

Temperature probe Instruction Manual

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This manual provides in detail that instructions of product intended use, function and operation, please read this manual carefully before use, which is the prerequisite for correct operation and safety of patient or operator.

Taijia is responsible for the safety, reliability and performance of the product, only if:

1. The product is used according to the instruction manual.
2. The product is not damaged by human factors. Human factors refer to unintentional falling or intentional damage, etc.

Please contact our sales dept. for return, and let's know the product REF number, series number and return reason, if the goods are returned to us without recognizable series number, the return shipment will not be accepted.



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Product Introduction

1. Product Name: TJ Temperature Probe Series
2. Product Model: Refer to the mark on the label
3. Manufacturer: Shenzhen Taijia Electronics Co.,Ltd.
4. The Medical Device Manufacturing Enterprise License number : China SFDA 2211237, 2014
5. Execution Standard No.: YZB/YUE 0258-2014
6. Function and Structure:

The product is made up of temperature probe interface(plug),dual shielded line(cable) and temperature sensor.

7. Main Technical Parameters :

- 1) Temperature measurement range: 20°C~45°C (68°F~113°F).
- 2) Measurement precision: $\pm 0.2^{\circ}\text{C}$.

8. Working Environment Requirements:

Temperature:5°C~40°C;
Relative humidity: $\leq 80\%$;
Air pressure:700hPa~1060hPa

9. Intended Use:

Temperature probe can continuous measurement of body temperature of the human body, it is through the contact area of the body, the body temperature by thermistor pass to monitor, finally displayed on the monitor data, medical personnel record data archive, TJ series of temperature sensors for adults/children/baby/infant body temperature continuous monitoring. Suitable for all kinds of non invasive temperature testing equipment, such as medical monitoring, monitoring instrument to use

Operation instruction

1. Please check the probe before use whether there are cracks, holes, cracks and so on. If there is any deformation of the cable and damaged, please treat it according to local laws and regulations or hospital waste disposal system, do not discard it. When used in the esophagus or rectum, the user must determine the type of temperature probe is suitable and more soft.
2. For cavity temperature probe: put the probe in rectum or esophagus according to measurement needs, for the surface temperature probe: the recommended position is armpit, if it is inconvenient, it can be put in other relevant position. Such as arm.
3. Put probe under the arm or on the relevant parts of the body surface, fixed it by plastic sheets, make sure the metal surface contact with the patient.
4. Connect probe with equipment according to equipment manual.

Operation notice:

1. Choice probe according to the type of patient.
2. The thermal resistance of probe and other parts on the surface is insulated.
3. Misoperation or improper use may damage the insulation
4. Probe cable can not be wrapped with the cable of surgical equipment, high-frequency electrical interference may affect the measurement accuracy.
5. Use the metal surface in contact with the patient in operation
6. When needed, we will provide Circuit draw, parts list, diagram note and revision etc.

Warnings:

1. This product must be used in connection with the specified equipment only.
Please choose the suitable temperature probe extension cable according to equipment connector.
To use with unverified equipment may lead to inaccurate test result, or even hurt the patient and operator.
2. Disposal must be in accordance with local regulation or hospital waste disposal system
3. Carefully route cables to reduce the possibility of patient entanglement or strangulation
4. Don't use Temperature probe during MRI scanning, Conducted current may cause burns.
5. Improper use or misoperation may have the following bad results: cored wire of cables was damaged and electrical insulation failed, the inaccuracy of measurement.
6. The probe can not be calibrated by itself, regular inspection should be made monthly in hospital to ensure the normal working. Temperature probe can be tested by matched equipment, when the open-circuit, short circuit, intermittent or completely incorrect reading happened, it shows that the core wire has been damaged. If the accuracy beyond the margin of error, it can not be used. When any damage occurs, they should be treated in accordance with the relevant regulation of hospital.
7. It should not be used for active patients nor prolonged use, move it in each 4 hours.
8. The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
9. TJ Series temperature probe can not be used in high-intensity radio frequency condition (such as MRI equipment and electronic equipment in surgery), otherwise, it may result in inaccurate measurements, probe damage and burning patients for local overheating. If the temperature probe need to be used with high-intensity radio frequency equipment, please try to reduce the possibility of burning patients. Do not let the cable connected patients and form a ring, or let the cable directly contact with the skin. Ensure there is adequate electrical grounding insulation between the matched equipment and radio equipment.

Cleaning/Disinfection

Cautions

1. Never immerse or soak the probe
2. Exercise caution during cleaning/disinfection to avoid wetting the pins.
3. We recommend that the probe be disinfected only when necessary as determined by your hospital's policy, to avoid long term damage to the probe
4. Never use cleaning agents/disinfectants other than the recommended.

Cleaning

1. Clean the sensor with cotton or soft cloth moistened with water
2. After cleaning, wipe off the water with the soft cloth
3. Allow the sensor to air dry

Disinfection

The recommended disinfectants include: ethanol 70%. isopropanol 70%. Glutaraldehyde type 2% liquid disinfectants.

1. Clean the sensor as instructed above
2. Disinfect the sensor with cotton or soft cloth moistened with one of the recommended disinfectants.
3. After disinfection, be sure to wipe off the disinfectant left on the sensor with a soft cloth moistened with water
4. Allow the sensor to air dry.

Symbol



Attention, please refer to the file attached.



Production batch number sign



Series number sign



Product life time sign



Production date sign



Manufacturer Sign



Don't use it because of damaged package



Comply with the requirements of the Council Directive 2007/47/EEC.



Refer to instruction manual



Ingress Protection level



The symbol means that electrical and electronic equipment wastes can't throw away as unsorted waste disposal, and must be recycled according to the provision of the hospital recycling processing.

Product model and compatible machine

Product Model	Compatible
TJW0051B2、TJW0061B2、TJW0071B2、TJW0011Q2、TJW0021Q2、TJW0031Q2、TJW0041Q2	MINDRAY
TJW0011Q1、TJW0021Q1、TJW0031Q1、TJW0041Q1、TJW0051Q1、TJW0061Q1、TJW0071Q1、TJW0031B2、TJW0011B1、TJW0041B3、TJW0021B4、TJW0011Q4、TJW0021Q4、TJW0014B1、TJW0025B1、TJW0034B2、TJW0044B3、TJW0041B2、TJW0013Q1、TJW0023Q1、TJW0033Q1、TJW0043Q1、TJW0053Q1、TJW0063Q1、TJW0073Q1	YSI
TJW0031B4、TJW0011B4	OHMEDA
TJW0013B1、TJW0033B2、TJW0043B3	PHILIPS
TJW0013Q4、TJW0032B4、TJW0023Q4	OTHER

Application Standard

Temperature probe and accessories comply with the following standard:

ISO 10993-1:2009、ISO 10993-5:2009、ISO 10993-10:2010、ISO 14971:2009、IEC60601-1:2005、IEC60601-1-2:2007、ISO80601-2-61:2011、ISO 14155:2011

Transportation and storage

Storage: Packed sensor should be stored in a no corrosive gas, clean and well-ventilated room.

With the temperature range: -20°C~40°C and relative humidity 0%-85%, atmosphere: 700hPa~1060hPa

Transportation: The pack carton should be placed properly according to the mark on the carton, and to prevent a collision, severe vibration and direct pouring of rain and snow

Product Life Time : one year



Shenzhen Taijia Electronics Co.,Ltd.

Add:East 4F, Aimeite Science Park,HuangFengling Industry area, ShiYan town,Bao' An district,ShenZhen city,GuangDong province.

Postal code: 518108

Tel: (+86)0755-81795727 81795618 Fax: (+86)0755-81795638

Website: www.taijia.com

European Representative:

Company : DongBang AcuPrime (EU) Limited

Address : 1 Forrest Units, Hennock Road East, Exeter, EX2 8RU UK

Tel : +44 (0)1392829550

Fax : +44(0)1392823232

E-mail: info@acuprime.com