

# Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/064

Issued: 5<sup>th</sup> August 2008

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION REQUEST	✓



**HEALTH ESTATES**

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	Section			
<p><b>Medical Device/Equipment:</b> Emergency and transport EMS ventilator circuits, product code W196-002, lot number 20070709, manufactured by Galemed Corporation and supplied by Smiths Medical.</p>	▶ ①			
<p><b>Problem:</b> Extension of recall – valve in the breathing system will not open, resulting in a lack of oxygen delivery.</p>	▶ ②			
<p><b>Action by:</b> All those using the Parapac, Ventipac, Rescupac and Transpac models of ventilator.</p>	▶ ③			
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• Locate and quarantine EMS ventilator circuits with lot number 20070709.</li> <li>• Contact Smiths Medical to arrange disposal and replacement of any affected devices.</li> <li>• If replacement breathing systems are not immediately available then follow the Action advice on page 2.</li> </ul>	▶ ④			
<p><b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b></p>	▶ ⑤			
<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥			
<p style="text-align: center;"><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p> <table border="1" style="width: 100%;"> <tr> <td style="width: 33%;"> <p><b>Acknowledge Receipt of Alert:</b> 7<sup>th</sup> Aug 2008</p> </td> <td style="width: 33%;"> <p><b>Action Under Way:</b> 12<sup>th</sup> Aug 2008</p> </td> <td style="width: 33%;"> <p><b>Action Complete:</b> 26<sup>th</sup> Aug 2008</p> </td> </tr> </table>	<p><b>Acknowledge Receipt of Alert:</b> 7<sup>th</sup> Aug 2008</p>	<p><b>Action Under Way:</b> 12<sup>th</sup> Aug 2008</p>	<p><b>Action Complete:</b> 26<sup>th</sup> Aug 2008</p>	▶ ⑦
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This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

These are breathing systems for use with Smiths Medical emergency and transport ventilators including: Parapac, Ventipac, Rescupac and Transpac models. These ventilators are used in emergency situations and during the transport of adults, children and infants.

These models of ventilators are also known as, and referred to in the instructions for use as, 2/2D, 20/20D and 200/200D. This is with the exception of the Resuspac model, which is referred to as the 2D/2DM.

## 2. PROBLEM:

Further to the NIAIC's Medical Device/Equipment Alert MDEA(NI)2007/88, issued in October 2007, Galemed has expanded its recall to include an additional lot number. This further recall was necessary because the manufacturer identified that some affected valves had been incorporated into breathing circuits which had not been listed in the previous recall notification. There is no change to the underlying cause of the problem.

The previous recalled lot numbers were 20070528 (May 2007 manufacture), 20070620 (June 2007 manufacture) and 20070910 (September 2007 manufacture). The lot number that is affected in this recall is 20070709 (July 2007 manufacture). No product was manufactured during August and Galemed believe that no further product should be affected by this issue.

Galemed Corporation made changes to its manufacturing method and quality assurance checks to try and prevent this issue from recurring. All new product is manufactured using the improved techniques.

## 3. ACTION BY:

All those using the Parapac, Ventipac, Rescupac and Transpac models of ventilator.

## 4. ACTION:

- If replacement breathing systems are not immediately available then ensure that alternative ventilators and their breathing systems are available.
- If no alternative ventilators and breathing systems are available then:
  - hospital trusts should ensure that pre-use checks are undertaken for all EMS ventilator circuits (see appendix)
  - ambulance trusts should check ambulance stock immediately and further stock should be checked before being placed on the vehicle (see appendix).
- Ensure that an alternative oxygen supply and means of ventilation are always available when using any ventilator e.g. a self-inflating bag and oxygen cylinder.
- Inform the NIAIC of any similar incidents that occur involving the EMS ventilator circuits

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- A&E departments
- Ambulance services directors
- Anaesthesia, directors of
- Clinical governance leads
- Coronary care departments
- Critical care units
- Day surgery units
- EBME departments
- Health and safety managers
- Intensive care units (adult, paediatric, neonatal)
- Intensive care, directors of
- Medical directors
- Medical physics departments
- Nursing executive directors
- ODP managers
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- SCBU
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Bob Roe or Claire Kallmeier  
Smiths Medical International  
Colonial Way  
Watford  
Herts  
WD24 4LG

Tel: 01923 241 411

Fax: 01923 256 790

Enquiries to NIAIC should quote reference number MDEA(NI)2008/064 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

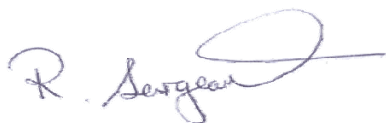
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:  
7<sup>th</sup> Aug 2008

Action Under Way:  
12<sup>th</sup> Aug 2008

Action Complete:  
26<sup>th</sup> Aug 2008



Robert Sergeant  
NIAIC Operational Manager

#### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

# APPENDIX to MDEA(NI)2008/064

## From (a) Set Up

Connect the output hose (6) as indicated by signs on the module.

**WARNING: To avoid harm to the patient, pre-use checks must be performed before each use.**

## (b) Functional Check

The following procedure should be followed when first setting up the ventilator to check that it has been assembled correctly and is operating safely. It should be repeated periodically as specified under 'Maintenance'.

1. Check the ventilator controls as follows:-

Main Pneumatic Switch:	'Demand'	(Model 200D)
	'0'	(Model 200)
Frequency		12 b/min (detent position)
Tidal Volume:		900mL
Air Mix Switch		'No Air Mix'
Relief Pressure:		40 x100Pa (40 cmH <sub>2</sub> O)

2. Connect the probe on the input hose to an appropriate gas outlet.

3. If connected to a cylinder regulator turn on cylinder valve slowly.

*NOTE:* The gas source must be capable of maintaining a pressure of at least 305 kPa ( 3 bar) whilst delivering a flow of 65 L/min.

4. Check that the visual alarm for supply gas failure has changed from red to white.

5. Switch the main pneumatic switch to '1' (Model 200) or 'CMV/Demand' (On) (Model 200D). The ventilator should commence cycling and all the alarm lights flash in turn. A single burst of the high priority audible alarm is given at the same time. The orange silencing indicator should flash for 60 seconds. Check that the flow is coming from the patient connection port by feeling the flow when placed close to the back of the hand or to the face.

6. Occlude the output port on the patient valve and check that the manometer gives a reading of between 30 and 50 cmH<sub>2</sub>O during each inspiratory phase. The pneumatic audible alarm should also sound, accompanied by the high inflation pressure visual alarm. After occlusion for one second, once the silencing period has elapsed, the high priority electronic audible alarm will also sound. Check that the unit cycles regularly about every 5 seconds.

7. Switch over to 'Air Mix' and repeat step 6. The change in the manometer reading should not exceed 5 x100Pa (5 cmH<sub>2</sub>O).

*NOTE:* After the 60 second initial silenced period the electronic audible alarms will operate if an alarm condition persists. These can be silenced for as long as required by depressing the silencing button each time the silencing indicator switches off.

8. Set the 'Tidal Volume' control to its minimum setting. Occlude the output port and check that at least 20 x100Pa pressure is attained on the manometer. Gradually increase the flow setting and observe how the pressure rises - demonstrating the pressure generator principle. At the end of the green segment the pressure should be attaining the nominal set value.

## APPENDIX to MDEA(NI)2008/064

9. Set the 'Tidal Volume' control to its minimum setting. Occlude the output port and check that at least 20 x100Pa pressure is attained on the manometer. Gradually increase the flow setting and observe how the pressure rises - demonstrating the pressure generator principle. At the end of the green segment the pressure should be attaining the nominal set value.
9. Reset the 'Tidal Volume' control to its minimum setting and select 'No Air Mix'. Occlusion of the output port should now cause the manometer to rise sharply to between 30 and 50 x100Pa and the alarms should operate.
10. Allow the ventilator to cycle with no obstruction at the output port and check that the low inflation pressure (disconnect) alarm operates after 10 seconds.
11. Set the 'Frequency' and 'Tidal Volume' control knobs to the extremes of their range. By listening to the gas flow, check that the ventilator is responding to the controls and that no irregularities of performance can be discerned.
12. If the ventilator is likely to be used with very small babies the following additional test should be carried out during the periodic test and after reassembly of the patient valve every time it is dismantled:-  
  
Connect the ventilator to a gas source and set the 'Tidal Volume' control to minimum and the air mix switch to 'Air Mix'. Attach a flexible reservoir bag (preferably 1/2 litre) to the patient connector of the patient valve and switch on the main pneumatic switch. Roll up the end of the reservoir bag to decrease its effective volume until the end inspiration inflation pressure rises to about 10 x100Pa. Check that this pressure can be attained consistently every breath. If it cannot, dismantle the patient valve, turn the valve element (rubber disc) about a quarter of a turn and reassemble and retest. If after two or three adjustments consistent performance cannot be achieved the valve element must be replaced.
13. Finally, set the controls as specified in step 1 so that the ventilator is left set for emergency use.

**WARNING: Deviations noted at functional check should be reported immediately to Pneupac and the unit must be taken out of service to avoid the risk of death or serious injury.**

**WARNING: Avoid smoking or naked flame. To avoid the risk of ignition, do not use oil, grease or combustible lubricants (only those approved for oxygen use) in contact with any part of the ventilator, regulator or cylinder.**

**WARNING: To avoid ignition by adiabatic compression, connect the ventilator to the regulator before opening the cylinder valve slowly. Similarly, prior to changing cylinders, turn off the cylinder valve, switching on the ventilator. When the ventilator stops, it is safe to release the pin index yoke.**

**PRECAUTION: It is recommended that the valve on the gas cylinder is turned off after use to ensure that the cylinder contents are not lost during storage due to small leakages.**