



To: Muscat

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 266.. dated 21/12/23 Regarding NCMDR Field Safety Corrective Action of Atlan from (mfr: Draeger Medical Systems Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Circular No. 266 / 2023

08 -06-1445 H

21 -12-2023

نتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman

Field Safety Corrective Action of Atlan from Draeger Medical Systems Inc

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19808
Product	Atlan.
Description	Anesthesia workstation
Manufacturer	Draeger Medical Systems Inc
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	Draeger anesthesia workstation Atlan .
Reason	Possible shutdown of anesthesia workstation Atlan due to Possible backup battery failures when is being operated without main supply (running on batteries).
Action	1. Please follow the immediate actions need to be taken in the attachment. 2. The supplement to the Atlan instruction for use will be released by Draeger. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General



Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

**To our customers of
Dräger anesthesia workstation Atlan**

November 2023

Urgent Safety Notice!

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

Dear Madam/Sir,

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 supply. This resulted in an unexpected shutdown of the device while it was running on batteries. The affected Atlans 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 was generated as specified. No patient consequences have been reported to Draeger 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**
- **adjust the APL-valve and**
- **ventilate the patient with the manual breathing bag.**

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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 Piske
Anton Schrofner

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

The following immediate actions need to be taken by you:

The Atlan is safe to use if you

- **avoid short discharging/charging cycles. If possible, do not intentionally disconnect the Atlan from mains when the device is switched on**

AND if you

- **perform a short test of the battery as follows:**
 - **Completely charge the battery for at least 8 hours.**
 - **Disconnect mains power supply.**
 - **Operate the device in volume-controlled ventilation mode for 30 minutes with the following settings:**
VT = 500ml / RR10 / I:E 1:1.5 / PEEP 5 / 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.

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

Repeat this test every three months.

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

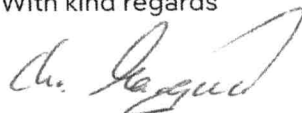
Identification of the affected medical devices:

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

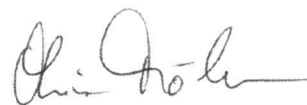
Contact:

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



Christoph Marquardt
Product Management
Business Unit Therapy



Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs