RENISHAW mayfield

URGENT FIELD SAFETY NOTICE

Neuroinspire - surgical planning software

Date: 06 July 2022

Renishaw Mayfield FSN Reference: VR22-1

Dear Customer,

A scenario using neuroinspire has been identified that could lead to remote risk to patient safety. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- the actions planned by Renishaw Mayfield to correct the problem.

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to Renishaw Mayfield and the national Competent Authority if appropriate.

If you need any further information or support concerning this issue, please contact your local Renishaw representative.

This notice has been reported to the appropriate Regulatory Agency.

Renishaw Mayfield apologises for any inconvenience caused by this problem.

Stéphane Vinot
Regulatory Affairs Manager

RENISHAW MAYFIELD
31, rue Ampère
69680 CHASSIEU
Tél. 04 37 23 89 00 - Fax 04 78 90 75 22

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URGENT FIELD SAFETY NOTICE

Neuroinspire - surgical planning software
Display error when using Enhanced DICOM format in the Sagittal plane

AFFECTED PRODUCTS	neuroinspire - surgical planning software When using **Enhanced DICOM format** data series only
PROBLEM DESCRIPTION	Display of image series is flipped after importing a sagittal oriented image series stored using the **enhanced DICOM format**
HAZARD INVOLVED	When an **enhanced DICOM format sagittal image series** is used within surgical planning, the series is flipped (right/left) resulting in the image becoming a mirror of the actual image. Within surgical planning and image fusion this will cause unacceptable fusion with the other image series used for the planning, due to the incorrectly displayed image series. The flipped image will not line up with the other image series and will not provide a clinically acceptable 3D image of the head/brain within the stereotactic space. The clinician is informed of the fusion and is required to accept the fusion result based on their clinical judgement. The workflow allows the images and fusion to be reviewed further and image series to be removed and/or exchanged as required. Unacceptable fusion with the other image data series would be expected due to the non-symmetrical nature of the human head and brain. It is not possible to create a plan with sagittal image series only as this would not allow positioning of the patient in relation to the frame/robot space. Unacceptable fusion would result in a delay to the surgery as the clinician obtains an additional scan series and completes a new fusion of the images. Only if the fusion, using sagittal image series in **enhanced DICOM format**, is accepted and used in the surgery, could the implantable be delivered to a non-intended target, this may result in death or serious deterioration of health.
HOW TO IDENTIFY AFFECTED PRODUCTS	All neuroinspire software versions **When using Enhanced DICOM format data series only**
ACTION TO BE TAKEN BY CUSTOMER / USER	Images stored in **enhanced DICOM format** should not be imported into neuroinspire until a solution has been implemented. As per the current IFU, care should continue to be taken when reviewing the outcome of the fusion process between image series to ensure that the solution is clinically acceptable
ACTIONS PLANNED BY RENISHAW	A solution to the problem is being investigated and will be implemented in a future software version
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Renishaw representative.

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Customer Reply Form

This response form is to confirm receipt of the enclosed Renishaw Mayfield Urgent Field Safety Notice VR22-1, dated 06 July 2022.

Please return acknowledgement of this FSN to:
neuromate-quality@renishawmayfield.com, your local Renishaw representative or post the form back to Renishaw Mayfield SARL, 31 rue Ampère 69680 Chassieu France

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

Customer action undertaken on behalf of Healthcare Organisation

☐	I confirm receipt of the Field Safety Notice and that I have read and understood its content.
☐	The information and required actions have been brought to the attention of all relevant users.

Print Name;	
On behalf of (Organisation name)	
Signature:	
Date:	