



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Philips Respironics Recalls Certain BiPAP Machines for Plastic Issue that May Expose Patients to Volatile Organic Compounds

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| 9/14/2022 | Philips BiPAP A30, Rx Only Provides noninvasive ventilation support for patients with obstructive sleep apnea syndrome (OSA) and respiratory insufficiency. | Philips Respironics, Inc. Murrysville, Pennsylvania | Motor assemblies manufactured with nonconforming plastic that contributes to off-gassing of VOCs. |
| 9/14/2022 | Philips BiPAP A40, Rx Only Provides noninvasive ventilation support. | Philips Respironics, Inc. Murrysville, Pennsylvania | Off-gassing of VOCs. |
| 9/14/2022 | Philips BiPAP V30 Auto, Rx Only Provides noninvasive ventilation support. | Philips Respironics, Inc. Murrysville, Pennsylvania | Off-gassing of VOCs. |
| 9/14/2022 | Philips OmniLab Advanced+, Rx Only Provides noninvasive ventilation support. | Philips Respironics, Inc. Murrysville, Pennsylvania | Off-gassing of VOCs. |
| 9/14/2022 | Philips OmniLab Advanced+ Intl (Flow Gen), Rx Only Provides noninvasive ventilation support | Philips Respironics, Inc. Murrysville, Pennsylvania | Off-gassing of VOCs. |
| 9/14/2022 | Philips BiPAP V30 Auto, Rx Only Provides noninvasive ventilation support | Philips Respironics, Inc. Murrysville, Pennsylvania | Off-gassing of VOCs. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|-----------------------------|
| I | <p>Philips BiPAP A30, Rx Only UDI-DI: 606959042667, 606959042681, 606959042698, 606959042728, 606959067585, 606959067530 Model No.: 1109581-1116156, CN1111143, CN1111169, R1111124, R1111177 Serial No.: N287725308B25- N2909533975A0</p> | 146 Units Nationwide including California | September 2022 and prior |
| I | <p>Philips BiPAP A40, Rx Only UDI-DI: 606959042742, 606959042766, 606959042797, 606959067677, 606959067714, 606959042834, 606959067752, 606959067721, 606959068025; Model No.: 1109596-1116156, CN1111169, R1111177 Serial No.: V287427181CF7- V305001089095</p> | 1091 Units Nationwide including California | September 2022 and prior |
| I | <p>Philips BiPAP V30 Auto, Rx Only UDI-DI: 606959039377, 606959067936 Model No.: 1111155, 1111178 Serial No. N2908453138CE- N306372146A8B</p> | 295 Units Nationwide including California | September 2022 and prior |
| I | <p>Philips OmniLab Advanced+, Rx Only UDI-DI: 606959028791 Model No.: 1109581 Serial No. L28664716B714- L304097046ACC</p> | 85 Units Nationwide including California | September 2022 and prior |
| I | <p>Philips OmniLab Advanced+ Intl (Flow Gen), Rx Only UDI-DI: 606959029415, 606959028791 Model No.: 1109582, 1109585 Serial No. L28664715858F- L28664713E0B9</p> | 34 Units Nationwide including California | September 2022 and prior |
| | | | |

| | | | |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-----------------------------|
| I | Philips BiPAP V30 Auto, Rx Only UDI-DI: 606959067837, 606959068001 Model No.: 1111124, R111124 Serial No. L29084645477C- L30398849CD80 | 8 Units Nationwide including California | September 2022 and prior |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-----------------------------|

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

CDPH Food and Drug Branch
MS 7602 • P.O. Box 997435 • Sacramento, CA 95899-7435
(916) 650-6500 • (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov

