

*Cleaning and Disinfecting
ergoline Medical Devices*

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Information

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This document is a supplement to the Operator's Manual supplied with each ergoline product. The complete device documentation includes both the Operator's Manual and this document. The most recent version of all Operator Manuals for specific products are available for download at the ergoline website www.ergoline.com.

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1 Cleaning/Disinfection – General Information

1.1 Cleaning Agents

1.1.1 Approved Cleaning Agents

- 50% isopropanol (isopropyl alcohol)
- Mild detergent (mild soap)
- Neutral cleaning agent (neutral cleaner)
- All products suitable for cleaning plastic
- All products suitable for cleaning sensitive surfaces



1.1.2 Unapproved Cleaning Agents

The use of products containing any of the following active ingredients is prohibited:

- Ethanol (90%)
- Acetone
- Hexane
- Scouring powder
- Substances harmful to plastic
- Organic solvents
- Ammonia-based cleaning agents
- Abrasive detergents

1.2 Disinfectants

1.2.1 Approved Disinfectants

- Isopropyl alcohol (70%)
- Propanol (35%)
- Aldehydes (2–4%)
- Ethanol (50%)



B. Braun Melsungen AG:

- Hexaquart plus® (0.5%/ 5.0%)
- Hexaquart S® (1.5%/ 5.0%)
- Meliseptol®
- Melsept SF® (0.5%/ 5.0%)

ECOLAB:

- Incidin Foam®

Paul Hartmann AG:

- Bacillo® 30 Foam / Bacillo® 30 Tissues (10% propan-1-ol, 15% propan-2-ol, 20% ethanol)

Schülke & Mayr GmbH:

- Antifect® AF, FF, FD 10
- Mikrozyd® AF (25% ethanol, 35% propan-1-ol)
- Quartamon Med®
- Terralin® (0.5%)

1.2.2 Unapproved Disinfectants

- 100% alcohol, Virex
- HB Quat®
- Conventional detergents
- Conductive solutions

2 Cleaning and Disinfecting the Device Components

2.1 Device Surfaces (Plastic/Metal)

Thoroughly inspect the device and the accessories before cleaning them:

- Check for damage (visual inspection).
- Check keys/buttons and connectors for proper mechanical function.
- Carefully bend the cables and check for damage, heavy wear, exposed wires, and bent connector pins.
- Check that all connectors mate properly.
- Clean the surface of the device housing and connection cables by wiping them with a lightly moistened (not wet) cloth. Where necessary a domestic non-caustic cleaning agent or a 70% alcohol solution can be used for grease and finger marks.
- Immediately wipe off all excess cleaning agent.

Wipe the device surface down with a cloth only moistened with soap water or a disinfectant.

Make sure that the cloth is not dripping wet to prevent liquid from entering the device.

2.2 Handlebar/Seat (Saddle)

Only a soft, dry or moistened cloth with one of the cleaning agents listed in section 1.1.1 should be used for cleaning.

The parts should be disinfected after each use with one of the disinfectants listed in section 1.2.1.

2.3 Pedals

Only a soft, dry or moistened cloth with one of the cleaning agents listed in section 1.1.1 should be used for cleaning.

The parts should be disinfected after each use with one of the disinfectants listed in section 1.2.1.

2.4 Displays of Control Terminals

The film on the displays should be cleaned with a soft cloth and vinegar-based household cleaner. Soak the cloth in the cleaning agent, wring dry and carefully press the moist cloth onto the display. Then remove soiling in circular motion. Finally wipe the cleaned surface with a moist cloth to remove any residue of the cleaning agent. For disinfection, we recommend using an alcohol-based disinfectant according to the manufacturer's instructions.

Never use abrasive cleaners/tools such as steel wool or scouring agents to remove heavy soiling.

2.5 Upholstery

Wipe the upholstery down with a soft cloth moistened with soap water.

The cloth should only be moist and not dripping wet.

If the cleaning agents and disinfectants used are caustic or contain alcohol, they may damage and/or discolor the upholstery.

2.6 Blood Pressure Cuff

2.6.1 Removing the Microphone

Pull the end of the cuff through the metal clasp and fold out the cuff.

Pull on the short Velcro tab to open the microphone pocket and carefully remove the microphone.

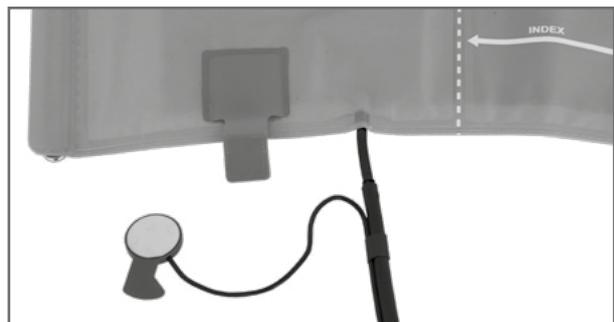


Figure 2 – 1: Removing the microphone

2.6.2 Cleaning

Clean the cuff and tubing with a moist cloth. You can use a dishwashing liquid or mild soap water.

Clean the microphone with a cloth moistened with alcohol or mild soap water.

Allow the microphone to dry before reinserting it in its pocket.

Warning



Equipment Damage

• Cuff, microphone and tubing may not under any circumstances:

- be immersed in liquids,
- be cleaned in a water bath or in running water.

2.6.3 Disinfection

For disinfection, spray a disinfectant sparingly on the cuff, the tubing and the microphone.

After the exposure time indicated by the manufacturer, wipe all components dry.

The parts should be disinfected after each use with one of the disinfectants listed in section 1.2.1.

Notice



Strictly observe the manufacturer's instructions for use.

2.6.4 Inserting the Microphone

Slip the microphone into the pocket, the metal side facing the arm.

Guide the microphone cable out of the pocket and to the right of the Velcro tab. Then close the tab.

Fold the end of the cuff over and introduce it into the metal clasp.

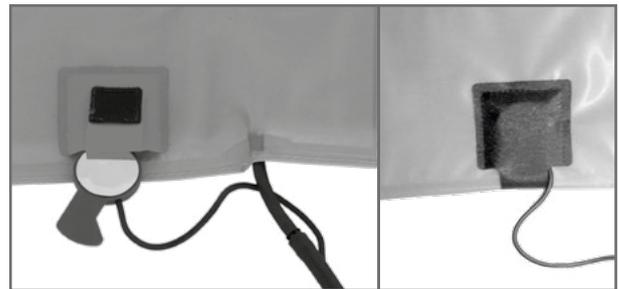


Figure 2-2: Inserting the microphone

2.6.5 Inspection and Functional Test

Visually inspect the cuff and tubing for damage.

Worn, porous, or otherwise damaged cuffs and tubing must not be used.

2.7 ECG Electrodes/Suction Leads

2.7.1 Cleaning

ECG electrodes and suction leads should be cleaned after each use to ensure optimal hygiene and durability.

Take care not to scratch or damage the surface of the suction electrodes.

The number of cleaning cycles under normal operating conditions does not adversely affect the service life. Thorough cleaning ensures constant, high quality signal transmission and extends the lifetime.

Only a soft, dry or moistened cloth with one of the cleaning agents listed in section 1.1.1 should be used for cleaning.

2.7.2 Disinfection

To ensure complete disinfection, the manufacturer's directions must be strictly observed, the prescribed exposure times being of particular importance.

The parts should be disinfected after each use with one of the disinfectants listed in section 1.2.1.

- Spray the disinfectant onto the exterior of the suction leads and the suction cups. Observe the exposure time specified by the manufacturer.
- In the case of heavy soiling of the suction leads and suction cups, disinfect their exterior with disinfection wipes or impregnated cleaning tissues.
- Spray the disinfectant on the inside of the electrodes. Observe the exposure time specified by the manufacturer.
- Disinfect the sealing lips and electrode surfaces with disinfection wipes or impregnated cleaning tissues.

Notice



- *Strictly adhere to the manufacturer's instructions for use of the substances, e.g., regarding dosage and exposure times.*

Warning



Equipment Damage

- *Use only cleaning agents and disinfectants recommended by ergoline. Unsuitable products may damage the device.*
- *Do not, under any circumstances, immerse the device in liquids or allow liquid to enter the interior of the device.*

2.8 SoftTip SpO2 Sensors

2.8.1 Aids for Cleaning/Disinfection

- Approved, non-protein-fixing cleaning agent and disinfectant (preparation in strict respect of the manufacturer's recommendations).
- Compressed air
- Soft disposable tissues
- Electric cleaning brushes
- Demineralized water

Commercially available cleaning agents and disinfectants approved for this application based on aldehydes, alcohol, amines, alkalis, or quaternary ammonium compounds are suitable for cleaning and disinfecting the SpO2 sensors if the combination and concentration of active ingredients is similar to the examples listed below.

Product Name	Manufacturer	Application
Gigasept Instru AF (glycoderivative)	Schülke & Mayr GmbH www.schuelke-mayr.com	Manual cleaning and disinfection
Gigasept FF (aldehyde)		Manual cleaning and disinfection
Perfektan TB	Dr. Schumacher GmbH www.schumacher-online.com	Manual disinfection
Descoton forte (aldehyde)		Manual disinfection
Neodisher LM2	Chem. Fabrik Dr. Weigert GmbH & Co. KG www.drweigert.de	Manual cleaning

Validated alkaline cleaning agents and disinfectants

2.8.2 Manual Cleaning and Disinfection of the SoftTip Sensors

1. After each use and before application on another patient, the sensor must be carefully cleaned and disinfected.
It is recommended to reprocess the sensor immediately after use because dried material is difficult to remove.
2. Disconnect the sensor from the monitor before cleaning or disinfecting it.
3. Thoroughly rinse the sensor to remove soiling from the surface.
4. Clean the inner and outer surfaces with a brush or a disposable tissue impregnated with cleaning agent or disinfectant (observe manufacturer's instructions). It is recommended to turn the silicone housing of the sensor inside out for cleaning of the interior. The SoftTip sensors can be immersed in cleaning solution (see list of approved cleaning agents).
5. Subsequently rinse the sensor for at least 1 minute in approx. 200 ml of demineralized water. Water must enter the connector, and the openings in the connector and socket must be repeatedly flushed and drained.
6. Make sure that the sensor has been thoroughly cleaned without any residue.
7. Repeat the entire manual cleaning process if necessary.
8. Manually dry the sensor with a lint-free cloth. Dry the cavities of sensors with sterile compressed air.

Notice



Safety information Standards to be complied with

- *SoftTip sensors must not be machine-cleaned/ autoclaved.*
- *SpO2 sensors must not be cleaned in an ultrasonic bath. Ultrasonic cleaning will destroy the sensors.*
- *Reprocessing with cleaning agents that react with silicone is prohibited.*
- *Instructions for use of the cleaning agent and disinfectant supplied by the manufacturers must be observed.*
- *The standard DIN EN ISO 17665-1 2006/11 – Sterilization of health care products.*
- *The standard DIN EN 556-1 2002/03 – Sterilization of medical devices.*
- *Compliance with hygiene requirements and the relevant, recognized procedures and regulations.*

2.8.3 Cleaning the Cables

- Disconnect the cable from the device.
- Wipe the cables with a moist cloth (soap water) – never immerse the cables in liquids.

2.8.4 Inspection and Functional Test

Visually inspect the sensors for damage.

Worn, deformed, porous, or otherwise damaged sensors must not be used.

2.9 Ear Clip

- Wipe the ear clip with a cloth moistened with 70% isopropyl alcohol.
- After cleaning, wipe the ear clip with a clean cloth moistened with water.



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