



MHRA SAFETY ROUNDUP

September 2026

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

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National Patient Safety Alert

Patient hoists and slings (all types): risk of death and serious harm from falls (NatPSA/2026/005/MHRA)

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The MHRA has conducted a review into the use of wireless cardiotocography (CTG) systems that use radiofrequency (RF) telemetry channels. Signal crossover, erroneous CTG traces and signal dropouts have been identified as patient safety risks associated with these devices. In rare circumstances, signal crossover may result in the fetal heart rate from one CTG monitor being displayed on another CTG monitor operating on the same RF channel. These risks may result in misinterpretation of CTG traces and inappropriate clinical decisions which could lead to adverse consequences.

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Device Safety Information / Drug Safety Update

Filters should be used during the administration of Parenteral Nutrition for patients in all care settings

Administration of parenteral nutrition without a filter has been associated with a number of adverse incidents including an embolism which resulted in a fatal outcome. Healthcare professionals are advised to use integrated or add-on filters during the administration of parenteral nutrition for patients in all care settings. All parenteral nutrition solutions should be administered via a filter with a pore size no larger than 1.2µm. Where available, it is good practice to administer aqueous/lipid-free parenteral nutrition solutions with a 0.2µm filter.

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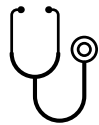
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**National Patient Safety Alert:
Patient hoists and slings (all
types): risk of death and serious
harm from falls
(NatPSA/2026/005/MHRA)**



[Access the full article](#)

Specialisms: Anaesthesia and intensive care, Care home staff, Critical care, Emergency medicine, Neurology, Orthopaedics, Pain management and palliation, Physiotherapy and occupational therapy, Radiology and imaging, Rheumatology, and Theatre practitioners

Device Details:

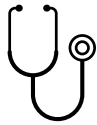
Patient hoists and slings (All types)

Summary

Fatal and serious harm continues to occur when patients fall from hoists or slings during transfers and repositioning. A review of recent incidents with a fatal outcome and wider surveillance data shows an average of two deaths per year since 2015. This is not confined to any manufacturer, model, or care setting. The most common causes of fatal and serious patient falls from hoists include:

- Detachment at critical load-bearing interfaces, including spreader bar hooks, clips, carabiners, fasteners, or other parts that are missing, worn, damaged or incorrectly assembled.
- Incompatible hoist and sling combinations, including use of third-party slings not validated for the specific hoist.
- Failure to identify damaged or incorrectly seated sling loops, or incorrect attachment to spreader bars during fitting and use.
- Failure to conduct effective pre-use checks that would identify unsafe equipment.
- Inadequate or overdue maintenance, servicing and examination under the [Lifting Operations and Lifting Equipment Regulations 1998 \(LOLER\)](#). This included continued use of a hoist or component parts beyond their indicated service life without risk assessment.
- Use of wrong size or type of sling for the patient.
- Insufficient staff training and competence assessment for the relevant hoist and sling types, including failure to follow correct manual handling procedures.
- Non-compliance with manufacturer's instructions for use (IFU)





Radiofrequency (RF) Safety Considerations for Wireless Cardiotocography (CTG) Monitoring Systems (DSI/2026/012)

[Access the full article](#)



Specialisms: pregnancy, Obstetrics and Gynaecology

Device Details:

Wireless cardiotocography (CTG) systems that use radiofrequency (RF) telemetry to monitor fetal heart rate (FHR) and uterine contractions

Summary

The MHRA has conducted a review into the use of wireless cardiotocography (CTG) systems that use radiofrequency (RF) telemetry channels. Signal crossover, erroneous CTG traces and signal dropouts have been identified as patient safety risks associated with these devices. In rare circumstances, signal crossover may result in the fetal heart rate from one CTG monitor being displayed on another CTG monitor operating on the same RF channel. These risks may result in misinterpretation of CTG traces and inappropriate clinical decisions which could lead to adverse consequences.

The risk relates to classic telemetry systems operating within the Industrial, Scientific and Medical (ISM) frequency band where a limited number of channels are available.

Actions for Healthcare Professionals including Clinical and Medical equipment management staff:

- ensure that two or more wireless CTG devices are not operating on the same RF channel unless there is sufficient distance between them to prevent signal crossover or interference (see under Operational Controls in the Actions for NHS Organisations section for further details). For example, in the absence of any obstacles such as walls or pillars, a distance of 100 metres may be required between two devices operating on the same RF channel to avoid signal crossover. Note that the wall between adjacent rooms may not be sufficient to prevent signal crossover. There is also the potential for signal crossover between floors. The Instructions for Use and/or manufacturer guidance should be consulted for device-specific advice on this matter



- verify CTG traces clinically at the commencement and throughout the period of monitoring. Ensure CTG traces correlate with other clinical features such as:
 - maternal pulse;
 - clinical assessment of fetal and maternal condition;
 - verification that displayed FHR belongs to the correct patient
- ensure access to a wired CTG system as a backup in the event of signal drop out or crossover
- ensure RF CTG transducers are correctly docked and paired to the base station
- prior to the commencement of monitoring, ensure correct transducer pairing
- ensure base stations and transducers are clear of gel after each use and prior to returning to the base station or charging rack
- report any suspected adverse incidents associated with these devices through the [Yellow Card website](#), or if in Scotland to [Incident Reporting & Investigation Centre \(IRIC\)](#)



Filters should be used during the administration of Parenteral Nutrition for patients in all care settings

Access the full [DSU](#) and [DSI](#) articles



DSU



DSI

Specialisms: Anaesthesia and intensive care, Cancer, Care home staff, Critical care, Emergency medicine, General practice, General surgery, GI, hepatology and pancreatic disorders, Haematology and oncology, Nutrition and dietetics, Paediatrics and neonatology, Pain management and palliation, Pharmacy

Summary

Administration of parenteral nutrition without a filter has been associated with a number of adverse incidents including an embolism which resulted in a fatal outcome. Healthcare professionals are advised to use integrated or add-on filters during the administration of parenteral nutrition for patients in all care settings. All parenteral nutrition solutions should be administered via a filter with a pore size no larger than 1.2µm. Where available, it is good practice to administer aqueous/lipid-free parenteral nutrition solutions with a 0.2µm filter.



Key Advice for Healthcare Professionals:

- parenteral nutrition is used to provide nutrients directly into the bloodstream bypassing the patient's digestive system
- administration of parenteral nutrition without a filter has been associated with adverse incidents, including an embolism which resulted in a fatal outcome
- ensure all parenteral nutrition solutions are administered using a filter with a pore size no larger than 1.2µm
- where the solution is aqueous/lipid free, it is good practice to use a filter with a pore size of 0.2µm during administration
- filters and administration sets should be changed with each new parenteral nutrition container, based on the parenteral nutrition shelf-life, local infection control policies, and filter shelf-life
- use of filters integrated into administration sets are preferred but add-on filters are a suitable alternative providing infection control guidelines are followed
- report suspected adverse reactions associated with parenteral nutrition on a [Yellow Card](#)

Key Advice for Healthcare Professionals to Provide to Patients:

- parenteral nutrition is used to provide nutrients directly into the bloodstream while avoiding the digestive system
- it is usually administered by a healthcare professional but may also be administered by patients or carers in the home after receiving the appropriate training
- filters should be used when administering parenteral nutrition to avoid any unwanted particles entering the bloodstream which may be harmful to the patient
- an integrated filter may already be part of your administration set, if it is not, an add-on filter will be required
- if you or your family member administer parenteral nutrition at home and an add-on filter is needed, you should be given appropriate training on this
- speak to your healthcare professional if you have concerns on the use of filters with your parenteral nutrition
- report suspected side effects to parenteral nutrition on a [Yellow Card](#)



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

Direct Healthcare Professional Communications

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

- [SOLIVITO N: reports of discolouration of individual vials and advice to inspect the product before use](#)
- [Tecovirimat SIGA▼ \(tecovirimat monohydrate\): restriction of indication due to lack of efficacy shown in randomised clinical trials in patients with mpox](#)
- [Asthalin 100 microgram Inhaler \(Salbutamol Sulphate\), PLGB 36390/0330 – Clarification of paediatric dosing information on the outer carton](#). Sent to relevant stakeholders in August 2026.
- [ALECENSA® \(alectinib\): Guidance for Management of Severe Hypertriglyceridaemia](#). Sent to relevant stakeholder in August 2026.
- [Erelzi▼ \(etanercept\) 50 mg solution for injection in pre-filled pen: Interim supply of stock containing the Danish Version of the Patient Information Leaflet](#)
- [Isturisa 5 mg film-coated tablets \(osilodrostat\) \[PLGB 15266/0030\]: Interim Supply of Polish, Romanian and Hungarian Language Stock to Mitigate Supply Disruption](#)
- [Isturisa 1 mg film-coated tablets \(osilodrostat\) \[PLGB 15266/0029\]: Interim Supply of Czech Republic, Slovakian and Slovenian Language Stock to Mitigate Supply Disruption](#)
- [Tyenne 162 mg solution for injection in Pre-filled syringe \(tocilizumab\): Interim Supply of Estonia/Lithuania/Latvia Stock to Mitigate Supply Disruption](#)
- [Avacopan Vifor \(previously known as Tavneos\) – suspension of use, sale, supply and offer for sale or supply due to unfavourable benefit–risk balance](#)

Medicine Recalls and Notifications

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

Class 4 Medicines Defect Notification: Martindale Pharmaceuticals Ltd, Clobazam Martindale Pharma 5 mg/5 mL and 10 mg/5 mL Oral Suspension 150ml, EL(26)A/38. Issued 17 September 2026.

Martindale Pharmaceuticals has informed the MHRA of an error with the linear barcode of some batches of Clobazam 5mg/5mL and 10mg/5mL Oral Suspension 150mL.



Class 4 Medicines Defect Notification: B. Braun Melsungen AG, Meropenem 1000 mg powder and solvent for solution for infusion, EL(26)A/39. Issued 23 September 2026.

B. Braun Melsungen AG has notified the MHRA that errors have been identified in the Patient Information Leaflet (PIL) included in some batches of Meropenem 1000 mg powder and solvent for solution for infusion.

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

Reporting for medical devices

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



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

Fluenz; be aware of increased risk of fainting following administration

The product information for [Fluenz](#) has been updated to reflect that there is an increased risk of syncope (fainting) immediately following administration of the nasal spray, particularly if the individual has previously fainted following vaccination. Procedures should be put in place to prevent injury from fainting and manage syncopal reactions. Due to timing constraints, this information is not included in the patient information leaflet for this season's campaign. Therefore, please ensure that parents and patients are informed of this potential risk before administration.

Intra-articular Steroid Injections: Reminder of the risks of Anaphylactic Reactions

Healthcare professionals who prescribe or administer intra-articular steroid injections are reminded that, although rare, anaphylactic reactions can occur following treatment (see the Summary of Product Characteristics for details). These injections are commonly used for the treatment of painful joints and tendons and remain a useful treatment option for patients requiring relief from joint pain.

Anaphylaxis can occur unpredictably after exposure to a wide range of medicines, including steroid injections. An individual's likelihood of experiencing a reaction can vary, and in some cases a reaction may occur only after repeated exposure to a medicine.

Patients receiving intra-articular steroid injections should be directed to appropriate patient information, including NHS guidance on the [side effects of hydrocortisone injections](#) and should be provided with a copy of the patient information leaflet. They should also be advised to call 999 or seek urgent medical attention if they develop symptoms suggestive of anaphylaxis after their injection, such as shortness of breath, swelling of the tongue or lips, or tightness in the throat.

Healthcare professionals administering these injections should ensure they are familiar with anaphylaxis protocols and the location of emergency adrenaline medication in their workplace. The [Resuscitation Council UK anaphylaxis algorithm](#) is available online.



Apalutamide and enzalutamide: laboratory test interference leading to falsely elevated digoxin plasma level results

Laboratory test interference has been identified in patients treated with apalutamide or enzalutamide, which may cause falsely elevated digoxin plasma level results when measured using the chemiluminescent microparticle immunoassay (CMIA) method. This can occur regardless of whether the patient is taking digoxin.

Apalutamide and enzalutamide are androgen receptor inhibitors indicated for the treatment of prostate cancer. Digoxin is a cardiac glycoside used to treat patients with certain types of heart rhythm problems and heart failure. Both apalutamide and enzalutamide share structural similarities with the portion of the digoxin molecule recognised by the CMIA, which may explain this assay-specific interference.

Healthcare professionals should interpret digoxin results obtained using CMIA with caution in patients taking apalutamide or enzalutamide. Elevated or unexpected results should be confirmed using an alternative assay method not affected by this interference before making decisions about digoxin dose adjustment or discontinuation. They should also consider reviewing previously reported test results.

Laboratories should consider adding an advisory comment to serum digoxin level reports.

The product information for apalutamide and enzalutamide has been updated to include this risk and is available on the [MHRA products website](#). The risk was also highlighted in a recent MHRA-agreed [safety communication](#) for enzalutamide.

Publication of flu vaccine factsheet

The MHRA has published a new flu vaccine factsheet, designed to provide information and guidance for patients, parents and carers on influenza (flu) and flu vaccination.

The factsheet outlines the safety and effectiveness of flu vaccines, who is eligible for vaccination in the UK, and the different types of flu vaccines available. It also provides information on flu vaccination during pregnancy, how flu vaccines are updated each year, and possible side effects.

This resource is available for healthcare professionals to use when discussing flu vaccination and to support patients, parents and carers in understanding flu vaccines and the protection they provide. For further details, view the full [Influenza \(Flu\) Vaccine Factsheet – Information for Patients, Parents and Carers](#).

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

