

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/27

Issued: 22 March 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Patient monitoring system: ApexPro/ApexPro CH telemetry system manufactured by GE Healthcare.</p>	▶ ①
<p>Problem: Possibility of no visual or audible system failure alarms.</p>	▶ ②
<p>Action by: Cardiac care staff, intensive care staff and technical staff.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Ensure you have received the urgent medical device correction notice from GE (see appendix). • Ensure the ST monitoring default system is enabled at both the CIC and individual patient monitors and follow the advice in the GE letter regarding their continued use until the upgrade is complete (short term recommendation). • Ensure that arrangements are made to upgrade the software to remove this problem. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required.</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

The intended use of this device is early mobilisation of patients who still require ECG monitoring. Data can be accessed from the bedside monitor or from a central station. ApexPro/ApexPro CH telemetry system with software versions V3.8 and earlier are affected.

2. PROBLEM:

System failures, such as 'ECG LEADS FAIL', will not activate the visual or audible alarms if the ST monitoring is disabled and a pre-existing continuous message or advisory level alarm is active. Although these alarms may not be activated, the user would still see the 'LEADS FAIL' or other system fail messages but a user's attention may not necessarily be drawn to these messages.

The MHRA is issuing this alert because GE is uncertain of the location of all the devices.

3. ACTION BY:

Cardiac care staff, intensive care staff and technical staff.

4. ACTION:

- Ensure you have received the urgent medical device correction notice from GE (see appendix).
- Ensure the ST monitoring default system is enabled at both the CIC and individual patient monitors and follow the advice in the GE letter regarding their continued use until the upgrade is complete (short term recommendation).
- Ensure that arrangements are made to upgrade the software to remove this problem.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Cardiologists
- Cardiology departments
- Cardiology nurses
- Clinical governance leads
- Coronary care departments
- EBME departments
- Equipment stores
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- In-house maintenance staff
- Intensive care units
- Medical directors
- Medical physics departments
- Nursing executive directors
- Recovery wards
- Risk managers

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Max Norwood ACQI
GE Healthcare
71 Great North Road
Hatfield
Hertfordshire
AL9 5EN

Tel: 01707 263 570 x4200

Fax: 01707 260 065

E-mail: max.norwood@ge.com

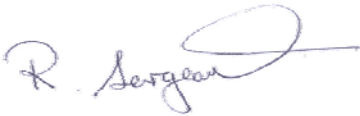
Enquires to NIAIC should quote reference number MDEA(NI)2007/27 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Appendix to MDEA(NI)2007/26

URGENT MEDICAL DEVICE CORRECTION

August 4, 2006

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

Address
Address
Address

Subject: Potential for missing SYSTEM WARNING alarm under certain conditions

Affected Products: ApexPro/ApexPro CH Telemetry System

Dear Sir or Madam:

GE Healthcare would like to inform you about a corrective action associated with our ApexPro/ApexPro CH Telemetry system. We have identified a potential issue that may occur in the operation of this telemetry system. This issue occurs in software versions v3.8 and earlier. According to GE Healthcare's records, you currently own a GE Healthcare ApexPro/ApexPro CH Telemetry system.

Our investigation determined that when a patient being monitored with ApexPro/ApexPro CH Telemetry with ST monitoring disabled is in a pre-existing condition of continuous MESSAGE or ADVISORY level alarm preceding a SYSTEM WARNING level alarm, the SYSTEM WARNING audible alarm and flashing yellow border around the patient panel at the CIC (Clinical Information Center) does not occur.

Consider the scenario of a patient with chronic atrial fibrillation. The patient is admitted to the CIC and the AFIB alarm is currently set to MESSAGE status. Subsequently, if the reference lead or two limb leads are removed, the AFIB text remains but no audible alarm or flashing yellow border occurs on the CIC for the LEADS FAIL condition.

It is important to note that the following additional alarms are not affected and will function as expected:

- The ADU line at the CIC displays the red alarm block with "LEADS FAIL".
- The CIC displays "LEADS FAIL" in both the single and multiple viewer windows.
- The patient window at the CIC does not display a waveform.
- A paging system installed with an ApexPro/ApexPro CH Telemetry system receives a LEADS FAIL alarm notification.
- An ADU system installed with an ApexPro/ApexPro CH Telemetry system receives a LEADS FAIL alarm notification.
- The LEDs on the ApexPro/ApexPro CH Telemetry transceiver will not display when Verify Leads is pressed.

Short Term Recommendation:

You may continue to use the ApexPro/ApexPro CH Telemetry system provided the ST monitoring in the Telemetry Unit Defaults is enabled at the CIC and the clinicians keep the ST monitoring enabled in the individual patient's ECG Menu. If the default setting of ST monitoring is enabled, the SYSTEM WARNING alarm will function properly. If there are certain patients or care scenarios that do not benefit from ST monitoring, the clinician can consider setting the ST limits to +/- 12 mm to avoid nuisance alarms.

Appendix to MDEA(NI)2007/26

For assistance with configurations, please contact 01707 263570 and ask for Clinical Applications for CIC.

Note: For currently admitted patients, changes must be done on an individual basis at the CIC.

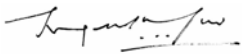
Long Term Solution:

A software upgrade that corrects this situation is available and will be provided to you at no charge.

If you should have any further questions regarding this notice, please contact your local GE Healthcare Service Representative, or call 01707 263570 x4200.

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

Sincerely,



Rajeev Kapoor
Global Product Manager Telemetry and Wireless
Clinical Systems Monitoring Solutions
T: (800) 558-5120 ext 2727
Rajeev.Kapoor@med.ge.com