



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref#32060

To: Nurse Manager, Labor & Delivery/ NICU
Manager, Respiratory Therapy/ Director of Risk Management
Manager Biomedical/Clinical Engineering
Chairman Medical Board and relevant Head of Departments

RE: Lullaby Resus plus - positive end expiratory pressure ("PEEP) maintained at the end of the T-piece is lower than what is displayed on the Manometer".

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

GE Healthcare has recently become aware of a potential issue related to inaccurate manometer reading of Lullaby Resus Plus devices when used for T-piece resuscitation. During the neonatal resuscitation process using T-piece on Resus Plus devices, the Manometer shows higher PEEP reading than actual maintained at the end of T-piece. Less than expected PEEP may lead to insufficient ventilation. There have been no injuries reported as a result of this issue.

Safety Instructions



If you routinely use PEEP and want to continue this practice, follow the directions in the attached addendum. This will ensure that this offset value is included in the actual PEEP intended during use. Specifically:

- 1) Add the new addendum to Section 3.2 of the operator manual of your device(s).
- 2) Train users to the new addendum.
- 3) Perform this check every time the device is used on a new neonate until the correction is available.

If your facility does not use PEEP or your facility is stopping its use of this practice, no further action is needed by you.

Affected Product Details

All Lullaby RESUS Plus Systems -Part number: 2070100-001 (Lullaby Resus Plus - NIST) & 2070100-002 (Lullaby Resus Plus- DISS)

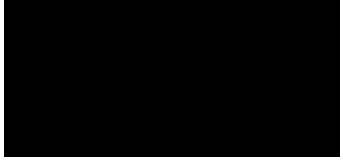
Affected Product Lullaby RESUS Plus Systems	NOT Affected Product Lullaby Resus Prime
 <p data-bbox="407 1833 724 1854">2070100-001 & 2070100-002</p>	

Product Correction GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at Service center.

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 per the contact information above.

Sincerely,



James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare




Jeff Hersh, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare

1 Addendum – Manometer reading offset correcting procedure, to be done before every patient use

2 Introduction

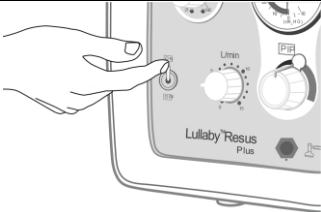
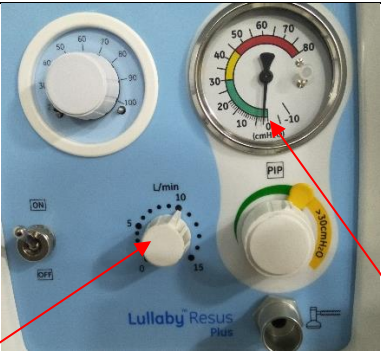
The main purpose of this document is to explain the procedure to correct the offset observed in Manometer reading during PEEP cycle of the resuscitation.


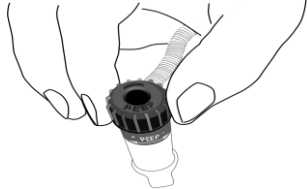

	CAUTION: Do not try to open/dismantle/dis-assemble the device to correct the offset observed in Manometer reading
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	CAUTION: Offset Pressure should be noted only when the T-piece is not connected to the device.
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3 Procedure for compensating the offset values observed in Manometer reading

Please follow the below step by step procedure to compensate the offset observed in PEEP setting in addition to the instructions listed in Section 3.2 of the Operator Manual.

Step No	Description	Illustration
1.	Connect the Oxygen and Air supply to the device as per hospital policy and make sure that supply pressure of both oxygen and air is same. (between 40psi and 80psi)	
2.	Turn ON the device ON/OFF switch. Note: Please do not connect the T-piece at this step.	
3.	<p>Additional step: Please check for the offset shown at the Manometer for different flow rate settings, Example: 5L/min, 8L/min, 10L/min and 15L/min. Note the reading indicated by Airway manometer. This will indicate the offset pressure for this device at the set flow rate.</p> <p>Example: This image shows an offset at 10 LPM is 2 cmH2O.</p> <p>Note: The offset pressure increases as the flow rate increases.</p>	 <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px; text-align: center;">Flow control knob Indicating set flow rate (LPM)</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">Airway Manometer indicating offset pressure</div> </div>

Step No	Description	Illustration
4.	Adjust the flow control knob to a desired flow rate as determined by your institutional policies/practices. Ensure that the offset pressure for the set flow is noted.	
5.	Attach the T-piece circuit to the T-piece circuit connection port on the front panel of the unit.	
6.	<p>To adjust the PEEP, remove thumb from the PEEP control knob, retain the end cap and rotate the PEEP control knob on the T-piece circuit to set the desired pressure as determined by your institutional policies/practices.</p> <p>The offset recorded in Step 4 should be added to the desired PEEP setting.</p> <p>Example: If the desired PEEP is 5 cmH2O at 10 LPM, then the set PEEP indicated on the manometer should be 7 cmH2O.</p> <p>SET PEEP = (Desired PEEP) + (Offset Pressure)</p> <p>Since in this case, Offset Pressure = 2 cmH2O Desired PEEP= 5 cmH2O SET PEEP = 5 + 2 = 7 cmH2O</p>	  <div data-bbox="781 1171 976 1255" style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">Set PEEP Pressure</div>
7.	Note: Use the offset pressure noted in Step 3 whenever there is a need for a change in the flow rate and repeat the Step 6 accordingly.	