ResMed Astral Ventilator Safety Notice

FDA Class I Recall Classification — What Changed & What Didn't

Update prepared: July 30, 2026 | Page originally published: July 8, 2026

UPDATED 7/30/26

FDA Classifies Astral Notice as Class I Recall

Use this as the badge/label text wherever the site surfaces page updates (homepage tile, Safety Notices index, or a banner on the page itself). Shorter alt if space is tight: **"UPDATED 7/30/26: Now a Class I Recall"**

ResMed Astral Ventilator Safety Notice

Last Updated: July 30, 2026 *(Originally published July 8, 2026)*

> **Update (July 30, 2026):** Since this page was originally published, the U.S. Food and Drug Administration (FDA) has formally classified ResMed's Manufacturer Field Safety Notice as a **Class I Device Recall**. This classification does not change the current recommendations for patients. Patients should continue using their ventilator as prescribed unless directed otherwise by their treating clinician or Respire. **YOU SHOULD NOT RETURN OR DISCONTINUE USE OF YOUR VENTILATOR ON YOUR OWN.**

Quick Facts

Has this been classified as a recall?

Yes. ResMed originally issued this as a Manufacturer Field Safety Notice. On July 28, 2026, the FDA classified the action as a Class I Device Recall. Patients should continue using their ventilator unless directed otherwise by their physician or Respire.

Has the guidance changed?

No. The FDA classification does not change the current recommendations. Continue using your ventilator as prescribed while Respire coordinates inspections and any required corrective actions.

What's affected

Certain Astral 100 and Astral 150 ventilators made before October 2024

Who issued this

ResMed (the manufacturer) — Field Safety Notice Astral-2026-FSN-01

Do I need to do anything right now?

No. Keep using your ventilator as prescribed

Will I be contacted?

Yes, if your specific device needs inspection or service

How common is the issue?

ResMed reports it affects about 0.1% of devices

What's Happening

ResMed has identified that an internal component in some Astral 100 and Astral 150 ventilators can wear down over time and, in rare cases, cause the device to unexpectedly stop delivering therapy.

On July 28, 2026, the FDA classified this manufacturer action as a Class I Device Recall while continuing to advise patients not to discontinue therapy unless instructed by their treating clinician.

Respire is working directly with ResMed to check every affected device, contact impacted patients, and coordinate any needed repairs.

What This Means for You

Keep using your ventilator as prescribed. Don't stop therapy or return your equipment on your own — only your physician or Respire should direct a change like that.

While we complete our review, please make sure:

- Your backup ventilator or manual resuscitator is on hand and ready to use
- Caregivers know how to respond to a ventilator alarm
- You know how to reach Respire if something seems wrong

What Respire is Doing

- Checking every Astral ventilator in our patient population against the manufacturer's criteria
- Prioritizing patients based on clinical need, in coordination with treating physicians
- Working with ResMed on inspections and repair parts
- Reaching out directly to any patient whose device needs follow-up
- Updating patients, providers, and referral partners as additional guidance becomes available. *[NEW]*
- Continuing to monitor communications from both ResMed and the FDA and implementing any additional required actions.

If you don't hear from us, no action is needed on your end right now — we're continuing to monitor the situation and will follow up if that changes.

Frequently Asked Questions

Why did this notice change?

When this notice was originally published, ResMed had issued a Manufacturer Field Safety Notice. On July 28, 2026, the FDA formally classified that action as a Class I Device Recall. Although the regulatory classification changed, the recommendations for patients remain the same. Continue using your ventilator unless directed otherwise by your physician or Respire.

What does a Class I Recall mean?

A Class I Recall is the FDA's highest recall classification, used when there is a reasonable probability that a device issue could cause serious health consequences if not properly managed. In this case, the FDA continues to recommend that patients do not stop using their ventilator unless instructed by their treating clinician, because abruptly stopping ventilator therapy may present a greater immediate risk than continuing to use the device while Respire coordinates the manufacturer's corrective actions.

Should I stop using my ventilator?

No. Continue your prescribed therapy unless your physician or Respire tells you otherwise.

Is my ventilator safe to use?

ResMed reports this issue is uncommon, occurring in about 0.1% of devices. As always, keep backup equipment ready in case it's ever needed.

How will I know if my ventilator is affected?

Respire is checking device serial numbers against the manufacturer's list. You don't need to check this yourself — we'll contact you if your device needs attention.

What if my ventilator alarms or stops working?

Follow your emergency respiratory plan, switch to backup equipment if needed, and call Respire right away. If you're having trouble breathing, call 911 immediately.

I'm a physician or referral partner — where can I get more details?

Contact our clinical team below for the full manufacturer notice, the patient prioritization framework, and guidance on managing affected patients.

Contact Us

Phone: (888) 800-9445

Email: notices@respirehomecare.com

Medical Emergency? Call 911.