

URGENT – FIELD SAFETY NOTICE

Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 1.5T S, Ingenia 1.5T CX, SmartPath to dStream for 1.5T, Ingenia 3.0T, Ingenia Ambition S, Ingenia Ambition X, Ingenia Elition S, Ingenia Elition X, Ingenia 3.0T CX, SmartPath to dStream for XR and 3.0T

When using manual mode, the tabletop may not completely move in or out

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.

30-JUL-2021

Dear Customer,

A problem has been identified in the Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 1.5T S, Ingenia 1.5T CX, SmartPath to dStream for 1.5T, Ingenia 3.0T, Ingenia Ambition S, Ingenia Ambition X, Ingenia Elition S, Ingenia Elition X, Ingenia 3.0T CX, SmartPath to dStream for XR and 3.0T Magnetic Resonance (MR) systems that could pose a risk for patients. This Field Safety Notice letter is intended to inform you about:

1. What the problem is and under what circumstances it can occur

Philips has identified an issue that may cause the table to become stuck when using the manual mode only to move the table. Note the motorized mode is not affected by this issue. The issue may occur when using manual mode due to the interaction between the gear profile and the Flexrack of the Horizontal Drive Unit (HDU). The HDU moves the Magnetic Resonance (MR) system tabletop using primarily a motorized function, but there is secondarily a manual function provided as a backup if the motorized horizontal tabletop movement is not functioning properly or if the need arises to quickly evacuate a patient from the bore for any emergent reason.

The table may become stuck if the following two conditions are present simultaneously in an MR system HDU:

- 1) the gear profile is non-rounded AND
- 2) the Flexrack is slightly bowed

When these two conditions occur, the tabletop outward motion may be blocked when using the manual mode only. Motion is not blocked when using the primary motorized function because the point of engagement between the gear profile and Flexrack is different than in the manual mode.

No related customer complaints have been reported up to and including July 2021.

2. Describe the hazard/harm associated with the issue

There may be a potential delay in patient evacuation from the bore, which could result in a delay of needed treatment. If the need arises to quickly evacuate a patient from the bore for any emergent reason by using the manual function, a potential delay could occur since the manual function may be stuck and the user must use the motorized function instead. The table motorized function moves the table more slowly than the manual function, which may lead to delays of 15-90 seconds in patient evacuation. Please be advised that this issue does not impact the motorized function to perform table movement.

3. Affected products and how to identify them

Product Code	Product Description	Product Code	Product Description
781341 781396	Ingenia 1.5T	781342 781377	Ingenia 3.0T
781315	Ingenia 1.5T Evolution	781357	Ingenia Elition S
781347	Ingenia 1.5T S	781358	Ingenia Elition X
781261 781262	Ingenia 1.5T CX	781271	Ingenia 3.0T CX
781260	SmartPath to dStream for 1.5T	781270	SmartPath to dStream for XR and 3.0T
781359	Ingenia Ambition S	781356	Ingenia Ambition X

*The Product Code of your system is located on the system identification label in the technical room.

4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients or users

Philips is requesting customers to perform the following:

1. Verify the manual function is working:

Please perform the following steps as soon as possible:

1. Use the tumble switch to move the tabletop into the bore until it cannot go any further.
2. Press the Emergency Table Stop button on the side of the patient support.
3. Pull the tabletop manually out of the bore until it reaches the fully out position.
4. Press the resume button to return to normal work.
5. If the tabletop moves freely out of the bore, no additional action is needed, you can continue to use the MR system in either primary motorized or manual mode.
6. If the tabletop does not move freely, please immediately contact Customer Care Solutions Center (1-800-722-9377) and reference FCO78100527 to arrange for a Philips Field Service Engineer to visit your site to inspect and fix the HDU in your MR system. Until a Philips Service Engineer visits your site, you may continue to utilize the primary motorized function for the MR system.

2. Communication to users of the MR system:

1. Please advise your staff that they may continue to utilize the primary motorized function for the MR system. The identified issue with the HDU does not occur in the motorized mode. If you utilize the manual function and it is not functioning properly, then you must perform table movement using the primary motorized function.
2. Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm.

3. Post this notice near the affected MR unit(s) for ease of reference.

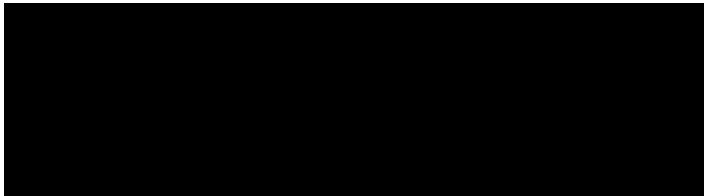
5. Describe the actions planned by Philips MR to correct the problem

Out of an abundance of caution, a Philips Field Service Engineer (FSE) will contact you to schedule an on-site visit to perform a check of the HDU. If the issue is detected in the HDU, the Philips FSE will replace the necessary mechanical component(s) to resolve the issue.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is Philips' highest priority. If you need additional information or support concerning this issue, please contact the Customer Care Solutions Center (1-800-722-9377) and reference FCO78100527.

Sincerely,



URGENT FIELD SAFETY NOTICE RESPONSE FORM**Reference:**

When using manual mode, the tabletop may not completely move in or out (FCO 78100527).

Instructions: Please complete and return this form to Philips promptly upon receipt and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

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1. Please advise your staff that they may continue to utilize the primary motorized function for the MR system. The identified issue with the HDU does not occur in the motorized mode. If you utilize the manual function and it is not functioning properly, then you must perform table movement using the primary motorized function.
2. Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm.
3. Post this notice near the affected MR unit(s) for ease of reference.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice letter and confirm that the information from this letter has been properly distributed to all Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 1.5T S, Ingenia 1.5T CX, SmartPath to dStream for 1.5T, Ingenia 3.0T, Ingenia Ambition S, Ingenia Ambition X, Ingenia Elition S, Ingenia Elition X, Ingenia 3.0T CX, SmartPath to dStream for XR and 3.0T users.

URGENT FIELD SAFETY NOTICE RESPONSE FORM

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date
(DD/MM/YYYY): _____

Please complete and return the attached acknowledgment form to Philips MR via email to:
DIFCO@philips.com