

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

Continuous Ventilator, Non-life Supporting



A-Series BiPAP A40
(not marketed in US)



A-Series BiPAP A30
(not marketed in US)