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Philips Respironics Medical Device Recall Information for durable medical equipment providers (DMEs), distributors and home health partners - Philips Trilogy 100/200 Devices

Support, at every step of the way

Understand how we're handling the recall and know what to expect

We are beginning to rework the affected Trilogy 100/200 devices at US Philips Respironics Service Centers and designated sites.

While we work to remediate devices as quickly as possible, we want you to feel informed about each step of the remediation process.

Based on the normal cadence of patient visits and Philips Respironics' capacity and lead-times, we project that the full remediation process for Trilogy 100/200 will take approximately 12-14 months to complete. From the time that you ship a given device, to the time you have it returned, is estimated to take four weeks, barring any additional required service.

As the situation is constantly evolving, we will continue to make sure that you have the most up-to-date information. For further information, and to read more about the voluntary recall notification, visit philips.com/src-update.

Visit our information page

1. Registering Affected Trilogy Devices

A Philips Respironics representative will be contacting customers with registered Trilogy 100/200 devices to:

a) Review and opt to sign a Recalled Device Services Agreement for Trilogy contract for payment for return of devices

b) Review registrations and clarify where the remediated device should be shipped upon repair via the Trilogy Shipping and Repair Information Form

c) Review options should further service be required for the returned Trilogy device

2. Returning An Affected Device

To help maintain continuity of patient therapy and remediate these devices as efficiently as possible, we need your help to exchange Trilogy devices with Philips Respironics each month in order to reach 100% of patients over the next year.

Assuming approximately 10% of Trilogy devices are returned each month and no additional vent service is required, we estimate that the remediation timeframe for devices will be approximately 4 weeks per device including ship time to and from Philips.

When returning the device, Philips will provide information to initiate the return.

To return a device you will need to:

1. Complete Trilogy Shipping and Repair Information Form to include devices and serial numbers prepared for return, packaging needed, etc. Philips will then provide the RA and return call tags.
2. You will need to remove the following items from the affected device:
   - SD card
   - Power cord
   - Accompanying accessories
3. Please package and return the device only. Specific packaging of individual and palletized Trilogy is avaliable via your Philips Account Manager.

3. The Remediation Process

Philips Respironics will complete remediation and return the Trilogy device to you without an SD Card.

If a Trilogy device is determined to require service outside of the foam replacement, you will be contacted with a quote and service timeframe or action performed based on your pre-selected option.

If service is declined, the device will be returned to you with the affected foam replaced, and a label that further service is required.

If you have signed Recalled Device Services Agreement for Trilogy with Philips Respironics for the Trilogy return, Philips Respironics will reimburse you upon completion of the rework and the return of the device to the DME, per signed agreement terms.

What is the remanufacturing process?
The steps we take to remediate a device include:

- Check in test and clean device
- Download data
- Inspection*
- Replace foam
- Replace label, no MR symbol and REV 15
- Check out test - at check out this is where we will identify if there is repair outside of the foam required.
- Complete documentation

*IF particulate is found:

- Entire air path will be replaced and device will be returned to you

How do I know the new foam is safe?

While recalled devices contained a polyester-based polyurethane (PE-PUR) sound abatement foam component, the sound abatement foam in remediated devices is a silicone foam.

Additional information on testing conducted by Philips Respironics on the new silicone foam can be found here.

4. Receiving A Remediated Device

As each Trilogy device is returned, Respiratory Therapists, clinicians, and customers can use this to replace patients' affected devices to ensure steady exchange of ventilators on patients.

How will I know if a device has been remediated?

- Label on bottom will be REV 15 or higher
- Service and PMs are authorized for Trilogy trained service centers to complete on devices REV 15 or higher on the product label. Service and PMs should be in line with version 14 of the Trilogy Service Manual (PN 1002735).

5. Setting Patients Up With A Remediated Device

Once you have received a replacement device, please take the following steps:

- Configure Trilogy settings for your patient according to your institutions' protocol
- Visit patients to replace the affected device with the remediated one
- Inspect and replace any circuits with particulate according to the Trilogy Accessory cleaning and inspection.
- If applicable, update Care Orchestrator patient and hub pairing with the new serial number
- Return affected device which restarts the process

Need further assistance?

Please contact a Philips Respironics Sales Representative or call 800-345-6443 for more assistance.

You can read our FAQs here

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