Urgent Field Safety Notification - Recall
Olympic Brainz Monitor (Digital Acquisition Box)

Part#	UDI#	Serial Number
OBM00002	00382830010825	001 through OBM00002H3613, note earlier version serial numbers did not contain the sequence of OBM…

Date:

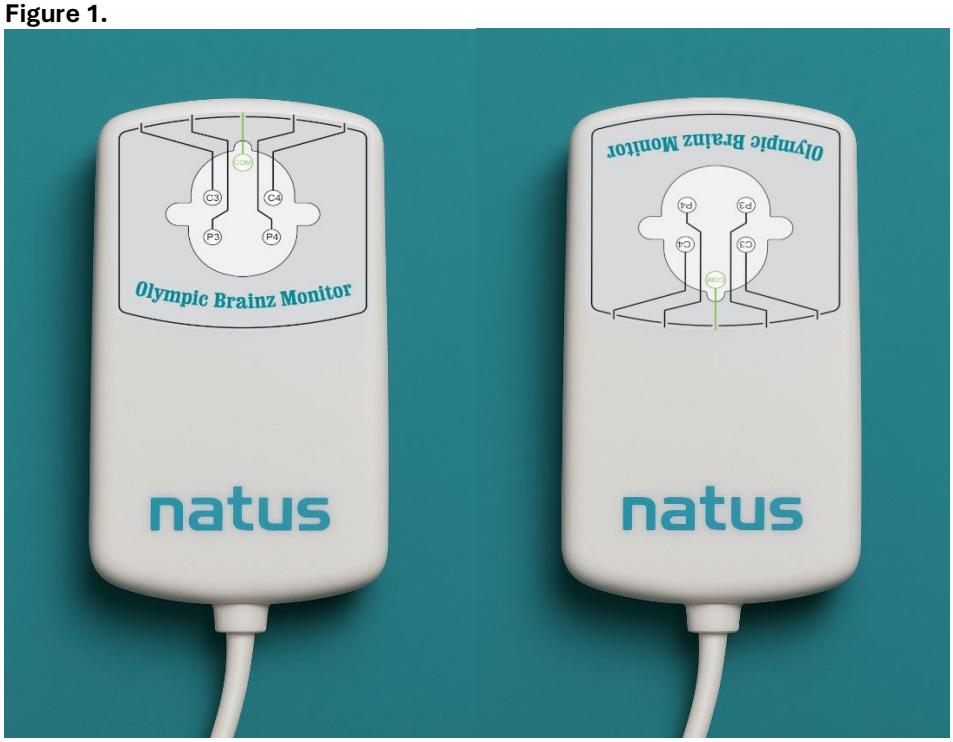
Dear Valued Customer,

Natus Medical Incorporated ("Natus") is initiating a field corrective action for the product listed above. This notice is being sent to you as our records indicate you have purchased or are currently using an Olympic Brainz Monitor (DAB). This letter contains important information that requires your attention. Please acknowledge receipt of this communication by sending an email to FCA@Natus.com as soon as possible, no later than 10 days.

ISSUE & IMPACT:

- Natus has become aware of two complaints related to the Olympic Brainz Monitor where the electrode placement labels on the DATA ACQUISITION BOX (DAB) were on backwards.

Figure 1.



Correct orientation Incorrect orientation

	• This labelling error may lead to a use error where the electrodes are connected incorrectly, causing the left and right channels to be misaligned. As a result, the recorded data may be misinterpreted, potentially leading to a misdiagnosis of seizure location in neonates monitored with this device. • There is no impact to the Olympic Brainz Monitor where the electrode placement labels on the product are placed in the correct orientation. • There is no impact to the Olympic Brainz Monitor where the electrodes were correctly connected to the neonate following standards of care for EEG (odd numbered electrodes are placed on the left side of the head and even numbered electrodes are placed on the right side of the head).
ACTION:	• Natus is requesting you to check your Olympic Brainz Monitor stock and determine if your devices have the incorrect label orientation present per Fig. 1 above. • Immediately cease use of the affected product and quarantine until you receive the shipping instructions from Natus to return it. • If you have any devices with incorrect orientation labelling, please complete the enclosed form and return to FCA@Natus.com. You will receive shipping instructions from FCA@Natus.com. • If the product labelling is incorrect, a replacement device(s) will be made available to you at no cost, once you provide the completed Customer Reply Form that is listed below and return to FCA@natus.com. In the event you have affected product, Technical Service will be in contact with you to arrange for a provision of replacement device(s).
RESOLUTION:	• Issue is resolved upon replacement of the mislabelled Olympic Brainz Monitor. • Natus has identified the root cause of this issue and has implemented corrective actions to prevent future recurrence.
INTENDED USE:	The Olympic Brainz Monitor (OBM) is a three-channel electroencephalograph (EEG) acquisition system intended to be used in a hospital environment to record, collect, and display and facilitate manual marking of aEEG recordings. • The signals acquired from P3-P4, C3-P3 and C4-P4 channels are intended for use only with neonatal patients (defined as from birth to 28 days post-delivery, and corresponding to a post-conceptual age of 24 to 46 weeks) to display aEEG for monitoring the state of the brain. • The signals acquired from P3-P4 channel is intended to assist in the prediction of and severity of Hypoxic-Ischemic Encephalopathy and long-term outcome in full term neonates (post-conceptual age of 37-46 weeks) who have suffered a hypoxic-ischemic event. The Olympic Brainz Monitor does not provide any diagnostic conclusion about the patient's condition.

Please share this information with your organization staff and retain this notification as part of your organization Quality System documentation. If you have forwarded any of the affected product listed above to another organization, please provide them with a copy of this letter.

If you have any questions regarding this notice, please contact FCA@Natus.com.

Please be aware that your Competent Authority / Regulatory Agency has been informed of this communication.

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

Sincerely,

Courtney Walton
Vice President, Quality & Regulatory Affairs

Enclosure:
Customer Response Form

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 Olympic Brainz Monitor (DAB) by Natus Medical Incorporated.

Customer Name:	
Facility Name:	
Facility Address:	
City, State Country	
Postal Code	
Email address:	
Contact Name:	
Phone Number:	
Serial number(s):	
Qty:	

Please mark as appropriate:

☐ We will return the affected product

☐ We do not have the affected product

Name of Person completing these actions (please print): _____

Signature: _____ **Date:** _____

Title: _____ **Phone:** _____