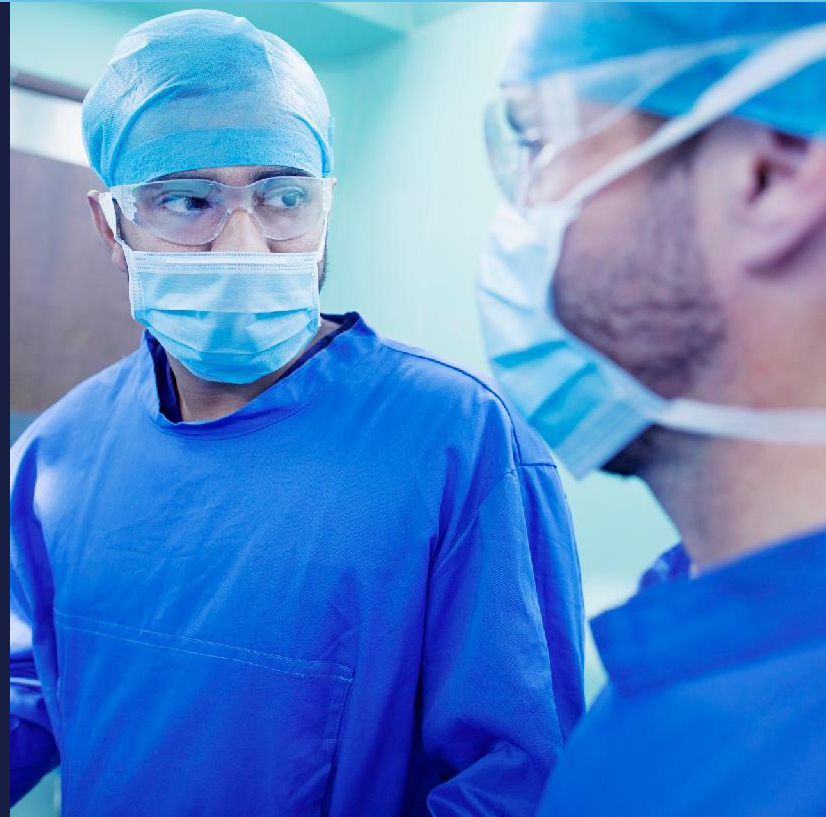


CLEANING, DISINFECTION, **AND STERILIZATION** PROTOCOLS

Respiratory
Interventions & Patient
Monitoring Solutions



Medtronic
Further, Together



NOTES:

- Always follow your institution's infection control guidelines. Do not attempt to sterilize or reuse single-patient use items.
- Medtronic recognizes that cleaning, sterilization, sanitation, and disinfection practices vary widely among healthcare institutions. It is not possible to specify or require specific practices that will meet all needs or to be responsible for the effectiveness of cleaning, disinfection, and other practices carried out in patient care settings. We recommend that users of these products requiring cleaning and disinfection consider standards published by the Association for the Advancement of Medical Instruments (AAMI) as well as the Centers for Disease Prevention and Control (CDC).

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NELLCOR™ PULSE OXIMETRY

NELLCOR™ PORTABLE SPO2 PATIENT MONITORING SYSTEM (PM10N)



Cleaning

The monitoring system may be surface-cleaned by using a soft cloth dampened with either a commercial, nonabrasive cleaner or one of the solutions listed below. Lightly wipe all surfaces of the monitoring system.

- Quaternary ammonium compounds
- Quaternary ammonium compounds in combination with polyhexanide
- Alcohols, such as 70% isopropyl
- Glucoprotamin
- 10% chlorine bleach solution
- PDI™* Sani-System™* sanitizer



WARNING: Remove batteries from the monitoring system before cleaning.

NELLCOR™ BEDSIDE SPO2 PATIENT MONITORING SYSTEM (PM100N)



Cleaning

For surface cleaning of the monitoring system, follow institutional procedures or the recommended actions below.

Surface cleaning – Periodically surface clean the monitoring system by using a soft cloth dampened with a commercial, nonabrasive cleaner. Lightly wipe the top, bottom and front surfaces of the monitoring system lightly.

Avoid spilling liquid on the monitoring system, especially in connector areas, but if a spill occurs, clean and thoroughly dry the monitoring system before reuse. If in doubt about monitoring system safety, refer the monitoring system to a qualified service technician for examination.



WARNINGS:

- Do not spray, pour, or spill any liquid on the monitoring system, its accessories, connectors, switches, or openings in the chassis.
- Remove batteries from the monitoring system before cleaning.

NELLCOR™ BEDSIDE RESPIRATORY PATIENT MONITORING SYSTEM (PM1000N)



Cleaning

For surface cleaning and disinfection of the monitoring system, follow institutional procedures or the recommended actions below.

- **Surface cleaning** – Use a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, lightly wiping the surfaces of the monitoring system.
- **Disinfection** – Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water, lightly wiping the surface of the monitoring system



WARNING: Do not spray, pour, or spill any liquid on the monitoring system, its accessories, connectors, switches, or openings in the chassis.

NELLCOR™ PULSE OXIMETRY DS-100A SENSOR WITH OXIMAX™ TECHNOLOGY



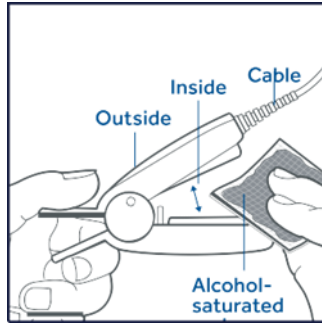
Cleaning

You can surface clean the Nellcor™ pulse oximetry DS-100A sensor by wiping it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (5% to 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur.

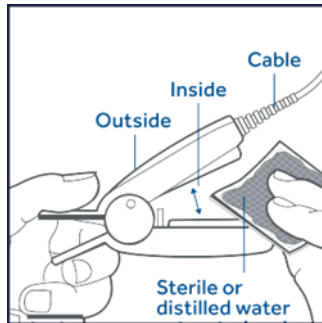
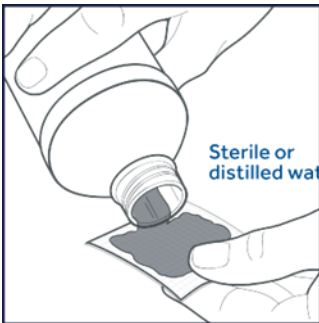


CAUTION: Do not expose the connector pins to cleaning solution as this may damage the sensor.

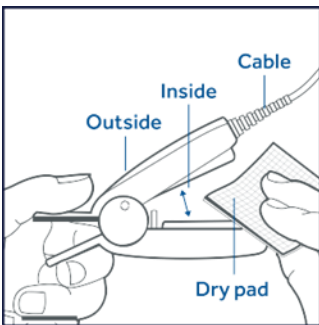
1. Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad.



2. Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.



3. Dry the sensor and cable by wiping all surfaces with a clean dry gauze pad.



CAUTION: Do not sterilize with irradiation, steam, or ethylene oxide. Such sterilization could damage the sensor.

NELLCOR™ FLEXIBLE SPO2 SENSOR



Cleaning

It is necessary to clean and disinfect the sensor before attaching it to a new patient. Routine cleaning or low-level disinfection is recommended when using the sensor on the same patient.

To clean the sensor:

1. Disconnect the sensor from the monitor before cleaning or disinfecting.
2. Rinse the sensor and cable with distilled water for at least two minutes.
3. Wipe the cable with a cotton pad soaked in 70% Isopropyl alcohol.
4. Immerse the sensor housing in 70% Isopropyl alcohol for 5 minutes.
1. Allow ten minutes for the sensor, cable, and connector to dry after rinsing.

To disinfect (low-level):

1. Disconnect the sensor from the monitor before cleaning or disinfecting.
2. Rinse the sensor and cable with distilled water for at least two minutes.
3. Prepare 1:10 bleach dilution in distilled water. Wipe the cable with a cotton pad soaked with the solution of diluted bleach.
4. Immerse the sensor housing in the solution of diluted bleach for five minutes.
5. Rinse the sensor and cable by immersing them in distilled water for five minutes.
6. Allow ten minutes for the sensor, cable, and connector to dry after rinsing.

To disinfect (high-level):

1. Rinse sensor to remove surface dirt – the sensor housing may be fully immersed in liquid.
2. Clean the sensor and patient contact surfaces. Prolystica¹ is recommended as a cleaning agent. Follow the manufacturer's instructions for use. Immerse the sensor housing in the solution and wipe the inner and outer surfaces with a soft brush or cloth to remove any visible soil. Rinse sensor with water following cleaning and wipe dry prior to disinfection.
3. CIDEX OPA² is recommended for high-level disinfection. Follow the manufacturer's instructions for use. Immerse the sensor housing in the solution for 12 minutes and remove.
4. Thoroughly rinse the sensor with water following disinfection (5 minutes minimum distilled water rinse/soak).
5. Manually dry the sensor and verify the sensor, cable, and connector are dry prior to use.



CAUTION: Do not immerse the connector at the sensor cable in liquid.

MICROSTREAM™ CAPNOGRAPHY

CAPNOSTREAM™ 35 PORTABLE RESPIRATORY MONITOR



Cleaning

Germicidal disposable cloth wipes, or wipes moistened with Isopropyl alcohol or 96% Ethanol may be used to clean the monitor. Cleaning with a wipe moistened with these solutions should be followed by wiping the monitor with distilled water. Caustic or abrasive cleaners should not be used to clean the monitor.



WARNING: The device is not sterile. Do not autoclave or sterilize this device.



CAUTIONS:

- Do not spray or pour any liquid directly on the monitor, accessories, or consumables.
- Do not use caustic or abrasive cleaners, or harsh solvents, including petroleum-based or acetone solutions, to clean the device.
- Microstream™ etCO₂ consumables are designed for single patient use and are not to be reprocessed. Do not attempt to clean, disinfect, or blow out the Filterline as the monitor can be damaged.

CAPNOSTREAM™ 20p PORTABLE BEDSIDE MONITOR



Cleaning

To clean the monitor's surfaces, lightly dampen a cloth with a 70% alcohol solution and wipe all surfaces. Alcohol wipes may also be used. Frequency of the cleaning procedure should be in keeping with hospital policy. To clean the screen, use a damp lint-free cloth.



WARNING: Do not autoclave or sterilize this device.



CAUTIONS:

- Do not spray or pour any liquid directly on the monitor, accessories, or consumables.
- Do not use caustic or abrasive cleaners, or harsh solvents, including petroleum-based or acetone solutions, to clean the device.
- If a 1:10 bleach dilution (0.5% to 1% Sodium Hypochlorite solution) in the form of wipes is used to disinfect external surfaces of the monitor, exposure of the connectors and the display to the bleach solution should be avoided. Repeated cleaning with bleach over time may cause discoloration and residue on the surfaces.
- Microstream™ etCO₂ consumables are designed for single patient use and are not to be reprocessed. Do not attempt to clean, disinfect or blow out the Filterline as the monitor can be damaged.

VIDEO LARYNGOSCOPY

MCGRATH™ MAC VIDEO LARYNGOSCOPY†



Cleaning and Low Level Disinfection

The device and battery should be cleaned and low level disinfected separately after each patient use. Cleaning and low level disinfection should be carried out as per instructions below in accordance with local regulations. Follow hospital policy and protocol when handling and cleaning soiled items.

The following methods have been approved:

Product	Cleaning	Low Level Disinfection
McGRATH™ Disposable Laryngoscope Blade	Supplied sterile. Do not preprocess.	Supplied sterile. Do not reprocess.
McGRATH™ MAC with McGRATH™ 3.6V Battery removed	70% IPA Wipe	70% IPA
McGRATH™ 3.6V Battery	70% IPA Wipe	70% IPA



WARNINGS:

- Ensure the device is completely dry before using.
- Do not autoclave the device.
- Do not reprocess this device in an ultrasonic cleaner.

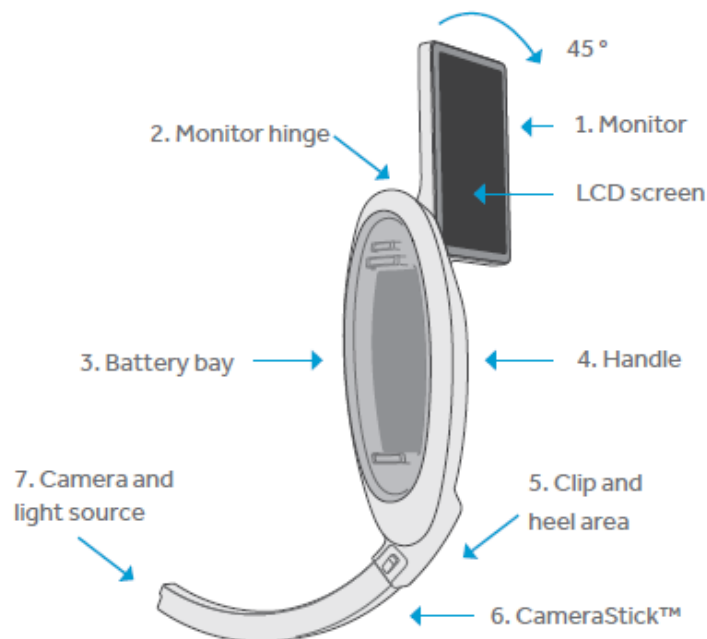
Dispose of 70% IPA wipes in accordance with local regulations and hospital policy.

When cleaning and low level disinfecting the McGRATH® MAC with the battery unit removed, low level disinfection claims will only apply to exposed surfaces of the McGRATH™ MAC and McGRATH™ 3.6V Battery.

Device Cleaning

Clean with a 70% IPA wipe with the McGRATH™ 3.6V Battery removed. The following process steps should be followed to clean the device: Using a 70% IPA wipe, clean the device systematically working from Steps 1 through 7 (from top to bottom of the device). Ensure that the 70% IPA wipe comes in contact with all surfaces of the device even if no visible soiling is present. Ensure a minimum contact time of 1 minute on all surfaces when using 70% IPA wipes.

1. **Monitor:** Ensure the 70% IPA wipe gets into the various grooves around the screen.
2. **Monitor hinge:** Rotate the monitor to the upright position. Feed the 70% IPA wipe into the space between the monitor and handle to ensure effective penetration. Rotate the monitor to its opposite position and repeat.
3. **Battery bay:** Ensure all surfaces of the battery bay (with battery removed) are thoroughly treated with the 70% IPA wipe. Ensure that the join between the battery module and the handle is thoroughly treated with the 70% IPA wipe.
4. **Handle:** Ensure all surfaces of the handle are thoroughly treated with the 70% IPA wipe.
5. **Clip and heel area:** Take particular care in ensuring that the small metal clip feature is clean, in particular the internal corner between the clip and the surrounding plastic body.
6. **CameraStick™:** Ensure all surfaces of the camera stick are thoroughly treated with the 70% IPA wipe.
7. **Camera lens:** Clean the camera lens with the 70% IPA wipe, ensure that the interface between the metal CameraStick™ and camera lens is clean.



Subsequent cleaning should be repeated where visible soiling is still present using a new 70% IPA wipe.

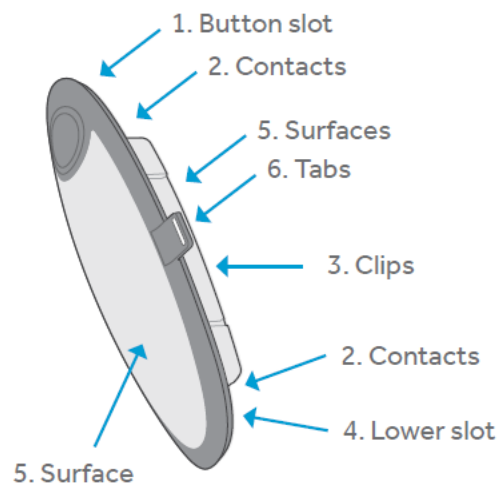
Device Low Level Disinfection

Disinfect with a 70% IPA wipe with the McGRATH™ 3.6V Battery removed. Follow the same process steps as per cleaning, to low level disinfect the device. Using a new 70% IPA wipe, disinfect the device systematically working from Steps 1 through 7 as per cleaning instruction (from top to bottom of the device). Ensure that the 70% IPA wipe comes in contact with all surfaces of the device. Ensure a minimum contact time of 1 minute on all surfaces when using 70% IPA wipes.

Battery Cleaning

Clean the McGRATH™ 3.6V Battery with a 70% IPA wipe. The following process steps should be followed to clean the battery. Using a 70% IPA wipe, clean the device systematically working from Steps 1 through 6 (from top to bottom of the battery cover). Ensure that the 70% IPA wipe comes in contact with all surfaces of the device even if no visible soiling is present. Ensure a minimum contact time of 1 minute on all surfaces when using 70% IPA wipes.

1. **Battery slot:** Ensure the 70% IPA wipe gets into the two button slots at the back of the battery push button.
2. **Contacts:** Ensure the 70% IPA wipe gets into the space around and under the two metal battery contacts.
3. **Clips:** Run the 70% IPA wipe along and into the gaps around the battery retaining clips.
4. **Lower slot:** Ensure the 70% IPA wipe gets into the lower slot at the base of the battery.
5. **Surfaces:** Wipe all surfaces of the battery cover with the 70% IPA wipe.
6. **Tab:** Run the 70% IPA wipe along all surfaces of the tab.



Subsequent cleaning should be repeated where visible soiling is still present using a new 70% IPA wipe.

Battery Low Level Disinfection

Disinfect the McGRATH™ 3.6V Battery with a 70% IPA wipe. Follow the same process steps as per cleaning, to low level disinfect the battery. Using a new 70% IPA wipe, disinfect the device systematically working from Steps 1 through 6 as per cleaning instruction (from top to bottom of the device).

MECHANICAL VENTILATION

PURITAN BENNETT™ 980 SERIES VENTILATOR



Surface Cleaning of Exterior Surfaces

External surfaces of the GUI, BDU, and standard or compressor base may become soiled and should be cleaned periodically.

To clean the GUI, BDU, and base surfaces

1. Moisten a soft cloth with one of the surface cleaning agents listed or use Sani- Cloths (PDI, Inc.). See table below.
2. Wipe the GUI, BDU, and base, removing any dirt or foreign substances.
3. Dry all components thoroughly.
4. If necessary, vacuum any cooling vents on the GUI and BDU with an electrostatic discharge (ESD)-safe vacuum to remove any dust.

Surface Cleaning Agents

Part	Procedure	Comments/Caution
Ventilator exterior (including touch screen and flex arm)	<p>Wipe clean with a cloth dampened with one of the cleaning agents listed below or equivalent.</p> <p>Use a damp cloth and water to rinse off chemical residue as necessary.</p> <ul style="list-style-type: none"> ▪ Mild dishwashing detergent solution ▪ Isopropyl alcohol (70% solution) ▪ Bleach (10% solution) ▪ Window cleaning solution (isopropyl alcohol and ammonia) ▪ Ammonia (15% solution) ▪ Hydrogen peroxide (3% solution) ▪ Formula 409™* cleaner (Clorox Company) ▪ CaviCide™* surface disinfectant (Metrex Research Corporation) ▪ Control III™* germicide (Maril Inc.) ▪ Mr. Muscle Window & Glass (SC Johnson) ▪ Sani Cloths (PDI, Inc.) ▪ [Propan-2-ol, Isopropanol, Isopropyl Alcohol]³ 	<ul style="list-style-type: none"> ▪ Do not allow liquid or sprays to penetrate the ventilator openings or cable connections. ▪ Do not attempt to sterilize the ventilator by exposure to ethylene oxide (ETO) gas. ▪ Do not use pressurized air to clean or dry the ventilator, including the GUI cooling vents. ▪ Do not submerge the ventilator or pour cleaning solutions over or into the ventilator.
Ventilator cooling vents	Vacuum the vents at the back of the GUI and BDU to remove dust.	N/A

Component Cleaning and Disinfection

Risks associated with reuse of single-patient use items include but are not limited to microbial cross-contamination, leaks, loss of part integrity, and increased pressure drop. When cleaning reusable components, do not use hard brushes or implements that could damage surfaces.



WARNING: To avoid microbial contamination and potential performance problems, do not clean, disinfect, or reuse single-use or disposable components. Discard per local or institutional regulations.

Component Cleaning Agents and Disinfection Procedures

Part	Cleaning Agent/Procedure	Comments/Cautions
EVQ	<p>Before disinfection, presoak in EMpower™* Dual Enzymatic Solution (Metrex Inc.).</p> <p>Perform high level disinfection using liquid chemical disinfectant with any of the following agents:</p> <ul style="list-style-type: none"> ▪ Cidex™* (2.5%) (ASP⁴) ▪ Cidex™* OPA (0.55%) ASP⁴ ▪ Sporox™* II (Sultan) <p>See Exhalation Flow Sensor Assembly (EVQ) Disinfection on page 14 for specific instructions.</p>	Do not drop the EVQ or handle roughly during disinfection or storage.
Neonatal door/adapter	<p>Before disinfection, presoak in EMpower™* Dual Enzymatic Solution (Metrex Inc.).</p> <p>Perform high-level disinfection using liquid chemical disinfectant with any of the following agents:</p> <ul style="list-style-type: none"> ▪ Cidex™* (2.5%) (ASP⁴) ▪ Cidex™* OPA (0.55%) ASP⁴ <p>Follow the manufacturer's instructions.</p>	N/A
Reusable patient circuit tubing	Disinfect per manufacturer's instructions for use.	<ul style="list-style-type: none"> ▪ Inspect for nicks and cuts and replace if damaged. ▪ Run SST to check for leaks when reinstalling the circuit or when installing a new circuit.
Breathing circuit in-line water traps	Disinfect per manufacturer's instructions for use.	<ul style="list-style-type: none"> ▪ Inspect water traps for cracks and replace if damaged. ▪ Run SST to check for leaks when reinstalling the circuit or when installing a new circuit.
Breathing circuit components	Disinfect per manufacturer's instructions for use.	<ul style="list-style-type: none"> ▪ Inspect components for nicks and cuts and replace if damaged. ▪ Run SST to check for leaks when reinstalling the circuit or when installing a new circuit.

Part	Cleaning Agent/Procedure	Comments/Cautions
Inlet air filter	Wash the bowl with mild soap solution, if needed.	<ul style="list-style-type: none"> ▪ Avoid exposing the inlet air filter bowl to aromatic solvents, especially ketones. ▪ Replace if cracks or crazing are visible.
Battery	Wipe with a damp cloth using one of the surface cleaning agents listed on page 12.	Do not immerse the battery or get the contacts wet.
Cooling fan filter	Clean every 250 hours or as necessary.	Wash in mild soap solution, rinse, and air dry.
Other accessories	Follow manufacturer's instructions for use.	N/A

To clean and disinfect parts

1. Wash parts in warm water using a mild soap solution.
2. Thoroughly rinse parts in clean, warm water (tap water is acceptable) and wipe dry.
3. Clean or disinfect ventilator surfaces and component parts per the procedures listed for each component. See the Surface Cleaning Agents table on page 12 and the Component Cleaning Agents and Disinfection Procedures table on page 13 for lists of acceptable cleaning and disinfecting agents.
4. Visually inspect the components for cracks or other damage prior to use.
5. Dispose of damaged parts according to the institution's policy.



Note: Steps 1 through 3 above do not apply to the EVQ. See Exhalation Flow Sensor Assembly (EVQ) Disinfection below for disinfection instructions.

Whenever replacing or reinstalling a component, run SST before ventilating a patient.

Exhalation Flow Sensor Assembly (EVQ) Disinfection

The EVQ contains the exhalation flow sensor electronics, exhalation valve diaphragm, exhalation filter seal, and pressure sensor filter. The exhalation flow sensor electronics consist of the hot film wire and the thermistor.



Note: Follow the institution's infection control protocol for handling, storage, and disposal of potentially biocontaminated waste.



CAUTION: To avoid damaging the hot film wire, do not insert fingers or objects into the center port when disinfecting the EVQ.

PURITAN BENNETT™ 840 SERIES VENTILATOR



How to Clean, Disinfect, and Sterilize Ventilator Parts

The table below describes how to clean, disinfect, and sterilize ventilator components.



WARNINGS:

- Do not attempt to remove, clean, or flush the flow sensor with liquids or pressurized air.
- To avoid patient exposure to sterilizing agents, be sure to sterilize parts in accordance with the techniques described in the Procedures to Clean, Disinfect, and Sterilize parts table on page 15. Exposure to sterilizing agents may reduce the useful life of some parts.
- Handle filters with care, to minimize the risk of bacterial contamination or physical damage.


Procedures to Clean, Disinfect, and Sterilize Parts

Part	Procedure	Comments
Ventilator exterior (including touch screen and flex arm)	Wipe clean with a damp cloth and mild soap solution or with one of the chemicals listed or its equivalent. Use a damp cloth and water to rinse of chemical residue as necessary. <ul style="list-style-type: none"> ▪ Mild dishwashing detergent ▪ Isopropyl alcohol (70% solution) ▪ Bleach (10% solution) ▪ Window cleaning solution (with isopropyl alcohol and ammonia) ▪ Ammonia (15% solution) ▪ Hydrogen peroxide (3% solution) ▪ Formula 409™* cleaner (Clorox Company) ▪ Amphyl™* disinfectant (Reckitt Benckiser Inc.) ▪ CaviCide™* surface disinfectant (Metrex Research Corporation) ▪ Control III™* germicide (Maril Inc.) ▪ Glutaraldehyde (3.4% solution) 	<ul style="list-style-type: none"> ▪ Do not allow liquid or sprays to penetrate the ventilator or cable connections. ▪ Do not attempt to sterilize the ventilator by exposure to ethylene oxide (ETO) gas. ▪ Do not use pressurized air to clean or dry the ventilator, including the GUI vents.
	Vacuum the vents at the back of the GUI to remove dust.	



CAUTIONS:

- To avoid damaging filter materials use on the back of the GUI, do not use hydrogen peroxide to clean the GUI. (This is applicable to the 9.4 inch GUI, which is an earlier version of the GUI.)
- To prevent damage to ventilator labeling and ventilator surfaces in general, use only the listed chemicals to clean the ventilator exterior.

Part	Procedure	Comments
Patient circuit tubing	Disassemble and clean, then autoclave, pasteurize, or chemically disinfect. Single-patient use patient circuits: Discard.	<ul style="list-style-type: none"> ▪ If you submerge the patient circuit in liquid, use pressurized air to blow the moisture from inside the tubing before use. ▪ Inspect for nicks and cuts and replace if damaged. ▪ Run SST to check for leaks when a new patient circuit is installed.
 <p>CAUTION: Steam sterilization is a viable sterilization method for 840 ventilator patient circuits supplied by Medtronic, but it may shorten the tubing's life span. Discoloration (yellowing) and decreased tubing flexibility are expected side effects of steam sterilizing this tubing. These effects are cumulative and irreversible.</p>		
In-line water traps	Disassemble and clean, then autoclave, pasteurize, or chemically disinfect.	Inspect the water traps for cracks. Replace traps if damaged.
Couplings and connectors	Autoclave, pasteurize, or chemically disinfect.	Inspect the collector vial for cracks. Replace the collector vial if damaged.
Expiratory collector vial	Reusable expiratory filter assembly: Clean, then autoclave or chemically disinfect the collector vial. Single-patient use expiratory filter assembly: Discard.	Inspect the collector vial for cracks. Replace collector vial if damaged.
Expiratory and inspiratory bacteria filters	Reusable filters: Autoclave. Single-patient use: Discard. Before discarding, disinfect or sterilize according to your institution's protocol.	<ul style="list-style-type: none"> ▪ Effective sterilization of Medtronic inspiratory and expiratory filters occurs by steam autoclaving at 132°C (270°F) for 20 minutes for gravity displacement cycles. ▪ Do not chemically disinfect or expose to ETO gas. ▪ Check filter resistance before reuse. ▪ Follow manufacturer's recommendations for reusability.
Compressor inlet filter	Clean every 250 hours or as necessary: wash in mild soap solution, rinse, and air-dry.	Replace filter element if torn or damaged.
Drain bag, tubing, and clamp	Discard the drain bag when filled to capacity or when you change the patient circuit. Clean and autoclave the reusable tubing. Wipe the reusable clamp with alcohol or pasteurize.	<ul style="list-style-type: none"> ▪ Do not autoclave the clamp. ▪ Replace the clamp if visibly damaged.
Air inlet filter bowl	Wash the bowl exterior with mild soap solution if needed.	<ul style="list-style-type: none"> ▪ Avoid exposure of the air inlet filter bowl to aromatic solvents, especially ketones. ▪ Replace if cracks or crazing are visible.
Other accessories	Follow manufacturer's instructions.	N/A

How to Clean Components

Do not clean or reuse single-patient use or disposable components. When cleaning reusable components, do not use hard brushes or other implements that could damage surfaces.

1. Wash the parts in warm water and mild soap solution.
2. Rinse the parts thoroughly in clean, warm water (tap water is acceptable) and wipe dry.
3. After you clean the components, inspect them for damage, such as cracks and crazing. Replace any damaged components.

Whenever you replace or reinstall parts on the ventilator, always run short self test (SST) before you begin to ventilate a patient.



CAUTION: Follow the soap manufacturer’s instructions. Product exposure to soap solution more highly concentrated than necessary can shorten the useful life of the product. Soap residue can cause blemishes or fine cracks, especially on parts exposed to elevated temperatures during sterilization.

Disinfection and Sterilization

Do not disinfect, sterilize, or reuse single-patient use or disposable components. When you sterilize reusable tubing, coil the tubing in a large loop. Avoid kinks and do not cross the tubing. The tubing lumen should be free of any visible droplets before you wrap it in muslin or equivalent paper, in preparation for the autoclave. The Disinfection and Sterilization Procedures table below summarizes disinfection and sterilization procedures.



CAUTION: Formaldehyde and phenol-based disinfectants are not recommended because they can cause plastic parts to crack and craze.

Disinfection and Sterilization Procedures

Autoclave Sterilization	Pasteurization	Chemical Disinfection
<p>Effective sterilization occurs by steam autoclaving at 132°C (270°F) for 20 minutes for gravity displacement cycles. Follow the steam sterilizer manufacturer’s instructions.</p>	<p>Place the parts in a heat pasteurizer at 76°C to 79°C (169 to 174°F) for 30 minutes.</p>	<p>Immerse the parts in disinfectant and follow the manufacturer’s instructions. Acceptable disinfectants include the following or their equivalents:</p> <ul style="list-style-type: none"> ▪ Ammonia (15% solution) ▪ Amphy ™* ▪ Bleach (10% solution) ▪ Cavicide™* ▪ Cidex™* ▪ Control III™* ▪ Isopropyl alcohol (70% solution) <p>NOTE: The exposure of the parts to more concentrated disinfectant for excessive time may shorten the life of the product.</p>

Autoclave Sterilization	Pasteurization	Chemical Disinfection
<ol style="list-style-type: none"> 1. Disassemble the component. 2. Clean the component parts. (See “How to Clean Components” on page 16 for details.) 3. Wrap each component part in muslin or equivalent paper for autoclaving. 4. Place the wrapped parts in the steam autoclave and sterilize. 5. Inspect the sterilized parts for damage. Discard the component if you detect damage. 6. Reassemble the component. 7. Install the component on the ventilator. 8. Run SST. 	<ol style="list-style-type: none"> 1. Disassemble the component. 2. Clean the component parts. (See “How to Clean Components” on page 19 for details.) 3. Place parts in the heat pasteurizer and pasteurize. 4. Inspect the pasteurized parts for damage. Discard the component if you detect damage. 5. Reassemble the component. 6. Install the component on the ventilator. 7. Run SST. 	<ol style="list-style-type: none"> 1. Disassemble the component. 2. Clean the component parts. (See “How to Clean Components” on page 19 for details.) 3. Place parts in the cleaning solution to disinfect. 4. Inspect the disinfected parts for damage. Discard the component if you detect damage. 5. Reassemble the component. 6. Install the component on the ventilator. 7. Run SST.
<p>NOTE: To prevent the occurrence of spots and blemishes on parts exposed to elevated temperatures, thoroughly rinse and dry parts prior to autoclave sterilization or pasteurization.</p>		

REUSABLE VENTILATOR FILTERS

PURITAN BENNETT™ RE/X700 EXPIRATORY FILTER



Cleaning and Sterilization

If it is necessary to clean the filter housing, wipe it down with a damp cloth. Any cleaning solution used for external wipe-down must be compatible with polysulfone plastic (filter housing and end cap material). The reusable Re/X700 filter is designed for sterilization by steam autoclaving at temperatures not to exceed 135°C (275°F). Effective sterilization occurs at a minimum cycle of 132°C (270°F) for 20 minutes for gravity-displacement cycles, or 132°C (270°F) for 4 minutes for pre-vacuum cycles (requires minimum 20 minute drying cycle after sterilization). Wrap the filter in muslin or equivalent paper before autoclaving. Follow the steam sterilizer manufacturer’s instructions.



WARNINGS:

- To avoid damage to the filter, do not immerse in liquid, or attempt to scrub or touch the filter media. Soaking or rinsing of the filter may cause retention of harmful residues and/or increased air flow resistance. Damage to the filter media can reduce its filtration efficiency.
- Do not use ethylene oxide (ETO) to sterilize this filter. When handling the filter, always follow your hospital's infection control guidelines for handling infectious material.



CAUTION: If nebulized medication is used, monitor filters more frequently as nebulized medication build up can occlude filter medium.

PURITAN BENNETT™ RE/X800 EXPIRATORY BACTERIAL FILTER



Sterilization

Separate the filter from collector vial and wrap each in muslin or equivalent paper before autoclaving. Effective sterilization of the filter occurs by steam autoclaving at 132 °C (270 °F) for 20 minutes for gravity displacement cycles, or 132 °C (270 °F) for 4 minutes for prevacuum cycles (requires minimum 20 minute drying cycle after sterilization). Follow the steam sterilizer manufacturer's instructions.

RE/FLEX™ REUSABLE INSPIRATORY FILTER



Cleaning and Disinfection

If necessary, wipe filter housing clean with damp cloth. Any cleaning solution used for external wipe-down must be compatible with polysulfone plastic (filter housing and end cap material). The reusable Re/Flex filter can be steam autoclaved at temperatures not to exceed 135 °C (275 °F). Effective disinfection normally occurs at a minimum cycle of 132 °C (270 °F) for 20 minutes for gravity-displacement cycles, or 132 °C (270 °F) for 4 minutes for pre-vacuum cycles (requires minimum 20 minute drying cycle after sterilization). If filter is provided with a coupling, separate coupling from filter before autoclaving. Wrap filter in muslin or equivalent paper before autoclaving. Follow the steam autoclave manufacturer's instructions.

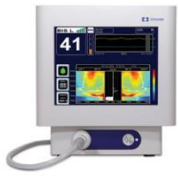


WARNINGS:

- To avoid damage to the filter, do not immerse in liquid, or attempt to scrub or touch filter media. Soaking or rinsing filter may result in retention of harmful residues and/or increased air flow resistance. Damage to the filter media can reduce filtration efficiency.
- Do not use ethylene oxide (ETO) to disinfect the filter. When handling the filter, always follow your hospital's infection control guidelines for handling infectious material.

BRAIN MONITORING

BIS™ BRAIN MONITORING SYSTEM



Care and Cleaning



WARNING: Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Contaminated materials should be disposed of in accordance with national and local waste disposal legislation and requirements.

Cleaning the Monitor and BISX™

Clean any spillage of blood or solutions on either the monitor or BISX™ as soon as possible. Dried blood is very difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the PIC connector ends with alcohol and allow to dry completely. Residual moisture inside the connector may affect BISX™ performance.

Disinfecting the Monitor and BISX™

Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant (e.g. Lysol™* Professional Disinfectant Foam Cleaner Spray or PDI Germicidal Disposable Wipes). After cleaning, dry all areas except the monitor display screen (see below) with a lint-free absorbent paper towel. Wipe the BISX™ and PIC connector ends with alcohol and allow to dry completely.



WARNINGS:

- Whenever an event such as spillage of blood or solutions occurs, re-test leakage current before further use.
- Do not mix disinfecting solutions (e.g. bleach and ammonia) as hazardous gases may result.



CAUTIONS:

- Do not autoclave the BISX™ or monitor. Autoclaving will seriously damage both components.
- Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

Cleaning the Monitor Display


Clean the monitor display screen with a mild solution of detergent and warm water or a commercial display screen cleaner, available through personal computer dealers. To avoid scratching the screen, never use abrasive cleaners.

CEREBRAL/SOMATIC OXIMETRY

INVOS™ 5100C CEREBRAL/SOMATIC OXIMETER




Cleaning the INVOS™ System

1. Disconnect the AC power from the INVOS™ monitor. Turn the system off by selecting the green ON/OFF  key.
2. Clean the outside surface of the enclosure with a cloth dampened with isopropyl alcohol–70% or a mild soap and water solution.
3. Clean the faceplate and screen with a clean, soft cloth and isopropyl alcohol or a commercial glass cleaner. Do not use acetone or abrasives.
4. If necessary, the INVOS™ system and cables can be wiped clean with commercial germicidal agents.
5. Allow the INVOS™ system monitor to completely dry before reconnecting the AC power.



WARNINGS:

- Electrical shock warning.  Disconnect the INVOS™ system from the AC power before cleaning.
- Do not immerse the INVOS™ system in any liquids as they may cause electric shock hazard or damage the device.



CAUTIONS:

- Do not autoclave the INVOS™ system.
- Do not gas sterilize the INVOS™ system.

INVOS™ 7100 SYSTEM



Cleaning the Monitoring System



WARNING: To ensure proper performance, avoid shock, and prevent device damage or failure, do not expose the monitoring system to extreme moisture, such as direct exposure to rain. Do not immerse in water, solvents, or cleaning solutions, since the monitoring system and connectors are not waterproof.



CAUTIONS:

- Do not autoclave or gas sterilize any components of the monitoring system.
- To prevent device damage or failure, do not expose the monitor to isopropyl alcohol.

Materials

- Lint-free cloths
- Water
- Sodium hypochlorite (8.25% household bleach diluted 1:500 with tap water)
- Quaternary ammonium germicidal detergent (PDI Sani-Cloth™* AF3)
- Phenolic germicidal detergent (Lysol™* concentrate diluted 1:100 with tap water)
- CaviCide™* disinfectant (Metrex CaviWipes™*)

Procedure

To clean the monitoring system:

1. Power off the monitoring system and disconnect AC power.
2. Clean the outside surface of all monitoring system components with a cloth dampened with a cleaning agent or a pre-moistened wipe.
3. Clean the faceplate and screen. Do not use acetone or abrasives.
4. Allow the monitoring system to completely dry before reconnecting the AC power or returning to use.

¹From serial number 300706 onwards.

¹Polystyca is a registered trademark of Steris Corporation.

²CIDEX OPA is a registered trademark of Johnson and Johnson Corporation.

³Chemicals states are the generic equivalent of Mr. Muscle Window & Glass.

⁴Advanced Sterilization Products.

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