PRODUCT MISLABELING NOTICE

April 24, 2025

Dear Valued McKesson Customer:

Resmed has notified McKesson Medical-Surgical Inc. (MMS) of a Product Mislabeling Notice regarding specific lot(s) of their AirFit F20 Non Magnetic Full Face Masks. This notice has been issued due to the potential presence of a magnetic frame packed in the masks system package. Affected product first shipped March 1, 2024.

McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For questions regarding this notification, please contact Resmed at **(800) 424-0734**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table below for a list of affected item(s) previously distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)
1245601	64029	MASK, NASAL N/MAGNETIC AIRFIT F20 COMPLETE SYSTEM MED	1771288
			1771295

McKesson Customer Instructions:

1.) Quarantine and inspect any existing stock on hand from the affected lots listed above for the presence of blue magnetic headgear clips on the mask frame.

2.) A copy of the Urgent Medical Device Recall from Resmed has been included for reference.

3.) Contact Resmed at **(800) 424-0737** to organize for the return and free replacement if your mask is impacted by this notice. Please indicate that you are a McKesson Medical-Surgical customer when requesting the return.

4.) Once you have received the return instructions from Resmed, return the product to them following their instructions. After the product has been returned, replacement will be issued to you.

5.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this notification.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

Dear Valued Customer,

Resmed has become aware of an issue regarding the potential presence of a magnetic mask frame packed in the AirFit F20 Non Magnetic full face mask system package.

Resmed is issuing this notification to alert customers to the product packaging error and mislabelling noted below, and to provide instructions for screening and return of affected product.

The packing configuration renders the mask unusable by patients for therapy, as the magnetic mask frame is not physically compatible with the non-magnetic headgear clips. As such, there is no risk to patients who are contraindicated against the use of masks containing magnets. To date, Resmed has not received any reports of an adverse event related to this issue.

Products Affected

This notice is limited to two lots of AirFit F20 Non Magnetic full face masks sold from March 2024.

Refer to **Appendix A** for instructions on how to identify a product lot number.

Product Name	Product Number	Lot Number	UDI
AirFit F20 NM (Medium)	64029	1771288	619498642090
AirFit F20 NM (Medium)	64029	1771295	619498642090

Note: A notice related to Lot No. 1771288 was previously communicated in Apr-24. If you have previously received communications related to this issue, please note the addition of Lot No. 1771295 to the scope and re-acknowledge this email below.

Actions by Resmed

Resmed is reaching out to all customers who have purchased masks from the affected lots and is providing replacement masks free of charge for products identified to exhibit this issue.

Actions to be taken by customers/healthcare providers

Based on Resmed's review of affected product, this issue may not affect every mask manufactured within this lot. Therefore, customers are required to:

- Quarantine and inspect any existing stock on hand from the affected lots for the presence of **blue** magnetic headgear clips on the mask frame. Refer to **Appendix B** for instructions on how to identify affected masks.
- If an affected mask(s) is identified: please contact Resmed Customer Support on 1(800) 424-0737 to organize for the return and free replacement of the mask(s).
- If an affected mask(s) is not identified: no further action is required. These mask(s) remain acceptable for use.

~~Please click the button below to confirm you have read and understood the content of this notice at your earliest convenience.~~

~~Acknowledge~~

~~If you are not the appropriate contact to acknowledge this message, please forward this email to the most appropriate person within your organization~~.

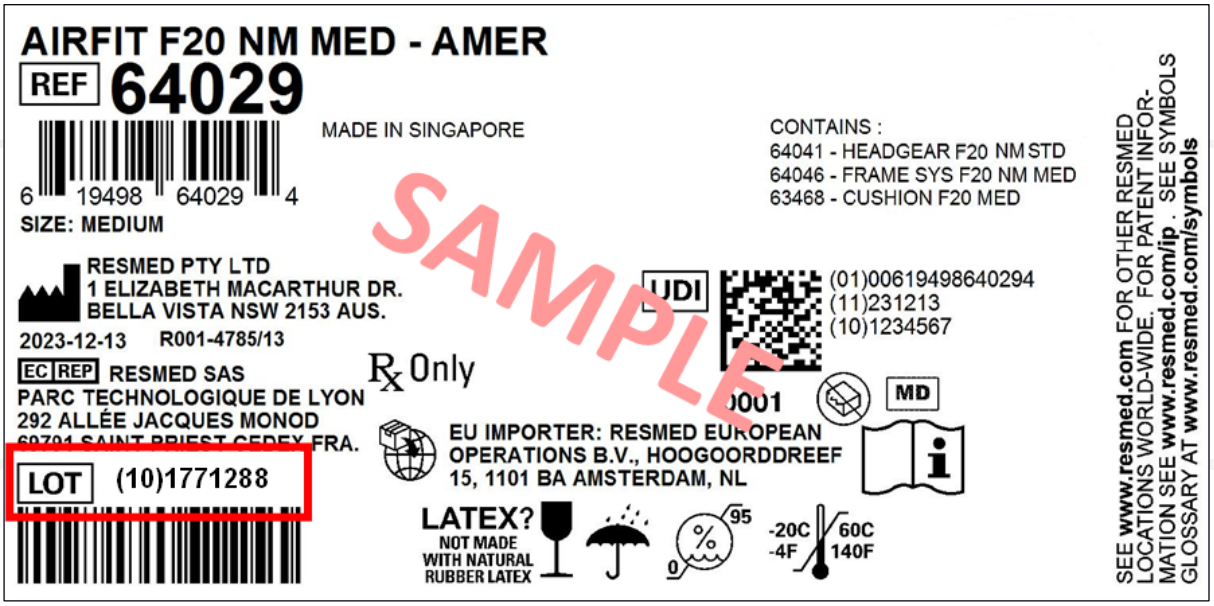
We appreciate your support in this matter. We consider this action necessary to align with our commitment to provide our customers and patients products of the highest quality.

Sincerely,

Dawn Haake
Chief Quality Officer, Resmed

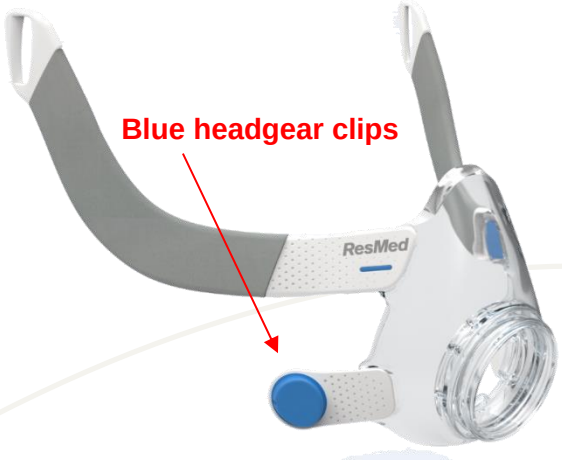
Appendix A – How to identify the lot number of a Resmed mask

The lot number is located on the mask packaging label in the following location:



Appendix B – How to identify a magnetic mask frame

Magnetic mask frames can be identified by the presence of **blue** headgear clips, located on the front of the mask (see images below). For non-magnetic mask frames, the clips are gray.

Affected Masks	Non-Affected Masks
Blue magnetic headgear clips on mask frame	Gray non-magnetic headgear clips on mask frame
 *Figure 1: AirFit F20 Magnetic Mask Frame*	 *Figure 2: AirFit F20 Non Magnetic Mask Frame*