

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/21

Issued: 19 August 2003

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Philips monitors containing the EASI™ 12-lead ECG algorithm	▶ ①
Problem: The EASI™ 12-lead ECG derived from five electrodes is inappropriate for diagnosis of acute ischaemic heart disease. Its use may lead to inappropriate therapy and treatment.	▶ ②
Action by: All nursing and medical personnel using these devices.	▶ ③
Action: Diagnosis of acute ischaemic heart disease should not be based on the EASI™ 12-lead ECG. Users should instead use the conventional 10-electrode, 12-lead diagnostic ECG configuration.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	▶ ⑤ General Medical Practitioners
Contacts NIAIC contact details.	▶ ⑥
Feedback Requirements to NIAIC None	▶ ⑦

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

1. DEVICE/EQUIPMENT:

The following Philips monitoring devices contain the EASI™ 12-lead ECG algorithm. The devices may also be labelled Hewlett Packard, Agilent or Zymed.

M3001A – Multi-Measurement Server
M2600A – Telemetry System
MP60/MP70/M90 – IntelliVue Patient Monitor
M3150, M3151A, M3155B – IntelliVue Information Center
V24/V26 Family of Monitors
M1165A, M1166A, M1167A – Component Monitoring System
1810 and 2010+ Holter Series

2. PROBLEM:

The EASI™ 12-lead ECG algorithm derives a 12-lead ECG from five electrodes. Some users are not following the manufacturer's instructions for use. The EASI™ 12-lead ECG algorithm is intended for monitoring purposes and is not intended to be a replacement for the conventional 10-electrode, 12-lead diagnostic ECG.

The Medicines and Healthcare products Regulatory Agency (MHRA) has received reports where a patient was suspected of having ischaemic heart disease or rapidly changing ST segments and the EASI™ 12-lead ECG did not correlate with the conventional 12-lead ECG.

Users employing only the EASI™ 12-lead ECG may, therefore misdiagnose certain conditions particularly myocardial infarction, leading to inappropriate use of thrombolytic therapy.

3. ACTION BY:

All nursing and medical personnel using these devices.

4. ACTION:

A conventional 12-lead ECG recording should always be taken whenever a clinical decision with regards to a suspected acute myocardial infarction is being made.

Follow the manufacturer's instruction for use for EASI™ ECG monitoring.

Verify on the monitor display, reports and recordings if the "EASI" marking is present, indicating that the EASI™ 12-lead ECG is in use. If present do not base diagnostic decisions on such displays, reports or recordings.

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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Device/Equipment Co-ordinators
- Medical Directors
- Nurse Directors
- Consultants in Cardiology, general medicine, anaesthetics and accident and emergency
- Adult and Paediatric Intensive Care Units
- Independent Health and Social Care Providers – Private Clinics
- Operating Theatre Staff
- Recovery Rooms
- Outpatient Departments
- Accident & Emergency Departments
- Coronary Care Units
- Paediatric Units including outpatients

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr J Povey
Safety Manager
Philips Medical Systems
Cardiac Monitoring
The Observatory
Castlefield Road
Reigate
Surrey RH2 0SG

Tel: 01737 230 588

Fax: 01737 230 522

E-mail: john.povey@philips.com

Enquires to NIAIC should quote reference number MDEA(NI)2003/21 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.



Brian Godfrey
NIAIC 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 Safety Notice SN (NI) 2003/01. 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