



California Medical Device Recall Information



Recall Name

GE Healthcare Recalls Resuscitation Systems Due to Assembly Error Affecting Delivery of Oxygen

Recall Date	Product Description	Recalling Firm	Recall Reason
10/01/13	<ul style="list-style-type: none"> • Giraffe Warmer with Resuscitation System • Panda Warmer with Resuscitation System • Giraffe Stand-Alone Resuscitation System • Resuscitation System Upgrade Kits • Panda Freestanding with Resuscitation System <p><i>These products are also referred as: Giraffe Warmer, Panda Warmer, Panda iRes Warmer, Giraffe and Panda iRes Infant Warmer, Giraffe and Panda Bag and Mask Resuscitation System, Giraffe and Panda Warmer TPiece, and T-Piece Resuscitation System.</i></p>	GE Healthcare Wauwatosa, WI	<p>The oxygen and air wall inlet fittings on the back panel of the systems were reversed during assembly.</p> <p>This may interfere with oxygen delivery resulting in inaccurate oxygen regulation in newborns (neonates) and may lead to low blood oxygen (hypoxia) or high blood oxygen (hyperoxia).</p> <p>This may cause serious health consequences in neonates, preterm and low-birth weight babies.</p>
Recall Class	Product Identification	Distribution	Affected Dates
I	<p>Affected Codes:</p> <ul style="list-style-type: none"> • Giraffe and Panda Warmer TPiece Resuscitation System • Giraffe and Panda Bag and Mask Resuscitation System • Giraffe and Panda iRes Infant Warmer 	CA, nationwide	<p>Manufactured from</p> <p>April 1, 2007 through October 31, 2013</p> <p>Distributed from</p> <p>October 1, 2007 to October 31, 2013</p>

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm387097.htm>