FSCA NUMBER: CAPA 23-028

FSCA Date: 10/07/2023

STEPHANIX
MEDICAL IMAGING SOLUTIONS

To the attention of:
Name
Company
Address
Postal Code - City
COUNTRY

URGENT FIELD SAFETY NOTICE

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

Dear Sir or Madam,

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

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

- The device concerned.
- 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 concerned people.

We kindly ask you to complete, sign and return the enclosed customer reply form (page 3) within 10 days.

Best regards,

Quality Department

URGENT FIELD SAFETY NOTICE
PHOENIX / MOVIX DREAMY

FSN Type	☒ New ☐ Update of FSN of concerning the FSCA reference:
Device Type	Digital mobile X-ray unit
Primary clinical purpose of device	The Digital Mobile X-ray unit is an equipment designed for general radiography in hospitals, clinics, radiology imaging centers and medical practices.
Device model	PHOENIX / MOVIX DREAMY
Description of the product problem	The product may present an error condition indicated by the blinking of the LED light (magenta) situated on the tube head of the system. This error displays when the drive system is compromised due to the error condition of the bumper. If the user keeps trying to move the system, then some erratic movements may occur. The potential erratic movement would be a backward movement at high speed.
Hazard giving rise to the FSCA	Erratic movements could cause harm to patient, user or others parties
Actions to be taken by the user	Until the new software is installed, please take the following precautions: 1 - Do not continue using the unit when in error condition (magenta LED status lights blinking) if the error cannot be reset. 2 - In case of undesired or erratic movements perceived by the user, release the handle and park the unit immediately. Do not try to fight against the erratic movements of the system with the handle. 3 - Call immediately your technical team to restore the unit to operational status. If the unit must be moved, power off the unit (do not use the emergency stop button) and use either the manual driving brake release button or the manual clutch screws.
Corrective actions taken by STEPHANIX	The solution to this problem is a new SW package installation. This corrective action must be implemented in all devices concerned. Your technical team will contact you in order to fix an appointment to perform this corrective action. Should you need some more information or technical assistance, please call your usual contact.
The Competent Authority information	The relevant European competent authorities concerned have been informed of this communication.
Contact details of local representative	STEPHANIX 10, rue Jean Moulin – ZI du Bayon – 42150 LA RICAMARIE - FRANCE Guy JONON, Medical Vigilance Alert Correspondent quality@stephanix.com +33(0)4 77 47 81 60
Customer Reply Required	☒ Yes (please fill the customer reply form attached within 10 days) ☐ No

URGENT FIELD SAFETY NOTICE
PHOENIX / MOVIX DREAMY
CUSTOMER REPLY

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.

Thank you for your cooperation.

Healthcare Organisation name: _____

Installation address of the device(s) concerned: _____

_____

_____

Device(s) model concerned: _____

Serial number(s) concerned: _____

☐ **I confirm that I have received, read and understood the Field Safety Notice (page 2) 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:
- Name:
- Address:
- Contact:

☐ The device concerned was dismantled/destroyed.
- Date:
- By:

Name and function	
Telephone number and e-mail	
Date	
Signature and stamp	
Please return this document completed and signed to the following email/fax: **quality@stephanix.com** **+334 77 37 55 19**	

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.