Frequently Asked Questions
Philips Recall Notice

What does the Philips recall mean? What is being recalled? On June 14th, 2021 the FDA announced that certain models of CPAP, BiPAP and ventilators from Philips Respironics were being recalled. Philips is instructing any patient using an affected CPAP or BiPAP device, to discontinue use of the affected units and talk to your doctor. Philips is instructing patients using an affected life-sustaining ventilator to continue treatment until they are able to discuss treatment options with their physician. You can view the official recall page by Philips Respironics here (CLICK HERE).

The voluntary recall is in response to potential health risks related to these devices' sound abatement foam, which is used to reduce sound and vibration in the affected devices, and may break down into particles and enter the device's air pathway. If this occurs, black debris from the foam or certain chemicals released into the device's air pathway may be inhaled or swallowed by the person using the device.

Are affected devices safe for use? Should affected devices be removed from service?

- The recall notification advises patients and customers to take the following actions:
  - For patients using BiPAP and CPAP devices: Discontinue use of affected units and consult with your physician to determine the benefits of continuing therapy, alternatives and potential risks.
  - For patients using life-sustaining mechanical ventilator devices: **DO NOT** discontinue or alter prescribed therapy, without consulting with your physician to determine appropriate next steps.
- Philips is recommending that customers and patients stop using ozone-related cleaning products (like SoClean), and adhere to their device Instructions for Use for approved cleaning methods.

I use this equipment: how will this impact me? There are still many unanswered questions from Philips Respironics about this recall. Several steps should be taken by the member or caregiver affected by the recall.

- Register your device with Philips at the following link: https://www.philipssrcupdate.expertinquiry.com/ or, if you have questions, call 877-907-7508.
- Contact your physician to decide on a suitable treatment for your condition while following the recommendations listed in the safety communication from Philips.

What can my Durable Medical Equipment (DME) provider do to help me? Your DME provider can help keep you informed of any progress made by Philips. However, they cannot advise you if it is safe to continue to use your device and will not make repairs to your device. At this time there is no information on whether devices will be able to be repaired or replaced.

Important note: Because of the COVID-19 pandemic and the fact that this recall has the potential to affect 3-4 million people worldwide, supplies of ventilators, CPAPs and BiPAPs are extremely limited. DME providers will use a triage system to determine availability of replacement devices to those who need a replacement device prior to the Philips solution. It is important to work with your physician to determine if you need a new device prior to Philips fixing or replacing your device.

What can Virginia Medicaid do to assist? Virginia Medicaid, it's Managed Care Organizations (MCOs), PACE sites and DME providers are working together to help our members through this process. We understand this is a very uncertain and unsettling time and we are all committed to keeping our members informed and working with our DME providers, PACE sites and MCOs.. As quickly as we receive information from Philips on their plans or timelines for repair/replacement of affected devices it will be made available to any and all affected members. You will be contacted by Philips with updates as they become available Your DME provider will also be contacting you via phone, email, or letters with updates as they get them.

- Most of our members receive care through one of our MCOs (Anthem, Aetna, Optima, Magellan, VA Premier or United Health Care) and may have access to a Care Coordinator who can help you register your device if you have problems. Care Coordinators will have updated information as soon as it becomes available. If you do not know who your Care Coordinator may be, please contact the following numbers:
    - Anthem: 1-855-323-4687, press #4, TTY 711
    - Aetna: 1-855-652-8249, press #1 for Care Coordinators
    - Optima: 1-866-546-7924
    - Magellan: 1-800-424-4524
    - VA Premier: 1-877-719-7358
    - United Health Care: 1-877-843-4366
- If you are a regular Medicaid FFS member (not enrolled with one of the managed care organizations above) you can contact your DME provider to assist you if you have problems registering your device.
- If you are enrolled in the PACE program you can contact your PACE site to assist you if you have problem registering your device.
    - AllCare for Seniors: 276-964-7101

- Centra PACE Farmville, Gretna, Lynchburg: 434-200-6300
- InnovAge Blue Ridge, Richmond, Peninsula, Salem: 757-578-0354
- Mountain empire Older Citizens Inc.: 276-523-4208
- Sentara Senior Community Care Norfolk or Portsmouth: 757-252-3665

General questions can also be sent to dme@dmas.virginia.gov and we will be responding as quickly as possible. We will also post updates on our website.

CPAP and BiLevel PAP Devices

All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers

Continuous Ventilator, Minimum Ventilatory Support, Facility Use

E30
(Emergency Use Authorization)

Continuous Ventilator, Non-life Supporting

DreamStation
ASV

DreamStation
ST, AVAPS

SystemOne
ASV4

C Series
ASV, S/T, AVAPS

OmniLab Advanced Plus
In-Lab Titration Device

Non-continuous Ventilator

SystemOne
(Q series)

DreamStation
CPAP, Auto CPAP, BiPAP

DreamStation GO
CPAP, APAP

Dorma 400, 500
CPAP

REMStar SE Auto
CPAP

Mechanical Ventilators

All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers

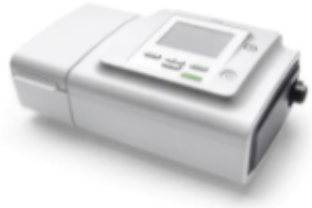
Continuous Ventilator

Trilogy 100
Ventilator

Trilogy 200
Ventilator

Garbin Plus, Aeris, LifeVent
Ventilator

Continuous Ventilator, Minimum Ventilatory Support, Facility Use



A-Series BiPAP Hybrid A30
(not marketed in US)

A-Series BiPAP V30 Auto
Ventilator