Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

August 2026

Summary of the latest safety advice for medicines and medical device users

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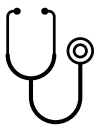


National Patient Safety Alert: ResMed Astral 100 and 150 Ventilators: Potential for Patient Harm due to Unexpected Interruption of Ventilation Therapy (NatPSA/2026/004/MHRA)

Access the full article

Specialisms: *Anaesthesia and intensive care, Care home staff, Critical care, Ear, nose and throat, Emergency medicine, Paediatrics and neonatology, Respiratory disease and allergy*

Device Details:

Astral 100 and Astral 150 ventilators and associated spare parts manufactured prior to October 2024. Use the FSN for identification of affected devices and corrective action instructions.

Summary

ResMed has issued a Field Safety Notice (FSN) regarding Astral 100 and 150 ventilators and associated Printed Circuit Board Assembly (PCBA) spare parts manufactured prior to October 2024. An internal supercapacitor may leak electrolyte, causing damage to specific circuitry of the PCBA and unexpected interruption of ventilation therapy.

If the issue occurs while the ventilator is delivering therapy, ventilation therapy stops immediately; a high priority audible alarm activates, and the user interface may display therapy alarms and a Safety System Fault red screen. If the issue occurs while the device is in standby, a maximum volume alarm activates, and the user interface message may

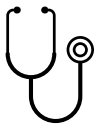
not be displayed. Once the fault occurs, the ventilator becomes inoperable and cannot be restarted. Alternative ventilation is required immediately.

Astral ventilators are used in hospital, community and home settings to provide life-sustaining ventilation for adults and children, including tracheostomy-ventilated, ventilator-dependent and mouthpiece-ventilated patients. Although the reported occurrence rate is low at 0.1% over the device service life of 8 years, interruption of ventilation may result in serious injury or death if an alternative means of ventilation is not immediately available.

Replacement PCBAs are currently subject to global supply constraints. ResMed cannot currently provide a definitive timeline for completion of corrective actions across all affected devices. Therefore, available replacements are being prioritised for patients according to highest clinical risk.

Organisations experiencing difficulty obtaining suitable replacement or alternative ventilators should escalate through local procurement arrangements and the DHSC National Supply Disruption Response (NSDR) service where appropriate at: nsdr@dhsc.gov.uk.

NOTE : Patients should not stop using their ventilator unless they are advised to do so by their clinical team and an alternative means of ventilation is available.



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

Access the full article

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.

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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.

Key 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

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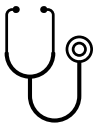
- if you have made products available to a third party, ensure a copy of the FSN is forwarded to them
- complete the reply card at the end of the FSN and return this to your Dräger representative

Key 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



Belzer UW® Cold Storage Solution and Belzer MPS® (UW Machine Perfusion Solution): manufactured by Carnamedica (UKRP: Bridge to Life): Updated advice on the contamination of fluid DSI/2026/006 (update to DSI/2023/005)

Access the full article

Specialisms: *Critical care, Endocrinology, diabetology and metabolism General surgery, GI, hepatology and pancreatic disorders, Haematology and oncology, Immunosuppression and transplantation, Infection prevention, Paediatrics and neonatology, Pathology, Renal medicine, Theatre practitioners, Urology and nephrology, Vascular and cardiac surgery*

Device Details:

Belzer UW ® Cold Storage Solution and Belzer MPS ® (UW Machine Perfusion Solution)

Summary

The MHRA is providing an update on defects previously identified with Belzer solutions. These included leakage and discolouration, resulting in fluid which was potentially contaminated and posed a risk of significant patient harm. This DSI replaces advice in DSI/2023/005, which should no longer be followed. Corrective action has been taken

by Carnamedica and Bridge to Life to resolve the issues identified and as a result the suspension to sales of the product has now been lifted. Healthcare professionals should follow the instructions detailed in this update when using these solutions during organ donation and transplantation procedures.

Key Advice for Healthcare Professionals:

In line with standard clinical processes, healthcare professionals should follow these normal routine steps when administering the product:

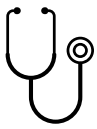
- identification and reporting of defective products
    - prior to use, each bag should be visually inspected for:
        - Discolouration – the fluid should be clear and transparent to slightly yellow (no more than Y6 according to the colouration scale in the current edition of Eur. Ph.)
        - Particulate matter – hold up to a light source for this check to be effective
        - Leakage – squeeze the bag firmly to check for leaks
        - Mould or contamination on the outside of the bags, especially around the connectors
    - bags with any of these defects should not be used
    - further guidance on pre-use checks can be found in the updated instructions for use provided with the Belzer UW® and Belzer MPS® (UW Machine Perfusion Solution) products
    - report any defects to Bridge to Life (Quality@B2LL.com), your national incident reporting authority (in England, Wales and Northern Ireland to the Yellow Card website or via the Yellow Card app; in Scotland to Incident Reporting & Investigation Centre (IRIC)), and through NHS Blood and Transplant (NHSBT)
    - quarantine defective bags and return them to the manufacturer for further investigation and testing
- routine use of products
    - when using bags without a visible product defect please continue to follow any local guidelines and procedures that govern the sampling and testing of fluid for microbial contaminants
    - as part of routine monitoring of patients who have received an organ preserved with Belzer UW® Cold Storage Solution or Belzer MPS® (UW Machine Perfusion Solution), healthcare professionals should be particularly alert to:
        - a transplant recipient developing an infection with an unusual organism or with an unusual antibiotic resistance pattern after

receiving an organ or cells from an organ preserved with the named Belzer solutions.
    - a transplant recipient developing unexpected vascular complications, including regional ischaemia, regional necrosis and delayed graft function after receiving an organ, or cells from an organ preserved with the named Belzer solutions.
- please report any events described above through both NHS Blood and Transplant (NHSBT) and your national incident reporting authority (in England, Wales and Northern Ireland to the Yellow Card website or via the Yellow Card app; in Scotland to Incident Reporting & Investigation Centre (IRIC))

Key Advice for Healthcare Professionals to Provide to Patients:

The advice in this DSI is aimed at the healthcare team responsible for providing and monitoring organ transplantation.

If you have any concerns, contact the specialist team who is responsible for your care.



Devices supplied without valid UKCA/CE conformity markings or certification: remove from use and place in quarantine (DSI/2026/007)

Access the full article

Specialisms: *General practice, General surgery, Pathology, Haematology and oncology, Theatre practitioners, Emergency medicine, Dentistry, Infection prevention, Pharmacy*

Device Details:

Device	Manufacturer
VAKU-8 Blood Collection / Infusion / Scalp Vein Set	Hindustan Syringes & Medical Devices Ltd
Bipson's Gauze Swab Sterile	Bipson Surgical Private Ltd
Technocut Scalpel	HMD Healthcare India Pvt. Ltd., (Formerly Niraj Industries Pvt Ltd.,)
Romsons Alco Swabs	Romsons Group Private Ltd

Medi Grip Adhesive Bandage (Antiseptic)	Precision Coatings (P) Ltd
Bone Marrow Biopsy Needle	Meditech Devices Pvt. Ltd.

Summary

The MHRA has become aware of a number of medical devices being supplied on the UK market that do not comply with the requirements of the UK Medical Device Regulations 2002 (UK MDR 2002) or with the EU Medical Devices Regulation (EU) 2017/745 (EU MDR). While the MHRA has not identified a specific defect or safety concern associated with these products, they do not meet the regulatory requirements for supply on the UK market, meaning assurance regarding their safety, sterility and performance cannot be fully guaranteed. The affected devices may be used in a variety of clinical settings, including blood collection and infusion, surgical procedures, biopsy procedures, wound management and skin preparation/ disinfection.

Key Advice for Healthcare Professionals:

- review whether your organisation holds, uses or supplies any of the devices listed in this DSI
- immediately stop using and supplying any identified product(s) and quarantine all remaining stock
- identify and use alternative compliant products
- retain affected devices pending further advice from the MHRA
- alert the MHRA that you are in possession of an affected device via devices.compliance@mhra.gov.uk quoting the DSI reference number (DSI/2026/007)
- providers should ensure all relevant members of staff receive this Device Safety Information (DSI) and that they understand the problem and actions to be taken
- report any suspected or actual adverse incidents involving these devices. There are specific reporting arrangements for healthcare professionals to follow in each region
- healthcare professionals should report incidents:
    - in England and Wales to the Yellow Card scheme or via the Yellow Card app
    - in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system

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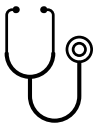
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures

Key Advice for Healthcare Professionals to Provide to Patients:

- there is no advice for healthcare professionals to provide to patients regarding this DSI



Rectal catheters sold for personal use (gas and colic relievers): Do not use in infants, including for the treatment of colic, gas-related discomfort or constipation (DSI/2026/008)

Access the full article

Specialisms: *General Practice, GI, hepatology and pancreatic disorders, Paediatrics and neonatology*

Device Details:

All rectal catheters sold for personal use (gas and colic relievers)

Summary

Do not use rectal catheters sold for personal use (gas and colic relievers) in infants, including for colic, gas-related discomfort or constipation. Stop using these products immediately and dispose of any unused devices. The MHRA does not recommend their use because there is insufficient clinical evidence to demonstrate effectiveness, and the potential risks associated with these products are unknown.

Please note this advice is not applicable for rectal catheters that are used for specialist medical treatment for conditions such as Hirschsprung's, meconium ileus and gastroschisis where parents/caregivers have been trained by healthcare professionals.

Rectal catheters sold for personal use (gas and colic relievers) are single use, hollow, plastic tubes with a stopper that are inserted into the infant's rectum (bottom) and are

commonly used by parents and caregivers to attempt to provide relief from gas-related discomfort.

If parents or caregivers have any concerns about their baby, they should speak to their healthcare professional.

Key Advice for Healthcare Professionals:

- advise parents and caregivers not to use rectal catheters sold for personal use (gas and colic relievers) in infants, including to treat colic, gas, bloating, or constipation and dispose of any unused products
- the use of these devices may delay diagnosis of serious gastrointestinal conditions, such as bowel obstruction or volvulus, by temporarily alleviating symptoms like gas without addressing the root cause
- the risks of rectal trauma, perforation, bleeding or pain associated with the use of rectal catheters in infants are unknown
- please refer to the NICE Clinical Knowledge Summary for information on the management of colic in infants
- report any incidents associated with the use of rectal catheters sold for personal use in infants to the MHRA via the Yellow Card scheme or via local reporting routes. For more detailed reporting instructions please see 'Reporting advice' below

Key Advice for Healthcare Professionals to Provide to Patients:

- do not use rectal catheters sold for personal use (gas and colic relievers) in your child, including to treat colic, gas, bloating, or constipation and dispose of any unused products
- the risks of injury to the infant's bottom (rectum), bleeding, pain or perforation (a hole in the bowel) associated with use of these devices in infants are unknown
- please refer to NHS guidance for the management of colic
- if you are concerned about your baby, it's best to speak to your health visitor, call NHS 111, see a GP, or call 999 in an emergency
- if you suspect that your child has had a side effect related to the use of rectal catheters sold for personal use (gas and colic relievers) report it to the MHRA via the Yellow Card website

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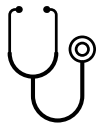

NGPod pH testing device: quarantine and dispose of all devices (DSI/2026/009)

Access the full article

Specialisms: *GI, hepatology and pancreatic disorders, General Surgery, Nutrition and dietetics, Paediatrics and neonatology*

Device Details:

NGPod handheld device and NGPod sensor

Summary

The NGPod handheld device and NGPod sensor, used to test pH to aid the placement of nasogastric tubes, is being withdrawn from the UK market. The manufacturer has ceased trading in the UK and cannot support continued use of the product. Users should quarantine all remaining stock and dispose of all NGPod devices.

While the cessation of trading is not directly related to a current safety concern, a Field Safety Corrective Action (FSCA) was initiated earlier this year, due to two UK adverse incident reports, including one with a fatal outcome. In these instances, the device provided a green result, indicating contact with acidic pH, suggesting that the nasogastric tube was correctly placed when, in fact, it was found in the lung.

The Field Safety Notice (FSN) provides further details and should be read in conjunction with this Device Safety Information (DSI).

Key Advice for Healthcare Professionals:

- stop use of the NGPod handheld device and sensor immediately
- identify, quarantine and dispose of all NGPod devices, as the manufacturer is unable to accept device returns
- return the FSN acknowledgement form to the manufacturer
- use alternate pH testing methods to inform placement of nasogastric tubes, in line with local and national guidelines. pH testing methods should be CE-marked and intended by the manufacturer to test human gastric aspirate
- review local stocks of alternative pH testing devices to ensure continuity of care
- report any suspected or actual adverse incidents involving these devices. There are specific reporting arrangements for healthcare professionals to follow in each region

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card scheme 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

Key Advice for Healthcare Professionals to Provide to Patients:

- there is no advice for healthcare professionals to provide to patients regarding this DSI as this DSI requires action by healthcare professionals only

Letters, medicines recalls and device notifications sent to healthcare professionals in August 2026

Direct Healthcare Professional Communications

We received notification that the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals in August 2026:

- Finasteride and dutasteride - Updated safety warnings for psychiatric side effects and sexual dysfunction
- ChloraPrep 2% w/v / 70% v/v cutaneous solution 1.5 mL Frepp presentation, chlorhexidine digluconate / isopropyl alcohol - Interim Supply of US Stock to Mitigate Supply Disruption in the UK
- Ventolin® Solution for Intravenous Infusion 5mg in 5ml (Salbutamol Sulfate): Interim Supply of Portuguese Stock to Mitigate Supply Disruption
- Fabrazyme 5mg powder for concentrate for solution for infusion (agalsidase beta), Fabrazyme 35mg powder for concentrate for solution for infusion (agalsidase beta), Nexviadyme▼ 100mg powder for concentrate for solution for infusion (avalglucosidase alfa) – intermittent supply distribution
- Fostair® 200/6 microgram pressurised metered-dose inhaler (pMDI) - Supply of batches without a dose counter
- ChloraPrep 2% w/v / 70% v/v cutaneous solution, 1.5 mL Frepp presentation, chlorhexidine digluconate / isopropyl alcohol - Interim Supply of US Stock to Mitigate Supply Disruption in the UK. *Sent to relevant stakeholders in July 2026*
- ChloraPrep 2% w/v / 70% v/v impregnated cutaneous swab (1.75 mL single swab sticks, supplied in packs of 48 units), chlorhexidine digluconate / isopropyl alcohol -

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Interim Supply of US Stock to Mitigate Supply Disruption in the UK. *Sent to relevant stakeholders in July 2026*

Medicine Recalls and Notifications

In August 2026, recalls and notifications for medicines were issued on:

Class 2 Medicines Recall: Zentiva Pharma UK Limited, Fingolimod Zentiva 0.5 mg Capsules, EL(26)A/37. Issued 20 August 2026.

Zentiva UK Pharma Limited are recalling one batch of Fingolimod Zentiva 0.5 mg Capsules (BN 4L01372H) as a precautionary measure due to a potential risk of contamination with metal particles.

Medical Device Field Safety Notices

Find recently published Field Safety Notices

Report suspected drug reactions and device incidents on a Yellow Card

Please continue to report suspected adverse drug reactions and device incidents. Your report will help us safeguard public health.

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates and particularly if a side effect continued or started after treatment was stopped.

Report a medicine

Healthcare professionals should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

Reporting for medical devices

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app

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- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)
- 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

Reporting for Patients

Report a medicine or medical device

Patients should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

News Roundup

Increased liver monitoring for sotorasib (Lumykras▼) patients with recent immunotherapy

Sotorasib is indicated for *KRAS G12C*-mutated non-small cell lung cancer (NSCLC) in patients who have progressed on platinum-based chemotherapy and/or anti PD-1/PD-L1 immunotherapy. Hepatotoxicity is a common side effect of sotorasib, and may lead to drug-induced liver injury

Following an update to the Summary of Product Characteristics (SmPC) for sotorasib, healthcare professionals should conduct more frequent liver function testing for patients who received immunotherapy recently (within 3 months) before starting sotorasib.

The update follows a review of clinical data, showing a higher incidence of hepatotoxicity in this patient group compared with those who started sotorasib more than 3 months after the last dose of immunotherapy, or who never received immunotherapy. Recent immunotherapy prior to starting sotorasib may also be a risk factor for interstitial lung disease (ILD).

Sotorasib should be withheld in patients with severe hepatotoxicity, or if ILD is suspected. For monitoring recommendations and dose modifications, refer to the SmPC for sotorasib.

Elranatamab: risk of progressive multifocal leukoencephalopathy

Progressive multifocal leukoencephalopathy (PML) is a recognised adverse reaction of elranatamab (Elrexfio). The MHRA has received 10 reports of PML with elranatamab as of 6 August 2026, including fatal reports.

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Patients should be monitored for any new onset of, or changes in pre-existing neurological signs or symptoms. If PML is suspected, treatment with elranatamab should be withheld and appropriate diagnostic testing initiated. If PML is confirmed, elranatamab must be discontinued.

Updated MHRA guidance on point of care testing

The MHRA has updated its guidance on the management and use of point of care testing (POCT) *in vitro* diagnostic (IVD) medical devices. Healthcare professionals involved in establishing or managing POCT services are encouraged to review the revised guidance, particularly the sections on incident reporting and accreditation.

The updated incident reporting section (4.12) provides clearer information on when incidents involving POCT devices should be reported to the MHRA, the reporting routes available across the UK, and the records that should be retained to support investigations and Yellow Card submissions. Healthcare professionals should ensure local reporting procedures align with this guidance.

The accreditation section (4.9) has also been revised to include updated information and links relating to UKAS accreditation under ISO 15189:2022. Organisations providing POCT services should review their current arrangements and consider how they meet the accreditation requirements highlighted in the guidance.

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