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28 July 2025

CRITICAL – PRODUCT ALERT

Nellcor™ Bedside SpO_2 Patient Monitoring System

TGA Reference: **RC-2025-RN-00605-1**

ARTG: 179890

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	

See Attachment A, Identifying Subject Devices

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 product alert for its Nellcor™ Bedside SpO_2 Patient Monitoring System. This notice follows receipt of multiple reports from customers stating that the device alarm did not sound or was not heard or recognised, 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. You are receiving this letter because Medtronic records indicate that one or more of these devices were shipped to your facility.

Problem 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, limitations in Operator's Manual have been identified that may contribute to mismanagement of critical alarm settings. Key existing information is also being reiterated.

- **Sensor Off Alarm Behaviour** – The sensor off alarm is defined as a low priority technical alarm. When triggered, the alarm sounds every 16 seconds and displays a steady yellow

visual indicator. This alarm is activated when the sensor comes off the patient or the cable is disconnected from the monitor, or no perfusion is detected.
The manual does not explain how the users can adjust this alarm to a higher priority, nor does it provide guidance on the potential clinical implications of the current default setting. Specifically, if a sensor-off event occurs immediately after a higher priority alarm, the higher priority alarm will be terminated as a result of sensor-off condition. In such cases, user may incorrectly assume the higher priority alarm issue has resolved when in fact the sensor has lost contact and the patient's condition remains unknown.

- **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.

- **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. As already stated in the manual, do not silence or decrease the volume of the audible alarm if patient safety could be compromised.

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 haemoglobin (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 customised 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 Behaviour

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 haemoglobin (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 customised 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

Technical Service at 800-255-6774 option 1, then option 2 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 Behaviour**
  - Respond to all alarms, irrespective of priority. If alarms occur, the patient may require medical attention.
  - The monitor's "Sensor off" alarm is triggered when the sensor becomes detached from the patient or the cable is detached from the monitor. Inadvertent sensor disconnections require immediate assessment and reconnection as once the sensor is off, other physiological alarms will not be sounded.

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. Inadvertent sensor disconnections require immediate assessment and reconnection as once the sensor is off, other physiological alarms will not be sounded. 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.

- **Contact patients/caregivers who are using PM100N device outside of a hospital or hospital-type environment to ensure that the device 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 organisation and to any organisation where the product has been transferred or distributed.
- Please complete and return the enclosed Customer Response Form to re.anzrecalls@medtronic.com even if you do not have inventory.

Additional Information

Medtronic will provide additional information, including strengthening the instructions for use, when the information is finalised.

Medtronic is initiating this action in consultation with the Therapeutic Goods Administration.

Local contact details

We are committed to patient safety and welcome any questions you may have regarding this communication. Please do not hesitate to contact John Paul Ribeiro at +61439320204, or john.paul.ribeiro@medtronic.com.

Sincerely,

Lewis Hong

Sr Post Market Vigilance Specialist | Quality and Regulatory Affairs

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Attachment A

Identifying Subject Devices

PM100N: For Use in Clinical Facility and Homecare Environments

10005941: For Use in Clinical Facility Environments

Also sold within kit-N-BS

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CRITICAL – PRODUCT ALERT

Response Form

Nellcor™ Bedside SpO_2 Patient Monitoring System

TGA Reference: RC-2025-RN-00605-X

ARTG: 179890

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		A8845211634501	PT00156324	

To assist us in this corrective action, please complete and sign this Acknowledgement Form.

By signing this acknowledgement form, I confirm that I have read and understood the URGENT– PRODUCT ALERT Notification regarding Nellcor™ Bedside SpO2 Patient Monitoring System, dated July 2025.

Please complete the form and email to rs.anzrecalls@medtronic.com to the attention of Recalls.

Hospital/Facility:_____

Hospital/Facility Address:_____

Customer Name:_____

Customer Title: _____

Customer Signature: _____

Date:_____

Telephone: _____

For questions, contact John Paul Ribeiro at +61439320204, or john.paul.ribeiro@medtronic.com.