz to 800MHz Frequency on, Formulas with higher frequency bands should be used			
Note 2:These guidelines may not be suitable for all situations, Electromagnetic propagation is influenced by the absorption and reflection of buildings, objects and the human body.			

Chapter 4: Fault analysis and troubleshooting

The specific exclusion method is prompted by the following table:

Fault	Cause analysis	Exclusion method
TEA Device Unable to start	Battery charge is empty	Please follow the instructions to Stimulator Charging And try to start again.
	Hardware failure	Please set TEA Device “return to the original maintenance”.
TEA Device no output	Electrode line failure	Please replace the electrode line.
	Stimulus intensity is too low	Please check TEA Device in stimulation mode, and stimulus strength is set within the range of sensations.
	Electrode Plate Damage	Please replace the electrode sheet.
	Hardware failure	As mentioned above, method invalid, please set TEA Device “Return to the original maintenance”.
Battery module cannot be charged	USB power adapter failure	Please contact the after-sales department for replacement of the USB power adapter.
	USB charging cable failure	Please contact the after-sales department for replacement of the USB charging cable.
	Battery aging	Battery over service life, please contact after-sales department for return of the TEA Device.
	Hardware failure	Please contact the after-sales department for return to replace the TEA Device
Bluetooth device cannot connect TEA Device	Bluetooth devices, such as phones, do not properly install the correct version of the app software.	Please download and install the correct TEA App.
	Bluetooth devices, such as mobile phones, do not	Please refer to the system requirements List of mobile phone configuration requirements to replace the phone.

	support app software	
	Bluetooth devices, such as mobile phones, are not set up correctly and authorize TEA app to use Bluetooth modules.	Go to the Bluetooth Device Settings page and authorize the app software to use the Bluetooth module.
	Bluetooth Devices and TEA Device are too far away from each other.	Please reduce the distance between TEA Device and the Bluetooth device (phone). Try the connection again.
	Bluetooth device and/or TEA Device Software failure.	Please restart TEA Device and Bluetooth device (phone), keep a close distance and try connecting again.
	The cause of hardware failure of product communication.	If the aforementioned means are invalid, please set TEA Device to "Return to the original maintenance".

Chapter 5: Product Maintenance

5.1 Maintenance

Please clean TEA Device often. If the skin is oily or wet, please wipe it with a dry soft cloth. If necessary, it can be disinfected by gently wiping with a cotton round dipped in sterilized alcohol.



1) Do not use diluent, gasoline, volatile oil and so on to wipe.

2) do not clean or wet products and accessories.

3) Please do not keep in the following cases:

- Where there is water.
- A place of high temperature, humidity, non-ventilation, direct sunlight, dust, or salty air.
- A place where it can produce tilt, vibration, or shock.
- Chemical storage sites and places where corrosive gases are produced

"Note" If you do not comply with the above precautions and other correct use methods, the company does not assume quality responsibility.

Users are not allowed to repair TEA Device. For repairs, sent to the manufacturer or a designated franchise distributor.

5.2 Waste Disposal

- TEA Device does not produce any waste during normal use.
- TEA Device and its accessories can be treated as electronic medical products in accordance with relevant national environmental protection requirements for treatment and waste disposal.

Chapter 6: Product Warranty

TEA Device is covered by a one-year warranty from the date of purchase (proof of purchase is required).

Warranty applies to the TEA Device itself and does not cover lead cable, USB charging cable, electrode pads, holding strap and holding clip.

Within that period, the manufacturer will replace your faulty TEA Device at no charge (except shipping & handling fees), provided that the device:

- has been used for the intended purpose and in the manner described in this manual
- has not been connected to an unsuitable power source
- has not been subjected to misuse or neglect
- has not been modified or disassembled
- has not been damaged by accidental fall

Legal rights are not affected by this warranty.

To request the warranty service, please bring this product to the store or send it directly to manufacturer.

Chapter 7: Technical Specifications

Name	Transcutaneous Electrical Acustimulator (TEA)
Model	SNM-FDC01
Power supply	
Power	Internal battery
Battery type	Rechargeable 3.7V Lithium-Polymer Battery 650 mAh
Charging Input	5V through USB 2.0 (custom USB charging cable is included)
Battery life	300 Charge Cycles ($\geq 80\%$ Nominal capacity)
Stimulation	
Stimulation Channels	1
Stimulation waveform	Rectangular alternating
Stimulation mode	Continuous, Burst
Voltage compliance	65 V
Maximum output current	9.5 mA
Current or voltage regulation	Current regulation
Stimulation pulse width range	50 – 500 μ s
Stimulation frequency range	1 – 100 Hz
Electrode pad physical specifications	
Type	Self-adhesive (single-patient, multiple applications)
Shape and size	Round, diameter 20 mm
TEA Device physical specifications	
Dimensions	65 x 49 x 17 mm
Weight	44 g
Housing	ABS plastic
Environment	
Operating/storage/transport temperature	5 to 40°C
Operating/storage/transport humidity	25% to 80% RH
Storage/transport atmospheric pressure	70 to 106 kPa
Electric shock	Internally Powered Equipment, type BF Applied Parts
IP Rating	IpX2
Classification of safety levels	Not suitable for is in the presence of flammable mixtures: No Ap/apg
Running mode	Continuous Operation
EMC	Group 1, Class B
Smart phone compatibility	
Google Android	Android 6.0 (or later) smart phone with Bluetooth 4.0 (or higher)
Apple iOS	Not supported

Chapter 8: Applied Standards

Standard number	Description
IEC 60601-1: 2005+A1:2012	General requirements for basic safety and essential performance
IEC 60601-1-2: 2014	Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6: 2010+A1:2013	Collateral standard: Usability
IEC 60601-1-11: 2015	Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in homecare environment
IEC 60601-2-10: 2012	Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 62133-2: 2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes
IEC 62304: 2006+A1:2015	Medical device software - Software life cycle processes
ISO 15223-1: 2016	Symbols to be used with medical devices labels, labeling and information to be supplied
ANSI/AAMI EC12: 2000/(R)2015	Disposable ECG Electrodes
FCC 47 CFR Part 15 Subpart C	Radio Frequency Devices: Intentional Radiators
ISO 10993-5: 2009/(R)2014	Biological Evaluation of Medical Devices: Tests for in vitro cytotoxicity
ISO 10993-10: 2010/(R)2014	Biological Evaluation of Medical Devices: Tests for irritation and skin sensitization
ISO 14971: 2007	Application of Risk Management to Medical Devices

Chapter 9: FCC Statement

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.

Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This product 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 product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Manufacturer information

Ningbo MedKinetic Medical Device Co., Ltd.

Address: Lushan West Road, 167-8, Ningbo Free Trade Zone(South), 315806 Ningbo

Phone: +86 574 86808886

Fax: +86 574 86808885

Email: support@medkinetic.com

USA Authorized Representative

Medipace Inc

Address: 420 S Madison Ave, Suite 206, Pasadena, CA 91101, USA

Phone +1 626-497-9441

Email support@medipaceinc.com