

**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



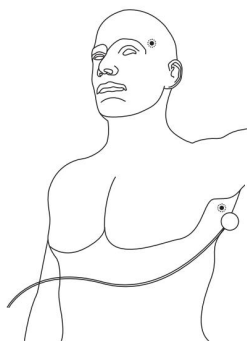
Caution: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

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

**Contraindications:** Do not apply this product on a site with tissue damage.

**Operation instruction:**

- 1) Confirm that the packaging bag is intact and undamaged, and tear the packaging bag to take out the temperature probe;
- 2) Please verify the compatibility of the probe to ensure that the equipment is compatible with the probe;
- 3) Ensure that the connector of the probe matches with the temperature interface of the equipment;
- 4) Completely dry the skin surface where the probe will be placed. The preferred measurement site is the armpit (as shown in the figure below).
- 5) Peel off the release paper on the probe, and paste the probe on the site dried beforehand. If there is a thermal radiation source around, cover the probe with a reflective sticker to avoid radiation from affecting the accuracy of the probe.
- 6) Place the cable in a location that does not interfere with measurements 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 5 minutes to get a correct reading; after the response time is over, the patient's temperature can be monitored.
- 9) Refer to the operation manual of monitoring equipment for specific operation procedures.
- 10) The position of the probe should be checked at least every 4 hours, ensuring it's applied appropriately and securely.

**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 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.
- 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



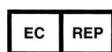
Waste electrical and electronic equipments must be disposed of in accordance with the local applicable regulations, not with domestic waste.

**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.



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

Refer to instruction manual/ booklet



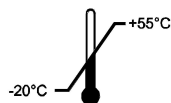
Sterilized using ethylene oxide



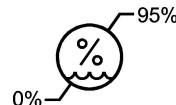
Contains no natural rubber latex



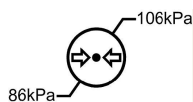
Storage Temperature limitation



Storage Humidity limitation



Atmospheric pressure imitation



Do not re-use



Protection against vertically falling water drops

**IPX1**

Type BF applied part



Batch code

**LOT**

Medical device

**MD**

Date of Manufacturer



Unique Device Identifier

**UDI**

Model number

**#**