

URGENT MEDICAL DEVICE CORRECTION



Date of Letter Deployment

GE HealthCare Ref. # 34134

To: Director of Respiratory
Health Care Administrator / Risk Manager
Director of Biomedical / Clinical Engineering

RE: **Potential for elevated levels of Formaldehyde from EVair and EVair 03 (Jun-Air) Compressors when used with the CARESCAPE R860 or Engström Carestation/Pro ventilators**

Safety Issue

GE HealthCare has become aware of elevated levels of formaldehyde when the EVair or EVair 03 (Jun-Air) optional compressors are used with the CARESCAPE R860 or Engström Carestation/Pro ventilators, respectively. These elevated results were observed in preliminary testing that was conducted at an elevated room temperature of 40°C (104°F), at the lowest possible flow condition of 2 L/min (worst-case, minimum bias flow with no additional ventilation), and all of the gas being supplied from the compressor (i.e., FiO₂ of 21% / no supplemental oxygen). GE HealthCare is continuing to evaluate the root cause for these elevated levels of formaldehyde.

While these test conditions are not representative of typical clinical use conditions, GE HealthCare is taking this action to further reduce the potential for patient exposure. The amount of exposure to formaldehyde during typical clinical use and the potential risks to health from such exposure, if any, are currently unknown. However, in an unlikely scenario in which the compressors are used at the conditions described above, the formaldehyde levels may lead to adverse pulmonary affects such as the potential for transient, reversible airway irritation or inflammation that could lead to airway hyperresponsiveness (e.g. asthma) in neonates or infants, resulting in additional medical intervention (e.g., bronchodilator administration, adjustment of ventilator settings, increased duration or degree of ventilatory support and/or oxygen support).

Compressors are optional accessories for ventilators and are only used when wall air is not available, which is not typical in most hospital settings.

GE HealthCare has not received any reports of patient injury or adverse effects related to potential exposure to formaldehyde from the use of the compressors with ventilators.

Actions to be taken by Customer/User

1. GE HealthCare recommends that the EVair and EVair 03 (Jun-Air) compressors are not used to supply air to ventilators for neonatal and infant patients (0-2 years of age).
2. Since the elevated levels of formaldehyde are observed when the compressors are used at higher room temperatures, GE HealthCare is also lowering the maximum room air temperature for operation of the compressors from 40°C (104°F) to 30°C (86°F).
3. Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.
4. Retain this document and the Addendum to the user instructions for your records. Please keep a copy of the Addendum available near the areas where the compressors are used.
5. Complete and return the attached acknowledgement form to Recall_FMI_34134@ge.com.

Affected Product Details

EVair Compressor (M1230849; M1230847; GTIN: 76402146418924, 00195278366078, 07640214641892, 07640149381030, 00195278366061, 07640214641854, 07640149381023, 76402146418542) used with CARESCAPE R860 ventilator

EVair 03 (Jun-Air) Compressor (1609000; 1609002; GTIN: Not Applicable) used with Engstrom Carestation/Pro ventilators

Intended Use for EVair:

The EVair medical air compressor (EVair) is intended to be connected to a Datex-Ohmeda Inc. critical care ventilator [CARESCAPE R860] as a supply of compressed medical breathing air (compressed air). The ventilator must be operated with at least one additional supply of compressed medical breathing air or oxygen besides the EVair.

Intended Use for EVair 03 (Jun-Air):

The EVair 03 compressor is intended for use as an optional accessory to Datex-Ohmeda critical care ventilators [Engstrom Carestation/Pro] as a breathable compressed air supply. If the compressor is the primary air supply to the system, ensure that a compressed oxygen supply is also connected.

Product Correction

GE HealthCare has provided the attached Addendum with the updated operating conditions (30°C (86°F) maximum room air temperature) and indications for use specifying that the compressors are not recommended for use with neonates and infants (0-2 years of age).

Contact Information

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with any medical device. Health care personnel employed by facilities that are subject to the [FDA's User Facility Reporting Requirements](#) should follow the reporting procedures established by their facilities. Voluntary reports can be submitted through MedWatch: [The FDA Safety Information and Adverse Event Reporting program](#) online at www.fda.gov/medwatch/report.htm.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us per the contact information above.

Sincerely,

Handwritten signature of Laila Gurney in blue ink, featuring a stylized 'L' and 'G' followed by a long horizontal flourish.

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Handwritten signature of Scott Kelley in blue ink, consisting of the letters 'SK' followed by a loop and a tail.

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: Recall_FMI_34134@ge.com.



Addendum

This addendum is a replacement of information in the User's Reference Manual (URM), the updated information for this version is identified in **Bold** text. Keep this addendum with the product User's Reference Manual. To obtain the latest version of an Instruction for Use, go to: "<https://customer-doc.cloud.gehealthcare.com>". Enter the document number in the search field. Launch the Search or use the Search By dropdown fields if the document number is not known.

EVair User's Reference Manual, 2066030-001

Indications for use

The EVair medical air compressor (Evair) is intended to be connected to a Datex-Ohmeda Inc. critical care ventilator (ventilator) as a supply of compressed medical breathing air (compressed air). The Evair is installed in the ventilator cart, delivers filtered, oil-free, odorless and dehumidified compressed air and is intended to be operated by trained medical personnel.

The EVair compressor is not intended for use with neonatal or infant patients, age 0 to 2 years.

Using the integrated backup function, the Evair can be connected inline with an existing compressed air supply network and the ventilator. If the air supply network fails, the Evair automatically cuts in and supplies compressed air to the ventilator.

The ventilator must be operated with at least one additional supply of compressed medical breathing air or oxygen besides the Evair.

Note Although this device features a high standard of quality and safety and is built and tested according to the current standards, improper usage or misuse can result in injuries with serious consequences.

Therefore please read this user's reference manual carefully and keep this documentation within reach of the device.

Environmental specifications

	Temperature	Humidity	Ambient Pressure
Operating	10-30°C (50-86°F)	15-95% RH, non condensing	67-107 kPa (500-800 mmHg, 667-1067 mbar)
Storage	-20-65°C (-4-149°F)	15-95% RH, non condensing	50-107 kPa (375-800 mmHg, 500-1067 mbar)

Engström Carestation URM (Software 5.X M1087105, Software 6.X M1175267, Software 7.X M1205553) and Engström Pro URM

(Software 4.X M1142527, Software 5.X M1149390, Software 6.X M1175295, Software 7.X M1205978)

EVair 03 compressor (optional)

The EVair 03 compressor is intended for use as an optional accessory to Datex-Ohmeda critical care ventilators as a breathable compressed air supply. The EVair compressor can act as the primary air supply or as the backup air supply if pipeline air is connected to the compressor. If the pipeline air pressure drops below 250 kPa (36 psi), the EVair automatically turns on to provide an air supply to the ventilator.

The EVair 03 compressor is not intended for use with neonatal or infant patients, age 0 to 2 years.

The compressor has no alarm functions. All alarm functions and reactions to failure of the compressed gas supply are provided by the ventilator.

The compressor should be installed in the base of the ventilator cart. The compressor is powered from AC mains.

If the compressor is the primary air supply to the system, ensure that a compressed oxygen supply is also connected.

WARNING A compressor should be used if a reliable air pipeline source is not available.

⚠ Do not block air inlet or exhaust vents. Do not place near a radiator or heating unit. Compressor may overheat and shut down.

⚠ The cooling air exhaust grill may become hot to the touch during use.

⚠ Do not use compressor in poorly ventilated area. Compressor will produce heat when in use.

⚠ Do not place the compressor near a source of airborne contamination such as cleaning products or other chemicals, vapors, odors, or exhaust gases. The compressor uses air from its surroundings for delivery to the ventilator and patient.

⚠ If the compressor is the primary air supply to this system, ensure that a compressed oxygen supply is also connected.

Environmental specifications

	Thermal	Humidity	Altitude
Operating range	10 to 30°C (50 to 86°F)	15 to 95% RH, non-condensing	-440 to 3565 m (800 to 500 mmHg)
Storage range	-20 to 65°C	15 to 95% RH, non-condensing	-440 to 5860 m (800 to 375 mmHg)