URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Depolyment>

GEHC Ref #34066

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

Affected product: **imtmedical AG, EVair Compressor** (an optional accessory to GE Healthcare Engstrom Carestation, Engstrom Pro, and CARESCAPE R860 ventilators)

Dear Customer,

This letter is to notify you that the manufacturer of the EVair Compressor, imtmedical AG, is conducting a field corrective action involving the imtmedical AG, EVair Compressor, which is an optional accessory to GE Healthcare Engstrom Carestation, Engstrom Pro, and CARESCAPE R860 ventilators. GE Healthcare is implementing the field corrective action as to these affected GE Healthcare ventilators.

A copy of the imtmedical AG notice is included in this mailing. Please review the imtmedical AG notice carefully as it provides greater detail of the issue, including information on how to identify whether your device is affected. If you have any questions regarding this field correction or the identification of an affected EVair Compressor, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

Please ensure that all potential users and supervisors at your facility are made aware of this correction notice immediately. If you have transferred this device to another location, please forward a copy of this notice to them and notify GE Healthcare of the device's new location as soon as possible.

nience this action may have caused and thank you for your continued cooperation and

[redacted]

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Date of Letter Deployment: June 25, 2015 imtmedical Reference no. 2015_1

imtmedical AG
Regulatory Affairs Department
Gewerbestrasse 8
9470 Buchs
Switzerland

To: GE Healthcare
Attn: Chad Melotte, Supplier Quality Lead Engineer

RE: Important **customer safety notice** regarding the field corrective action of EVair compressors used as optional accessory to GE Healthcare ventilators

imtmedical has recently become aware of a potential safety issue due to potential hardware failures associated with the EVair accessory compressors for the Engström Carestation, Engström Pro, and CARESCAPE R860 ventilators. **Please ensure that all potential users are made aware of this safety notification and the recommended actions.**

Safety Issue imtmedical has identified that potential friction of cables and tubing internal to the EVair compressor may result in an inability for the compressor to output compressed air. There is a potential for temporary oversupply of oxygen to the patient as a result of this failure because the GE Healthcare ventilators are designed ventilate with 100% oxygen in the case of loss of input air supply pressure. **There are no reports of patient or user injury related to this issue.**

Safety Instructions You can continue to use EVair compressors with GE Healthcare ventilators. If a compressor exhibits a failure resulting in a low air supply pressure alarm on the ventilator, use of the compressor should be discontinued. Repair will be required.

Affected Product Details EVair compressors (M1230847, M1230849) that were provided to GE Healthcare by imtmedical prior to May 30, 2015 may be affected by this issue. See the serial number list provided in the appendix for a full list of affected devices.

Product Correction imtmedical will provide GE Healthcare with field correction kits (REF 302.810.000) to GE Healthcare. GE Healthcare will contact all affected customers, and correct all affected systems.

Contact Information For questions or concerns regarding this notification, please contact imtmedical at sales@imtmedical.com.

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

Sincerely,

Hans-Jörg Reinhold
Regulatory Affairs Manager
imtmedical AG

imtmedical
imtmedical ag
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