Reusable Temperature Probes

User's Manual

CE 0123

Scope of application

It is matched with a compatible monitoring device with body temperature monitoring function, and is used when collecting and transmitting the patient's body temperature signal.

Components

Sensor,Connector and Cable

Model:

Model (REF)	Intended measuring position	Intended population	Compatible monitor
T1306	Skin-surface	Adult	Subject to supporting host
T3306	Skin-surface	Pediatric	Subject to supporting host

Intended user

The Temperature Probes are intended for use by qualified medical professionals only.

Intended patient population

The Temperature Probes are intended to be used for adult and pediatric patients.

Intended purpose

The temperature probes, which are designed to measure skin surface temperature or body cavity temperature of adult and pediatric patients, are indicated for use by qualified medical professionals in hospital environments.

SPECIFICATIONS:

Temperature measurement range: 20 ℃ ~ 45 ℃

Temperature measurement accuracy: ± 0.1 ℃

CONDITIONS OF USE

Temperature range: 5℃ to 40℃

Humidity (Operating): ≤80% (no dew)

Hyperbaric Pressure: 86kPa～106kPa

Power supply:DC3-5V

TRANSPORTATION AND STORAGE

Temperature range: -20℃ to 55℃

Humidity (Operating):≤93% (no dew)

Hyperbaric Pressure: 86kPa～106kPa

REPLACING & DISUSE

Replacing: If the wire is broken, the skin is damaged, and the service life has expired, please replace it with a new one in time.

Waste: Do not dispose of this product at will. Please comply with all local and/or government regulations when handling this product and its packaging; For information about the regulations applicable to this product, please consult your local government.

Contraindications

- For esophageal measurement:

The esophageal probe is contraindicated for critically ill patients, or patients with esophageal diverticulum and undergoing a tracheostomy or insertion of an internal jugular catheter.

- For skin measurement:

The skin probe is not applied to the patient's non-intact skin for monitoring of skin surface temperature.

CLASSIFICATION RULE

As the device can be used for continuous surveillance of vital physiological parameters in anesthesia, intensive care or emergency care, it falls under the classification of IIb in accordance with the 1st paragraph and 3rd indent exceptional case of Rule 10 in Chapter III of Annex VIII of Regulation (EU) 2017/745. Additionally, this classification is supported by Note 3 mentioned on page 43 of MDCG 2021-24. Therefore, the device should be classified as a Class IIb medical device.

Compatibility:

In order to ensure compatibility and claimed accuracy of the devices Shenzhen MedKe Technology Co., Ltd. SpO2 sensors are only to be used with the specified equipment for which they have been designed and labeled use for.

WARNING ⚠

- The sensor can only be used with specified equipment. The user is responsible for reading the instruction manual of the device or contacting the company for consultation before use to confirm the compatibility of the sensor and the device.
- Do not be used close to or stacked with other electrical equipment, otherwise there may be very slight electromagnetic interference to other electrical equipment;
- Always use caution when applying, inserting, or removing a temperature probe from a patient.
- When using these probes, follow standard application practices recommended by your medical facility.
- Improper use or misoperation of the temperature probes may produce the following undesirable results: damage to the core of the cable, failure of the electrical insulation of the cable, inaccurate measurement values, etc.
- The temperature probes can be detected by matching equipment. If an open circuit, short circuit, intermittent reading or completely incorrect reading is found, it indicates that the body temperature sensor is damaged.
- If the accuracy of the temperature probes exceeds the error range, it cannot be used. When the temperature sensor is damaged in any form, it should be handled in accordance with the relevant regulations of the hospital.
- It should not be used for patients in an active state. When the patient is monitored for a long time (not more than 4 hours), the measurement site should be inspected and replaced at least every 2 hours.
- Certain patients may require more frequent examinations, such as patients with sensitive skin. Because continuous and long-term monitoring may increase unpredictable skin changes, such as allergies, redness, and blistering.
- The temperature probes must not be used in the presence of high-intensity radio frequency sources (such as electronic equipment and MRI equipment in surgery), otherwise it may cause inaccurate measurement values and damage the sensor.
- If the temperature probes must be used with high-intensity radio frequency equipment at the same time, do not let the cable connected to the patient form a loop; do not let the cable directly contact the skin; ensure that the temperature probes matching

equipment and the radio frequency equipment have sufficient electrical grounding insulation.
- The product is a BF type application part.
- Please read the instructions before use.

NOTE ⚠

Be sure to observe the following:
- Please select the temperature probes according to the patient type.
- The thermistor in the temperature probes end is insulated from the surface of other parts of the sensor, but improper use or misoperation will damage its insulation.
- Do not twist the temperature probes cable with the cable of the electrosurgical equipment, because high-frequency electrical interference may affect the accuracy of the measurement.
- When using a skin temperature probes, the probe surface of the sensor must be in contact with the patient's skin.
- The temperature probes is a non-intravascular medical device.
- The continuous use time of the product is no more than 4 hours.
- When necessary, the company provides product connection diagrams, legends and other materials.
- This manual contains instructions for use and technical specifications.
- 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.

Confirmation of temperature accuracy
- Technical performance：Accuracy: 0.1℃
- Intended clinical benefits：Diagnosis of fever
- The Temperature Probes with its Technical performance has been validated and tested for compliance with ISO 80601-2-56.

Cleaning the equipment:
- When cleaning or disinfecting, do not connect the probe to the monitor.
- When cleaning, first dip a clean and dry sponge pad in the cleaning fluid, and wipe the entire surface of the sensor and cables with this sponge pad.
- Soak in 75% alcohol for 10 minutes.
- Dip another clean, dry sponge pad with sterile or distilled water. Use this sponge pad to wipe all surfaces and cables of the sensor;
- Finally, use a clean, dry sponge pad to dry the sensor end and all surfaces of the cable.
- The connector pins must not be in contact with the cleaning fluid, otherwise it may cause permanent damage to the sensor and monitoring equipment.

Installation / Use:
- Please check the temperature probes for cracks, small holes, cracks, etc. before use. If there is any deformation or damage to the cable, please follow the relevant local regulations or the hospital’s waste disposal system, and do not discard it at will. The user must judge whether the type of temperature probes is suitable and has sufficient flexibility.
- Place the body surface temperature probes under the armpit or the relevant part of the body surface, and pay attention to contact the probe surface with the patient's skin.
- Connect the temperature probes to the device according to the operating instructions of the device.
- The response time of the temperature probes is ≤ 150s.
- This manual can be provided to users electronically or in paper form, if necessary, please contact email: info@medke.com.
- Electronic manuals for corresponding products can be downloaded from the company's website: www.medke.com.
- Skin Type Temperature Probes

a、Dry the skin surface where the temperature probes is placed. For the body surface temperature sensor: the recommended measurement site is under the armpit. If it is inconvenient, the probe can be placed on other relevant parts of the body surface.

b、Uncover the protective paper, put the temperature sensor into the armpit or the relevant part of the body surface, fix it with tape, and pay attention to the metal surface in contact with the patient's skin.

c、The temperature probes is connected to the monitor through an adapter cable, and the body temperature is measured according to the method provided in the monitor's instruction manual.

- General/Rectal Type Temperature Probes

a、Please select the verified temperature probes and measurement location according to the actual situation of the patient.

b、According to the measurement needs, insert the temperature probes into the rectum or esophagus by referring to the scale mark on the tail of the sensor. Make sure that the sensor is placed in the proper position.

c、The temperature probes is connected to the monitor via a transfer cable and takes the temperature measurement according to the method provided in the monitor instructions.

After service
Please contact your local customer center for warranty information about this product.

Warranty/Liability
Shenzhen MedKe Technology Co., Ltd. offers a six month warranty against defects in material and /or workmanship from the date of purchase. Medke does not cover the damage or breakage due to the abusive use or negligent care of the sensor.
Shenzhen MedKe Technology Co., Ltd. guarantees that the equipment conforms to the specifications of the safety and performance standards currently in force and applicable to it.

Version information
- Version: A.1
- Date of issue: Dec 05, 2023

Symbol explanation

	Manufacturer		LOT	**IPX2**	When the probe is tilted from vertical to 15 degrees, dripping water will not cause damage to the equipment
	Use-by date		See instructions before use		Latex Free
	Compliance with WEEE Standard		Date of manufacture		NON-sterile
	Catalogue number		Authorized representative in the European Community		Type BF Applied Parts
	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning		Medical device		UDI
	Temperature limit		Humidity limitation		Atmospheric pressure limitation
	Consult instructions for use	/	/	/	/

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IEC 60601-1-2：2014 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class A product

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for Professional healthcare facility environment and so on.

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.

Warning： 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.

Warning: 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."

Warning：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 Reusable Temperature Probes: T1306,T3306, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

If any：a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any：the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

Technical description

1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV input/output lines：±1 kV 100 kHz repetition frequency	Power supply lines：±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s)：±0.5, ±1 kV line(s) to earth：±0.5, ±1, ±2 kV	line(s) to line(s)：±0.5, ±1 kV line(s) to earth：±0.5, ±1, ±2 kV
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz： 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz	150KHz to 80MHz： 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians 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**	**Maximum Power**(W)	**Distance** (m)	**IEC 60601-1-2 Test level** (V/m)	**Compliance level** (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27	27
	450	430– 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28	28
	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28	28
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28	28
	5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	9