These instructions for use are valid for temperature probes listed on cover page 2.
Line 1: Rectal/esophageal application
Line 2: Skin contact application

Intended use

The reusable temperature probes are intended to be used for the continuous measurement and monitoring of patient temperature using YSI, HP, Philips (e.g. IntelliVue series), GE Healthcare (e.g. Carescape B450, B650 or B850 series monitors), Siemens thermometers (e.g. SC 7000 and SC 9000) and other devices that are designed for use of series 400 temperature probes (YSI compatible resistance curve). They are available in various designs (rectal/esophageal, skin contact).
The temperature probes are indicated for use by professional medical personnel and for professional health care facility application only.
The materials being in contact with the patient during application comply with the requirements of biocompatibility tested according to ISO 10993-1 series of standards.

Warning

1. Improper use of probes can lead to damage of the internal wiring and to the loss of electrical insulation as well as incorrect temperature readings or loss of temperature readings. In case of a possible probe damage the probe must not be used and has to be replaced immediately.
2. Stop using the probe immediately if it becomes visibly damaged, including pits or cracks in the surface of the probe or connector, or exposed wires. Perform an inspection of the measuring accuracy in the predetermined interval to avoid measuring uncertainty caused by drift or aging.
3. Do not use the probe if hygienic safety cannot be guaranteed. Do not apply the skin probe on areas with open wounds or lesions. Remove the probe if allergic reactions occur. Follow the reprocessing information below.
4. This temperature probe is intended for use in combination with compatible monitors only. Usage in combination with other devices can lead to malfunction or hazards from electric shock.
5. Strong sources of electromagnetic fields, e.g. electro-surgical devices, can adversely affect the functioning of the equipment. If possible, the probe should be completely removed from the patient before a surgical device or other HF source is activated! Check the protective earthing if you intend to use HF devices and temperature measuring equipment simultaneously. Minimize the potential risk by selecting a temperature measurement point far away from the HF current path.
6. Use of the product with magnetic resonance imaging (MRI) or computed tomography (CT) devices is not permissible.
7. Avoid the risk of strangulation and asphyxiation when connecting the probe to the patient and the monitor. Make sure that the contact between the probe and the skin surface is not interrupted (e.g. by the patient moving). This can lead to incorrect measurements.
8. For further information and warnings please read the usage instructions accompanying the temperature-measuring device.

Instructions for use

1. Temperatures can be measured in the esophagus, on the skin surface or rectally. If necessary, use water-based lubricants only. Maximum continuous contact duration for rectal and esophageal application is 24 hours, and for skin contact application less than 30 days.
2. **Skin:** Place the skin probe disk in direct contact with intact skin using medical adhesive tape. In special circumstances, the extremities such as fingers or toes may also be used. Make sure that movement does not interrupt the skin contact.
3. **Esophagus:** The probe should be placed in the lower third of the esophagus.
4. **Rectally:** The probe is in correct position when it has passed the sphincter.
5. Thoroughly clean immediately after use to prevent soil from drying on the probe – refer to reprocessing instructions below.

Specifications

Operating mode:	Direct mode	
Overall length:	280 cm (nominal)	
Temperature range:	Storage/Transport:	-30 °C to +70 °C
	Operation:	+0 °C to +50 °C
Humidity range:	Storage/Transport:	10 to 95 % r. h. non-condensing
	Operation:	10 to 100 % r. h.
Ambient pressure:	Storage/Transport:	800 to 1060 hPa
	Operation:	800 to 1060 hPa
Accuracy:	±0.1 °C (range 25 °C to 45 °C)	
Transient response time (2 K transient):	Adult types:	< 50 s
	Pediatric types:	< 30 s
	Neonatal types:	< 25 s

Reprocessing instructions

Initial treatment:	Before cleaning or disinfecting the probe, it has to be detached from the monitor. Special handling during transport is not necessary. For removal of visible soil see under 'Manual cleaning' or 'Machine cleaning'. Damage to the outer cable jacket of the probe must be avoided (for example by sharp items during transportation).
Preparation before cleaning:	The probe does not contain any parts to be disassembled before cleaning. Check the probe for damage before cleaning (visual inspection). If damage is found, take the probe out of operation and dispose of it according to local regulations for medical waste.
Cleaning: Manual cleaning:	To remove visible soil, clean the probe by wiping it with a cleaning agent and a soft cloth or by placing it in an immersion bath with cleaning agent (see below). Then rinse the probe sufficiently (softened or deionized water recommended) and let it dry in ambient air for at least 30 minutes. Follow the manufacturer's instructions when using the cleaning agent including dilution from concentrate. Avoid high mechanical force to the probe during cleaning process. Cleaning agents: neodisher® Mediclean Forte: 10 min exposure time; max. 40 °C Prolystica®: 15 min exposure time; max. 55 °C
Ultrasound cleaning:	Do not use ultrasonic cleaning methods on the temperature probes – this may damage the probe components.
Machine cleaning:	The probe can be cleaned by washing in a machine (cleaning and disinfection device) at up to 95 °C (cleaning agent e.g. neodisher® Mediclean Forte). Follow the manufacturer's instructions when using the cleaning agent and the automated washing equipment instructions for maximum load size. The recommended settings are: • Step 1 cleaning 0.5 % cleaner 30 °C for 1 min • Step 2 cleaning 0.5 % cleaner 55 °C for 12 min • Step 3 rinsing with demineralized water for 1 min
General:	Inspect probes after cleaning to ensure all visible soil is removed. If the device is determined not to be visually clean, repeat the cleaning steps or safely dispose of the device.

Disinfection: Chemical:	Intermediate level disinfection: Disinfection by wiping the probe with a disinfecting agent and a soft cloth or by placing it in an immersion bath with disinfecting agent (e.g. Incidin® plus). Then rinse the probe sufficiently (softened or deionized water recommended) and let it dry in ambient air for at least 30 minutes. High level disinfection (skin contact probes only): Disinfection by placing it in an immersion bath with disinfecting agent (e.g. Cidex® OPA). Then rinse the probe sufficiently (high-purity or distilled water recommended) and let it dry in ambient air for at least 30 minutes. In any case, refer to the “Instructions for Use” supplied by the disinfectant manufacturer. Avoid the use of disinfectants containing ketones.
Thermal:	Thermal disinfection at 90 °C with 5 min exposure time possible.
Water Quality:	Use water quality appropriate to the reprocessing step, including for dilution preparation of agents (distilled water recommended), rinsing after cleaning, and particularly after high level disinfection (high purity or distilled water). Automated cleaner and/or disinfector machines may have specific water requirements as well. See also: AAMI TIR34, Water for the reprocessing of medical devices.
Drying:	Drying after cleaning, disinfection or sterilization for at least 30 minutes at room temperature. For more information on the drying process, see **Cleaning** and **Disinfection**. Do not dry the probe with hot air above 90 °C.
Inspection and maintenance:	If damage to the probe (e.g. cracks in the cable jacket, deformation of plastic parts or connectors) can be detected, the probe must not be used and shall be replaced. If the regular function with the medical device is not given (e.g. caused by open circuit), the probe must also be replaced as well.
Packaging:	Steam sterilization has been validated using ASSURE Plus sterilization pouches (REF: 83005). Probes must be packed in an appropriate pouch (according to DIN EN ISO 11607-1/-2) immediately after the cleaning/ disinfection or before the sterilization process.
Sterilization:	The temperature probe can be sterilized with hot steam. The following parameters are allowed (minimum values): Gravity process: 132 °C, 10 min hold time, 30 min drying time or 134 °C, 5 min hold time, 20 min drying time Forced vacuum process: 132 °C, 3 min hold time, 16 min drying time Temperatures up to 134 °C and higher hold time as described above are acceptable. Follow the generally applicable instructions and regulations. Clean the temperature probe before sterilization and disinfect the probe according to applicable reprocessing rules.
Reuse life:	The temperature probes have been validated for the following reprocessing cycles: Manual cleaning/disinfection: up to 300 cycles Machine washing/disinfection: up to 300 cycles Sterilization: up to 100 cycles Stop using the probe immediately if it becomes visibly damaged, including pits or cracks in the surface of the probe or connector, or exposed wires.

Storage:	Store protected from dust in original packaging or comparable packaging. Avoid continuous direct sun light. Further information under **Specifications**.
Transport:	Transport to the place of use protected from dust in original packaging or comparable packaging.

Maintenance/Service

The temperature probes do not contain serviceable or replaceable components. Modification or replacement of components is prohibited. It is recommended to run an inspection of accuracy at intervals of two years.

Reporting of serious incidents

If a serious incident occurs related to the use of this product, it should be reported. The incident should be reported to the manufacturer and to the health authority or authority responsible for the installation site of the product. A major incident occurs when the death or temporary or permanent serious deterioration in the health of a patient, user or other person occurs.

In this case, send an email to the email address given on the last page of these instructions for use. Please include the following:

- Part number (REF) and model type of the affected product
- Serial number of the product
- Date of the serious incident
- Description of the serious incident, including impact on the patient or any other harm
- Your contact information (name of institution, address, contact person (or representative), position and telephone number

Returning the product

Every product sent to us for inspection must include a signed confirmation that the product has been cleaned and disinfected beforehand.

Disposal

Before disposing the product, it may be necessary to clean and disinfect it. Local regulations may apply for disposal of used medical devices.