California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Covidien Recalls IVENIX INFUSION SYSTEM LVP Blood Products Administration Set

Recall Date	Product Description	Recalling Firm	Recall Reason
6/9/25	Newport HT70 Ventilator, REF: HT70M-JP-NA, HT70M-CN-NA, HT70M-ES-EU, HT70M-PT-BR, HT70M-SY-EU, HT70M-WW-EU, HT70M-WW-NA, HT70-SY-EU. Newport HT70Plus Ventilator, REF: HT70PM-ES-EU, HT70PM-ES-NA, HT70PM-JP-NA, HT70PM-PT-BR, HT70PM-SY-AS, DLHT70PM-WW-NA, HT70PM-SY-NA, HT70PM-SY-UK, HT70PM-WW-EU, HT70PM-WW-UK, HT70PM-SY-EU, HT70PM-WWNA. HT70-2 CONTROL BOARD ROHS X1, REF: GR105796. HT70P CONTROL BOARD ROHS X1, REF: GR105795. HT70 Conversion Kit, REF: GRFSKHT70M-2.	Covidien	Ventilator Printed Circuit Board Assembly may have two separate capacitors that may fail, which may result in the ventilator either shutting down during use, thus necessitating use of an alternate form of ventilation, or the shutdown alert alarm fails to alarm effectively during shut down, which may result in respiratory failure, hypoventilation, low oxygen saturation, hypoxia, treatment delay.

Recall Class	Product Identification	Distribution	Affected Dates
I	REF/UDI-DI/Serial Numbers	4842 Units Globally	May 2025 and prior.

For additional information, please visit the FDA Website.