

Magnetic Resonance

FSN78100490

December 2018

URGENT - Field Safety Notice Medical Device Correction

Ingenia Elition S, Ingenia Elition X

Unintended table movement after pressing 'stop-button'

Dear Customer,

A problem has been detected in the Philips Ingenia Elition MR systems, that, if it were to re-occur, could pose a risk for patients or users. This FSN 78100490 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 for patients
- 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.

Please retain a copy with the equipment Instruction for Use.

If you need any further information or support concerning this issue, please contact your local Philips representative:

0800 80 3000

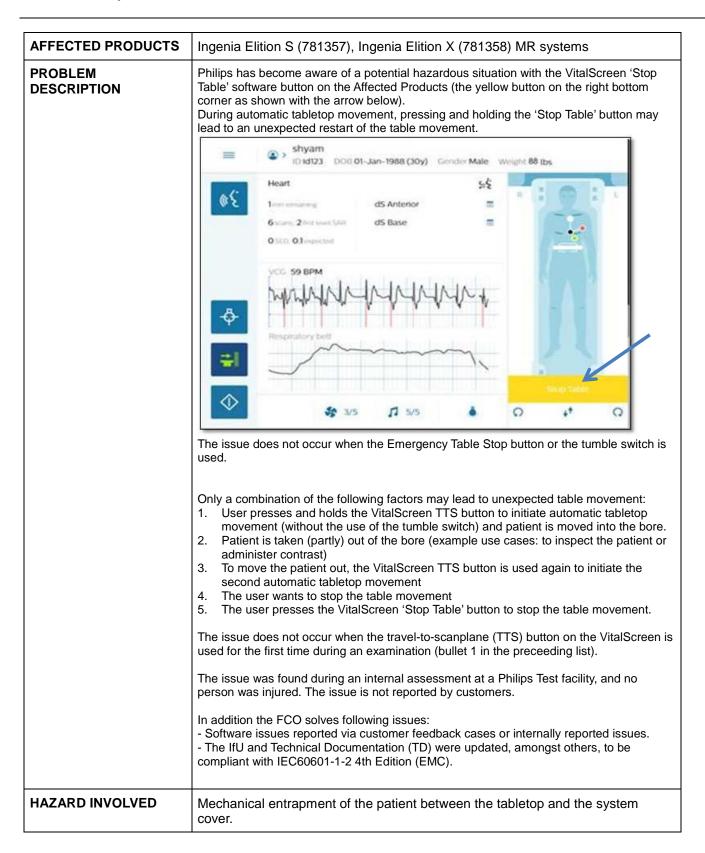
This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Paul Sherlock Head of Quality and Regulatory BIU, Magnetic Resonance Imaging







HOW TO IDENTIFY AFFECTED PRODUCTS	Ingenia Elition S (781357) and Ingenia Elition X (781358) MR systems, with software R5.5.0.0
ACTION TO BE TAKEN BY CUSTOMER / USER	The user must follow the Instructions for Use to verify that no part of the patient's body, hair, clothing, cables or infusion lines can get trapped or injured by any part of the equipment. Additionally, the VitalScreen shows positioning guidance regarding arm supports and padding.
	The user should avoid the use of the yellow 'Stop Table' button on the VitalScreen. The user must always use the tumble switch or physical 'Emergency Table Stop' button for cases which require the table movement to stop.
ACTIONS PLANNED BY PHILIPS	Via FCO78100490 Service Pack 1 for R5.5.0 will be rolled out to the affected systems. With this Service Pack the 'Stop Table' software button on the VitalScreen will be removed. The additional items mentioned in the problem description are implemented.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: 0800 80 3000