

Urgent - Medical Device Correction
Philips SureSigns VS & VM Monitors, and View Station (VSV)
Battery Management Software Release

Dear Customer,

In July 2018, Philips communicated the attached Field Safety Notice (FSN86000255,256) to all affected customers with Philips SureSigns VS & VM Monitors, and View Station (VSV) devices.

We are notifying all customers that Philips has released a customer installable system software update for all the SureSigns Monitors (VS2/3/4, VM3/4/6/8 & VSV) called out in this prior document. This system software will enhance the users' ability to monitor battery condition and will alert users when it is time to replace the battery.

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 notification.

If you need any further information or support concerning this issue, please contact your local Philips representative:

<Philips representative contact details to be completed by the KM / country>

Philips apologizes for any inconveniences caused by this problem. Your satisfaction with Philips' products and with our response to this issue is very important to us.

Sincerely,



Vivian Dai
Post Market Surveillance Manager

HOW TO IDENTIFY AFFECTED PRODUCTS

You can determine whether your device is affected by identifying the product number. This can be performed by;

- a) Locate and verify the Product Number of your SureSigns Monitor, found on the cover page of the *Instructions for Use* or on the back label of the monitor.



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

ADVICE ON ACTIONS BY CUSTOMER / USER

Upon receipt of this notification, promptly perform the software upgrade to each of your SureSigns monitors (VS3/4, VM3/4/6/8 & VSV), as called out in the attached *Battery Management Software-Installation Instructions*. It details how to obtain and install the Battery Management software. It also provides instructions on how to export the file that is created during system software installation and instructions where and how to email the file to Philips.

Along with the software, the user will download the *Instructions for Use Addendum* and *Service Guide Addendum*. Review this information with all staff members who are responsible for device management of the Philips SureSigns monitors. Please store the *Addendums* with your Philips SureSigns Monitors *Service Guide* and *Instructions for Use* documentation.

Should it be necessary, a replacement battery can be ordered using the standard Philips replacement processes. Details on how to replace the battery can be found in the Philips SureSigns monitor *Service Guide*.

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.

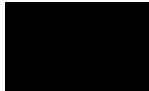
Philips has received several reports in which SureSigns monitors with lithium ion batteries that have exceeded their specified replacement interval have overheated or ignited. These batteries should be replaced every 3 years or upon reaching 300 charge-discharge cycles. Although the monitors can display 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