



Urgent Field Safety Notification – Recall

Component Neuromonitoring System (Moberg CNS Monitor Model CNS-350)

Date: 08 March 2023

Dear Valued Distribution Partner,

You are receiving this information as our records indicate you have purchased or are currently using a Component Neuromonitoring System (Moberg CNS-350 Monitor), which contains a backup battery. This notice should be shared within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Description of the issue:

Moberg Research, Inc. has become aware that the backup batteries (Part Number/SKU: E10COMMFO100R01) inside the CNS-350 Monitor product may malfunction, causing leakage.

Intended use:

The Component Neuromonitoring System (CNS) is intended as a short-term neurological monitoring system that collects, displays, and stores multiple physiological measurements. The CNS can record continuous EEG (with or without video) using an EEG amplifier and/or video camera. Other physiological measurements, such as ICP, PbtO₂, Cerebral Perfusion, HR, SpO₂, etc., can be monitored from third-party interfaced medical devices. It is intended for use on patients of all ages within a hospital or medical environment, including the operating room, intensive care unit, emergency room, and clinical research settings.

Table 1 - Affected items:

Please see below table with details of legal manufacturer and the devices affected in this FCA:

Legal Manufacturer	Part Description	Part Number	UDI Number
Moberg Research, Inc. 224 South Maple St. Ambler, Pennsylvania, 19002 USA	Component Neuromonitoring System (CNS Monitor Model CNS-350)	CNS-350	B485CNS3501

*For a list of affected serial numbers, see **Appendix A**.*

Hazard associated with this issue:

The battery leakage can cause corrosion to the metal enclosure near the electrical interface. Prolonged contact to corrosive materials could cause injury to skin.

DOC-063531 Rev 01

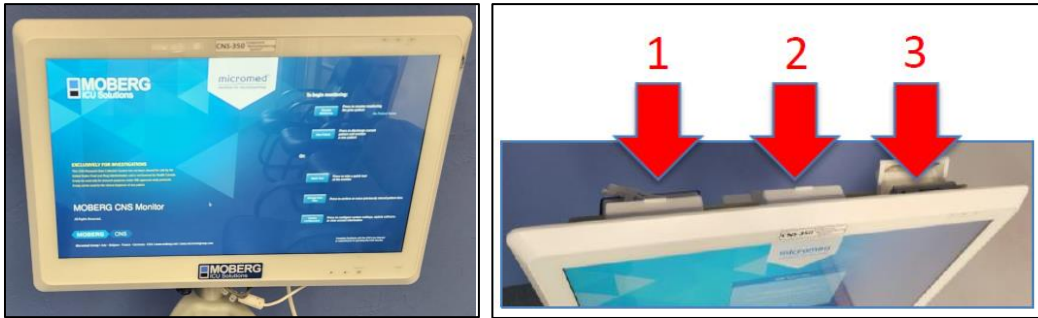
DCO#59520

Natus Medical Incorporated

www.natus.com

Actions requested:

- 1) Ensure that the CNS is turned off and unplugged from the power outlet. Perform the next step while using proper personal protective equipment (PPE), including gloves, eye protection and apron. On the top of the CNS-350 device, open each of the three (3) battery ports and remove any backup battery.



- 2) Inspect the battery and the battery port for any white, brown, or green/blue buildup, or for any corrosion of the metal contact locations. If corrosion or build up is present:
 - a. On the battery, dispose the battery at your local battery recycle facility.
 - b. In the battery ports, cease use of the device and contact Moberg Technical Service Department.

If leakage or corrosion is suspected, cease use of the CNS-350 device and contact Moberg Technical Service Department.

A new replacement battery will be shipped to you. The Moberg Technical Service Department will be in contact with you in relation to the provision of the replacement product. For new battery replacement, installation instructions will be provided with the battery.

This Field Action is being reported to your Competent (Regulatory) Authority.

If required by local country regulations, please report this field action without delay to your competent authority or regulatory agency. If there is no requirement to report, please communicate this back to Natus. Please let Natus know when you report or contact Natus for assistance in reporting if needed.

Thank you for your assistance in helping us to manage this recall.



Appendix A: Affected CNS-350 Monitor Serial Numbers

A-CNS-22501
A-CNS-22503
A-CNS-22504
A-CNS-22505
A-CNS-22514
A-CNS-22515
A-CNS-22516
A-CNS-22517
A-CNS-22518

A-CNS-22519
A-CNS-22520
A-CNS-22521
A-CNS-22522
A-CNS-22523
A-CNS-22524
A-CNS-22531
A-CNS-22532
A-CNS-22533

A-CNS-22538
A-CNS-22539
A-CNS-22540
A-CNS-22576
A-CNS-22579
A-CNS-22594
A-CNS-22595
A-CNS-22597



**CUSTOMER REPLY FORM
TO BE COMPLETED BY RECIPIENT**

On behalf of this organization, I acknowledge receipt of the Urgent Field Safety Notification Recall relating to the Component Neuromonitoring System (Moberg CNS Monitor Model CNS-350) by Moberg Research, Inc.

Organization	
Name	
Title	
Email	
Telephone	
Date	
Signature	

Please mark as appropriate:

- The battery has been removed from each CNS-350 device and has been disposed.
- Battery leakage or corrosion are suspected on the CNS-350 and the device is quarantined.
- We do not have the affected CNS product(s)

List serial number(s) of affected CNS-350 Monitor:

Shipping address of replacement product (if applicable):

Contact Name:

Facility Name:

Facility Address:

City, State, Country:

Zip Code / Postal Code:

Please complete and return this form to: FCA@Natus.com