DEAS s.r.l.
via dell'Industria n. 49
48014 Castel Bolognese (RA) Italy
Tel. +39 0546 656845 · Fax +39 0546 54706
E-mail: deas@deasnet.it · deas@pec.deasnet.it
Web: www.deasnet.it
N. Reg. Imprese Ravenna, C.F., P.IVA: 01063890394
Capitale Sociale € 98.800,00 interamente versato

Urgent Field Safety Notice

FSCA-identifier: 2019-266 **Date:** 22/10/2019

Medical Device: DEAS Autofeed Humidification Chamber REF 04314 (sterile version) or 04314 NS (non sterile version). These devices has been sold singularly or packed with related breathing circuits.

The current notice is related to following products and lots numbers:

REF	DESCRIPTION	LOT
153303	Breathing circuit with humidification chamber	184734, 184735, 185445, 192739
154309	Breathing circuit with humidification chamber	185446, 185985
154310	Breathing circuit with humidification chamber	192171, 190879, 192930

Manufacturer: DEAS S.r.l., Via Dell'Industria 49 - 48014 Castel Bolognese (RA) Italy

Attention: Medical Device Safety Officers (MDSO)

Distribution: All Responsibles and all clinical staff of Intensive Care, Adult and Neonatal, Neonatology

Description of the problem: Deas received an isolated report showing that the floating system of our disposable autofeed humidification chamber REF 04314 NS Lot 184671 failed. Water overfilling occurred.

Cause: a violent impact, following a drop of the product, presumably during the putting into use phase (unpacked product) caused the disconnection of an element of the floating system.

Transmission of this Field Safety Notice:
This Field Safety Notice should be transmitted to all those who need to be aware within your organisation, or to any organisation where potentially these devices have been transferred.

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Type of action:

1) **Corrective Action being taken by manufacturer DEAS**

- DEAS revised the attached instructions for use including additional advertisements as follow:
  - DO NOT use the chamber if it has been dropped;
  - Before starting ventilation, make sure the water level is not above the black maximum fill line.

Through this Field Safety Notice, Deas informs its distributors and the clinical staff of health facilities, and it verifies the completeness of feedback information.

2) **Action to be taken by the distributor and clinical staff**

- Take notes about the attached revised instructions for use;
- Complete the Urgent FSN Response Form to be forwarded to us, to confirm receipt of our FSN;
- Make sure that our FSN is passed on to all those who need to be aware of it within the organization or to any organisation where potentially these products have been transferred;
- Maintain awareness of our FSN and resulting action for an appropriate period to ensure effectiveness of our corrective actions.

The undersigned confirms that this Field Safety Notice has been notified to the concerned Ministries of Health and our notify body.

DEAS apologises for any inconvenience this may cause. If you have any questions, please contact:

Deas S.r.l.
Tel.: +39 0546 656845
Fax: +39 0546 54706
Email: deas@deasnet.it

Domenico Scardovi, Quality Manager, DEAS S.r.l.

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Urgent Field Safety Notice

Please return this form filled out and signed to:

Deas S.r.l.
Tel.: +39 0546 656845
Fax: +39 0546 54706
Email: deas@deasnet.it

It is confirmed the receipt of the Field Safety Notice regarding these products and lots numbers:

REF	DESCRIPTION	LOT
153303	Breathing circuit with humidification chamber	184734, 184735, 185445, 192739
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It is ensured that:

- all Safety Responsible of Organizations involved will be made aware of this Field Safety Notice;
- it will be maintained awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Name of Organisation / Hospital: _____

Department: _____

Name and Title: (please print) _____

Signed: _____

Date: _____