California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Philips Respironics, Inc. DreamStation Auto CPAP. Non-Continuous Ventilator.

Recall Date	Product Description	Recalling Firm	Recall Reason
08/08/25	DreamStation Auto CPAP. Non-Continuous Ventilator.	Philips Respironics, Inc.	Devices may possess a programming error resulting in an incorrect device configuration.
08/08/25	DreamStation Auto BiPAP. Non-Continuous Ventilator.	Philips Respironics, Inc.	Devices may possess a programming error resulting in an incorrect device configuration.
08/08/25	DreamStation Auto. Non-Continuous Ventilator.	Philips Respironics, Inc.	Devices may possess a programming error resulting in an incorrect device configuration.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model No. UDSX500S11F; UDI: 606959429765; Serial No. J204432084D03, J206957368810, J207023218478, J21450857096A, J219786492F58, J222909239F3E, J22718022B9D6, J22924665CF8A, J230303131D07, J23148826984B, J23307132CC16, J2379520271A4, J23933071851F, J23963189F617, J242941498857, J243763392C02, J24551698A015, J247575014664, J24858283A8C3, J24994323EB40, J2529261301FF, J2543728920D9, J254401628C83, J25467463E51E, J25493556DA17, J254990254097,	57 units worldwide	June 2025 and prior.

	J255312624BAB, J256278994969, J25782569130A, J257828377BB3, J260977942F33, J2617246993BE, J26312750F8BD, J263183345586, J26751119CCB4, J27018735B4C6, J270987383503, J271152226FB8, J27220570C1F1, J27464550B547, J275917117696, J277824942640, J282846981F7D, J28582229DE76, J2901054169AB, J2902459395E1, J2921836070C5, J29746839268B, J2982204155F4, J299187060F67, J29925204838B, J299567590A7A, J2997189741CA, J30005981C03D, J301116505688, J3067824786A4, J30982199BB1D.		
I	Model No. UDSX700S11F; UDI: 606959429772; Serial No. J18909076CC90, J2091514323C5, J2164570462CB, J23391208BCBE, J26552747A030, J2909781691D2, J294724447698, J301490021E77.	8 units worldwide	June 2025 and prior.
I	Model No. UFRX500S14; UDI: 606959069824; Serial No. J19093383C0FD, J195817171415, J195967969739, J1999161223D4, J208714453211, J21638786344A, J216718740A24, J22792026797C, J23016752559D, J23025544A4CA, J235207601E36, J236974697023, J24378890CB57, J24404277EDBB, J251606314EAA, J255220797791, J25755126C4A9, J262274772766, J26263484C9C9, J26377226BCF1, J26525214B253, J2661985603DE, J26673715FBD4, J27099876ED61, J272180530173, J27467764497E, J305016887150, J30708300FB50.	28 units worldwide	June 2025 and prior.

For additional information, please visit the FDA Website for Model No. UDSX500S11F, Model No. UDSX700S11F, and Model No. UFRX500S14.

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