

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.

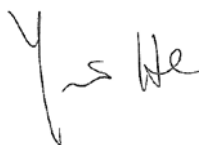
Philips has identified that some SureSigns VSi, VS2+ products (see AFFECTED PRODUCTS section), have the Date of Manufacture on its serial number label as “%DoM”, instead of the specific date in the format of YYYY-MM.

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>AFFECTED PRODUCTS</p>	<p>Model: SureSigns VSi - NBP Product: 863275 Serial Numbers: CN42727374~CN42727379 CN42727563~CN42727569 CN42728139~CN42728173 CN42727495; CN42727496; CN42727640; CN42727706; CN42727893; CN42728040; CN42728058; CN42728728; CN42728729; CN42728809; CN42728810; CN42728811; CN42728922</p> <p>Model: SureSigns VSi - NBP/SPO2 Product: 863276 Serial Numbers: CN42727131~CN42727133 CN42727315~CN42727371 CN42727401~CN42727494 CN42727588~CN42727699 CN42727700~CN42727705 CN42727891~CN42727899 CN42728012~CN42728067 CN42728140~CN42728369 CN42728644~CN42728700 CN42728734~CN42728736 CN42728808~CN42728929</p> <p>Model: SureSigns VSi - NBP/SPO2/Temp/Wireless Product: 863277 Serial Numbers: CN42727134; CN42727386; CN42727387; CN42727388; CN42727389; CN42727390; CN42727391; CN42727392; CN42727393; CN42727394; CN42727395; CN42727396; CN42728255; CN42728256; CN42728573; CN42728768; CN42728769; CN42728770</p> <p>Model: SureSigns VS2+ NBP/SPO2 Product: 863278 Serial Numbers: CN42726965; CN42726970 CN42727135~CN42727285 CN42727308~CN42727314 CN42727372~CN42727407 CN42727452~CN42727497 CN42727523~CN42727587 CN42727647~CN42727681 CN42727707~CN42727759 CN42727845~CN42727865 CN42727900~CN42727901 CN42728006~CN42728011</p>
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	<p>CN42728108~CN42728176 CN42728370~CN42728399 CN42728400~CN42728432 CN42728565~CN42728588 CN42728701~CN42728793 CN42728804~CN42728867 CN42728918~CN42728933</p> <p>Model: SureSigns VS2+ NBP/SPO2/Wireless Product: 863279 Serial Numbers: CN42727427~CN42727499 CN42727500~CN42727522 CN42727709~CN42727733 CN42727866~CN42727892 CN42728206~CN42728254 CN42728593~CN42728599 CN42728600~CN42728602</p>
PROBLEM DESCRIPTION	Some SureSigns VSi, VS2+ products have the Date of Manufacture on its serial number label as “%DoM”, instead of the specific date in the format of YYYY-MM.
HAZARD INVOLVED	Not applicable. No hazard / harm to any patients or users.
HOW TO IDENTIFY AFFECTED PRODUCTS	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.
ACTION TO BE TAKEN BY CUSTOMER / USER	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.
ACTIONS PLANNED BY PHILIPS	Philips will provide a new label with “Date of Manufacture” 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.
FURTHER INFORMATION AND SUPPORT	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.