

-1/3-

FSN86201571A

July 09, 2014

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,

Rusty Kelly

Molly

Quality and Regulatory Senior Manager





-2/3-

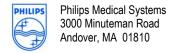
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AFFECTED PRODUCT	Product: 866120 (Expression MR200 MRI Patient Monitoring System)			
	Serial Numbers: US33600004, US33600005, US33600006, US33600007, US33600008, US33600009, US33600010, US33600011, US33600012, US33600013, US33600014, US33600015, US33600016, US33600017, US33600018, US33600019, US33600020, US33600022, US33600023, US33600024, US33600025, US33600026, US33600027, US33600028			
PROBLEM DESCRIPTION	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.			
HAZARD INVOLVED	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.			
HOW TO IDENTIFY AFFECTED PRODUCTS	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.			





-3/3-

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ACTION TO BE TAKEN BY CUSTOMER / USER	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:			
	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:	NIBP	Notification area (top	
	MEASUREMENT	Measurement	center area of display)	
	FAILED	Failure		
	NiBP:	NIBP	Notification area (top	
	MEASUREMENT	Measurement	center area of display)	
	TIMEOUT	Timeout	Notification and then	
	NiBP: HARDWARE ERROR	NIBP Hardware Error	Notification area (top center area of display)	
	NiBP: INFLATION	NIBP Inflation	Notification area (top	
	TIMEOUT	Timeout	center area of display)	
	1. If the device displays one of these error messages, follow "Recommended Action" as provided in the device's Instruction Use (part number 989803184961) for the given error message. Recommended Action fails to clear the error message, discouse and contact your local Philips representative: <fre>representative contact details to be completed by the KM / counting dashes instead of numerical NIBP data, discontinue use and contact Philips representative: <philips be="" by="" completed="" condetails="" country="" km="" representative="" the="" to="">.</philips></fre>			
ACTIONS PLANNED BY PHILIPS	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.			
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this problem, please contact your local Philips representative: <philips be="" by="" completed="" contact="" country="" details="" km="" representative="" the="" to="">.</philips>			

