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URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 34064

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

RE: **Aespire 7900 Central Processing Unit (CPU) Circuit Board**

GE Healthcare has recently become aware of a potential safety issue due to potential hardware failures associated with the CPU circuit board in the Aespire 7900 Anesthesia Machine. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue Due to an issue with certain circuit boards, specific Aespire 7900 Anesthesia Machines have an increased likelihood of failure of the CPU circuit board. This could result in a blank display or loss of mechanical ventilation. To mitigate the risk of Hypoxia, immediately switch to manual ventilation if loss of mechanical ventilation occurs.

Safety Instructions In the event the issues described above do occur the "Minimum Shutdown" audible alarm would trigger which would indicate to the user that the machine is experiencing unexpected system performance.

You can continue to use your Aespire 7900 in Manual Ventilation mode. In addition, contact your local GE Healthcare Service Representative.

Affected Product Details Specific Aespire 7900 Anesthesia Machines with serial numbers as identified in the appendix and Field Replaceable Units (part # M1084610) shipped between January 9, 2015 and January 26, 2015.

Product Correction GE Healthcare will correct all affected systems at no cost to you. A GE Healthcare Service Representative will contact you to arrange for this correction.

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

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,

James W. Dennison
Vice President Devices
GE Healthcare

Werner Van den Eynde, M.D.
Acting Chief Medical Officer
GE Healthcare

Appendix

Serial Number List of affected Aespire 7900 Anesthesia Machines:

ANCU00101	ANCU00118	ANCU00136	ANCU00149
ANCU00102	ANCU00119	ANCU00138	ANCU00150
ANCU00103	ANCU00120	ANCU00139	ANCU00151
ANCU00105	ANCU00121	ANCU00140	ANCU00152
ANCU00108	ANCU00124	ANCU00141	ANCU00153
ANCU00112	ANCU00125	ANCU00142	ANCU00172
ANCU00113	ANCU00126	ANCU00143	ANCU00175
ANCU00114	ANCU00129	ANCU00145	ANCU00178
ANCU00115	ANCU00130	ANCU00146	ANCU00179
ANCU00116	ANCU00134	ANCU00147	ANCU00193
ANCU00117	ANCU00135	ANCU00148	