

To our customers of

Atlan A300, Atlan A300XL

Atlan A350, Atlan A350XL

August 2021

Important Safety Notice

Artefacts on pressure and flow curve

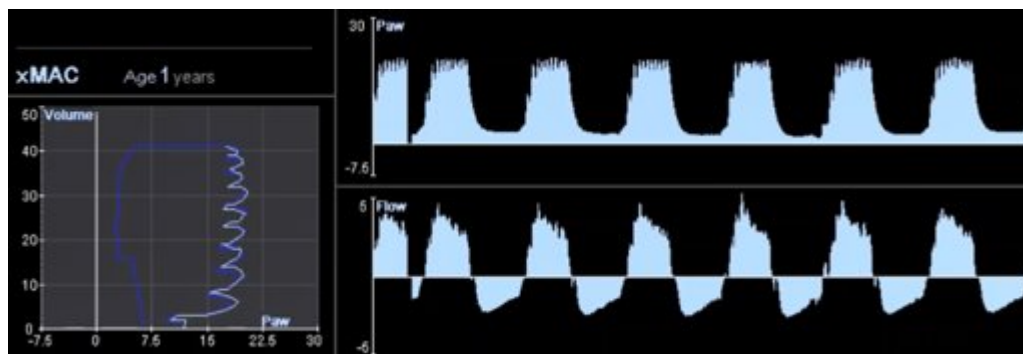
Only the following products are affected:

Atlan A300 (8621300), Atlan A300XL (8621400), Atlan A350 (8621500), Atlan A350XL (8621600), only devices with SW1.01 Build 63421 are affected.

Dear Sir or Madam,

During the course of our global market surveillance activities, we have become aware of very rare cases in which the Atlan Anesthesia Workstation with SW 1.01 has shown artefacts on the pressure and flow curves while the devices are being operated in one of the following ventilation modes: PC - CMV, PC - SIMV, PC - SIMV / PS, VC - CMV / Autoflow, VC - SIMV / Autoflow, VC - SIMV / PS / Autoflow, CPAP / PSV.

The other ventilation modes: VC – CMV, VC – SIMV, VC-SIMV / PS, Man/Spon are not affected.



Artefacts on pressure and flow curve

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT no. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Fiske
Anton Schrotner

Our investigation revealed that these artefacts occur only in rare combinations of certain resistance and compliance combinations of the whole system of e.g. filters, breathing hoses, ET-tube, patient lung and leakages. Although these artefacts are visible on the displayed pressure and flow curve and may be audible during auscultation, the pressure or flow spikes will not reach the patients lungs, due to the low pass filter effect of the resistance in the endotracheal tube and the upper airways.

However, we cannot exclude that the pressure and flow pattern shown on the display might cause confusion to the clinical user, potentially resulting in an improper therapy decision. As of today, no injury has been reported to Dräger in this context.

Dräger is currently working on a software update, which will remedy the issue. Your local Dräger representative will contact you as soon as the new software is available, in order to schedule the device update. The software update will be provided free of charge

Actions to be taken:

Until the software update is available you may continue using the device and affected ventilation modes, making sure that therapy decisions are not made based only on these artefacts.

Despite the visual artefacts on the pressure and flow curves and loops, the displayed readings for expiratory tidal volume and minute volume as well as all gas concentrations are always shown correctly.

Switching to one of the unaffected ventilation modes, will prevent occurrence of these artefacts.

Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward a copy of this information.

Please keep this information available to all users at least until the mitigation measure has been completed.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records you have received Atlan devices with SW1.01 Build 63421 manufactured by Drägerwerk AG & Co. KGaA that is affected by this issue. In order to identify the SW version installed on your device/s, you may enter the “System Setup” and click on “System Status”.

Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative.

We apologize for any inconvenience caused by this measure.

We thank you for your support.

With kind regards



Hans Ulrich Schüler
Global Product Management Anesthesiology
Business Unit Therapy
Drägerwerk AG & Co. KGaA]
(Single Registration Number: DE-MF-000005329)