URGENT - Field Safety Notice
Juno DRF

Additional safety label for table base

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 Juno DRF, 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:

<Philips representative contact details to be completed by the KM / country>

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

Sincerely,

Karmen Gruenert
Director Q&R DXR Hamburg (Print Name)

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AFFECTED PRODUCTS	Juno DRF
PROBLEM DESCRIPTION	Philips distributes the Juno DRF system on behalf of the system's manufacturer, Villa Sistemi Medicali SpA, Italy. We became aware that an operator got hurt while relocating a patient from Juno DRF table onto the patient's bed. Standing behind the table top between the left table top support arm and the detector holder, he got squeezed between the left table top support arm and the detector holder. The analysis showed that the incident was caused by a chain of four faults: 1.) The injured person overcame a physical barrier (the tabletop support arm, height ca. 60 cm) to access a prohibited area not intended as a working position. 2.) The directions for use (device labeling and instructions for use) did not contain an explicit exclusion of the prohibited area. 3.) The movement was activated inadvertently and continuously, and it was not released (the movement requires continuous activation). 4.) Delayed activation of the emergency stop. The current state of the art regarding medical device safety requires a single fault proof design. In this case, a chain of four faults, three of which were outside the manufacturer's control, caused the incident. For this reason, if the directions for use (device labeling and instructions for use) contained an explicit exclusion of the prohibited area, the device would meet the applicable technical safety requirements requiring safety under any single fault condition.
HAZARD INVOLVED	Failure in providing adequate directions for use containing an explicit exclusion of the prohibited area may expose the operator to risk of squeezing. This hazard is present only if 3 other conditions are present at the same time: 1.) The operator overcomes a physical barrier (the tabletop support arm, height ca. 60 cm) to access a prohibited area not intended as a working position. 2.) The movement is activated inadvertently and continuously, and it was not released (the movement requires continuous activation). 3.) None of the emergency stops is activated in a timely manner.
HOW TO IDENTIFY AFFECTED PRODUCTS	If you receive this letter your Juno DRF is affected by this FCO.

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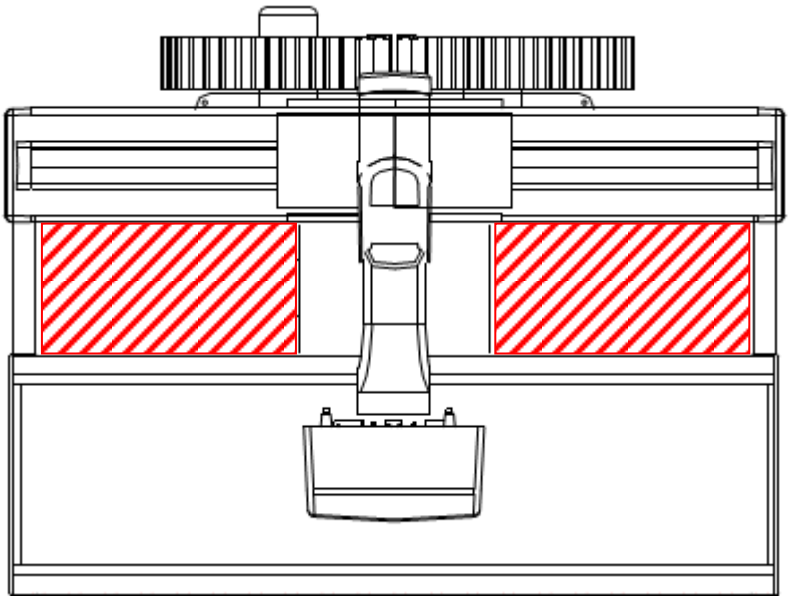
ACTION TO BE TAKEN BY CUSTOMER / USER	Pending the correction, the system can be operated instructing the operators to operate according to the following information. This information needs to be passed to all users of Juno DRF and to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. In the areas highlighted in the following picture the **risk of squeezing** is present between the detector carrier structure and the tabletop supporting arms in case the motorized movements are activated.  **It is forbidden to enter or stay in such areas when the system is powered on.**

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ACTIONS PLANNED BY PHILIPS	Philips will provide improved directions for use (including device labeling) that include:
	• An additional warning sign ISO 7010:2011 W019
	 
	• A prohibition sign banning access to the prohibited area
	• Additional Safety information to be attached the the IfU precisely explaining
	  ○ the prohibited area
	  ○ the hazard
	  ○ countermeasures in case of a violation of the prohibition
	  ○ the additional device labeling..
	
	You will be contacted by Philips to schedule the installation.
	
	Should you need to communicate with Philips with regard to this program, please reference FCO-70900032.

FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative.