



Australian Government

Department of Health
Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION*

LEVEL: Consumer

CLASS: Class I

REFERENCE: RC-2021-RN-01373-1

DATE AGREED: 1/07/2021

PRODUCT: Philips Respironics CPAP and Bi-Level PAP Devices

E30 (Emergency Use Authorization)
DreamStation ASV
DreamStation ST, AVAPS
SystemOne ASV4
C-Series ASV
C-Series S/T and AVAPS
OmniLab Advanced+
SystemOne (Q-Series)
DreamStation
DreamStation Go

Multiple Product Codes (see below)

All devices manufactured before 26 April 2021

ARTG's: 133792, 209934, 235674, 257012, 257013, 295664, 285420,
327227, 335508

SPONSOR: Philips Electronics Australia Ltd

PHONE: 1800 009 579 – Philips Recall Support Hotline

REASON: Two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators:

1) PE-PUR foam may degrade into particles which may enter the devices' air pathway and be ingested or inhaled by the user. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone; and

2) the PE-PUR foam may off-gas certain chemicals. Product testing has demonstrated that off-gassing mostly occurs during initial operation and may possibly continue throughout the device's useful life.

The potential risks associated with these issues include: headache / dizziness, irritation (eyes, nose, respiratory tract, skin), inflammatory response, asthma, adverse effects to other organs (e.g. kidneys and liver), hypersensitivity, nausea / vomiting, toxic and carcinogenic effects.

To date, there is no definitive evidence of long-term harm and there have been no reported deaths as a result of these issues.

**PROPOSED
CUSTOMER
ACTIONS:**

Patients:

Stopping treatment suddenly could have an immediate and detrimental effect on patient health. Please contact and make an appointment with your physician or care provider before making any changes to your prescribed therapy. Together with a physician, determine if the benefit of continuing therapy with the device outweighs the risks identified and discuss alternative long term therapy options.

Register the device on the recall website: www.philips.com/src-update

Physicians:

Please review the information outlined above. For patients who request review of their therapy and/or patients on affected devices owned by physicians and/or their organisation undertake a patient-specific risk assessment to determine whether the benefits of continuing therapy outweighs the risks identified.

Retailers/Distributors:

Cease all supply and distribution of impacted devices.

Where possible, Philips will replace the affected foam component in impacted devices.

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: Various retailers, distributors and consumers nationally

Product export status: New Zealand

This issue was first identified by the Sponsor

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

Product Code	Product Description
1029759	BiPAP Synchrony, International.Core Pkg
1038916	BiPAP Auto SV w/ Smartcard Int.
1042900	BiPAP autoSV Advanced w/SmartCard, INTL
1043342	OmniLab Advanced, Core, (International)
1068942	BiPAP Auto SV w/ Smartcard Int.
1111126	OmniLab Advanced plus w/Humidifier INTL
1111127	OmniLab Advanced plus w/HT Humidifier INTL
AU1029756	BiPAP Synchrony Australia
AU1060486	BiPAP AVAPS, C SERIES, AUSTRALIA
AU1061419	BiPAP AVAPS, C Series Core Package with Humidifier
AU1061421	PR BiPAP ST, C SERIES, AUSTRALIA
AU1061423	BiPAP ST, C SERIES, Core Package with Humidifier
AU1161S	BiPAP AVAPS 60 series platform
AU1161X	BiPAP AVAPS, 60/C Series, AU, 30cmH2O
AU251HS	Philips/Respironics New Gen RemStar Plus, w/Humid, w/SD Card, Aust
AU251S	Philips/Respironics New Gen RemStar Plus w/SD Card, Aust
AU451HS	Philips/Respironics New Gen RemStar Pro w/Humid w/SD Card, Aust
AU451S	Philips/Respironics New Gen RemStar Pro w/SD Card Aust
AU461HS	REMstar Pro System One 60 Series with Heated Humidifier
AU461S	REMstar Pro System One 60 Series
AU461TS	REMstar Pro System One 60 Series with Heated Tube Humidifier
AU551HS	Philips/Respironics New Gen RemStar Auto A-Flex w/Humid w/SD Card Aust
AU551S	Philips/Respironics New Gen RemStar Auto A-Flex w/SD Card Aust
AU561HS	REMstar Auto System One 60 Series with Heated Humidifier
AU561S	REMstar Auto System One 60 Series
AU561TS	REMstar Auto System One 60 Series with Heated Tube Humidifier
AU751HS	Bipap Auto w/Humid w/SD Card Aust, OBS..Discontd..
AU751S	Philips/Respironics New Gen Bipap Auto w/SD Card Aust
AU761HS	BiPAP Auto System One 60 Series with Heated Humidifier
AU761S	BiPAP Auto System One 60 Series
AU761TS	BiPAP Auto System One 60 Series with Heated Tube Humidifier
AU951HS	BiPAP Auto SV Advanced System One with Humidifier
AU951S	BiPAP Auto SV Advanced System One (OBS. Repl AU961S)
AU961HS	BiPAP autoSV Syst One 60 Srs with Heated Humidifier
AU961S	BiPAP autoSV System One 60 Series
AU961TS	BiPAP autoSV Sys One 60 Srs with HT Humid Obsolete (Repl by DS)
AUG400H15	DreamStation Go CPAP with Humidifier
AUG400S15	DreamStation Go CPAP with Bluetooth®, Australia
AUG500H15	DreamStation Go Auto CPAP with Humidifier, AU
AUG500S15	DreamStation Go Auto CPAP with Bluetooth®, Australia
AUX1131T15	DreamStation BiPAP AVAPS Hum HT

AUX1131T15C	DreamStation BiPAP AVAPS Cellular with Humidifier & Heated Tube
AUX400S15	DreamStation CPAP Pro
AUX400T15	DreamStation CPAP Pro Hum HT
AUX400T15C	DreamStation CPAP Pro Humid HT Cellular
AUX500S15	DreamStation Auto CPAP
AUX500T15	DreamStation Auto CPAP Hum HT
AUX500T15C	DreamStation Auto CPAP Hum HT Cellular
AUX700T15	DreamStation Auto BiPAP Hum HT
AUX700T15C	DreamStation Auto BiPAP Hum HT Cellular
AUX900T15	DreamStation AutoSV Hum HT
AUX900T15C	DreamStation AutoSV Hum HT Cellular
GBX400S15	GB DreamStation CPAP Pro
GBX500S15	GB DreamStation Auto CPAP
INX9999H19	BiPAP E30 Ventilator w/Humidifier, IN