HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

AVEA Ventilator

Priority 2 – Warning

HPRA Safety Notice: SN2015(07) **Issue Date: 14 May 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
CareFusion Respiratory Systems	V24077

ISSUE
AVEA Ventilators can over time develop a failure where the AVEA ventilator activates either a false Extended High Ppeak alarm, or a false occlusion alarm. As designed, when this occurs, the safety valve is opened immediately and the AVEA stops ventilating. If this issue were to occur, it is recommend by Carefusion that the AVEA ventilator be taken out of service and a CareFusion representative is contacted. There is a risk of serious injury to the patient if the issue were to occur while the patient is using the ventilator, as the patient would have to be moved to another ventilator to continue receiving treatment. All Avea Ventilators manufactured between July 1 2011 and March 2015 are potentially affected. This issue was highlighted in a field safety notice (FSN) that was circulated by the manufacturer in April 2015. Please refer to the attached FSN for additional details on the isssues affecting the devices, the list of affected serial numbers and the actions proposed by the manufacturer.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Ensure that you have read and followed the instructions that were provided in the manufacturer's field safety notice (FSN) that was circulated in April 2015. 2 Complete and return the Response Card included with the FSN if you have not already done so. This will allow for CareFusion to arrange for the inspection and modification of your device.

3 Forward this HPRA Safety Notice to all those who need to be made aware within your organisation or to any organisation/person where these devices have been transferred.

4 Ensure that relevant personnel receive a copy of the attached FSN.

TARGET GROUPS	
HSE Hospital Staff Private Hospital Staff Hospice Staff Clinical Engineers/Medical Physics	Risk Managers Purchasing Managers Supplies Managers

BACKGROUND

The issue of the device is caused by the failure of the pressure transducer. The pressure transducer fails due to a disconnection of bond wires within the 5 PSI pressure transducers. This component is not manufactured by CareFusion and is a semiconductor part. On some machines, the wires attaching the semiconductor die to a circuit board within the pressure transducer are disconnecting because of process variability of the component manufacturer leading to silicon dust being present and preventing the formation of a proper weld or forcing the connection to disconnect as silicon crystals grow and expand. The failure manifests itself within 1-3 years from the date of manufacture. It is possible for this malfunction to occur during treatment and during start up of the ventilator. When you have acknowledged receipt of the FSN, your CareFusion distributor will contact your facility by telephone to coordinate implementation of the corrective action at your site. The action will involve the replacement of the pressure transducer.

The HPRA is communicating this Safety Notice at this time to ensure that all users of the device are aware of the issue.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

CareFusion Respiratory Systems
22745 Savi Ranch Parkway
Yorba Linda
92887
USA

Telephone: + 1 (714) 919 3349
Fax: +1 (714) 283 8420
E-mail: Donald.sherratt@carefusion.com
Website: www.carefusion.com

Enquiries to the **distributor** should be addressed to:

Oxygen Care Ltd,
2 Holfeld Business Park
Kilmacangoue
Co. Wicklow

Telephone: +353 (0)1 276 9700
Fax: + 353 (0)1 276 4970
E-mail:
Website: www.oxygen-care.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie