URGENT – MEDICAL DEVICE RECALL
Expression MRI Patient Monitoring System
Loose Caster (Wheel)

Dear Customer,

A problem has been detected in the Philips Invivo Expression MRI Patient Monitoring System that, if it were to re-occur, could pose a risk for patients or users. 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 user in order to prevent risks for patients or users
- the actions planned by Philips Invivo 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.

Please retain a copy with the equipment Instruction for Use.

This notice is intended for Philips Invivo customers using the Expression MRI Patient Monitoring System. During transport of the system's cart with a docked Display Controller Unit (DCU), a front caster (wheel) may become loose and fall off. If this occurs, the cart will become unbalanced and fall.

Our records indicate that you may have an affected system. Serial numbers affected by this problem are listed on the following page. The following page also provides additional instructions and actions to be taken; refer to the "Action to be Taken by Customer/User" section for more information.

This issue has been reported to the local regulatory authority.

We sincerely apologize for any inconvenience this problem may have caused you. Your satisfaction with Philips Invivo products and with our response to this issue is very important to us. If you need additional information or support regarding this issue, please contact your local Philips Invivo representative: <Philips Invivo representative contact details to be completed by the KM / country>.

Sincerely,

[redacted]

[redacted]
Quality and Regulatory Manager

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AFFECTED PRODUCTS	**Product:** 865214 (Service Numbers 453564155341, 453564180091 and 453564181201) **Serial Numbers:** US93600111, US93600112, US93600113, US93600114, US93600142, US93600144, US93600167, US93600170, US00200119, US00200132, US00200133, US00200134, US00200135, US00200136, US00200139, US00200140, US00200141, US00200142, US00200143, US00200144, US00200162, US00200163, US00200164, US00200165, US00200166, US00200167, US00200168, US00200169, US00200170, US00200171, US00200172, US00200173, US00200192, US00200193, US00200194, US00200195, US00200196, US00200197, US00200219, US00200220, US00200221, US00200222, US00200223, US00200224, US00200238, US00200239, US00200240, US00200241, US00200242, US00200243, US00200258, US00200259, US00200260, US00200261, US00200262, US00200263, US00200283, US00200284, US00200285, US00200286, US00200292, US00200293, US00200294, US00200295, US00200296, US00200299, US00200300, US00200301, US00200302, US00200343, US00200344, US00200345, US00200352, US00200354, US00200361, US00200362, US00200371, US00200372, US00200381, US00200382, US00200383, US00200393, US00200394, US00200395, US00200396, US00200399, US00200434, US00200435, US00200436, US00200454, US00200455, US00200456, US00200457, US00200458, US00200459, US00200528, US00200529, US00200530, US00200531, US00200532, US00200557, US00200558, US00200560, US00200561, US00200562, US00200563, US00200564, US00200565, US00200566, US00200567, US00200568, US00200569, US00200600, US00200601, US00200602, US00200603, US00200619, US00200621, US00200636, US00200667, US00200668, US00200669, US00200670, US00200671, US00200672, US00200673, US00200674, US00200687, US00200688, US00200689, US00200690, US00200709, US00200726, US00200727, US00200729, US00200736, US00200737, US00200742, US00200743, US00200744, US00200745, US00200746, US00200747, US00200749, US00200750, US00200770, US00200780, US00200784, US00200785, US00200812, US00200823, US00200824, US00200827, US00200828, US00200829, US00200830, US00200831, US00200851, US00200865, US00200866, US00200872, US00200873, US00200888, US00200889, US00200890, US00200891, US00200892, US00200893, US00200907, US00200908, US00200909, US00200915, US00200916, US00200917, US00200918, US00200919, US00200920, US00200921, US00200922, US00200923, US00200932, US00200933, US00200958, US00200959, US00200960, US00200961, US00200966, US00200967, US00200968, US00200975, US00200977, US00200978, US00200984, US00200990, US00201002, US00201003, US00201022, US00201023, US00201024, US00201025, US00201053, US00201054, US00201055, US00201056, US00201057, US00201058, US00201065, US00201066, US00201067, US00201068, US00201112, US00201113, US00201114, US00201115, US00201116, US00201117, US00201118, US00201131, US00201132, US00201133, US00201135, US00201137, US00201146, US00201147, US00201148, US00201149, US00201150, US00201151, US00201152, US00201162, US00201210, US00201213, US00201214, US00201215, US00201216, US00201217, US00201219, US00201221, US00201222, US00201223, US00201224, US00201225, US00201226, US00201227, US00201229, US00201230, US00201251, US00201252, US00201253, US00201254, US00201255, US00201256, US00201257, US00201258, US00201259, US00201260, US00201261, US00201262, US00201297, US00201298, US00201299, US00201300, US00201301, US00201302, US00201303, US00201304, US00201305, US00201306, US00201364, US00201365, US00201368, US00201381, US00201382, US00201383, US00201384, US00201385, US00201386, US00201388, US00201389, US00201408, US00201409, US00201417, US00201451, US00201452, US00201453
PROBLEM DESCRIPTION	During transport of the cart with a docked DCU, a <u>front</u> caster (wheel) may become loose and fall off. If this occurs, the cart will become unbalanced and fall. **NOTE:** If one of the <u>rear</u> casters becomes loose and falls off and a DCU is docked on the cart, the cart will tilt back, but it will not fall. Also, if a front or rear caster becomes loose and falls off and a DCU is not docked on the cart, the cart will only lean in the direction of the missing caster, but does not fall.
HAZARD INVOLVED	If the problem were to occur, the device could fall directly onto the user's foot or onto the patient. Also, accessories and consumables that are applied to the patient and connected to the cart (for example: an IBP transducer, NIBP cuff and hose, temperature probe or cannula) could be disconnected from the patient.

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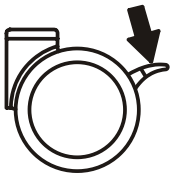
HOW TO IDENTIFY AFFECTED PRODUCTS	 The picture to the left shows the backside of the cart. The serial number of the device can be found in the area that is circled.
ACTION TO BE TAKEN BY CUSTOMER / USER	Until your cart is updated, follow these guidelines to reduce the risk of harm:  Wheel Lock 1. Frequently inspect all casters to ensure that they are secure. If you find a loose caster, lock the loose caster in place, limit movement of the cart and contact your local Philips Invivo representative: <Philips Invivo representative contact details to be completed by the KM / country>. 2. When the cart is in motion, maintain control of the cart at all times by holding the handle of the cart. Should the cart become unstable, discontinue movement of the cart, lock the casters and contact contact your local Philips Invivo representative: <Philips Invivo representative contact details to be completed by the KM / country>. 3. Ensure that lengths of patient-applied accessories and consumables are long enough to reduce the possibility of disconnection should a caster become loose and fall off and the cart fall. If the length of any patient-applied part is increased, caution should be taken to avoid tripping or rolling over any of the accessory or consumable items.
ACTIONS PLANNED BY PHILIPS INVIVO	A Philips Invivo representative will contact you regarding your affected device. All affected devices will have a locking compound applied to the hardware that secures the casters in place in order to correct the problem. This corrective action will be implemented free of charge by Philips Invivo.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips Invivo representative: <Philips Invivo representative contact details to be completed by the KM / country>.

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