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URGENT Field Safety Notice

MobileDiagnost wDR Unintended Motion

January 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 which could occur with the MobileDiagnost wDR systems identified in Section 3 of this notice. This Urgent Field Safety Notice letter is intended to inform you about:

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

If a user, while cleaning or disinfecting the MobileDiagnost wDR system, uses excessive liquid or if liquid is sprayed directly on the system, it is possible for liquid to enter the edges of the handgrip buttons and cause metal corrosion or an electrical short circuit to the overlay connector (Refer Figure 1). The system has four (4) buttons on the handgrips which control the motion of each driving wheel (forwards / backwards) and if the system experiences an electrical short circuit due to this issue, the system may move on its own in slow (20 cm/s) motion. At this speed, a person or bystander can easily move away from the system without any injury. The user can easily access the Emergency Stop button and stop the system movement. The issue does not occur once the liquid dries.

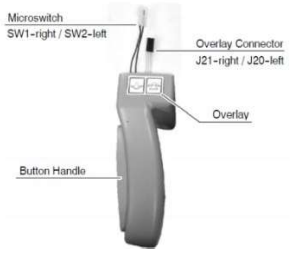

Figure 1 Microswitch and overlay connectors on the handgrip

Philips has received 39 complaints regarding liquid ingress causing a short circuit of the fine positioning control button. Philips investigation concluded that this issue is related to the excessive use of disinfectant cleaning solutions. Customers may continue to use the device according to its intended use.

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2. **Hazard/harm associated with the issue**

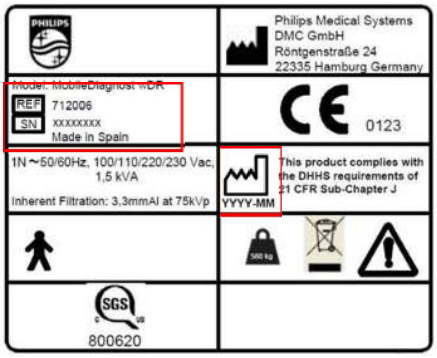
If a person cleaning the system does not notice the unintended movement, there is a potential they could trip, which could result in physical injury including hematoma, abrasion, and bone fracture.

If unintended movement occurs while a system is being cleaned in a patient room and the system makes contact with a life supporting device, there is a potential it could disrupt the patient care resulting in cardiac arrest, heart failure, renal failure, and/or respiratory failure.

3. **Affected products and how to identify them**

Impacted Systems:

The impacted systems can be identified by the Model Name, Model Number (REF), and Manufacture Date. The Model Name, Model Number (REF), and Manufacture Date can be found on the system label, as indicated by Figure 2.

Figure 2. System Label Example	Model Name	Model Number (REF)	Manufacture Date (YYYY-MM)
	MobileDiagnost wDR	712001, 712002, 712005, 712006, 9890-010-89522	Before 2022-08

Intended Use:

Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures for the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing, or lying in the prone or supine positions.
Not for mammography.

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

a. You may continue to use your system(s) in accordance with the intended use.
   - If unintended motion occurs:
     - Press Emergency Stop button to prevent further movement
     - Allow unit to dry. Once dry, the system will move as intended.
   - During Cleaning:
     - Do not spray disinfectants directly on the buttons, since this may cause electrical short circuits or metal corrosion.
     - Follow the cleaning instructions provided in the *Maintenance, Cleaning and Disposal* section of the instructions for use (IFU).

b. Circulate this notice to all users of the system so that they are aware of the issue and associated hazard/harm.

c. Please retain this Urgent Field Safety Notice letter with your system(s) until the solution is installed; ensure the notice is in a place likely to be seen/viewed.

d. Please complete and return the attached response form to Philips DXR promptly and no later than 30 days from receipt of this letter via email to: Philips.Recall@Philips.com.

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 implement the following (reference FCO71200255):

- Install a plastic overlay on the grip to prevent liquid from entering the gaps around the fine positioning control buttons.
- Install a firmware upgrade that stops system movement if triggered by a short circuit or extended activation of the control button.

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,

Naveen Huilgol
Head of Quality - DXR

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URGENT Field Safety Notice Response Form

Reference: MobileDiagnost wDR Unintended Motion (FCO71200255)

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 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:
Follow the instructions provided in Section 4 of the Urgent Field Safety Notice Letter.

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 users that handle the affected 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 acknowledgement form to Philips DXR via email to: *<Insert contact here>.*