PHILIPS

URGENT Field Safety Notice

Radiography 7000 M
No Drive After Exposure Issue

September 2026

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 become aware of a potential safety issue impacting the Radiography 7000 M system (Model 712010) where the drive function may fail immediately after an exposure, causing the system to remain stationary.

1. Issue Description

The issue may occur with the Radiography 7000 M system immediately after an exposure, causing the drive function to fail and preventing repositioning of the system. The system may remain stationary instead of driving upon activation of the handlebar. The issue is intermittent and has been observed during routine mobile radiography use.

2. Hazard/harm associated with the issue

The inability to reposition the system after exposure may result in delayed access to a patient and potential delay to treatment or therapy. As of July 2026, Philips has received 35 complaints associated with this issue. There has been one (1) report where the no-drive condition impeded active patient resuscitation during emergency use.

3. User instruction

The actions that you, as a customer, can take to minimize the effect of the issue:

A. You may continue to use your Radiography 7000 M system in accordance with its intended use.
B. If the no-drive issue occurs and prevents repositioning of the system, system movement may be restored through one or more of the following options:
    - Option 1: System reboot
        - Power OFF the unit, wait at least 10 seconds, and then power system ON
        - While system startup may take up to **4 minutes**, drive functionality will be available within approximately **8 seconds** after the unit is powered on.
        - Confirm that drive functionality has been restored before continuing clinical use.
    - Option 2: Use alternate registered RFID card
        - Use a **different registered RFID card** than the one most recently used to log into the system (for example, the backup RFID card kept with the system).
        - Hold the RFID card over the RFID reader until an audible beep is heard (typically within **1 to 3 seconds**).
        - Confirm that drive functionality has been restored before continuing clinical use.

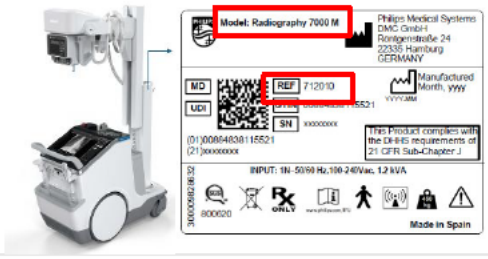
- Option 3: Manually unlock the wheels using tools provided on the system to free the movement of the system
  - As referenced in the Instructions for Use (IFU: Operation section ->Transport -> Motion Control -> Manual Clutch Screws), use the clutch tools provided on the system to remove the mounted hubcap and remove the clutch screws (x2) of each wheel.

C. Circulate this notice to all users of the device so they are aware of the issue and associated hazard/harm.
D. Retain this notice with your system until the correction described in Section 4, Manufacturer's Actions, has been implemented.
E. Please complete and return the attached response form (at the end of this notice) no later than 30 days from receipt of this letter.

4. Identification of Affected Product

The impacted systems can be identified by the product name (model) and product number (REF). The product name (model) and product number (REF) can be found on the system label, as indicated in Table 1. below

Table 1.

Label Example	Product Name (model)	Product Number (Ref)	Product UDI
	Radiography 7000 M Release 1.0	712010	00884838115521

Intended Use:

Radiography 7000 M is intended for use by adequately trained, qualified, and authorized healthcare professionals on both adult and pediatric patients who cannot be transferred to the stationary X-ray system for taking diagnostic radiographic exposures for the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in prone or supine positions.

5. Manufacturer Actions

Philips will be implementing a software correction to address the issue. A Philips representative will contact you to schedule implementation when the correction becomes available. Reference 2026-PD-DXR-012. If you need any further information or support concerning this issue, please contact your local Philips representative: **+31 40 700 1210, option 2, option 2, option 2.**

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Philips

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URGENT Field Safety Notice

Reference: No Drive After Exposure Issue; Radiography 7000 M; FSN 2026-PD-DXR-012

Instructions: Please complete and return this form to Philips promptly and no later than 30 day from receipt **(BNL_Quality_CR@philips**). Completing this form confirms receipt of the Urgent 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:

- Follow the instructions provided in Section 2 of the Urgent Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the Radiography 7000 M

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____