



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION*

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2024-RN-00195-1

DATE AGREED: 15/03/2024

PRODUCT: Astral 100 and Astral 150 ventilators

Affected Product: Astral ventilators manufactured between 2013 and 2019

Multiple serial numbers (see below)

ARTG 219429
(Portable ventilator electric)

SPONSOR: Resmed Pty Ltd

CONTACT INFORMATION: (02) 8884 1000 – Resmed Pty Ltd

REASON: ResMed’s Astral ventilator is designed to sound a Total Power Failure alarm, for at least 2 minutes, when a Total Power Failure occurs. It has been identified that a component problem in affected ventilators may cause this alarm to sound for less than 2 minutes, or in some cases, to not sound at all (Note: this alarm is only activated when there is a Total Power Failure).

This problem does not affect the ability of the Astral ventilator to provide ventilation. All other alarms (including low and critically low battery alarms) will function as normal.

Phase 1 of this action was completed as part of recall action RC-2023-RN-00744-1; this action is aimed to address phase 2.

PROPOSED CUSTOMER ACTIONS: Phase Two: R6.2 Software Release:
In September 2023, ResMed updated the Astral service process to improve detection of this issue during service. ResMed will continue to replace circuit boards for ventilators that are identified in service to be affected by this issue.

In March 2024, ResMed released SX544-0603 Astral Software application Release 6.2 for Astral 100/150 ventilators to improve detection of this issue during ventilator use.

All ResMed service centres will upgrade the software of any Astral 100/150 ventilator to SX544-0603 Astral Software application Release 6.2, when returned for any service activity.

It is mandatory that all affected Astral ventilators are upgraded to this latest software version by the end of March 2025.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 53 facilities nationally excluding ACT and NT

Product export status: Number of countries affected 85

This problem was first identified by the Sponsor

This information has been published in the TGA's searchable database, the System for Australian Recall Actions (SARA) –

<https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2024-RN-00195-1>

*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>

Serial Numbers

20142352284	22152030694	22171734687	22182023611
20142352288	22152030695	22171734695	22182023613
20142352289	22152030697	22171838105	22182023614
20150141856	22152030698	22171838119	22182023615
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22141205251	22161207226	22181176101	22182023625
22141205260	22161207231	22181200435	22182023627
22141205263	22161207232	22181200440	22182023629
22141205269	22161207233	22181271732	22182023630
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22151640474	22171485751	22181944542	22211185393
22151779253	22171491720	22181977410	22211740819
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22151849087	22171600159	22182023605	22211764304
22151849089	22171661045	22182023607	22211764306
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