

Urgent Field Safety Notice

PMAC71RSC - Reusable Sensor Cable for PM7100 and PMAC71RIC - Reusable Infant Sensor Adapter Cable for PM7100

Recall

January 2024

Medtronic Reference: FA1388

EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Healthcare Professional, Risk Manager, Operating Room Supervisor,

The purpose of this letter is to advise you that Medtronic is initiating a recall limited to specific production lots, (see table below), of INVOS™ PM7100 Reusable Sensor Cables, Part Numbers PMAC71RSC and PMAC71RIC. This recall follows receipt of customer reports of system error messages including "Check Sensor" or "Replace Sensor" displayed on the monitor. It was discovered that some reusable sensor cables contain manufacturing defects which can also result in the "Check Sensor" or "Replace Sensor" error messages. Please note, the INVOS™ PM7100 system is intentionally designed to provide these error messages in numerous situations where valid data cannot be displayed, which can occur for many legitimate reasons in addition to these cable manufacturing defects. Corrective actions have now been implemented at the manufacturing facility to resolve these issues moving forward. You are receiving this letter because Medtronic records indicate that potentially affected cables were shipped to your facility.

Issue Description:

Our investigation of these customer reports identified manufacturing defects within the PMAC71RSC and PMAC71RIC sensor cable connectors. These defects can lead to "Check Sensor" or "Replace Sensor" error messages, which result in a non-functioning channel that cannot obtain a regional oxygen saturation (rSO₂) reading when using an affected cable. Based on engineering analysis, the manufacturing defects were also confirmed to potentially lead to inaccurate rSO₂ readings. Inaccurate readings on these affected cables are typically biased low but may also read high. The magnitude of inaccuracy has been observed to vary by 1 to 45 rSO₂ percentage points from expected value, with 1-10 rSO₂ percentage points being most common.

The exact outcome on an INVOS™ PM7100 system can vary across individual uses of a single cable, since a portion of affected cables may behave differently across varying use cases, environmental factors, and signal strengths (e.g., A cable may function properly with high signal strengths but may not function properly with lower signal strengths, or it may produce error messages at low signal strengths and provide inaccurate readings at higher signal strengths). As a result of these potential inconsistent cable behaviors, there are no reliable methods for customers to determine if cables from affected lots will truly function correctly in all clinical use cases. Therefore, all cables from affected lots are part of this recall, even if they appear to be working upon initial use.

Risk to Health:

Inability to obtain rSO2 readings due to a faulty INVOS™ PM7100 cable can result in a delay to the surgical procedure. Inaccurate rSO2 readings can result in potential harms including low oxygen saturations in cerebral/somatic tissue (hypoxia) or high oxygen saturations in cerebral/somatic tissues. As of 18-Dec-2023 there have been 121 complaints for PMAC71RSC and 4 complaints for PMAC71RIC worldwide that are potentially related to this issue. None of these complaints indicated that patient harm occurred due to either of these INVOS™ PM7100 cables. There are no additional patient management recommendations that should be employed for patients in which potentially affected cables were previously used.

Product Scope/Affected Lots:

Part Number	Description	Product GTIN	Lot Number
PMAC71RSC	INVOS™ reusable sensor cable for PM7100	10884521780125	2023-02-22 2023-04-28 2023-05-04 2023-07-20
PMAC71RIC	INVOS™ reusable infant sensor adapter cable for PM7100	10884521806436	20221220 20230721

Actions to be taken by Customer:

1. Quarantine and stop using all product from the affected lots of INVOS™ Reusable Sensor Cables PMAC71RSC and PMAC71RIC.

- See attachment A for guidance on how to identify affected devices via cable box packaging or cable hang tag.
- 2. Complete and return Customer Confirmation Form Complete and return the enclosed Customer Acknowledgement Form even if you do not have any affected lots remaining.
- 3. Reach out to Medtronic to obtain Returned Goods Authorization (RGA#) number.
 - Your Medtronic Representative can assist in initiating product return as necessary.
- 4. Return all product from the affected lots in your possession to Medtronic as described in the Return Instruction.
- 5. Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected product from the specified lots has been transferred or distributed.

Actions to be taken by Medtronic:

- Medtronic will proactively send free replacement cables to those customers with impacted product (based on prior shipments) at the earliest product availability. Medtronic is working urgently to provide replacements as quickly as possible, but if you have not received your replacement on or before the end of March 2024, please contact Medtronic Representative.
- Medtronic will provide RGA # and customer service support as needed.

Additional Information:

- Medtronic has notified the Competent Authority of your country of this action.
- Please note that the reusable sensor cables (PMAC71RSC and PMAC71RIC) have a service life of approximately one year and are suggested to be replaced annually (as stated in the PM7100 Operators Manual and Service Manual).
- If you have disposed of cable packaging and removed the identifying information on the cable hang tag, please do not return these cables to Medtronic. Please contact Medtronic Representative to coordinate a solution.

We are committed to patient safety and appreciate your prompt attention to this matter. We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic Sales Representative or via email: rs.regulatoryuk-ire@medtronic.com.

Sincerely,

H. Hussain

Heidar Hussain

Associate Regulatory Affairs Specialist

Enclosures:

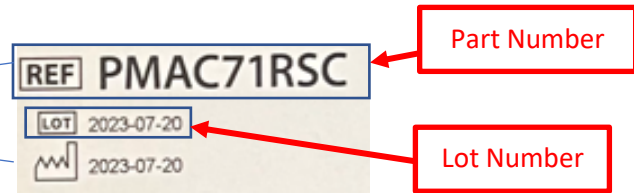
Attachment A: Identifying Affected Devices

Customer Acknowledgement Form

Attachment A:
IDENTIFYING POTENTIALLY AFFECTED DEVICES
Locate product information on product labels in your inventory

PMAC71RSC

Cable Box:



Cable:



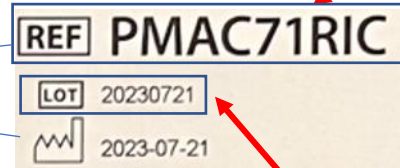
Lot Number

Part Number

PMAC71RIC

Cable Box:

Part Number



Lot Number

Cable:



Lot Number

Part Number