
Urgent Field Safety Notice

Correction of Tubing for Option Diffusion at the Vyntus[®] BODY

concerning

Vyntus BODY with Option Diffusion (Catalogue No. V-378500)

Hoechberg, 2017-11-30

Addressee: User, operator

Identification of the affected Medical Devices:

Affected are products within the serial number range of 42500-052 to 42500-199, except the devices without the Option Diffusion. Not affected devices (catalogue No. 178500) can be identified, because they don't have a Demand Valve inside the cabin and a Gas Bottle outside the cabin.

A detailed list of the affected serial numbers are documented in the feedback form.

Problem description including the root cause:

The medicinal gas mixture (i.e. „PROMED pul-p“) can flood inside the cabin, if

- The gas bottle is not regularly closed after finishing the diffusion measurement
- **And** the tubing inside the cabin has a significant leakage (audible fizzle).

Risk Evaluation:

- The medicinal gas mixture (i.e. „PROMED pul-p“) includes a substance of 0.3% CO (carbon monoxide) amongst others as an active agent.
The Inhalation of large quantities of the gas mixture can result in dizziness and headache, if the whole content of the gas bottle is emptied into the closed cabin.

Actions to be taken by the Addressee:

You can continue to use your Medical Device without limitations, as long as you take notice of the following precautions:

- Perform a diffusion measurement basically with wide opened cabin door or outside the cabin.
- After finishing the diffusion measurement please always close the gas bottle valve hand-tight.
- Make sure, that during all other measurements (except diffusion measurement) the gas bottle is closed.
- Be sure of sufficient ventilation of the rooms.
- Follow the instructions of the medicinal gas manufacturer.



Actions to be taken by CareFusion

The Technical Support of CareFusion or its Distribution Partner will contact you within the next six weeks to arrange the onsite correction process of the affected devices. The closure of this Field Safety Corrective Action is planned to be completed by 2018-03-31.

Passing on of this Information:

Please ensure within your organization, that all users of the above mentioned products and other relevant persons receive this information about this **Urgent Field Safety Notice**. As far as you have forwarded the products to other persons, please forward a copy of this information to them and inform the below named contact person.

Please keep this information with your records, at least until the correction process has been completed.

The Federal Institute of Drugs and Medical Devices (BfArM) in Germany has received a copy of this „Urgent Field Safety Notice“.

Contact Person:

Please use the chart provided below for questions and support

Customer Support CareFusion	CareFusion Germany 234 GmbH Herr: Harald Beienz Tel.: +49 931 4972 – 146 Email: Support.RT.EU.JAE@vyaire.com	FSCA-related Questions
<i>Name of CareFusion-Business Partner</i>	ENTER BUSINESS PARTNER INFO HERE	Reporting of undesirable events of the product during Technical Support

We appreciate your prompt return of the enclosed Response Card to expedite the correction process and acknowledge receipt of this Notification.

We recognize the inconvenience this issue may cause your facility and thank you for your support in this important matter.

Sincerely,

Detlef Grotheer
Safety Officer for Medical Devices
CareFusion Germany 234 GmbH

Enclosure: Customer Response Card
Country specific affected Serial Numbers