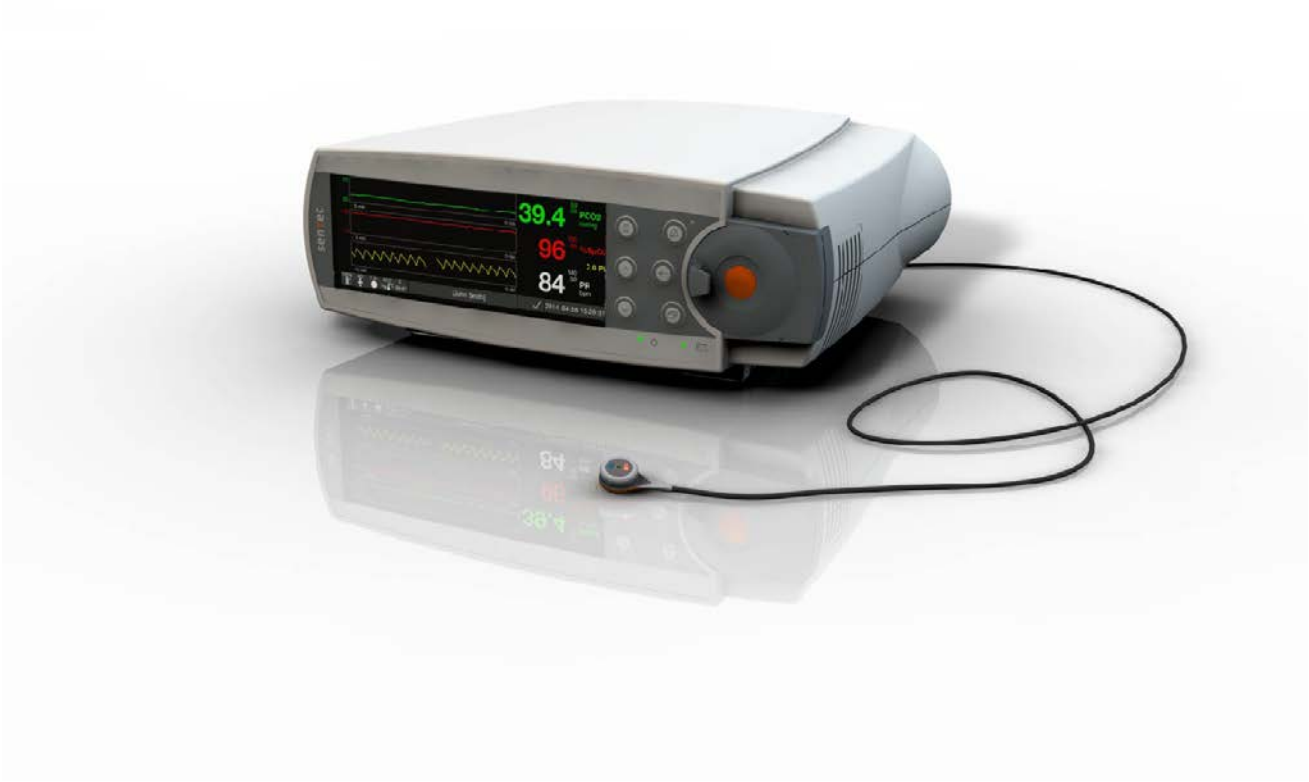
sentec.

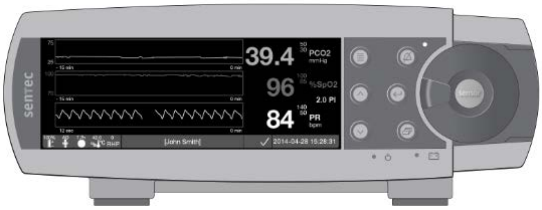
Sentec Digital Monitoring System



Installation at Home User Site by Instructed Personnel

Care with Confidence

Required & recommended components for setup

REF: SDM 	**Sentec Digital Monitor** Class I ME equipment IPX1 Transport/Storage 0 °C/32 °F 50 °C/122 °F Operation 10 °C/41 °F 40 °C/104 °F
REF: RFT100VA-V1 / RFT100VA-V2 	**Sentec Isolation Transformer** (see chapter 3.2 for technical data) Pri: IP42 Transport/Storage -10°C/14 °F 50 °C/122 °F 80 kPa (<2000m a.s.l)
	**Water Protection Box (not included)** IP44 Note: **Recommended - a similar product with a minimum degree of IPX2 (ingress protection) may be used.**
	**SDM Mains Cable (enclosed with SDM)** Caution: **Use only hospital-grade power cords provided by Sentec.** Note: **Mains cables are country specific, and may differ in shape and/or color.**

This manual provides systematic guidance for an instructed person from a homecare provider on setting up the SDMS at the patient's home/site. The SDMS shall only be used if all of the following steps have been carried out successfully.

Note: **Installation of the SDMS including configuration of the monitor (SDM) shall only be performed by an instructed person from a homecare provider. This instructed person must have received the appropriate training by a Sentec AG representative. SDMS-related tutorials are available for online viewing at http://www.sentec.com/tv .**

The instructed person from the homecare provider is responsible

- Before starting the installation at home environments, to disable the menu access of the monitor in order to avoid patients changing monitor settings accidently or on purpose. (see section 1)
- To affix the enclosed label (EV-010188, depicted below) to the monitor.

- For setting up the monitor at the patient's home/site and installation of the Isolation Transformer (see section 2.3)
- For selecting appropriate measurement site(s), instructing the patient how to use Sentec Digital Monitoring System (SDMS) and providing the "Directions for Lay Users", HB-010069, to the patient. Other relevant manuals to the SDMS are also available on www.sentec.com/ifu.
- To instruct the lay operator regarding the following:
  - In the event of unforeseen incidents, error messages or unexplained changes in the performance of the device, patients shall contact their home care provider's instructed person.
  - To use the SDM and the Isolation Transformer only in-house and under the specified environmental conditions.
  - To carefully route and fix cables to reduce the possibility of entanglement or strangulation.
  - To make no changes to the device setup.
- For switching off and uninstalling the SDMS and disconnecting the Isolation Transformer (see section 2.4).
- For ensuring maintenance (see section 3).

Note: **The patient as lay operator cannot modify the SDM's configuration by using the SDM's menu.**

If the SDMS has been stored below 10 °C / 50 °F, it must be acclimatized for two hours at room temperature before it can be connected to the mains or switched on. The SDMS may not be installed and operated in moist rooms (e.g. bathroom).

The Sentec Digital Monitoring System (SDMS) is to be operated by instructed personnel only. Carefully read this manual, the Technical Manual for the SDM (HB-005752), accessory Directions for Use, all precautionary information, and specifications before operating the device (available on www.sentec.com/ifu)

As an additional means of protection, Sentec recommends to connect equipment to a supply main with protective earth and to ensure that power and protective ground lines are connected correctly (see socket and wiring testing in the Annex).

During operation, the monitor must be connected to the AC power via the Isolation Transformer.

Use only accessories and spare parts supplied or recommended by Sentec AG. Do not perform other service and repair activities than specified and described by Sentec AG. Failure to comply may result in physical injury, inaccurate measurements, and/or damage to the device.

Electromagnetic interferences

Electrostatic discharge and transient bursts from mains may temporarily interfere with the measurement. This can lead to wrong measurements.

Equipment emits electromagnetic fields. This can, for example, disturb other medical devices or Radio Services.

The SDM should not be used adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If adjacent or stacked use is necessary, the SDM should be observed to verify normal operation in the configuration it is to be used.

Interference from interventional devices

The SDM is protected against electrostatic/ defibrillator discharge. Parameter display may be temporarily affected during electrostatic discharge/defibrillation, but will rapidly recover. Nevertheless, during electro-surgery the SDM, sensor and cables are to be physically separated from the electro-surgical equipment. The sensor must not be placed between cutting and counter electrode.

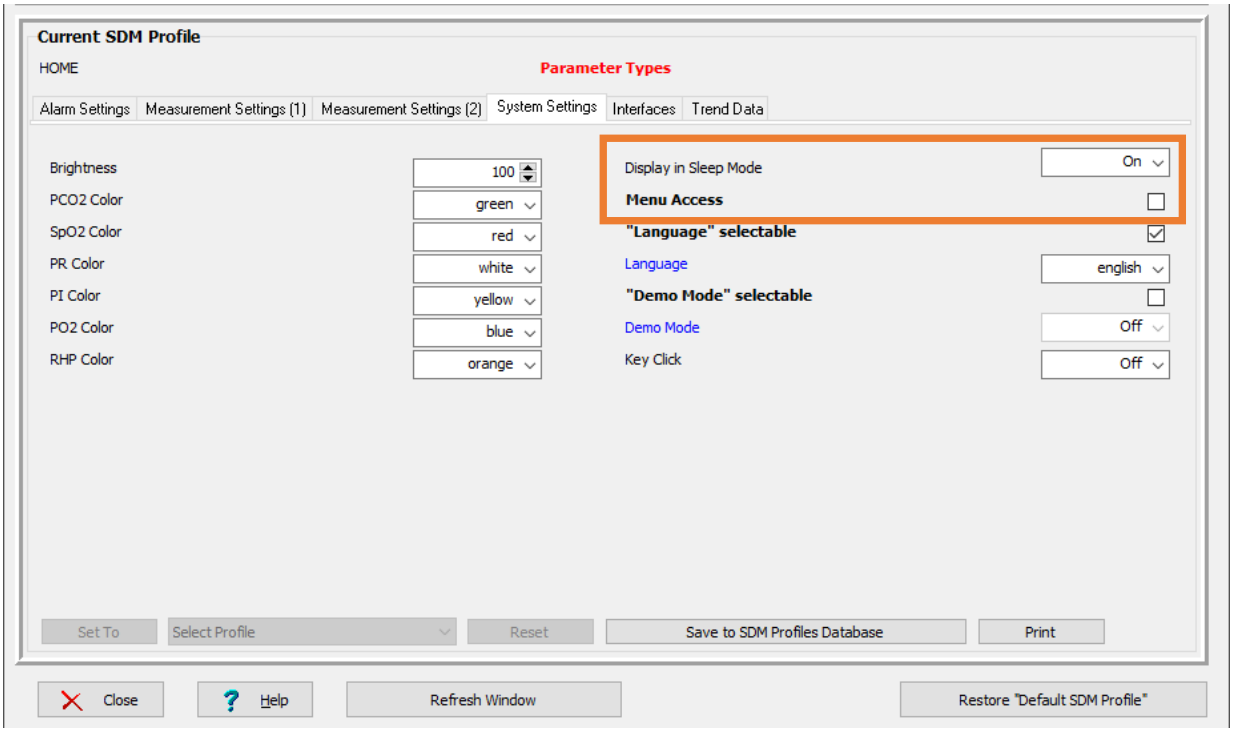
Radio equipment

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 SDM, including cables specified by the manufacturer. Wireless mobile devices must be held away from the SDMS by at least 1 m (39.4 inches). Otherwise, degradation of the performance of this equipment and at worst, incorrect measurements could result.

1. Configuring the SDM

The menu access of the monitor must be disabled in V-STATS™ to avoid patients changing monitor settings accidently or on purpose.

Either select the preconfigured SDM Home Profile of V-STATS™ or follow the below steps:

1	Switch off auditory alarm signals permanently using V-STATS™.
2	Set the patient's individual measurement parameters.
3	Then, select 'System Settings/Display in Sleep Mode'.
4	Disable patient menu access by unticking the Menu Access box within the V-STATS™ system settings 

For further information, refer to the V-STATS™ Instruction Manual HB-006042.

2. Instructions for connecting the Isolation Transformer (REF: RFT100VA-V1 and RFT100VA-V2)

2.1 Classification

The monitor SDM is a Class I ME equipment and IPX1 according to IEC 60601-1. The Isolation Transformer is an additional MOPP according to IEC 60601-1-11.

2.2 Technical data Isolation Transformer

Type of single-phase transformer:	RFT100VA-V1	RFT100VA-V2
Primary Voltage:	100 – 120 V	230 V ±10%
Primary Current:	104 – 0.90 A	0.47 A
Secondary: Voltage:	100 – 120 V	230 V ± 10%
Secondary Current:	0.98 – 0.84 A	0.44 A
Frequency	50 – 60 Hz	50 – 60 Hz
Output:	100 VA	100 VA
Energy efficiency:	~ 94 %	~ 94 %
Earth leak current	<100 µA (127V)	<100 µA (254V)
Overheating Protection	120 °C / 248 °F	120 °C / 248 °F
Isolation class	ta 40/B	ta 40/B
Protection class plugs	IP 20	IP 20
Protection class transformer	IP 42	IP 42
Dimensions (LxWxH) ca.	160 x 126 x 73 mm	160 x 126 x 73 mm
Storage temperature	-10 °C to +50 °C / 14 °F to 122 °F	-10 °C to +50 °C / 14 °F to 122 °F
Operating Temperature	5 °C to +40 °C / 41 °F to 104 °F	5 °C to +40 °C / 41 °F to 104 °F
Weight	3.1 kg	3.1 kg

Expected lifetime: Under normal wear and tear, the expected lifetime for the Isolation Transformer is 7 years, provided the recommended procedures are carried out and the device is not subject to misuse, neglect or accident.

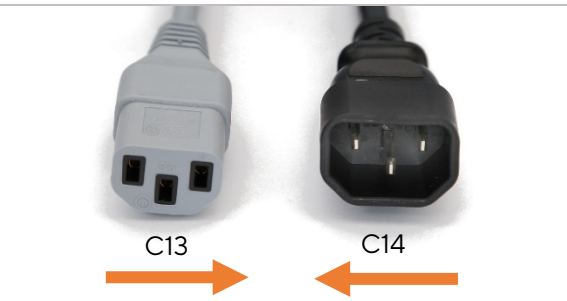
Operating positioning in normal use: horizontally, on the floor.

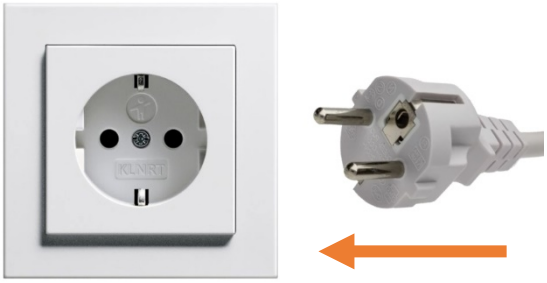
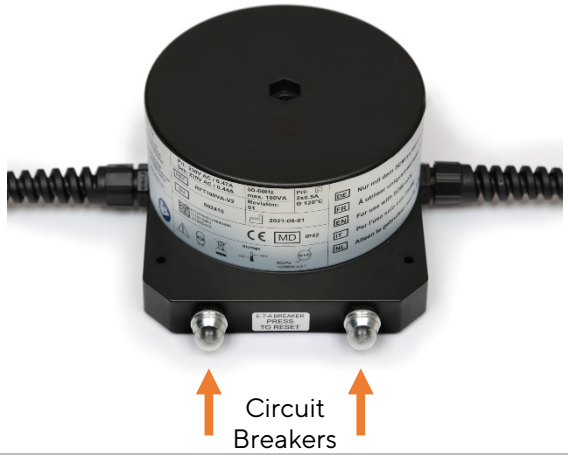
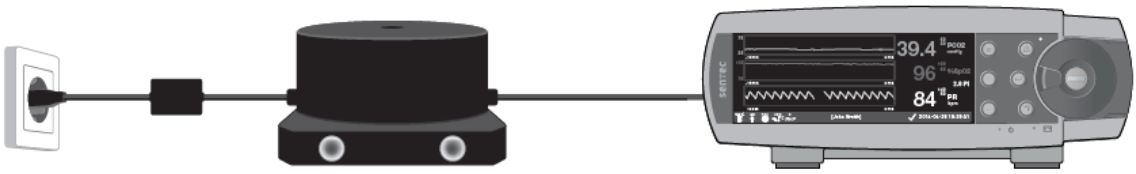
2.3 Connecting the Isolation Transformer

Important notes:

- **The Isolation Transformer (RFT100VA-V1 and RFT100VA-V2) is intended for use only with the Sentec Digital Monitor (SDM). Any modification to the Isolation Transformer, to the SDM or to the installation procedure as described in this manual, may result in physical injury, inaccurate measurements, and/or damage to the device.**
- **Do not use the Isolation Transformer if the housing or cables are damaged.**
- **Do not throw or drop the Isolation Transformer. This may damage the inside of the unit.**
- **Never connect the SDM mains cable to multiple socket outlets or extension cords.**

The Isolation Transformer is only to be used below 2000 m a.s.l. (<80 kPa).

1		Place Isolation Transformer horizontally on the floor. Make sure the SDM mains cable is disconnected from mains and from the SDM. Connect the SDM mains cable (C13) to the isolation transformer (C14).
2		Use the Water Protection Box (or similar product) to secure the cable connection and place it on a flat surface on the floor. Note: **Do not immerse Water Protection Box in water.**
3		Connect the transformer (C13 plug) to the SDM (C14 socket).

4	 *Country specific example (CEE 7/7)*	Plug the SDM mains cable into the wall socket. Do not use extension cables or multipliers. Ensure that the mains connection can be easily disconnected from the mains supply. Note: **As an additional means of protection, Sentec recommends to perform a socket and wiring test prior to use (see Annex).**
5	 	In case the circuit breakers on the back of the Isolation Transformer are triggered, they can be reset by pushing them back into their lock position. Note: **The Isolation Transformer has an overheat protection inside, which responds at approx. 120°C and switches off the transformer. The overheat protection is self-resetting and will only switch on the transformer again when it has cooled down.**
	 Simplified depiction of final SDM & Isolation Transformer assembly	

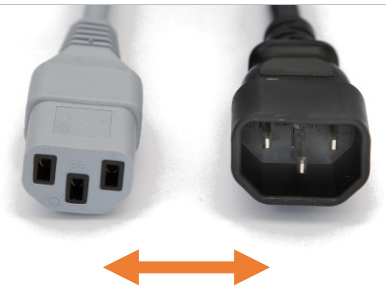
Instructed personnel from the homecare provider shall electrically test the Isolation Transformer at least every 6 months (chapter 3.1).

Refer to the Instruction Manual for the SDMS (HB-005771) or Technical Manual for the SDMS (HB-005752) for additional information, e.g. transport and storage conditions.
Troubleshooting is provided in the 'Service Manual for the SDMS' (HB-005615) available on www.sentec.com/ifu.

Leave this Instruction Manual (HB-010103) at the patient's home during monitoring (also available on www.sentec.com/ifu).

Provide the Lay User Manual (HB-010069-Directions for Lay Users) to the patient (also available on www.sentec.com/ifu).

2.4 Disconnecting the Isolation Transformer from SDM

1		Disconnect mains supply plug from the wall socket.
2		Open the Water Protection Box, remove and disconnect the cables (C13, C14).
3		Disconnect the isolation transformer from the SDM.

3. Maintenance

Note: Instructed personnel/homecare providers must not repair the Isolation Transformer. If the Isolation Transformer is defective, please contact qualified service personnel or your local Sentec representative.

Expected Useful Life[1] of electrical devices:

Product Name	REF	Expected Useful Life[1]
Sentec Digital Monitor	SDM	7 years
Digital Sensor Adapter Cable	AC-150 AC-250 AC-750	7 years
Isolation Transformer	RFT100VA-V1 RFT100VA-V2	7 years
V-Sign™ Sensor 2	VS-A/P/N	up to 36 months
OxiVenT™ Sensor	OV-A/P/N	12 months

[1]The average amount of time that an item is estimated to function when installed new, assuming correct / diligent handling and routine maintenance is practiced. For the avoidance of doubt, the indicated expected useful lifetime is for information purposes only and as such does not constitute, imply or establish any warranty or guarantee.

Shelf Life of accessories and disposables (expiration date is stated on the packaging of the device):

Product Name	REF	Shelf Life ex. Sentec AG
Ear Clip	EC-MI	12 months
Multi-Site Attachment Ring (Easy) for mature/intact skin	MAR-MI MARe-MI	12 months
Multi-Site Attachment Ring (Easy) for sensitive/fragile skin	MAR-SF MARe-SF	9 months
Service Gas	GAS-0812	12 months
Contact Gel	GEL-04 GEL-SD	12 month

3.1 Routine Checks

The Isolation Transformer shall be electrically tested at least every 6 months by the homecare provider's instructed personnel.

Visual Inspection:
The Isolation transformer shall be visually inspected (mandatory).

- Visual inspection according to IEC 62353
- Visual inspection of integrity of the cable isolation
- Visual inspection of integrity of circuit breakers

Electrical testing:
The Isolation transformer shall be tested according to IEC 62353 (mandatory); altered limits shall be applied where mentioned below.

- Measuring of protective earth resistance with 25 A (recommended current for measurement).
  Measure resistance between primary protective earth (C14 plug) and secondary protective earth (C13 plug).
  The resistance shall not exceed 100 mΩ.

- Measuring of the insulation resistance with 500V DC. Primary live & neutral shortened as well as secondary live & neutral shortened.
  Measure:
  - primary vs. secondary
  - primary vs. protective earth
  - secondary vs. protective earth

  The insulation resistance shall not be below 100 MΩ.

- Earth leakage currents:
  Device under test must be in normal operating condition. The current shall be measured with the mains polarity normal and reversed.
  Measure current from secondary (live and neutral separately) to protective earth through the leakage current measuring device.
  The leakage currents shall not exceed 100 µA.

Functional Test
The Isolation transformer shall be tested according to IEC 62353 in combination with the Sentec Digital Monitor (mandatory).

3.2 Cleaning/Disinfection

For cleaning and/or disinfecting the SDM, the TC Sensors and the Digital Sensor Adapter Cable, please refer to www.sentec.com/ifu.

For cleaning the Isolation Transformer, use a dry or damp cloth. For disinfection, use a 70% isopropanol moistened wipe.

Note: **Instructed personnel/home care providers must clean and if necessary, disinfect the SDM, the TC Sensors, the Digital Adapter Cable and the Isolation Transformer between uses on different patients.**

4. Annex: Instructions for socket and wiring testing (recommended)

As an additional means of protection, Sentec recommends performing a socket and wiring test prior to SDMS installation to verify proper socket installation. The socket testing procedure must only be carried out by a homecare provider's instructed person.

The SDMS (including the isolation transformer) shall be connected to the tested socket only.

1	**Socket Visual Inspection** Check the socket for visual damages and make sure the socket is clean. Otherwise, the socket must not be used. If in doubt, please contact a qualified electrician or your local Sentec representative.
2	**Socket Wiring Test** Check the socket for verification of proper electrical wiring. • Verify no wire is missing. • Verify live / neutral are connected to L/N terminals (may be inverted). • Verify protective earth is connected to the PE terminal (N/PE must not be inverted!) - Voltage between protective earth and neutral shall not exceed 50V AC - Voltage between protective earth and live shall be similar to mains voltage (e.g. 230V AC) Note: **A socket tester may be used. Simple (passive) testers acc. to below example are not able to detect N/PE inverted. Make sure the tester is working properly before testing. Do not leave the tester with the patient.** The socket must not be used if it does not meet above criteria. If in doubt, please contact a qualified electrician or your local Sentec representative.

5. Example Socket Tester for Installation at Home Use Sites

A basic socket tester similar to below example may be used to verify proper socket installation and wiring.

The below example may be substituted by other products.

For further information, refer to the respective socket tester's Instructions for Use.

Plug Type	Rated operating voltage	Brand Name Socket Tester	Manufacturer
F + E (CEE 7/7) Compatible to Schuko plug	230 V/AC 50Hz	Voltcraft VC40 	Conrad Electronic International GmbH & Co. KG www.conrad.com

6. Glossary of Symbols

Symbol	Name	Description of Symbol
	Warning	Warnings alert users about a situation that, if not avoided, could result in hazards or other serious adverse consequences from the use of a medical device.
	Caution	Cautions alert users to exercise appropriate care for safe and effective use of the product and the care necessary to avoid damage to the product that may occur as a result of use or misuse.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Medical Device	Indicates that the device is a medical device.
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Manufacturer	Indicates the medical device manufacturer.
	Refer to instruction manual/ booklet	Indicates that the instruction manual must be read
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
IP XY	IP class of device	Degree of ingress protection: X: Protection against solids Y: Protection against liquids
	CE mark	Indicates that the product complies with the requirements of the Medical Device Directive 93/42/EEC June 1993 or Medical Device Regulation MDR EU 2017/745. If applicable, the 4-digit Notified Body number is added near or below the CE symbol.
	WEEE Disposal	European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2012/19/EU: 1. All electrical and electronic waste must be stored, collected, treated, recycled and disposed of separately from other waste. 2. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country. **Note:** By recycling materials or other forms of utilizing old devices, you are making an important contribution to protecting our environment.

Symbol	Name	Description of Symbol
	Transformer	Indicates that the product is a non-short-circuit proof isolating transformer
	Circuit Breakers	Circuit breakers for transformer protection on the primary side against overloads and short-circuits.
	Defibrillation Proof Type BF	Degree of protection against electrical shock: Defibrillation-proof, Type BF applied part
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Atmospheric pressure limitation	Indicates the atmospheric pressure limits to which the medical device can be safely exposed.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