

Til vores kunder med
Dräger-anæstesiarbejdsstationer af typen Atlan

April 2026

Vigtig sikkerhedsmeddelelse!

Potentiel fejl i den automatiske respiration
på grund af en fejl i motorelektronikken

Det er KUN Atlan-anæstesiarbejdsstationer, der fremgår af bilaget, som er berørt.
Andre anæstesiapparater er IKKE berørt!

Kære kunde

Som en del af en korrigerende foranstaltning i oktober 2024 udsendte vi den **vedhæftede vigtige sikkerhedsmeddelelse** og udskiftede som en sikkerhedsforanstaltning respiratormotorer, der var blevet beskadiget af en midlertidig afvigelse i produktionsprocessen.

I forbindelse med vores løbende markedsovervågning har vi konstateret, at et begrænset antal yderligere Atlan-enheder er berørt af denne meddelelse fra oktober 2024, og som en sikkerhedsforanstaltning udskifter vi disse respiratormotorer.

Se venligst den vedhæftede **vigtige sikkerhedsmeddelelse** dateret oktober 2024 og listen over berørte Atlan-enheder.

Sørg for, at alle brugere af Dräger Atlan og andre berørte personer i din virksomhed er opmærksomme på denne vigtige sikkerhedsmeddelelse.

For bekræftelse bedes du udfylde det vedlagte svarkort og sende det tilbage til os inden for 14 dage.

Hvis du har delt produkterne med tredjeparter, skal du sende dem en kopi af nærværende vigtige sikkerhedsmeddelelse.

Opbevar denne vigtige sikkerhedsmeddelelse, indtil de berørte komponenter er blevet udskiftet. De kompetente myndigheder er blevet informeret om denne handling.

Identifikation af berørt medicinsk udstyr:

Ifølge vores registreringer har du modtaget mindst én Atlan-
anæstesiarbejdsstation, der er produceret af Drägerwerk AG & Co. KGaA
(europæisk fælles registreringsnummer DE- MF-000005329), som kan være
berørt af dette problem. Se venligst den vedhæftede liste over berørte Atlan-
enheder. Vores Dräger-serviceafdeling vil kontakte dig og aftale en tid til
udskiftning af respiratormotoren uden omkostning for dig.

Hvis du har spørgsmål, er du meget velkommen til at kontakte din lokale Dräger-
repræsentant. Vi beklager de gener, som denne foranstaltning måtte medføre for
dig.

Med venlig hilsen

Signe Koch

Signe Koch

QEHS Manager - Quality

Dräger Danmark A/S

Lyskær 9B

2730 Herlev

Bilag:

- **Vigtig sikkerhedsmeddelelse**
- **Liste over berørte Atlan-enheder**
- **Svarkort**

BILAG 1: VIGTIG SIKKERHEDSMEDDELELSE fra oktober 2024



Technology for Life

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To our customers with
Dräger Atlan workstations

October 2024

Important safety notice! Possible failure of the automatic ventilation due to an error in the motor electronics

**This only affects Atlan anaesthesia workstations with serial numbers
according to the attached list.
Other anaesthesia machines are NOT affected!**

Dear Sir or Madam,

In the course of our global market surveillance, we have become aware of cases in which the Atlan anaesthesia workstations either indicated a failure of the piston ventilator before use or suffered a failure of the mechanical ventilation during use. There have not been any reports of patient injuries to date.

Our investigations revealed that the cases are due to an error in the motor electronics, which was caused by a temporary deviation in the assembly process. This may have affected Atlan anaesthesia workstations with the mentioned serial numbers. According to our records, you have received one or more devices from the serial number range affected from us.

If the error occurs before use, e.g. in standby or system test mode, mechanical ventilation cannot be started. If the error occurs during a procedure, the mechanical ventilation may fail, and the device alerts the user by displaying the "Ventilator error!!!" message. Manual ventilation or spontaneous breathing remains possible in both cases. It may be necessary to manually ventilate the patient to prevent patient injury. With ongoing alarm of the ventilation failure the Atlan continues to provide the Man/Spon ventilation mode, fresh-gas and agent delivery as well as all monitoring functions without restriction.

Drägerwerk AG & Co. KGaA
Molsinger 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

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 7595 HL
UID-Nr. DE135082211

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefen Leuer

Executive Board:
Stefan Dräger (chairman)
Stefanie Hirsch
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner



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Our Dräger Service will contact you and arrange an appointment for replacing the motor, free of charge.

Until then, please continue operating your devices with the customary care by only using the device under permanent supervision in line with the Atlan instructions for use. If the mechanical ventilation fails, use Man/Spon ventilation mode to ventilate the patient manually as needed.

If necessary, you can downgrade the alarm priority of the "Ventilator error!!!" alarm with "ALARM RESET".

We regret any inconveniences this may cause.

Please ensure that all users of the Dräger Atlan as well as other persons concerned within your organization are made aware of this Important Safety Notice. Please complete and return the attached reply card to confirm this.

If you have made the products available to third parties, please forward a copy of this Important Safety Notice to them.

Please store this Important Safety Notice at least until the motor has been replaced.

The responsible authorities have been notified of this action.

Identification of affected medical devices:

According to our records, you have received at least one Atlan anaesthesia workstation manufactured by Drägerwerk AG & Co. KGaA that may be affected by this issue.

Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative. We apologise for any inconvenience this measure may cause.

Yours faithfully,

Christoph Marquardt
Product Management
Business Unit Therapy

Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs

BILAG 2:

Enhed	Artikelnummer	Basis-UDI DI
Atlan A100	8621100	040486751301035FK19X030W4
Atlan A100 XL	8621200	
Atlan A300	8621300	040486751301035FK19ZOOOW9
Atlan A300 XL	8621400	
Atlan A350	8621500	040486751301035FK19T010V2
Atlan A350 XL	8621600	

UDI'er for Atlan A100

(01)4048675594963(11)231025(21)ASSL-0427(93)8621100-04	(01)4048675594963(11)231107(21)ASSM-0033(93)8621100-04
(01)4048675594963(11)231108(21)ASSM-0029(93)8621100-04	(01)4048675594963(11)231107(21)ASSM-0034(93)8621100-04
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(01)4048675594963(11)231108(21)ASSM-0032(93)8621100-04	

UDI'er for Atlan A100 XL

(01)4048675594956(11)231025(21)ASSL-0422(93)8621200-04	(01)4048675594956(11)231108(21)ASSM-0028(93)8621200-04
(01)4048675594956(11)231108(21)ASSM-0027(93)8621200-04	

UDI'er for Atlan A300

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(01)4048675556183(11)231204(21)ASSM-0494(93)8621600-15	(01)4048675556183(11)230106(21)ASSA-0099(93)8621600-13

Respiratorsæt, produktion

Produktions-måned	Serienumre
01-2023	ASSA-... ...-0396, ...-0465
02-2023	ASSB-... ...-0224, ...-00233, 0768,0769
03-2023	ASSC-... ...-0653, ...-0666, ...-0670, ...-0711, ...-0721
04-2023	ASSD-... ...-0333, ...-0334
05-2023	ASSE-... ...-0003, ...-0008, ...-0009, ...-0011, ...-0041, ...-0057, ...-0059, ...-0060, ...-0064, ...-0099
06-2023	ASSH-... ...-0258, ...-0259, ...-0264-0268, ...-0270-0274, ...-0276, ...-0279, ...-0280

Svarkort

Returner venligst denne formular til din Dräger-repræsentant via fax eller e-mail!

D R Ä G E R	Til: < Udfyldes af relevante datterselskaber/forhandlere >
	Afdeling: _____
	Dräger repræsentant: _____
	Fax: _____
	Telefon: _____
	E-mail: _____

Titel: Supplement til vigtig sikkerhedsinformation vedrørende Dräger Atlan, april 2026

(Udfyld venligst)

K U N D E N S D A T A	Hospital: _____
	Kundens navn: _____
	Telefon: _____ Fax: _____
	E-mail: _____
	Adresse: _____
	Adresse 2: _____
	By/sted: _____ Land: _____
	Mængde af berørte enheder: _____

Vi bekræfter modtagelsen af sikkerhedsmeddelelsen, og at alle berørte brugere er blevet gjort opmærksomme på oplysningerne i denne.

(Udfyld og underskriv)

Titel/stilling: _____
Navn: _____ (Skriv med store bogstaver)
Underskrift: _____ Dato: _____