

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.

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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
UID-Nr. DE135082211

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefan Lauer

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

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

Attachment to Important Safety Notice – list of affected devices

Device	Model Number	Basic UDI DI
Atlan A100	8621100	040486751301035FK19X030W4
Atlan A300	8621300	040486751301035FK 19ZOOOW9
Atlan A300 XL	8621400	
Atlan A350	8621500	040486751301035FK19T010V2
Atlan A350 XL	8621600	

Atlan A100

Manufacturing Month	Serial Numbers	
01-2024	ASTA-...	-
02-2024	ASTB-...	0211
03-2024	ASTC-...	-
04-2024	ASTD-...	0285; 0286
05-2024	ASTE-...	0056; 0083; 0199; 0200; 0245; 0370; 0371; 0372; 0373; 0374; 0375
06-2024	ASTF-...	0155
07-2024	ASTH-...	0023; 0088; 0119; 0209
08-2024	ASTJ-...	-
09-2024	ASTK-...	0001; 0037

Atlan A300

Manufacturing Month	Serial Numbers	
01-2024	ASTA-...	0314; 0315; 0325; 0338; 0340; 0384; 0411; 0425
02-2024	ASTB-...	0002; 0010; 0018; 0151; 0160; 0161; 0165; 0175; 0176; 0177; 0178; 0179; 0180; 0181; 0182; 0214; 0215; 0218; 0232; 0233; 0234; 0235; 0236; 0248; 0249; 0250; 0262; 0263; 0264; 0265; 0266; 0276; 0277; 0278; 0279; 0280
03-2024	ASTC-...	0008; 0025; 0036; 0037; 0038; 0039; 0040; 0041; 0042; 0046; 0047; 0048; 0049; 0050; 0062; 0063; 0064; 0077; 0078; 0079; 0080; 0081; 0089; 0090; 0091; 0092; 0093; 0102; 0103; 0104; 0123; 0124; 0125; 0126; 0127; 0133; 0139; 0140; 0150; 0151; 0152; 0153; 0154; 0169; 0176; 0177; 0178; 0179; 0182; 0183; 0184; 0185; 0186; 0187; 0192; 0195; 0196; 0200; 0201; 0202; 0203; 0242
04-2024	ASTD-...	0028; 0051; 0052; 0080; 0081; 0082; 0083; 0084; 0085; 0086; 0087
05-2024	ASTE-...	0012; 0013; 0014; 0015; 0041; 0042; 0043; 0044; 0063; 0064; 0065; 0084; 0176; 0177; 0178; 0179; 0243; 0244; 0282; 0299
06-2024	ASTF-...	0005; 0006; 0019; 0027; 0028; 0029; 0048; 0049; 0050; 0072; 0073; 0074; 0075; 0082; 0093; 0110; 0111; 0162; 0166; 0167; 0197; 0198; 0220; 0221; 0222; 0301; 0406; 0434
07-2024	ASTH-...	0001; 0002; 0003; 0024; 0025; 0041; 0042; 0043; 0044; 0097; 0098; 0099; 0115; 0116; 0117; 0118; 0149; 0150; 0151; 0152; 0153; 0195; 0196; 0197; 0198; 0220; 0221; 0222; 0227; 0228; 0229; 0230; 0257;

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08-2024	ASTJ-...	
09-2024	ASTK-...	0033; 0034; 0035; 0062

Atlan A300 XL

Manufacturing Month	Serial Numbers	
01-2024	ASTA-...	-
02-2024	ASTB-...	0051; 0053; 0054; 0055; 0063; 0065; 0093; 0162
03-2024	ASTC-...	-
04-2024	ASTD-...	-
05-2024	ASTE-...	0219; 0220; 0221; 0222; 0377
06-2024	ASTF-...	0472; 0473
07-2024	ASTH-...	0005; 0006; 0026; 0027; 0047; 0186; 0223; 0224; 0401
08-2024	ASTJ-...	0170
09-2024	ASTK-...	-

Atlan A350

Manufacturing Month	Serial Numbers	
01-2024	ASTA-...	0279; 0293; 0302; 0303; 0304; 0306; 0334; 0335; 0336; 0344; 0347; 0348; 0360; 0369; 0373; 0375; 0376; 0377; 0379; 0380; 0381; 0386; 0389; 0390; 0392; 0393; 0399; 0412; 0422; 0433; 0435; 0437; 0438
02-2024	ASTB-...	0009; 0011; 0012; 0015; 0016; 0017; 0019; 0024; 0025; 0026; 0027; 0035; 0036; 0038; 0039; 0042; 0043; 0044; 0045; 0047; 0050; 0056; 0058; 0059; 0060; 0062; 0067; 0069; 0070; 0072; 0073; 0085; 0086; 0087; 0088; 0089; 0090; 0091; 0092; 0096; 0097; 0098; 0099; 0100; 0101; 0102; 0104; 0105; 0106; 0107; 0108; 0109; 0110; 0111; 0112; 0113; 0114; 0115; 0116; 0117; 0118; 0119; 0120; 0121; 0123; 0124; 0125; 0126; 0127; 0128; 0129; 0130; 0131; 0132; 0133; 0135; 0136; 0137; 0138; 0139; 0140; 0141; 0142; 0143; 0144; 0145; 0146; 0147; 0148; 0149; 0152; 0153; 0154; 0155; 0156; 0157; 0158; 0159; 0163; 0164; 0166; 0167; 0168; 0169; 0170; 0171; 0172; 0173; 0174; 0183; 0184; 0185; 0186; 0187; 0188; 0189; 0190; 0191; 0192; 0193; 0194; 0196; 0197; 0198; 0199; 0200; 0201; 0202; 0203; 0204; 0205; 0207; 0208; 0209; 0210; 0212; 0213; 0221; 0222; 0223; 0224; 0225; 0226; 0227; 0228; 0229; 0230; 0231; 0238; 0239; 0240; 0241; 0242; 0243; 0244; 0245; 0246; 0247; 0251; 0252; 0253; 0254; 0255; 0256; 0257; 0258; 0259; 0260; 0261; 0267; 0268; 0269; 0270; 0271; 0272; 0273; 0274; 0275; 0281; 0282; 0283; 0284; 0285; 0292; 0293; 0294; 0295; 0296; 0297; 0298; 0299; 0300; 0301; 0302; 0303; 0310; 0311; 0312; 0313; 0314; 0315; 0316

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04-2024	ASTD-...	0001; 0002; 0003; 0004; 0005; 0006; 0007; 0017; 0018; 0019; 0020; 0021; 0022; 0023; 0024; 0025; 0029; 0030; 0031; 0032; 0033; 0034; 0035; 0036; 0037; 0038; 0039; 0040; 0041; 0042; 0043; 0044; 0045; 0046; 0047; 0048; 0049; 0053; 0054; 0055; 0056; 0057; 0058; 0059; 0060; 0067; 0068; 0069; 0070; 0071; 0072; 0073; 0074; 0075; 0076; 0077; 0078; 0079; 0104; 0105; 0106; 0107; 0108; 0109; 0110; 0111; 0112; 0113; 0114; 0115; 0116; 0117; 0118; 0119; 0125; 0126; 0127; 0128; 0136; 0137; 0138; 0139; 0140; 0141; 0142; 0143; 0148; 0149; 0150; 0151; 0152; 0153; 0155; 0156; 0157; 0158; 0170; 0171; 0177; 0178; 0179; 0180; 0184; 0185; 0186; 0196; 0197; 0198; 0199; 0200; 0201; 0202; 0206; 0207; 0208; 0209; 0210; 0211; 0212; 0213; 0214; 0215; 0216; 0217; 0218; 0219; 0220; 0221; 0222; 0223; 0224; 0234; 0235; 0236; 0237; 0247; 0248; 0249; 0250; 0251; 0252; 0253; 0254; 0255; 0256; 0257; 0258; 0259; 0260; 0261; 0262; 0263; 0264; 0269; 0270; 0271; 0272; 0273; 0274; 0275; 0276; 0277; 0278; 0279; 0280; 0281; 0282; 0283; 0284
05-2024	ASTE-...	0001; 0002; 0003; 0004; 0005; 0006; 0007; 0008; 0009; 0010; 0011; 0018; 0019; 0020; 0021; 0022; 0023; 0024; 0025; 0026; 0027; 0028; 0029; 0030; 0031; 0032; 0033; 0036; 0037; 0038; 0039; 0040; 0045; 0046; 0047; 0048; 0049; 0050; 0051; 0052; 0053; 0054; 0055; 0061; 0066; 0067; 0068; 0069; 0070; 0071; 0072; 0073; 0074; 0075; 0076; 0080; 0081; 0082; 0088; 0089; 0090; 0091; 0092; 0093; 0094; 0095; 0096; 0097; 0098; 0099; 0100; 0101; 0102; 0103; 0104; 0105; 0106; 0107; 0109; 0110; 0111; 0112; 0113; 0114; 0115; 0116; 0117; 0118; 0119; 0120; 0121; 0132; 0133; 0134; 0135; 0136; 0137; 0138; 0139; 0140; 0141; 0142; 0143; 0144; 0145; 0146; 0147; 0148; 0149; 0150; 0151; 0152; 0153; 0154; 0155; 0156; 0157; 0158; 0159; 0160; 0161; 0162; 0167; 0168; 0169; 0170; 0180; 0181; 0182; 0183; 0184; 0185; 0186; 0188; 0189; 0190; 0191; 0192; 0193; 0194; 0204; 0205; 0206; 0207; 0208; 0209; 0210; 0211; 0212; 0213; 0214; 0215; 0216; 0217; 0218; 0227; 0228; 0229; 0230; 0231; 0232; 0233; 0234; 0235; 0236; 0237; 0238; 0239; 0240; 0241; 0242; 0251;

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07-2024	ASTH-...	0004; 0013; 0014; 0015; 0016; 0017; 0018; 0019; 0020; 0021; 0022; 0028; 0029; 0030; 0031; 0032; 0033; 0034; 0035; 0036; 0037; 0038; 0048; 0049; 0050; 0051; 0052; 0053; 0054; 0055; 0056;

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08-2024	ASTJ-...	0026; 0027; 0028; 0029; 0030; 0073; 0074; 0075; 0076; 0103; 0162; 0197; 0198; 0199; 0200; 0208; 0256
09-2024	ASTK-...	0003; 0004; 0005; 0006; 0007; 0008; 0009

Atlan A350 XL

Manufacturing Month	Serial Numbers	
01-2024	ASTA-...	0253; 0289; 0290; 0307; 0309; 0311; 0327; 0349; 0350; 0351; 0353; 0362; 0363; 0365; 0394; 0404; 0405; 0408; 0409; 0426; 0427; 0428; 0429; 0430
02-2024	ASTB-...	0003; 0005; 0007; 0028; 0029; 0030; 0031; 0032; 0033; 0048; 0075; 0076; 0077; 0079; 0080; 0081; 0082; 0083; 0084; 0134; 0195; 0206; 0219; 0220; 0237; 0286; 0287; 0288; 0289; 0290; 0291; 0304; 0305; 0306; 0307; 0308; 0309; 0317; 0318; 0319; 0320; 0321; 0322
03-2024	ASTC-...	0001; 0002; 0003; 0004; 0006; 0007; 0026; 0068; 0069; 0070; 0082; 0083; 0099; 0100; 0101; 0105; 0106; 0107; 0108; 0109; 0118; 0119; 0136; 0137; 0138; 0163; 0180; 0181; 0194; 0229; 0230; 0243; 0244; 0245
04-2024	ASTD-...	0008; 0009; 0010; 0011; 0012; 0013; 0014; 0015; 0016; 0050; 0061; 0062; 0063; 0064; 0065; 0066; 0129; 0130; 0131; 0132; 0133; 0134; 0135; 0154; 0159; 0160; 0161; 0162; 0163; 0164; 0165; 0166; 0167; 0168; 0169; 0181; 0182; 0183; 0193; 0194; 0195; 0203; 0204; 0205; 0225; 0226; 0227; 0228; 0229; 0230; 0231; 0238; 0239; 0240; 0241; 0242; 0243; 0244; 0245; 0265; 0266; 0267
05-2024	ASTE-...	0016; 0017; 0034; 0035; 0057; 0058; 0059; 0060; 0062; 0077; 0078; 0079; 0085; 0086; 0087; 0108; 0122; 0123; 0124; 0125; 0126; 0127; 0128; 0129; 0130; 0131; 0163; 0164; 0165; 0166; 0171; 0172; 0173;

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06-2024	ASTF-...	0001; 0002; 0003; 0004; 0014; 0015; 0016; 0017; 0018; 0030; 0031; 0032; 0033; 0034; 0035; 0036; 0037; 0051; 0052; 0053; 0054; 0055; 0061; 0062; 0063; 0070; 0071; 0076; 0077; 0078; 0079; 0080; 0081; 0112; 0113; 0121; 0122; 0123; 0124; 0125; 0135; 0136; 0137; 0138; 0139; 0140; 0141; 0168; 0169; 0170; 0194; 0195; 0196; 0409; 0410; 0411; 0435; 0436; 0437; 0438; 0471; 0474; 0475; 0476; 0477; 0478
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