



Urgent Field Safety Notice

April 2009

Attention: Director of Clinical Engineering
Healthcare Administrator / Risk Manager
Nurse Manager, Labor and Delivery

Address

Address

Address

Subject: GE Corometrics 250 Series Maternal/Fetal Monitors
Affected Products: COROMETRICS® Model 250 Maternal/Fetal Monitors

Serial Numbers of affected product are prior to SN: SBE 07 32 XXXX XX

↓ ↓

Year Week

<Salutation>.

GE Healthcare would like to inform you that we have identified an issue associated with the Corometrics® Model 250 Series Maternal/ Fetal monitors with the Ultrasound channel(s) not functioning properly. The root cause of this issue was determined to be dislodging/disconnecting of a copper-beryllium ground clip that connects the front bezel to the chassis resulting in loss of ground connection for the ultrasound bezel connector.

Testing has shown that this clip may become dislodged upon opening the front panel (bezel) of the monitor for servicing. The loosening or absence of the clip results in three (3) dashes (---) being displayed on the screen where the ultrasound fetal heart rate would be displayed, and **INOP** (transducer not connected) message on the strip chart for the ultrasound parameter, even if the transducer is connected properly. Please note that other parameters on the monitor will not be affected and function as normal.

Short Term Recommendation:

If you do not experience this problem, you may continue to use your Corometrics® Model 250 Series Maternal/ Fetal monitor(s) until you receive your upgrade kit. However, if you are experiencing this problem, please contact your local GE Healthcare Service Representative.

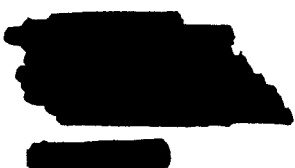
Long Term Recommendation:

A technical solution has been developed to alleviate this ground disconnection issue. In the near future, a GE Healthcare Service representative will contact you regarding the execution of the upgrade.

If you have any question or request for assistance regarding this notice, please contact your local GE Healthcare Service Representative.

We apologize for any inconvenience caused by this action and thank you for your continued cooperation and support.

Sincerely,

A large black rectangular redaction box covering the signature and name of the sender.

Executive, Regulatory Affairs, Clinical Systems - QARA
9900 Innovation Drive
Mail Stop: RP2138
Wauwatosa, WI 53226
US