California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

PyrAmes Inc Boppli: Bedside Device Kit and Sensor Band

Recall Date	Product Description	Recalling Firm	Recall Reason
04/02/2025	Boppli: Bedside Device Kit REF: 54-0002 Sensor Band REF: 51-0007	PyrAmes Inc	Single-use battery-powered blood pressure monitor, for use on neonates and infants, due to vibratory noise, may not adequately detect changes in blood pressure per specification. Containment actions: 1) Ventilator lines not to touch the isolette (e.g. mattress, side rails, pillow) or patient, 2) Move affected monitor to patient's foot.

Recall Class	Product Identification	Distribution	Affected Dates
II	Software version: 2.2.3 Part: 54-0002 UDI-DI: 10860007282925 Lot: 24020902 - 23103002	1 unit in California	February and prior

	Part: 51-0007 UDI-DI: 10860007282901 Lot: 24011702, 24111301	10 units in California	

For additional information, please visit the FDA Website.