PHILIPS

August 25, 2006

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), the M1020B Pulse Oximetry Module Philips FAST SpO_2 and M1020B Pulse Oximetry Module Nellcor® OxiMax® Compatible 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 (SpO_2) 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.

Further, with the sensor attached to a patient the affected devices may temporarily display an incorrect high and unstable oximetry saturation reading, if the patient's pulse rate is in a narrow range around 185 BPM. With lower saturation levels, the possible deviation is decreasing. Consequently, deep desaturations will be captured and reported even in this situation.

In very specific circumstances, with the sensor attached to a patient the affected devices may temporarily display an incorrect high and unstable oximetry saturation reading. If the patient has a very high pulse rate in a narrow range around 185 BPM, and with poor perfusion, and with a weak pulse, the readings may be observed to show rapid fluctuations. This scenario could be observed, for example, with a critically ill neonate patient, or other severely compromised ICU patient.

The likelihood of these problems occurring during actual clinical use is remote. From our installed base of approximately 70,000 potentially affected M3001A's, Philips has received eight reports of readings with a sensor not attached to the patient. There has been one report indicative of incorrect high readings with the sensor attached to a patient. With the M1020B no report has been received so far. These occurrences with the M3001A should not significantly impact use. In case of readings with a sensor not attached to the patient there are multiple other indicators of the quality of the SpO_2 saturation level on monitor displays. With the sensor attached to a patient, a heart / pulse rate limit alarm will be triggered when the patient's heart / pulse rate enters the critical range, if the heart / pulse rate alarm limits are set as described under "PROCEDURE TO MITIGATE RISK".

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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 Multi-Measurement Server and Module can be used safely, following good clinical practices and the "PROCEDURE TO MITIGATE RISK" as well as considering all the Instructions for Use. However, we are now planning a proactive free of charge software upgrade for the affected MMS's and Modules 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 alarms, 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 SpO_2 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 the Customer Care Center, by telephone 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.

Sincerely,

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

PHILIPS

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

August 25, 2006

AFFECTED PRODUCTS	**Product:** Philips Multi-Measurement Server (MMS) Model M3001A, M1020B Pulse Oximetry Module Philips FAST SpO_2 and M1020B Pulse Oximetry Module Nellcor® OxiMax® Compatible which is used with various Philips patient monitors **Units Affected:** M3001A options A01, A01C06, A01C12, and A01C18 with serial number prefix DE512 and DE610 and SpO_2 DSP Fw-Rev. A.01.41 or A.01.42 M3001A options A02, A02C06, and A02C18 with serial number prefix DE441, DE512 and DE610 and SpO_2 DSP Fw-Rev. A.01.41 or A.01.42 M1020B Options A01 and A02 with serial number prefix DE524 and DE612 and SpO_2 DSP Fw-Rev. A.01.42 **Manufactured by:** Philips Medical Systems, Hewlett-Packard Str. 2, 71034 Böblingen, Germany
REASON FOR VOLUNTARY CORRECTION	In rare cases, a pulse Oximetry (SpO_2) 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: • a technical alarm (SpO_2 LOW PERF) displayed on the monitor and central station • question marks next to the SpO_2, 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) 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. Further, with the sensor attached to a patient, an incorrect high SpO_2 reading or a varying SpO_2 reading may be displayed, if the patient's pulse rate is in the range of 185 +/-15 BPM.
HAZARD INVOLVED	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 SpO_2 and users who do not set the heart / pulse rate alarms as described under PROCEDURE TO MITIGATE RISK, may miss a desaturation episode.
HOW TO IDENTIFY	**To identify an affected M3001A MMS:** The option and serial number can be found on the bottom of the MMS. The SpO_2 DSP Fw-Rev can be displayed on the monitor screen by pressing "Setup" then "Revision", then "M3001A", then "SpO_2". For more details, please refer to the IntelliVue Instructions for Use or M3/4 Instructions for Use. **To identify an affected M1020B Module:** The serial number can be found on the back of the Module. The SpO_2 DSP Fw-Rev can be displayed on the monitor screen by pressing "Setup" then "Revision", then if the module is plugged in the FMS press additionally "M8048", then "SpO_2". For more details, please refer to the IntelliVue Instructions for Use.

REQUIRED ACTION	• Philips Medical Systems will contact you regarding the upgrade of your MMS or Module. • During the interim period, as you await the upgrade for your device, you may continue to use the M3001A Multi-Measurement Server and the M1020B Options A01 and A02, 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.
PROCEDURE TO MITIGATE RISK	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, • Never ignore the SpO_2 LOW PERF alarm or other technical 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 SpO_2 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 SpO_2 sensor's instructions for use, adhering to all warnings and cautions. Further, make sure that the heart / pulse rate alarm is enabled and the limits are set in a way that a pulse rate in the critical range (185 +/- 15 BPM) triggers a heart / pulse rate alarm. Philips recommends not to solely rely on the SpO_2 measurement of an affected device for monitoring of a patient's oxygen saturation, if the patient's heart / pulse rate does not allow setting the limits as described before.