

## **URGENT – Medical Device Correction Philips Patient Monitor**

Dear Customer,

A labeling error has been detected on some Philips SureSigns VSi, SureSigns VS2+ monitors. This Field Safety Notice is intended to inform you about:

- what the problem is
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

### **This document contains important information for the 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 identified that some SureSigns VSi, VS2+ products (see AFFECTED PRODUCTS section), have a printing error on the Date of Manufacture. This FCO86000250A supersedes the previous FCO86000241A which was put on hold.

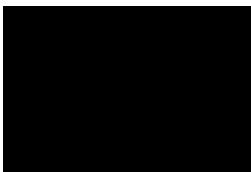
If you need any further information or support concerning this issue, please contact your local Philips representative:

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

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Yini He  
Director of Quality and Regulatory  
VSS, BG PCMS

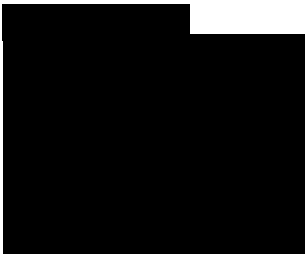
## URGENT – Medical Device Correction

### Philips Patient Monitor

<b>AFFECTED PRODUCTS</b>	<p><b>Model:</b> SureSigns VSi - NBP <b>Product:</b> 863275</p> <p>[REDACTED]</p> <p><b>Model:</b> SureSigns VSi - NBP/SPO2 <b>Product:</b> 863276 <b>Serial Numbers:</b></p> <p>[REDACTED]</p> <p><b>Model:</b> SureSigns VSi - NBP/SPO2/Temp/Wireless <b>Product:</b> 863277</p> <p>[REDACTED]</p> <p><b>Model:</b> SureSigns VS2+ NBP/SPO2 <b>Product:</b> 863278 <b>Serial Numbers:</b></p> <p>[REDACTED]</p>
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### Philips Patient Monitor

	<p>CN42728701~CN42728793 CN42728804~CN42728867 CN42728918~CN42728933</p> <p><b>Model:</b> SureSigns VS2+ NBP/SPO2/Wireless <b>Product:</b> 863279</p> 
<b>PROBLEM DESCRIPTION</b>	Some of SureSigns VSi, VS2+ products labels have a printing error on the Date of Manufacture. This FCO86000250A supersedes the previous FCO86000241A which was put on hold. New labels need to be applied to the affected units.
<b>HAZARD INVOLVED</b>	Not applicable. No hazard / harm to any patients or users.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	The AFFECTED PRODUCTS section of this notice lists the models, product numbers and serial numbers affected by this correction. The product, model, and serial number are located on the identification label on the rear case of the device.
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	The affected products may continue to be used because this Date of Manufacture information on the serial number label, does not impact any of device function or operation.
<b>ACTIONS PLANNED BY PHILIPS</b>	Philips will provide a new label with no printing error for each affected unit. An instruction will be provided to the impacted customer on how to do the correction. A Philips Healthcare representative will contact you to arrange for the correction.
<b>FURTHER INFORMATION AND SUPPORT</b>	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>