

Smiths Medical International Ltd
Bramingham Business Park,
Enterprise Way,
Luton, Beds, LU3 4BU
UK

URGENT FIELD SAFETY NOTICE
For Single Limb Circuit for Pneupac® Ventilators, with PEEP Valve

Affected Devices: Single Limb Circuit for Pneupac® Ventilators, with PEEP Valve

Type of Action: Field Safety Corrective Action - Correction

Date: 19 January 2015

Attention: Risk/ Safety Managers, Respiratory Department, Nursing, Emergency Departments, Radiology/ Diagnostic Imaging Department, MRI Unit, and other users of these devices

Details on affected devices: See Attachment A for list of Reorder and Lot Numbers

Dear Valued Customer:

Smiths Medical is providing this Urgent Field Safety Notice to advise its customers of a Field Safety Corrective Action for certain Single Limb Circuits for Pneupac® Ventilators, with PEEP Valve (“Single Limb Circuit“) described in the attached list of Reorder and Lot Numbers (see Attachment A). Smiths Medical is voluntarily taking this action with the knowledge of the relevant Regulatory Agencies.

Certain Single Limb Circuits were labelled as “MR Conditional” (see Figure 1) but contained PEEP valves that should have been labelled as “MR Unsafe” (see Figure 2).



Figure 1



Figure 2

If the affected products are used in an MR environment, there is a potential for the PEEP valve to become dislodged during the MRI procedure. The effect of a reduction of PEEP pressure could be a reduction in oxygen saturation of the blood which would be detectable by clinical observation of signs and symptoms and through oximetry. Also there is the potential for the affected products to create artifacts in the MRI scan; however, these artifacts would be highly detectable by the clinician reading the MRI. Smiths Medical has received no reports of any incidents or injury related to this issue.

Only those Product Reorder Numbers and Lot Numbers listed in Attachment A are affected by this Action.

Action to be taken by the User:

If your facility does not use the Single Limb Circuit in the MRI Suite, then these products remain safe and effective for use as intended. Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers to perform the following:

Your Facility Uses the Single Limb Circuit in the MRI Suite

1. Inspect your inventory for the Single Limb Circuits listed in Attachment A and quarantine the affected devices.
2. Complete and return the attached Confirmation Form by fax to +44 (0)1582 430001 or by email to Singlecircuit@smiths-medical.com within five (5) days of receipt of this notice. Upon receipt of the completed form, a customer service representative will contact you to arrange for exchange of your unused affected devices for replacement.

Your Facility Does Not Use the Single Limb Circuit in the MRI Suite

1. Complete and return the attached Confirmation Form by fax to +44 (0)1582 430001 or by email to Singlecircuit@smiths-medical.com within five (5) days of receipt of this notice. No further action is necessary, as these products remain safe and effective for use as intended.

Transmission of this Urgent Field Safety Notice

This notice shall be passed on to all personnel who need to be aware within your organization, including points of use or to any organization where the potentially affected devices have been transferred. If you or your facility has distributed these affected products to other persons or facilities, please promptly forward the recipients a copy of this Urgent Field Safety Notice.

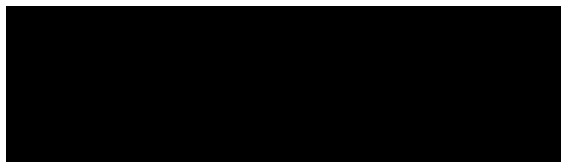
Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this action.

Customers shall report any issues with these products to Smiths Medical's Global Complaint Department at +00 800 76 48 47 00 or globalcomplaints@smiths-medical.com.

If you should have any questions regarding this information, please contact Smiths Medical's Customer Service Department at (0) 845 850 0445.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may have caused.

Sincerely,



George Wiechert
Manager, Quality Systems (UK)
Smiths Medical International Ltd

Enclosures: Attachment A – List of Affected Reorder and Lot Numbers
Attachment B – Confirmation Form

ATTACHMENT A

PRODUCT NAME/DESCRIPTION, REORDER NUMBER, & LOT NUMBER

Product Name/ Description	Reorder No.	Lot No.
Single Limb Circuit for Pneupac® DEMAND type Ventilators, with PEEP Valve	100/905/301	121105, 130128, 130225, 130408, 130624, 131209, 140217, 140407, 140428, 140616
Single Limb Circuit for Pneupac® DEMAND type Ventilators, with PEEP Valve and Pressure Monitoring Line with In-Line Filter	100/905/302	120229, 120326, 120402, 120507, 120716, 120820, 130318, 130520, 130819, 131007, 131125, 131216, 140526, 140707, 140714

ATTACHMENT B

<for Distributor’s Customers>

**URGENT FIELD SAFETY NOTICE CONFIRMATION FORM
Single Limb Circuit for Pneupac® Ventilators, with PEEP Valve**

19 January 2015

Customer Account No. _____

Please complete and return this Form by fax to +44 (0)1582 430001 or by email to Singlecircuit@smiths-medical.com

<input type="checkbox"/> YES – I acknowledge receipt and understanding of the attached Urgent Field Safety Notice. Our facility does not use the Single Limb Circuit in the MRI Suite.	
<input type="checkbox"/> YES – I acknowledge receipt and understanding of the attached Urgent Field Safety Notice. Our facility does use the Single Limb Circuit in the MRI Suite. I have unused inventory of Single Limb Circuit for Pneupac® Ventilators, with PEEP Valve which I will return for replacement Please complete products details on page 2	Total number of affected products:
<input type="checkbox"/> NO – I do not have any of the affected products.	
<input type="checkbox"/> I no longer have any of the affected products. I transferred them to the following location: <i>(please provide name, address, and phone number):</i>	
<input type="checkbox"/> I did have affected products; they were already used/ have been disposed of.	
Facility Name:	Facility Address:
Signature:	Facility Shipping Address:
Print Name:	Date:
Email:	Phone Number: ()

