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Urgent: Medical Device Correction

Nellcor™ Bedside SpO_2 Patient Monitoring System

Product Description	Item Code	GTIN	IFU Part Number	Affected Serial Numbers
Nellcor™ Bedside SpO_2 Patient Monitoring System	PM100N	10884521196728	PT00156509 Rev A PT00156328 A	All serial numbers
	10005941	10884521163454	PT00156324	
		A8845211634501	PT00156324	
	10005941-SG	10884521171534	PT00156324	
	10005941J	10005941JP	PT00156324	
	10005941JP	884521512019	PT00156324	
	10005941JPN	884521188689	PT00156324	
	DLPM100N	10884521527607	PT00156509 Rev A PT00156328 A	
	DL10005941	10884521173293	PT00156324	
	DS10005941	DS10005941	PT00156324	
	DSPM100N	DSPM100N	PT00156509 Rev A PT00156328 A	

See Attachment A: Identifying Subject Devices

23 June 2025 | 13:10 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Facility Risk Manager and Clinicians prescribing use of Nellcor™ Bedside SpO_2 Patient Monitors:

The purpose of this letter is to advise prescribing clinicians that Medtronic is issuing a safety notification for its Nellcor™ Bedside SpO_2 Patient Monitoring System. This notice follows receipt of multiple reports from customers stating that the device alarm was not heard or recognized, resulting in a delay to treatment or lack of response to low oxygen saturation,

respiratory failure, or arrythmia. There have also been reports of death during some of these circumstances. While our investigation and analysis of the devices returned in relation to the customer reports did not identify any anomalies or non-conformances with the products, you are receiving this letter because Medtronic records indicate that one or more of these devices were shipped to your facility.

Issue Description

To date, our analysis of the returned devices found that all devices passed functional testing requirements. All alarms were found to be functioning, and the devices were confirmed to meet the manufacturing specifications set for the product. Based on available information, the Nellcor™ Bedside SpO_2 Patient Monitors continues to be safe for use in patient care. While our investigation continues, we are highlighting for you important information found in the Operator's Manual.

- **Setting Alarm Volume** – The volume of the device needs to be set to a level appropriate to be heard throughout the care environment at all times of day or night. Do not silence or decrease the volume of the audible alarm if patient safety could be compromised.
- **Sensor Off Alarm Behavior** – The sensor off alarm is defined as a low priority where the alarm sounds every 16 seconds and displays a steady yellow visual indicator. If the sensor comes off the patient, or no perfusion is detected, the device will notify 'sensor off' as a low priority alarm condition. If a low priority alarm immediately follows a higher priority alarm, a user may not recognize the higher priority clinical condition.
- **Setting PM100N Monitor to the Mode Appropriate for the Care Environment** – Monitors should be set to Standard Mode when in use in a hospital or hospital-type environment by trained medical personnel and set to Homecare Mode when a lay person will be using the monitor outside of a hospital or other professional care setting. With the monitor not in Homecare Mode, alarms could be silenced/muted and alarm limits altered.

I. Risk to Health

Not responding to an audible alarm can result in a delay to treatment of low oxygen saturation, respiratory failure, or arrythmia, and can result in death.

II. Information for Prescribing Clinicians on Patient Management

a. For Clinicians Using Models PM100N, 10005941 in Clinical Facility Environments

i. Continue to use in accordance with the Operator's Manual

Manuals can be found at http://manuals.medtronic.com

The Nellcor™ Bedside SpO_2 Patient Monitoring System can continue to be used for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate as prescribed and in accordance with the Operator's Manual. The Nellcor™ SpO_2 patient monitoring systems are equipped with alarms that can be customized to allow for specific parameters for the patient being monitored and for the patient's care environments.

- Consult the Operator's and Service manuals to set alarm configurations, volume and confirm that the Nellcor™ Bedside SpO_2 Patient Monitoring System is appropriately set for the patient being monitored and for the patient's care environment.
    - Be sure the PM100N model is set to Standard Mode for general use and only set to Sleep Study Mode when conducting a sleep study.

ii. Alarm Volume

Set the monitor's alarm volume to a level that is audible throughout the care environment. As warned in the Operator's Manual, "*Do not silence or decrease the volume of the audible alarm if patient safety could be compromised.*"

iii. Alarm Behavior

Respond to all alarms, irrespective of priority. If alarms occur, the patient may require medical attention.

b. For Clinicians Who Prescribe the PM100N for Use in a Homecare Environment

i. Continue to use in accordance with the Operator's Manual

The Nellcor™ Bedside SpO_2 Patient Monitoring System can continue to be used for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate as prescribed and in accordance with the Operator's Manual. The Nellcor™ SpO_2 patient monitoring systems are equipped with alarms that can be customized to allow for specific parameters for the patient being monitored and for the patient's care environments.

- Consult the Operator's and Service manuals to set alarm configurations, volume and confirm that the Nellcor™ Bedside SpO_2 Patient Monitoring System is appropriately set for the patient being monitored and for the patient's care environment.

ii. Before Prescribing Clinicians Send a PM100N Monitor into a Homecare Environment

- **Homecare Mode (PM100N only)**
    - When a Nellcor™ Bedside SpO2 Patient Monitoring System is in use in a homecare environment where the caregiver is not a clinician, the device should be set to Homecare Mode prior to use in the home. A device configured to Homecare mode limits settings available to the lay user.
    - Consult the Operator's Manual for instructions on setting the monitor to Homecare Mode prior to sending the device home with a patient.
    - Confirm that any model PM100N device in use outside of a hospital or hospital-type environment is set to Homecare Mode. Contact your local Medtronic representative to obtain a four-digit password required to set a monitor to Homecare Mode.

iii. Prescribing Clinicians Should Recommend to Home Caregivers

- **Alarm Volume**
  - Set the monitor's alarm volume to a level that is audible throughout the care environment. As warned in the Operator's Manual, "Do not silence or decrease the volume of the audible alarm if patient safety could be compromised."

- **Alarm Behavior**
  - Respond to all alarms, irrespective of priority. If alarms occur, the patient may require medical attention.

iv. Home Use Guide for PM100N Nellcor™ Bedside SpO2 Patient Monitoring System

- As noted in the Operator's Manual, provide the Home Use Guide to home caregivers and recommend that they use it. This guide provides basic information for setup, operation, and cleaning of the monitoring system.

Actions Prescribing Clinicians should take

- Be sure you read and understand the information contained in this Notice.
- Communicate the information from this notice to your home use patients and their caregivers. Suggested language to use with your patients and their caregivers:

  For the safety of the patient, be sure the monitor's alarm volume is set to a level that can be heard throughout your home at all times of day or night. Respond to all alarms because whenever an alarm occurs the patient's health may be at risk. Notify your clinician if alarms occur.

  Whenever you reconnect the sensor to the patient or the monitor check that the oxygen level and heart rate are acceptable. Read and follow the Home Use Guide provided to you. This guide provides basic information for safe use of your monitoring system.
- Consult the Operator's and Service manuals to set alarm configurations, volume and confirm that the Nellcor™ Bedside SpO_2 Patient Monitoring System is appropriately set for the patient being monitored and for the patient's care environment.
- Confirm that any model PM100N device in use outside of a hospital or hospital-type environment is set to Homecare Mode. Contact your local Medtronic representative to obtain a four-digit password required to set a monitor to Homecare Mode.

Actions facility risk managers should take

- Pass on and post this notice for all those who need to be aware within your organization and to any organization where the product has been transferred or distributed.
- Please complete and return the enclosed Customer Confirmation Form to your local Medtronic representative even if you do not have inventory.

Additional Information

Medtronic is communicating this information to the appropriate regulatory agency in your country.

Local contact details:

Adverse reactions or quality problems experienced with this product should be reported to your local Medtronic representative.

Medtronic will provide additional information, including strengthening the instructions for use, when the information is finalized. We are committed to patient safety and appreciate your prompt attention to this notice. If you have any questions regarding this communication, please contact your local Medtronic Representative.

Sincerely,

Quality and Regulatory Affairs Director

Southeast Asia

Enclosures:

Attachment A: Identifying Devices

Consignee Confirmation Form

Attachment A

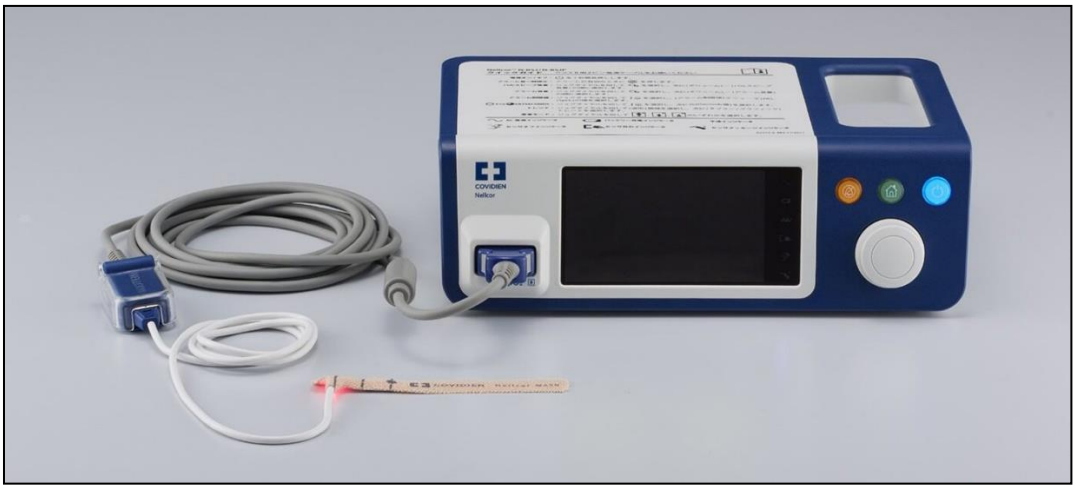
Identifying Subject Devices

PM100N: For Use in Clinical Facility and Homecare Environments

10005941 and 10005941-SG: For Use in Clinical Facility Environments
Also sold within kit-N-BS

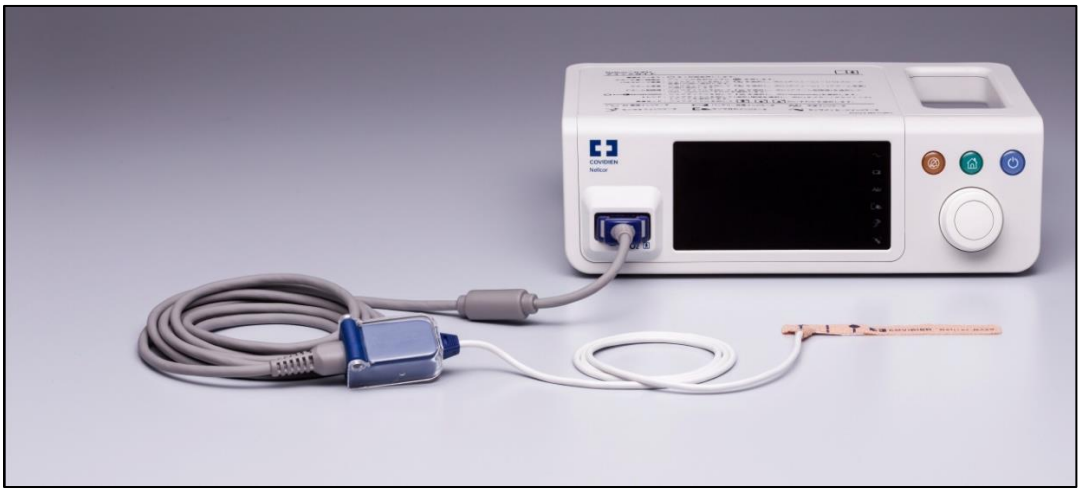
10005941J/JPN: For Use in Clinical Facility and Homecare Environments

Also sold within kit N-BSJ



10005941JP: For Use in Clinical Facility and Homecare Environments

Also sold within kit N-BSJP



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Customer Confirmation Form

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Nellcor™ Bedside SpO_2 Patient Monitoring System

For completion by Medtronic Customers Only – Please complete all fields below and and return this form immediately even if you no longer have inventory.

Customer Contact Details		Medtronic Contact Details
Distributor/Hospital/Clinic/Patient name:		**Name:**
		Contact:
Address:		**Email:**
Phone no:	**Email:**	

By signing this form, I confirm that I have read the Urgent: Medical Device Correction Notification Letter, dated 23 June 2025 | 13:10 SGT from Medtronic regarding *Nellcor™ Bedside SpO2 Patient Monitoring System* and have taken appropriate action including contacting home use patients as required.

Please complete all fields and sign the form as indicated below and return the completed form to your local Medtronic representative.

Pass on this notice to any organization or individual where the product has been transferred or distributed.

Name (print): _____ Signature: _____ Stamp: _____ Date: ☐☐ ☐☐☐ ☐☐☐☐

For questions, please contact your local Medtronic Representative.

Note: The addressee may continue to receive reminders of this notice until a response is received.