Medicines & Healthcare products Regulatory Agency

DEVICE SAFETY INFORMATION (DSI)

Dräger Atlan Anaesthesia workstations: risk of ventilator failure (DSI/2026/005)

Specialisms: *Anaesthesia and intensive care, Theatre practitioners, Paediatrics and Neonatology, Emergency medicine*

DEVICE DETAILS

Atlan Anaesthesia workstations, models A 100, A 100 XL, A 300, A 300 XL, A 350 and A 350 XL.

The Atlan Anaesthetic workstations are used to deliver inhalational anaesthesia and/or provide ventilation during surgical or diagnostic interventions in adults, paediatric patients, and neonates.

AFFECTED LOT SERIAL NUMBERS

See **Field Safety Notice** for affected product codes.

MANUFACTURED BY

Drägerwerk AG & Co. KGaA

Summary

In April 2026, Dräger issued a follow-up Field Safety Notice (FSN) expanding the number of Atlan Anaesthesia workstation devices affected by a manufacturing defect that may result in piston ventilator failure before or during use. The FSN extends from a previous FSN issued in October 2024 concerning the same issue. Failure of mechanical ventilation may interrupt ventilation delivery and require immediate transition to manual/spontaneous ventilation. Dräger is correcting the affected devices and warning users of the risks and mitigations while corrective actions are being completed. As of 29 July 2026, the manufacturer reports no confirmed patient injuries or deaths associated with this issue.

Advice for Healthcare Professionals:

- identify whether your site uses Atlan Anaesthesia workstations and check if the devices are listed as affected in the FSN
- ensure Dräger replaces the motor assemblies in all your affected Atlan Anaesthesia workstations. Dräger will be in touch to arrange replacement of the motor assembly
- whilst waiting for Dräger to replace the motor assemblies, affected devices can continue to be used only with permanent supervision as per the instructions for use
- if mechanical ventilation fails, use manual/ spontaneous ventilation mode to ventilate the patient as needed
- if the error occurs during use, the mechanical ventilation may fail, and device alerts the user by displaying “Ventilator error!!!!”” with acoustic alarm. During ventilator failure the Atlan workstation will continue to provide:
  - manual/spontaneous ventilation mode
  - fresh gas and agent delivery
  - all monitoring functions without restriction
- clinical staff should make sure they are familiar with the device’s manual ventilation mode, and local protocols for ventilation failure, prior to use of the device
- monitor the patient’s condition continuously during the manual/spontaneous ventilation mode, for ventilation failure, to prevent potential significant injury
- once manual ventilation has been started in manual/spontaneous mode, the alarm priority of the “Ventilator error!!!” can be downgraded using “Alarm Reset” if required
- if the failure occurs, inform relevant staff and ensure the affected device is not used for any future procedures where mechanical ventilation may be required until it has been repaired
- ensure all users of the Dräger Atlan, as well as other affected people within your organisation, are made aware of this FSN
- keep a copy of the FSN accessible until the motor assembly is replaced for all your devices
- if you have made products available to a third party, ensure a copy of the FSN is forwarded to them
- complete the reply card at the end of the FSN and return this to your Dräger representative

Advice for Healthcare Professionals to Provide to Patients:

- no action is required by patients
- if you are concerned by this issue, please contact your healthcare professional

Advice for Distributors:

- there is no advice for distributors related to this DSI

Explanation of identified safety issue

The Atlan Anaesthetic workstations are used to deliver inhalational anaesthesia and/or provide ventilation during surgical or diagnostic interventions in adults, paediatric patients, and neonates.

Dräger has expanded their previous FSN issued in October 2024 to include additional Atlan Anaesthesia workstation devices affected by a manufacturing defect. This is due to a temporary deviation in the manufacturing process that may lead to ventilator piston failure before or during use. Interruption in the ventilation of a patient could lead to hypoxia and potentially death if not recognised and managed promptly.

If the error occurs before use e.g. in standby mode or system test mode, mechanical ventilation cannot be started. If the error occurs during use, the mechanical ventilation may fail, and the device alerts the user by displaying “Ventilator error!!!!”” and generating an acoustic alarm. Manual ventilation or spontaneous breathing remains possible in both cases.

If the device fails in use, it will be necessary to manually ventilate the patient to prevent injury. Clinical staff should ensure they are familiar with the device’s manual ventilation mode, and trust protocols for ventilation failure, prior to use of the device.

Dräger is 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. Dräger is not aware of any reports of patient injuries.

Dräger will replace the ventilator motor assembly for affected devices. Customers will be contacted by their local Dräger Service Representative to arrange a date for this replacement.

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures

Additional information:

You can sign up to receive email updates on alerts and device safety information from the MHRA.

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

Stakeholder engagement:

- NHS England National Patient Safety Team
- Incident Reporting and Investigation Centre (IRIC) for Scotland
- Welsh Government
- Medical Device and Estates Safety (MDES) within the Department of Health Northern Ireland