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Philips Medical Systems

Important Medical Device Notification

Increased Number of Reports of Adverse Events Referencing Patient Monitoring Alarms

Dear Hospital Risk Manager:

As part of Philips Medical Systems' quality system, we routinely review reports of adverse events submitted to us. Over the last three years, these reviews have noted an increased number of reports of adverse events that refer to alarms on patients being monitored by **Philips bedside patient monitors connected to central monitoring stations**. These reports were not limited to any particular patient monitor, and when investigated, the monitors were found to have performed to specification.

This increase in reports coincided with the issuance by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), of a National Patient Safety Goal (NPSG) specifically addressing clinical alarm systems. JCAHO's NPSG's are intended to promote specific improvements in patient care at accredited organizations in the USA. From 2003 to 2004, one such goal for accredited hospitals was to improve the effectiveness of their clinical alarm systems by requiring the implementation of regular preventive maintenance and testing, as well as assurance that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit. JCAHO specifically expected hospitals to implement policies and procedures that ensure the proper set-up of and response to alarms. In 2004, JCAHO determined that hospitals' compliance with the requirements under this NPSG had reached a high level and that it was sufficient to maintain appropriate standards for clinical alarms systems. The goal remains for some other health care organizations.

Philips is sending this letter because it believes that the findings of our recent review of adverse event reports may be helpful to hospitals as they refine their alarm policies and procedures after several years of intense focus under the NPSG. The review found three major factors contributing to the increased number of reports:

- Turning off ECG/Heart Rate alarms;
- Switching the alarm source from Heart Rate to Pulse without considering that ECG and arrhythmia alarming is not available in this mode; and
- Treating technical or INOP alarms (e.g., such as those that indicate that a patient's ECG electrodes may have become disconnected) to be low-priority, even though they indicate that the patient may no longer be monitored.

Other causes are sometimes noted in alarm-related adverse event reports, such as alarm volume settings inappropriate for the clinical setting, but their incidence was not found to have significantly increased over the period of the review.

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3000 Minuteman Road
Andover, Massachusetts 01810
Tel: (978) 687 1501, Fax: (978) 794 7646
www.philips.com

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Philips strongly recommends that hospital policies and procedures ensure that clinical staff receive appropriate and regular training on the appropriate clinical response to alarms, as well as on the operation of Philips patient monitoring systems based on the instructions for use and other learning materials supplied by Philips. In addition, hospital policies should require that alarm configuration and settings be regularly reviewed to ensure that they continue to meet the clinical requirements of the specific units where the monitors are located. Philips instructions for use include detailed information on available alarm configurations and settings and should be consulted as part of these reviews. Lastly, hospital policies and procedures should require regular preventive maintenance and testing of monitoring systems as specified in Philips labeling, which may also help detect unauthorized changes to alarm configurations and settings. Please contact your local Philips Medical Systems Sales or Support Representative if you would like to obtain product information or training. Replacement or additional copies of Philips product documentation are available for purchase from GlobalWare Solutions at aftermarket@gwsmail.com or (800)527-6871 in the USA.

Philips hopes that the information in this notice will assist users of its patient monitoring equipment in their continuing efforts to improve the effectiveness of their clinical alarm systems. We also encourage users to report to Philips adverse events that may be related to the use of our monitoring equipment.

Sincerely,

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

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Increased Number of Reports of Adverse Events Referencing Patient Monitoring Alarms FAQ

Q. Does this pertain to my monitors?
A. You are receiving this letter because you have purchased patient monitors from Philips Medical Systems. These monitors may have been purchased when we operated under the name of Agilent Technologies or Hewlett-Packard. These reports were not limited to any particular patient monitor, which we have manufactured.

Q. What is an adverse event?
A. The FDA does not have a single regulatory definition of the term 'adverse event'. For the purposes of this notice only, we consider a serious adverse event to be one that may significantly compromise clinical outcomes, or an event for which a facility fails to take appropriate corrective action in a timely manner.

Q. Is Philips doing this because the FDA said they had to?
A. No. As a medical device manufacturer we have accountability to the FDA, other governing bodies and to our customers. We investigate any adverse event of which we become aware involving our products and we monitor the frequency of occurrence of these events. We also take actions intended to promote the safe usage of our equipment, which may include notifications such as this one.

Q. How can I tell if I turn off my ECG/Heart Rate Alarms?
A. The indicators you see when the alarm is off will depend on the type of Philips Patient Monitor you have and possibly the revision of software in that device. Sometimes the device configuration prevents the end user from being able to turn off the ECG/HR alarms. At a minimum there will be an X-Bell icon or X-Triangle icon next to HR on the resting display. Your best source of information is to refer to the Instructions for Use/ User's Guide that shipped with your product. If you need a replacement manual one can be obtained from GlobalWare Solutions at aftermarket@gwsmail.com or (800) 527-6871 in the USA

Q. How does selecting Pulse as the alarm source affect monitoring of the ECG and arrhythmias?
A. As the Philips devices are designed to alarm either for the heart rate or the pulse values, only one of these parameters can have the alarms active at any given point in time. Thus, if Pulse is selected as the alarming source, then the device does not generate any alarms for the ECG rhythm or ECG rate. Using ECG as the alarm source is the most typical monitoring method but there are times when monitoring ECG is not possible. These are the circumstances where a clinician may choose to use Pulse as the alarm source.

Q. Why do I need to respond to technical alarms as quickly as patient alarms?
A. With the Philips devices, we separate patient related alarms from technical (INOP) alarms. The patient related alarms alert the user to a change with the patient while the technical alarms alert the user to device issues. Some technical issues can cause a disruption in monitoring. It is important to respond to technical (INOP) alarms promptly as a particular patient may not be able to tolerate a loss in monitoring.

Q. How can I find out about the training options available for my equipment?
A. Your Philips sales representative is your best resource for training information as he/she can assess your needs and knows which Philips products you have purchased. The available tools may vary based on the products you have purchased. Some of these training tools can be obtained from GlobalWare Solutions at aftermarket@gwsmail.com or (800) 527-6871 in the USA.