

URGENT – Field Safety Notice Expression MR200 MRI Patient Monitoring System

Failure to Produce NIBP Measurement

Dear Customer,

A problem has been detected in the Philips Expression MR200 MRI Patient Monitoring System. 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 to patients, and
- 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.

It is possible that a wire harness in the non-invasive blood pressure (NIBP) wiring assembly is improperly assembled, which could cause one or more wires to become dislodged. If one or more wires become dislodged, the device will not produce NIBP measurements. This could result in a delay of treatment or diagnosis of the patient.

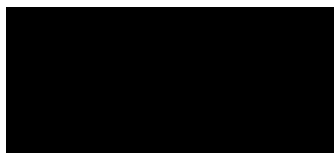
Our records indicate that you have an affected device. The following page provides additional instructions and actions that will be taken to address this problem.

If you need any further information or support concerning this issue, please contact your local Philips representative: **<Philips representative contact details to be completed by the KM / country>**.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,




Quality and Regulatory Senior Manager



Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810

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<p>AFFECTED PRODUCT</p>	<p>Product: 866120 (Expression MR200 MRI Patient Monitoring System)</p> <p>Serial Numbers: US33600004, US33600005, US33600006, US33600007, US33600008, US33600009, US33600010, US33600011, US33600012, US33600013, US33600014, US33600015, US33600016, US33600017, US33600018, US33600019, US33600020, US33600022, US33600023, US33600024, US33600025, US33600026, US33600027, US33600028</p>
<p>PROBLEM DESCRIPTION</p>	<p>It is possible that a wire harness in the non-invasive blood pressure (NIBP) wiring assembly is improperly assembled which could cause one or more wires to become dislodged.</p>
<p>HAZARD INVOLVED</p>	<p>Should one or more wires become dislodged; the device will not produce NIBP measurements. This could result in a delay of treatment or diagnosis of the patient.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p>The picture to the left shows the MR200. The serial number of the MR200 can be found on the back of the Wireless Processing Unit which is outlined in red.</p> </div> </div>



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ACTION TO BE TAKEN BY CUSTOMER / USER	<p>If the problem occurs, the device will display dashes instead of numerical NIBP data and the device may sound an audible alarm. The device may also display one of the following error messages:</p> <table border="1" data-bbox="522 600 1385 1161"> <thead> <tr> <th>Displayed Error Message</th> <th>Meaning</th> <th>Message Location</th> </tr> </thead> <tbody> <tr> <td>MSMT FAIL</td> <td>Measurement Failure</td> <td>NIBP vital sign box</td> </tr> <tr> <td>MSMT TO</td> <td>Measurement Timeout</td> <td>NIBP vital sign box</td> </tr> <tr> <td>HW ERR</td> <td>Hardware Error</td> <td>NIBP vital sign box</td> </tr> <tr> <td>INFL TO</td> <td>Inflation Timeout</td> <td>NIBP vital sign box</td> </tr> <tr> <td>NiBP: MEASUREMENT FAILED</td> <td>NIBP Measurement Failure</td> <td>Notification area (top center area of display)</td> </tr> <tr> <td>NiBP: MEASUREMENT TIMEOUT</td> <td>NIBP Measurement Timeout</td> <td>Notification area (top center area of display)</td> </tr> <tr> <td>NiBP: HARDWARE ERROR</td> <td>NIBP Hardware Error</td> <td>Notification area (top center area of display)</td> </tr> <tr> <td>NiBP: INFLATION TIMEOUT</td> <td>NIBP Inflation Timeout</td> <td>Notification area (top center area of display)</td> </tr> </tbody> </table> <ol style="list-style-type: none"> If the device displays one of these error messages, follow the “Recommended Action” as provided in the device’s Instructions for Use (part number 989803184961) for the given error message. If the Recommended Action fails to clear the error message, discontinue use and contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>. If no error message is displayed but the device repeatedly displays dashes instead of numerical NIBP data, discontinue use and contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>. 	Displayed Error Message	Meaning	Message Location	MSMT FAIL	Measurement Failure	NIBP vital sign box	MSMT TO	Measurement Timeout	NIBP vital sign box	HW ERR	Hardware Error	NIBP vital sign box	INFL TO	Inflation Timeout	NIBP vital sign box	NiBP: MEASUREMENT FAILED	NIBP Measurement Failure	Notification area (top center area of display)	NiBP: MEASUREMENT TIMEOUT	NIBP Measurement Timeout	Notification area (top center area of display)	NiBP: HARDWARE ERROR	NIBP Hardware Error	Notification area (top center area of display)	NiBP: INFLATION TIMEOUT	NIBP Inflation Timeout	Notification area (top center area of display)
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ACTIONS PLANNED BY PHILIPS	<p>A Philips representative will contact you regarding your affected device. To correct the problem, the NIBP assembly will be replaced in all affected devices. This corrective action will be implemented free of charge by Philips.</p>																											
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this problem, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>.</p>																											

