Sensatronic

Single-use Temperature Probes

de	Einweg-Temperatursensoren	xx
en	**Single-use Temperature probes**	**xx**
fr	Capteurs de température jetables	xx

1	**GP-75-9P / GP-75-12P / SD-75P / TD-75P**
2	**EC-15-PM / EC-30-PM**

en **Instructions for Use for single-use medical temperature probes**

Important information
Please read all warnings and instructions before use. Observing this information ensures safe use of the products, maintaining functionality and reducing the risk of injury. This IFU applies to all types of temperature probes listed on page 2 (table row 1) of this document.

Intended use
The single-use medical temperature probes are intended for continuous measurement and monitoring of patient temperature.

Product description and indications
The single-use temperature probes are available for different applications (rectal/esophageal, skin contact, inner ear measurement). The probes can be used with patient monitors and other measuring devices from Philips (IntelliVue monitors, modules and extensions, PM6000 monitor series, Efficia monitors, G-series monitors and Intrepid defibrillators). The temperature probes are not designed for a direct connection to a monitor. In any case an extension cable must be used that is compatible with the patient monitor (see page 2 (table row 2)). Consult the user manual of the monitoring device to ensure compatibility.
The single-use temperature probes are approved only for use by healthcare professionals and in professional healthcare environment. The materials being in contact with the patient during use meet the requirements of biocompatibility and are tested according to the applicable standards of the ISO 10993-1 series.

Contraindications
Do not place skin temperature probe in areas with injured skin, open wounds or lesions. Do not use the General Purpose probe in patients where insertion of the probe into the esophagus may be considered unsafe.

Warnings
1. Improper use of the probe and extension cable may result in damage to the internal wires and loss of electrical safety, as well as incorrect temperature display or failure of the temperature display. If possible damage is suspected, the probe or extension cable must not be put into operation and must be replaced immediately.
2. If the temperature probe or the associated extension cable is damaged, e.g. due to cracks in the cable jacket, deformation of plastic parts or plugs or exposed cables, use must be stopped immediately. Replace the defective products.
3. Do not use the probe if hygienic safety cannot be ensured (e.g. opened packaging). Do not place the temperature probe in areas with injured skin, open wounds or lesions. In any case, remove the probe if allergic reactions occur (e.g. in the area of the adhesive pad). Please note the cleaning instructions listed below.
4. The single-use probes are intended to be used only once. Do not re-use this product. Re-use can cause severe harm to the patient caused by insufficient hygienic safety or other damage to the product caused by repeated use.
5. This temperature probe is intended for use only with compatible monitors and devices and compatible extension cables. Use of incompatible monitoring devices and components may result in malfunction or risk of electric shock and in performance issues.
6. When connecting the probe to the patient and monitor, avoid the risk of strangulation and suffocation. Make sure that the contact of the probe with the skin surface is not interrupted (e.g. by movement of the patient). This can lead to incorrect measurements.
7. Remove probe from patient prior to cardioversion or defibrillation.
8. Use of these temperature probes 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.
9. 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.
10. The device function may be affected by strong electromagnetic sources, e.g. electrosurgical devices. Remove the probe completely from the patient before activating the surgical device or another source of electromagnetic disturbance. When using RF devices and temperature monitors simultaneously, check grounding protection. Minimize the risk potential by choosing a temperature measuring point far away from the HF current path.
11. 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 temperature probes, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
12. The use of the probes and extension cables together with MRI or CT devices is not permitted.
13. The temperature probes do not contain serviceable or maintainable parts. Modifying the probes or exchange of components can lead to hazards and malfunction.
14. For further information and warnings, please read the operating instructions of the temperature-measuring device or monitor used.

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.

Application of single-use temperature probes
Connect the temperature probe to the adaptor cable and connector the adaptor cable to the corresponding port of the monitoring device. Refer to the instructions for use of the monitoring device for more details. Attach the probe tip to the patient as described below.
General purpose probes (rectal/esophageal application):

- Temperatures can be measured in the esophagus or rectally. Please only use water-based lubricants. The maximum continuous contact time is 24 hours.
- Esophagus: The sensor should be placed in the lower third of the esophagus.
- Rectal: The sensor is in correct position when it has passed the sphincter.

Skin probes:

- Place the sensor with the patch in direct contact with intact skin or in special cases on the extremities such as fingers or toes. Make sure movement does not affect the skin contact.
- The maximum continuous contact time is 24 hours.

Specification

Operating mode:	Direct mode	
Overall length:	75 cm (nominal)	
Temperature range:		
Storage/Transport:	-30°C…+60°C	
Operation:	+0°C…+50°C	
Humidity range:		
Storage/Transport:	10… 95 % r. F. not condensing	
Operation:	10…100 % r. F.	
Ambient pressure:		
Storage/Transport:	800…1060 hPa	
Operation:	800…1060 hPa	
Accuracy:	± 0.1°C (range 25°C…45°C)	
Transient response time (2 K transient):	GP probes:	< 25 s
	Skin probes:	< 40 s
Minimum measuring time:	GP probe 9FR:	35 s
	GP probe 12FR:	49 s
	Skin probe:	29 s

(Note: minimum measuring time is tested as the time interval needed to change the displayed temperature of the monitoring system from 25.0 to 44.0°C).

Cleaning instructions
The temperature probes are designed as single-use products and are ready for use without any additional cleaning or processing. The single-use probes are not intended for reprocessing.

Maintenance/Service
The temperature probes do not contain any components that require maintenance or replacement. Modification or replacement of components is generally not permitted. Defective products or products with damaged packaging must not be used and have to be replaced with functional and undamaged products.

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 or batch 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
Follow local regulations that may apply for disposal of used medical devices and accessories.

Product branding

PHILIPS Philips serves solely as the distributor for this product.

Sensatronic is the legal manufacturer of this product.

Symbols and explanations

	Do not dispose in domestic waste!		Caution! Follow the warnings in the instructions for use!
	Read the instructions for use of the medical device! Symbol appears blue on device.		Product is free of phthalates.
	Product is free of latex.		Product is supplied non-sterile.
	Temperature limit.		Probe type.
	For prescription use only.		MR unsafe.
	Medical Device.		CE Mark (Manufacturer).
	Manufactured in Germany.		Manufacturer.
	LOT number.		Part number.
	Atmospheric pressure limitation.		Humidity limitation.
	Keep away from sunlight.		Unique Device Identifier.
	Box quantity.		Expiry date.
	Do not re-use.		Swiss Representative
			UK Representative

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