

1. DEVICE/EQUIPMENT:

The LTV series ventilators are used for transport, long and short term ventilation and in domiciliary (homecare) settings.

2. PROBLEM:

Pulmonetic Systems Inc. is undertaking several safety upgrades and improvements to its LTV series ventilators. These upgrades include enhancements to high-pressure alarm management and the event log. In the past several different agents have been involved in the supply of these ventilators, leading to an incomplete record of their distribution. This has resulted in these devices receiving only a few upgrades or none at all. Carina VT, the newly appointed manufacturer's agent, is now responsible for these free upgrades and needs to know the locations of all devices.

3. ACTION BY:

Staff responsible for the maintenance and servicing of LTV series ventilators.

4. ACTION:

- Staff responsible for the maintenance and servicing of LTV series ventilators should contact Carina VT, which is undertaking all upgrades free of charge on behalf of Pulmonetics Systems Inc.
- Staff using the LTV series ventilators should be made aware of the clinical application information contained in the attached bulletin.

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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Nurse Directors
- Ambulance Staff and Paramedics
- Adult and Paediatric Intensive Care Units
- Accident & Emergency Departments
- Directors of Anaesthetic Departments
- Theatre Managers
- Directors of Public Health
- Community Care Staff
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing homes through R&I Units.

6. CONTACTS:

Locations of LTV series ventilators in use should be notified to:

Mr Wayne Moore
Carina VT
Wellington House
Westcott Venture Park
Aylesbury
Buckinghamshire
HP18 OXB

Tel: 08454 900 231

Fax: 08454 900 241

E-mail: wmoore@carinavt.com

Enquires to NIAIC should quote reference number MDEA(NI)2003/37 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

7. FEEDBACK:

None required.



Brian Godfrey
NIAIC 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 Safety Notice SN (NI) 2003/01. 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

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

Appendix to MDEA(NI)/2003/37



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Service Bulletin / Clinical Information

To: All LTV Series Ventilator Users (United Kingdom)
From: Pulmonetic Systems, Inc.
Date: September 5, 2003
Reference: **Service Bulletin**
Release #: 070803 – 13SVC

Service/Maintenance Information

Effective July 1, 2003, Carina VT Ltd. has assumed distribution, maintenance and service for ALL LTV Series Ventilators in the United Kingdom.

If you have any LTV Series Ventilators in your program or inventory, please contact Wayne Moore at Carina VT Ltd. at 08454 900 231 or via email at wmoore@carinavt.com, to determine what upgrades remain outstanding for devices in your inventory and to schedule your devices for upgrade no later than the next planned service interval. Contacting Carina VT Ltd. will also ensure that you will be notified of any future upgrades should they become available/necessary over the life of the device.

Since its introduction in early 1999, Pulmonetic Systems, Inc. has initiated several mandatory product recalls affecting certain serial number devices in the LTV Series of Ventilators. Carina VT Ltd. will install any necessary recall upgrades to your inventory of devices that remain outstanding.

Pulmonetic Systems, Inc. has also periodically provided software updates to enhance the performance of the LTV series of ventilators. It is important that all of the LTV Series of Ventilators receive these updates as recommended by Pulmonetic Systems, Inc. The current software service package is version 3.11. Recent updates include high-pressure alarm management and event trace enhancements. The installation of these updates to all affected devices is provided by the distributor responsible for the service and maintenance of the particular device or Pulmonetic Systems, Inc.

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The product recall upgrades and software updates referenced are provided to all ventilators affected in distribution worldwide at no charge.

Clinical Application Information

- On the LTV 1000 only, when using a high-pressure oxygen source, the delivered oxygen concentration may vary from the value set on the ventilator. Pulmonetic Systems, Inc. recommends the use of an Oxygen Concentration Monitor to ensure the appropriate oxygen concentration is delivered.
- In all applications, it is always imperative to monitor the patient, the ventilator, and to properly set all alarms and monitors.

Please contact Carina VT Ltd. or Pulmonetic Systems, Inc. Customer Care at 001.763-398-8500 for any additional information.