

Name
Company
Adress
Zip Code - City
COUNTRY

URGENT FIELD SAFETY NOTICE

Product name: D²RS

Serial number(s) concerned: XXXX

FSCA NUMBER: RC1706820

Nature of action: Device Modification

Attached document: Acknowledgment to return



***This document provides an important information to ensure
the safe use of your equipment,
Please read it carefully***

La Ricamarie,
Date: XXXX

Dear Sir or Madam,

This letter is sent to inform you that STEPHANIX has detected a potential issue that could pose a risk to patients, users, or third parties. STEPHANIX is taking corrective action on all **D²RS** devices.

The objective of this field safety notice is to inform you of:

- The nature of the issue and under which circumstances this could happen.
- The actions that the users have to take to ensure the safety of patients, users and third parties.
- The actions implemented by STEPHANIX to eliminate this risk.

You will find the detail of this dysfunction page 2.

Please, communicate this information note to the people concerned.

We kindly ask you to complete, sign and return the acknowledgment enclosed within 10 days.

Best regards,

Guy Jonon,
Medical Vigilance Alert Correspondent

URGENT FIELD SAFETY NOTICE

<p>Identification of the devices concerned</p>	<p>D²RS, including VISIONARY DRF and DX-D800 models.</p>
<p>Issue Description</p>	<p>We have detected a potential risk that could lead to a collision between the table column and the ceiling structure. This hazard could generate a breakdown of the column.</p> <p>This incident is due to the appearance of two simultaneous problems: a command has been kept active and the table software encountered a malfunction which does not allow to take into account the clearance parameters of the room anymore.</p>
<p>Risks related to the issue</p>	<p>Possible risk to harm a patient, a user, or a third if the column breaks.</p>
<p>Actions to be implemented by the users concerned.</p>	<p>As a precautionary measure and before your usual maintenance team intervention, the user should look at the equipment during all of its movement. He has to immediately release the command if an abnormal movement is detected. If necessary, he should use the emergency switch to stop the system.</p> <p>If unexpected problems occur, the user should contact XXXX .</p>
<p>Corrective actions taken by STEPHANIX</p>	<p>STEPHANIX plans to update the table software to completely eliminate this potential risk and ensure the safety of patients, users and third parties.</p> <p>Your technical team will contact you in order to make an appointment to perform this corrective action.</p> <p>For your information, the competent authorities concerned have been informed of this corrective action.</p>
<p>Additional information</p>	<p>If you need more information or technical assistance, you can phone your usual contact.</p>

La Ricamarie,
Date:

**URGENT FIELD SAFETY NOTICE
ACKNOWLEDGMENT**

We kindly ask you to return by email or by fax this document within 10 days, in order to attest that you have received this information note to the competent authorities.

Thanks you for your cooperation:

Company name:

Address:

Manufacturer reference:

RC1706820

Product concerned and serial number:

I confirm that I have received and read the following safety information and communicated it to the people and or/organisations concerned.

Please specify if:

The device concerned was sold / transferred to another customer:

Please specify the address below:

- Nom :
- Address :
- Contact :

The device concerned was dismantled/destroyed.

- Date :
- By :

Nom et fonction :	
Date :	
Signature and stamp	

Please, return this document completed and signed to the following email:
quality@stephanix.com