

State of California—Health and Human Services Agency California Department of Public Health



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Resmed Recalls Airtouch And Airfit Masks For Magnetic Interference

Recall Date	Product Description	Recalling Firm	Recall Reason
12/27/2023	Airtouch F20 Full Face Mask and User Guide	RESMED LTD. Bella Vista, Australia	Masks non-invasive interface for chann- eling airflow to pat- ients have magnets that have potential magnetic interfere- nce with active medi- cal implants that int- eract with magnets, and metallic implants /objects containing ferromagnetic mate- rial so contraindicat- ions and warnings about safe distance to medical devices /implants are being updated for patients using masks or any- one in close physical contact
12/27/2023	Airtouch N20	RESMED LTD.	Magnetic
	Nasal Mask and User Guide	Bella Vista, Australia	Interference
12/27/2023	Airfit F30	RESMED LTD.	Magnetic
	Full Face Mask and User Guide	Bella Vista, Australia	Interference
12/27/2023	Airfit N10	RESMED LTD.	Magnetic
	Nasal Masks and User Guide	Bella Vista, Australia	Interference
12/27/2023	Airfit F20	RESMED LTD.	Magnetic
	Full Face Mask and User Guide	Bella Vista, Australia	Interference

12/27/2023	Airfit F30i	RESMED LTD.	Magnetic
	Full Face Mask and User Guide	Bella Vista, Australia	Interference
12/27/2023	Airfit N20	RESMED LTD.	Magnetic
	Nasal Mask and User Guide	Bella Vista, Australia	Interference

Recall Class	Product Identification	Distribution	Affected Dates
Ι	Airtouch F20 All mask lots used with User Guide 638220/version 2020-02, and prior. UDI-DI/GTIN: 619498630028 - 619498630370	3,816,138 Units Nationwide	Febuary 2020 and prior
Ι	Airtouch N20 All mask lots used with User Guide 638218/version 2020-02, and prior. UDI-DI/GTIN: 619498639069 - 619498639212	424309 Units Nationwide	Febuary 2020 and prior
I	Airfit F30 All mask lots used with User Guide 638234/version 2020-07, and prior. UDI-DI/GTIN: 619498641048 - 619498641147	2,660,776 Units Nationwide	July 2020 and prior
Ι	Airfit N10 All mask lots used with User Guide 628153/version 2020-07, and prior. UDI-DI/GTIN: 619498632008 - 619498632176	199796 Units Nationwide	July 2020 and prior
I	Airfit F20 All mask lots used with User Guide 638220/version 2020-02, 638238/version 2020-12, 638221/version 2020-01, and prior. UDI-DI/GTIN: 619498634019 - 619498634194	11,885,039 Units Nationwide	December 2020 and prior
I	Airfit F30i All mask lots used with User Guide 638225/version 2020-02, and prior. UDI-DI/GTIN:	2037323 Units Nationwide	Febuary 2020 and prior

	619498633326 - 619498633074		
Ι	Airfit N20 All mask lots used with User Guide 638218/version 2020-02, 638243/version 2020-06, and prior. UDI-DI/GTIN: 619498635016 - 619498635153	7,724,968 Units Nationwide	June 2020 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE at Airtouch <u>F20</u>, Airtouch <u>N20</u>, Airfit <u>F30</u>, Airfit <u>F20</u>, Airfit <u>F30i</u> and Airfit <u>N20</u>

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