Class 1 Recall Ventilator

See Related Information[21]

Date Posted	April 14, 2014
Recall Status[1]	Terminated on April 14, 2014
Recall Number	Z-2250-2012
Recall Event ID	62856[22]
Premarket Notification 510(K) Numbers	K090888[23] K111146[24]
Product Classification	Ventilator, Continuous, Facility Use[25] - **Product Code** CBK[26]
Product	Newport HT70 and HT70 Plus Ventilators, Model Number: HT70 and HT70 Plus. Product Usage: The HT70 ventilator system is intended to provide continuous or intermittent positive pressure mechanical ventilatory support for the care of individuals who require mechanical ventilation through invasive or non-invasive interfaces. Specifically, the HT70 family of ventilators is applicable for infant, pediatric and adult patients greater than or equal to 5 kg (11 lbs.). The HT70 is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. The HT70 is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.
Code Information	Model Number: HT70 and HT70 Plus. Serial numbers: N12HT700514226 to N12HT700514231, N12HT700514233 to N12HT700514236, N12HT700514238 to N12HT700614280, N12HT700614282 to N12HT700614299, N12HT700614301 to N12HT700614309, N12HT720410266 to N12HT720410268, N12HT720410271, N12HT720410273, N12HT720410282, N12HT720410283, N12HT720410286, N12HT720410288, N12HT720410289, N12HT720410290, N12HT720410294 to N12HT720510300, N12HT720510302, N12HT720510322 to N12HT720510330, N12HT720510332 to N12HT720510344,
Recalling Firm/ Manufacturer	Newport Medical Instruments Inc 1620 Sunflower Ave Costa Mesa, California 92626-1513
Manufacturer Reason for Recall	May emit a continuous high priority alarm and the ventilator may stop ventilating, due to a component failure on the control board.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	Newport Medical sent an Urgent Field Correction Notice letter dated August 3, 2012 to all affected customers, via DHL and FedEx courier services. The letter identified the affected product, reason for recall and actions to be taken. Customers were instructed to immediately stop using the affected ventilator and retrieve the replacement kit provided free of charge. In addition, the letter states that if the product was further distributed, to contact their customers and notify them of the recall. Customers were asked to complete and return the enclosed Replacement form as replacements are completed. For questions contact Newport Medical Technical Support Department at 800-451-3111, extension 282, for U.S. customers; 714-427-5811, extension 500, for international customers.".
Quantity in Commerce	72