

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Datex-Ohmeda, Inc. Recalls Aespire 100 for Potential Issues if Breathing Circuit is Mistakenly Connected to Auxillary Common Gas Outlet

Recall Date	Product Description	Recalling Firm	Recall Reason
10/18/2024	Aespire 100. This anesthesia gas machine is intended to provide general inhalation anesthesia and ventilatory support to patients and are to be used only by medical professionals trained and qualified in the administration of general anesthesia.	Datex-Ohmeda, Inc.	Potential issue that may arise if the limb of a patient breathing circuit is mistakenly connected to the Auxiliary Common Gas Outlet (ACGO) port.

Recall Class	Product Identification	Distribution	Affected Dates
I	GTIN: 00840682102261-needs to be contacted 800-437-1171	Product Quantity: N/A: Worldwide distribution - US Nationwide and the countries of Aland Islands, ALBANIA, Algeria, Argentina, Australia, Austria, Azerbaijan, BAHAMAS, Bahrain, Bangladesh, BARBADOS, BELARUS, Belgium, Benin, Bermuda, Bolivia, BONAIRE, Bosnia and Herzegovina, Brazil, Brunei, Bulgaria, Cambodia, Cameroon, Canada, Chile, CHINA, Colombia, Costa Rica, Croatia, Curacao, Cyprus, Czech	October 2024 and prior

		Republic, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, ETHIOPIA, Falkland Islands, Finland, France, French Polynesia, Gabon, Georgia, Germany, Ghana, Gibraltar, Greece, Guadeloupe, Guatemala, Guyana, Honduras, Hong Kong, Hungary, ICELAND, India, Indonesia, Iran, IRAQ, Ireland, Israel, Italy, Jamaica, JAPAN, Jordan, Kazakhstan, KENYA, Korea (Republic Of), Korea, Republic of, Kuwait, Laos, LATVIA, Lebanon, Libya, LITHUANIA, Macedonia, Malaysia, Maldives, Malta, MAURITIUS, Mexico, Moldova, Montenegro, Morocco, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Nigeria, North Macedonia, Norway, Oman, PAKISTAN, Palestine, State of, Panama, Paraguay, Peru, Philippines, Poland, Portugal, PUERTO RICO, Qatar, REUNION, ROMANIA, Russia, San Marino, Saudi Arabia, Senegal, Serbia, SINGAPORE, Slovakia, Slovenia, South Africa, Spain, Sudan, Sweden, Switzerland, Syria,	
--	--	---	--

		Taiwan, Tanzania, THAILAND, Trinidad and Tobago, Tunisia, Turkey, Türkiye, Uganda, UKRAINE, United Arab Emirates, United Kingdom, Uruguay, UZBEKISTAN, Venezuela, Vietnam, Yemen.	
--	--	---	--

For additional information, please visit the [FDA Website](#).