Urgent Field Safety Notice - Recall
Embletta Gold USB Cable

Date: August 2020
FSN Reference: CAPA004899
FSCA Reference: V44530

Dear Valued Customer,

You are receiving this information as our records indicate you have received the Embletta Gold 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 Gold USB cable is used for connecting the ambulatory recorder (i.e. the Embletta Gold) to a computer via the USB connector. This allows initializing the device before the study starts and downloading the recording once the study ended. The cable includes the electrical barrier to protect the patient, in case a user connects the medical device (i.e. Embletta Gold) to a non-medical device (i.e. a computer).

Description of the issue:
The Embletta Gold 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:

Part Description	Part Number
Embletta Gold USB cable	2020303

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
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:** _____