

## 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.

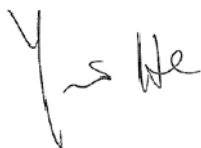
Please retain a copy with the equipment Instruction for Use.

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 or the UK Philips Customer Care Service Centre on 0870 532 9741. 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

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<p><b>AFFECTED PRODUCTS</b></p>	<p><b>Model:</b> SureSigns VSi - NBP  <b>Product:</b> 863275  <b>Serial Numbers:</b>  CN42727374~CN42727379  CN42727563~CN42727569  CN42728139~CN42728173  CN42727495; CN42727496; CN42727640; CN42727706; CN42727893; CN42728040;  CN42728058; CN42728728; CN42728729; CN42728809; CN42728810; CN42728811;  CN42728922</p> <p><b>Model:</b> SureSigns VSi - NBP/SPO2  <b>Product:</b> 863276  <b>Serial Numbers:</b>  CN42727131~CN42727133  CN42727315~CN42727371  CN42727401~CN42727494  CN42727588~CN42727699  CN42727700~CN42727705  CN42727891~CN42727899  CN42728012~CN42728067  CN42728140~CN42728369  CN42728644~CN42728700  CN42728734~CN42728736  CN42728808~CN42728929</p> <p><b>Model:</b> SureSigns VSi - NBP/SPO2/Temp/Wireless  <b>Product:</b> 863277  <b>Serial Numbers:</b>  CN42727134; CN42727386; CN42727387; CN42727388; CN42727389; CN42727390;  CN42727391; CN42727392; CN42727393; CN42727394; CN42727395; CN42727396;  CN42728255; CN42728256; CN42728573; CN42728768; CN42728769; CN42728770</p> <p><b>Model:</b> SureSigns VS2+ NBP/SPO2  <b>Product:</b> 863278  <b>Serial Numbers:</b>  CN42726965; CN42726970  CN42727135~CN42727285  CN42727308~CN42727314  CN42727372~CN42727407  CN42727452~CN42727497  CN42727523~CN42727587  CN42727647~CN42727681  CN42727707~CN42727759  CN42727845~CN42727865  CN42727900~CN42727901  CN42728006~CN42728011  CN42728108~CN42728176  CN42728370~CN42728399  CN42728400~CN42728432  CN42728565~CN42728588</p>
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	<p>CN42728701~CN42728793 CN42728804~CN42728867 CN42728918~CN42728933</p> <p><b>Model:</b> SureSigns VS2+ NBP/SPO2/Wireless <b>Product:</b> 863279 <b>Serial Numbers:</b> CN42727427~CN42727499 CN42727500~CN42727522 CN42727709~CN42727733 CN42727866~CN42727892 CN42728206~CN42728254 CN42728593~CN42728599 CN42728600~CN42728602</p>
<p><b>PROBLEM DESCRIPTION</b></p>	<p>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.</p>
<p><b>HAZARD INVOLVED</b></p>	<p>Not applicable. No hazard / harm to any patients or users.</p>
<p><b>HOW TO IDENTIFY AFFECTED PRODUCTS</b></p>	<p>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.</p>
<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>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.</p>
<p><b>ACTIONS PLANNED BY PHILIPS</b></p>	<p>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.</p>
<p><b>FURTHER INFORMATION AND SUPPORT</b></p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.</p>