

Patient Safety Alert

Veterans Health Administration Warning System
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AL10-11

May 13, 2010

Item: Philips IntelliVue Non Invasive Blood Pressure (NIBP) monitors may display only Mean Arterial Pressure (MAP) results: Models MP20/30/40/50/60/70/80/90

Specific Incident: A VA facility reported repeated instances of partial non-invasive blood pressure (NIBP) readings with patients on monitoring systems in a Post Anesthesia Care Unit (PACU) where instead of displaying systolic, diastolic and mean non-invasive blood pressure readings, the monitor would display only the clinically inadequate non-invasive mean arterial pressure (MAP). In these situations, staff needed to perform manual blood pressure readings, taking time away from other patient care activities for these physiologically unstable patients. Instances of non-invasive MAP readings also occurred to a lesser extent in other monitored areas outside of the PACU.

Phillips identified that rapidly changing blood pressure or patient movement could present a challenge to the oscillometric measurement software. The facility installed a software patch from Philips that improves the likelihood of obtaining the Systolic and Diastolic NIBP readings in these situations. In addition, the facility implemented different Philips NIBP cuffs that have indicators on them to help eliminate cuff placement errors and size issues.

General Information: In June 2008 Philips released a software patch (F.01.46 for Multi Measurement Servers (MMS) (models M3001A/2A, M8102A/5A, and M8105AT), a White Paper (Reference 1) and an Application Note (Reference 2) addressing NIBP measurements. The patch was to be provided at no cost to any facility that identified inconsistent NIBP measurements as a problem.

In some instances when only the Mean Arterial Pressure is displayed, users can activate a STAT mode NIBP measurement to get more complete results. The software patch will reduce those instances.

This Alert provides the tools (see Attachments) for any VHA facility with affected equipment to implement the patch. Depending on the installed software revision level, upgrades to the facility's Server's software may be necessary.

The White Paper (see Reference 1) provides the principles of operation of oscillometric NIBP measurements, describes the limitations of the technique and cites typical reasons for inaccurate or

incomplete NIBP readings such as arrhythmias, low or rapidly changing blood pressure, poor cuff application, patient movement, and improper cuffs and cuff sizes. The Application Note (see Reference 2) discusses the oscillometric measurement technique and the two NIBP reference choices available to the equipment users, either intra-arterial or auscultatory.

Note: All NIBP monitors should be set to the auscultatory reference since clinicians will be using a manual auscultatory technique when the monitor displays only a mean arterial blood pressure (MAP) or displays no blood pressure.

Actions:

1. By Close of Business (COB) May 14, 2010, the **Facility Director (or designee)** will ensure that all applicable Nursing, Medical, Anesthesiology, Surgical and Biomedical Engineering staff are made aware of this Patient Safety Alert.

2. By COB May 28, 2010, the **Biomedical Engineering Supervisor (or designee)** will ensure that:

- a. All affected patient monitors with NIBP in their facility are identified and the software revision level is determined.
- b. Discussions have been held with the Nurse Managers or their designees regarding implementing the software patch and configuring the auscultatory NIBP reference method described in Reference 2 for their patient care units' equipment.
- c. Biomedical Engineering or Philips Medical service personnel are scheduled to install the software correction on all affected NIBP monitors and to configure the auscultatory reference method. The Software Compatibility Matrix for these monitors is available (see Reference 3).

NOTE 1: Philips Viridia models 24/26 and CMS, Release C.1; and models M3/M4, Release D & E patient monitors with NIBP have no software patch available, but should be configured to select the NIBP auscultatory reference method for consistency within the facility.

NOTE 2: Installations do not need to be done by this date, just the scheduling of the installations.

3. By COB May 28, 2010, **Nurse Managers (or designees)** where the affected NIBP monitors are used shall review the White Paper (Reference 1) and the Application Note (Reference 2) to:

- a. increase familiarity with the limitations of NIBP monitoring
- b. make their staff aware of possible partial NIBP readings
- c. inform their staff of the techniques recommended for improved accuracy and repeatability of results
- d. make sure they have the correct NIBP cuffs
- e. inform their staff to be aware that even after implementation of the software update, there will be clinical situations where a mean only NIBP reading can occur

4. By COB June 30, 2010, the **Biomedical Engineering Supervisor (or designee)** has verified that the software installations are complete.

5. By COB July 14, 2010, the **Patient Safety Manager** will document on the VHA Hazard Alerts and Recalls website that facility leadership has reviewed and implemented these actions.

Source: A VA Medical Center

- References:**
1. Philips White Paper - NIBP Mean-Only Readings
<http://www.patientsafety.gov/alerts/AL10-11-PMD - White Paper - NIBP Mean Only Readings.pdf>
 2. Philips Non Invasive Blood Pressure Measurement Application Note –
<http://www.patientsafety.gov/alerts/AL10-11-PMD - Non-Invasive Blood Pressure Measurement - Application Note.pdf>
 3. Philips software compatibility matrix for the various MMS systems –
<http://www.patientsafety.gov/alerts/AL10-11-IntelliVueSoftwareCompatabilityMatrix.pdf>

- Attachments:**
1. Determining the software revision level and acquiring the Rev G Support Tool and related documents from the Philips InCenter support site
 2. Philips InCenter Service Site screen capture showing the sequence getting to the Intellivue Support Tool Rev G.00.07

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Philips Customer Care Solutions Center at (800) 722-9377.

Attachment 1 Determining the software revision level and acquiring the Rev G Support Tool and related documents from the Philips InCenter support site

From the Service Menu of the monitor, Biomedical Engineering staff can access the software revision level. If the software revision is at level G, the patch is already included. If the revision level is lower than F.01.46, the patch can be installed if the site has the Rev G Support Tool from Philips.

If the site does not have the Rev G Software Support Tool, Biomedical Engineering staff can follow the steps below to access the Rev G Support Tool and related documents from the internet site in step 1; however the file is large, 1.15 GB. A DVD is also available. See Step 6 to order the DVD.

1. Go to <http://incenter.medical.Philips.com>
2. Enter the email address: IntellivueSW@hotmail.com and the Password: downloadG.00.07 then click on the Log In button.
3. The next web page will appear. At the top bar, select Service, move your cursor down one line over Software, then over Software Downloads, and then click on the Patient Monitoring tab.
4. A new page appears. Under the Patient Monitoring label in the box on the left, select Bedside Monitors and then click on Intellivue Series.
5. The last web page appears. Select Intellivue Support Tool G.00.07. That will provide the Support Tool G.00.07 Download Instructions and other documents for downloading as well as the Intellivue Support Tool license key request which you will need to use the Support Tool.
6. If, instead, you require the G.00.07 Support Tool on a DVD, you can order it by using the form on the web page, http://www3.medical.philips.com/resources/hsg/docs/en-us/custom/intellivue_order.asp

Attachment 2 Philips InCenter Service Site screen capture showing the sequence getting to the Intellivue Support Tool Rev G.00.07

The box on the left side of the screen shows the sequence as the service person clicks through the items on the “You are here;” line, finally reaching the Intellivue Support Tool, Rev G.00.07 page.

