

Gemünden, 9th July 2015

Field Safety Notice

related to power supplies used with the AKITA JET and AKITA² APIXNEB inhalation systems manufactured by Vectura GmbH (former Activaero GmbH)

Subject:

Additional safety and precautions information on the power supply used with the AKITA JET and AKITA² APIXNEB inhalation systems.

Announcement about midterm replacement of power supplies of the AKITA JET inhalation system and of the AKITA² APIXNEB

From:

Vectura GmbH
Wohraer Straße 37
35285 Gemünden
Germany

To:

All users and distributors of AKITA JET inhalation system or AKITA² APIXNEB

Affected Devices

AKITA JET Inhalation System and AKITA² APIXNEB Inhalation System

- Power supply FW7405M/24



Dear User or Distributor of AKITA JET inhalation system or AKITA² APIXNEB,

Description of the problem

Vectura GmbH has become aware of a potential defect on our power supply that is used with AKITA JET inhalation system and AKITA² APIXNEB devices. The defect may lead to a potential overheating with the potential to deform the plastic shell of the power supply. This overheating of the power supply may occur under certain rare circumstances. It is unlikely but not impossible that undetected overheating may present a fire hazard risk.

Example of an intact enclosure of the Power supply



Example of a deformed enclosure of the Power supply



Advice on action to be taken by the user

Vectura has performed a risk assessment and came to the conclusion that users may continue the use of their AKITA JET and AKITA² APIXNEB inhalations systems as usual. Nevertheless it is recommended to follow the following safety precautions:

- Do not cover the power supply during use.
- After taking your inhalation treatments please disconnect the power supply from the socket outlet
- In case you observe deformation of the power supply enclosure or notice an unusual smell, immediately disconnect the power supply from the socket outlet. After the power supply has cooled down, return the power supply to your distributor or Vectura GmbH
- If the device ceases to function without any reason, disconnect the power supply from the socket outlet and contact your service representative or Vectura GmbH.

Further corrective action

Vectura GmbH has already initiated a design change to qualify a suitable alternative power supply for the use with the AKITA JET and AKITA² APIXNEB inhalation systems. After approval of a suitable alternative power supply, Vectura GmbH will replace the current power supplies (Model FW7405M/24) in the field. Users or Distributors will be contacted by Vectura GmbH staff in a timely manner.

Distribution of this Field Safety Notice:

This notice needs to be distributed to all users of the devices or persons who are involved with the use of the devices. If you are not the user of the systems, please ensure that your customer and / or end-user become aware of it by forwarding a copy to this person. Please maintain awareness on this notice and resulting action until the power supply has been replaced.

Acknowledgement:

Please fill out the attached acknowledgment form and have it send back to Vectura via fax, scan or regular mail immediately after its receipt.

Contact Person:

For any further information or concerns please contact:

Vectura Group:

Contact name: Neil Raw, Director - Quality and QP

Email: mdi@vectura.com

Phone: +44 (0)1249 667593 Direct Dial

Mobile phone: +44 (0) 7918 158707

Address: Vectura Limited, a subsidiary of Vectura Group plc

Registered in England CRN 01696917 at

One Prospect West, Chippenham, Wiltshire, SN14 6FH

or

Vectura GmbH:

Contact name: Heike Schaaf, Senior Quality Officer

Email: mdi@vectura.com

Phone: +49 89 89 79 69 0 Switch Board

Address: Vectura GmbH, a subsidiary of Vectura Group plc

Registered in Germany HRB Marburg Nr 4102 at

Robert-Koch-Alle 29, 82131 Gauting, Germany

The undersign confirms that this notice has been notified the appropriate Regulatory Agency (BfArM)

Sincerely

Vectura GmbH

09. JULI 2015



Dr. Raimund Gleixner

Medical Device Safety Officer

 9th July 2015

Neil Raw

Director, Quality

**Acknowledgement of the receipt of the Field Safety Notice regarding power supplies of devices
AKITA JET inhalation system and AKITA² APIXNEB manufactured by Vectura GmbH (former
Activaero GmbH) dated 06.07.2015**

I hereby confirm the receipt and notice of the urgent field safety information regarding the power supplies of the medical devices **AKITA JET inhalation system and AKITA² APIXNEB** manufactured by Vectura GmbH.

Signature/Stamp/Date

Please return the signed Acknowledgement to Vectura GmbH by:

Email-scan to: mdi@vectura.com or

Fax: +49 (0) 645364181 22 or

Regular Post mail to: Vectura GmbH, Wohraer Straße 37, 35285 Gemünden, Germany