



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Draeger Recalls Software for Infinity CentralStation

Recall Date	Product Description	Recalling Firm	Recall Reason
3/04/2022	Draeger Infinity CentralStation Software versions VG2.1.2 and VG2.1.2 SU12. For patient monitoring with Infinity M300 wireless telemetry devices.	Draeger Medical Systems, Inc. Andover, Massachusetts	Software issue resulting in temporary loss of central monitoring functionality.

Recall Class	Product Identification	Distribution	Affected Dates
II	Unique Device Identifier (UDI): (01)04049098001878(11)200626 (21)10Q84F-01013(93)MS2 6800-40 to (01)04049098001878(11)160122 (21)12738M00293(93)MS26800- 20 Additional US Serial Numbers (w/o UDI): 12946M00316 to 11097M00451	11 Units in California	March 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

