

Field Advisory Notice

Products concerned: Nexstim NBS System 4, Nexstim NBS System 5

Type of action: Advice regarding the use of the device and subsequent voluntary device modification

Date: March 14, 2017

Attention: Users/operators of Nexstim NBS System 4 and Nexstim NBS System 5
Distributors of Nexstim NBS systems

Affected devices:

Nexstim NBS System 4, software versions 4.0 or higher
Nexstim NBS System 5, software versions 5.0 or higher

Description of the problem:

Nexstim has become aware of an issue with the NBS System 4 software which also affects NBS System 5 software. When a DICOM image series with a duplicate copy of one or several files is copied into the system, NBS software will in certain circumstances, incorrectly interpret left-right orientation and display the head mirrored. If MRI images are transferred as instructed and trained, without duplicate copies, mirroring on the NBS display will not happen.

Mirroring is limited to how NBS displays MR information. The DICOM export function of the NBS system maintains the original orientation of the anatomical MRI. The apparent location of NBS mapping responses, when viewed outside of NBS (e.g. in neuronavigators), will therefore not concur with the physically mapped hemisphere making the generated NBS map unusable for preprocedural planning purposes.

Safety evaluation:

The issue has not caused death or serious injury. Based on the risk assessment made by Nexstim the issue is not likely to cause death, serious injury or serious deterioration in state of health of due to multiple control points being in place in the surgical planning procedures, and the fact that the information NBS system provides is only indicative with respect to the brain anatomy and shall be always confirmed by other examinations.

Advice to current NBS users:

Nexstim advises users/operators storing an MRI image stack to NBS system MRI data folder to ensure duplicate slices are not generated during the MRI image stack transfers. In an event that a single slice has been accidentally transferred to the folder before the whole MRI stack is transferred the single slide should be first removed and after that the whole stack placed into the Nexstim NBS system MRI data folder.

This notice should be passed on to all those who need to be aware of the issue within your organization or to any organization where the potentially affected devices have been transferred.

Planned voluntary field action:

Nexstim will enhance the software of NBS systems to overcome this issue. The enhanced software versions are currently planned to be available by the summer. At that time, all NBS System 4 and NBS System 5 users will be contacted to agree on the delivery of the coming software update.

Nexstim apologises any inconvenience this issue may cause. The undersigned confirms that this notice has been communicated to the appropriate Regulatory Agencies. Please do not hesitate to contact Nexstim in case of concern or questions.

Sincerely,



Rainer Harjunpää
Vice President, Quality Assurance and Regulatory Affairs
Nexstim Plc, Helsinki, Finland