



California Device Recall Information Sheet

Smiths Medical Asd Inc. Recalls Pneupac Parapac Ventilator Kit For Malfunction In Gas Flow

Recall Date	Product Description	Recalling Firm	Recall Reason
3/27/2024	Smiths Medical Pneupac Parapac Plus 310 Ventilator Kit With PEEP and CPAP, REF P310NUS	SMITHS MEDICAL ASD INC. Minneapolis, Minnesota	When a paraPAC plus ventilator is switched to the operating mode of VENTILATE, the ventilator may intermittently provide continuous positive gas flow instead of the intended cycling like a human breath. This non-cycling and continuous positive gas flow when in the cycling mode, is a malfunction, not allowing the ventilator to properly function as designed.
3/27/2024	Smiths Medical Pneupac Parapac Plus 300 Ventilator Kit Without PEEP and CPAP, REF P300NUS	SMITHS MEDICAL ASD INC. Minneapolis, Minnesota	When a paraPAC plus ventilator is switched to the operating mode of VENTILATE, the ventilator may intermittently provide continuous positive gas flow instead of the intended cycling like a human breath. This non-cycling and continuous positive gas flow when in the cycling mode, is a malfunction, not

			allowing the ventilator to properly function as designed.
--	--	--	---

Recall Class	Product Identification	Distribution	Affected Dates
I	Smiths Medical Pneupac Parapac Plus 310 Ventilator Kit Serial Numbers: 24224, 24225, 130135, 220977, 1002250 to 1912189, 2001004 to 2304066, 2907203, 10902166, 14073331, 17012469, %, 01108170, 02/06/387, 0203636, 0306318, 0406217, 0407200, 0603279, 0603611, 0604298, 0702091, 2106024, 2106025, 2106026, 2106027, 2106028, 2106029, 2N69, 2v13, 530A1167, SD1054, 0702349 See attached link for complete serial numbers	10140 Units Worldwide	February, 2024 and prior
I	Smiths Medical Pneupac Parapac Plus 300 Ventilator Kit Serial Numbers: 70085 to 70299, 1007188, 1206210 to 1912309, 2002051 to 2303037, 3540877, 1605167A, 2106048 to 2106059, G;10328, GC00001 to GC00250, GL10006 to GL19479, RF20267 to RF70298 See attached link for complete serial numbers	2902 Units Worldwide	February, 2024 and prior

For additional information, please visit the FDA website [Plus 310](#), [Plus 300](#)

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

