

DXR

Quality Management System DXR

DXR Field Safety Notice

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FSN MA-FCO 71200182

2018-May-17

URGENT - Field Safety Notice ***MobileDiagnost wDR***

Pinch point warning label missing on sliding column

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips MobileDiagnost wDR we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue

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, please contact your local Philips representative:

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,


Michael Mizrachi
Head of Q&R DXR

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AFFECTED PRODUCTS	MobileDiagnost wDR
PROBLEM DESCRIPTION	When the operator or a bystander touches the area of the inner part of the vertical sliding column (on which the tube arm moves up or down), without paying attention of the tube arm movement, the fingers can be pinched.
HAZARD INVOLVED	A hazard evaluation concluded that a pinched finger could cause a haematoma or in worst case it could be possible to cause a broken finger. The instruction for use require to keep all body parts and clothing free of the equipment to avoid getting caught or trapped within the moving components of this medical equipment.
HOW TO IDENTIFY AFFECTED PRODUCTS	MobileDiagnost wDR systems are affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	No action is needed on your part. There are no restrictions to usage of this device. Customers may continue to use the device according to its intended use. Should you feel uncertain regarding these instructions, please contact Philips.
ACTIONS PLANNED BY PHILIPS	Philips plans to install a new label at affected systems, which will eliminate this issue. A Philips Service Engineer will contact you when the Field Action Kit is available to be implemented. Should you need to communicate with Philips with regard to this program, please reference Field Change Order 71200182.
FURTHER INFORMATION AND SUPPORT	If you would like any further information or support concerning this issue, please contact your local Philips representative.