GE Healthcare

URGENT FIELD SAFETY NOTICE

November 2009 GEHC Ref: 32013

To: Nurse Manager, Labor & Delivery
Nurse Manager, NICU
Manager, Respiratory Therapy
Director of Risk Management

RE: **T-Piece Resuscitation Circuits – PEEP valve**

Dear Ladies and Gentlemen,

GE Healthcare has become aware of a manufacturing quality issue associated with the T-piece circuits for the Panda and Giraffe resuscitation system that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

T-piece circuit with PEEP Valve

This issue occurs when the PEEP valve on the T-piece Resuscitation circuit cannot be adjusted low enough to meet specifications and may be unable to deliver the lower range of the desired PEEP levels. This could result in elevated PEEP levels delivered to the patient.

This issue was caused by a problem with the plastic mold that led to an incorrect dimension on the PEEP valve aperture. This problem has been corrected, and new circuits are undergoing a 100% inspection.

The built-in Airway Pressure Manometer of the Resuscitation system is not affected by this issue and will accurately display airway pressure. Clinicians should always use the airway pressure manometer to verify PEEP.

Affected Product Details

This issue is an intermittent failure and may affect T-piece circuits manufactured from October 1, 2007 to September 1, 2009.

M1091335	Kit, Circuit, T-Piece Disposable, 10 pack
M1091316	Kit, Circuit, T-Piece Disposable, W MASK Size 0, 10 pack
M1091365	Kit, Circuit, T-Piece Disposable, W MASK Size 1, 10 pack

Newly manufactured circuits have been inspected and cleared for this issue and are marked with inspection stamps as shown below. **All boxes or circuits without an inspection stamp should be considered affected by this recall.**

Circuits with inspection stamps are not affected:	Item	Notes
	Inspection stamp	Valid stamps will have QA-xx, where xx denotes the inspector ID number and may vary
	Box Label	Each box will be labeled with an inspection stamp

	Individual Circuits	Each individual circuit will be labeled with an inspection stamp

Safety Instructions

Customers are instructed to take the following actions, **immediately**:

1. Inspect existing stock of T-piece circuits to look for the inspection stamp
2. **Separate affected circuits from usable stock and destroy affected circuits**
3. Fill out customer acknowledgment form and fax or forward to GE contact address on the form

Further, it is recommended that healthcare professionals continue to emphasize recommended pre-use checkout practices, and do not use a patient circuit that does not reach the desired PEEP pressure level.

As noted by the American Academy of Pediatrics, using positive end expiratory pressure (PEEP) may present a hazard. Clinicians should always use the airway pressure manometer to verify PEEP.

Each Panda and Giraffe Resuscitation system also comes equipped with a secondary gas outlet that can be used with an alternate manual resuscitator, such as a flow-inflating or self-inflating bag system.

Product Correction

Each customer will be provided replacement circuits at no cost in the quantity of 1 box per warmer at their site (10 circuits per box). Customers are instructed to call the GE Healthcare Customer Center and place an order for their replacement circuits. Replacement circuit orders will be filled on a first-come, first-served basis, as new production quantities are available.

Contact Information

For more information please call your local GE Healthcare Customer & Technical Support.

This information has been communicated to the appropriate National Competent Authorities.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Thank you,

[redacted]
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URGENT FIELD SAFETY NOTICE

RE: RECALL CONFIRMATION

ATTN: GE Healthcare Customer Center

It is important that we confirm our customers have received this recall notice. As such, we request that you **complete this confirmation form and fax it to your local GE Healthcare Customer Center.**

Forms may also be scanned and emailed to your local GE Healthcare Customer Center.

_____ We have received your Recall Notice and no longer have any of the affected T-Piece patient circuits.

_____ We have received your Recall Notice and have alerted appropriate personnel at our facility. We have collected and destroyed all of the affected T-Piece patient circuits.

Name of Hospital:_____

Street Address: _____

City/State/Zip:_____

Telephone Number:_____

Name:_____ Title:_____

Signature:_____ Date:_____

Thank you for your assistance with this matter.