

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/02

Issued: 9 January 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: Patient monitoring system - Philips Medical Systems Multi-Measurement Server (MMS) Model: M3001A and SpO₂ Module M1020B.</p>	▶ ①
<p>Problem: The pulse oximeter channel of the MMS or the SpO₂ module in these monitors when used with disposable SpO₂ transducers/probes may display a 100% saturation when the transducer is not attached to a patient. Should this happen in the case of a hypoxic patient, no alarm will be given.</p>	▶ ②
<p>Action by: Anaesthetists, operating theatre practitioners, intensive care, A&E, ambulance and technical staff.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Ensure you have received the urgent device correction notice from Philips (see appendix). 	▶ 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:

Philips Multi-Measurement Server (MMS) Model M3001A

Units affected:

- M3001A options A01, A01C06, A01C12 and A01C18 with serial number prefix DE512 and MMS software revision C.0 or B.1; SpO₂ Firmware A.01.41 or A.01.42
- M3001A options A02, A02C06 and A02C18 with serial number prefix DE441 and DE512 and MMS software revision C.0 or B.1; SpO₂ Firmware A.01.41 or A.01.42

SpO₂ Module M1020B that is used with various Philips patient monitors M1020B SpO₂ Module

Units affected:

- M1020B options A01 and A02 with serial numbers prefix DE524 and DE612; SpO₂ Firmware A.01.42 Manufactured by Philips Medical Systems, Hewlett-Packard

2. PROBLEM:

A pulse oximetry (SpO₂) saturation level of 100% may be displayed when the M3001A is used with bandage type disposable sensors such as Nellcor MAX-A and MAX-N. The display will be accompanied by the following indicators simultaneously:

- a technical alert (SpO₂ LOW PERF) displayed on the monitor central station
- question marks next to the SpO₂, Pulse and Perf. labels on the display
- non-physiological pulse rate variations from 40 to 260bpm
- a small, non-physiological pleth. waveform
- an extremely low perfusion index (approximately 0.04 – 0.02)

There is no problem when reusable cuff or clip type sensors are used.

3. ACTION BY:

Anaesthetists, operating theatre practitioners, intensive care, A&E, ambulance and technical staff.

4. ACTION:

- Ensure you have received the urgent device correction notice from Philips (see appendix).
- Identify suspect devices (as described in the appended letter) and contact Philips to either request a software upgrade or to confirm that you will be upgrading the equipment yourself.
- Follow the advice at the end of the appended letter regarding their continued use until the upgrade is complete (procedure to mitigate the risk).

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:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Ambulance services directors
- Ambulance staff
- Anaesthetists
- Biomedical engineering staff
- Coronary care departments
- Directors of anaesthetics
- EBME departments
- High dependency units
- Practice Nurses
- Independent Health and Social Care Providers – Hospitals & Clinics through RQIA
- In-house maintenance staff
- Intensive care, directors of
- Medical directors
- Medical physics departments
- Nurse executive directors
- Operating theatre practitioners
- Paediatric intensive care units
- Risk managers
- Special care baby units
- Theatre managers

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Mr John Povey
Philips Medical Systems
The Observatory
PO Box 263 Castleford Road
Reigate
Surrey RH2 0FY

Tel: 01737 230 588

Fax: 01737 230 522

E-mail: john.povey@philips.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/02 and be addressed to:

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

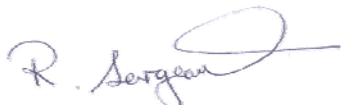
Tel: 028 9052 3868

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

The Observatory, PO Box 263, Castlefield Road, Reigate, Surrey, RH2 0FY

Tel: 01737 230588

Fax: 01737 230522

e-mail: john.povey@philips.com

To: The Manager - EBME Department

16th October 2006

Dear Sir/Madam,

Re: Device Correction Notice & Customer Letter
MultiMeasurement Server & SpO2 Module

Please find enclosed a copy of a device correction notice and customer letter concerning a **potential safety issue** relating to the MMS and SpO2 module when using some types of **disposable** sensors such as the Nellcor MX-A and MAX-N.

Please bring this information to the attention of all members of staff who need to know.

A Mandatory Field Change Order (860 00673) has been issued to upgrade the software and firmware to correct the problem. A copy is enclosed for your information.

We are making arrangements to carry out the necessary work where customers would like us to carry it out for them. Alternatively, where you have a technician who has attended a Philips training course on the Intellivue monitor, they will have been given the access code necessary to download the latest version of the Intellivue Support Tool from the Philips InCentre website. Before proceeding to carry out the FCO, please read the procedure very carefully and make sure that the monitor(s) to be used to transfer the software and firmware are at the required revision level.

To help us plan our resources, could you please indicate on the acknowledgement form whether you will be carrying out this upgrade yourself in-house and return to us at the above address by no later than the 30th November 2006.

contd:-

Appendix to MDEA(NI)2007/002

As we have to account for all MMS and SpO2 modules that could be affected I have enclosed a print out of the serial numbers of the units that were originally supplied to your site. However, some of your units may have been exchanged and so I would ask you please to check the list enclosed against your inventory list and put a single line through the serial numbers you no longer have, so that the number can still be read. Please also provide a list of serial numbers that you have that are not included on the Philips list so that we have a comprehensive list. Please return your checked list with the acknowledgement form.

If you have any questions concerning this matter please contact our customer support centre on 0870 532 9741.



Yours faithfully,
John Povey
Safety Manager

June 30, 2006

Please return to:

Mr J.I. Povey, Safety Manager
Philips Medical Systems
PO Box 263
Castlefield Road
Reigate
Surrey RH2 0FY

fold here for use with window envelope

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Acknowledgement Form - Customer letter and Device Correction Notice for MultiMeasurement Server/SpO2 Module

Hospital

I acknowledge receipt of the Customer letter and Device Correction Notice for MMS and SpO2 modules concerning Unexpected Pulse Oximetry Readings. The information has been brought to the attention of all users.

I am returning the list of originally shipped units you sent, marked up to show those units still held on this site.

We will / will not * be carrying out this upgrade in-house.

* please delete as appropriate

Name _____

Signed _____

Date _____

Appendix MDEA(NI)2007/002

URGENT - DEVICE CORRECTION

Dear Healthcare Customer:

This letter is to inform you that Philips Medical Systems is conducting a voluntary correction of the M3001A Multi-Measurement Server (MMS) used with your IntelliVue or M3/M4 patient monitor. Our records indicate that you may have received at least one of the potentially affected devices. In these devices, when using pulse oximetry with some types of disposable sensors such as the Nellcor MAX-A and MAX-N, in rare cases, a pulse oximetry (SpO₂) saturation level of 100% may be displayed for an extended period of time even though a sensor is not attached to the patient. This behavior has never been reported and could not be demonstrated with reusable cuff or clip-type sensors or other types of disposable sensors.

The likelihood of this problem occurring during actual use is remote. From our installed base of approximately 50,000 potentially affected M3001A's, Philips has received eight reports of this occurrence in clinical use. This occurrence should not significantly impact use, as there are multiple other indicators of the quality of the SpO₂ saturation level on monitor displays.

Please see the attached Urgent Device Correction Notice, which provides information on how to identify affected devices and instructions on actions to be taken. Please follow the "REQUIRED ACTION" and "PROCEDURE TO MITIGATE RISK" sections of the attached notice.

Philips is convinced that the pulse oximetry function of the M3001 Multi-Measurement Server can be used safely, following good clinical practices and considering all the Instructions for Use. However, we are now planning a proactive free of charge software upgrade for the affected M3001A MMS's and you will be contacted by your Philips Medical Systems support team to schedule this software upgrade.

It is commonly known with pulse oximetry that minimal sensor movement, ambient light or electromagnetic interference can give intermittent unexpected readings with the sensor not attached to a patient. Philips monitors offer a number of indicators, such as technical alerts, pleth waveform and the perfusion index, to warn the user of such conditions and to allow the user to assess the quality of the signal and measured SpO₂ and pulse rate. For the safe use of pulse oximetry it is essential to follow good clinical practices, e.g. proper sensor application and periodically checking the measurement site, as well as to consider all information and to follow all the instructions provided in the Instructions for Use of the monitor and supplied with the sensors even after the upgrade of your device.

We apologize for the inconvenience that this will cause you. Ensuring that you have the highest quality patient monitors is our priority. Your satisfaction with Philips products as well as with our response to this problem is very important to us. Should you have any questions or concerns about the Device Correction, please contact your local Philips Medical Systems support team on 0870 532 9741.

Sincerely,

David R. Jones
Director, Worldwide Quality & Regulatory Affairs
Patient Monitoring



PHILIPS

URGENT DEVICE CORRECTION NOTICE
Philips Medical Systems
M3001A Multi-Measurement Server

June 30, 2006

<p>AFFECTED PRODUCTS</p>	<p>Product: Philips Multi-Measurement Server (MMS) Model M3001A, which is used with various Philips patient monitors</p> <p>Units Affected: M3001A options A01, A01C06, A01C12, and A01C18 with serial number prefix DE512 and MMS software revision C.0 or B.1 M3001A options A02, A02C06, and A02C18 with serial number prefix DE441 and DE512 and MMS software revision C.0 or B.1</p> <p>Manufactured by: Philips Medical Systems, Hewlett-Packard Str. 2, 71034 Böblingen, Germany</p>
<p>REASON FOR VOLUNTARY CORRECTION</p>	<p>In rare cases, a pulse Oximetry (SpO₂) saturation level of 100% may be displayed for an extended period of time even though a sensor is not attached to a patient. This display is nevertheless always accompanied by the following indicators of a potentially non-physiologic saturation level:</p> <ul style="list-style-type: none"> • a technical alert (SpO₂ LOW PERF) displayed on the monitor and central station • question marks next to the SpO₂, Pulse and Perf. Labels on the display • non-physiologic pulse rate variations from 40 to 260 bpm • a small, non-physiologic pleth waveform • an extremely low perfusion index (approximately 0.04 - 0.02) <p>This behavior has only been observed and reproduced when the M3001A Multi-Measurement Server is used with bandage-style disposable sensors such as the Nellcor MAX-A and MAX-N, and not with reusable cuff or clip-type sensors.</p>
<p>HAZARD INVOLVED</p>	<p>Users who are unaware that a sensor has become detached from a patient and who rely solely on the displayed numeric saturation level and audio alarms to determine whether the patient is being adequately monitored for SpO₂, may miss a desaturation event.</p>
<p>HOW TO IDENTIFY</p>	<p>To identify an affected M3001A MMS: The option and serial number can be found on the bottom of the MMS. The device software version number can be displayed on the monitor screen by pressing "Setup" then "Revisions", then "Product", then "M3001A". For more details, please refer to the IntelliVue Instructions for Use or M3/4 Instructions for Use.</p>



PHILIPS

URGENT DEVICE CORRECTION NOTICE
Philips Medical Systems
M3001A Multi-Measurement Server

<p>REQUIRED ACTION</p>	<ul style="list-style-type: none"> • Philips Medical Systems will contact you regarding the upgrade of your MMS. • During the interim period, as you await the upgrade for your device, you may continue to use the M3001A Multi-Measurement Server, provided you follow the precautions included in the section below, PROCEDURE TO MITIGATE RISK. • If you have questions about this notice, contact your local response center at: 1-800-722-9377 (USA) and 1-800-323-2280 (Canada). Customers outside North America should contact their local Philips Medical Systems support team.
<p>PROCEDURE TO MITIGATE RISK</p>	<p>Careful attention to the instructions for use of the sensors and the pulse oximetry features of Philips monitors will significantly reduce any risk from this behavior. In particular,</p> <ul style="list-style-type: none"> • Never ignore the SpO₂ LOW PERF INOP or other technical alerts and alarms, small non-physiologic pleth waveforms, varying pulse rates or extremely low perfusion values on the monitor display. • Routinely check both the pleth waveform and perfusion index to assess the appropriate confidence to be given to the displayed saturation value. If the perfusion index is below 0.3, the clinician should question the SpO₂ measurements and determine whether the cause of the decreased signal strength is due to a clinical condition or due to the need to reposition or reattach the sensor. • Pay attention to correct sensor application and periodically check and verify the proper placement of the sensor on the patient. • Follow the SpO₂ sensor's instructions for use, adhering to all warnings and cautions.