

Field Safety Notice

Height Adjustable (HA) FlexTrak Trolley
 Potential falling hazard resulting from HA FlexTrak Trolley oil leakage

May 03, 2024

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 this letter for your records.

Dear Customer,

Philips has identified an issue with HA FlexTrak Trolley accessories used with MR systems. This Field Safety Notice is intended to inform you about:

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

Philips has identified that oil may leak from the HA FlexTrak Trolley when pressing the hydraulic pedal, resulting in a potential slipping/falling hazard.

Philips has received no reports of adverse events associated with this issue as of April 2024.

2. Hazard/harm associated with the issue


If oil leakage occurs, the risk to patients, operators, and service personnel may include physical harm from falling (e.g. abrasion, bruise, laceration, fracture, concussion).

3. Affected products and how to identify them

Identification of Impacted Products:

Impacted products can be identified by the product name and product number (REF) as shown in Figure 1.

Figure 1. Example Product Label

Example Product Label	Product Name	Product Number (REF)
	HA FlexTrak	989710006411
		989710006412

	<p>HA FlexTrak II</p>	<p>989710008732</p>
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The HA FlexTrak identification label is positioned on the handgrip side of the trolley below the pump pedal, as shown in Figure 2.

Figure 2. HA FlexTrak Label Location



Intended Use:

The HA FlexTrak Trolley is part of the patient transport functionality to transport the patient from the preparation area to the MR system, which allows patient preparation for an examination while the previous patient is being scanned. Positioning of coils, positioning aids, monitoring, and triggering equipment can be done outside the examination room. For patients with limited mobility, the HA FlexTrak Trolley can be lowered and raised to an ergonomic working height for the patient and operator. The operator can lift the HA FlexTrak Trolley via a foot-operated hydraulic pump unit.

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

- A. If you see hydraulic fluid (oil) leakage:
 - First remove fluid from the floor using a paper towel. Then remove any remaining oil film from the floor using a cleaning agent (e.g. soap and water) and paper towel.
 - Contact your local Philips service representative.
- B. You may continue to use your HA FlexTrak Trolley in accordance with the intended use.
- C. Circulate this notice to all users of this device so that they are aware of the issue and associated hazard/harm until this issue has been resolved.
- D. Please post this letter near the associated MR system(s) for ease of reference.
- E. Complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site to inspect the HA FlexTrack Trolley and correct if required (reference FCO78100580).

Please be assured that maintaining a high level of safety and quality is our highest priority. 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 Agencies.

Sincerely,



David Hanly
Head of Quality
Precision Diagnosis

Field Safety Notice Response Form

Reference: HA FlexTrak Trolley for MR systems (FCO78100580)

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

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- A. If you see hydraulic fluid (oil) leakage:
 - First remove fluid from the floor using a paper towel. Then remove any remaining oil film from the floor using a cleaning agent (e.g. soap and water) and paper towel.
 - Contact your local Philips service representative.
- B. You may continue to use your HA FlexTrak Trolley in accordance with the intended use.
- C. Circulate this notice to all users of this device so that they are aware of the issue and associated hazard/harm until this issue has been resolved.
- D. Please post this letter near the associated MR system(s) for ease of reference.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this notice has been properly distributed to all users that handle the impacted MR system(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please complete and return the attached response form to Philips via email to: **[Local Markets to input Contact Information]**