URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment> GEHC Ref# 32040

To: Labor and Delivery Managers
Bio-Medical Engineering Department Managers
Risk Management Directors

RE: Fetal Heart Rate (FHR) lower alarm limit configured incorrectly

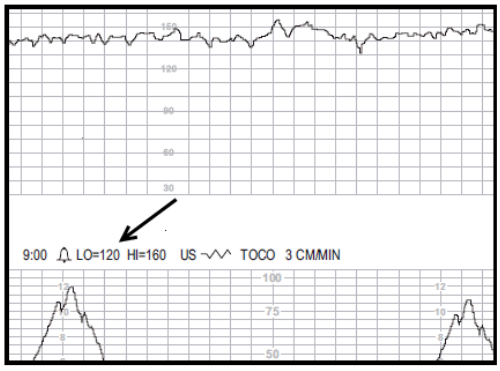
GE Healthcare has recently become aware of a potential safety issue due to the FHR lower alarm limit factory setting associated with the Corometrics 170 series monitors. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

GE Healthcare has become aware that some of the Corometrics 171, 172, 173 and 174 series monitors were delivered with the FHR lower alarm limit configured incorrectly at 50 BPM (proper factory default setting is 120 BPM). A lower than expected FHR, if left undetected, could result in fetal bradycardia and oxygen deprivation to the fetus. There have been no injuries reported as a result of this issue.

Safety Instructions

1. Review the monitors in your organization and determine if you have any affected products in use at your facility (See Affected Product Details below for list of affected serial numbers). Continue with the steps below as each affected monitor is available.
2. Check the current FHR lower alarm limit values for each affected system. If it is set at an organizationally appropriate setting, continue to use the monitor.
   Note: the FHR lower alarm limit value can be checked by either of the following two methods:
   a. Printed on the strip chart paper at startup & every 10 minutes when alarms are enabled (see below)



   OR
   b. Shown in User Setup mode on the monitor display – see Appendix 1 attached to this letter for details.
3. If the monitors are not set at your organizational required levels or at the default level of 120 BPM, set them to either 120 BPM or a level that best meets your organizational requirements following the instructions in Appendix 1 attached to this letter.
4. Record the serial number of each product checked on the attached Medical Device Correction Confirmation Form (see Appendix 2 attached to this letter), and fill out the remaining items on the form. Please send the form to GE Healthcare within 2 weeks of receiving this letter. See form for directions on sending back to GE Healthcare.

Affected Product Details	Corometrics 171, 172, 173 and 174 series monitors with serial numbers in the range of SAS12048362PA to SAS15114103PAS.
Product Correction	Follow the Safety Instructions provided above.
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,

[redacted]

James W. Dennison
Vice President QA, Devices
GE Healthcare

[redacted]

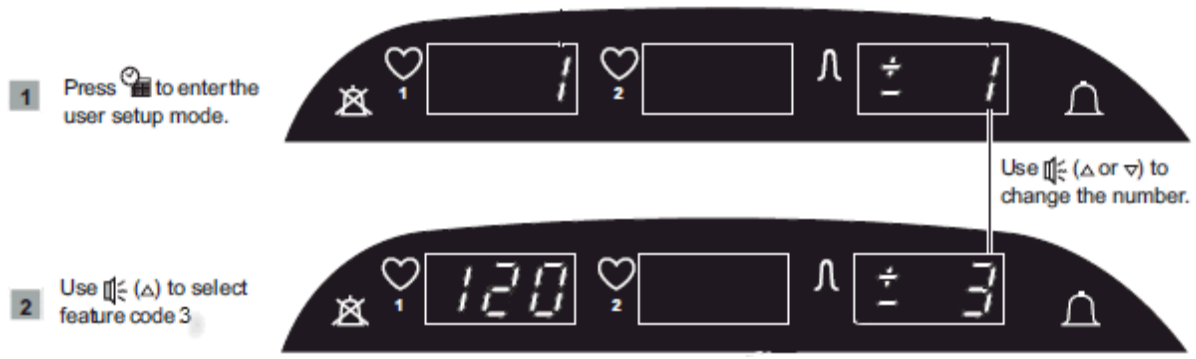
Jeff Hersh, M.D.
Chief Medical Officer – Medical Solutions
GE Healthcare

GE Healthcare

GE REF: 32040 – Appendix 1

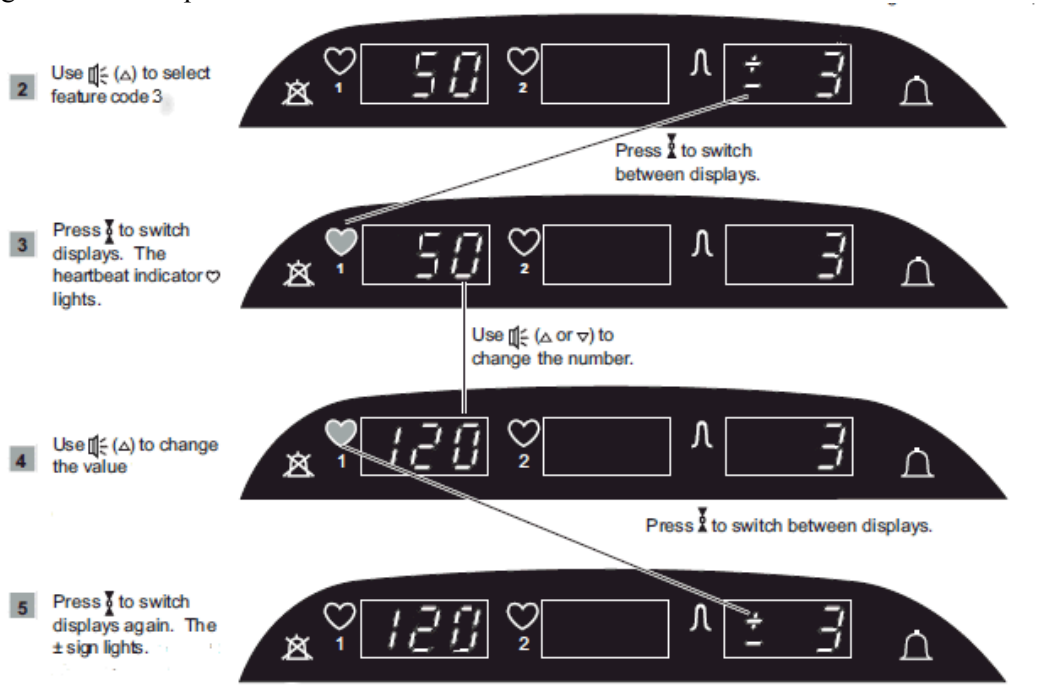
How to check/change the current FHR lower alarm limit values using User Setup mode

Note: You may enter the user setup mode during a monitoring session. The fetal heart rate and uterine activity trends print without interruption; however you will be unable to see the heart rate and uterine activity values on the display while in the user setup mode. If an alarm is in progress when you exit the user setup mode, any changes to an alarm setting do not take effect until the alarm condition is resolved.



If the FHR lower alarm limit value is set an organizationally appropriate setting, press the Setup button to exit the user setup mode and continue to use the monitor.

If the FHR lower alarm limit value are <u>not</u> set at your organizational required levels or at the defaul level of 120 BPM, follow the steps below to set them to either 120 BMP or a level that best meets your organizational requirements:



Press the Setup button to exit the user setup mode and continue to use the monitor.

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GE REF: 32040 – Appendix 2

MEDICAL DEVICE CORRECTION CONFIRMATION

CUSTOMER RESPONSE REQUIRED

We request that you PLEASE COMPLETE and return this form to GE Healthcare within two (2) weeks.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

It is important that we confirm our customers have received this correction notice. By sending back this notice, you acknowledge receipt of the Medical Device Correction Notice and have alerted the appropriate personnel at your facility regarding the safety issue and instructions. Please check one of the following and complete the requested information:

☐ We have performed the actions as instructed in the Medical Device Correction Notice on all potentially affected systems as indicated and confirm the default levels are at a level that best meets our organizational requirements. List all Device/System Serial Number(s) checked (attachment can be used):_____

_____

_____

☐ We have received your Medical Device Correction Notice and no longer have a system affected by this Medical Device Correction Notice. (Please check appropriate disposition. If multiple systems or further information, attachment can be used.)

☐ Sold ☐ Returned ☐ Scrapped ☐ Other: _____

Device/System Serial Number(s): _____

New Owner, if known: _____

Contact Name: _____

Street Address: _____

City/State/Country: _____

Contact (i.e. Email, Phone): _____

Please provide the name of the individual with responsibility for risk and compliance.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return this form using one of the following methods:

1. **Scan or take photo of completed form and email to MIC.Recall@ge.com**
   Note: QR code can be used to email the form: click QR code, attach photo to email, click Send
2. **Take photo of completed form and send via SMS text to +1-443-414-1290**
   Note: QR code can be used to text the form: click QR code, attach photo to text, click Send
3. **Fax completed form to Fax Number: +1-410-630-5938**
4. **Place completed form in envelope provided and mail to:**
   GE Healthcare, Attn: Dave Blair, 8880 Gorman Road, Laurel, MD, 20723, USA

QR (text)

QR (email)