

## **URGENTE - Azione correttiva per dispositivo medico**

### **Monitor Philips SureSigns VS3/VS4 Versione software**

Gentile Cliente,

è stato riscontrato un problema nei monitor Philips SureSigns (VS3/VS4) che, se dovesse verificarsi di nuovo, potrebbe rappresentare un rischio per i pazienti. La presente comunicazione ha lo scopo di segnalare quanto segue:

- la natura del problema e le circostanze in cui potrebbe verificarsi
- le misure da adottare da parte del Cliente/utilizzatore per prevenire eventuali rischi per i pazienti o gli operatori
- le contromisure previste da Philips per risolvere il problema

**Il presente documento contiene informazioni importanti per continuare a utilizzare la strumentazione in modo sicuro e corretto.**

La invitiamo a leggere con attenzione le informazioni riportate di seguito e a divulgarne i contenuti a tutto il personale operativo di reparto. È fondamentale comprendere le implicazioni di questa comunicazione.

Conservare una copia da allegare alle Istruzioni d'uso delle apparecchiature.

Sebbene l'etichettatura corrente per il monitor Philips SureSigns VS3/VS4 con algoritmo Philips FAST-SpO2 (con tecnologia di soppressione degli artefatti secondo l'analisi di Fourier) riporti specifiche operative relative a frequenze del polso fino a 300 battiti al minuto, il software di sistema non rileva, visualizza e segnala con un allarme frequenze del polso superiori a 240 battiti al minuto. Per ripristinare la funzionalità specificata, Philips ha rilasciato un aggiornamento del software di sistema<sup>1</sup> per i monitor SureSigns VS3/VS4.

Per informazioni sull'identificazione dei dispositivi interessati e sui provvedimenti da adottare, La invitiamo a leggere attentamente le pagine seguenti. La invitiamo, inoltre, ad attenersi alle indicazioni fornite nella sezione "Misure da adottare da parte del cliente" del documento.

La presente comunicazione è stata inoltrata all'ente competente.

Philips si scusa per eventuali inconvenienti causati da questo problema. La soddisfazione dei nostri Clienti per i prodotti Philips e per la risposta che saremo in grado di dare in questa circostanza, sono per noi di primaria importanza. Per qualsiasi domanda o chiarimento sulla presente azione correttiva, **La invitiamo a contattare il rappresentante Philips di zona:**

Distinti saluti,

Rusty Kelly  
Head of Q&R - General & Specialty Care, Quality & Regulatory

<sup>1</sup> Tale aggiornamento include il software ottimizzato di gestione della batteria comunicato nel precedente avviso FSN86000255/CIL86000256.


<b>PRODOTTI INTERESSATI</b>	<p>Questa azione correttiva interessa i seguenti monitor SureSigns con versioni software A.07.32 e precedenti.</p> <table border="1" data-bbox="513 275 1253 697"> <thead> <tr> <th data-bbox="513 275 716 331">Codice prodotto</th> <th data-bbox="722 275 1253 331">Descrizione</th> </tr> </thead> <tbody> <tr> <td data-bbox="513 340 716 373">863069</td> <td data-bbox="722 340 1253 373">SureSigns VS3 con NBP</td> </tr> <tr> <td data-bbox="513 382 716 415">863070</td> <td data-bbox="722 382 1253 415">SureSigns VS3 con NBP, Temp</td> </tr> <tr> <td data-bbox="513 424 716 457">863071</td> <td data-bbox="722 424 1253 457">SureSigns VS3 con NBP, SpO2</td> </tr> <tr> <td data-bbox="513 466 716 522">863072</td> <td data-bbox="722 466 1253 522">SureSigns VS3 con NBP, SpO2, registratore</td> </tr> <tr> <td data-bbox="513 531 716 564">863073</td> <td data-bbox="722 531 1253 564">SureSigns VS3 con NBP, SpO2, Temp</td> </tr> <tr> <td data-bbox="513 573 716 627">863074</td> <td data-bbox="722 573 1253 627">SureSigns VS3 con NBP, SpO2, Temp, registratore</td> </tr> <tr> <td data-bbox="513 636 716 669">863283</td> <td data-bbox="722 636 1253 669">SureSigns VS4 con NBP, SPO2</td> </tr> <tr> <td data-bbox="513 678 716 711">863286</td> <td data-bbox="722 678 1253 711">SureSigns VS4 Government Bundle</td> </tr> </tbody> </table>	Codice prodotto	Descrizione	863069	SureSigns VS3 con NBP	863070	SureSigns VS3 con NBP, Temp	863071	SureSigns VS3 con NBP, SpO2	863072	SureSigns VS3 con NBP, SpO2, registratore	863073	SureSigns VS3 con NBP, SpO2, Temp	863074	SureSigns VS3 con NBP, SpO2, Temp, registratore	863283	SureSigns VS4 con NBP, SPO2	863286	SureSigns VS4 Government Bundle
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<b>DESCRIZIONE DEL PROBLEMA</b>	<p>Sebbene l'etichettatura corrente per il monitor Philips SureSigns VS3/VS4 con algoritmo Philips FAST-SPO2 (con tecnologia di soppressione degli artefatti secondo l'analisi di Fourier) riporti specifiche operative relative a frequenze del polso fino a 300 battiti al minuto, il software di sistema non rileva, visualizza e segnala con un allarme frequenze del polso superiori a 240 battiti al minuto.</p>																		
<b>RISCHI CONNESSI</b>	<p>La mancata visualizzazione e segnalazione con un allarme di frequenze del polso superiori a 240 battiti al minuto può causare la mancata individuazione da parte del medico di una criticità nelle condizioni del paziente, con conseguente ritardo nella somministrazione della terapia o del trattamento e lesioni moderate al paziente stesso.</p> <p>Philips non è a conoscenza di ritardi nella somministrazione di trattamenti necessari o lesioni a un paziente causati dalla mancata rilevazione, visualizzazione e segnalazione con un allarme da parte di questi dispositivi di frequenze del polso superiori a 240 battiti al minuto.</p>																		

**COME IDENTIFICARE I PRODOTTI INTERESSATI**

È possibile determinare se il dispositivo in uso è interessato dalla presente comunicazione identificandone il numero di parte e la versione software. Questa operazione può essere eseguita nei seguenti modi:

- a) Individuando e verificando il numero di parte del monitor SureSigns VS3/VS4 in uso, presente sull'etichetta posteriore del monitor



- b) Individuando e verificando la versione software del monitor (System Menu  / Software Version (Menu di sistema / Versione software)



**MISURE DA ADOTTARE DA PARTE DEL CLIENTE/UTENTE**

Alla ricezione della presente notifica:

- Eseguire tempestivamente l'aggiornamento del software su ciascuno dei monitor SureSigns VS3/VS4 in uso, come indicato nelle *istruzioni per l'installazione del software per la frequenza del polso* allegate. Questo documento fornisce istruzioni su come ottenere e installare l'aggiornamento del software di sistema. Fornisce inoltre istruzioni su come esportare il file creato durante l'installazione del software e inviarlo

	<p>per e-mail a Philips.</p> <ul style="list-style-type: none"><li>• Unitamente alle istruzioni per scaricare il software, l'utente riceverà anche l'<i>addendum alle Istruzioni d'uso</i> e l'<i>addendum alla Service Guide</i> (Guida per l'assistenza tecnica, disponibile solo in inglese). Rivedere queste informazioni con tutti i membri dello staff che utilizzano il dispositivo e sono responsabili della gestione del dispositivo per i monitor Philips SureSigns. Conservare gli <i>Addendum</i> insieme alla <i>Service Guide</i> (Guida per l'assistenza tecnica, disponibile solo in inglese) e alle <i>Istruzioni d'uso</i> dei monitor Philips SureSigns VS3/VS4.</li></ul> <ul style="list-style-type: none"><li>• Inviare nuovamente il file per email a Philips come indicato nelle istruzioni.</li></ul>
<b>ULTERIORI INFORMAZIONI E ASSISTENZA</b>	<p>Per ulteriori chiarimenti e per ricevere assistenza, La invitiamo a contattare l'organizzazione locale di Philips:</p> <p><b>0800 80 3000</b></p>

## SureSigns VS3/VS4 Vital Signs Monitors Pulse Rate Software Installation Instructions

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### Overview

These Installation Instructions are intended for biomedical engineers, technicians, or personnel responsible for troubleshooting, repairing, and maintaining Philips patient monitoring systems.

These Installation Instructions are strictly to update the device with the software to monitor the health of the battery. These instructions require access to password-protected functions on the device.

These Installation Instructions are to be used in conjunction with the monitor's Service Guide for the following devices with software releases up to and including A.07.32.

Product	Description
863069	SureSigns VS3 NBP
863070	SureSigns VS3 NBP, Temp
863071	SureSigns VS3 NBP, SpO <sub>2</sub>

863072	SureSigns VS3 NBP, SpO <sub>2</sub> , Rec
863073	SureSigns VS3 NBP, SpO <sub>2</sub> , Temp
863074	SureSigns VS3 NBP, SpO <sub>2</sub> , Temp, Rec
863283	SureSigns VS4 NBP, SpO <sub>2</sub>
863286	SureSigns VS4 Government Bundle

## Philips InCenter

You will need access to the Philips InCenter, which requires an active registration and password.

Before you register, obtain the serial number of the monitor you plan to include in your registration. The serial number is located on the product identification label on the rear of case of the monitor.

To register:

Step	
1.	Access the Philips InCenter website at <b><a href="http://incenter.medical.philips.com">incenter.medical.philips.com</a></b> .
2.	Click <b>Need Help?</b> .
3.	Under <b>Software Updates</b> , Click <b>Click here for SureSigns patient monitor account registration</b> . The <b>SureSigns InCenter Registration Form</b> appears.
4.	Enter your personal information and answer the questions, and then click <b>Submit</b> .  After your information is processed, an email with temporary login information is sent to the email address you entered. It may take 3 days to receive the email.

## Prior to Software Installation

### Retrieving Documentation


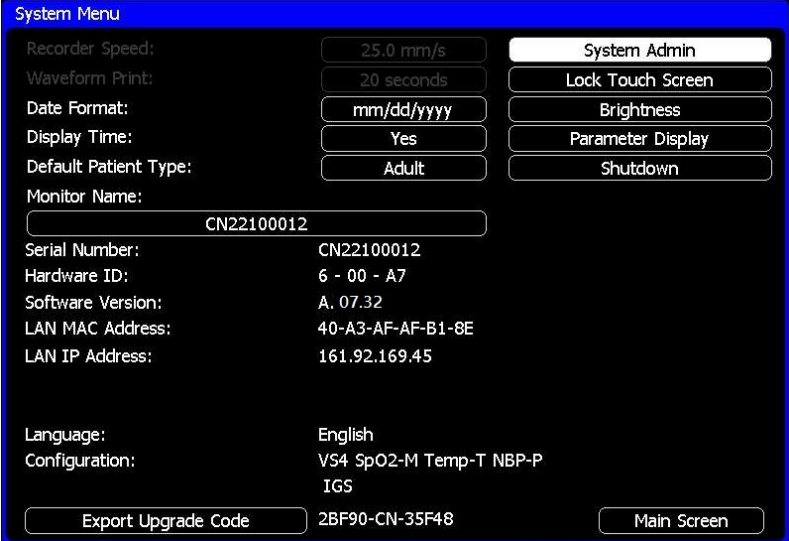
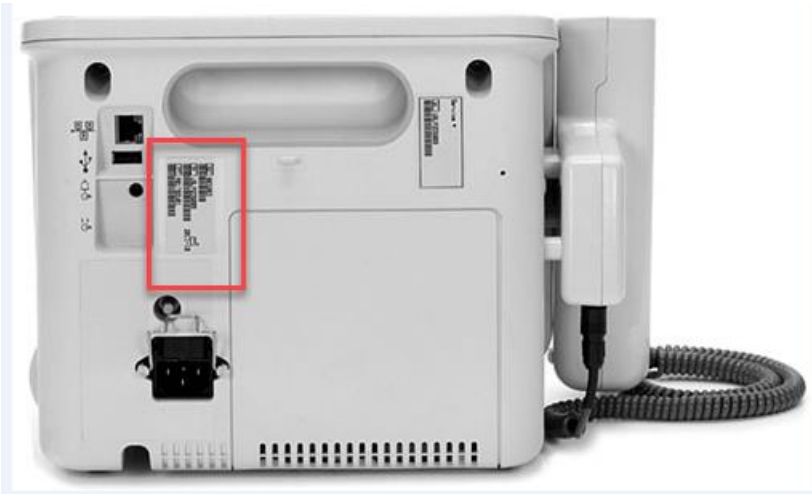
The following documentations should be readily available when performing the installation. These documents can be retrieved from Philips InCenter.

- Installation and Configuration Guide (453564649971/453564650041)
- Service Guide (453564649981/453564650051) and Addendum (453564865971)
- Instruction for Use (453564303651/453564643641) and Addendum (453564862721)

### Checking System Serial Number

The serial number displayed on the monitor must match the serial number on the back of the monitor label.

You can verify the monitor's serial number by following the steps below.

Step	
1.	<p>From the main screen, press the <b>System Menu</b> key  .</p> <p>The <b>System Menu</b> appears. See figure 1.</p>  <p><b>Figure 1 System Menu</b></p>
2.	Locate the <b>Serial Number</b> (halfway down the <b>System Menu</b> Screen).
3.	<p>Locate the serial number on the back of the monitor.</p> <p>The serial number appears in a label (marked <b>SN</b> ) on the back of the monitor. See figure 2.</p>  <p><b>Figure 2 Back View</b></p>
4.	If the serial number matches, proceed to the <i>Inspecting the Battery</i> section.
5.	<p>If the serial number does not match, the serial number will need to be reset per the steps outlined in the Service Guide Section, section “Resetting the serial number”.</p> <p>The Service Guide can be downloaded from Philips InCenter.</p>

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## Inspecting the Battery

It is very important that a Battery Maintenance, as described in Service Guide Addendum is performed. This document can be downloaded from Philips InCenter.

Performing Battery Maintenance requires access to the **Battery Info** screen. (password required)

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**NOTE** - A replacement battery may need to be ordered and available before continuing with the software installation.

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The battery in the device must meet the expected SOH and cycle count (charge/discharge).

## Retrieving Software

The system software will need to be downloaded from the Philips InCenter to a USB Flash Drive.

InCenter Login: [incenter.medical.philips.com](http://incenter.medical.philips.com)

Location of Software:

Service > Software > Software Downloads > Patient Monitoring > Bedside Monitors > SureSigns > SureSigns VS3 or SureSigns VS4 > A.07.33

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## NOTES –

- Philips recommends using a SanDisk® or Kingston® USB flash drive for software upgrades.
  - The software upgrade folder must be located in the top directory of the USB flash drive.
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## Clearing Patient Data

All patient data **MUST** be transferred to your EMR before performing the following steps.

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**WARNING** - These steps will delete all patient data on the monitor, make sure you have transferred the data to your EMR.

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Two methods are available for deleting patient data:


- Clearing data by using the **Clear Data** option (password required)
- Deleting patient records from the **Display Mode** button on the main screen

To clear the data by using the **Clear Data** option:

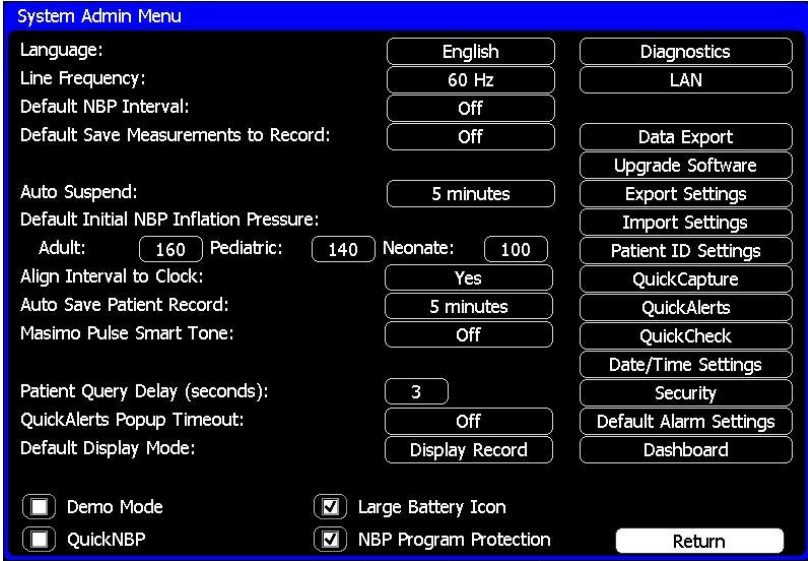
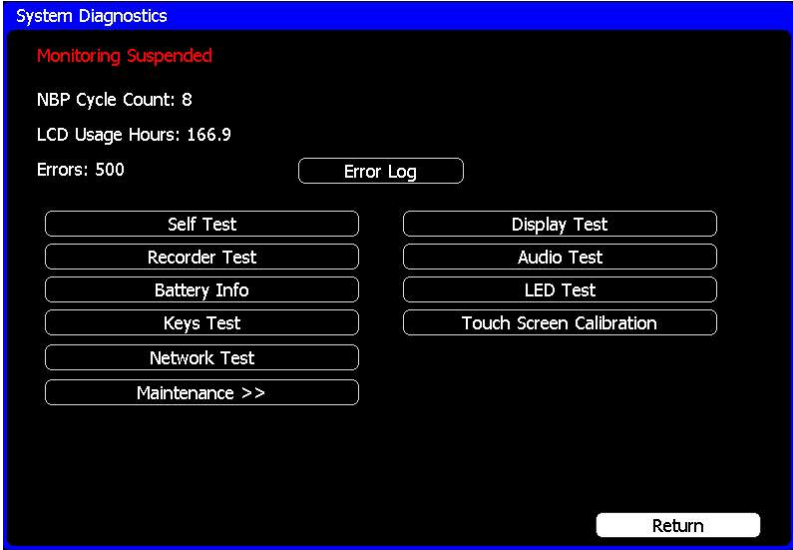
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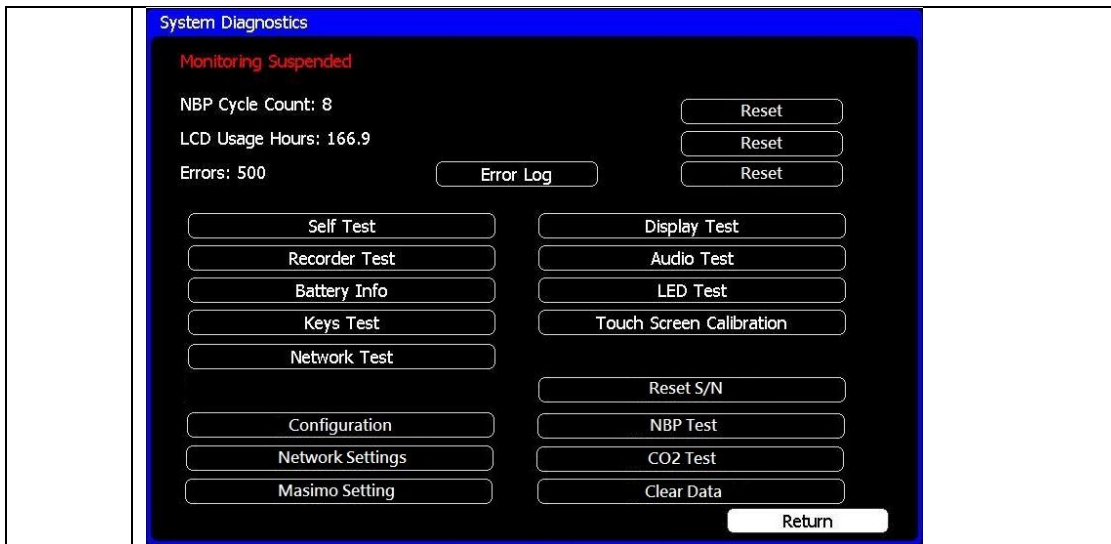
**NOTE** - This method will clear all patient data in memory. It does not clear calibration and hardware configuration data.

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Step	
1.	From the main screen, press the <b>System Menu</b> key  . The <b>System Menu</b> appears. See figure 1.
2.	Select the <b>System Admin</b> button, a <b>Password</b> window appears.



<p>3.</p>	<p>Enter the Administrator password. Click on the <b>OK</b> button.</p> <p><b>NOTE</b> – <i>The default Administor password is 2-1-5. For VS4, it is recommended to change the default Administrator password to a password defined by your institution.</i></p> <p>The <b>System Admin Menu</b> appears. See figure 3.</p>  <p><b>Figure 3 System Admin Menu</b></p>
<p>4.</p>	<p>Select the <b>Diagnostics</b> button.</p> <p>The <b>System Diagnostics</b> menu appears. See figure 4.</p>  <p><b>Figure 4 System Diagnostics</b></p>
<p>5.</p>	<p>Select the <b>Maintenance&gt;&gt;</b> button. A <b>Password</b> window appears.</p>
<p>6.</p>	<p>Enter the Maintenance password (1-2-9). Click on the <b>OK</b> button.</p> <p>The complete <b>System Diagnostics</b> menu appears, including all <b>Maintenance</b> functions. See figure 5.</p>

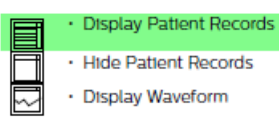


**Figure 5 System Diagnostics with Maintenance functions**

7.	<p>Select the <b>Clear Data</b> Button.</p> <p>A confirmation window appears. <b>Clear Data and restart system?</b></p> <p>Select <b>Yes</b>.</p> <p>The monitor clears the patient data and error log, and then restarts.</p>
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To delete patient records from the **Display Mode** button on the main screen:

**NOTE** - This method will clear all patient records in memory. It does not clear calibration and hardware configuration data.

Step	
1.	From the main screen, select the <b>Display Mode</b> button.
2.	<p>Select <b>Display Patient Records</b>.</p>  <p>A list of <b>Patient Records</b> appears.</p>
3.	Select the <b>Delete</b> button.
4.	<p>Select <b>Delete All Records</b>.</p> <p>A confirmation window appears. <b>Are you sure?</b></p> <p>Select <b>Yes</b>.</p> <p>The monitor clears the patient data.</p>

## Other Recommendations

Before you upgrade the software, it is recommended that you back up the system settings by exporting the current configuration settings or by recording them on the worksheets provided in the *Installation and Configuration Guide* for your monitor.

When you upgrade the software:

- Charge the battery before upgrading the software.
- Never perform a software upgrade with the monitor connected to a patient.
- Disconnect any USB peripherals.
- Do not upgrade software through a USB hub.
- If the USB port has a clamp in place, remove the clamp to ensure that the USB flash drive can be inserted completely into the USB port.

After the upgrade starts:

- Do not unplug the monitor.
- Do not remove the USB flash drive.
- Do not press any key.

## Upgrading Software

The following are the steps to upgrade the system software with a USB flash drive.

When you upgrade the software, the monitor saves all of the system settings, including the System Admin Menu settings, and the Error log.

Before you place an upgraded monitor back into service, Philips recommends that your facility establish a protocol to train users about any changes in the functionality of the monitor resulting from the software upgrade.


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**NOTE** – You will need the Administrator password to perform this task.

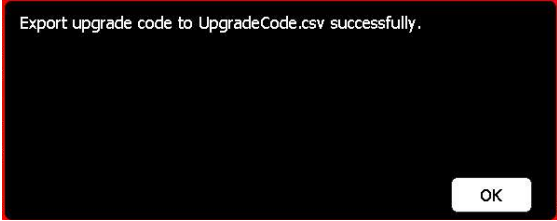
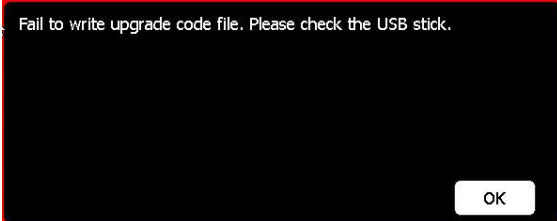
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To perform a software upgrade:

Step	
1.	Connect the monitor to AC power and power up the monitor. <b>NOTE</b> - <i>Your monitor must be connected to AC power and have a fully charged battery before upgrading the software.</i>
2.	Verify <b>Serial Number</b> displayed on the device matches the serial number on the back of the device label. Refer to <i>Checking System Serial Number</i> section for complete details.
3.	Verify Battery Maintenance has been performed. Refer to <i>Inspecting the Battery</i> section for complete details.
4.	Verify Patient Data has been deleted. Refer to <i>Clearing Patient Data</i> section for complete details. <b>NOTE</b> - <i>All Patient data must be deleted before performing the upgrade.</i>
5.	Download the system software from Philips InCenter onto a USB flash drive. <b>NOTES</b> –

	<p>The software upgrade folder must be located in the top directory of the USB flash drive.</p> <p>The USB flash drive must not be write-protected, as the upgrade code will need to be exported to the USB after the upgrade has been completed.</p> <p>Refer to <i>Retrieving software</i> section for complete details.</p>
6.	<p>Insert the USB flash drive with the software upgrade into the USB port on the back of the monitor.</p> <p><b>NOTE</b> - The USB flash drive must not be write-protected, as the upgrade code will need to be exported to the USB after the upgrade has been completed.</p>
7.	<p>From the main screen, select <b>System Menu</b> key  .</p> <p>The <b>System Menu</b> appears. See figure 1.</p>
8.	<p>Select the <b>System Admin</b> button, a <b>Password</b> window appears.</p>
9.	<p>Enter the Administrator password. Click on the <b>OK</b> button.</p> <p><b>NOTE</b> – The default Administrator password is 2-1-5. For VS4, it is recommended to change the default Administrator password to a password defined by your institution.</p> <p>The <b>System Admin Menu</b> appears. See figure 3.</p>
10.	<p>Select <b>Upgrade Software</b>.</p>
11.	<p>The monitor searches for a valid software image on the USB flash drive, and then displays the software image information in the <b>Upgrade Software</b> window. See figure 6.</p> <div data-bbox="418 1171 1247 1749" data-label="Image"> </div> <p><b>Figure 6 Upgrade Software</b></p> <p><b>NOTE</b> - If the monitor cannot find a valid software image, the screen returns to the <b>System Admin Menu</b>.</p>

	<p><b>Caution: Do not downgrade the software to an earlier version, because it may cause hardware incompatibility and loss of system settings and patient records.</b></p>
12.	<p>Select the <b>Upgrade</b> button to start the upgrade.</p> <p><b>Caution:</b></p> <p><b>After the upgrade starts:</b></p> <ul style="list-style-type: none"> <li>• Do not unplug the monitor.</li> <li>• Do not remove the USB flash drive.</li> <li>• Do not press any keys.</li> </ul> <p><b>If the upgrade is inadvertently interrupted and the main board data is lost, the main board will need to be replaced. Refer to the Service Guide for more information.</b></p>
13.	<p>The <b>Upgrade in Progress</b> indicator increments while the upgrade is in progress.</p> <p>Keep the USB flash drive in the monitor until all steps are completed.</p> <p>When the upgrade is complete, the <b>Checking Memory CRC</b> and <b>Upgrade Successful</b> messages appear.</p> <p>After the software upgrade, the monitor automatically shuts down and restarts.</p> <p><b>NOTE</b> - <i>If the upgrade fails for any reason the monitor will initiate an error message and stop the upgrade. Close the upgrade software menu. The monitor will continue running with the original revision software.</i></p>
14.	<p>After the monitor restarts, the main screen is displayed.</p>
15.	<p>From the main screen, select <b>System Menu</b> key  .</p> <p>The <b>System Menu</b> appears. See figure 1.</p>
16.	<p>Locate the <b>Export Upgrade Code</b>, at the bottom of the screen.</p> <p>The <b>Export Upgrade Code</b> button will create or update the <i>UpgradeCode.csv</i> file on the USB flash drive with the Serial number and Upgrade Code of the device.</p> <p><b>NOTE</b> - <i>When the same USB flash drive is used to update several units, the <b>UpgradeCode.csv</b> file is also updated with each successful Export Upgrade Code.</i></p> <p><i>For example, if the USB flash drive was used to update 5 devices, the UpgradeCode.csv file will contain the confirmation information for each of the 5 devices.</i></p>
17.	<p>After the system has successfully exported the upgrade code, a message will appear and you can remove the USB Flash Drive.</p>

	 <p>If no USB Flash drive, the device is unable to export the file, the following message appears.</p>  <p><b>NOTE</b> - Please contact your local Service Response Center for additional assistance if unable to export the upgrade code.</p>
18.	Select <b>OK</b> to return to the main screen.
19.	<p>Remove the USB Flash Drive from the back of the monitor.</p> <p><b>NOTES –</b></p> <p><i>The USB Flash Drive will be needed for the Installation Completion steps. Before placing the monitor back in service, it is recommended to perform the following steps detailed in the Verification of Software Installation:</i></p> <ul style="list-style-type: none"> <li>• <i>Power-on Self test</i></li> <li>• <i>System settings test</i></li> <li>• <i>Battery Management test</i></li> <li>• <i>System serial number and upgrade code test</i></li> </ul>

## Verification of Software Installation

Philips requires that you complete the following tests after upgrading the software.

### Power-on Self Test


Step	
1.	Connect the monitor to an AC power source.
2.	Press the <b>On/Standby</b> key to power up the monitor.
3.	<p>Make sure that the monitor powers up successfully as described in the following sequence:</p> <ul style="list-style-type: none"> <li>• The screen displays color bars for about five seconds.</li> <li>• The LCD turns off for three seconds, and the charging LED lights.</li> <li>• The Philips splash screen appears for one second, and a startup tone sounds.</li> <li>• It may be possible, that the Date/Time Menu appears for a new time setting. Enter Date &amp; Time.</li> </ul>

	<ul style="list-style-type: none"> <li>The main screen appears.</li> </ul>
<b>Verification Results</b>	
Pass	Expected result is that the monitor starts up and displays the main screen.
Fail	<p>Refer to the device Service Guide for details, if any of the below occurs:</p> <ul style="list-style-type: none"> <li>If the start-up and power up sequences are not as expected.</li> <li>If the LEDs do not function as expected.</li> <li>If the display does not function as expected.</li> <li>If you do not hear a startup tone, or the monitor displays the <b>Speaker Malfunc</b> error message.</li> </ul> <p><b>NOTE</b> - Please contact your local Service Response Center for additional assistance if unable to obtain expected results after the software upgrade.</p>

### System Settings Test


<b>Step</b>	
1.	From the main screen, verify that your system settings are preserved and as expected.
<b>Verification Results</b>	
Pass	Expected result is that the system settings are preserved and as expected.
Fail	<p>Refer to the device Service Guide for details, if any of the below occurs:</p> <ul style="list-style-type: none"> <li>If the system settings are not preserved and as expected.</li> </ul> <p><b>NOTE</b> - Please contact your local Service Response Center for additional assistance if unable to obtain expected results after the software upgrade.</p>

### Battery Management Test

<b>Step</b>	
1.	<p>From the main screen, verify the bottom left hand corner does not display any battery warning or alarm messages.</p> <p>If a battery warning or alarm is displayed, refer to the provided Service Guide addendum for actions to resolve the battery failure.</p>
2.	<p>From the main screen, elect the Battery Status Icon .</p> <p>Verify the following displayed values are not in RED.</p> <ul style="list-style-type: none"> <li><b>State of Health (SOH)</b></li> <li><b>Cycle Count</b></li> </ul> <p>If the above parameters and values are in RED, refer to the Service Guide addendum for actions to resolve the displayed RED values.</p>

Verification Results	
Pass	<p>Expected results are:</p> <ul style="list-style-type: none"> <li>• Monitor main screen displays <b>no</b> battery error code, battery warning or alarm messages.</li> <li>• Battery Status displays <b>no</b> SOH or Cycle Count parameters or values in RED.</li> </ul>
Fail	<p>Refer to the device Service Guide for details if any of the below occurs:</p> <ul style="list-style-type: none"> <li>• Battery error codes, Battery warning or alarms are displayed on the lower left hand corner.</li> <li>• Battery status displays SOH or Cycle Count parameter and value in RED.</li> </ul> <p><b>NOTE</b> - Please contact your local Service Response Center for additional assistance if unable to obtain expected results after the software upgrade.</p>

### System Serial Number & Software Version Test

Step	
1.	<p>From the main screen, select <b>System Menu</b> key  .</p> <p>The <b>System Menu</b> appears. See figure 1.</p>
2.	<p>Locate the <b>Serial Number</b> (halfway down the <b>System Menu</b> Screen). Verify the Serial Number matches the Serial Number on the back of the monitor.</p>
3.	<p>Locate the Software Version (just below the Serial Number). Verify the software version is A.07.33.</p>
Verification Results	
Pass	<p>Expected results are:</p> <ul style="list-style-type: none"> <li>• Serial Number matches Serial Number on the back of the monitor.</li> <li>• Software Version matches the Software Version A.07.33.</li> </ul>
Fail	<p>Refer to the device Service Guide for details if any of the below occurs:</p> <ul style="list-style-type: none"> <li>• Serial Number <b>does not</b> match Serial Number on the back of the monitor.</li> <li>• Software Version <b>does not</b> match the Software Version A.07.33.</li> </ul> <p><b>NOTE</b> - Please contact your local Service Response Center for additional assistance if unable to obtain expected results after the software upgrade.</p>



## Installation Completion

After completing the above verifications, please provide confirmation that the monitors in your institution have been updated with the Battery Management Software.

The confirmation for each upgraded monitor should have been successfully exported to the *UpgradeCode.csv* file on the USB Flash drive. The .csv file contains the system serial number and upgrade code for each upgraded monitor.

Philips has provided an easy method for sending the device confirmation back to Philips.

### Email Address

Step	
1.	Insert the USB Flash Drive used to perform the software upgrade into the USB port on the PC.
2.	Attach the <b><i>UpgradeCode.csv</i></b> file to an email.
3.	Send the email to the following address: <b><u>recall.response2@philips.com</u></b>
4.	An email will be sent confirming the receipt of the email. <b>NOTE</b> - <i>You may want to keep a copy of the email and UpgradeCode.csv file, in case you are contacted for clarification at a later date.</i>

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453564830061 Revision B



## Monitor dei segni vitali SureSigns VS3 e VS4 Addendum alle Istruzioni d'uso per la versione software A.07.33

### Italiano

Il presente Addendum contiene informazioni aggiornate per le *Istruzioni d'uso* di SureSigns VS3 e VS4 versione A.07. Conservare il presente Addendum con la documentazione di SureSigns VS3 e VS4 per consultazioni future.

Le informazioni fornite nel presente Addendum riguardano le modifiche apportate negli allarmi e nel menu Batteria. Per garantire l'uso sicuro del monitor e ottimizzarne le prestazioni, è necessario attenersi alle istruzioni fornite nel presente Addendum.

---

**Nota** — Le uniche batterie supportate per i monitor dei segni vitali SureSigns VS3 e VS4 sono le batterie smart agli ioni di litio Philips con numero di parte 989803144631 o 989803194541. L'uso di qualsiasi altra batteria non supportata (o non riconosciuta) potrebbe comportare un prolungamento dei tempi di carica e prestazioni impreviste.

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### Menu Info batteria

Il menu Info batteria, visualizzato quando si preme l'icona di stato della batteria , include gli stessi parametri presenti nel menu Diagnostica tranne Produttore della batteria, Proprietà chimiche, Errore max e Voltaggio nominale.

Il menu Info batteria (Strumenti->Amministrazione sistema->Diagnostica) mostra i parametri e i valori relativi alla batteria.

Nelle condizioni descritte di seguito, nel menu Info batteria vengono visualizzati valori in rosso:

- Il conteggio dei cicli è maggiore di 300; il valore di tale parametro viene visualizzato in rosso.
- L'età della batteria è > 3 anni, la data di produzione della batteria viene visualizzata in rosso.
- Nel rapporto di integrità (SOH), Capacità totale/Capacità nominale è  $\leq 80\%$ ; SOH viene visualizzato in rosso.
- La temperatura della batteria è  $\geq 45$  °C; il parametro e il valore vengono visualizzati in rosso.
- La batteria è sovraccarica o surriscaldata, il Registro stato viene visualizzato in rosso.
- Si è verificata una condizione di errore associata alla carica della batteria, Stato caricabatterie viene visualizzato in rosso.

Se non è possibile recuperare i dati relativi alla batteria, viene visualizzato un messaggio di avvertenza.

---

**Nota** — Il testo a comparsa dello stato della batteria rappresenta una stima e non deve essere utilizzato per la valutazione dell'accuratezza.

---

### Stato Deep Sleep

Quando la temperatura della batteria del monitor è  $\geq 60$  °C, viene visualizzato un messaggio con la richiesta di attivare lo stato Deep Sleep. Se non si accetta la richiesta entro 25 secondi, il monitor passa automaticamente nello stato Deep Sleep.

## Specifiche di allarme, Appendice A

Sono stati aggiunti i seguenti allarmi tecnici non bloccati.

Messaggio di allarme	Priorità	Causa
Batteria non riconosciuta, carica lenta	Bassa	La batteria collegata non è supportata.
Errore carica batteria	Bassa	Errore di alimentazione per la carica della batteria o malfunzionamento della batteria.
Batteria sovraccarica	Bassa	La batteria è sovraccarica.
Temp. batteria alta, carica interrotta	Bassa	La temperatura della batteria è $\geq 50$ °C oppure la batteria è nello stato "Temperatura superata".
Surriscald. batteria, arresto in corso	Alta	La temperatura della batteria è $\geq 60$ °C oppure la batteria è nello stato "Temperatura superata". La carica della batteria si interrompe immediatamente e il monitor si spegne automaticamente dopo la conferma del messaggio di errore o se il messaggio di errore viene visualizzato per 25 secondi.
Sostituire la batteria	Bassa	Il conteggio dei cicli della batteria è $> 300$ oppure il SOH della batteria è $\leq 80\%$ .
Sostituire la batteria immediatamente	Alta	Il conteggio dei cicli della batteria è $> 400$ oppure il SOH della batteria è $\leq 75\%$ .

Gli allarmi sopracitati vengono generati nel file di registro e sul monitor stesso. È possibile creare rapporti che includono questi nuovi allarmi tecnici, registri per errori e guasti della batteria, condizioni di sovraccarica, di surriscaldamento, ecc..

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453564830041 Revisione B



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## Nachtrag zur Dokumentation des SureSigns VS4 Vitalparameter-Monitors Rev. A.07.33 oder höher

Dieser Nachtrag enthält zusätzliche Informationen zum SureSigns VS4 Monitor. Bitte legen Sie diesen Nachtrag als Referenz mit der SureSigns Dokumentation ab.

### Nachtrag zu Masimo Alarminstellungen

---

<b>Warnung</b>	Die Masimo rainbow SET-Technologie gibt nur aus dem Plethysmogramm abgeleitete Pulsfrequenzwerte bis max. 240/min an. Bei einer Pulsfrequenz über 240/min sind die Pulsfrequenz- und SpO <sub>2</sub> -Werte möglicherweise ungenau und können die Zuverlässigkeit der Alarme beeinträchtigen. Um Pulsfrequenzalarme zu erhalten, stellen Sie die obere Alarmgrenze auf einen Wert unter 240/min ein.
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## Adendum Dokumentasi Monitor SureSigns VS4 Vital Signs Rilis A.07.33 atau lebih tinggi

Adendum ini berisi informasi tambahan untuk monitor SureSigns VS4. Silakan simpan Adendum ini bersama dokumentasi SureSigns Anda untuk referensi di masa depan.

### Adendum Pengaturan Alarm Masimo

---

<b>Peringatan</b>	Teknologi Masimo rainbow SET hanya memberikan nilai laju denyut hingga 240 BPM. Ketika Pulse Rate (Laju Denyut) di atas 240 BPM, maka laju denyut dan nilai SpO <sub>2</sub> mungkin tidak akurat dan dapat mempengaruhi keandalan alarm. Untuk mendapatkan alarm laju denyut, atur batas alarm tinggi ke kurang dari 240 BPM.
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## Addendum alla documentazione del monitor dei segni vitali SureSigns VS4 versione A.07.33 o versioni successive

Il presente Addendum fornisce informazioni supplementari per la documentazione relativa al monitor SureSigns VS4. Conservare il presente Addendum con la documentazione di SureSigns per consultazioni future.

### Addendum dell'impostazione degli allarmi per Masimo

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<b>Avvertenza</b>	la tecnologia Masimo rainbow SET fornisce esclusivamente valori di frequenza del polso fino a 240 BPM. Quando la frequenza del polso supera 240 BPM, è possibile che i valori della frequenza del polso e della SpO <sub>2</sub> non siano accurati e che influiscano sull'affidabilità degli allarmi. Per ottenere gli allarmi relativi alla frequenza del polso, impostare il limite di allarme superiore al di sotto di 240 BPM.
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## Tillegg til dokumentasjon for SureSigns VS4-monitor for tallverdier versjon A.07.33 eller nyere

Dette tillegget inneholder ytterligere informasjon for SureSigns VS4-monitoren. Oppbevar dette tillegget sammen med dokumentasjonen for SureSigns for fremtidige behov.

### Tillegg til Masimo-alarminnstilling

---

<b>Advarsel</b>	Masimo rainbow SET-teknologien gir bare pulsfrekvensverdier på opptil 240 slag/min. Når pulsfrekvensen er over 240 slag/min, kan det være at pulsfrekvensen og SpO <sub>2</sub> -verdiene ikke er nøyaktige, noe som kan påvirke påliteligheten til alarmene. Hvis du vil ha alarmer for pulsfrekvens, stiller du inn den øvre alarmgrensen til under 240 slag/min.
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## SureSigns VS3/VS4 Vital Signs Monitors Service Guide Addendum for Software Release A.07.33

This Addendum contains updated information for the SureSigns VS3, VS4 Release A.07 Service Guide. Please store this Addendum with your SureSigns VS3, VS4 documentation for future reference.

The topic of this Addendum is about changes in the Battery replacement, test, software upgrade and error codes. To optimize the safe use of your monitor and its performance, adherence to the instructions included in this addendum is required.

### Maintaining the Battery

#### About the Battery

The rechargeable lithium ion battery used in the VS series vital signs monitors is a smart battery with built-in circuitry that communicates battery status information to the monitor. Battery power lasts a minimum of four (4) hours of continuous monitoring with no printing and one NBP measurement every 15 minutes.

To properly maintain the battery and prevent damage to the monitor, observe these guidelines:

- If a battery shows damage or signs of leakage, replace it **immediately**.
- **Never** use a faulty battery in a monitor.
- **Never** dispose of the battery in a normal waste container.
- **Never** leave a battery inside the monitor if the monitor is not being used for a long period of time.
- **Never** store a battery that is charged to more than 50% capacity.

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#### NOTES -

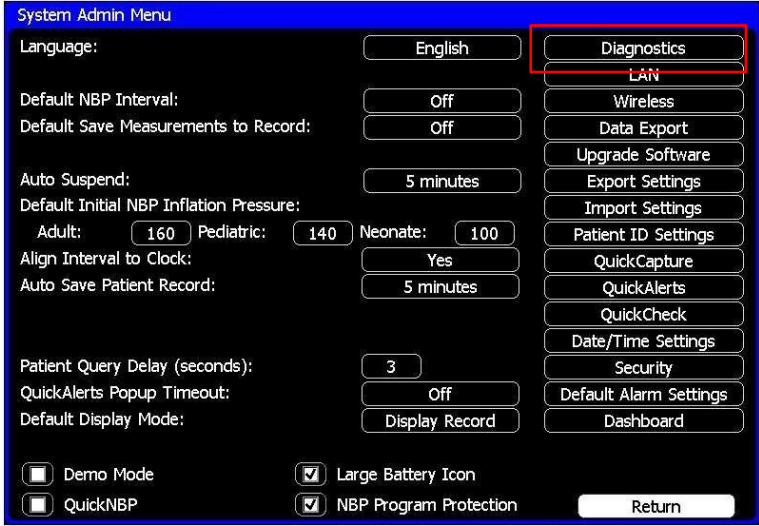
- Images shown are from a VS4 vital signs monitor. The VS3 may appear slightly different.
  - For information about the battery status indicator, please see the Instructions for Use provided with your monitor.
- 

### Viewing Battery Information

As a battery ages, its capacity decreases, and the battery status indicator becomes increasingly less accurate as the total number of charges and discharges increase. You can view the **Battery Info** screen to display information about the battery. Ensure that the monitor is connected to AC power before attempting to review battery information.

**NOTE** - If a VS3 monitor with a **Hardware ID** (displayed on the **System Menu**) of **1-1-A1** is disconnected from AC power, the **Battery Info** window displays the following message: **No data from battery. Please see Service Guide.** To view the information about the battery, reconnect the monitor to AC power.

**To view information about the battery:**

Step	
1.	On the main screen, touch <b>System</b> .  <b>NOTE</b> - <i>The VS4 vital signs monitor utilizes a touch screen. On a VS3 monitor, you must rotate the control wheel to highlight the desired menu option, then press the wheel to select it.</i>
2.	Touch <b>System Admin</b> and enter the administrator password (default is 215). The System Admin Menu appears.
3.	Touch <b>Diagnostics</b> to open the System Diagnostics menu.   <p>Figure 1 System Admin Menu</p>
4.	Touch <b>Battery Info</b> to open the Battery Info screen.

System Diagnostics

Monitoring Suspended

NBP Cycle Count: 8  
LCD Usage Hours: 166.9  
Errors: 500      Error Log

Self Test      Display Test  
Recorder Test      Audio Test  
**Battery Info**      LED Test  
Keys Test      Touch Screen Calibration

Network Test  
Maintenance >>

Return

Figure 2 System Diagnostics

5. To view the list of results, select the list to activate scrolling.

Battery Info

Parameter	Value
SOH	94% (Full Capacity/Design Capacity)
Manufacturer	EONEMOLI
Chemistry	LIION
Serial Number	#35592
Manufact. Date	04/23/2017 (mm/dd/yyyy)
Cycle Count	1
Max Error	2%
Relative Charge	74%
Absolute Charge	76%
Battery Name	E013R3
Voltage	11404 (mV)
Current	-795 (mA)
Temperature	300.60 (K) 27.60(C)
Full Capacity	7403 (mAh)
Design Voltage	11100 (mV)

Recondition      Return

Figure 3 Battery Info Screen

The **Battery Info** screen provides detailed information about battery capacity and charging status, including:

- **SOH:** State of Health, the Full Capacity/Design Capacity.
- **Cycle Count:** The number of full charge and discharge cycles calculated by the battery.

- **Max Error:** The expected margin of error in the state of the charge calculation. The Max Error value is the difference between the Relative Charge value and the Absolute Charge value.
- **Relative Charge:** The predicted remaining battery capacity, expressed as a percentage of Full Capacity. The value in the Relative Charge decreases as the battery ages. The Battery Status icon is a graphic representation of the relative charge.
- **Absolute Charge:** The predicted remaining battery capacity, expressed as a percentage of Design Capacity.
- **Full Capacity:** The predicted capacity of the battery when it is fully charged. The value in the Full Capacity field decreases as the battery ages. The difference between the value in the Full Capacity field and the value in the Design Capacity field is an indication of battery condition.
- **Design Capacity:** The capacity of a new battery.

If the battery **SOH** is  $\leq 80\%$ , or battery cycle count exceeds the recommended limit of **300 cycles**, the battery will need to be replaced (see Figure 3).

---

**NOTE** - If the message, “No data from battery. Please see Service Guide.” appears, you must reset the battery. Refer to your SureSigns VS3, VS4 Service Guide for more information.

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## WARNING

The risk of battery failure increases when a battery remains in use past 300 charge-discharge cycles or when the SOH is  $\leq 80\%$ . Such failures can result in overheating that in rare cases can cause the battery to ignite.

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## Reconditioning the Battery

Reconditioning the battery reduces the Max Error value, in turn, increases the accuracy of the Relative Charge. Philips recommends that you condition the battery by fully discharging and recharging it when the Max Error is 10% or greater.

To recondition the battery:

Step	
1.	Open the Battery Info window (see <b>Viewing Battery Information</b> ).
2.	Disconnect the monitor from AC power.
3.	Rotate the wheel to select <b>Recondition</b> , then press the wheel. The <b>Relative Charge</b> percentage will decrease to 0%.



4.	When the monitor shuts down, reconnect the monitor to AC power and allow the battery to recharge to 100%.
5.	Repeat steps 1 - 4. <b>NOTE</b> - <i>If the battery does not recharge after four reconditioning cycles, replace it.</i>

## Replacing the Battery

Replace the battery if the following conditions occur:

- After reconditioning, if the monitor operates for less than one hour on a fully charged battery before the low battery (**Low Batt**) alarm occurs, or
- The **Max Error** cannot be brought  $\leq$  8% after several recondition cycles.
- The battery **SOH** is  $\leq$  80%.
- The battery **Cycle Count** is greater than 300<sup>1</sup>.
- The monitor reports “Replace Battery” alert.
- The monitor reports “Replace Battery Immediately” alert.

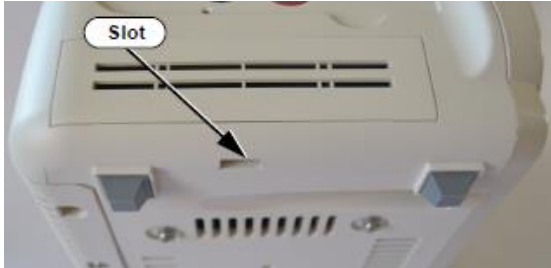
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### WARNING

**Dispose of aged batteries in an environmentally responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements.**

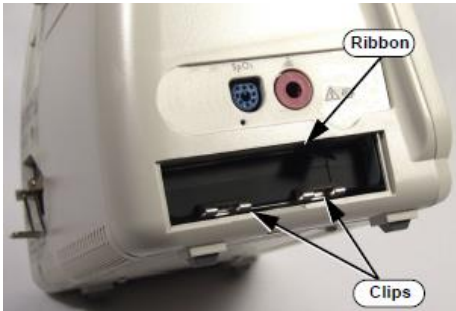
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To replace the battery:

Step	
1.	Shut down the monitor.
2.	Disconnect the AC power cord from the rear of the monitor.
3.	Tip the monitor and insert a flathead screwdriver into the slot in the bottom of the case under the battery cover. 

---

<sup>1</sup> This applies to the Lithium-ion, Smart Battery. The only supported batteries in the SureSigns VS Series Monitors are the Lithium-ion, Smart Battery (Part Number 989803194541 or 989803144631).


	<p><b>CAUTION</b></p> <p><b>Do not try to remove the battery cover by inserting the screwdriver into the vents in the cover. This can damage the battery case cover.</b></p>
4.	Twist the screwdriver slightly to pop the battery cover off of the case.
5.	<p>Press down on the battery retaining clips and pull the old battery out of the monitor using the ribbon.</p> 
6.	Orient the replacement battery so that the contacts and ribbon are on the right.
7.	Insert the replacement battery into the empty compartment, and push until the battery snaps into place behind the metal retaining clips.
8.	Replace the battery cover by inserting it into the battery opening with the two tabs facing up.
9.	Snap the cover into place by pressing it firmly against the monitor case.

## Battery Test

Philips requires that you complete Battery Test after:

- Upgrading the software
- Opening the monitor for any reason
- Replacing any internal part (except NBP parts, SpO<sub>2</sub> board)

**To test the battery:**

Step	
1.	<p>Make sure there are no battery error codes, battery warnings or alarm messages in the lower left corner of the main menu.</p> <p><b>NOTE</b> - <i>If a battery error code, warning or alarm message is displayed, refer to the Error Codes below for resolution.</i></p>
2.	<p>Select the Battery Status Icon . Make sure there are no battery parameters in RED.</p> <p><b>NOTE</b> - <i>If a battery value is RED, refer to the Error Codes below for resolution.</i></p>

## Ordering a Replacement Battery

To order a replacement lithium ion battery, contact your Philips Customer Care center. For more information on how to contact Philips Customer Care for your country, go to <http://www.healthcare.philips.com>. Select your country and language, then navigate to the Customer Care page.

Product	Description	Battery PN*	Battery PN**
863069	SureSigns VS3 NBP	989803194541 (11.1V 7800 mAh, ME202EK)	989803144631 (11.1V 7200 mAh, ME202CJ)
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		
863283	SureSigns VS4 NBP/SPO2		
863286	SureSigns VS4 Government Bundle		

\* World-wide, except China

\*\* China only

## Battery Messages and Alarms

The condition of the battery is reported by technical alarms and error codes.

### Technical Alarms

The following battery technical alarms appear in the monitor's message area:

- **Low Batt:** remaining battery power is less than 30%.
- **Extreme Low Batt:** remaining battery power is less than 21%.
- **Unknown Battery, slow chrg** or **Unrecognized Battery, slow charge:** The battery plugged in is not supported.
- **Battery Charge Failure:** Battery charge power failure or battery malfunction.
- **Battery Overcharged:** Battery is overcharged.
- **HI Battery Temp, chrg stop** or **High Battery Temp, charge stopped:** The battery temperature is  $\geq 50^{\circ}\text{C}$  or the battery issues an "Over Temperature" status.
- **Batt Overhear, shut down** or **Battery Overheat, shutting down:** Battery Temperature is  $\geq 60^{\circ}\text{C}$  or the battery issues an "Over Temperature" status.

The battery will stop charging immediately and the monitor will shut down automatically after you confirm the error message or if the error message is displayed for 25 seconds.

- **Replace Battery:** The battery cycle count is > 300 or the battery SOH is  $\leq$  80%.
- **Replace Battery Immediately:** The battery cycle count is > 400 or the battery SOH is  $\leq$  75%.

## Error Codes

An error code (for example, **257 System Error**, indicating a battery charger power failure) appears in the Error Log. To view the Error Log, see “Viewing, Printing, and Exporting the Error Log” in the Service Guide. For a complete list of error codes and the actions to take, see Chapter “Troubleshooting,” in the Service Guide.

The following error codes have been added.

Code	Description/Cause	Error Message	Action
257	Battery Charger Power Failure	System Error	Replace battery. If the problem persists, replace the main board. If the problem persists, replace the AC power module.
261	Battery Over Charge	System Error	Run monitor without AC power. If the problem persists, replace the battery. If the problem persists, replace the main board.
264 <sub>temp</sub> value	Battery Over Temperature	System Error	Perform hard shutdown. If the problem persists, replace the battery. If the problem persists, replace the main board.
265	Battery cycle count is > 300 or Battery SOH is $\leq$ 80%.	System Error	Replace battery.
265	Battery cycle count is > 400 or Battery SOH is $\leq$ 75%.	System Error	Replace battery.
266	Unrecognized Battery	System Error	Replace battery.



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