



Sterilizing reusable SpO₂ sensors

Cleaning and disinfecting SpO₂ sensors

SoftTip® plus • SoftTip® • MultiSoft®

Intended purpose

Please read these instructions carefully before cleaning/disinfecting your SpO₂ sensors. EnviteC Wismar GmbH, as producer and seller of the product, accepts no liability for direct damages or consequential damages resulting from improper use, handling, preparation, sterilisation or maintenance. The sensors may only be used in the medical field for their intended purpose by appropriately trained and qualified personnel.

Manual cleaning / disinfection	SoftTip® plus, SoftTip®, MultiSoft®
Automated cleaning / disinfection / sterilisation	Only SoftTip® plus



Safety information / applicable standards

- SpO₂ sensors must not be cleaned in ultrasound baths. This process will destroy the sensors.
- Cleaners that react with silicone must not be used to prepare the sensors for reuse.
- Observe the instructions provided by the manufacturer for the cleaning and disinfecting device, the cleaning and disinfecting agents and the autoclave or steriliser.
- DIN EN ISO 17665-1 2006/11 – Sterilization of health care products.
- DIN EN 556-1 2002/03 – Sterilization of medical devices.
- Requirements for observing good hygiene practices and the respectively applicable procedures and rules.

The user must ensure that the process used to prepare the sensors for reuse is suitable for achieving the necessary results, including with regard to the suitability of resources, materials and personnel. National standards and laws require compliance with validated preparation processes according to modern technological principles.

Defective products / disposal

Defective products must be cleaned and disinfected according to these instructions before being sent back for repair. Defective products must be disposed of properly.

Storage

In accordance with §4 of the Medical Devices Operating Ordinance (MP BetriebV) and DIN 58946, sterilised sensors must be stored in a dry, clean, dust-free environment at moderate temperatures of between 5°C to 40°C.

Transport

The sensors must be transported in closed containers to prevent damage to the sensors and contamination of the environment.

Preparation

It is recommended that sensors be prepared for reuse immediately after use since dried residue can be difficult to remove. **Avoid overfilling instrument sieves and wash trays.**

Aids for cleaning / disinfection*:

- Approved cleaning and disinfecting agent without protein-fixing effect (always observe the recommendations of the manufacturer when mixing).
- Compressed air
- Soft, disposable cloths
- Automated cleaning brushes
- Demineralised water

Commercially available cleaning and disinfecting agents approved for this purpose and based on aldehydes, alcohols, amines, bases or quaternary ammonium compounds are suitable for cleaning and disinfecting the SpO₂ sensors as long as they exhibit similar active ingredient compositions and concentrations to the examples listed below.

Product Name	Manufacturer	Use
Gigasept Instru AF (glyco derivative)	Schülke & Mayr GmbH	Manual cleaning and disinfection
Gigasept FF (Aldehyde)	www.schuelke-mayr.com	Manual cleaning and disinfection
Perfektan TB	Dr. Schumacher GmbH	Manual disinfection
Descoton Forte (Aldehyde)	www.schumacher-online.com	Manual disinfection
Neodisher LM2	Chemische Fabrik Dr. Weigert GmbH & Co. KG www.drweigert.de	Manual cleaning
Neodisher MediClean forte		Automated cleaning (thermal disinfection)
Neodisher MediKlar		Automated rinsing (thermal disinfection)
Deconex 22 LIQ / 24 LIQ	Borer Chemie AG www.borer.ch	Automated cleaning (thermal disinfection)
Deconex 26 plus		Automated cleaning (neutralisation / pre-rinsing)

Table 1: Tested alkaline cleaning and disinfecting agents

* The Robert-Koch-Institute recommends alkaline cleaning agents

Manual cleaning / disinfection
SoftTip® plus, SoftTip®, MultiSoft®

1. The sensor must be carefully cleaned or disinfected after every use, and before use with a different patient.
2. Prepare the sensor as detailed in the >Preparation< section.
3. Disconnect the sensor from the monitor before cleaning or disinfecting.
4. Thoroughly rinse the sensor to remove surface dirt.
5. Clean all surfaces of the sensor (inside and outside) with a brush or disposable cloth and cleaning agent or disinfectant (observe manufacturer's instructions). We recommend turning the silicone housing of the sensor inside out for cleaning of the inside surfaces. The SoftTip sensors can be submersed in cleaning liquid (see Tab. 1: List of approved cleaning agents).
6. Now rinse the sensor for at least 1 minute in approximately 200 ml of fully demineralised water. When doing so, the water must flow into the connector and the connector/socket holes must be repeatedly filled and emptied.
7. Ensure that all residue has been cleaned off the sensor.
8. If necessary, repeat the entire manual cleaning process.
9. Drying (see >Drying< section)

Automated cleaning / disinfection / sterilisation
according to prEN 15883
Only permitted for SoftTip® plus sensors!

- Place the sensors in the cleaning device in such a way as to allow water to flow out of the connector and so as to leave no areas unwashed.
- Select a suitable cycle on the cleaning and disinfecting device (see also the manufacturer instructions of the cleaning and disinfecting device as well as the cleaning and disinfecting agent).
- When removing the sensors, the anti-kink sleeve, the connector and the sensor housing must be inspected for visible residues. Ensure that all residue has been cleaned off the sensor.
- If necessary, repeat the cycle or clean manually.

Standard cycle for automated cleaning and ...

Thermal disinfection:	Chemical-thermal disinfection:
Pre-rinsing: Cold water, possibly demineralised	Pre-rinsing: Cold water, possibly demineralised
Cleaning: 40-60°C, 5 min., preferably alkaline, possibly with demineralised water	Cleaning: 40-60°C, 5 min., preferably alkaline, possibly with demineralised water
Rinsing: Warm or cold water, possibly demineralised	Disinfection: Demineralised water ≤ 60°C and suitable disinfecting agent
Disinfection: Demineralised water, 80-95°C. Automated thermal disinfection must take place in consideration of the national requirement regarding the AO value (see also ISO 15883).	Final rinsing: Demineralised water max. 60°C

Drying

The air temperature used for drying as part of the cleaning/disinfecting cycle must not exceed 95°C. The outside of the sensors is dried during the drying cycle of the cleaning / disinfecting device.

A lint-free cloth can be used for additional manual drying, if necessary. Sensor cavities must be dried with sterile compressed air.

Inspection and function test

Visually inspect the sensors for damage. Worn, deformed, porous or otherwise damaged sensors must not be reused.

Packing

- The packaging used must be standardised packaging material suitable for steam sterilisation in accordance with ISO 11607 and DIN EN ISO 11607-1.
- The packaging material, such as bags, must be large enough to easily accommodate a single sensor such that the sensor is not under stress.

Sterilisation

Thermal sterilisation

The use of a thermal sterilisation process with saturated steam according to DIN EN ISO 17665-1 is recommended at 134°C with a dwell time of at least 3 min. or at 121°C with a dwell time of at least 15 min.

To avoid the formation of spots and corrosion, the steam must be completely pure.

The recommended limits for the water content and steam condensate are defined in DIN EN 285.

Chemical-thermal sterilisation

SoftTip®plus sensors must be sterilised according to the Sterrad* process (low-temperature plasma sterilisation procedure) validated by the company Advanced Sterilization Products.

Please observe the manufacturer instructions.

Maximum number of reuses

The service life of the product is determined by wear and damage during normal use and preparation for reuse.

If the instructions given here are followed and the recommended and tested cleaning and disinfecting agents are used, the product may be reused for up to 100 reuse cycles.