Urgent Field Safety Notice - Recall
PURU3 Cable

Date: May 2020
FSN Reference: CAPA004849
FSCA Reference: V43869

Dear Valued Customer,

You are receiving this information as our records indicate you have received the PURU3 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 of the PURU3 Cable:
This cable connects the Patient Unit to the Bedside Unit (N7000). The system comes with the cable already connected to the patient Unit. The other end of the cable plugs into the Patient Unit Interface on the bottom end of the Bedside Unit. This cable should not be disconnected from the patient Unit. However, if the cable needs to be replaced, it can be detached from the Patient Unit by unscrewing the two screws that secure it to the unit.

Description of the issue:
The PURU3 cable label currently bears the CE Mark as depicted below. This product is not covered under the scope of the CE cert 41314534-01 which was issued by Intertek SEMKO AB on January 16, 2019. Therefore, this product should not display this CE mark as illustrated below with the notified body number 0413.

Illustration of Label

Affected Items:

The affected item is the PURU3 cable part number 2020011, details of lots affected are as per table 1 below.

Table 1 – PURU3 Affected Items

Product Description	Item Number	Lot Number
Embla Patient to Bed unit 3m	2020011	S1826001
		S1815001
		S1819001
		S1833001
		S1843001
		S1845001
		S1902001
		S1912001
		S1917001
		S1934001

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

We are currently working on a solution in relation to this issue and we will be in contact with further information in due course.

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:** _____