Urgent Field Safety Notice - Recall
RemLogic Software Version 4.0

Date: March 2020
FSN Reference: CAPA004791
FSCA Reference: V43204

Dear Valued Customer,

You are receiving this information as our records indicate you have received RemLogic Software. 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 RemLogic Software:
The RemLogic software is intended for Polysomnography studies on pediatric and adult patients, and allows recording, displaying, analysis, printing and storage of physiological signals to assist in the diagnosis of various sleep disorders. The RemLogic software also allows:
- Sleep report templates which summarize recorded and scored sleep data using simple measures including count, average, maximum and minimum values as well as data ranges for trended values;
- An optional automated analysis of physiological signals that is intended for use only in adults;
- An optional audio/visual alert for user defined threshold on calibrated DC input. These alerts are not intended for use as life support such as vital signs monitoring or continuous medical surveillance in intensive care units.

The RemLogic software is intended for use only by qualified and trained medical practitioners in research and clinical environments, who evaluate the software output with their clinical experience and judgment to provide diagnostic conclusions about the patient's condition.

Description of the issue:
Natus has become aware that the RemLogic Software part number 026259 was labelled with an incorrect notified body number. The affected items were labelled with the Notified Body number CE 0086 instead of CE 0413.

Affected Items:

The affected item is the RemLogic Software part number 026259. This part number affects the following sales orders:

Product Line	Sales Order Number	Item
Embla Remlogic	1692637666	026259
Embla Remlogic	1692614368	026259
Embla Remlogic	1696198583	026259
Embla Remlogic	1692318161	026259
Embla Remlogic	1693764410	026259
Embla Remlogic	1694156877	026259

Hazard associated with this issue:
There is no risk to the patient or user as a result of this issue. There is no impact to the device form, fit, function or intended use.

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

Natus is asking customers to discard the affected items you currently have in stock. Natus will send you a replacement part. Natus are asking customers to complete the below customer reply form, once the item has been discarded. Please return the completed form to Natus at the following address:

Email: Ottawa.techsupport@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 Incorporated.
Please mark as appropriate:
□ We do not have any of the affected products
□ We do have the affected product(s) and have discarded it/them

Name of Person completing these actions (please print): _____

Number of units discarded: _____

Signature: _____ **Date: _____**

Title: _____ Phone: _____