Evaluation of Airborne Chemicals from Neonatal Incubators – Letter to Health Care Providers

UPDATE: June 13, 2023

The FDA is providing an update about our ongoing evaluation and work with manufacturers on the potential for exposure to airborne chemicals that may be released from neonatal incubators. Specifically, GE HealthCare has conducted preliminary testing on their newly manufactured neonatal incubators that suggests the potential for higher levels of formaldehyde that rapidly decrease over one week. Based on this information, GE HealthCare has the following recommendations for their customers:

- If you have received a new GE HealthCare Giraffe OmniBed Carestation or Giraffe Incubator Carestation that has not been put into clinical use, please assemble the new incubator with all components and run it for a week in a well-ventilated space with maximum heat and humidity, and portholes and bedside panels closed, prior to clinical use.
- **If your incubator is in clinical use, continue to use it.** Incubators are critical for neonates (infants less than four weeks old) that cannot maintain their body temperature.

Unique Device Identifier (UDI (/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system)) information provided by GE HealthCare:

- Giraffe OmniBed Carestation: 00840682116862
- Giraffe Incubator Carestation: 00840682116855

GE HealthCare has not received any reports of patient injury or adverse effects related to potential exposure to formaldehyde in incubators. At the present time there is not evidence that the levels of formaldehyde observed in GE HealthCare incubators have led to adverse health effects.

The recommendations provided below have not changed for neonatal incubators by other manufacturers. The FDA continues to collect and analyze data to evaluate this issue and will continue to keep health care providers informed as additional information becomes available.

February 23, 2023

The U.S. Food and Drug Administration (FDA) is informing health care providers and facilities about the potential for exposure to airborne chemicals (https://www3.epa.gov/airtoxics/3_90_024.html) that may be released from neonatal incubators. The FDA is evaluating published literature that reports elevated levels of formaldehyde, cyclohexanone, and other volatile chemicals (such as human-made chemicals used and produced in manufacturing) from neonatal incubators. Potential sources of these airborne chemicals include materials used to make neonatal incubators as well as natural and human-made sources external to the incubator.

The FDA is working with manufacturers of neonatal incubators to collect and evaluate data from their products to determine whether these airborne chemicals are released, and if so, the amount of exposure and the potential risks to health from such exposure, if any, for newborns and others (such as health care providers). Currently, the FDA is not aware of any reported adverse events related to the use of neonatal incubators and exposure to these airborne chemicals.

Recommendations

At this time, the FDA has the following recommendations for health care providers and facilities:

- **Continue to use neonatal incubators.** The FDA recognizes that incubators are critical for neonates (infants less than four weeks old) that cannot maintain their body temperature.
- Be aware that the FDA is working with manufacturers to understand the potential for exposure to airborne chemicals (formaldehyde, cyclohexanone, and other volatile chemicals) that may be released from neonatal incubators, potential health risks, and mitigation strategies, if needed. Remain alert for further updates and recommendations from the FDA and neonatal incubator manufacturers.
- Review your current plan for proper air ventilation in neonatal settings.
- While the FDA further evaluates this issue, as an interim precautionary measure, consider running new neonatal incubators prior to use with patients for a week in a well-ventilated space using clinically relevant conditions for temperature and humidity, as the release of these airborne chemicals may decline over time.
- Follow the neonatal incubator manufacturer's instructions for use, including disinfection and cleaning, prior to first use with patients.
- Report any issues with neonatal incubators to the FDA.

Background

Neonatal incubators are critical to care for newborns in hospital settings such as neonatal intensive care units (NICU). The incubators help create an optimal environment for newborns that need support in regulating their body temperature, by providing heated and

humidified air within an enclosed bed compartment.

After initial review of the current literature evidence, the FDA has concluded that the information reported is inadequate to assess the potential exposure and risk to newborns and others (such as health care providers) of airborne chemicals (formaldehyde, cyclohexanone, and other volatile chemicals) that may be released from neonatal incubators. Factors that may contribute to the release of these chemicals into the air from neonatal incubators include increased temperature and humidity. In addition, the concentration of these airborne chemicals may decrease over time. However, further testing and analysis is needed to determine whether these airborne chemicals are released from certain neonatal incubators, the types of chemicals being released, contributing factors to the release of chemicals, the amount and length of time of exposure, and the potential risk of exposure to health.

Exposure to airborne chemicals (https://www3.epa.gov/airtoxics/3_90_024.html) can result from natural (such as radon gas in the ground) and human-made sources (such as a byproduct of some manufacturing processes, cleaning products, cigarette smoke, and different types of plastics). However, the health effects of different airborne chemicals depend on several factors including the chemical itself, the amount of the chemical to which a person is exposed, the frequency of exposure, the length of time exposed, and the individual susceptibility of the person exposed.

Exposure to elevated levels of formaldehyde or cyclohexanone may lead to problems such as neurological impairment or respiratory problems (such as asthma, decreased lung function, inflammation, or irritation), which is concerning for neonates who may have immature pulmonary functions, and other co-morbidities. Currently, the FDA is not aware of adverse events related to the use of neonatal incubators and exposure to airborne chemicals.

FDA Actions

The FDA is working with neonatal incubator manufacturers and external stakeholders to conduct additional testing for these airborne chemicals to further evaluate this issue. As additional data and analysis are completed, the FDA will work with manufacturers to determine if mitigation strategies are needed. The FDA will inform the public when significant new information or recommendations become available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with any medical device. Prompt reporting can help the FDA identify and better understand the risks associated with medical devices and improve patient safety.

- Health care personnel employed by facilities that are subject to the FDA's User Facility Reporting Requirements (https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-

and-device-user-facilities#3) should follow the reporting procedures established by their facilities.

- Voluntary reports can be sumbitted through MedWatch: The FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (DICE) (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice).