Nordic Neuro Lab

FSN Ref: FSN_ 562 FSCA Ref: CPA-2022-562

Date: 28th June 2022

# Urgent Field Safety Notice

For Attention of*:

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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| Not Applicable as sold directly to the customer |

## Urgent Field Safety Notice (FSN)
## Device Commercial Name
## Risk addressed by FSN

| | 1. Information on Affected Devices* |
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| 1. | 1. Device Type(s)* |
| | nordicBrainEx is an advanced visualization and processing software, with specific focus on providing algorithms designed to analyze functional MR data of the brain. The software runs on a standard "off-the-shelf" PC workstation and can be used with data and images acquired through DICOM compliant imaging devices and modalities |
| 1. | 2. Commercial name(s) |
| | nordicBrainEx |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 7090042059015 |
| 1. | 4. Primary clinical purpose of device(s)* |
| | nordicBrainEx is an advanced visualization and processing software, with specific focus on providing algorithms designed to analyze functional MR data of the brain. The software runs on a standard "off-the-shelf" PC workstation and can be used with data and images acquired through DICOM compliant imaging devices and modalities. The software is intended to be used by medical personnel, such as radiologists or medical technicians, trained in the methods provided by the application. In order to best accommodate this group of users, it is specifically designed to have an easy to use and streamlined workflow, as well as an intuitive graphical user interface. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | Version 2.3.10 |
| 1. | 6. Software version |
| | Version 2.3.10 |
| 1. | 7. Affected serial or lot number range |
| | 2.2.1 to 2.3.10 |
| 1. | 8. Associated devices |
| | NA |

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| | **2 Reason for Field Safety Corrective Action (FSCA)*** |
| 2. | 1. Description of the product problem* |
| | When exporting merged results from the BOLD, DSC, and DCE modules of nordicBrainEx, where both the underlay and overlay originated from a multiframe dataset, the resulting output may have left/right sides flipped. The issue was discovered by a customer on April 4th, 2022, and no satisfactory work-arounds were found. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | Rated as high because there exists a workaround, but the workaround is not satisfactory. The bug does not stop the software from functioning but can lead to wrong results. According to customer conversations, other quality checks are in place, so the defect has a low risk of leading to patient harm. |
| 2. | 3. Probability of problem arising |
| | There is only 1 known incident, but it is believed that most customers who do fMRI with Siemens scanners and who have upgraded scanner software will have the issue. We do not have data to further support the probability (such as which scanner vendor the customers use). |
| 2. | 4. Predicted risk to patient/users |
| | Probability<br><br>Since the date of complaint, April 4th, 2022, until now, June 27th, 2022, there has been no reported issues apart from the original one. Although there is a chance this can happen with any scanner vendor or scanner version, we anticipate that the probability of such cases happening is low. At the same time, if a patient will undergo surgery, they will have been examined multiple times using different methods. The radiologists and neurosurgeons will therefore know which side of the brain the tumor is located and will likely notice if the image shows the tumor on the contralateral side. This is based on conversation with the affected user. Based on this, and following definitions as per the procedures, we set the probability to be "Occasional – can happen, but not often, <1%".<br><br>**Severity**<br>If the error is not detected, worst possible outcome is surgery on the wrong side of the brain which can have severe consequences. A more likely scenario is that the error leads to delayed treatment which can also have consequences, but likely not as severe as the first scenario.<br>Based on this, and following definitions as per the procedure, we set the severity to be "Critical – Results in permanent impairment or life-threatening injury".<br><br>There is no direct or indirect risk of harm to the end user.<br><br>Thus the final risk to patient is - ***Intolerable*** |
| 2. | 5. Further information to help characterise the problem |
| | We have issued 609 software licenses of the product versions that are affected. Only one licensee has reported the issue and since the date of the initial incident, we have not received any further complaints related to the issue. The defected product versions have been in the market since 2015. One separate site has, upon NNL's request, successfully recreated the issue, but it required a deviated setup of operation. |
| 2. | 6. Background on Issue |
| | The issue was detected by a customer in Canada on April 4th, 2022, who had recently upgraded their scanner software (Siemens). No other known incidents have been reported. Root cause is identified as insufficient testing. The company is developing a new software that will supersede the defective software in functionality. The new software is developed with better and more secure coding practices, practices for testing and continuous improvement. |
| 2. | 7. Other information relevant to FSCA |

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| | Until recently, Siemens have used a proprietary image format within the DICOM definition called mosaic, but recently they have updated to use the accepted DICOM standard for this (multiframe). Therefore, there has previously not existed Siemens data with the configuration leading to the error. Data from other vendors may also lead to the issue, but it has not been observed. |

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| | **3. 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 | |
| | Existing Software version to be updated with new release. | |
| 3. | 2. By when should the action be completed? | Specify where critical to patient/end user safety<br>30 June 2022 |
| 3. | 3. Particular considerations for: Diagnostic Imaging device<br>Is follow-up of patients or review of patients' previous results recommended?<br>NO as no patient was involved. | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Choose an item. |
| 3. | **5. Action Being Taken by the Manufacturer** | |
| | ☐ Product Removal ☐ On-site device modification/inspection<br>☒ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None | |
| | The customer has been contacted and has acknowledged the receipt of the information regarding the nordicBrainEx issue. They have also been provided with the updated software version as of 27th June 2022. | |
| 3 | 6. By when should the action be completed? | 30 June 2022 |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | N/A |
| 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. | |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | Update |
| 4. | 2. For updated FSN, reference number and date of previous FSN | FSN provided to users |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | **FSN in the form published in EU commission website** | |
| 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: | |
| | Update device has been already provided to users | |
| 4 | 6. Anticipated timescale for follow-up FSN | 4th July 2022 |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | **NordicNeuroLab AS** |
| | b. Address | **Møllendalsveien 1** |
| | c. Website address | **www.nordicneurolab.com** |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *<br>YES | |
| 4. | 9. List of attachments/appendices: | NA |
| 4. | 10. Name/Signature | [redacted]<br>[redacted]<br>28 June 2022 |

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| | **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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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.