URGENT FIELD SAFETY NOTICE

GE Healthcare
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GEHC Ref: ██████

To: Hospital Administrator
      Head of Biomedical Engineering
      Nursing Manager

RE: Potential for loss of communication between the Transport Pro® Monitor and the CARESCAPE™ Patient Data Module

GE Healthcare has become aware of a safety issue that can occur when using the Transport Pro Monitor with the CARESCAPE Patient Data Module (PDM). This condition affects all released versions of software.
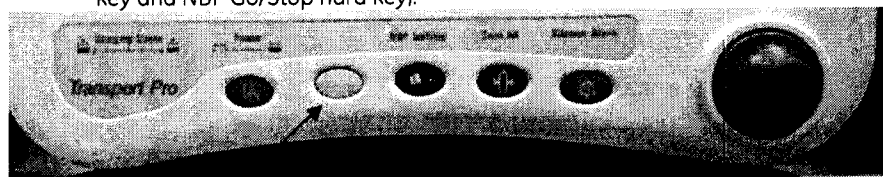
Safety Issue Transport Pro stops communication with PDM after 414 days of <u>continuous</u> run time. This time will equate to different amounts of real time depending on how much the units is actually in service per day. Transport Pro contains an internal timer that is used to control the software and remind users to perform preventive maintenance. When this internal timer rolls-over, the Transport Pro will display an "EC1" message. If the Transport Pro is continued to be used without clearing the EC1 message, after additional 19 days of service time loss of communication between the Transport Pro and a connected CARESCAPE Patient Data Module (PDM) will occur. This results in the loss of the displayed parameter information (e.g. waveforms, numerical data, alarms).

Affected Product Details This condition affects all released versions of software.

Safety Instructions Clearing the "EC1" error message can be done by following the instructions below. Please note that this will also clear event logs on the device.

The following procedure will clear the "EC1" condition:
1. Disconnect the CARESCAPE Patient Data Module from the Transport Pro Monitor.
2. Remove the external power supply from the Transport Pro Monitor and operate on battery power only.
3. Power down the Transport Pro Monitor (press the power key for at least one second.
   Wait for the Transport Pro Monitor to completely power down.
4. Press and hold the blank hard key on the Transport Pro Monitor and power up the Transport Pro Monitor (note: the blank key is between the Power hard key and NBP Go/Stop hard key).

"blank hard key"

5. Continue to hold the blank hard key until the ALL ALARMS OFF CONNECT PDM OR TRAM TO ACTIVATE ALARMS window is displayed.

(Pressing and holding the blank hard key while Transport Pro Monitor is powered up will clear the internal "EC1" timer and the "EC1" message will be removed from the display.)

6. Verify all parameter limits, user settings and alarm levels are set to the desired values. This procedure also clears event logs.
7. Connect a CARESCAPE Patient Data Module or Tram and confirm the EC1 condition is removed and monitoring continues.

Note: Configuration memory is not cleared. Feature settings, IP addresses, unit name, bed name, etc. remain unchanged.

Product Correction

Instructions have been added to the Transport Pro Monitor service manual in the preventive maintenance section to explain clearing the "EC1" message. The relevant amendment to the manual is attached to this letter. Please add this amendment to your copy of the Transport Pro service manual. Preventive maintenance should be performed annually. This addendum is in English language as the Service manual is for authorized Service professionals only.

In addition, GE is developing a Software update for the Transport Pro that will correct the PDM communication issue associated with the "EC1" timer. We will contact you when this Software update is available.

Contact Information

If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

GE Healthcare confirms that this notice has been provided to the appropriate Regulatory Agency.

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.

Thank you,

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