KT100 User Manual

Insect bite helper

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User Notice

Dear users, thank you very much for purchasing the Insect bite helper (hereinafter referred to as device).

This Manual is written and compiled in accordance with the council directive MDR(2017/745/EU) for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

It is a medical device, which can be used repeatedly.

The Manual describes, in accordance with the device's features and requirements, main structure, functions, specifications, correct methods for transportation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the patient and device. Refer to the respective chapters for details.

Please read the User Manual carefully before using this device. The User Manual which describes the operating procedures should be followed strictly. This instruction will describe the operation procedures that require attention, operation practices that may lead to abnormality, damage that occur to the product and the operator or user. As for any abnormality or damage to the machine or people caused by operation, maintenance and storage violating this instruction, our company is not responsible for safety, reliability and performance guarantee and the manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

Our company has the final interpretation to this manual. The content of this manual is subject to change without prior notice.

Warnings

Remind that it may cause serious consequences to tester, patient or environment.

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Explosive hazard—DO NOT use the device in environment with inflammable gas such as anesthetic.
- DO NOT use the device while examining by MRI or CT, as the induced current may cause burn.
- The maintenance to the device or replacement of the battery (non-detachable lithium battery) can only be performed by qualified service personnel specified by manufacturer, dangers (such as over-temperature, fire or explosion) may occur when replacing the battery by the personnel not fully trained. Patients are not permitted to maintain or refit the device by themselves. Unauthorized modification of the device would result unacceptable risk.
- Depending on the sensitivity of the person using the device and of the area of skin, the treatment temperature may feel unpleasant and cause slight skin redness and, in rare faces, irritated skin. If the heat function feels too hot, stop treatment immediately.
- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation disturbance users. If required, you can use the heat function of the insect bite healer on the sting/bite again after a break of 5 minutes or also use it immediately on another sting/bite in a different area. The maximum number of 5 applications per hour on the same treatment area must not be exceeded.
- For some special patients who need a more careful inspection on the test site, please don't place the device on the edema or tender tissue.
- Each part of the device is firmly fixed, if accidental falling leads to the small parts such as a button to fall off, avoid swallowing of these parts, it may cause suffocation.
- The device contains PC and ABS materials, whose biocompatibility has been tested in accordance with the requirements in EN ISO 10993-1, and it has passed the recommended biocompatibility test. The person who is allergic to PC or ABS can not use this device.
- Do NOT strand the lanyard to avoid device drop and damage. The lanyard is made of insensitive material. Please do not use it if any person is allergic to lanyard. Do not wrap the lanyard or USB cable around neck to avoid an accident.
- The packaging materials must be placed in the region where the children are out of reaching.
- The device can not be used with the equipment not specified in the Manual. Only the accessories appointed or recommended by the manufacturer can be used, otherwise it may cause injury to the tester and operator or damage to the device.
- Check the device before use to make sure that there is no visible damage that may affect patient's safety and device performance. When there is obvious damage, please replace the damaged parts before use.
- When using the device, please keep it away from the equipment which can generate strong electric field or strong magnetic field. Using the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.
- When storing the device, keep it away from children, pets and insects to avoid affecting its performance.
- Do not place the device in places exposed to direct sunlight, high temperature, humidity, dust, cotton wool or easy to splash water, to avoid affecting its performance.
- When several products are used on the same patient simultaneously, danger may occur which is arisen from the overlap of leakage current.
- The intended operator of the device may be a patient.
- Avoid maintaining the device during using.
- Patients should read the product manual carefully before use and operate according to the requirements.

This product is a medical device and shall be disposed of in compliance with the EU WEEE Directive (2012/19/EU) and other applicable local environmental regulations.

To prevent pollution and promote resource recovery, this device—including its battery and electronic components—must, at the end of its service life, be directed to an authorized WEEE collection facility or a locally approved medical device recycler, and must not be disposed of as unsorted municipal waste.

Please dispose of this product at a designated collection point as required by local regulations. Contact the local authority for information on specific disposal methods and collection points.

1 Overview

1.1 Features

A. Quickly relieve itching cause by insect bites.
B. Adopt physical heating, skin-friendly materials, chemical free.
C. Compact and portable design.
D. Accurate and reliable temperature control, safe to use.
E. Two temperature modes (3 positions of heating time for each mode).
F. Easy to use at night.

1.2 Intended purpose

Insect bite helper is a medical device for the symptomatic treatment of itching and swelling caused by insect stings and bites, for example by mosquitoes, wasps, bees, hornets or horseflies. If the device is applied immediately after the sting/bite, the symptoms can normally be prevented altogether. Even if the device is used slightly later, the symptoms can fade away sooner.

Patient population: Patient aged 2 years and older. (Note: Do not use this device for persons under 2 years old.)

Intended users: Adults and children aged 12 years and older.

Environment:

All environments except oxygen rich environment.

Side effect: Non.

Residual risk:

Skin injuries may occur when the device is used on sensitive areas or by specific populations with sensory disturbance.

Contraindications:

— Not for use on mucus membranes (e.g. inside of the mouth, nose, etc.).

— Not for use on or near the eyes. Do not simultaneously use with medication and/or cosmetics.

— Not for use in case of heavy or chronic skin inflammation or severe internal diseases, in which the use could cause deterioration, such as:

- Open wounds, damaged skin
- Scalded or burnt skin
- Frostbite
- Small-fiber neuropathy, allodynia, hyperalgesia
- Tumors and malignant changes of the skin
- People with reduced sensitivity due to physical or medical complaints.
- If you have a fever.
- On sensitive areas of skin.
- Skin areas with poor blood supply.
- If you have any sensory impairment that reduces the feeling of pain (e.g. metabolic disorders).
- If you are using lotions, creams and gels locally at the same time.
- On moist skin.
- If you suffer from persistently irritated skin due to long-term heat application on the same area of skin.

1.3 Environment requirements

Storage Environment
a) Temperature: -40 ℃ ~ + 60 ℃
b) Relative humidity: ≤ 95%
c) Atmospheric pressure: 500 hPa ~ 1060 hPa
Operating Environment
a) Temperature: +5 ℃ ~ + 40 ℃
b) Relative Humidity: ≤ 75%
c) Atmospheric pressure: 700 hPa ~ 1060 hPa

1.4 Precautions

Point out conditions or practices that may cause damage to the device or other properties.

- Before using the device, make sure that it locates in normal working state and operating environment.
- When the device is carried from cold or hot environment to warm or humid environment, please do not use it immediately.
- If the device is splashed or coagulated by water, please stop operating.
- DO NOT operate the device with sharp things.
- High temperature, high pressure, gas sterilizing or immersion disinfection for the device is not permitted. Refer to User Manual in the relative chapter (6.1) for cleaning. Please turn off the device before cleaning.
- The device may not be suitable for all patients, if you can't get a satisfactory result, please stop using it.
- The device has 3-year service life, date of manufacture sees the label.
- At normal temperature, the maximum temperature of the plastic enclosure of the adapter during operation may reach about 65 ℃. In order to prevent scalding, the contact time is recommended not to exceed 10 seconds.
- Do not contort or drag the wire of the device.
- The device can not be used during charging.
- If necessary, our company can provide some information (such as circuit diagrams, component lists, illustrations, etc.), so that the qualified technical personnel of the patient can repair the device components designated by our company.
- The device has been calibrated before leaving factory.
- Please select medical power adapter to charge it, when connecting the special adapter with the socket, make sure there is no shelter near the socket and it is easy to plug and unplug, otherwise the power will not be cut off in time when necessary, causes damage.

Before using the device, consult your doctor if any of the following apply to you:

- You have any skin conditions.
- You suffer from a serious illness, in particular if you have a propensity to thromboembolic conditions or recurrent malignant growths.
- You have unexplained chronic pain in any part of the body.

Medical advice should be sought in the following cases:

- Persistent symptoms while using the device.
- Worsening symptoms while using the device. Until these have been clarified, you should stop using the device.
- Tick bites, as bites of these arachnids can cause the transmission of pathogens such as Lyme disease or tick-borne encephalitis (TBE).

In the event of severe hypersensitivity reactions after an insect bite or sting (anaphylactic reaction), the device is not a replacement for emergency treatment. You should immediately call a doctor at the first signs of any such reaction (e.g. increased itching, reddening, swelling or formation of a welt; dizziness, nausea, difficulties breathing, hypotension or hypertension).

2 Principle

Insect bite helper works solely by concentrated heat and is thus completely free from chemicals.

Hence, Insect bite helper is also suitable for pregnant women, allergy sufferers and children.

The application of concentrated heat (local hyperthermia) is a physical mode of action based on the application of a brief, concentrated thermal stimulus to a small, limited area of skin. This localised pulse of heat may be sufficient to trigger a response from the body that reduces itching and subsequently causes any swelling to go down.

If the device is applied immediately after the sting/bite, the symptoms can normally be prevented altogether, so the affected site on the body should be treated as quickly as possible. Even if the device is used slightly later, the symptoms can fade away sooner.

3 Functions

A. Dual-switch over-temperature protection design.

B. Two temperature modes (6 positions of heating time) can be selected, and the set position can be automatically saved.

C. Indicate the temperature grade by indicator lights.

D. Low-battery indication.

E. Automatic standby function.

F. Type-C charging port.

4 Product Introduction

4.1 Appearance

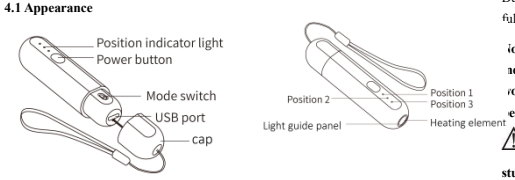

Figure 1 Appearance

A. Mode switch: switch the temperature mode, L: low temperature mode (the position indicator light is blue), H: high temperature mode (the position indicator light is pink).

B. Power button: exit the standby mode and start heating; switch the heating time (3 positions of heating time for each mode). The position indicator light indicates the position (as shown in Figure 1) of the heating time, Position 3: the heating time is longest, Position 2: the heating time is moderate, Position 1: the heating time is shortest.

4.2 Connection of USB cable

Open the USB plug of the device, insert the micro end of USB cable into the USB port interface, the other end into computer or power adapter.

4.3 Structure, accessories and software description

A. Structure: main unit, lanyard, USB cable, power adapter (optional).

B. Accessories: one power adapter (optional).

Name	Model	Supplier
Power adapter	CMS0105-5EU	Contec Medical Systems Co., Ltd.

In addition to the adapter provided by our company, users may use other 5V/1000mA adapters that comply with the IEC 60601-1 standard to ensure safety and proper charging performance.

Please check the device and accessories according to the list to avoid that the device can not work normally.

C. Software description

Release version: V1.0

5 Operating

5.1 Use

A. Long press the "Power button" to exit the standby mode and start heating (default position when exiting the standby mode for the first time: position 1). During heating, the position indicator light and the Light guide panel are constantly on.

B. During heating, short press the "Power button" to switch the position, and the corresponding position indicator light will be on.

Note: Based on skin sensitivity, two temperature modes (three positions for each mode) are designed for selection.

It is recommended to use the low temperature mode (L).

Note: Due to the slight burning pain caused by the heating pad, children under 12 years old or people who are more sensitive to the pain should first use the Low temperature mode (L). If the effect is not obvious, then gradually adjust it to the high temperature mode (H) to feel whether it is acceptable. It is recommended to adjust the position in an order from low temperature to high temperature (low temperature mode (L): position 1, position 2, position 3, high temperature mode (H): position 1, position 2, position 3) to find an appropriate one.

C. After heated to the specified temperature, it will give an audible signal.

D. Place the heating element (round ceramic disc at the tip of the device) on the part that needs to be heated.

Note: The applied part of this device is the heating element.

E. After the heating is completed, it will enter the standby mode immediately.

Note: The device has the temperature position memory function. After setting a temperature position, it will still start in that position the next time it exits the standby mode, no need to set it again.

Note: Over-temperature protection function. When the continuous heating time exceeds 60 s, it will enter the standby mode automatically.

5.2 Charging

The device can be charged by a power adapter.

During charging, the three indicator lights will be on circularly. It indicates that it has been fully charged when all indicator lights are on.

Note: When low battery occurs, the device can still be used a few times, but the position indicator light will flash when heating. If the battery power is too low, the device can not work normally. After exiting the standby mode, all indicator lights will flash once, then be off.

⚠ **Before use, make sure that there is no insect sting remaining in the area that was stung. Remove the sting carefully before use. Use immediately after the insect bite or sting achieves the best results, as the toxins have not yet been able to take full effect in the skin. If you wait too long to treat the area that has been stung or bitten and itching, inflammation and swelling has already started, the insect bite healer can only have a limited effect. Nevertheless, treat the area with the insect bite healer. Usually, itching can be relieved and healing can be sped up.**

6 Maintain, Transport and Storage

6.1 Cleaning

Before cleaning, ensure good room ventilation, remove the inflammable and combustible materials around it, and avoid open flame and electrical power source, etc.

When cleaning, turn off the device and remove the cap, then wipe the outer surface (excluding the lanyard) of the device with a medical gauze dipped in isopropanol (70%) (note: isopropanol produced by any formal company can be used.) for at least 1 minute. Dry them naturally or clean them with a clean and dry cloth.

Determine whether the cleaning is adequate by visual inspection. If stains are found, please repeat the above steps.

6.2 Maintenance

A. Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patients safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.

B. Please clean the device before/after using it according to the User Manual (6.1).

C. Please charge the battery in time when low battery appears.

D. Recharge the battery soon after over-discharge. The device should be recharged every three months when it is not used for some time. It can extend the battery life following this guidance.

E. The device need not to be calibrated during maintenance.

6.3 Transport and Storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. During transportation, avoid strong shock, vibration and splashing with rain or snow, and it can not be transported mixed with toxic, harmful, corrosive material.

B. The packed device should be stored in room with no corrosive gases and good ventilation.

7 Troubleshooting

Trouble	Possible Reason	Solution
The device no longer gets hot enough	1) The device is not used in environment required by the manual. 2) The device works abnormally.	1) Please use the device in normal environment. 2) Please contact the after-sales.
The device can not be turned on	1) Low battery or the battery is drained away. 2) The device works abnormally.	1) Please charge the battery. 2) Please contact the after-sales.
The device can not be used for full time after charge.	1) The battery is not charged fully. 2) The device works abnormally.	1) Please charge the battery. 2) Please contact the after-sales.
The battery can not be fully charged even after 10-hour charging time.	The device works abnormally.	Please contact the after-sales.

8 Symbols

Symbols	Meaning
	Refer to instruction manual/booklet for information related to safety.
	Caution
	Type BF applied part
	Manufacturer
	Date of manufacture
SN	Serial number
	Recycling garbage WEEE (2012/19/EU)
	USB
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	This way up
	Fragile, handle with care
	Keep dry
	Power button
	Recyclable
IP22	It means this Insect bite helper is protection against ingress of solid foreign objects of 12.5mm and greater, protection against ingress of water dripping when device tilted up to 15°.
UDI	Unique device identifier
MD	Medical device
EU REP	Authorized representative in the European Community
CE 0123	This item is compliant with Regulation(EU)2017/745 of the European Parliament and of the Council of 5 April 2017.

Note：Your device may not contain all the following symbols.

9 Specification

Heating temperature and time	
Low temperature mode	47 ℃, heating time: Position 1: 4 s Position 2: 7 s Position 3: 9 s
High temperature mode	51 ℃, heating time: Position 1: 3s Position 2: 5 s Position 3: 6 s
Safety class	Internally powered equipment, type BF applied part
International Protection	IP22
Working voltage	DC 3.6 V - 4.2 V
Working current	≤ 250mA
Power supply	A rechargeable lithium battery (3.7V)
Battery life	Charge and discharge: no less than 500 times.
Operation time	About 500 times after fully charged under normal operating conditions.
Adapter specification	Output voltage: DC 5V Output current: 1000 mA
Dimension and Weight	
Dimension	111 mm(L) × 24 mm(W) × 22 mm(H)
Weight	About 45 g (including a lithium battery)

EMC

This equipment is suitable for professional healthcare facility environments and home healthcare environments.

Warning:

- Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM

DISTURBANCES is high.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note:

- This equipment needs special precautions regarding EMC and needs to put into service according to the EMC information provided below.
- The basic performance: heating temperature: 47 ℃, heating time: 4s, 7s, 9s; heating temperature: 51 ℃, heating time: 3s, 5s, 6s.
- When the device is disturbed, please use in another environment to ensure its accuracy.
- Other devices may affect this device even though they meet the requirements of CISPR.

Product configuration

Serial number	Name	Cable length	Whether to shield
1	USB cable	50cm	Yes

Table 1

Guidance and Declaration - Electromagnetic Emissions	
Emissions test	Compliance
Conducted and radiated RF EMISSIONS CISPR 11	Group 1
Conducted and radiated RF EMISSIONS CISPR 11	Class B
Harmonic distortion IEC 61000-3-2	Class A
Voltage fluctuations and flicker	Complies
IEC 61000-3-3	

Table 2

Guidance and Declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines 100 kHz repetition frequency	±2 kV for power supply lines Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	±1 kV line(s) to line(s) Not applicable
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % U_T; 0,5 .cycle .At 0°,45°,90°,135°,180°,225°,270° and315°. 0 % U_T; 1 cycle and 70 % U_T ; 25/30 cycles ;Single phase:at 0°. 0 % U_T ; 250/300 cycle	0 % U_T; 0,5 .cycle .At 0°,45°,90°,135°,180°,225°,270 °and315°. 0 % U_T; 1 cycle and 70 % U_T ; 25/30 cycles ;Single phase:at 0°. 0 % U_T ; 250/300 cycle
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15MHz - 80 MHz 6 V in ISM and amateur radio bands between 0,15MHz to 80 MHz 80%AM at 1kHz	3 V 0,15MHz - 80 MHz 6 V in ISM and amateur radio bands between 0,15MHz to 80 MHz 80%AM at 1kHz
Radiated RF IEC61000-4-3	10V/m 80 MHz-2,7GHz 80%AM at 1kHz	10V/m 80 MHz-2,7GHz 80%AM at 1kHz
NOTE U_T is the a.c.mains voltage prior to application of the test level		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC60601-1-2 Test level (V/m)	Compliance level (V/m)
	385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	27	27
	450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13,17	Pulse modulation b) 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28	28
	870					
	930					
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4,25; UMTS	Pulse modulation b) 217 Hz	28	28
	1845					
	1970					
	2450	2400 – 2570	Bluetooth, WLAN,	Pulse modulation b)	28	28
			802.11 b/g/n, RFID 2450, LTE Band 7	217 Hz		
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9	9
	5500					
	5785					

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity			
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	Compliance level (A/m)
	30 kHz	CW	8
	134,2 kHz	Pulse modulation 2.1 kHz	65
	13,56 MHz	Pulse modulation 50 kHz	7,5