



GE Healthcare



URGENT MEDICAL DEVICE CORRECTION

July 2008

Attention: Healthcare Administrator
Chief of Nursing
Director of Biomedical Engineering

Address
Address
Address

Subject: Potential for loss of Monitoring for 1-2 minutes

Affected Products: GE Healthcare Solar 8000M/i when used with Telemetry and Patient Data Module (PDM) during combination monitoring (Combo Mode)

Dear Healthcare Provider:

A software error has been discovered when using Combination Monitoring with Solar 8000M/i - PDM -Telemetry in combo mode. This error has only been noted with this particular configuration and mode of monitoring. It has not been observed in other monitoring applications.

The Combination Monitoring feature allows our telemetry system to be the source of ECG for the bedside monitor.

The software error will result in a reset of the Solar 8000M/i, causing a loss of monitoring for approximately 1-2 minutes at the Solar 8000M/i, when the following two conditions are met:

- A **SAMPLE ECG** history is requested via the telemetry transmitter or from the Clinical Information Center (CIC) and is stored within the telemetry alarm history, and
- The clinician initiates a change of ECG source from the combination monitoring (telemetry transmitter ECG source) to MONITOR (monitoring the ECG source from the PDM)

After the reset, the Solar 8000M/i will spontaneously resume combination monitoring (telemetry transmitter ECG source), resulting in the inability to change the ECG source to the Solar 8000M/i monitor. Any other parameters being monitored at the solar bedside will not be affected following the reset.

GE Healthcare recommends that this feature of combination monitoring not be used due to this issue. See Fig 1 for how to disable this feature.



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Depending on your particular workflow, options may be available that will allow you to continue use of combo mode. Please contact your local GE Healthcare representative, listed below, to discuss possible options.

GE Healthcare is working on a long-term solution, and will contact you when the solution becomes available

If you have concerns or questions on this notification please contact:

(Insert local contact here at time of translation; delete Faye's information only)

Faye Aebly Tel: 414 362 2508 email: Faye.Aebly@med.ge.com

Sincerely,

[Redacted]
[Redacted]
Global Marketing Manager
Clinical Systems, Monitoring Systems

[Redacted]
[Redacted]
Director, Regulatory Affairs
Clinical Systems



Fig.1

All Solar monitors leave the factory with the combination monitoring feature disabled. Combination monitoring must be activated through the password protected SERVICE MODE menu.

To confirm that the combination-monitoring feature is disabled perform the following steps:

1. Press the



```
SOFTWARE REVISION DISPLAY
STANDARD
MONITOR MAIN PROCESSOR
2002131-016 VER 5.0 22DEC06
RAC #1 COMM
404669-007 VER 6C 06SEP96
RAC #1 DAS
404671-008 VER 6C 31JUL96
RAC #2 COMM
RAC #2 DAS
PDM
2023776-001 1.0
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```

STANDARD is the factory default; COMBO or ROVER COMBO would indicate that a change has been made to work with Telemetry. To **disable** combination monitoring in the SERVICE MODE menu, please refer the Configuration chapter in the Solar 8000M/I service manual for this procedure.

