Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 266 / 2023

08 -05-1445 H
21 -12-2023

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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Dräger

Technology for Life

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.**

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
UID-Nr. 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 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