

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To our customers of Dräger anesthesia workstation Atlan

December 2023

Urgent Safety Notice!

Possible shutdown of Dräger anesthesia workstation Atlan due to possible backup battery failures

Affected devices: Atlan A300 (8621300), Atlan A300 XL (8621400), Atlan A350 (8621500),
Atlan A350 XL (8621600) - all serial numbers affected

Update of the Urgent Safety Notice from November 2023

Dear Sir or Madam,

Within our market surveillance activities regarding our anesthesia workstation Atlan, we became aware of a few cases in which the internal backup battery failed spontaneously while the Atlan is being operated without mains power supply. This resulted in an unexpected shutdown of the device while it was running on batteries. The affected Atlan devices started with a battery status of 100%, but quickly shut down and did not trigger the alarm for low battery. A secondary acoustic alarm signal which is independent from mains and battery power supply was generated as specified. No patient consequences have been reported to Dräger so far.

If your backup battery fails while the Atlan is being operated without mains supply, the screen goes dark and mechanical ventilation ends.

Until the device shuts down the backup battery status may be indicated as 100% and the Atlan might not generate the specified alarms for low battery prior to shutting down. In any case, the Atlan will generate a secondary acoustic alarm signal.

It will be necessary to ventilate the patient manually to prevent from serious injury or death.

To do so, you may either use an emergency ventilation bag or apply manual ventilation with the Atlan as follows:

- **adjust a suitable flow via Flow valve (Atlan devices with mechanically controlled gas mixer) or via the emergency O2 feature (Atlan device with electronically controlled gas mixer),**
- **select a suitable vaporizer concentration if applicable,**

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- **adjust the APL-valve and**
- **ventilate the patient with the manual breathing bag.**

Our analyses indicate that short discharging-/charging cycles, for example caused by briefly disconnecting the device from the mains power supply repeatedly while it is on, might contribute to the observed behavior. The internal battery is designed to back up a loss of mains power supply only. Currently we are preparing a supplement to the Atlan instructions for use.

The following immediate actions need to be taken by you:

1) Perform a short test of the battery as follows

(Not necessary for brand-new Atlan devices):

- **Make sure the device has been connected to mains power supply for at least 8 hours to ensure a completely charged battery.**
- **Disconnect mains power supply.**
- **Operate the device in volume-controlled ventilation mode for 30 minutes with the following settings:
VT = 500ml / RR = 10/min / I:E = 1:1.5 / PEEP = 5mbar / FGF 10 L/min.**

The battery has successfully passed this test, if the device is operating without any battery related alarm for the entire 30 minutes. After the successful test please reconnect mains power supply.

If the test fails, please contact your local Dräger representative to arrange replacement of the batteries before using the Atlan.

2) Avoid short discharging/ charging cycles. Do not intentionally disconnect the Atlan from mains power supply when the device is switched on.

If you ensure that the device is constantly supplied with mains power while switched on, you do not need to repeat step 1.

In any case the battery needs to be checked by a service technician during the regular inspection and safety check every 12 months.

If you cannot ensure that the device is constantly supplied with mains power while switched on, repeat step 1 every three months.

Please ensure that all users of the Dräger Atlan devices and other persons within your organization are made aware of this information.

Please replace the initial Urgent Safety Notice from November 2023 with this one.

If you have provided the products to third parties, please forward a copy of this information.

Please keep this information at least until the supplement to the Atlan instruction for use is available.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records, you have received Atlan manufactured by Drägerwerk AG & Co. KGaA that might be affected by this issue.

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.

With kind regards



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