Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 279 **dated** 25/12/23 **Regarding NCMDR Field Safety Corrective Action of Neuroinspire neurolocate - Neuromate Stereotactic System from (mfr: Renishaw Mayfield).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
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سلطنة عُمان
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Circular No. 279/ 2023

11 -06-1445 H

25 -12-2023

Field Safety Corrective action of Neuroinspire neurolocate - Neuromate Stereotactic System from Renishaw Mayfield

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19830
Product	Neuroinspire neurolocate - Neuromate Stereotactic System.
Description	Neurosurgical robot for stereotactic applications, used for the positioning of a tool guide.
Manufacturer	Renishaw Mayfield.
The affected products	Software version: V6.2.2 and above IFU Version number is found on the front page as shown in the examples in the attachment. Model/Catalogue/part number of the IFU: 047.0107C/EN neuroinspire neurolocate module – English Language.
Reason	Some of the images in the IFUs are incorrect and do not relate to the corresponding text in the IFUs.
Action	1. The images in the IFUs cited in section 1 in the attachment will be updated and new IFUs provided to affected sites. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
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ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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RENISHAW mayfield

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

Date: 2023-12-08

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.)*
R Rusling **Renishaw Mayfield SARL** **31 rue Ampère** **Chassieu** **69680** **France** **RNSRegulatory@renishaw.com**

RENISHAW mayfield

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

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

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. **Error 1** 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. **Error 2** 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

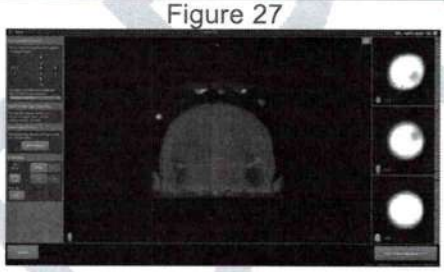
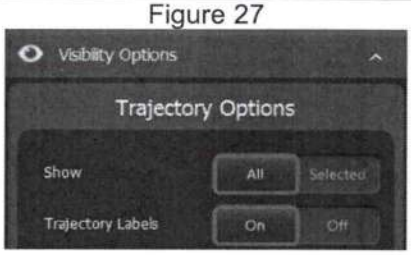
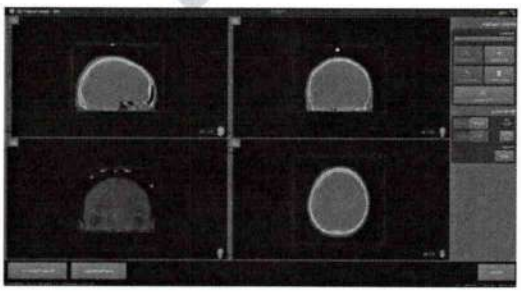
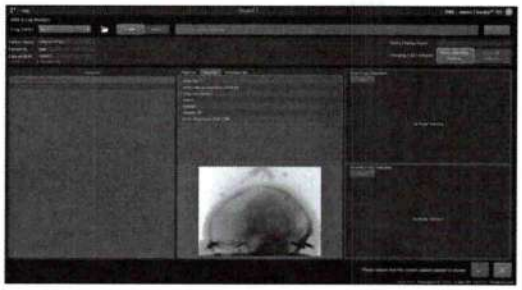
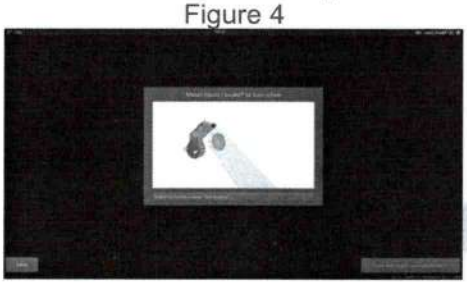
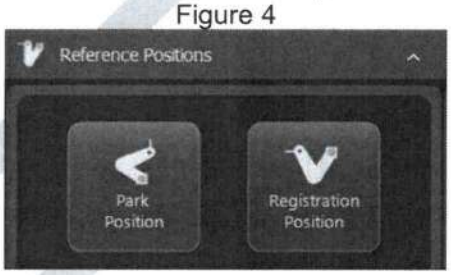
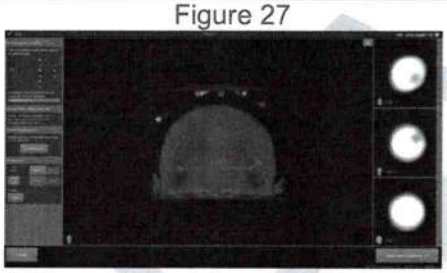
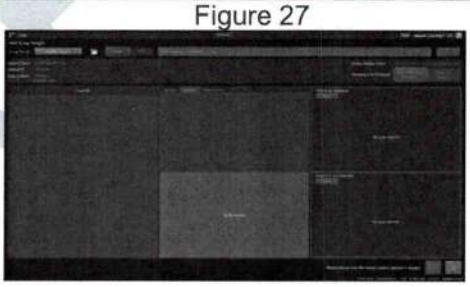
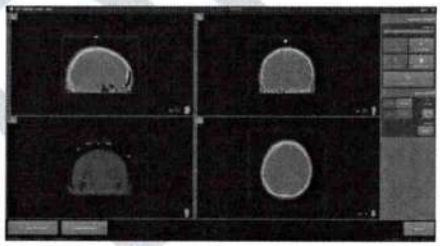

	

Figure 28	Figure 28
	

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.

	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:	
	Eg patient management, device modifications etc.	
4.	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
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:	If extensive consider providing web-link instead.
4.	10. Name/Signature	R Rusling Regulatory Affairs Manager

	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) 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.