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For the attention of the medical device vigilance correspondent

Antony, 15 May 2016

Product Safety Alert: R1602137 DANUBE HP supply system

Dear Sir/Madam,

Air Liquide Medical Systems is issuing a voluntary safety alert. Please send this information to all concerned.

This document contains important information for you to continue to use your equipment safely. Please send this information to your team members who should be made aware of the message.

Products affected	Danube Main Unit DNP – 9 Bar & 80 m3/h ref: AD078000 Danube Main Unit SNP – 5 Bar & 80 m3/h ref: AD078200 Danube Main Unit SNP – 5 Bar & 40 m3/h ref: AD078500
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Please note: this safety alert concerns all of the products listed up to batch 1526 (inclusive).

Information on potential risk and safety information	Water infiltration in the HP pressure regulator cap is possible in the products listed above. This is due to the position of the HP pressure regulator: the valve vent, facing upwards, allows water gravity-infiltration in the HP pressure regulator cap. Water may also infiltrate through the HP pressure regulator cap thread. This part of the cap is vented to the atmosphere and is not in contact with the gas. The inversion system may therefore not function properly.
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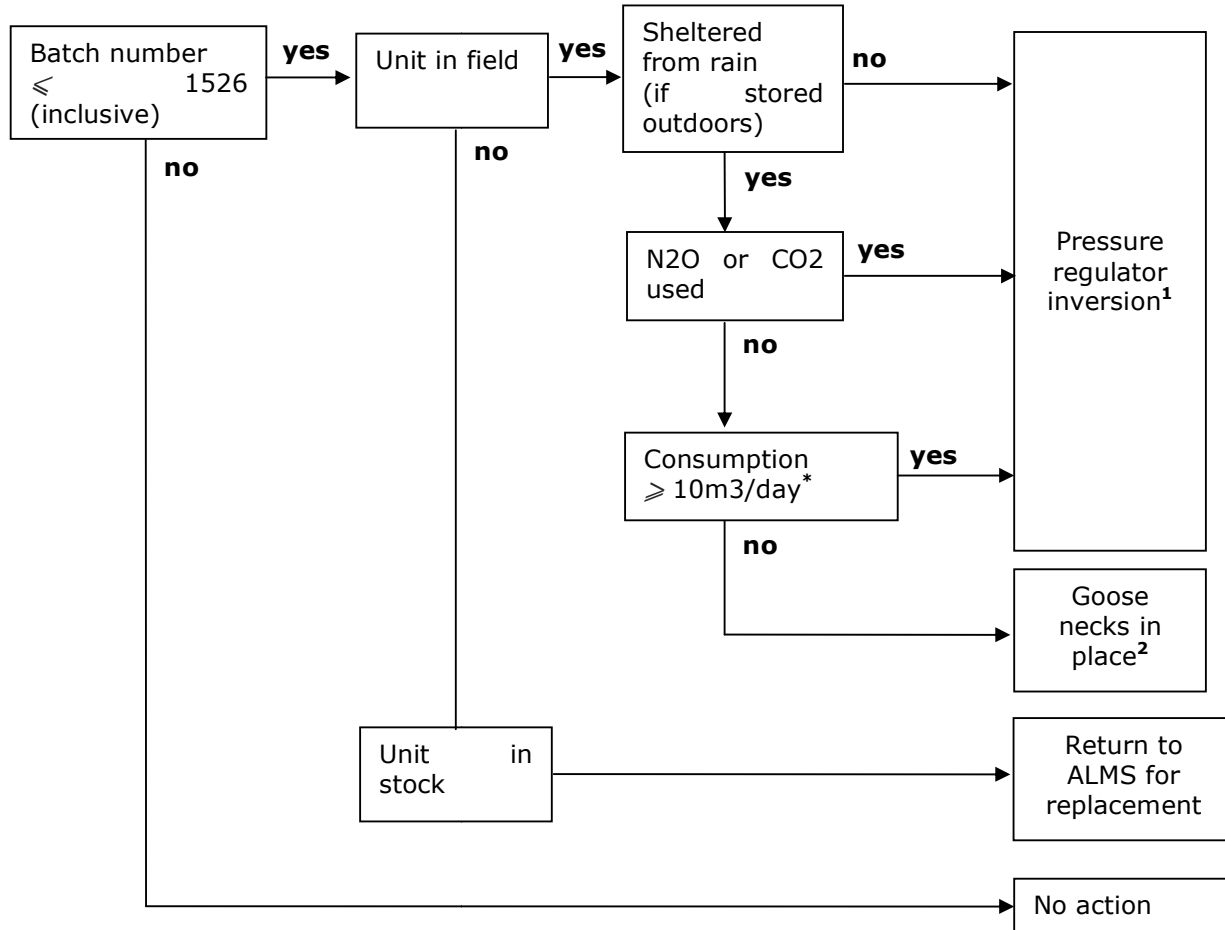
The following conditions cause water infiltration to occur:

- *Danube Unit not sheltered from rain:* rainwater infiltration.
 - *Danube Unit protected when using N₂O and CO₂:* condensation infiltration due to the temperature of the liquefied gases, which adds to temperature drop due to gas expansion.
 - *Danube Unit protected and used at high flow rate:* condensation infiltration due to compressed gas expansion, accentuated by the high flow rate.
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Action to be taken

Check:

- whether the references have been ordered
- the batch number or numbers of the equipment received (material safety data sheet, delivery slip)
- otherwise, the order date.
From 10/08/2015, only inverse units were delivered – orders placed 3 weeks earlier should be checked.
- Follow the decision tree below:



- Implement related measure.

***details:** 10m3 corresponds to a cylinder with 50L water capacity (B50). 10m3/day corresponds to 1 B50/day or 30 B50/month.

1. According to Technical Note 624
2. According to Technical Note 583

Monitoring	<p>For units purchased bearing a batch number earlier than 1526 (inclusive), the information below should be sent by e-mail to almedicalsystems.services@airliquide.com:</p> <ul style="list-style-type: none">- Distributor's name and address- Unit purchasing reference- Unit serial no.- Address of the site on which the unit is located- Measure implemented and date of implementation
Assistance	<p>For further information, contact customer services on +33 179 51 7000 Two technical notes can be requested by e-mail for implementing measures at: almedicalsystems.services@airliquide.com. They especially feature the pressure regulator inversion procedure (NT624) and the goose neck placement procedure (NT583)</p>

We hereby confirm that the relevant regulatory authorities have been informed of this safety alert.

Air Liquide Medical Systems implements a continuous device monitoring and improvement process, always aiming for quality and safety of the highest standard. Aware of the inconvenience this may cause, we would like to extend our thanks to you for reading this alert.

Yours Faithfully,

