



State of California—Health and Human Services Agency  
**California Department of Public Health**



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Hamilton Medical Inc. Recalls HAMILTON-C1, C2, C3, T1 Ventilators for Software Issues that May Cause Ventilators to Stop Without Notice**

Recall Date	Product Description	Recalling Firm	Recall Reason
8/30/2023	<b>Hamilton-C1</b> SW version <2.2.10 and neonatal option installed	<b>HAMILTON MEDICAL, INC.</b> Reno, Nevada	Due to a software anomaly after approximately 91 days of cumulative use, the ventilator may stop and enter the ambient mode without prior notice.
8/30/2023	<b>Hamilton-C2</b> SW version <2.2.5 and neonatal option installed	<b>HAMILTON MEDICAL, INC.</b> Reno, Nevada	software anomaly
8/30/2023	<b>Hamilton-C3</b> SW version <2.0.9 and neonatal option installed	<b>HAMILTON MEDICAL, INC.</b> Reno, Nevada	software anomaly
8/30/2023	<b>Hamilton-T1</b> SW version <2.2.10 and neonatal option installed	<b>HAMILTON MEDICAL, INC.</b> Reno, Nevada	software anomaly

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Hamilton-C1</b> REF: 161001 1610010 UDI-DI Code: 07630002800747 Serial Numbers: 6006-39140	673 Units Nationwide including California	June 2023 and Prior

I	<b>Hamilton-C2</b> REF: 160001 UDI-DI Code: 07630002800372 Serial Numbers: 1549-12581	250 Units Nationwide including California	June 2023 and Prior
I	<b>Hamilton-C3</b> REF 160005 UDI-DI Code: 07630002801881 Serial Numbers: 1001-15503	483 Units Nationwide including California	June 2023 and Prior
I	<b>Hamilton-T1</b> REF: 161006 1610060 161009 1610090 UDI-DI Code: 07630002801850 07630002813532 07630002806091 07630002813549 Serial Numbers: 3057-512586	2293 Units Nationwide Including California	June 2023 and Prior

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