

URGENT – Field Safety Notice Expression MRI Patient Monitoring System

FlexTEMP Application Site

Dear Customer,

An error has been discovered in the Invivo Expression MRI Patient Monitoring System's Instructions for Use (IFU). 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.

Recent revisions of the device's IFU (Part Number 989803162691, Rev. F- Rev. H) inaccurately indicate "endotracheal" as a body temperature application site. The FlexTEMP reusable temperature sensor is not intended to be used for endotracheal site placement. Should the FlexTEMP reusable temperature sensor be inserted into the patient's trachea, patient infection or airway blockage may occur if any part of the FlexTEMP reusable temperature sensor or FlexTEMP System Jacket is left in the patient upon removal, or if the FlexTEMP System Jacket is damaged and sterilization compromised.

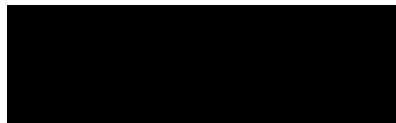
Our records indicate that you have an affected IFU. The following page provides additional instructions and actions that will be taken to address this problem.

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
Quality and Regulatory Senior Manager



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AFFECTED PRODUCT	Product: 865214 (Invivo Expression MRI Patient Monitoring System)
	Serial Numbers: US31204918, US31204919, US31204920, US31204924, US31204925, US31204926, US31204927, US31204928, US31204929, US31204930, US31204931, US31204933, US31204935, US31204943, US31204944, US31204945, US31204946, US31204950, US31204951, US31204952, US31204956, US31204959, US31204960, US31204962, US31204963, US31204964, US31204965, US31204966, US31204967, US31204970, US31204971, US31204972, US31205010, US31205029, US31205030, US31205037, US31205038, US31205054, US31205074, US31205075, US31205076, US31205078, US31205081, US31205082, US31205083, US31205089, US31205090, US31205091, US31205092, US31205106, US31205107, US31205108, US31205109, US31205141, US31205142, US31205143, US31205148, US31205180, US31205208, US31205209, US31205228, US31205229, US31205230, US31205232, US31205273, US31205274, US31205275, US31205276, US31205277, US31205278, US31205279, US31205282, US31205285, US31205286, US31205287, US31205300, US31205301, US31205314, US31205315, US31205317, US31205318, US31205334, US31205341, US31205345, US31205392, US31205393, US31205398, US31205401, US31205402, US31205414, US31205426, US31205427, US31205428, US31205435, US31205436, US31205437, US31205438, US31205459, US31205460, US31205461, US31205462, US31205464, US31205473, US31205509, US31205510, US31205512, US31205518, US31205524, US31205526, US31205568, US31205569, US31205570, US31205571, US31205579, US31205581, US31205582, US31205583, US31205607, US31205611, US31205618, US31205619, US31205623, US31205624, US31205625, US31205627, US31205654, US31205655, US31205656, US31205657, US31205658, US31205667, US31205704, US31205712, US31205713, US31205715, US31205726, US31205727, US31205728, US31205729, US31205730, US31205731, US31205732, US31205733, US31205734, US31205735, US31205802, US31205803, US31205804, US31205805, US31205848, US31205850, US31205851, US31205853, US31205879, US31205909, US31205910, US31205911, US31205912, US31205913, US31205914, US31205915, US31205916, US31205938, US31205939, US31205940, US31205941, US31205971, US31205972, US31205978, US31205979, US31205992, US31205993, US31206022, US31206023, US31206027, US31206062, US31206063, US31206064, US31206065, US31206098, US31206099, US31206100, US31206101, US31206120, US31206121, US31206122, US31206123, US31206130, US31206132, US31206133, US31206134, US31206135, US31206141, US31206142, US31206143, US31206167, US31206172, US31206173, US31206175, US31206176, US31206177, US31206178, US31206179, US31206180, US31206197, US31206198, US31206199, US31206203, US31206222, US31206228, US31206234, US31206235, US31206236, US31206237, US31206238, US31206241, US31206242, US31206247, US31206248, US31206249, US31206250, US31206304, US31206305, US31206306, US31206319, US31206324, US31206328, US31206329, US31206347, US31206357, US31206358, US31206359, US31206360, US31206361, US31206362, US31206390, US31206391, US31206392, US31206397, US31206398, US31206399, US31206400, US31206401, US31206415, US31206420, US31206421, US31206422, US31206423, US31206424, US31206446, US31206447, US31206458, US31206459, US31206460, US31206461, US31206465, US31206466, US31206467, US31206483, US31206484, US31206485, US31206486, US31206487, US31206488, US31206491, US31206503, US31206504, US31206505, US31206508, US31206509, US31206525, US31206533, US31206534, US31206535, US31206536, US31206539, US31206540, US31206541, US31206575, US31206590, US31206594, US31206595, US31206596, US31206597, US31206598, US31206626, US31206633, US31206634, US31206635, US31206636, US31206637, US31206638, US31206639, US31206640, US31206641, US31206642, US31206643, US31206668, US31206670, US31206671, US31206672, US31206673, US31206674, US31206675, US31206676, US31206677, US31206678, US31206679, US31206680, US31206681, US31206682, US31206683, US31206684, US31206685, US31206686, US31206689, US31206690, US31206691, US31206725, US31206726, US31206769, US31206770, US31206780, US31206781,



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PROBLEM DESCRIPTION	Recent revisions of the device's IFU (Part Number 989803162691, Rev. F- Rev. H) inaccurately indicate "endotracheal" as a body temperature application site. The FlexTEMP reusable temperature sensor is not intended to be used for endotracheal site placement.
HAZARD INVOLVED	Should the FlexTEMP reusable temperature sensor be inserted into the patient's trachea, patient infection or airway blockage may occur if any part of the FlexTEMP temperature sensor or FlexTEMP System Jacket is left in the patient upon removal, or if the FlexTEMP System Jacket is damaged and sterilization compromised.
HOW TO IDENTIFY AFFECTED PRODUCTS	 The picture to the left shows the Expression MRI Patient Monitoring System. The serial number of the Expression can be found on the back of the Wireless Processing Unit which is outlined in red.
ACTION TO BE TAKEN BY CUSTOMER / USER	1. Included with this letter, please find an errata sheet to the Expression IFU, which removes endotracheal as an application site. Please ensure that the information contained in the errata sheet is communicated to all users and retained with the Expression IFU. 2. Please sign and return the Reply Form on last page of this communication following the instructions on the Reply Form. Note: Devices with the Lumasense disposable temperature option remains unaffected and can continue to be used as instructed in the labeling provided with the device at the time of purchase (Part Number 989803162691, Rev. A – Rev. D).
ACTIONS PLANNED BY PHILIPS	Philips is working on a solution to this issue. Once a solution is available, we will provide you with another communication outlining our plans for implementing the solution.
FURTHER INFORMATION AND SUPPORT	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>.



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

I certify that our facility has read and understood FSN86201647A and that we have ensured that the information contained in the errata sheet was communicated to all users and retained with all copies the Expression IFU.

Signature: _____

Date: _____

Please email the completed reply form to Jennifer.Maglio@philips.com or fax it to +1 404-855-4900.

If you experience difficulty in carrying out the instructions contained in this communication, contact your local Philips representative: **<Philips representative contact details to be completed by the KM / country>**.

