

URGENT - Medical Device Correction

Philips SureSigns VS3/VS4 Monitors Software Release

Dear Customer,

A problem has been detected with the Philips SureSigns Monitors (VS3/VS4), that, if it were to re-occur, could pose a risk for patients. 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.

Although the existing labeling for the Philips SureSigns VS3/VS4 monitor with Philips FAST (Fourier Artifact Suppression Technology) SpO2 has performance specifications related to pulse rates up to 300 beats per minute, however the system software does not measure, display and alarm for pulse rates above 240 beats per minute. Philips is releasing a system software update¹ for the SureSigns VS3/VS4 monitors to restore the specified functionality.

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.

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 with questions or concerns about this correction:

0800 80 3000

Sincerely,

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

¹ The System Software update includes the optimized battery management software communicated previously on FSN86000255/CIL86000256.


AFFECTED PRODUCTS	<p>The following SureSigns Monitors with software revisions up to and including A.07.32, are subject to the correction.</p> <table border="1" data-bbox="513 212 1253 590"> <thead> <tr> <th data-bbox="513 212 716 275">Product Number</th> <th data-bbox="722 212 1253 275">Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="513 283 716 310">863069</td> <td data-bbox="722 283 1253 310">SureSigns VS3 NBP</td> </tr> <tr> <td data-bbox="513 319 716 346">863070</td> <td data-bbox="722 319 1253 346">SureSigns VS3 NBP, Temp</td> </tr> <tr> <td data-bbox="513 354 716 382">863071</td> <td data-bbox="722 354 1253 382">SureSigns VS3 NBP, SpO2</td> </tr> <tr> <td data-bbox="513 390 716 417">863072</td> <td data-bbox="722 390 1253 417">SureSigns VS3 NBP, SpO2, Rec</td> </tr> <tr> <td data-bbox="513 426 716 453">863073</td> <td data-bbox="722 426 1253 453">SureSigns VS3 NBP, SpO2, Temp</td> </tr> <tr> <td data-bbox="513 462 716 489">863074</td> <td data-bbox="722 462 1253 489">SureSigns VS3 NBP, SpO2, Temp, Rec</td> </tr> <tr> <td data-bbox="513 497 716 525">863283</td> <td data-bbox="722 497 1253 525">SureSigns VS4 NBP, SPO2</td> </tr> <tr> <td data-bbox="513 533 716 560">863286</td> <td data-bbox="722 533 1253 560">SureSigns VS4 Government Bundle</td> </tr> </tbody> </table>	Product Number	Description	863069	SureSigns VS3 NBP	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
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HAZARD INVOLVED	<p>Failure to display and alarm for pulse rates above 240 beats per minutes could cause the clinician to overlook a patient's distressed condition, which may cause moderate injury to a patient due to delay in therapy or treatment.</p> <p>Philips is unaware of any incident where the failure of these devices to measure, display and alarm for pulse rates over 240 bpm have resulted in a delay of necessary treatment or injury to a patient.</p>																		

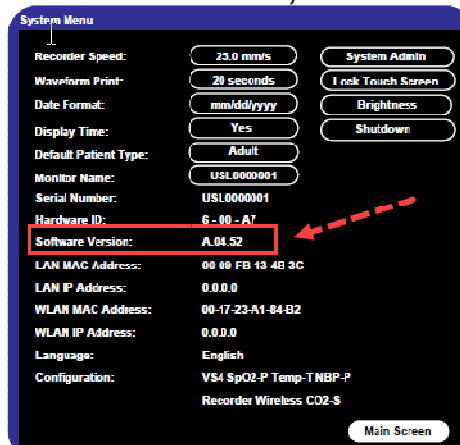
HOW TO IDENTIFY AFFECTED PRODUCTS

You can determine whether your device is affected by identifying the Product number and software revision. This can be performed by;

- a) Locate and verify the Product Number of your SureSigns VS3/VS4 Monitor, found on the back label of your monitor



- b) Locate and verify the software revision in the monitor (System Menu  / Software Version)



ACTION TO BE TAKEN BY CUSTOMER / USER

Upon receipt of this notification:

- Promptly perform the software upgrade to each of your SureSigns VS3/VS4 monitors, as called out in the attached *Pulse Rate Software-Installation Instructions*. It details how to obtain and install the system software update. It also provides instructions on how to export the file that is created during software installation and instructions where to email the file back to Philips.
- Along with the software download, the user will also receive *Instructions*

	<p><i>for Use Addendums and a Service Guide Addendum.</i></p> <p>Review this information with all staff members who are use the device and are responsible for device management of the Philips SureSigns monitors.</p> <p>Please store the <i>Addendums</i> with your Philips SureSigns VS3/VS4 Monitors <i>Service Guide</i> and <i>Instructions for Use</i> documentation.</p> <ul style="list-style-type: none">• Email the file back to Philips in accordance with the instructions.
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p>0800 80 3000</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 ₂

863072	SureSigns VS3 NBP, SpO ₂ , Rec
863073	SureSigns VS3 NBP, SpO ₂ , Temp
863074	SureSigns VS3 NBP, SpO ₂ , Temp, Rec
863283	SureSigns VS4 NBP, SpO ₂
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 incenter.medical.philips.com .
2.	Click Need Help? .
3.	Under Software Updates , Click Click here for SureSigns patient monitor account registration . The SureSigns InCenter Registration Form appears.
4.	Enter your personal information and answer the questions, and then click Submit . 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


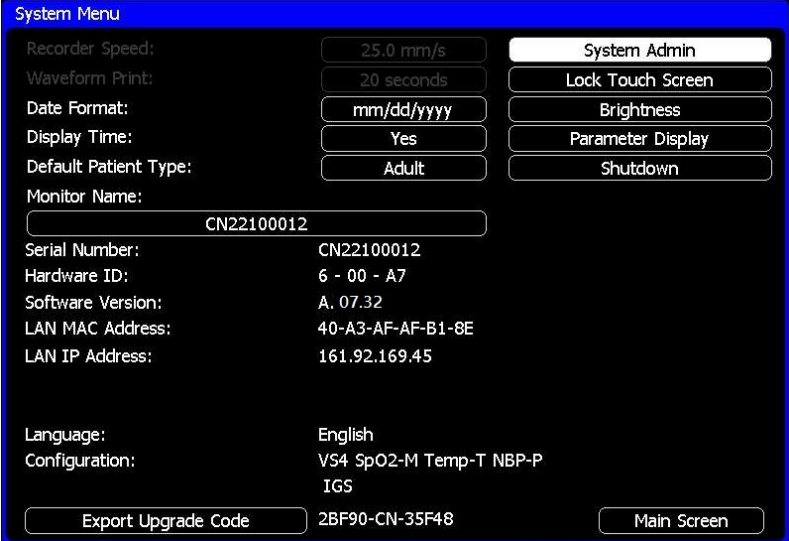
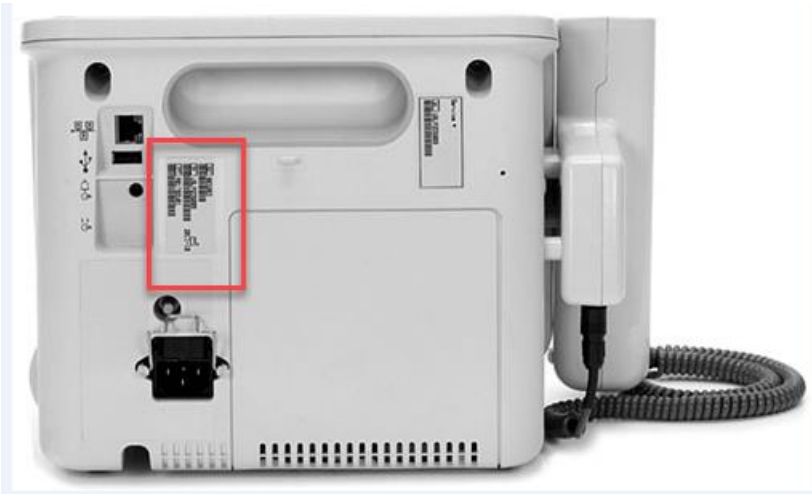
The following documentations should be readily available when performing the installation. These documents can be retrieved from Philips InCenter.

- 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 System Menu key  .</p> <p>The System Menu appears. See figure 1.</p>  <p>Figure 1 System Menu</p>
2.	<p>Locate the Serial Number (halfway down the System Menu Screen).</p>
3.	<p>Locate the serial number on the back of the monitor.</p> <p>The serial number appears in a label (marked SN) on the back of the monitor. See figure 2.</p>  <p>Figure 2 Back View</p>
4.	<p>If the serial number matches, proceed to the <i>Inspecting the Battery</i> section.</p>
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>

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)

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

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

Location of Software:

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

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.


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

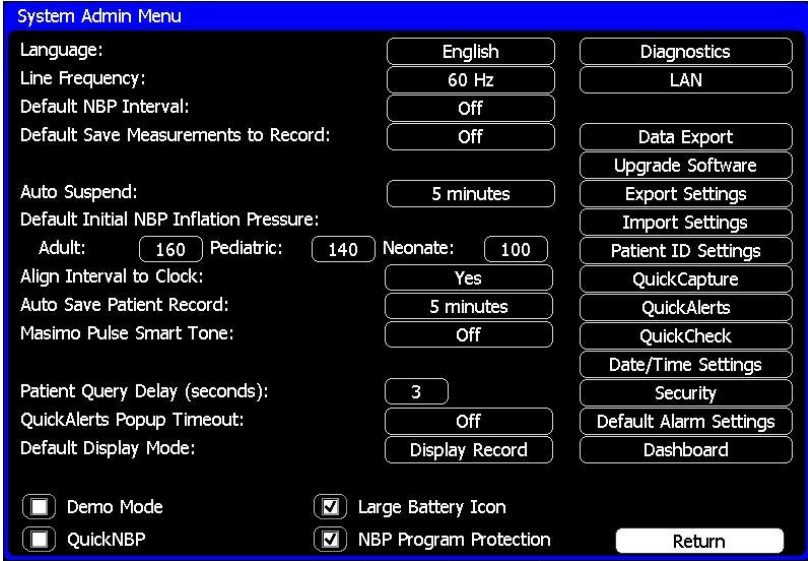
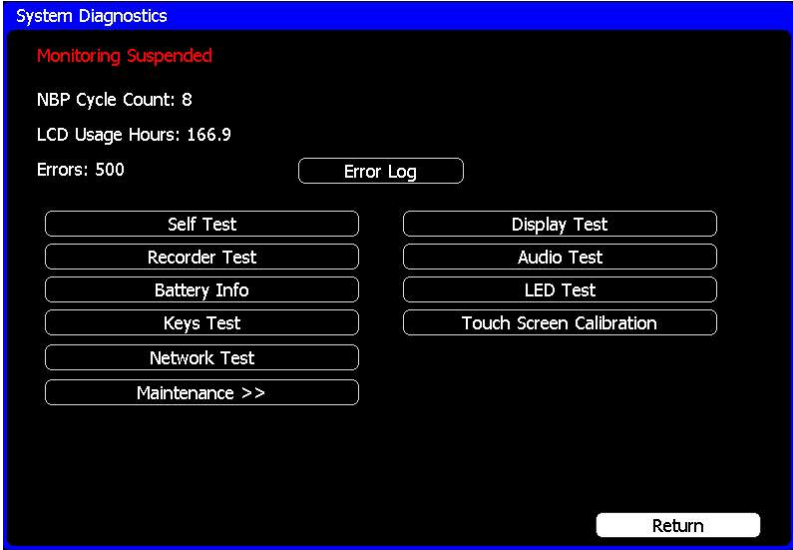
Two methods are available for deleting patient data:

- 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:

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

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

<p>3.</p>	<p>Enter the Administrator password. Click on the OK button.</p> <p>NOTE – <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 System Admin Menu appears. See figure 3.</p>  <p>Figure 3 System Admin Menu</p>
<p>4.</p>	<p>Select the Diagnostics button.</p> <p>The System Diagnostics menu appears. See figure 4.</p>  <p>Figure 4 System Diagnostics</p>
<p>5.</p>	<p>Select the Maintenance>> button. A Password window appears.</p>
<p>6.</p>	<p>Enter the Maintenance password (1-2-9). Click on the OK button.</p> <p>The complete System Diagnostics menu appears, including all Maintenance functions. See figure 5.</p>

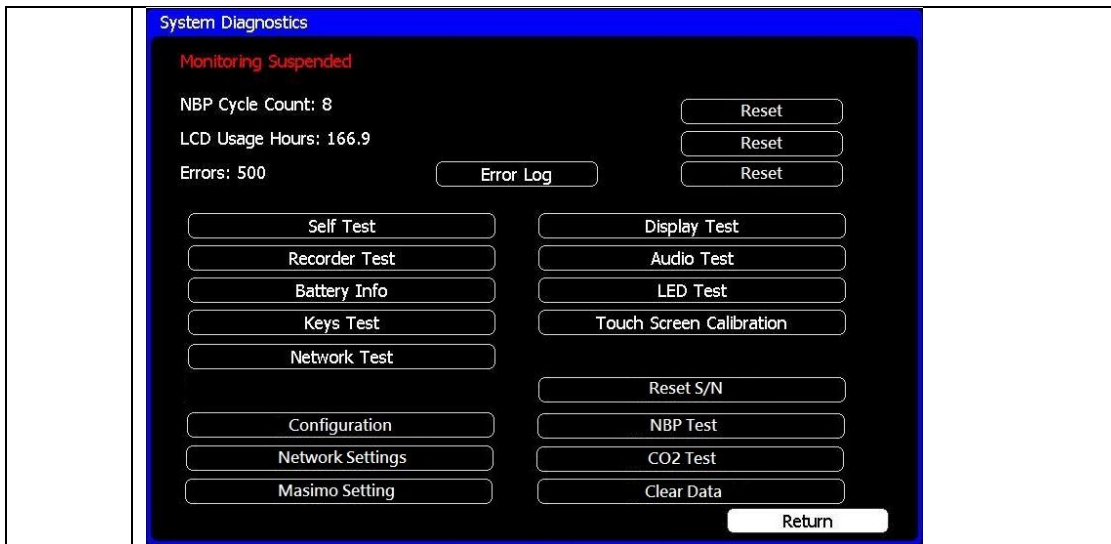
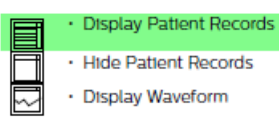


Figure 5 System Diagnostics with Maintenance functions

7.	<p>Select the Clear Data Button.</p> <p>A confirmation window appears. Clear Data and restart system?</p> <p>Select Yes.</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 Display Mode button.
2.	<p>Select Display Patient Records.</p>  <p>A list of Patient Records appears.</p>
3.	Select the Delete button.
4.	<p>Select Delete All Records.</p> <p>A confirmation window appears. Are you sure?</p> <p>Select Yes.</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.

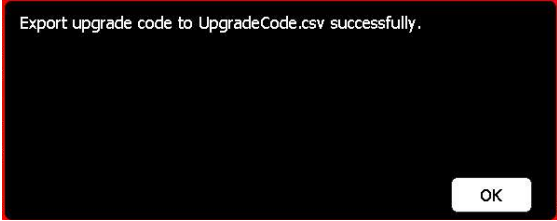
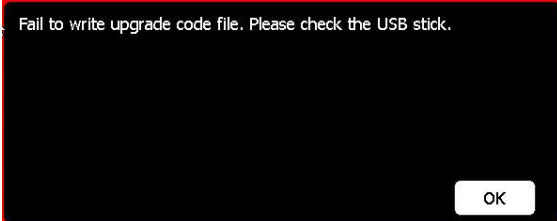
NOTE – You will need the Administrator password to perform this task.

To perform a software upgrade:

Step	
1.	Connect the monitor to AC power and power up the monitor. NOTE - <i>Your monitor must be connected to AC power and have a fully charged battery before upgrading the software.</i>
2.	Verify Serial Number 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. NOTE - <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. NOTES –

	<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>NOTE - 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 System Menu key  .</p> <p>The System Menu appears. See figure 1.</p>
8.	<p>Select the System Admin button, a Password window appears.</p>
9.	<p>Enter the Administrator password. Click on the OK button.</p> <p>NOTE – 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 System Admin Menu appears. See figure 3.</p>
10.	<p>Select Upgrade Software.</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 Upgrade Software window. See figure 6.</p> <div data-bbox="418 1171 1247 1749" data-label="Image"> </div> <p>Figure 6 Upgrade Software</p> <p>NOTE - If the monitor cannot find a valid software image, the screen returns to the System Admin Menu.</p>

	<p>Caution: Do not downgrade the software to an earlier version, because it may cause hardware incompatibility and loss of system settings and patient records.</p>
12.	<p>Select the Upgrade button to start the upgrade.</p> <p>Caution:</p> <p>After the upgrade starts:</p> <ul style="list-style-type: none"> • Do not unplug the monitor. • Do not remove the USB flash drive. • Do not press any keys. <p>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.</p>
13.	<p>The Upgrade in Progress 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 Checking Memory CRC and Upgrade Successful messages appear.</p> <p>After the software upgrade, the monitor automatically shuts down and restarts.</p> <p>NOTE - <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 System Menu key  .</p> <p>The System Menu appears. See figure 1.</p>
16.	<p>Locate the Export Upgrade Code, at the bottom of the screen.</p> <p>The Export Upgrade Code 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>NOTE - <i>When the same USB flash drive is used to update several units, the UpgradeCode.csv 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>NOTE - Please contact your local Service Response Center for additional assistance if unable to export the upgrade code.</p>
18.	Select OK to return to the main screen.
19.	<p>Remove the USB Flash Drive from the back of the monitor.</p> <p>NOTES –</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"> • <i>Power-on Self test</i> • <i>System settings test</i> • <i>Battery Management test</i> • <i>System serial number and upgrade code test</i>

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 On/Standby 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"> • The screen displays color bars for about five seconds. • The LCD turns off for three seconds, and the charging LED lights. • The Philips splash screen appears for one second, and a startup tone sounds. • It may be possible, that the Date/Time Menu appears for a new time setting. Enter Date & Time.

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

System Settings Test


Step	
1.	From the main screen, verify that your system settings are preserved and as expected.
Verification Results	
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"> If the system settings are not preserved and as expected. <p>NOTE - Please contact your local Service Response Center for additional assistance if unable to obtain expected results after the software upgrade.</p>

Battery Management Test

Step	
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"> State of Health (SOH) Cycle Count <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"> • Monitor main screen displays no battery error code, battery warning or alarm messages. • Battery Status displays no SOH or Cycle Count parameters or values in RED.
Fail	<p>Refer to the device Service Guide for details if any of the below occurs:</p> <ul style="list-style-type: none"> • Battery error codes, Battery warning or alarms are displayed on the lower left hand corner. • Battery status displays SOH or Cycle Count parameter and value in RED. <p>NOTE - 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 System Menu key  .</p> <p>The System Menu appears. See figure 1.</p>
2.	<p>Locate the Serial Number (halfway down the System Menu 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"> • Serial Number matches Serial Number on the back of the monitor. • Software Version matches the Software Version A.07.33.
Fail	<p>Refer to the device Service Guide for details if any of the below occurs:</p> <ul style="list-style-type: none"> • Serial Number does not match Serial Number on the back of the monitor. • Software Version does not match the Software Version A.07.33. <p>NOTE - 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 <i>UpgradeCode.csv</i> file to an email.
3.	Send the email to the following address: <u>recall.response2@philips.com</u>
4.	An email will be sent confirming the receipt of the email. NOTE - <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



SureSigns VS3 and VS4 Vital Signs Monitors Instructions for Use Addendum for Software Release A.07.33


English

This Addendum contains updated information for the SureSigns VS3 and VS4 Release A.07 *Instructions for Use*. Please store this Addendum with your SureSigns VS3 and VS4 documentation for future reference.

The topic of this Addendum is about changes in the Battery menus and alarms. To optimize the safe use of your monitor and its performance, adherence to the instructions included in this addendum is required.

Note — The only supported batteries for the SureSigns VS3 and VS4 Vital Signs Monitors are the Philips Lithium-ion Batteries with Part Numbers 989803144631 or 989803194541. The use of any other unsupported (or unrecognized) battery may result in longer charging times and unpredictable performance.

Battery Info menu

The Battery Info menu, displayed by pressing the battery status icon , shows the battery parameters and values.

The Battery Info menu displays values in Red when:

- Cycle Count is greater than 300, this parameter and value will be red.
- Battery Age is > 3 years, the Battery's Manufact. Date will be red.
- State of Health (SOH), Full Capacity/Design Capacity is $\leq 80\%$, the SOH will be red.
- Battery Temperature is $\geq 45^{\circ}\text{C}$, this parameter and value will be red.
- Battery is over charged or experiences an over temperature condition, the State Register will be red.
- Battery has a charging failure condition, the Charger Status will be red.

A warning message will be displayed if data cannot be retrieved for the battery.

Note — The battery status tool tip is an estimation and not to be used for testing accuracy.

Deep Sleep State

When the monitor's battery temperature is $\geq 60^{\circ}\text{C}$, the monitor will display a prompt to enter Deep Sleep state. If you do not acknowledge the request within 25 seconds, the monitor will automatically enter Deep Sleep.

Alarm Specifications, Appendix A

The following non-latched, technical alarms have been added.

Alarm Message	Priority	Cause
Unrecognized Battery, slow charge	Low	The battery plugged in is not supported.
Battery Charge Failure	Low	Battery charge power failure or battery malfunction.
Battery Overcharged	Low	Battery is overcharged.
High Battery Temp, charge stopped	Low	The battery temperature is $\geq 50^{\circ}\text{C}$ or the battery issues an "Over Temperature" status.
Battery Overheat, shutting down	High	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	Low	The battery cycle count is > 300 or the battery SOH is $\leq 80\%$.
Replace Battery Immediately	High	The battery cycle count is > 400 or the battery SOH is $\leq 75\%$.

The above mentioned alarms are generated in the log file as well as on the monitor itself. Reports can be created which include these new technical alarms, logs for battery error and failure, overcharging, overheating, etc..

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453564830041 Revision B



SureSigns VS4 Vital Signs Monitor Documentation Addendum Release A.07.33 or higher

This Addendum contains additional information for the SureSigns VS4 monitor. Please store this Addendum with your SureSigns documentation for future reference.

Masimo Alarm Setting Addendum

Warning	The Masimo rainbow SET technology only provides pulse rate values up to 240 bpm. When the Pulse Rate is above 240 bpm, the pulse rate and SpO ₂ values may not be accurate and may affect the reliability of alarms. To have pulse rate alarms, set the high alarm limit below 240 bpm.
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SureSigns VS4 生命徵象監視器文件附錄 A.07.33 或更高版本

此附錄包含 SureSigns VS4 監視器的額外資訊。請將這本附錄與您的 SureSigns 文件一同保存，以供未來參考之用。

Masimo 警告設定附錄

警告	Masimo rainbow SET 技術僅提供最高 240 bpm 的脈搏速率值。當脈搏速率高於 240 bpm 時，脈搏速率值和 SpO ₂ 值可能會不準確，也可能影響警告的可靠性。如要取得脈搏速率警告，請將警告上限設定為低於 240 bpm。
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Addendum bij documentatie van SureSigns VS4-monitor voor vitale warden versie A.07.33 of hoger

Dit addendum bevat bijgewerkte informatie voor de SureSigns VS4-monitor. Bewaar dit addendum voor eventueel toekomstig gebruik bij de documentatie van SureSigns.

Addendum voor alarminstelling Masimo

Waarschuwing	Met de Masimo rainbow SET-technologie worden polsfrequentiewaarden tot maximaal 240 spm verkregen. Wanneer de polsfrequentie hoger is dan 240 spm, zijn de polsfrequentie- en SPO ₂ -waarden mogelijk niet correct en kan de betrouwbaarheid van de alarmen worden beïnvloed. Stel de alarmbovengrens in op een waarde lager dan 240 spm als u polsfrequentiealarmen wilt verkrijgen.
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Addenda à la documentation relative au moniteur de paramètres vitaux SureSigns VS4 version A.07.33 ou ultérieure

Cet addenda contient des informations complémentaires pour la documentation du moniteur SureSigns VS4. Veuillez conserver cet addenda avec la documentation de votre moniteur SureSigns pour référence.

Addenda relatif au réglage des alarmes Masimo

Avertissement	la technologie Masimo rainbow SET ne fournit les valeurs de fréquence de pouls que jusqu'à 240 bpm. Lorsque la fréquence de pouls est supérieure à 240 bpm, les valeurs de fréquence de pouls et de SpO ₂ peuvent ne pas être précises et altérer la fiabilité des alarmes. Pour obtenir les alarmes de fréquence de pouls, configurez la limite d'alarme haute sur une valeur inférieure à 240 bpm.
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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.

NOTES -

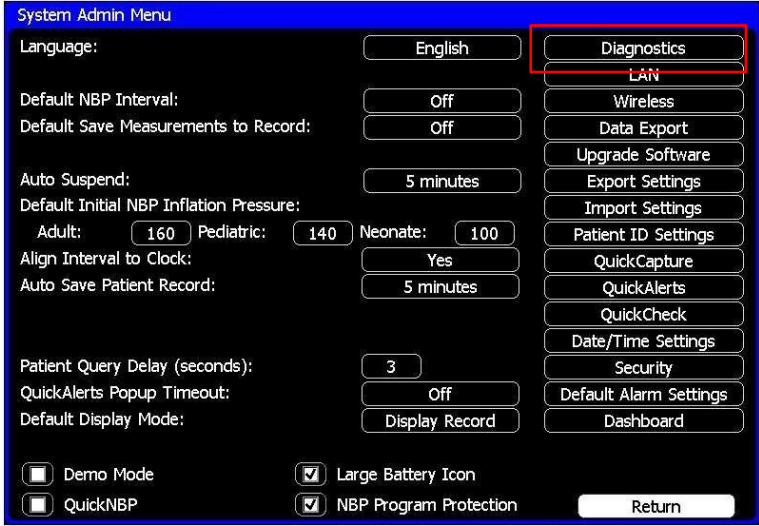
- Images shown are from a VS4 vital signs monitor. The VS3 may appear slightly different.
 - For information about the battery status indicator, please see the Instructions for Use provided with your monitor.
-

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 System . NOTE - <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 System Admin and enter the administrator password (default is 215). The System Admin Menu appears.
3.	Touch Diagnostics to open the System Diagnostics menu.  <p>Figure 1 System Admin Menu</p>
4.	Touch Battery Info 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.

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.

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 Viewing Battery Information).
2.	Disconnect the monitor from AC power.
3.	Rotate the wheel to select Recondition , then press the wheel. The Relative Charge 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. NOTE - <i>If the battery does not recharge after four reconditioning cycles, replace it.</i>

Replacing the Battery

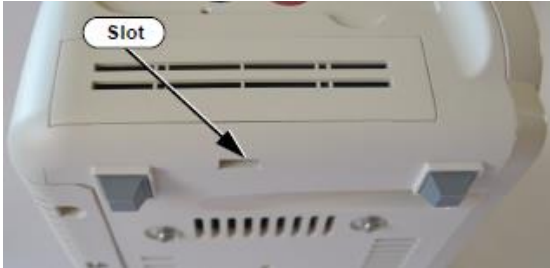
Replace the battery if the following conditions occur:

- 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 300¹.
- The monitor reports “Replace Battery” alert.
- The monitor reports “Replace Battery Immediately” alert.

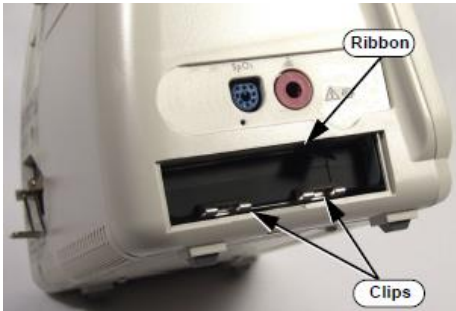
WARNING

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.

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. 

¹ 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>CAUTION</p> <p>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.</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, SpO₂ 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>NOTE - <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>NOTE - <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 _{temp} 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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