



URGENT Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

October 2012

GEHC Ref#37121

To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **Monitors B20 or B40 Software Version VSP-A_1.10 (or earlier) miss lethal arrhythmia alarm in NEONATAL mode**

GE Healthcare has recently become aware of a potential safety issue due to disabling of 'V Tachy' and 'V Fib' alarms in NEONATAL mode of your Monitor B20 or B40. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue The 'V Tachy' and 'V Fib' alarms of Monitor B20 or B40 are disabled in NEONATAL mode which could result in a missed lethal arrhythmia alarm and a potentially critical event. Other modes and parameters are not affected.

Safety Instructions The clinician should stop using monitor in NEONATAL mode.

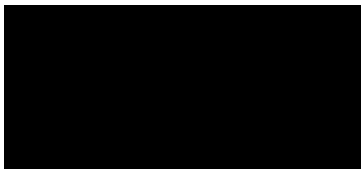
Affected Product Details The issue affects Monitor B20 or B40 devices with the software version VSP-A_1.10 (or earlier).

Product Correction GE Healthcare will provide a software solution at no charge to correct this issue.

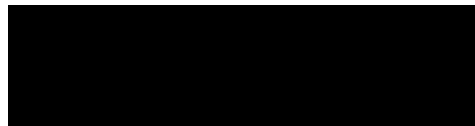
Contact Information If you have any questions regarding this medical device correction or the identification of affected items please contact Technical or your local Service Representative.

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,



Vice President QARA
GE Healthcare Systems



Chief Medical Officer
GE Healthcare