FSN Ref: DOC-078386 FSCA Ref: FCA#000066

Date: 06 MAY 2026

Urgent Field Safety Notice
SD LTM 64 PLUS

For Attention of*:Users of Micromed SD LTM 64 PLUS amplifiers, clinical engineering

Contact details of local representative (name, e-mail, telephone, address etc.)
[this field will be filled with the contact of the local distributor for each country]

Micromed S.p.A. a socio unico | via Giotto 2, 31021 Mogliano Veneto (TV), Italy | **natus.com**
Phone: +39.041.5937000 | Fax: +39.041.5937011 | email : micromed.it@natus.com | PEC: micromed@pec.it | SDI: MMKN5H7
Reg Impr./CF: 03906850262 | P.IVA/VAT n.: IT03906850262 | REA n.: TV-307680 | Cap.sociale: 1.000.000,00€
Reg. AEE IT08020000000841 Reg. Pile e Accumulatori: IT20070P00006337

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Urgent Field Safety Notice (FSN)

SD LTM 64 PLUS

Traces not synchronized

1 Information on Affected Devices

1.1 Device Type(s)

EEG Amplifier/recorder

1.2 Commercial name(s)

SD LTM 64 PLUS

1.3 Unique Device Identifier(s) (UDI-DI)

8033928120897

1.4 Primary clinical purpose of device(s)

SD LTM PLUS devices are intended for electroencephalographic exams and evoked potentials through electrodes. They are intended to be used in the diagnosis of neurological diseases characterized by episodic alteration of EEG parameters or evoked potentials. EEG and EP exams give information in the study of epilepsy, states of consciousness alteration and coma, sleep disturbances, encephalitis, encephalopathy, and in the evaluation of CNS involvement in metabolic or infectious systemic diseases. The device is particularly suitable for prolonged analysis, for example in Long-Term EEG Monitoring. The use of these devices is reserved to physicians, technicians, or other medical professionals that are trained in bio-potential recording.

1.5 Device Model/Catalogue/part number(s)

SD LTM 64 PLUS

1.6 Software version

Firmware 2021.02, 2022.01 or 2022.02

1.7 Affected serial or lot number range

See Appendix A – List of Affected devices (EEA+CH+UK)

2 Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem

Natus has become aware of two complaints related to the SD LTM 64 PLUS where the EEG traces acquired from two or four different amplifiers used in a multiple amplifier configuration (128 or 256 channels) running firmware version 2022.02 were displayed with a shift of 1 second between the 64 channel blocks.

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2.2 Hazard giving rise to the FSCA

In rare circumstances, a fixed 1-second temporal delay may appear between two 64-channel modules in a multi-module SEEG configuration, potentially leading to misinterpretation of results.

2.3 Other information relevant to FSCA

There is no impact to the SD LTM 64 PLUS with firmware 2023.01 or later.

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

- Natus is requesting you to check your SD LTM 64 PLUS stock and identify whether the devices are currently running firmware version 2021.02, 2022.01 or 2022.02. The information is displayed on the device screen when the device is switched on and you keep the switch on button pressed.

- Immediately cease use of the affected product in configurations with multiple amplifiers (i.e, systems with 128- or 256-channels) until you receive the instructions from Natus.
- If your SD LTM Plus is impacted (has firmware version 2021.02, 2022.01 or 2022.02), please complete the enclosed form and return to FCA@Natus.com. You will receive instructions from FCA@Natus.com to return the requested items or to schedule service locally.

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3.2 By when should the action be completed?
31 May 2026

3.3 Is customer Reply Required? *
Yes

3.4 Action Being Taken by the Manufacturer
☐ Product Removal ☒ On-site device modification/inspection
☒ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

- Issue is resolved by updating the product firmware to version 2023.01 or later.
- Natus has identified the root cause of this issue and has implemented corrective actions to prevent future recurrence.
- Technical Service will be in contact with you to arrange for local servicing or return the device(s) for service

3.5 By when should the action be completed?
Information will be provided to customers on return of the reply form

3.6 Is the FSN required to be communicated to the patient /lay user?
No

4 General Information

4.1 FSN Type New

4.2 Further advice or information already expected in follow-up FSN? No

4.3 Manufacturer information
(For contact details of local representative refer to page 1 of this FSN)

Company Name	**Micromed S.p.A.**
Address	**Via Giotto 2 – 31021 Mogliano Veneto (TV) - ITALY**
Website address	**www.natus.com**

The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *

4.4 List of attachments/appendices:
- Customer reply form
- Appendix A - List of Affected Devices (EEA+CH+UK)

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5 Transmission of this Field Safety Notice

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

We apologize for the inconvenience this may have caused your organization.

Sincerely,

Courtney Walton
Vice President, Quality & Regulatory Affairs

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Appendix A - List of Affected Devices (EEA+CH+UK)

Serial #	Serial #	Serial #	Serial #
BAA-0039/00-18	BAA-0181/03-20	BAA-0297/04-21	BAA-0371/04-22
BAA-0040/01-18	BAA-0182/03-20	BAA-0300/04-21	BAA-0372/04-22
BAA-0041/01-18	BAA-0183/04-20	BAA-0301/04-22	BAA-0373/04-22
BAA-0042/01-18	BAA-0184/04-20	BAA-0302/04-22	BAA-0374/04-22
BAA-0048/01-18	BAA-0185/04-20	BAA-0303/04-22	BAA-0375/04-22
BAA-0072/02-19	BAA-0186/04-20	BAA-0304/04-22	BAA-0376/04-22
BAA-0074/02-19	BAA-0187/04-20	BAA-0305/04-22	BAA-0377/04-22
BAA-0075/02-19	BAA-0188/04-20	BAA-0306/04-22	BAA-0378/04-22
BAA-0076/02-19	BAA-0189/04-20	BAA-0308/04-22	BAA-0379/04-22
BAA-0077/02-19	BAA-0190/04-20	BAA-0309/04-22	BAA-0380/04-22
BAA-0078/02-19	BAA-0196/04-20	BAA-0310/04-22	BAA-0389/04-22
BAA-0079/02-19	BAA-0203/04-20	BAA-0311/04-22	BAA-0397/04-22
BAA-0080/02-19	BAA-0204/04-20	BAA-0312/04-22	BAA-0398/04-22
BAA-0081/02-19	BAA-0205/04-20	BAA-0313/04-22	BAA-0401/04-23
BAA-0094/02-19	BAA-0206/04-20	BAA-0314/04-22	BAA-0402/04-23
BAA-0099/02-19	BAA-0244/04-21	BAA-0315/04-22	BAA-0403/04-23
BAA-0100/02-19	BAA-0246/04-21	BAA-0316/04-22	BAA-0407/04-23
BAA-0101/02-19	BAA-0247/04-21	BAA-0317/04-22	BAA-0408/04-23
BAA-0102/02-19	BAA-0248/04-21	BAA-0323/04-22	BAA-0409/04-23
BAA-0103/02-19	BAA-0249/04-21	BAA-0324/04-22	BAA-0432/04-23
BAA-0124/02-19	BAA-0251/04-21	BAA-0326/04-22	BAA-0433/04-23
BAA-0127/02-19	BAA-0252/04-21	BAA-0328/04-22	
BAA-0130/02-19	BAA-0254/04-21	BAA-0331/04-22	
BAA-0132/02-19	BAA-0258/04-21	BAA-0332/04-22	
BAA-0136/02-19	BAA-0260/04-21	BAA-0333/04-22	
BAA-0137/03-19	BAA-0261/04-21	BAA-0334/04-22	
BAA-0138/03-19	BAA-0262/04-21	BAA-0335/04-22	
BAA-0139/03-19	BAA-0264/04-21	BAA-0336/04-22	
BAA-0140/03-19	BAA-0265/04-21	BAA-0337/04-22	
BAA-0143/03-19	BAA-0267/04-21	BAA-0338/04-22	
BAA-0145/03-19	BAA-0270/04-21	BAA-0350/04-23	
BAA-0146/03-19	BAA-0271/04-21	BAA-0351/04-24	
BAA-0152/03-20	BAA-0273/04-21	BAA-0352/04-25	
BAA-0159/03-20	BAA-0274/04-21	BAA-0354/04-22	
BAA-0160/03-20	BAA-0275/04-21	BAA-0355/04-25	
BAA-0162/03-20	BAA-0276/04-21	BAA-0359/04-22	
BAA-0163/03-20	BAA-0277/04-21	BAA-0365/04-22	
BAA-0171/03-20	BAA-0278/04-21	BAA-0366/04-22	
BAA-0174/03-20	BAA-0279/04-21	BAA-0367/04-22	
BAA-0176/03-20	BAA-0281/04-21	BAA-0368/04-22	
BAA-0178/03-20	BAA-0294/04-21	BAA-0369/04-22	
BAA-0179/03-20	BAA-0296/04-21	BAA-0370/04-22	

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	DOC-078386
FSN Date	06 MAY 2026
Product/ Device name	SD LTM 64 PLUS
Product Code(s)	8033928120897
Batch/Serial Number (s)	See attachment 1 of DOC-078386

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organization (tick all that apply)			
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.		
☐	I performed all actions requested by the FSN.		
☐	The information and required actions have been brought to the attention of all relevant users and executed.		
☐	I ask to be contacted for servicing or returning the device(s).	Qty:	Serial Number:
☐	I do not have any affected devices.		
Print Name*			

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Signature*	
Date*	

4. Return acknowledgement to sender	
Email	FCA@natus.com
Deadline for returning the customer reply form*	31 May 2026

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

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