California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Hamilton Medical AG Recalls Breathing circuit set, coaxial, 1.80 m, with flow sensor and expiratory valve set

Recall Date	Product Description	Recalling Firm	Recall Reason
7/30/25	Breathing circuit set, coaxial, 1.80 m, with flow sensor and expiratory valve set, REF: 260128, used with HAMILTON-C1, HAMILTON-T1 and HAMILTON-MR1 ventilators.	Hamilton Medical AG	Ventilator coaxial breathing circuit may have a crack in blue tubing, which is used to deliver fresh gas to the patient. The crack will compromise inspiratory and expiratory flows, leading to partial or complete rebreathing of exhaled gases, which could lead to acute hypercapnia, respiratory acidosis, and if unrecognized organ dysfunction.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI: 07630002802963, Lots: 199675, 199676	US Nationwide distribution in the states of NH, NY, CT, PA, IL, ME, CO, NC, NJ, UT, TX, GA, SC, VA, IN, SD, MO, OR, TN, MA, AZ, NM.	June 2025 and prior.

For additional information, please visit the FDAWebsite