Sensatronic

Extension cable for single-use temperature probes

de	Verlängerungsleitungen für Einweg-Temperatursensoren	xx
en	**Extension cable for single-use temperature probes**	**xx**
fr	Câbles d'extension pour 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 extension cables 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 extension cables listed on page 2 (table row 2) of this document.

Intended use
The extension cables for single-use medical temperature probes are intended for connecting single-use temperature probes to monitoring devices.

Product description and indications
The extension cables are available in different cable lengths. The extension cables can be used with patient monitors and other measuring devices from Philips (IntelliVue monitors, modules and extensions and Intrepid defibrillators). The extension cable serves as the interface between a single-use temperature probe and a patient monitor. Extension cables are compatible with single-use temperature probes as listed on page 2 of this document (table row 1). Consult the user manual of the monitoring device to ensure compatibility.
The extension cables are approved only for use by healthcare professionals and in professional healthcare environments. The materials that are 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
There are no known contraindications.

Warnings
1. Improper use of the 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 damage is suspected, the extension cable must not be put into operation and must be replaced immediately.
2. If the extension cable is damaged or deteriorated, 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. Clean and disinfect extension cables before initial use and before re-use. Do not use if hygienic safety cannot be ensured. Do not autoclave or sterilize the extension cables. Please note the cleaning instructions listed below.
4. This extension cable is intended for use only with compatible monitors, devices and temperature probes. Use of incompatible monitoring devices and components may result in malfunction or risk of electric shock and in performance issues.
5. When connecting the extension cable to the temperature probe and monitor, avoid the risk of strangulation and suffocation.
6. Remove the extension cable and temperature probe from patient prior to cardioversion or defibrillation.
7. Use of these extension cables 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.
8. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
9. The device function may be affected by strong electromagnetic sources, e.g. electrosurgical devices. Remove the extension cable and 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.
10. 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.
11. The use of the extension cables together with MRI or CT devices is not permitted.
12. The extension cables do not contain serviceable or maintainable parts. Modifying the cables or exchange of components can lead to hazards and malfunction.
13. 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 extension cables for single-use temperature probes
Visually inspect the extension cables for damage or deterioration. Also check the connectors and pins for any type of damage. Place the connector end of the probe into the mating end of the extension cable. Check to make sure the mating ends are secure. Connect the extension cable to the corresponding port of the monitoring device. Refer to the instructions for use of the monitoring device for more details.

Specification

Overall length:	3.0 m or 1.5 m (118” or 59”)
Temperature range:	
Storage/Transport:	-30°C…+60°C (-22°F…140°F)
Operation:	+0°C…+50°C (32°F…122°F)
Humidity range:	
Storage/Transport:	10…95 % r. H. not condensing
Operation:	10…95 % r. H. not condensing
Ambient pressure:	
Storage/Transport:	700…1060 hPa
Operation:	700…1060 hPa

Reprocessing instructions

Initial treatment:	Before cleaning or disinfecting the extension cable, detach it from the monitor. Special handling during transport is not necessary. For removal of visible soil see under 'Manual cleaning'. Damage to the outer cable jacket must be avoided (for example by sharp items during transportation).
Preparation before cleaning:	The extension cable does not contain any parts to be disassembled before cleaning. Check the cable for damage before cleaning (visual inspection). If damage is found, take the cable out of operation and dispose of it according to local regulations for medical waste.
Cleaning: Manual cleaning:	To remove visible soil, clean the extension cable by wiping it with a cleaning agent and a soft cloth or by placing it in an immersion bath with cleaning agent. Do not soak or immerse the plug at either end of the cable. Do not expose the metallic connector pins to any cleaning or disinfection solution. Dampen a non-linting wipe with the cleaning solution. Clean the outer surface of the cable from one connector end to the other connector end including the outer surface of the connectors. To remove debris from both connectors, use a nylon brush dampened in the prepared cleaning solution. Do not expose the interior electrical components of the adapter cable to moisture. Rinse the cable 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 cable during cleaning process. Cleaning agents: Prolystica®: 15 min exposure time; max. 55°C
Machine cleaning:	The extension cable is not approved for machine cleaning. Machine cleaning will damage the cable and its components.
Ultrasound cleaning:	Do not apply ultrasound cleaning methods on the extension cable. This may damage the cable and its components.
General:	Inspect the cable after cleaning to ensure all visible soil is removed. If the cable is determined not to be visually clean, repeat the cleaning steps or safely dispose of the device.
Disinfection: Chemical:	Intermediate level disinfection: Disinfect cable by immersing it into 70% Isopropyl Alcohol, being careful to avoid immersing the connectors. Immerse the cable for 10 minutes and make sure that the complete surface is in contact with the solution (except the connectors). Prolonged immersion could cause a loss in cable flexibility. Disinfect connectors by wrapping them in a dampened lint-free wipes with 70% Isopropyl Alcohol for 10 minutes. Let it dry in ambient air completely before use. Avoid the use of disinfectants containing ketones.
Thermal:	Thermal disinfection of the cable is not permitted and will damage the cable and its components.
Drying:	Dry the cable completely after cleaning and disinfection at room temperature before further usage. For more information on the drying process, see **Cleaning** and **Disinfection**. Do not dry the cable with hot air.
Inspection and maintenance:	If damage to the extension cable (e.g. cracks in the cable jacket, deformation of plastic parts or connectors) is detected, the cable 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 cable must also be replaced as well.
Packaging:	Special handling during storage and transport is not necessary. Damage to the outer cable jacket must be avoided (for example by sharp items during transportation). We recommend to use the package material that has been supplied by the manufacturer.
Sterilization:	Sterilization of the cable is not permitted and will damage the cable and its components.
Useable life:	The extension cables have been validated for the following number of reprocessing cycles: Manual cleaning: up to 100 cycles Manual disinfection: up to 100 cycles Stop using the cable immediately if it becomes visibly damaged, including pits or cracks in the surface of the cable or connector, or exposed wires.
Storage:	Store in an environment 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 extension cable does 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 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.		Cable 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.		UK Representative
	Importer		Swiss Representative

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