NeuroLogica
A Subsidiary of Samsung Electronics Co., Ltd

Urgent – Field Safety Notice

[NAME/ADDRESS]

***Please provide this Notification to Field Safety/Recall representative**

Dear Customer,

As part of NeuroLogica Corporation's continuous focus on performance and safety of our devices we have identified a potential issue that may affect the OmniTom and OmniTom Elite (NL5000) computed tomography systems.

This Field Safety Notice is intended to provide you with information regarding:

- what the issue is, and what circumstances it may occur
- actions that should be taken by the customer / end user to prevent any risks for patients or users
- the actions planned by NeuroLogica for further investigation.

This document contains important information for the safe and proper use of NeuroLogica CT Products

Please review the following information with all members of your staff who need to be aware of the contents of this communication.

It is important to understand the implications of this communication.

If you need any further information or support concerning this issue, please contact your local NeuroLogica representative.

We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

The signature confirms that this Field Safety Notice has been notified by the manufacturer to the appropriate Regulatory Agency.

Sincerely,

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NeuroLogica
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Affected Products	**Device Name(s)**	***Serial Number/Lot Number/Reference Number***
	OmniTom/OmniTom Elite (NL5000)	Unique Device Identifier (UDI) Device Identifier / Global Trade Item Number (GTIN) • 10815411020335 • 10815411020663
How to Identify Affected Products	The system label is located near the main input plug or on the side of the system.  Identification of impacted systems can be found by locating the serial number on your device. Please refer to the above image for where label is found on the device. Once you have identified the serial number on your device, please complete the Customer Reply Form at the end of this notification, noting the serial number, and return to the referenced email address.	
Description of Problem	NeuroLogica Corporation has recently become aware of a potential issue related to the operational state of the scanner, specifically for the transport wheels loosening over time with use of the device. This could lead to the inability the effectively drive the device, further leading to a potential delay in patient treatment. Additionally, we were made aware by our battery vendor that certain serial numbers of the batteries used to power the NL5000 device contain contaminated boards, which may impact the ability to power on the device. Again, this could lead to delay for patient treatment.	
Root Cause(s)	Wheels: It was determined via in house testing that the wheel loosening failure was due improper tightening of bolt from the vendor, which secures the wheel to	

	the wheel shaft. This may be seen on systems that are used and moved frequently. Battery: It has been determined that the root cause is due to residual flux on a particular revision of the boards located within the batteries.
Potential Hazards	There could be a possibility of delay in patient treatment in an unlikely event that the system is not in operation. There may also be a possibility of the error during a scan if the battery fails during a procedure.
Remedial actions to be Taken by Users	Users may continue to use the NL5000 system with caution, ensuring they are aware of the potential drive issues due to the wheels. This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please fill in the attached Customer Reply Form as confirmation of notification.
Corrective Actions Planned by NeuroLogica	NeuroLogica will undertake the voluntary corrective action considering the possibility of delay in patient treatment if the scanner is not operational due to battery failure, as well as the potential for the scanner to halt mid scan. The hardware upgrades provide additional safeguards by improving the design to minimize any risks of the above situations from happening. Service engineers will correct all affected devices free of charge and contact you to arrange for the correction. All corrections in the field will be completed by December 31, 2023.
Support Contacts	If you need any further information or have any concerns with this issue, then please contact your local representative.

Customer Reply Form

NeuroLogica
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This reply form is to confirm receipt of the enclosed NeuroLogica Medical Device Field Safety Notice [FSN-NL5000_0XXXX] regarding replacement of parts for the transport wheels and battery. Please read the Notice and indicate the appropriate answers to the questions below.

I confirm receipt of the Notice and that I read and understood its content.	☐ Yes	☐ No	☐ N/A
I performed actions requested by the Notice.	☐ Yes	☐ No	☐ N/A
I have returned / destroyed / transferred affected devices.	☐ Return	☐ Transfer	☐ N/A

Affected serial number(s)		Quantity	
Company / facility name			
Address			
Responsible person	Name: Date: Signature:		

Please ensure all fields have been completed. Please return this form by e-mail to compliance@neurologica.com within 10 business days.

It is important that your organization takes the actions detailed in the Notice and confirms that you have received the Notice. Your organization's reply is the evidence we need to monitor the progress of the corrective action.