

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Philips Respironics, Inc. Recalls BiPAP Ventilators

Recall Date	Product Description	Recalling Firm	Recall Reason
07/09/2025	BiPAP A40 Ventilator. Used to provide noninvasive ventilation support for the purpose of treating adult and pediatric patients. BiPAP A40 Pro - sold OUS	Philips Respironics, Inc.	This device does not indicate for use in patients with respiratory failure.
07/09/2025	BiPAP V30 Auto Ventilator. Intended to provide non-invasive ventilatory support for pediatric and adult patients weighing over 10 kg.	Philips Respironics, Inc.	This device does not indicate for use in patients with respiratory failure.
07/09/2025	BiPAP A30 Ventilators. Intended to provide noninvasive ventilation support in adult and pediatric patients weighing more than 10 kg. BiPAP Hybrid A30 Ventilator. Used to provide noninvasive ventilation support for the purpose of treating adult and pediatric patients.	Philips Respironics, Inc.	This device does not indicate for use in patients with respiratory failure.

Recall Class	Product Identification	Distribution	Affected Dates
I	Please refer to code information	Worldwide distribution: US (Nationwide) including Guam and Puerto Rico; OUS (Foreign) to countries of: United Arab Emirates (AE), Argentina (AR), Austria (AT), Australia (AU), Bosnia and Herzegovina (BA), Belgium (BE), Brazil (BR), Canada (CA), Chile (CL), China (CN),	May 2025 and prior.

		Colombia (CO), Costa Rica (CR), Germany (DE), Denmark (DK), Spain (ES), France (FR), United Kingdom (GB), Hong Kong (HK), Hungary (HU), Indonesia (ID), Ireland (IE), India (IN), Italy (IT), Jordan (JO), Japan (JP), Korea, Republic of (KR), Lebanon (LB), Morocco (MA), Monaco (MC), Montenegro (ME), Mexico (MX), Malaysia (MY), Netherlands (NL), Norway (NO), Nepal (NP), Peru (PE), Philippines (PH), Pakistan (PK), Poland (PL), Portugal (PT), Qatar (QA), Romania (RO), Serbia (RS), Russian Federation (RU), Saudia Arabia (SA), Singapore (SG), Slovakia (SK), Thailand (TH), Turkey (TR), Taiwan (TW), Viet Nam (VN), South Africa (ZA).	
I	Please refer to code information	Worldwide distribution: US (Nationwide)including Guam and Puerto Rico; OUS (Foreign) to countries of: United Arab Emirates (AE), Argentina (AR), Austria (AT), Australia (AU), Bosnia and Herzegovina (BA), Belgium (BE), Brazil (BR), Canada (CA), Chile (CL), China (CN), Colombia (CO), Costa Rica (CR), Germany (DE), Denmark (DK), Spain (ES), France (FR), United Kingdom (GB), Hong Kong (HK), Hungary (HU), Indonesia (ID), Ireland (IE), India (IN), Italy (IT), Jordan (JO), Japan (JP), Korea, Republic of (KR), Lebanon (LB), Morocco (MA), Monaco (MC), Montenegro (ME), Mexico (MX),	May 2025 and prior.

		Malaysia (MY), Netherlands (NL), Norway (NO), Nepal (NP), Peru (PE), Philippines (PH), Pakistan (PK), Poland (PL), Portugal (PT), Qatar (QA), Romania (RO), Serbia (RS), Russian Federation (RU), Saudia Arabia (SA), Singapore (SG), Slovakia (SK), Thailand (TH), Turkey (TR), Taiwan (TW), Viet Nam (VN), South Africa (ZA).	
I	Please refer to code information	Worldwide distribution: US (Nationwide)including Guam and Puerto Rico; OUS (Foreign) to countries of: United Arab Emirates (AE), Argentina (AR), Austria (AT), Australia (AU), Bosnia and Herzegovina (BA), Belgium (BE), Brazil (BR), Canada (CA), Chile (CL), China (CN), Colombia (CO), Costa Rica (CR), Germany (DE), Denmark (DK), Spain (ES), France (FR), United Kingdom (GB), Hong Kong (HK), Hungary (HU), Indonesia (ID), Ireland (IE), India (IN), Italy (IT), Jordan (JO), Japan (JP), Korea, Republic of (KR), Lebanon (LB), Morocco (MA), Monaco (MC), Montenegro (ME), Mexico (MX), Malaysia (MY), Netherlands (NL), Norway (NO), Nepal (NP), Peru (PE), Philippines (PH), Pakistan (PK), Poland (PL), Portugal (PT), Qatar (QA), Romania (RO), Serbia (RS), Russian Federation (RU), Saudia Arabia (SA), Singapore (SG), Slovakia (SK), Thailand (TH), Turkey (TR), Taiwan (TW), Viet Nam (VN), South Africa (ZA).	May 2025 and prior.

For additional information, please visit the [FDA Website 1](#).

For additional information, please visit the [FDA Website 2](#).

For additional information, please visit the [FDA Website 3](#).