URGENT - Medical Device Correction

Philips SureSigns VS3/VS4 Monitors Software Release

<Date>
<Hospital/Clinic Name>
cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

A problem has been detected with the Philips SureSigns Monitors (VS3/VS4), that, if it were to re-occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Although the existing labeling for the Philips SureSigns VS3/VS4 monitor with Philips FAST (Fourier Artifact Suppression Technology) SpO2 has performance specifications related to pulse rates up to 300 beats per minute, however the system software does not measure, display and alarm for pulse rates above 240 beats per minute. Philips is releasing a system software update[1] for the SureSigns VS3/VS4 monitors to restore the specified functionality.

Please refer to the following pages, which provide information on how to identify affected devices and instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the notice.

This notice has been reported to the appropriate Regulatory Agency.

Philips sincerely regrets the inconvenience that this may cause you. Your satisfaction with Philips' products and with our response to this issue is very important to us. Please contact your local Philips representative <Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)> with questions or concerns about this correction.

Sincerely,

[redacted]

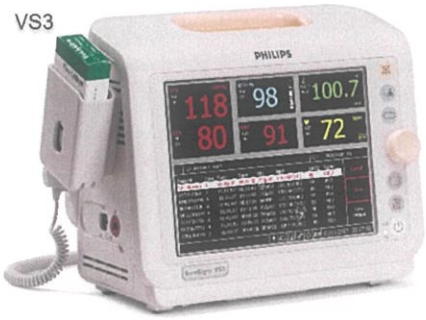
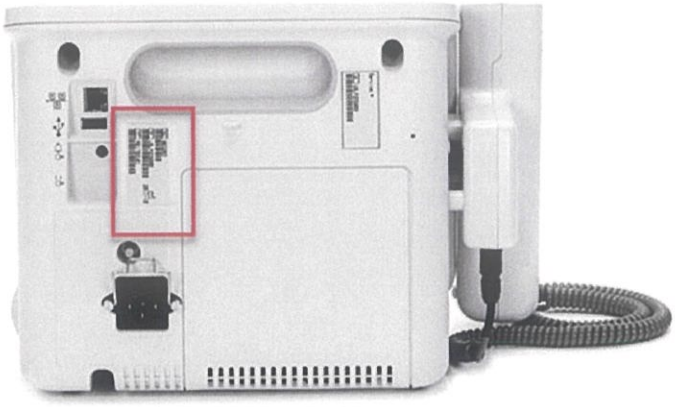
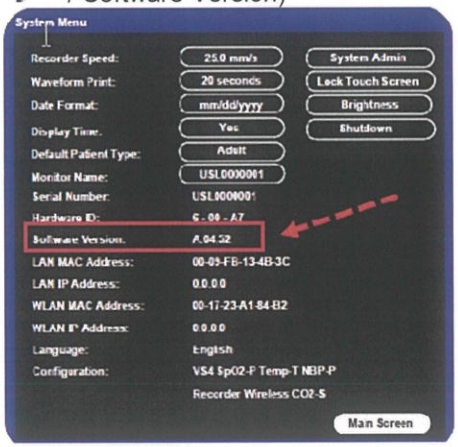
Rusty Kelly
Head of Q&R - General & Specialty Care, Quality & Regulatory

[1] The System Software update includes the optimized battery management software communicated previously on FSN86000255/CIL86000256.

<table>
<tr><td>AFFECTED PRODUCTS</td><td>The following SureSigns Monitors with software revisions up to and including A.07.32, are subject to the correction.

<table>
<tr><th>Product Number</th><th>Description</th></tr>
<tr><td>863069</td><td>SureSigns VS3 NBP</td></tr>
<tr><td>863070</td><td>SureSigns VS3 NBP, Temp</td></tr>
<tr><td>863071</td><td>SureSigns VS3 NBP, SpO2</td></tr>
<tr><td>863072</td><td>SureSigns VS3 NBP, SpO2, Rec</td></tr>
<tr><td>863073</td><td>SureSigns VS3 NBP, SpO2, Temp</td></tr>
<tr><td>863074</td><td>SureSigns VS3 NBP, SpO2, Temp, Rec</td></tr>
<tr><td>863283</td><td>SureSigns VS4 NBP, SPO2</td></tr>
<tr><td>863286</td><td>SureSigns VS4 Government Bundle</td></tr>
</table></td></tr>
<tr><td>PROBLEM DESCRIPTION</td><td>Although the existing labeling for the Philips SureSigns VS3/VS4 monitor with Philips FAST (Fourier Artifact Suppression Technology) SPO2 has performance specifications related to pulse rates up to 300 beats per minute, however the system software does not measure, display and alarm for pulse rates above 240 beats per minute.</td></tr>
<tr><td>HAZARD INVOLVED</td><td>Failure to display and alarm for pulse rates above 240 beats per minutes could cause the clinician to overlook a patient's distressed condition, which may cause moderate injury to a patient due to delay in therapy or treatment.

Philips is unaware of any incident where the failure of these devices to measure, display and alarm for pulse rates over 240 bpm have resulted in a delay of necessary treatment or injury to a patient.</td></tr>
</table>

HOW TO IDENTIFY AFFECTED PRODUCTS	You can determine whether your device is affected by identifying the Product number and software revision. This can be performed by; a) Locate and verify the Product Number of your SureSigns VS3/VS4 Monitor, found on the back label of your monitor VS4  VS3   b) Locate and verify the software revision in the monitor (System Menu / Software Version) 
ACTION TO BE TAKEN BY CUSTOMER / USER	Upon receipt of this notification: • Promptly perform the software upgrade to each of your SureSigns VS3/VS4 monitors, as called out in the attached *Pulse Rate Software-Installation Instructions.* It details how to obtain and install the system software update. It also provides instructions on how to export the file that is created during software installation and instructions where to email the file back to Philips. • Along with the software download, the user will also receive *Instructions*

	for Use Addendums and a *Service Guide Addendum.* Review this information with all staff members who are use the device and are responsible for device management of the Philips SureSigns monitors. Please store the *Addendums* with your Philips SureSigns VS3/VS4 Monitors *Service Guide* and *Instructions for Use* documentation. • Email the file back to Philips in accordance with the instructions.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative <Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)>