Urgent Field Safety Notice - Recall
1079 – Aircal Device

Date:
FSN Reference: CAPA004808
FSCA Reference:

Dear Valued Customer,

You are receiving this information as our records indicate you have received the Aircal 1079.
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 Aircal 1079

An air caloric stimulator is a device that delivers a stream of air to the ear canal at controlled rates of airflow and temperature and that is intended for vestibular function testing of a patient's body balance system. The vestibular stimulation of the semi-circular canals produces involuntary eye movements that are measured and recorded by a nystagmograph.

Description of the issue:
The affected devices were incorrectly shipped to European countries without fulfilling the requirements of EN 60601-1-2:2015 (IEC 60601-1- 2:2014 4th Edition) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. Compliance to the standard is a requirement of CE marking as of 31st Dec 2018.

Affected Items:
The affected item is the Aircal device Model number 1079. The affected serial numbers are as follows:

Item	Item Description	Sales Order Number	Serial Number
8-04-13321	1079 AirCal (Standard length - 3m)	1589814396	1809716 1812187
8-04-13321	1079 AirCal (Standard length - 3m)	1598055229	1811633
8-04-13321	1079 AirCal (Standard length - 3m)	1598097076	1927710 1927711
8-04-13321	1079 AirCal (Standard length - 3m)	1605338137	1828101
8-04-13321	1079 AirCal (Standard length - 3m)	1610696562	1931712
8-04-13321	1079 AirCal (Standard length - 3m)	1616110791	1829507
8-04-13321	1079 AirCal (Standard length - 3m)	1679672247	1829508
8-04-13321	1079 AirCal (Standard length - 3m)	1683285754	1809718
8-04-13321	1079 AirCal (Standard length - 3m)	1691072360	1809717
8-04-13322	1079 AirCal (Standard length - 4m)	1588801183	1911447
8-04-13322	1079 AirCal (Standard length - 4m)	1593169862	1807000
8-04-13322	1079 AirCal (Standard length - 4m)	1673810425	1927657 1927658 1927659

Hazard associated with this issue:
These devices do not meet the CE marking requirements.

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

Natus Medical Denmark, is asking customers to return the affected units to the address below. Replacement devices will be issued to all customers. Deliveries of the replacement devices will commence after the 01st April 2020.

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

Natus Medical Denmark
Hoerskaetten 9,
DK-2630 Taastrup,
Denmark

For questions or comments regarding this program, please contact Natus Quality Programs as follows:
Phone: +45 70 30 52 10
Email: otoservice@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 Denmark.
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:** _____