FSN Ref: VR-23-12.1 FSCA Ref: VR-23-12

Date: 2023-12-13

Urgent Field Safety Notice
Neuromate Stereotactic System
Neuroinspire – neurolocate module
Incorrect images in the IFU

For Attention of: Neurosurgeons, Neurosurgical Theatre Staff, Hospital Device Safety Officer

Contact details of local representative (name, e-mail, telephone, address etc.)*
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RENISHAW mayfield

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IFU for neuroinspire neurolocate module within neuroinspire surgical planning software (the software for the neuromate stereotactic robot)
1.	2. Commercial name(s)*
	neuroinspire neurolocate (optional module in the neuroinspire software)
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not Applicable for IFU
1.	4. Primary clinical purpose of device(s)*
	The device is used for stereotactic brain surgery. The affected part is the IFU for the additional/optional module for neuroinspire neurolocate .
1.	5. Device Model/Catalogue/part number(s)*
	047.0107C/DE neuroinspire neurolocate module - German Language 047.0107B/ES neuroinspire neurolocate module – Spanish Language 047.0107C/FR neuroinspire neurolocate module – French Language 047.0107C/IT neuroinspire neurolocate module – Italian Language 047.0107C/EN neuroinspire neurolocate module – English Language IFU Version number is found on the front page as shown in the examples below:

1.	6. Software version
	V6.2.2 and above
1.	7. Affected serial or lot number range
	IFUs as detailed above
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Some of the images in the IFUs are incorrect and do not relate to the corresponding text in the IFUs. **<u>Error 1</u>** 047.0107C/DE neuroinspire neurolocate module - German Language 047.0107B/ES neuroinspire neurolocate module – Spanish Language 047.0107C/FR neuroinspire neurolocate module – French Language 047.0107C/IT neuroinspire neurolocate module – Italian Language The images are consistently incorrect across all languages noted above. Section 3.8 – Figure 27 Section 3.9 – Figure 28 **There is no defect with the neuroinspire software or the neuromate robot.** --- Some of the images in the IFUs are incorrect and do not relate to the corresponding text in the IFUs. **<u>Error 2</u>** 047.0107C/EN – neuroinspire neurolocate module – English Language Page 1 – Front Image Section 2.2 – Figure 1 Section 2.4 – Figure 3 Section 2.5 – Figure 4 Section 2.6 – Figure 5 Section 2.7 – Figure 6 Section 2.7 – Figure 7 Section 3.3 – Figure 22 Section 3.4 – Figure 23 Section 3.5 – Figure 24 Section 3.6 – Figure 25 Section 3.7 – Figure 26 Section 3.8 – Figure 27 Section 3.8 – Figure 28

	Unless noted in error 1, the above images in error 2 only impact the English language version of the IFU. **There is no defect with the neuroinspire software or the neuromate robot.**
2.	2. Hazard giving rise to the FSCA*
	There is likely to be confusion if the surgeon or theatre staff try to use the images to support the text in the IFUs stated above.
2.	3. Probability of problem arising
	The neurolocate workflow has been designed to be very prescriptive using a step by step process within the software, the incorrect images presented in the IFUs are not available to select within the workflow as an option. These image errors would be very obvious to a trained user, they would be expected to be able to identify these errors. Therefore, a problem arising from these image errors is extremely unlikely. The images are obviously wrong and make no sense in relation to the corresponding text. The text is correct and is sufficient to support the trained user in the use of the software. All users are fully trained in the use of the system by Renishaw Field Service personnel. **Error 1** Figures 27 & 28 are images which are neurolocate module specific. The text is clear on the actions required, the images should give the expected view on the screen. The software user interface and the text in the IFU are sufficient for the surgeon to continue the surgery with no harm to the patient. The correct images are presented below and provide the correct view on the screen **Error 2** All the Figures are images which are neurolocate module specific. The text is clear on the actions required, the images give the expected view on the screen. The software user interface and the text in the IFU are sufficient for the surgeon to continue the surgery with no harm to the patient.
2.	4. Predicted risk to patient/users
	Very unlikely to result in patient harm
2.	5. Further information to help characterise the problem
	None
2.	6. Background on Issue
	This issue was detected within the Renishaw organisation. It has not been identified by a clinician in the field.
2.	7. Other information relevant to FSCA
	Previous Versions of the IFUs Impacted

The errors presented also impacted historic versions of this IFU. The identification of 1 of the historic IFUs follow a different numeric reference type, this was then subsequently transferred to a new numeric reference type.

Error 1

H-5630-3035-A3 – neurolocate module – instructions for use (English Language, French Language, Spanish Language, German Language, Italian Language)
047.0107A/EN – neurolocate module – instructions for use (English Language)
047.0107B/DE – neurolocate module – instruction for use (German Language)
047.0107B/FR – neurolocate module – instructions for use (French Language)
047.0107B/IT – neurolocate module – instructions for us (Italian Language)

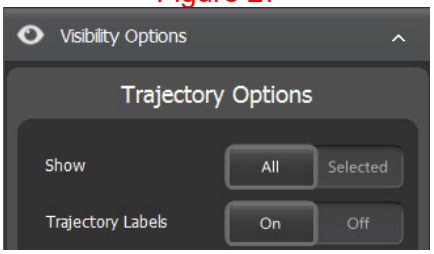
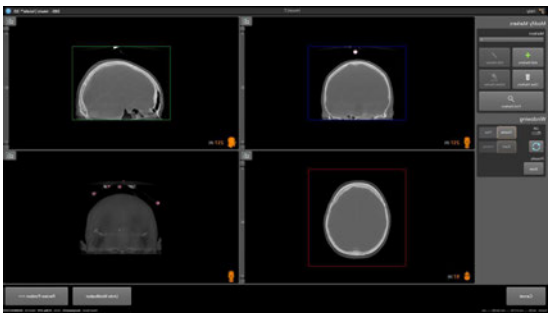
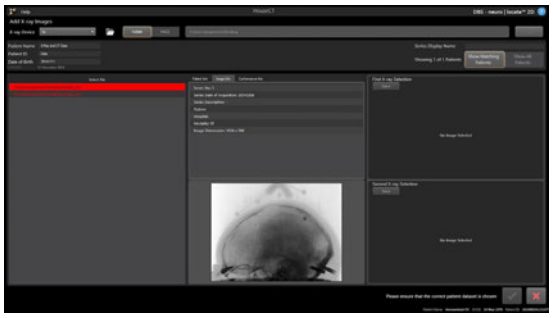
Please note that version A was not created for German, French, Italian or Spanish language.

Error 2

H-5630-3035-A3 – neuroinspire surgical planning software for use with neurolocate module
047.0107A/EN – neurolocate module – instructions for use (English Language)
047.0107B/EN – neurolocate module – instructions for use (English Language)

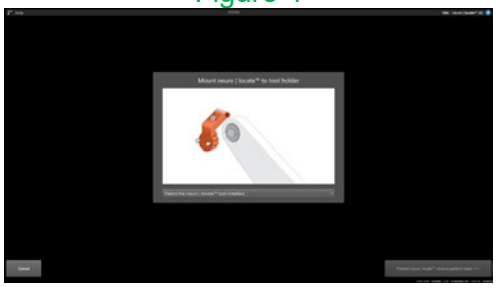
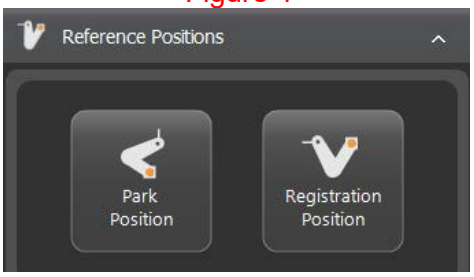
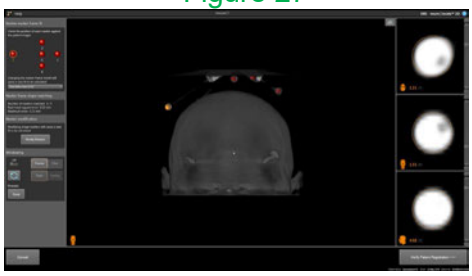
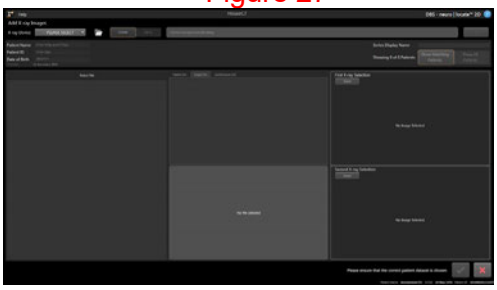
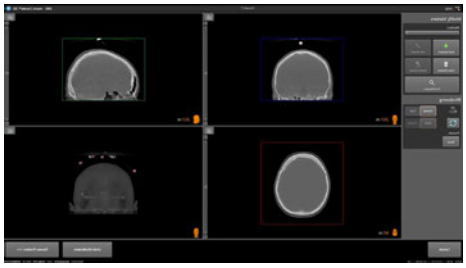
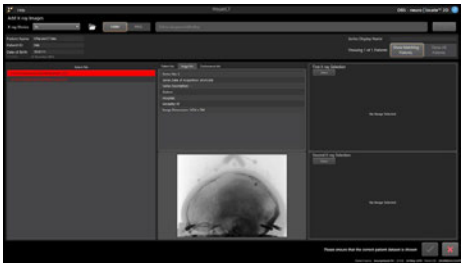
Details of the correct and incorrect images are detailed below :

Error 1

Correct ✓	Incorrect ✗
Figure 27 	Figure 27 
Figure 28 	Figure 28 

Error 2

The incorrect images where there is most likely to be confusion are detailed below.

Correct ✓	Incorrect ✖
2.5 neurolocate 2D patient localization process Figure 4 	2.5 neurolocate 2D patient localization process Figure 4 
Figure 27 	Figure 27 
Figure 28 	Figure 28 

A full list of images for Error 2 can be supplied upon request.

FSN Ref: VR-23-12.1 FSCA Ref: VR-23-12

	1. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Review should be immediate to identify incorrect IFUs
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No No impact on patient expected	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None The images in the IFUs cited in section 1 will be updated and new IFUs provided to affected sites.	
3.	6. By when should the action be completed?	January 2024
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	2. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	See Page 1
	b. Address	See Page 1
	c. Website address	See Page 1
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	Rupert Jones Managing Director [redacted]

	Transmission of this Field Safety Notice
	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)s 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 the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.