

## URGENT FIELD SAFETY NOTICE

### Neuroinspire Instructions for Use - Depth Offset Image Error

Date: October 12th, 2020

Renishaw Mayfield FSN Reference: VR-20-3

Dear Customer,

A problem has been detected relating to the Instructions for Use for Neuroinspire Neuromate Module (H-5630-3016 versions A2-A6) and the Plan Delivery USA Instructions for Use (H-5630-3050-A1). An incorrect image has been identified within these Instructions for Use that could pose a risk to patients. 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 to 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 of 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 Mayfield representative.

This notice has been reported to the appropriate Regulatory Agency.  
Renishaw Mayfield apologises for any inconveniences caused by this problem.

Sincerely,



Quality Assurance & Regulatory Affairs Manager  
Renishaw Mayfield S.A.R.L

**Renishaw Mayfield sarl**

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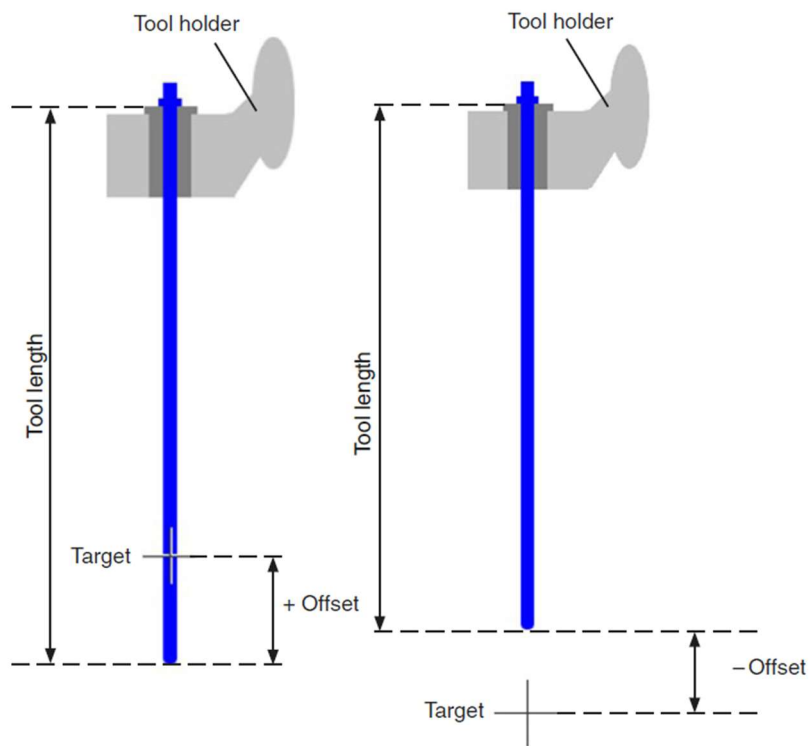
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### Neuroinspire Instructions for Use - Depth Offset Image Error

<p><b>AFFECTED PRODUCTS</b></p>	<p>Two Instructions for Use are affected:</p> <ul style="list-style-type: none"> <li>• Neuroinspire Neuromate Module Instructions for Use (H-5630-3016 versions A2-A6)</li> <li>• Plan Delivery USA Instructions for Use (H-5630-3050-A1)</li> </ul>
<p><b>PROBLEM DESCRIPTION</b></p>	<p>In Section <b>3.4 Move to Trajectory</b> of the Neuroinspire Neuromate Module Instructions for Use (H-5630-3016-A6) and the Neuroinspire Plan Delivery Instructions for Use (H-5630-3050 A1), the bottom right image (figure 1) showing a negative offset is incorrect. The horizontal dotted lines in the image have incorrectly shifted downwards in the image. The image (below, right) suggests that the tool length is taken from the top of the tool holder instead of the top of the guide bush.</p> <p><i>Figure 1 - Incorrect image:</i></p> <p><b>a.</b> The dotted lines are shifted on the bottom of the drawing; the tip of the tool does not touch the dotted line.</p> <p><b>b.</b> The datum point should be level with the guide bushing.</p> <p><b>c.</b> The dotted line should be level with the target</p>

	<p>Please note that it is clearly written and repeated in the instructions that “the tool length is <u>always</u> measured from the back face of the guide bushing” / “the tool length is the distance from the back face of the guide bushing to the tip of the instrument” .</p> <p>All other images and text in the IFU confirm the correct instructions. Training provided to the clinician also informs the user that the tool length is measured from the back of the bushing.</p>
<p><b>HAZARD INVOLVED</b></p>	<p>The difference in position of the back of the tool holder and the back of the bushing from the target is 2mm.</p> <p>This is in conflict with the other information provided and could cause confusion to the user.</p> <p><b>First scenario:</b> User experiences confusion and surgeon then carries out a confirmatory check or request further assistance from Renishaw to determine if tool/implantable can be delivered to the correct depth. The confirmatory check by the surgeon would lead to potential increase of general anaesthetic exposure to the patient.</p> <p><b>Second scenario:</b> By using this incorrect datum position, the user could unintentionally create a 2mm positive offset from the intended position of the tool/implantable. Upon delivery, the tool/implantable would be positioned 2 mm beyond the distal end of the planned position. The resultant harm to the patient would range from minor damage to brain structures, to serious harm.</p> <p>As surgical planning should always consider the overall accuracy of the system and the nearby structures, users are unlikely to create plans with critical structures being <math>\leq 2</math> mm from the of the end of the tool/implantable. Also, the incorrect image highlights the negative offset where the tip of the tool is planned at a point short of the target. The likelihood that a clinician would plan a surgery with critical structures within this 2mm region is considered very low.</p> <p>Due to all additional information within the IFU being correct and the user-training provided, the likelihood of the user being aware of the need to account for this 2 mm difference is considered low. The user is most likely to question the conflicting information and carry out their own checks or raise it with Renishaw service staff rather than acting against the training received.</p>
<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>Please stop using the referenced Instructions for Use and take note of amendment/reinforcement of the correct image relating to negative offset requirements.</p> <p>Users are informed that the following image (figure 2) is now corrected and will soon be provided in an updated Instructions for Use. Users are informed that all consideration of tool length should be measured from <b>the back face of the bushing</b> in all cases and to contact Renishaw should they have any queries</p>

*Figure 2 - Correct image:*



**ACTIONS  
PLANNED BY  
RENISHAW**

Renishaw Mayfield shall send the correct version of the affected Instructions for Use to affected sites free of charge. A software update shall be rolled out to correct the electronic IFU.