

Directions for Use

Sterile packaging is adopted

Today's quality patient care requires body temperature monitoring to be an integral part of any physiological measurements in the OR, ICU, CCU, or ER. Med-link offers a full line of sterile, sterilizable temperature probes to measure body temperature on your critical patients.

Model: See label.

Compatibility: see label.

Shelf life: 2 years.

Specifications

Temperature range: 25°C to 45°C

Accuracy: $\pm 0.1^\circ\text{C}$ from 25°C to 45°C.

Temperature limit: Operating: 5°C to +40°C; Storage/Transportation: -20°C to +55°C

Humidity limitation (Operating/Storage/Transportation): 0~95%RH

Atmospheric pressure limitation (Operating/Storage/Transportation): 86kPa~106kPa



Caution: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

Intended use: It is used in conjunction with medical equipment to collect and transmit the patient's body temperature signal.

Contraindications: The use of the esophageal/rectal sensor may be contraindicated in neonates and small infants undergoing tracheostomy or internal jugular vein catheterization and laser surgical procedures.

Operation instruction:

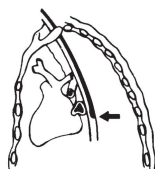
- 1) Please select the appropriate temperature probe according to the different body shapes of the patients;
- 2) Confirm that the packaging bag is intact and undamaged, and tear the packaging bag to take out the temperature probe;
- 3) Please verify the compatibility of the probe to ensure that the equipment is compatible with the probe;
- 4) Ensure that the connector of the probe matches with the temperature interface of the equipment;
- 5) The probe can be applied on different sites including the following:

- When being applied into esophagus:

The E.T. tube (endotracheal tube) should be inserted first if it's necessary, after which the temperature probe can be applied.

First lubricate the temperature probe, and then place the probe according to the corresponding medical operation procedures. The insertion depth recommended is 25-30cm for adults and 10 + (twice the age divided by 3) cm for pediatric.

Check the probe position according to the medical procedure. The probe shall not be inserted too deep, and the external cannula of the probe shall be exposed at least 5cm from the patient.



- When being applied into nasal cavity:

First lubricate the temperature probe, and then place the probe according to the corresponding medical operation procedures.

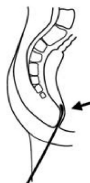
Check the probe position according to the medical procedure.



- When being applied into rectum:

First lubricate the temperature probe, and then place the probe according to the corresponding medical operation procedures. The insertion depth recommended is 6-10cm for adults and 2-3cm for pediatric.

Check the probe position according to the medical procedure.



- 6) If this location is appropriate, secure the cable with appropriate medical tape to avoid the change of insertion depth.

Place the cable in a position that does not interfere the measurement and ensures patient safety.

- 7) Plug the connector of the temperature probe into the temperature interface of the monitoring equipment.

- 8) It takes at least 3 minutes to get correct temperature reading. After the response time is over, the patient's temperature can be monitored. The specific operation procedures shall be in accordance with the operation manual of monitoring Equipment.

9) The position of the probe should be checked at least every 4 hours.

Caution:

- If the probe can not accurately monitor the temperature, it indicates that it's placed in inappropriate position or not properly placed. In case of the above situation, reposition the probe or select another type of probe.
- Handle with care. Do not pull the junction between the cable and the plug, or the junction between the cable and the sensing element.
- Do not knot or tightly bundle wires together. Do not wind the wires nor suspend them on the equipment.
- Once the temperature probe or optional connecting cable is damaged or invalid, it shall be discarded immediately in accordance with the method of dealing with medical waste issued by the local institution or under local regulations.
- Normally, the core temperature readings are different from skin temperature readings.
- This probe can only be used under the direct guidance of an authorized physician or healthcare provider, and can only be connected to a compatible patient monitor.

Warning: Be sure to read and understand all of the following warnings.

- Do not arbitrarily alter or modify this product as this will affect its performance including accuracy.
- Never boil or autoclave.
- The sterile probe is disposable. Do not reuse. Do not reapply the probe to another patient to prevent cross infection.
- Use temperature probes only under the direct guidance of authorized and trained healthcare professionals.
- Clean and disinfect the appropriate connecting cable before use.
- Check and replace the damaged or invalid temperature probe and optional connecting cable before use.
- Use these probes in accordance with the standard application practices recommended by your medical institution.
- To avoid patient injury:

Do not apply these temperature probes on patients undergoing Magnetic Resonance Imaging (MRI) procedures. Always pay attention to the warning information when placing or removing the temperature probe from the patient. When installing probes and cables, avoid situations that could entangle the patient, which could cause the patient to suffocate, choke, or at worst inhibit blood circulation of the patient. When installing probes and cables, avoid situations that could entangle the venous line and restrict venous flow.


Radio frequency and electrosurgery (ESU) warning

Verification of electromagnetic compatibility (EMC) includes testing in accordance with EMC international standards for medical devices. For more information, see the manufacturer's statement.

All patient-connected wire-lead sensor accessories, including temperature probes, are subject to reading error, localized heating, and possible damage due to the interference of high-density sources of RF energy. Electrosurgical (ESU) equipment represents one such source. The capacitive coupled current may form a grounding circuit through the probe cable and related instruments, resulting in patient burns.

Therefore, whenever possible, try to remove the probe from the patient before entering the surgical operating room or confronting with other RF sources. If the probe must be used together with the electrosurgical equipment, carefully check whether the equipment connected to the probe has a grounding circuit independent of the RF source. Reduce hazards by selecting a temperature monitoring point between the probe used and the return circuit away from the expected RF circuit.

Disposal

 Waste electrical and electronic equipments must be disposed of in accordance with the local applicable regulations, not with domestic waste.




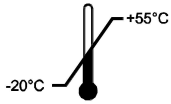
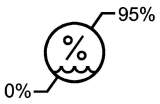
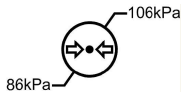







If you have questions regarding any of this information, contact your local representative.

Note: * All registered trademark and brand style mentioned in this information is always belonging to original made possessor.

 Shenzhen Med-link Electronics Tech Co., Ltd.
4th and 5th Floor, Building Two, Hualian Industrial Zone, Xinshi Community, Dalang Street, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
E-mail: sales@med-linket.com

 Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 Fax: +49-40-255726
UK Responsible Person: Lotus Global Co Ltd
Address: 23 Maine Street, Reading, RG2 6AG, England, United Kingdom Tel: 0044-20-70961611

The following symbols may appear on the product or product labeling:

| | | | | |
|---|--|---|--|--|
| <p>Refer to instruction manual/ booklet</p>  | <p>Sterilized using ethylene oxide</p>  | <p>Contains no natural rubber latex</p>  | <p>Storage Temperature limitation</p>  | <p>Storage Humidity limitation</p>  |
| <p>Atmospheric pressure limitation</p>  | <p>Do not re-use</p>  | <p>Protection against vertically falling water drops</p> <p>IPX1</p> | <p>Type BF applied part</p>  | <p>Batch code</p>  |
| <p>Medical device</p>  | <p>Date of Manufacturer</p>  | <p>Unique Device Identifier</p>  | <p>Model number</p>  | |