

Maternal-Infant Care (MIC) Global FAQs for COVID-19 (SARS-CoV-2)

- The FAQ is updated regularly. Please continue to check back for the latest information.
- Also be sure to check out the <u>GEHC COVID-19 Page</u> and the <u>GEHC COVID-19 Cleaning and Disinfection FAQ</u> page for responses to common questions.
- If you have a question that is not answered here, contact your GE Healthcare sales rep and we will research the answer, reply to your inquiry, and post the response as a new FAQ here.

Contents

| General | |
|---|---|
| Latest Information | 2 |
| Cleaning and Disinfection | 2 |
| Giraffe OmniBed / Incubator | 3 |
| Giraffe OmniBed / Giraffe Incubator for Isolation | 3 |
| Using Giraffe OmniBed / Giraffe Incubator Without Power | 3 |
| Giraffe OmniBed / Giraffe Incubator Air Filter | |
| Giraffe OmniBed / Giraffe Incubator Humidifier | |
| UV Cleaning of Giraffe OmniBed / Giraffe Incubator | 4 |
| Air Handling in Giraffe OmniBed / Giraffe Incubator | 5 |
| O2 Sensor Access Panel | 6 |
| Panda / Giraffe Warmers | |
| Plastic Cover for Warmers | |
| Corometrics and Novii | |
| Mini-Tele | |
| Other MIC Products | 8 |
| MIC Products to Support Home Use | 9 |
| Respiratory Support | 9 |

General

Latest Information

Question: What is the link for GE Healthcare's latest COVID-19 information?

Answer: Visit the COVID-19 portal for the latest updates and guidelines

www.gehealthcare.com/covid19

Cleaning and Disinfection

Question: What products can be used on MIC products?

Answer: Refer to the cleaning website: https://cleaning.gehealthcare.com/ which allows healthcare providers to find compatible cleaning products for medical devices. There is a cross reference to the EPA's (Environmental Protection Agency) list of cleaners for the coronavirus.

Question: The cleaning website lists approved products for the Giraffe OmniBed or Incubator. Super SaniCloth is listed, but is yellow- what does this mean?

Answer: Refer to the cleaning website: https://cleaning.gehealthcare.com/ which allows customers to find compatible cleaning products for medical devices. The orange caution highlights two areas of concern for the Super Sani cloth cleaner which is on the EPA list. These two areas are

- 1- humidifier- alternative is to steam sterilize which is approved
- 2- walls- at this time, the Super SaniCloth is known to cause crazing or haziness overtime; these effects may not be seen immediately however inspection of the device should be done to determine any product impact

Question: Can terminal cleaning on the Giraffe devices be completed with ultraviolet (UV) or possibly roll into a UV tent?

Answer: Patient safety is our first priority and until further testing is done, we cannot confirm the effects of UV on the performance of our device(s). Please refer to the cleaning website for further information: https://cleaning.gehealthcare.com/ which allows customers to find compatible cleaning products for medical devices from GE Healthcare.

Giraffe OmniBed / Incubator

Giraffe OmniBed / Giraffe Incubator for Isolation

Question: Can the Giraffe OmniBed or Incubator be used for isolation of the baby?

Answer: No, Giraffe OmniBed and Giraffe Incubator do not have the same properties as an isolation room however the Giraffe OmniBed and Incubator can be used as a physical barrier /contact barrier. Closed bed incubators cannot provide isolation room properties of negative pressure or reverse air flow.

Using Giraffe OmniBed / Giraffe Incubator Without Power

Question: Do you have anything written in the specifications or recommendations about using Giraffe OmniBed / Incubator with the power off?

Answer: Giraffe OmniBeds / Incubators are intended to be used with the power <u>on</u> for all patients. Patient temperature monitoring should be continued when using the bed. A range of AIR temperatures can be set to ensure patient thermal needs are maintained. A range of set points can also be set when operating in "BABY mode" and skin temperature can be monitored with a skin temperature probe. Refer to the http://micvideos.com/perinatal/micVideo.php for quick references to ensure proper bed use.

Giraffe OmniBed / Giraffe Incubator Air Filter

Question: Can the Giraffe Air Filters filter out COVID-19?

Is the Giraffe Air Filters filter the same filter as a N-95 filter on mask?

What micro-organisms do they if any filter?

Answer: The air filter does not serve as a filter for bacteria or microorganisms.

Question: When should the Air Filter be changed?

Answer: The air filter should be inspected each time the bed is cleaned. It should be changed:

- 1. every 3 months, at a minimum;
- 2. when it is visibly dirty; or
- 3. following bed use with an infectious patient

Giraffe OmniBed / Giraffe Incubator Humidifier

Question: Does using the humidity system in Giraffe OmniBed / Incubator increase the risk of infection?

Answer: All distilled water is boiled (sterilized) inside the heater assembly before it enters the compartment as steam. The water inside the humidifier reservoir is held at an elevated temperature of approximately 50°C to prevent bacterial contamination.

Refer to the Guidelines for Use of Humidity found at https://landing1.gehealthcare.com/USC-WB-19-08-LCS-MIC-Giraffe_Central_Guidelines.html

Refer to the paper titled "Testing for bacterial colonization in a Giraffe humidification system," reprinted with permission from Neonatal Intensive Care. Neonatal Intensive Care, Vol. 15 No. 2, March, April 2002 located at https://www.gehealthcare.com/-/media/Files/US/Non-Gated/Testing_for_bacterial_MIC-PDF-0004_v12.pdf

UV Cleaning of Giraffe OmniBed / Giraffe Incubator

Question: Can terminal cleaning on the Giraffe devices be completed with UV or possibly roll into a UV tent?

Answer: Patient safety is our first priority and until further testing is done, we cannot confirm the effects of UV on the performance of our device(s). Please refer to the cleaning website for further information: https://cleaning.gehealthcare.com/ which allows customers to find compatible cleaning products for medical devices from GE Healthcare.

Air Handling in Giraffe OmniBed / Giraffe Incubator

Question: When treating a potential or confirmed COVID-19 infant in a Giraffe Incubator or Giraffe OmniBed on a Aerosolized Generating Medical Procedure (AGMP) like nCPAP, will using Air Boost option divert or have the potential to divert the aerosolized droplets?

Answer: We have not conducted tests with respect to droplet diversion.

Question: Could using Air Boost decrease or even increase the expulsion of aerosolized droplets through the portholes of the incubator into the surrounding environment?

Answer: We have not conducted tests with respect to expulsion of aerosolized droplets through portholes to the surrounding environment, with or without Air Boost.

Question: Is there potential for viral particles to be dispersed into the room where the incubator is sitting?

Answer: We have not tested any of the bed models for this effect. We recommend following your local guidelines for proper handwashing and PPE use.

Question: Should a clinician or parent entering the portholes or lowering the side walls of the incubator of an intubated neonate (considered an Aerosolized Generating Medical Procedure (AGMP) as the Endotracheal Tube (ETT) is uncuffed) wear a surgical mask vs. N95?

Answer: We recommend following your local guidelines for proper handwashing and PPE use.

Question: How does air flow through the infant compartment?

Answer: Giraffe OmniBed Carestation, Giraffe OmniBed, Giraffe Incubator Carestation, and Giraffe Incubator all share the same design with respect to air flow. There is a fresh air inlet behind the water reservoir tank. That inlet should have an air filter installed. The air filter does not serve as a filter for bacteria or microorganisms. The air goes directly into the fan/heater area below the mattress to be warmed as needed before being sent into the incubator.

Inside the incubator, there are two air flow returns in the north and south end where air from inside the bed goes down into the fan/heater area below the mattress to be warmed as needed before being sent back into the incubator. The air returns to the incubator by being blown by the fan up through the east and west bed side panels (walls). The panels use a double-wall design that is open at the top to release the air back into the incubator.

Question: Is there any kind of filter on the exhaust from the incubator?

Answer: None of our bed models have a designed exhaust mechanism or port beyond the natural leakage of air that occurs via seams, porthole doors, side panel joints, grommets, and other unsealed cracks and crevices.

O2 Sensor Access Panel

Question: "What kind of precaution should we use for the 'hole under the bed when you pull the drawer out'."

Answer: The panel on the underside of a Giraffe OmniBed or Incubator that is accessible after the drawer is removed is an access panel for replacing the O2 sensors (if the servo option was selected). The access panel itself has small air circulation vents to prevent overheating of the O2 sensors if installed. GE Healthcare has not tested any of the bed models for presence of pathogens in these areas before or after cleaning and disinfection. Follow existing recommendations for cleaning and disinfection, including any accessible surfaces.

Panda / Giraffe Warmers

Plastic Cover for Warmers

Question: Is a plastic cover available for the Panda iRes Bedded warmer in Labor and Delivery?

Answer: No. We do not provide a plastic cover for the warmer.

Corometrics and Novii

Mini-Tele

Question: Can Mini-Telemetry with Corometrics 259cx be used for antenatal monitoring in an ICU setting?

Answer: Yes, Mini Telemetry can be used for both antepartum and intrapartum monitoring as needed in the hospital by an authorized user.

Question: Can a mom stay in the room on Mini-Telemetry with the Corometrics monitor outside of the room?

Answer: Yes, Mini-Telemetry can transmit fetal heart rate and uterine activity signals from the mother (without a wired transducer connection to Corometrics) with a line-of-sight antenna range of 500 meters/1540 feet. The battery-operated transmitter provides up to 12 hours of continuous transmission when charged for a period of 4 hours.

Question: Can we leave Mini-Telemetry plugged-in while monitoring mom?

Answer: We do not recommend connecting the transducer to the mother while the transmitter is placed on the receiver and charging, as it may result in accidental drop of the transmitter from the receivers' location. Extended charging presents the risk off overcharging the battery and may cause a battery capacity reduction. Never charge the transmitter during a shower/laboring in water. With the battery capacity of approximately 12 hours, we would recommend recharging the battery once the check battery low audio alarm sounds or battery charge level status indicator is low.

Other MIC Products

MIC Products to Support Home Use

Question: What products can be used in the home to avoid hospitalization or support early discharge?

Answer: The BiliSoft can be used in the home setting per clinical/medical order.

Respiratory Support

Question: Does GE Healthcare have equipment to support the respiratory needs if a newborn is infected?

Answer: Respiratory distress or pneumonia treatment recommendations for newborns have not been changed as there are no newborns reported to have COVID-19 at birth. Panda iRes Warmer, Giraffe Warmer, Giraffe Stand-a-lone Infant Resuscitator (StAR), Lullaby Resus Prime, or Lullaby Resus Plus can continue to be used per the intended use during resuscitation to support respiratory efforts.

Question: Can a filter be used on the t-piece?

Answer: GE Healthcare does not provide filters for use on manual resuscitators or on T-piece circuits for use with our neonatal integrated or stand-alone resuscitation systems (Panda iRes warmer, Giraffe w/integrated resuscitation, Giraffe StAR, Lullaby Prime or Lullaby Plus). We also do not recommend the use of unverified accessories with our devices. Patient safety is our first priority and until further testing is done, we cannot confirm the effects this filter may/may not have on the performance of our device(s) or the manual resuscitator (which GE Healthcare does not provide). GE Healthcare does provide T-piece circuits that are single-use disposable devices ideal for helping to reduce the risk of cross contamination.

Question: Is there a filter to protect the Panda iRes Warmer from infants who are PUI (Person Under Investigation) for COVID-19?

Answer: GE Healthcare does not provide filters for use on manual resuscitators or on T-piece circuits for use with our neonatal integrated or stand-alone resuscitation systems (Panda iRes warmer, Giraffe w/integrated resuscitation, Giraffe StAR, Lullaby Prime or Lullaby Plus). We also do not recommend the use of unverified accessories with our devices. Patient safety is our first priority and until further testing is done, we cannot confirm the effects this filter may/may not have on the performance of our device(s) or the manual resuscitator (which GE Healthcare does not provide). GE Healthcare does provide T-piece circuits that are single-use disposable devices ideal for helping to reduce the risk of cross contamination.

Question: "Does the GE Healthcare T-piece on the Panda iRes Warmer have some sort of valve to prevent the backflow of patient's respiratory secretions into the device, in an attempt to prevent cross-contamination?"

Answer: No. GE Healthcare does provide T-piece circuits that are single-use disposable devices ideal for helping to reduce the risk of cross contamination.