

Cleaning Protocol For Micromed Devices

- Micromed devices are non-critical items because they come in contact only with intact skin of the operators or patients: hence, low-level disinfection is adequate to maintain the desired biological safety of the device.
- Some of the electrodes/sensors could contact patient mucous (e.g. PSG flow sensors, pressure cannula) or come in contact with abraded/breached skin (EEG electrodes in some case). In these cases, high-level disinfection is recommended for reusable accessories. Disposables or accessories compatible with such processes need to be used. Needle/cortical electrodes are invasive and shall be sterile.
- Micromed makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospital's infection control officer or epidemiologist. Always follow the hygiene regulations from your clinical facilities.

1 Intervals

		When?		Clean		Disinfect
Part	Refer To Chapter	After every use	on changing patient	clean by hand	washing machine	disinfect by wiping
Amplification and stimulation main devices	2+3		✓	✓		✓
EEG/PSG recorders	2+3		✓	✓		✓
Patient-contacting parts (hand held stimulators, goggles, headphones)	2+3	✓		✓		✓
Cables	2+3		✓	✓		
Keyboards/keypads	8		✓	✓		✓
PC, camera and other IT devices	8		✓	Follow manufacturer instructions		
Carrying bags and belts	6		✓	✓	✓	
Trolleys , supports and cases	7		✓	✓		✓
Reusable Electrodes, Sensors and Accessories	5	✓		Follow manufacturer instructions		
Disposable Electrodes, Sensors and Accessories	4	Disposable item				

2 Clean

Notice!

Ingress of liquids could cause a short-circuit and damage devices, accessories and sensors.

1. Remove all disposable/used accessories. Leave the cable connected (disconnect on the interface side). On recorders, leave the memory card inside the device. If present, remove the batteries and close again accurately the battery holder cover.
2. Remove visible contamination from the connectors with a nylon brush
3. Prepare a solution with a hospital grade enzymatic or mild detergent
 - Follow the instructions accompanying the hospital grade cleaner
4. Dampen lightly a lint-free cloth with the solution
 - Do not pour or spray any liquids on the device
 - Do not allow any liquids to enter any openings on the device
 - Do not immerse the cables in liquid
 - Avoid contact of the cleaning solution to cable/electrode connectors
5. Wipe all surface areas thoroughly to remove all visible soil and contaminants. Wipe the component for at least 2 minutes. Use a soft bristle nylon brush if necessary.
6. Visually inspect the cleaned components to ensure no soil remains. Pay good attention to all junctions and details. Repeat steps 3 and 4 if necessary.
7. Allow components to air dry completely before disinfection (minimum of 3 minutes)

Never use acetone or other solvents as they can damage the device.

3 Disinfect

The devices cannot be cleaned by immersion or spraying.

1. For disinfection, take
 - a new wipe of Metrex CaviWipe towelettes or equivalent validated disinfectant, or
 - a wipe lightly dampened with a solution of sodium hypochlorite diluted with water (bleach) at 0.05% (500ppm), or
 - a wipe lightly dampened with ethanol 70-90% or other ethanol-based disinfectants.
2. Wipe all surface areas of the component except the connectors with the disinfectant for at least three minutes

If other disinfection materials are used than Metrex CaviWipe make sure:

- they are safe to use on metals and plastics
 - to read the instructions from the manufacturer regarding required contact time of the solution to provide sufficient disinfection
3. Allow components to air dry completely before next use (minimum 1 minute)
 4. Visually inspect the components under adequate lighting conditions (and magnification if needed) to confirm that the cleaning/disinfection process has not damaged components. Inspect for surface wear, discoloration, corrosion, or cracking.

4 Disposable items

Some of the accessories and sensors may be disposable items. Disposable items are intended to be used only once. Therefore, please do **not** reprocess them. Reprocessing disposable items may impair the functionality and safety of the product and lead to unforeseeable reactions as a result of ageing, wear, thermal load, the effects of chemical processes.

5 Reusable Electrodes, Sensors and Accessories

Follow the instructions enclosed with each accessory.

6 Carrying Bags and Belts

Caution: Dispose of the carrying bag in the event of potential pathogens needing high level disinfection such as MRSA

- Remove macroscopic soiling with a lint and a brush.

BAG MORPH, BAG LTM HP, BAG LTM 128:

- Velcro straps and the belts can be washed in a washing machine at 40 °C with mild detergent (Woolite-type). Leave the belts to dry in air.
- If needed, also the bag can be washed.
- Note: The metal ring on *BAG MORPH* could rust when washed.

Do not use bleach solution. Do not use a tumble dryer.

BAG LTM PLUS

- The bag can be cleaned and disinfected with the same process described for the devices. Discoloring can occur but does not affect the bag function.

7 Carrying trolleys

The mounting assembly may be cleaned with most mild, non-abrasive solutions commonly used in the hospital environment including water, mild soap, 3% hydrogen peroxide solution, diluted bleach solution, 70% to 91% isopropyl alcohol, 70 to 100% ethanol (Ethyl Alcohol), quaternary ammonium disinfectant, disinfectant cleaners, disinfectant wipes

We recommend testing any cleaning solution on a small area that is not visible to verify compatibility.

The surface finish will be permanently damaged by strong chemicals and solvents such as acetone and trichloroethylene. Steel wool or other abrasive material should never be used.

Disconnect the isolation transformer or any direct mains-powered devices on the cart from socket before cleaning. Use a dampened wipe to clean the trolley. Never submerge parts or allow liquids to enter arms, drawers, trolley sliding columns. Take particular care of electric parts mounted on the trolleys (e.g. PC, isolation transformer). Do not spray cleaners on surfaces, since this can lead to dripping on electric parts. Wipe any cleaning agents off immediately using a water-dampened cloth. Dry the trolley thoroughly after cleaning.

8 Non-medical devices

Follow the cleaning instructions in the Instructions for Use for the individual components in combination with the standard facility hygiene procedures.

2020 Addendum: COVID-19 specific precautions

SARS-CoV-2 surface permanence time is unknown, but it is a non-enveloped virus, so many of the commonly used disinfectant are effective for deactivating it. Some specific precautions are given:

- Use CaviWipes1 or CaviWipe Bleach instead of standard CaviWipe for cleaning and disinfection
- Other disinfectants from the list <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2> can be used as long as they are ethanol- or chloro-based respecting the provided concentration.
- Use disposable accessories as much as possible. When not possible, carefully follow decontamination, cleaning and disinfection protocols for the accessories.
- Disposable covers can be used for protecting the devices from droplets of contamination: they need not be model-specific (transparent plastic bag and film could be an adequate protection)
- Morpheus respiratory channels should ALWAYS be protected by a filter on the cannula (not only with potentially infectious diseases). Nevertheless, given the specific transmission of SARS-CoV-2, it is suggested to use information provided from RIP belts instead of direct flow pressure measurement through cannula.