

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN

CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Change Order pertaining to the Philips Ingenia Elition S (781357), Ingenia Elition X (781358) MR systems due to FCO 78100490. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <Affected serial number>

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date:

Magnetic Resonance

FSN781 00490

November 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 781 00490 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.

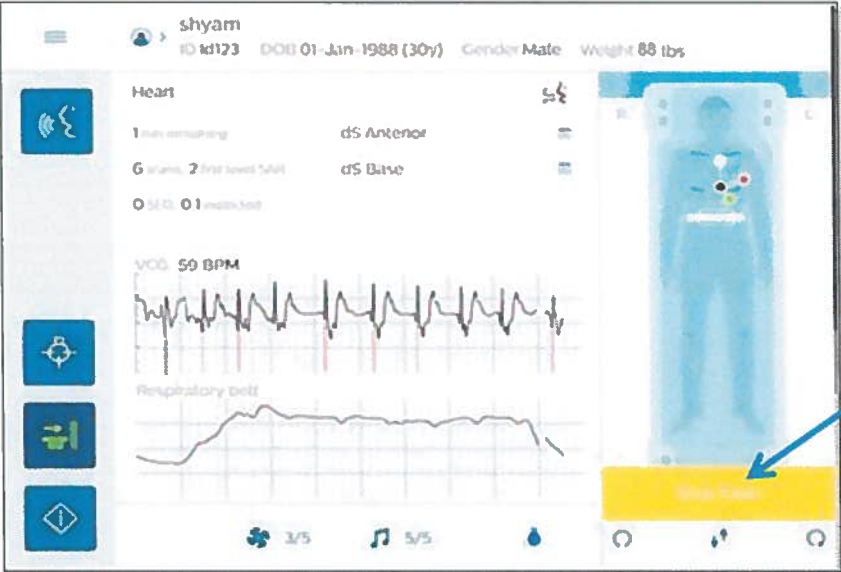
If you need any further information or support concerning this issue, please contact your local Philips representative:

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

<p>AFFECTED PRODUCTS</p>	<p>Ingenia Elition S (781357), Ingenia Elition X (781358) MR systems</p>
<p>PROBLEM DESCRIPTION</p>	<p>Philips has become aware of a potential hazardous situation with the VitalScreen 'Stop Table' software button on the Affected Products (the yellow button on the right bottom corner as shown with the arrow below).</p> <p>During automatic tabletop movement, pressing and holding the 'Stop Table' button may lead to an unexpected restart of the table movement.</p>  <p>The issue does not occur when the Emergency Table Stop button or the tumble switch is used.</p> <p>Only a combination of the following factors may lead to unexpected table movement:</p> <ol style="list-style-type: none"> 1. User presses and holds the VitalScreen TTS button to initiate automatic tabletop movement (without the use of the tumble switch) and patient is moved into the bore. 2. Patient is taken (partly) out of the bore (example use cases: to inspect the patient or administer contrast) 3. To move the patient out, the VitalScreen TTS button is used again to initiate the second automatic tabletop movement 4. The user wants to stop the table movement 5. The user presses the VitalScreen 'Stop Table' button to stop the table movement. <p>The issue does not occur when the travel-to-scanplane (TTS) button on the VitalScreen is used for the first time during an examination (bullet 1 in the preceding list).</p> <p>The issue was found during an internal assessment at a Philips Test facility, and no person was injured. The issue is not reported by customers.</p> <p>In addition the FCO solves following issues:</p> <ul style="list-style-type: none"> - Software issues reported via customer feedback cases or internally reported issues. - The IfU and Technical Documentation (TD) were updated, amongst others, to be compliant with IEC60601-1-2 4th Edition (EMC).
<p>HAZARD INVOLVED</p>	<p>Mechanical entrapment of the patient between the tabletop and the system cover.</p>

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	<p>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.</p> <p>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.</p>
ACTIONS PLANNED BY PHILIPS	<p>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.</p> <p>The additional items mentioned in the problem description are implemented.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative: <i><Philips representative contact details to be completed by the Market></i></p>