Medtronic
60 Middletown Avenue
North Haven, CT 06473
USA
www.medtronic.com

URGENT FIELD SAFETY NOTICE

Nellcor™ SpO_2 Forehead Sensor

December XX, 2016

Attention: Risk Management Director and OR Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific production lots of our Nellcor™ SpO_2 forehead sensor (Item Code: RS10). This Field Safety Corrective Action (FSCA) is being conducted due to a labeling error. The label indicates the product is latex free, but the headband component included with the forehead sensor does contain latex. The sensor array itself is latex free. The use of products containing latex may result in allergic reactions for patients and providers who have latex sensitivity. Allergic reactions can include skin rash, itching, dyspnea and anaphylaxis. There have been no reports of serious injury associated with this issue.

We request that you quarantine and return any unused products of the lots detailed below. Unused products from the affected lots should be returned as described in the "Required Actions" section below. If you have distributed the Nellcor™ SpO_2 forehead sensor products listed below, promptly forward this letter to those recipients. All unused products from the affected lots must be returned.

This FSCA affects only the item code and lots listed below; it does not affect MaxFast™ devices which are latex free.

Item Code	Product	Affected Lot Numbers				
RS10	Nellcor™ SpO_2 Forehead Sensor	161510095H	161620089H	161690203H	161760132H	161900091H
		161970090H	162040107H	162110103H	162320191H	162390212H

This action is being taken with the knowledge of [Insert local Competent Authority]. We request that you contact us if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: XXXXX@Medtronic.com

Required Actions:

1. Quarantine and discontinue use of the affected lots listed above.
2. Please return affected product as follows:

Medtronic

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased **directly** from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a **distributor**	Complete **all** fields on the form and contact your distributor directly to arrange for return of affected product	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor & to the Medtronic contact provided on the verification form.

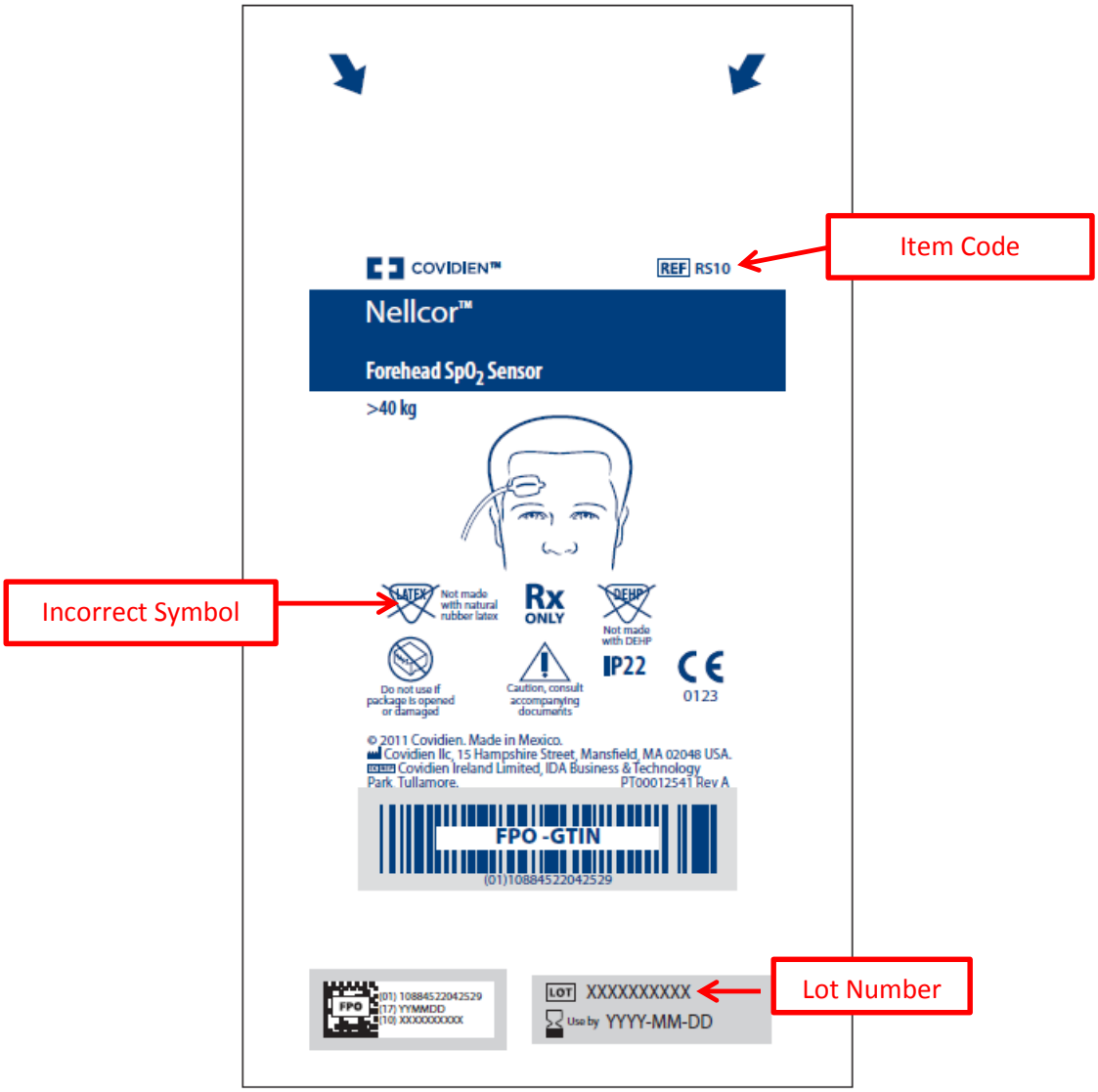
We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at XXX-XXX-XXXX.

Sincerely,

Subu Mangipudi

Vice President, Quality
Patient Monitoring and Recovery
Medtronic

Medtronic

Attachment A

Distinguish affected product by Item Code and Lot Number