



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
8-04-13321	1079 AirCal (Standard length - 3m)	1589814396
8-04-13321	1079 AirCal (Standard length - 3m)	1598055229
8-04-13321	1079 AirCal (Standard length - 3m)	1598097076
8-04-13321	1079 AirCal (Standard length - 3m)	1605338137
8-04-13321	1079 AirCal (Standard length - 3m)	1610696562
8-04-13321	1079 AirCal (Standard length - 3m)	1616110791
8-04-13321	1079 AirCal (Standard length - 3m)	1679672247
8-04-13321	1079 AirCal (Standard length - 3m)	1683285754
8-04-13321	1079 AirCal (Standard length - 3m)	1691072360
8-04-13322	1079 AirCal (Standard length - 4m)	1588801183
8-04-13322	1079 AirCal (Standard length - 4m)	1593169862
8-04-13322	1079 AirCal (Standard length - 4m)	1673810425

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:** _____