

**URGENT – Medical Device Correction  
SureSigns VSi/VS2 Patient Monitors**

Dear Customer,

A problem has been identified with some Philips SureSigns VSi/VS2+ patient monitors that, if it were to 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 in order to prevent risks for patients
- 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 Instructions for Use.

Philips has learned that the VSi/VS2+ patient monitor may not be properly secured to the GCX wall mount, which may go unnoticed. This may cause the VSi/VS2+ patient monitor to fall from the wall mount which could injure a user or patient.

Philips is conducting this voluntary correction to correct these devices. Please refer to the following page which provides instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the instructions.

This issue has been reported to the appropriate regulatory agencies.

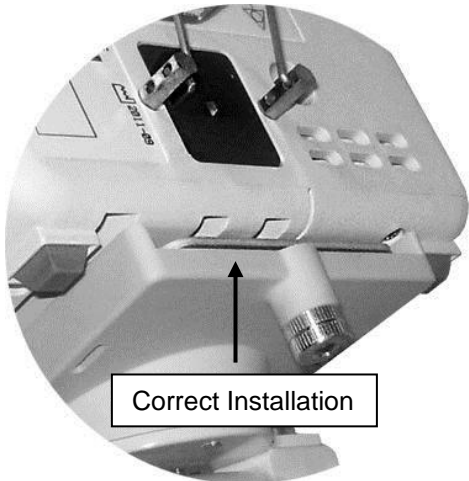
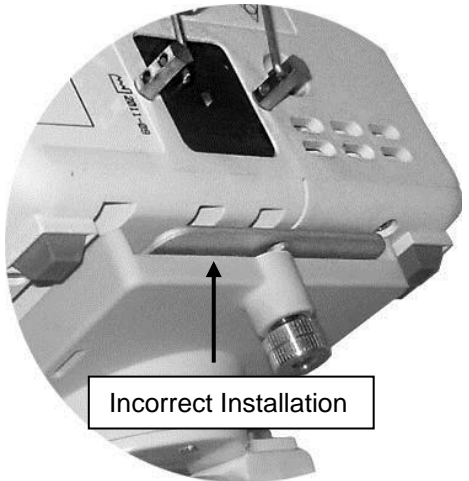
I sincerely regret the inconvenience that this may cause you. Philips has a well-earned reputation for providing products and services of the highest quality. Your satisfaction with Philips' products and with our response to this issue is very important to us. Contact your local Philips representative if you have any questions or concerns: at [<Philips representative contact details to be completed by the KM/country>](#).

Sincerely,



David J. Lanfranchi  
Director, Quality and Regulatory Affairs

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<p><b>AFFECTED PRODUCTS</b></p>	<table border="1"> <thead> <tr> <th>Model</th> <th>Part Numbers</th> <th>Serial Number Range</th> </tr> </thead> <tbody> <tr> <td>VSi/VS2+</td> <td>863275, 863276, 863277, 863278, 863279</td> <td>CN14800101-CN14801360 CN21201362-CN21202440, CN21202525, SP13701043, USPP101007</td> </tr> </tbody> </table>	Model	Part Numbers	Serial Number Range	VSi/VS2+	863275, 863276, 863277, 863278, 863279	CN14800101-CN14801360 CN21201362-CN21202440, CN21202525, SP13701043, USPP101007
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<p><b>PROBLEM DESCRIPTION</b></p>	<p>The VSi/VS2+ patient monitor may not be properly secured to the GCX wall mount, which may go unnoticed. This may cause the monitor to fall from the wall mount.</p>						
<p><b>HAZARD INVOLVED</b></p>	<p>An improperly secured SureSigns VSi/VS2+ monitor to the GCX wall mount may result in the monitor falling from the wall mount, which could cause injury to a user or patient.</p>						
<p><b>HOW TO IDENTIFY AFFECTED PRODUCTS</b></p>	<p>The AFFECTED PRODUCTS section of this notice lists the models, part numbers and serial numbers affected by this correction. The part number (REF) and serial number are located on the identification label on the rear of the device.</p>						
<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>If you use the SureSigns VSi/VS2+ patient monitors with the GCX wall mount designed for use with the device, please complete and return the enclosed Customer Reply Wall Mount Order Form indicating the number of wall mounts in use.</p> <p>Affected products may continue to be used while awaiting replacement of the mounting hardware provided that the device is properly secured per the instructions below.</p> <p>Ensure the monitor is slid fully into the wall mount bracket prior to tightening the wall mount locking screw. The edge of the mounting plate attached to the monitor should be flush with the rear edge of the wall mount bracket as shown in the picture below. After tightening the screw, push on the monitor to ensure it is securely mounted.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Correct Installation</p> </div> <div style="text-align: center;">  <p>Incorrect Installation</p> </div> </div>						

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<b>ACTIONS PLANNED BY PHILIPS</b>	After return of the enclosed Customer Reply Wall Mount Order Form, a Philips Healthcare representative will contact you to arrange for the replacement of the hardware in all affected devices.
<b>FURTHER INFORMATION AND SUPPORT</b>	If you need any further information or support concerning this issue, please contact <b>&lt;Philips representative contact details to be completed by the KM / country&gt;</b> .