



## **Urgent Field Safety Notice - Recall** **Embletta 128 USB Cable**

Date: August 2020  
FSN Reference: CAPA004898  
FSCA Reference:

### **Dear Valued Customer,**

You are receiving this information as our records indicate you have received the Embletta 128 USB cable.

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**

The Embletta 128 USB cable is used for connecting the ambulatory recorder (i.e the Embletta 128) to a computer via the USB connector. This allows initializing the device before the study starts and downloading the recording once the study ends. The design of the cable does not allow connecting a patient to the cable while the device is connected to the PC. In this way, it also acts as an electrical barrier between the medical device (i.e. Embletta 128 cable ) and the non-medical device (i.e. the computer).

### **Description of the issue:**

The Embletta 128 USB cable is not covered by CE cert 413 14534-01 issued by Intertek SEMKO AB on January 16, 2019 and therefore should not be displaying the CE mark with notified body number 0413.

### **Affected Items:**

<b><u>Part Description</u></b>	<b><u>Part Number</u></b>
Embletta 128 USB cable	2020302

### **Hazard associated with this issue:**

There is no risk to the patient or user as a result of this issue. This is a compliance issue and is considered a regulatory risk.

### **Action to be taken:**

We, Natus Medical Incorporated are performing a voluntary recall of the affected items listed in Table 1 above. Please return these affected items at your earliest convenience to the following address

Natus Manufacturing Ltd.  
IDA Business Park  
Gort,  
Co. Galway  
Ireland



Replacement cable are available. The Technical Service department will be in contact in relation to the provision of these cables.

Please complete and return the customer reply form to Natus at the following address:

Email: [Ottawa.TechSupport@natus.com](mailto:Ottawa.TechSupport@natus.com)

Phone number: 001 613 254 8877

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

**Name of Person completing these actions (please print):** \_\_\_\_\_

**Number of units discarded:** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Title:** \_\_\_\_\_ **Phone:** \_\_\_\_\_