

Singapore General Hospital

Outram Rd
Singapore 169608

25 July 2018

TO: WHOM IT MAY CONCERN

CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to the Philips SureSigns VS & VM Monitors, and View Station due to FCO 86000255. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: please refer to page 2

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date:



URGENT - Medical Device Correction

Philips SureSigns VS & VM Monitors, and View Station (VSV) User Maintenance of Lithium Ion Batteries

Dear Customer,

A problem has been detected in the Philips SureSigns Monitors (VS2/3/4, VM3/4/6/8 & VSV), that, if it were to re-occur, could pose a risk for patients or users. 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.

Philips has received several reports in which SureSigns monitors with lithium ion batteries that have exceeded their specified replacement interval have overheated or ignited. These batteries should be replaced every 3 years or upon reaching 300 charge-discharge cycles. Although the monitors can display the battery's status, the existing labeling for these monitors does not include full instructions on when to replace the batteries or the potential hazards if they fail to do so. Philips is therefore issuing a SureSigns Monitors (VS2/3/4, VM3/4/6/8 & VSV) *Service Guide addendum* with information to assist with managing the battery and its replacement. The *Service Guide Addendum* is included with this letter.

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.

Additionally, Philips is developing a system software update for the SureSign monitors that will make it easier for users to manage the monitors' battery over its lifetime. You will be notified when the software update is available. In the interim it is safe to use your monitor if the directions in this notice, the *Instructions for Use* and the *Service Guide addendum* are followed.

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* <Philips representative contact details to be completed by the KM / country> with questions or concerns about this correction.

Sincerely,



Yini He
Director of Quality and Regulatory Affairs

Director of Quality &
Regulatory
Affairs**AFFECTED
PRODUCTS**

The affected products are all SureSigns Monitors and Viewing Stations manufactured through May 3, 2018 that are capable of operating under battery power and have batteries presently installed.

Specifically, the following SureSigns Vital Signs Monitors with software releases up to and including A.07.24

Product	Description
863069	SureSigns VS3 NBP
863070	SureSigns VS3 NBP, Temp
863071	SureSigns VS3 NBP, SpO2
863072	SureSigns VS3 NBP, SpO2, Rec
863073	SureSigns VS3 NBP, SpO2, Temp
863074	SureSigns VS3 NBP, SpO2, Temp, Rec
863079	SureSigns VS2 NBP
863080	SureSigns VS2 NBP, SPO2
863081	SureSigns VS2 NBP, SpO2, Temp
863082	SureSigns VS2 NBP, SpO2, Temp, Rec
863283	SureSigns VS4 NBP, SPO2
863286	SureSigns VS4 Government Bundle

Additionally, the following SureSigns Patient Monitors with software releases up to and including A.03.96.

Product	Description
863063	SureSigns VM 4 Patient Monitor
863064	SureSigns VM 6 Patient Monitor
863065	SureSigns VM 6 Patient Monitor
863066	SureSigns VM 8 Patient Monitor
863068	SureSigns VM 8 Patient Monitor
863077	SureSigns VM 3 Patient Monitor
863085	SureSigns VM 4 Patient Monitor
863086	SureSigns VM 6 Patient Monitor
863317	SureSigns VM 8 SE Patient Monitor
863287	SureSigns VM4 Government Bundle
863288	SureSigns VM6 Government Bundle
863289	SureSigns VM8 Government Bundle

Lastly, the following SureSigns View Station (VSV) with software releases up to and including A.00.50.

Product	Description
863067	Vital Signs View Station (VSV)

NOTE: The VSi (863275, 863276, 863277), VS2+ (863278, 863279) and VM1 (863264, 863265, 863266) are not affected by this Field Safety Notice.

PROBLEM DESCRIPTION	<p>Philips has received several reports in which monitors with lithium ion batteries that had exceeded their battery life expectancy have overheated or ignited. These batteries should be replaced every 3 years or upon reaching 300 charge-discharge cycles.</p> <p>Although the Philips SureSigns VS & VM Monitors and View Station (VSV) can display actual information on either or both battery age and charge-discharge cycles, the existing labeling does not include full instructions on how to use this information to determine when to replace the battery.</p>
HAZARD INVOLVED	<p>An overheated battery may in turn cause the device case to overheat and possibly melt or cause the device to ignite, which can cause injury to a patient, nearby users, or cause damage to property.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>You can determine whether your device is affected by identifying the software revision. This can be performed by;</p> <ul style="list-style-type: none"> a) Locate and verify the model number of your SureSigns Monitor, found on the cover page of the <i>Instructions for Use</i>. b) Locate and verify the revision screen in the monitor software (System Menu / Rotate Wheel / Software Version Revision) or <p>To determine if your device is capable of battery operation, verify in the bottom right corner of the monitor's display if a battery symbol is exhibited.</p> <div data-bbox="565 1003 1291 1390" data-label="Image"> </div>

ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Upon receipt of this notification, carefully read the enclosed SureSigns Addendum to the <i>Service Guide</i>. Promptly perform the Battery Maintenance that is called out in the Addendum for each of your affected Philips SureSigns VS & VM Monitors and View Station (VSV) by determining if the <i>Battery Information Screen</i> indicates if the battery cycle count exceeds the limit of 300 cycles, or the battery is older than three (3) years. If so, the battery needs to be replaced. The replacement battery can be ordered using the standard Philips replacement processes.</p> <p>Details on how to replace the battery can be found in the Philips SureSigns VS & VM Monitors and View Station (VSV) <i>Service Guide</i>.</p> <p>Review this information with all staff members who are responsible for device management of the Philips SureSigns VS & VM Monitors and View Station (VSV).</p> <p>Please store the <i>Service Guide Addendum</i> with your Philips SureSigns VS & VM Monitors and View Station (VSV) Service Guide documentation.</p> <p>Complete and return the response card provided.</p>
ACTIONS PLANNED BY PHILIPS	<p>In addition to providing the <i>Service Guide Addendum</i> and this notice, Philips plans to release a customer installable, software update for SureSigns Monitors (VS2/3/4, VM3/4/6/8 & VSV) that will provide system warnings to assist users in managing the battery replacement cycle. You will be notified when the customer installable software update is available.</p> <p>In the interim, it is safe to use your monitor if the directions in this notice, the <i>Instructions for Use</i> and <i>Service Guide Addendum</i> are followed.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p><Philips representative contact details to be completed by the KM / country></p>