URGENT - Medical Device Correction
SureSigns VS and VM Monitors & VSV – Service Guide Addendum

Customer Reply for FSN86000255B
VS and VM Monitor & View Station (VSV) Service Guide Addendum

Please complete and fax to <mark><Philips representative contact details to be completed by the KM/country>.</mark>

Contact Name	
Telephone Number	
Email Address	
Facility Name	
Street Address City, State, Zip	

Please fax or email this completed form to the number or email address provided above.

CUSTOMER ACKNOWLEDGEMENT:

That the VS, VM & VSV Service Guide Addendum has been attached to the first page of the Maintaining the Battery section to ensure that it is not misplaced and is stored with the Instructions for Use for ready reference.

Confirm that all VS and VM monitors & View Station (VSV) batteries have been ordered and/or replaced if the *Battery Information Screen* indicates the battery has been in used longer than 3 years or the discharge/charge cycles is greater than 300.

_____   _____

CUSTOMER NAME (please print)   **TITLE**

_____   _____

CUSTOMER SIGNATURE   **DATE**

Please fax or email the completed reply form to <mark><Philips representative contact details to be completed by the KM / country>.</mark> If you experience difficulty carrying out the instructions contained in this communication, contact your local Philips representative.

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1/3-
URGENT – Notification de sécurité produit
Notice corrective de matériel médical

DigitalDiagnost

Mise à niveau logicielle vers DigitalDiagnost versions 4.1.9 / 4.2.6

Systèmes concernés	**La fusion à l'aide du capteur-plan SkyPlate est interrompue par intermittence :** concerne tous les systèmes DigitalDiagnost équipés des versions logicielles 4.1.x ou 4.2.x et dotés de la fonction de fusion **La fusion à l'aide du capteur-plan SkyPlate s'interrompt après la première image :** concerne tous les systèmes DigitalDiagnost équipés des versions logicielles 4.1.x ou 4.2.x et dotés de la fonction de fusion **Le CD du logiciel du système contient une référence incorrecte : concerne** tous les systèmes DigitalDiagnost équipés des versions logicielles 4.1.8 et 4.2.5
Description du problème	**La fusion à l'aide du capteur-plan SkyPlate est interrompue par intermittence :** Lors de l'acquisition d'images pour la fusion à l'aide du capteur-plan SkyPlate, le logiciel du système est conçu pour que l'intervalle prévu entre deux images consécutives ne soit pas inférieur à huit secondes. Si le temps de lecture du détecteur est plus rapide et que l'image suivante peut être lue en moins de huit secondes, la synchronisation entre les résultats du détecteur et du logiciel du système entraîne une interruption de la fusion. Dans ce cas, la fusion doit être recommencée depuis le début. **La fusion à l'aide du capteur-plan SkyPlate s'interrompt après la première image :** En cas de mauvaise synchronisation entre le capteur-plan SkyPlate et le système, l'image de prévisualisation décalée présente des artefacts. Si cela se produit, le logiciel du système identifie la mémoire de l'image de prévisualisation comme n'étant pas exploitable pendant la première partie de l'acquisition d'images pour la fusion. Par conséquent, la fusion est interrompue. Celle-ci doit être répétée. **Le CD du logiciel du système contient une référence incorrecte :** Les systèmes DigitalDiagnost équipés des versions logicielles 4.1.8 et 4.2.5 ont été livrés avec une version incorrecte du logiciel d'application sur le CD. Cette version incorrecte du logiciel d'application contient une erreur suite à laquelle l'image miroitée n'est pas identifiée comme étant une image miroitée.

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URGENT – Notification de sécurité produit
Notice corrective de matériel médical

DigitalDiagnost

Mise à niveau logicielle vers DigitalDiagnost versions 4.1.9 / 4.2.6

Risques liés au problème	**La fusion à l'aide du capteur-plan SkyPlate est interrompue par intermittence et la fusion à l'aide du capteur-plan SkyPlate s'interrompt après la première image :** ces défauts risquent de provoquer une exposition excessive au rayonnement. Dans les deux cas, l'image n'est pas exploitable et la réalisation d'un nouvel examen avec fusion est nécessaire. **Le CD du logiciel du système contient une référence incorrecte :** ce défaut entraîne un risque de mise en œuvre d'un traitement inapproprié car une ou plusieurs images miroitées ne sont pas identifiées comme étant miroitées. Pour toute question concernant cette notification, veuillez contacter Philips.
Identification des systèmes concernés	Pour les systèmes concernés par ces problèmes : - **La fusion à l'aide du capteur-plan SkyPlate est interrompue par intermittence :** tous les systèmes DigitalDiagnost équipés des versions logicielles 4.1.x ou 4.2.x et dotés de la fonction de fusion - **La fusion à l'aide du capteur-plan SkyPlate s'interrompt après la première image :** tous les systèmes DigitalDiagnost équipés des versions logicielles 4.1.x ou 4.2.x et dotés de la fonction de fusion La disponibilité de la fonction de fusion est indiquée dans le sous-onglet "General" (Général) de l'onglet "System" (Système) dans l'interface utilisateur Eleva. Pour les systèmes concernés par ce problème : **Le CD du logiciel du système contient une référence incorrecte :** tous les systèmes DigitalDiagnost équipés des versions logicielles 4.1.8 et 4.2.5 feront l'objet d'une mise à niveau logicielle vers les versions 4.1.9 ou 4.2.6, respectivement. Le problème n'est pas identifiable sur l'étiquette du CD, mais sur le logiciel installé sur le système. La version logicielle du système est indiquée dans le sous-onglet "General" (Général) de l'onglet "System" (Système) dans l'interface utilisateur Eleva.

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**URGENT – Notification de sécurité produit
Notice corrective de matériel médical**

DigitalDiagnost

Mise à niveau logicielle vers DigitalDiagnost versions 4.1.9 / 4.2.6

Action à mettre en œuvre par le Client Utilisateur	**La fusion à l'aide du capteur-plan SkyPlate est interrompue par intermittence et la fusion à l'aide du capteur-plan SkyPlate s'interrompt après la première image :** dans de tels cas de figure, il n'existe aucune mesure devant être prise par l'utilisateur. Le client est averti de l'échec de la fusion à la fin de celle-ci. Les clients peuvent continuer à utiliser l'appareil conformément à cette notification et aux instructions d'utilisation. **Le CD du logiciel du système contient une référence incorrecte :** Philips Healthcare recommande aux clients de toujours vérifier l'image miroitée afin d'éviter une erreur de diagnostic.
Actions menées par Philips France Commercial	Philips prévoit d'installer une mise à niveau logicielle sur les systèmes concernés, ce qui éliminera ce problème. Un ingénieur de maintenance Philips vous contactera dès que le kit d'action corrective sera disponible. Lors de vos communications avec Philips concernant ce programme, veuillez indiquer la référence d'action corrective 71200177.
Informations complémentaires et Assistance Technique	Si vous avez besoin d'informations supplémentaires ou d'assistance technique concernant cette notification, veuillez contacter notre Pôle d'Assistance Clients au 0810.835.624. ou votre prestataire habituel si votre établissement est situé hors de la métropole. **Les clients concernés par cette alerte vont recevoir un courrier de Philips**

SureSigns VS2/VS3/VS4 Vital Signs Monitors Service Guide Addendum – Replacement for Battery Maintenance Information

This addendum replaces the "Maintaining the Battery" section in Chapter 2 of the SureSigns VS2, VS3 and VS4 Vital Signs Monitors Service Guide. Please store it with your monitor documentation. Models are listed in the table at the end of this document.

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 VS2 and 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:

1. On the main screen, touch **System**.

    NOTE: *The VS4 vital signs monitor utilizes a touch screen. On a VS2 or VS3 monitor, you must rotate the control wheel to highlight the desired menu option, then press the wheel to select it.*

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.
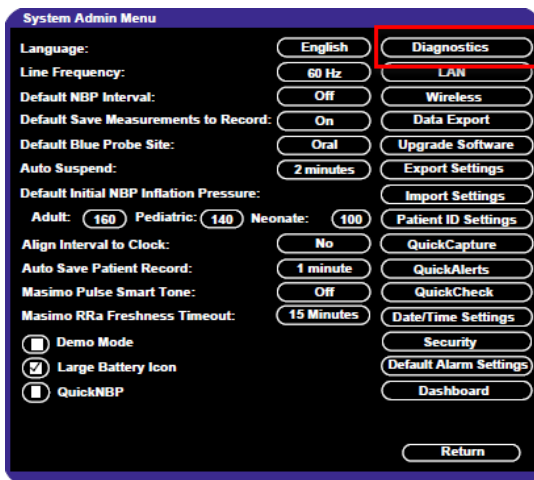

Figure 1 System Admin Menu

4. Touch **Battery Info** to open the **Battery Info** screen.
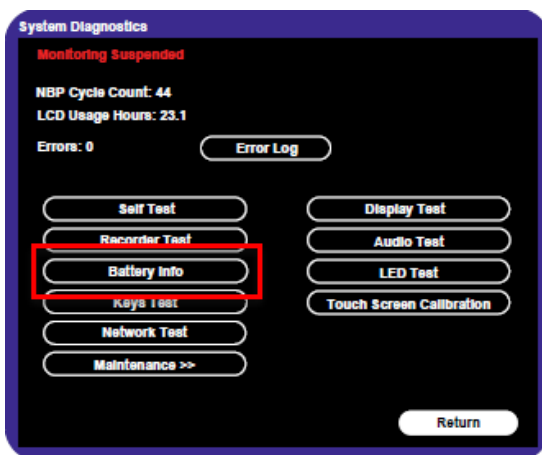

Figure 2 System Diagnostics

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

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

- **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 cycle count exceeds the recommended limit of ***300 cycles***, or if the battery is older than ***three (3) years***, the battery will need to be replaced (see Figure 3).

NOTE: *On VS3 monitors, battery manufacture date will be displayed only on software version A.02 or higher. If your VS3 monitor is running an older version of software, please see **Determining Battery Age**,*
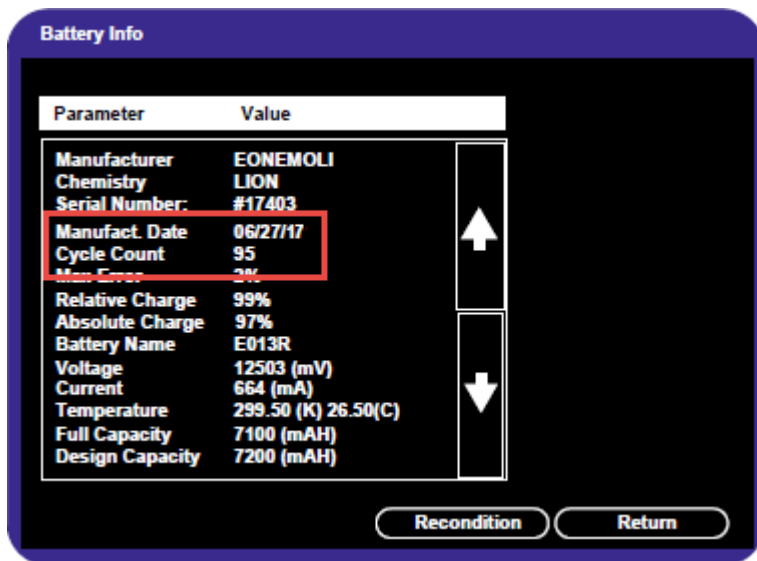

Figure 3 Battery Info Screen

NOTE: *If the message, "**No data from battery. Please see Service Guide**." appears, you must reseat the battery. Refer to your VS series Service Guide for more information.*

WARNING

The risk of battery failure increases with age, when a battery remains in use past 300 charge–discharge cycles or 3 years. Such failures can result in overheating that in rare cases can cause the battery to ignite.

Determining Battery Age

You can visually verify the battery manufacture date by checking the battery label. To determine the age of your battery, you will need to remove it from the monitor and check the battery label. See **Replacing the Battery** for instructions on safely removing the battery from your monitor. You should also check any spare batteries you may have on hand.

If the battery has a blue label as shown in Figure 4, the manufacturing date will be printed on the label.

Figure 4 Battery product label

If your label looks like one of the examples in Figure 5, or any other type of label other than the label in Figure 4, you will need to replace the battery.
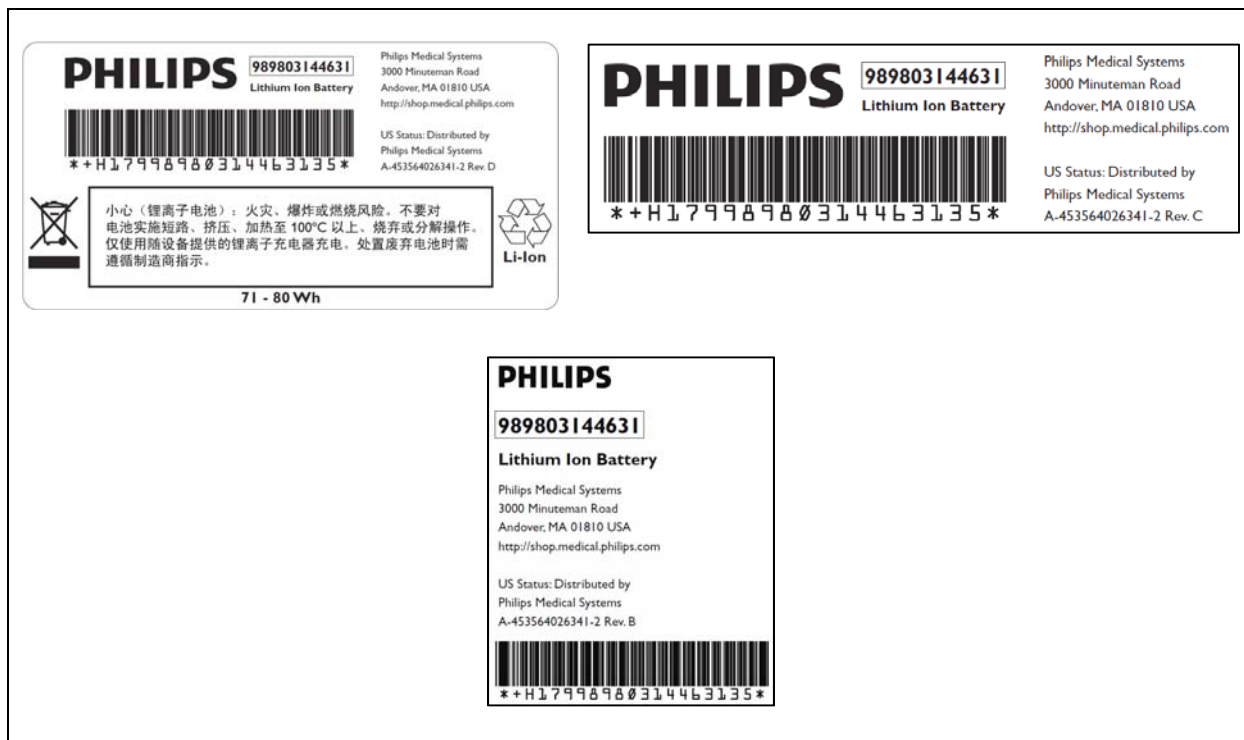

Figure 5 Battery product labels

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:

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: If the battery does not recharge after four reconditioning cycles, replace it.

Replacing the Battery
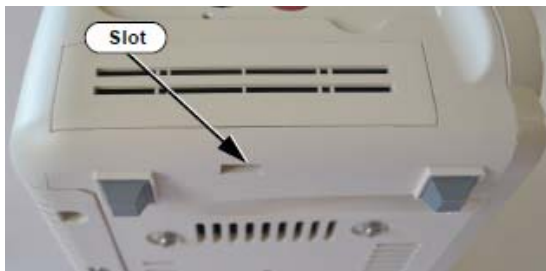
Replace the battery if the following conditions occur:

- 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 <= 8% after several recondition cycles, or

- The **Full Capacity** is 50% or less of the **Design Capacity**.

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.
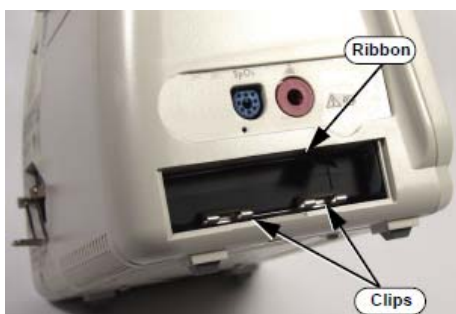

To replace the battery:

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.

CAUTION

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.

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4. Twist the screwdriver slightly to pop the battery cover off of the case.

5. Press down on the battery retaining clips and pull the old battery out of the monitor using the ribbon.

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.

Ordering a Replacement Battery

To order a replacement lithium ion battery, contact your Philips Customer Care center. For information on 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		
863079	SureSigns VS2 NBP		
863080	SureSigns VS2 NBP/SPO2		
863081	SureSigns VS2 NBP/SPO2/Temp		
863082	SureSigns VS2 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%.

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, on page 4–38 of the Service Guide. For a complete list of error codes and the actions to take, see Chapter 4, "Troubleshooting," in the Service Guide.

SureSigns Vital Signs ViewStation Service Guide Addendum Replacement for Battery Maintenance Information

This addendum replaces the "Battery Maintenance and Indicators" section in Chapter 4 of the SureSigns Vital Signs ViewStation (VSV) Service Guide. Please store it with your monitor documentation.

Battery Maintenace and Indicators

About the Battery

The rechargeable lithium ion battery used in the Vital Signs ViewStation 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.

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.

Battery Charge Indicators

You can check the level of charge in a battery by any of the following:

- The battery charging LED;
- The battery status pane;
- Battery messages and alarms.

For information on the battery charging LED and battery status pane, see "Charging the Battery" on page 2–2 of the Service Guide.

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 Test** screen to display information about the battery. Ensure that the monitor is connected to AC power before attempting to review battery information.

To view information about the battery:

1. On the main screen of your VSV, rotate the wheel to highlight **System**, then press the wheel.

2. Rotate the wheel to highlight **System Admin** then press the wheel.

3. In the window that appears, enter the administrator password (default is 215). Rotate the wheel to highlight **OK**, then press the wheel. The **System Admin Menu** appears.

4. Rotate the wheel to highlight **Diagnostics**, then press the wheel.

Figure 1 System Admin Menu

5. On the **Diagnostics** screen, rotate the wheel to highlight **Battery Test**. Press the wheel to open the **Battery Test** screen.

Figure 2 System Diagnostics

The **Battery Test** screen provides detailed information about battery capacity and charging status. If the charging cycle count exceeds the recommended limit of ***300 cycles*** or is older than ***three (3) years***, the battery will need to be replaced (see cycle count in Figure 3).
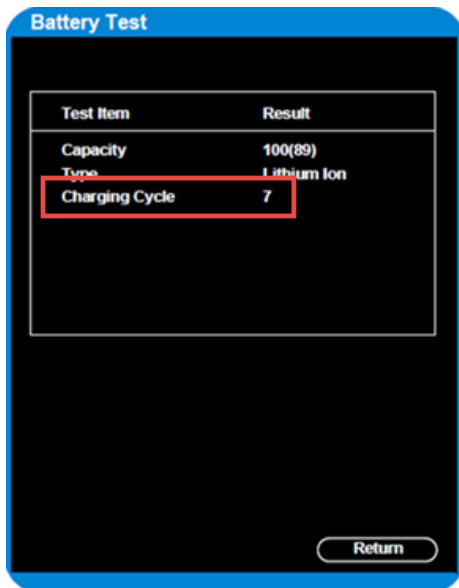

Figure 3 Battery Test Screen

NOTE: *If the message "**No data from battery. Please see Service Guide.**" appears, you must reseat the battery. Refer to your VSV Service Manual for more information.*

WARNING

The risk of battery failure increases with age, when a battery remains in use past 300 charge-discharge cycles or 3 years. Such failures can result in overheating that in rare cases can cause the battery to ignite.

Determining Battery Age

To determine the age of your battery, you will need to remove it from the VSV and check the battery label. See **Replacing the Battery** for instructions on safely removing the battery from your VSV. You should also check any spare batteries you may have on hand.

If the battery has a blue label as shown in Figure 4, the manufacturing date will be printed on the label.

Figure 4 Battery product label

If your label looks like one of the examples in Figure 5, or any other type of label other than the label in Figure 4, you will need to replace the battery.
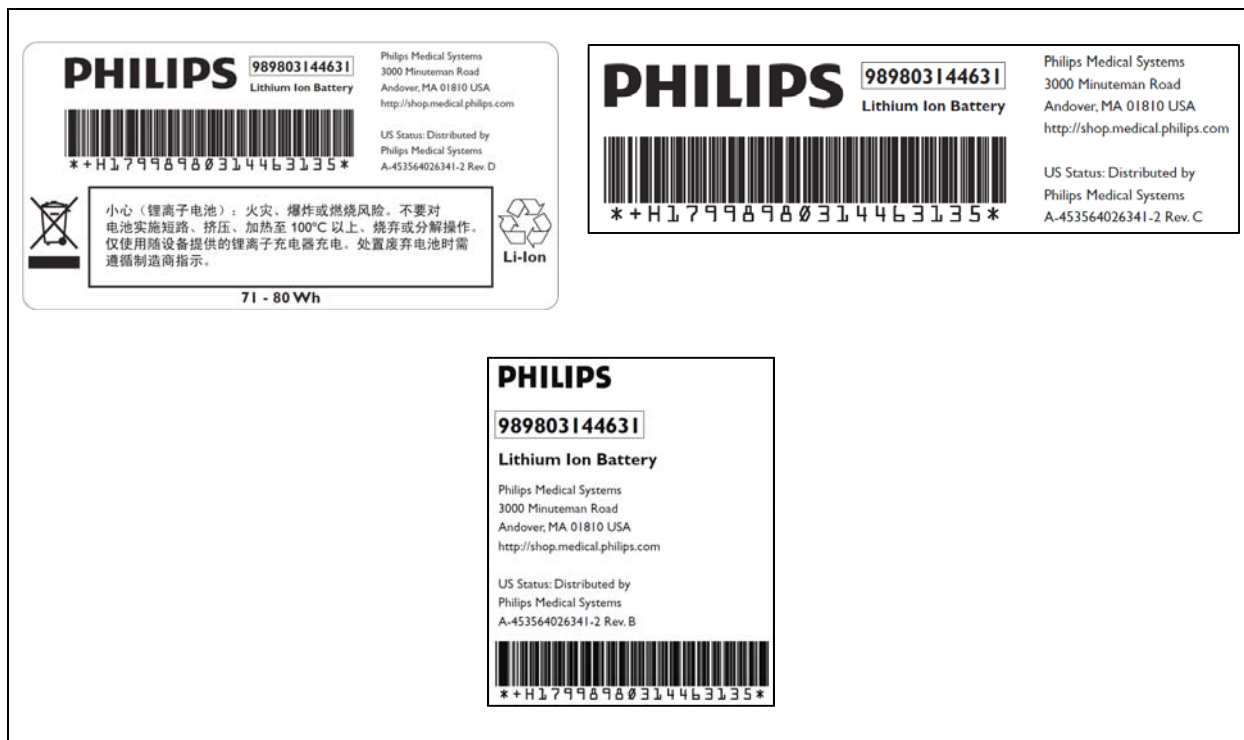

Figure 5 Battery product labels

Replacing the Battery

To replace the battery:

1. Shut down the VSV.

2. Disconnect the AC power cord from the rear of the monitor.

3. Tip the VSV and insert a flathead screwdriver into the slot in the bottom of the case under the battery cover.

CAUTION

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.

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4. Twist the screwdriver slightly to pop the battery cover off of the case.

5. Press down on the battery retaining clips and pull the old battery out of the monitor using the ribbon.

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.

Ordering a Replacement Battery

To order a replacement lithium ion battery, contact your Philips Customer Care center. For information on 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**
863067	Vital Signs ViewStation	989803194541 (11.1V 7800 mAh, ME202EK)	989803144631 (11.1V 7200 mAh, ME202CJ)

* World-wide, except China

** China only

Battery Messages and Alarms

A technical alarm could indicate a low and/or improperly functioning battery. For a complete list of battery-related technical alarms, refet to the *SureSigns Vital Signs ViewStation Instructions for Use*.

In addition, a service error code could indicate a problem with the battery. Service error codes are written to the Error Log. For a complete list of error codes and actions to take, see "**Error Codes**" on page 5-13 of the Service Guide.