



California Device Recall Information Sheet

Wipro Ge Healthcare Private Ltd. Recalls Incubator And Incubator Hood Models For Issue With Not Latching Properly

Recall Date	Product Description	Recalling Firm	Recall Reason
2/21/2024	<p>Ge Healthcare Neonatal Incubator Models: a) Care Plus, b) Care Plus 1000, c) Care Plus 2000, d) Care Plus 3000, e) Care Plus 4000, Plus 4000</p>	<p>WIPRO GE HEALTHCARE PRIVATE LTD. Bengaluru, India</p>	<p>GE HealthCare has become aware that the bedside panel of Care Plus, Care Plus, Model 1000, 2000, 3000 and 4000 Incubator, Lullaby Incubator, Lullaby TR Incubator, and Lullaby XP Incubator can be upright and look closed but not be latched if the red indicator is visible. The portholes also can look closed when not latched when the portholes are obstructed e.g., hood covers. If a patient impacts the bedside panel or porthole that is not latched, the panel can disengage and fall open, no longer protecting the patient from falling.</p>
2/21/2024	<p>Ge Healthcare Care Plus Hood Door Fru Kit Part Numbers: 6600-0082-850, 6600-0504-800, 6600-0148-800, and 6600-0970-500</p>	<p>WIPRO GE HEALTHCARE PRIVATE LTD. Bengaluru, India</p>	<p>Incubator can be upright and seem closed but not be latched when the red indicator is visible. Obstructed portholes</p>

			can also seem closed but not be properly latched.
2/21/2024	Ge Healthcare Lullaby Incubator Model Hood Door Fru Kit Part Numbers: M1169767, M1160674, M1187512, M1206646, M1166822	WIPRO GE HEALTHCARE PRIVATE LTD. Bengaluru, India	Incubator can be upright and seem closed but not be latched when the red indicator is visible. Obstructed portholes can also seem closed but not be properly latched.
2/21/2024	Ge Healthcare Care Plus Hood Field Replacement Unit (Fru) Kit Part Numbers: 6600-0047-851, 6600-0033-850, 6600-0081-850, 6600-0961-500, 6600-0083-850	WIPRO GE HEALTHCARE PRIVATE LTD. Bengaluru, India	Incubator can be upright and seem closed but not be latched when the red indicator is visible. Obstructed portholes can also seem closed but not be properly latched.
2/21/2024	Ge Healthcare Lullaby Incubator Model Hood Fru Kit Part Numbers: M1169566, M1160659, M1206259, M1206260, M1166836, M1166814	WIPRO GE HEALTHCARE PRIVATE LTD. Bengaluru, India	Incubator can be upright and seem closed but not be latched when the red indicator is visible. Obstructed portholes can also seem closed but not be properly latched.
2/21/2024	Ge Healthcare Neonatal Incubator Models: a) Lullaby Incubator, b) Lullaby Incubator XP, c) Lullaby Incubator TR	WIPRO GE HEALTHCARE PRIVATE LTD. Bengaluru, India	Incubator can be upright and seem closed but not be latched when the red indicator is visible. Obstructed portholes can also seem closed but not be properly latched.

Recall Class	Product Identification	Distribution	Affected Dates
I	<p>Ge Healthcare Neonatal Incubator</p> <p>A) Care Plus, Model Numbers: 6600-0040-900 to 6600-0235-901, CARE-PLUS; b) Care Plus 1000, Model Numbers: 8200, 6600-0264-901 to 6600-0272-901; c) Care Plus 2000, Model Numbers: 2073175-001, 6600-0273-901 to 6600-0282-901, M1050218 to M1242714, QCR043; d) Care Plus 3000, Model Numbers: 6600-0203-902 to 6600-0514-900, 6623-0010-903 to 6623-1511-900, 6626-0010-903 to 6626-1811-900, 6628-0011-900 to 6628-1521-920, M1050214 to M1137750, QCR045; e) Care Plus 4000, Plus 4000, Model Numbers: 6600-0203-901 to 6600-0421-900, 6624-0111-900 to 6624-1521-900, 6627-0010-913, 6627-0011-903, 6627-0020-913, 6627-0021-900, 6627-0021-903 to 6627-1921-900, 6629-0011-900, 6629-0011-905, 6629-0021-900, 6629-0021-903 to 6629-1511-900, M1052135 to M1137897; ALL SERIAL NUMBERS, See attached link for complete serial numbers</p>	21626 Units Worldwide	December, 2023 and prior
I	<p>Ge Healthcare Care Plus Hood Door Fru Kit</p> <p>ALL SERIAL NUMBERS</p>	1810 Units Worldwide	December, 2023 and prior
I	<p>Ge Healthcare Lullaby Incubator Model Hood Door Fru Kit</p> <p>ALL SERIAL NUMBERS</p>	17 Units Worldwide	December, 2023 and prior
I	<p>Ge Healthcare Care Plus Hood Field Replacement Unit (Fru) Kit</p> <p>ALL SERIAL NUMBERS</p>	1465 Units Worldwide	December, 2023 and prior

I	Ge Healthcare Lullaby Incubator Model Hood Fru Kit ALL SERIAL NUMBERS	1 Unit Worldwide	December, 2023 and prior
I	Ge Healthcare Neonatal Incubator A) Lullaby Incubator, Model Numbers: M1151042, QCR031; b) Lullaby Incubator XP, Model Numbers: 8320, M1151135, QCR034; c) Lullaby Incubator TR, Model Numbers: M1151357 ALL SERIAL NUMBERS	1410 Units Worldwide	December, 2023 and prior

For additional information, please visit the FDA website [Incubator Care Plus Models](#), [Care Plus Hood Door](#), [Lullaby Hood Door](#), [Care Plus Hood Replacement](#), [Lullaby Hood FRU](#), [Incubator Lullaby Models](#)

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