URGENT MEDICAL DEVICE CORRECTION UPDATE

Date of Letter Deployment

GE HealthCare Ref. # 34134-US-3

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

RE: **Update to GE HealthCare's communication of potential 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

Based on preliminary testing, GE HealthCare previously distributed an Urgent Medical Device Correction letter to inform you of the potential for the presence 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. A copy of the previous letter (Ref. # 34134) is attached for your reference (Attachment 1). As communicated in the previous letter, the test conditions were not representative of typical use conditions.

We have now completed comprehensive testing for the EVair Compressor and are providing an update to the previous letter in this communication.

UPDATE: Final testing has demonstrated that formaldehyde emissions are below the safety threshold set for the intended patient population **when using the EVair Compressor, even at worst-case conditions of**

- 40°C (104°F),
- the lowest flow condition of 2 L/min, and
- minimum bias flow.

Our comprehensive investigation of the preliminary test conditions that resulted in the issuance of the previous letter concluded that those preliminary tests were conducted in incorrect test conditions, which led to inaccurate formaldehyde results.

While the same incorrect test conditions were used for the preliminary testing of the EVair 03 (Jun-Air) Compressors, they have not been manufactured for more than seven years and there are no new/unused devices available for final testing.

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

EVair Compressors:
The recommended actions indicated in the previous letter for EVair Compressors no longer apply. As such:

1. The EVair Compressors can be used to supply air to CARESCAPE R860 ventilators **for all patient populations**, **including neonatal and infant patients (0-2 years of age).**
2. The EVair Compressor can be used in a room with maximum air temperature of 40ºC (104°F).

EVair 03 (Jun-Air) Compressors:
GE HealthCare has previously communicated End of Service Support for the EVair 03 (Jun-Air) compressors. If you choose to continue to use these, the instructions provided in the previous letter continue to apply. As stated above, while incorrect test conditions were also used for the testing that led to the issuance of the previous letter for use of these Compressors, GE HealthCare is unable to conduct testing at appropriate conditions because these compressors have not been manufactured for more than seven years. As such, the recommended actions previously communicated

in the attached letter (also provided below) still apply to EVair 03 (Jun-Air) compressors:

1. GE HealthCare recommends that the EVair 03 (Jun-Air) compressors are not used to supply air to ventilators for neonatal and infant patients (0-2 years of age).
2. GE HealthCare recommends that these compressors are used at a maximum room air temperature of 30°C (86°F).

Please ensure all potential users in your facility are made aware of this updated safety notification and the recommended actions.

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

Please replace the previously provided addendum with the new attached addendum for the EVair 03 (JunAir) Compressor (Attachment 2).

To access the EVair Compressor User Manual please go to https://www.gehealthcare.com/documentationlibrary. If you would like a hard copy, please contact GE HealthCare Service at the number provided below.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative at 1-800-437-1171.

Reporting to the FDA MedWatch Serious Injury Reporting Program:

- Online: By completing and submitting the report online at: www.fda.gov/medwatch/report
- Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

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,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Scott Kelley
Chief Medical Officer
GE Healthcare