Urgent Field Safety Notice - Recall
Olympic Brainz Monitor

Date:
FSN Reference: CAPA004782
FSCA Reference: **V43068**

Dear Valued Customer,

You are receiving this information as our records indicate you have received the Olympic Brainz Monitor. This notice needs to be passed to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations 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.

Intended use of the Olympic Brainz Monitor (OBM):
The Olympic Brainz Monitor (OBM) Cerebral Function Monitor (CFM) is a three channel electroencephalograph (EEG) acquisition system intended to be used in a hospital environment to record, collect, display and facilitate manual marking of aEEG recordings.

aEEG has become a standard bedside tool in many hospitals for monitoring the brains of infants with HIE undergoing therapeutic hypothermia and many other neurologic conditions, especially where seizures are suspected.

Description of the issue:
During manufacture of the OBM systems it was discovered that the system functional test (impedance and noise) was not carried out on the affected items prior to release to the customer. The manufacturer cannot attest to the system functionality of the affected items.

Affected Items:
The affected item is the Olympic Brainz Monitor part number OBM00002. The affected serial numbers are as follows:

OBM00002 S/N	OBM00002 S/N	OBM00002 S/N	OBM00002 S/N
OBM00002G2119	OBM00002G2149	OBM00002G2139	OBM00002G2159
OBM00002G2130	OBM00002G2150	OBM00002G2140	OBM00002G2160
OBM00002G2131	OBM00002G2151	OBM00002G2141	OBM00002G2161
OBM00002G2132	OBM00002G2152	OBM00002G2142	OBM00002G2162
OBM00002G2133	OBM00002G2153	OBM00002G2143	OBM00002G2163
OBM00002G2134	OBM00002G2154	OBM00002G2144	OBM00002G2164
OBM00002G2135	OBM00002G2155	OBM00002G2145	OBM00002G2165
OBM00002G2136	OBM00002G2156	OBM00002G2146	OBM00002G2166
OBM00002G2137	OBM00002G2157	OBM00002G2147	OBM00002G2167
OBM00002G2138	OBM00002G2158	OBM00002G2148	OBM00002G2168

Hazard associated with this issue:
These devices are used to record, collect display and facilitate manual marking of aEEG recordings from the patient. The data provided when using the affected OBM systems, may not be accurate.

Action to be taken:
Natus Medical Incorporated are performing a voluntary recall of the affected items.

Natus, are asking customers to return the affected units to the address below. Testing will be performed by Natus on your returned unit and will be returned to you following completion of testing. Natus will provide you with a **temporary replacement unit** during this time.

Customers are being asked to complete the below customer return form and return along with the device to the address provided.

Natus Medical Incorporated
5900 First Avenue
Seattle,
WA 98108
USA

For questions or comments regarding this program, please contact Natus Quality Programs as follows:
Phone: +1.800.272.8075
Email: Natus_Quality_Programs@natus.com

Please be aware that your Competent (Regulatory) Authority has been informed of this communication.

CUSTOMER REPLY FORM

TO BE COMPLETED BY RECIPIENT

Customer Name: _____

Facility Name: _____

Facility Address: _____

City, State Country _____

Postal Code _____

Email address: _____

Contact Name: _____

Phone Number: _____

SR number: _____

Please complete for received items

We hereby declare that we are aware of the product recall by Natus Medical Incorporated.
Please mark as appropriate:
□ We do not have any of the affected products
□ We do have the affected product(s) and will return it/them

List Serial Number(s) of affected device:

_____

_____

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

Signature: _____ **Date:** _____

Title: _____ **Phone:** _____