

URGENT Voluntary Medical Device Correction HeartStart MRx (M3535A/M3536A)

EtCO2 and Ventilation Rate values may be labeled incorrectly

Dear Customer,

This letter is to inform you that Philips has identified an issue with certain HeartStart MRx monitor/defibrillators (M3535A/M3536A).

Philips internal testing has identified that under certain conditions the EtCO2 values and ventilation rate values can display interchangeably (unexpectedly or randomly switch) either under the ventilation rate label or the EtCO2 label. If this were to occur and go unnoticed there is a potential that the patient may be treated incorrectly. For example, clinical management of EtCO2 values if confused with ventilation rate values may result in adversely affecting a patient's acid-base balance.

Customers that have HeartStart MRx monitor/defibrillators with software version F.01.00 or F.01.01 and all of the following hardware options EtCO2, Invasive Pressure (IP), Temperature (Temp) and Q-CPR with the current generation CPR meter (part # 453564145481) may be affected by this issue. This problem does not occur when using Q-CPR with the first generation CPR sensor (part M4761A).

As a preventive measure this action is also directed to customers with software version F.01.00 or F.01.01 and EtCO2, IP, and Temp options to preclude this problem from occurring should users perform future upgrades to the Q-CPR option with CPR meter.

This Field Safety Notice is intended to inform you about:

- What the problem is and under what circumstances it can occur
- Actions you must take
- Actions taken by Philips to address 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 see the attached Field Safety Notice, which describes how to identify affected devices and provides instructions for actions to be taken. Please follow the “ACTION TO BE TAKEN BY CUSTOMER/USER” section of the notice.

Should you have any questions or concerns about this Device Correction, please contact your local Philips representative at 1-800-722-9377.

This notice has been reported to the appropriate Regulatory Agencies.

Ensuring that you have the highest quality medical devices, accessories and supporting documentation is our top priority. Your satisfaction with Philips products is very important to us.

Sincerely,



John Cadigan
General Manager
Emergency Care Solutions

Attachments

Field Safety Notice

<p>AFFECTED PRODUCTS</p>	<p>Product: Philips HeartStart MRx monitor/defibrillator, models M3535A M3536A.</p> <p>Units Affected: All HeartStart MRx monitor/defibrillators, with software (SW) versions F.01.00 or F.01.01 and with all of the following hardware options EtCO2, IP and Temp.</p> <p>Manufactured by: Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.</p>			
<p>PROBLEM DESCRIPTION</p>	<p>The problem can only occur on HeartStart MRx monitor/defibrillators with software versions F.01.00 or F.01.01 and with all of the following hardware options EtCO2, IP, Temp, Q-CPR with CPR meter, present and active.</p> <p>The following device use modes can result in the EtCO2 and ventilation rate values displaying interchangeably under either the ventilation rate label or the EtCO2 label.</p> <table border="1" data-bbox="573 1096 1206 1394"> <tr> <td>Use Modes</td> </tr> <tr> <td>Entering manual therapy mode with hardware options IP, EtCO2, Q-CPR option with CPR meter, and Temperature active or plugged in.</td> </tr> <tr> <td>In manual therapy mode, individually activating or plugging in IP, EtCO2 and Q-CPR option with CPR meter in any order while Temperature is active.</td> </tr> </table> <p>The EtCO2 and ventilation values themselves can be identified by their color (for example if the ventilation rate label is white; the ventilation value is displayed as white). Note: This problem does not occur on devices with software version 9.x when using the Q-CPR option with CPR sensor.</p>	Use Modes	Entering manual therapy mode with hardware options IP, EtCO2, Q-CPR option with CPR meter, and Temperature active or plugged in.	In manual therapy mode, individually activating or plugging in IP, EtCO2 and Q-CPR option with CPR meter in any order while Temperature is active.
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Entering manual therapy mode with hardware options IP, EtCO2, Q-CPR option with CPR meter, and Temperature active or plugged in.				
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<p>HAZARD INVOLVED</p>	<p>The interchanged EtCO2 and Ventilation rate mismatches between label and numeric value/assigned color may not be noticed by the healthcare provider, in which case inappropriate treatment may be provided to the patient based on misinformation, which may result in patient injury.</p>			
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>HeartStart MRx monitor/defibrillators, Models M3535A and M3536A with software versions F.01.00 or F.01.01 and hardware options EtCO2, IP and Temp.</p>			

<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>Philips software (SW) version F.01.03 (for M3535A and M3536A) and R.01.00 (for M3536A, English only) corrects this problem.</p> <p>If you have affected product a Philips Service Engineer will contact you to install software version F.01.03 or R.01.00.</p> <p>Until your software is updated your HeartStart MRx monitor/defibrillator can remain in service. If you are using the device in one of the use modes listed above under “problem description”, make sure that operators are aware that even though the EtCO2 and ventilation rate values can display interchangeably (unexpectedly or randomly switch) under either the ventilation rate label or the EtCO2 label, the values themselves can be identified by their color (for example if the ventilation rate label is white, the ventilation value is displayed as white).</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips is voluntarily initiating a corrective action consisting of:</p> <ul style="list-style-type: none"> • Distribution of this Field Safety Notice (FSN). • Installation of updated software on affected devices. <p>Note: Since currently installed units without the Q-CPR option may be upgraded to Q-CPR with CPR meter by the user at a later date, Philips will be correcting all units with software version F.01.00 or F.01.01 and EtCO2, IP, and Temp options. This will eliminate the need to update the software should the device be upgraded at a later date with the Q-CPR option with CPR meter.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative at 1-800-722-9377.</p>