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RespArray[™] patient monitor Cleaning and disinfecting guide

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This guide explains how to clean and disinfect the RespArray[™] patient monitor and accessories. The guide contents are the same as what is found in the official instruction manual, and is not meant to replace the IFU.

General points

Keep your monitor, cables, and accessories free of dust and dirt. To prevent damage to the device, please follow these procedures:

- Use only the recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime, or cause safety hazards.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every

use. The validated cleaning agent for cleaning the monitor is mild near-neutral detergent. The validated cleaning agents for cleaning the reusable accessories are:

- Mild near-neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed by using a clean cotton swab or a clean, soft, nonabrasive cloth or paper towel each time. Refer to the cleaning agent manufacturer's instructions for use for information regarding concentration, temperature, and contact time.

For devices or accessories that have been in contact with mucosal surfaces, high-level disinfection must occur. For all other accessories, low-level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected.

The validated disinfectants for disinfecting the monitor are:

- Ethanol (70%)
- Isopropanol (70%)
- Hydrogen peroxide solution 0.5-1.0% concentration wipes
- PDI^{™*} Sani-Cloth^{™*} bleach germicidal disposable wipes (orange top) (Composition: 0.63% sodium hypochlorite)
- PDI^{™*} Super Sani-Cloth^{™*} germicidal disposable wipes (purple top) (Composition: 55% isopropyl alchohol, 0.25% alkyl dimethyl benzyl ammonium chlorides, 0.25% alkyl ethylbenzyl ammonium chloride)
- Diversey Oxivir^{™*} 1 wipes (gray top) (Composition: 0.5% hydrogen peroxide)
- Diversey Oxivir^{™*} Tb wipes (white top) (Composition: 0.5% hydrogen peroxide)
- Sodium hypochlorite solution 6500 ppm (household bleach diluted ~1:10)

Final dilution shall be determined according to the chlorine concentration in the specific household bleach solution bought from market.

The validated disinfectants for disinfecting the reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)
- Cidex^{™*} OPA (high-level disinfection of intracavitary temperature probe only)

Disinfecting agents should be applied and removed by using a clean cotton swab or a clean, soft, nonabrasive cloth or paper towel each time. Refer to the disinfecting agent manufacturer's instructions for use for information regarding concentration, temperature and contact time.

Precaution: If you spill liquid on the equipment, battery, or accessories or if they are accidentally immersed in liquid, contact the service personnel or service engineer of the manufacturer.

Note: Automated cleaning/disinfection of the equipment and accessories is prohibited.

Note: To avoid blocking and affecting noninvasive blood pressure (NIBP) measurement, the user should clean the battery compartment periodically by opening the door and dusting the vent. Do not use a wet cotton swab to clean the vent. If NIBP measurement is still affected after cleaning, contact the service personnel of the manufacturer.

Precaution: Do not use any disinfectant containing additional active ingredients other than those listed, such as the disinfectant didecyl dimethyl ammonium bromide, which contains quaternary ammonium salt.

Precaution: Although the monitor is chemically resistant to most common hospital cleaners, disinfectants, and noncaustic detergents, the use of unvalidated cleaners or disinfectants (such as the disinfectant didecyl dimethyl ammonium bromide, which contains quaternary ammonium salt) is not recommended and may stain the monitor.

Precaution: Do not use phenol disinfectants, because vinyl absorbs them. Do not use strong aromatic, chlorinated, ketone, ether, or ester solvents. Do not immerse the cables for any prolonged period in alcohol, mild organic solvents, or highly alkaline solutions. Never boil or autoclave the cable. Vinyl withstands temperatures up to 100°C but begins to soften at around 90°C. Handle gently when hot, and wipe away from the tip toward the cable.

Warning: The monitor and reusable accessories should be disinfected to avoid patient cross-contamination.

Cleaning and disinfecting the monitor

To surface-clean and disinfect the monitor, follow these steps:

- 1. Switch off the monitor and disconnect it from the power line.
- 2. Remove all residual foreign material from the surface of the monitor using a sterile cloth or paper towel until the surface is visually clean.
- 3. Use a clean cotton swab dampened with cleaning solution to wipe the surface apertures of the equipment until no visible contaminants remain.
- 4. Use a soft, clean cloth dampened with cleaning solution to wipe the entire exterior surface of the equipment until no visible contaminants remain.
- 5. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
- 6. If disinfecting is required, prepare the disinfectant solution or wipes.
- 7. Use a clean cotton swab dampened with the disinfectant solution (or wrapped with wipes) to wipe the surface apertures of the equipment. Follow the disinfectant manufacturer's recommended contact time and mode.
- 8. Use a soft, clean cloth dampened with the disinfectant solution (or use wipes) to wipe the entire exterior surface of the equipment. Follow the disinfectant manufacturer's recommended contact time and mode.
- 9. After disinfection, wipe off the disinfecting agent with a new sterile cloth dampened with water.
- 10. Dry the monitor for at least 30 minutes in a cool, ventilated place.
- 11. Inspect the monitor to ensure that there is no damage.

Cleaning and disinfecting reusable accessories

Cleaning and disinfecting the electrocardiogram (ECG) cables and NIBP hose

- 1. Remove the cables and hose from the monitor.
- 2. Remove all residual foreign material from the surface of the cables and hose using a sterile cloth or paper towel until the surface is visually clean.
- 3. Wipe the cables and hose with a soft cloth dampened with cleaning solution until no visible contaminants remain.
- 4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
- 5. Wipe off residual moisture with a dry cloth.
- 6. If disinfecting is required, prepare the disinfectant solution.
- 7. Wipe the cables and hose with a soft cloth dampened with the disinfectant solution.
- 8. Wipe off the disinfectant solution with a dry cloth after disinfection.
- 9. Leave the cables and hose to air dry for at least 30 minutes.
- 10. Inspect the cables and hose to ensure that there is no damage.

Cleaning and disinfecting reusable ECG electrodes

- 1. Remove the electrode from the monitor.
- 2. Remove all residual foreign material from the surface of the electrode using a sterile cloth or paper towel until the surface is visually clean.
- 3. Wipe the electrode with a soft cloth dampened with cleaning solution until no visible contaminants remain.
- 4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

- 5. Wipe off residual moisture with a dry cloth.
- 6. If disinfecting is required, prepare the disinfectant solution.
- 7. Wipe the electrode with a soft cloth dampened with the disinfectant solution.
- 8. Wipe off the disinfectant solution with a dry cloth after disinfection.
- 9. Leave the electrode to air dry for at least 30 minutes.
- 10. Inspect the electrode to ensure that there is no damage.

Note: Single-patient use ECG electrodes should not be cleaned/disinfected and should be discarded after patient use.

Cleaning and disinfecting the blood pressure cuff

Cleaning the cuff and air bladder:

- 1. Remove the NIBP cuff from the monitor and take out the air bladder.
- 2. Remove all residual foreign material from the surface of the cuff and air bladder using a sterile cloth or paper towel until the surface is visually clean.
- 3. Handwash the cuff with cleaning solution; clean the air bladder with a soft cloth dampened with cleaning solution. Clean the surface of the cuff and the air bladder thoroughly until no visible contaminants remain.
- 4. After cleaning, rinse the cuff and wipe off the cleaning solution from the air bladder with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
- 5. Prepare the disinfectant solution.
- 6. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
- 7. Leave the cuff and air bladder to air dry for at least 30 minutes.
- 8. Inspect the cuff and the air bladder to ensure that there is no damage.

Note: Prolonged use of disinfectant may cause discoloration of the cuff.

Replacing the air bladder:

After cleaning, replace the air bladder into the cuff following the steps below:

- 1. Roll the bladder lengthwise and insert it into the cuff via the large opening at one end of the cuff.
- 2. Thread the hose from within the cuff and out through the small hole at the top of the cuff.
- 3. Adjust the bladder until it is in position.

Cleaning and disinfecting the temperature (TEMP) sensors/probes

- 1. Remove the TEMP sensors/probes from the monitor.
- 2. Remove all residual foreign material from the surface of each TEMP sensor/probe using a sterile cloth or paper towel until the surface is visually clean.
- 3. Wipe the sensor/probe with a soft cloth dampened with cleaning solution until no visible contaminants remain.
- 4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
- 5. Wipe off residual moisture with a dry cloth.
- 6. If disinfecting is required, prepare the disinfectant solution.
- 7. Wipe the sensor/probe with a soft cloth dampened with the disinfectant solution.
- 8. Wipe off the disinfectant solution with a dry cloth after disinfection.
- 9. Leave the sensors/probes to air dry.
- 10. Inspect the TEMP sensors/probes to ensure that there is no damage.

Cleaning and disinfecting other accessories

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for methods of cleaning and disinfecting.

For Nellcor[™] SpO₂ sensors

Read the instructions for use enclosed with each reusable SpO_2 sensor before attempting to clean the sensor. Follow the sensor cleaning and disinfecting procedures located in the sensor's instructions for use. SpO_2 sensors which are not reusable should not be cleaned.

For MicrostreamTM Advance CO_2 sampling lines

All Microstream^M CO₂ sampling lines are not reusable and should not be cleaned.

Patient monitoring systems should not be used as the sole basis for diagnosis or therapy and are intended only as adjuncts in patient assessment.

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