



DEVICE SAFETY INFORMATION (DSI)

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

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

AFFECTED LOT SERIAL NUMBERS

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

MANUFACTURED BY

Various manufacturers

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 \(IRIC\)](#)

Actions for Healthcare Providers:

Procurement:

- it is important that Clinical teams work with local Clinical Engineering teams in procuring the device and extensively assessing the physical environment. Purchasing more devices than the number of available RF channels could lead to signal crossover, irrespective of whether the devices are from the same or different manufacturers
- assess the local RF environment, RF channel availability and the number of wireless CTG devices required before purchasing wireless CTG systems. Examine local infrastructure suitability

Installation:

- ensure installation involves Maternity Services, Clinical Engineering (EBME), Digital Teams (IT Departments), Clinical Safety Officer and manufacturer representatives
- configure RF channels appropriately to minimise interference and crossover risk

Introduce and maintain a register containing:

- wireless CTG systems;
- RF channels;
- frequencies;
- bandwidth allocation;
- deployment locations;
- paired devices

The register should be introduced and maintained by EBME/Clinical Engineering staff.

After installation:

- label transducers;
- label base stations;
- clearly identify paired components;
- place labels on all devices showing the RF channel being used

Environment & Infrastructure:

- monitor the RF environment regularly, particularly when introducing new RF devices, after infrastructure changes and following incidents related to RF CTG signal crossover, erroneous traces and signal dropouts
- consider structural factors such as walls, layout, distance between devices on the same floor and different floors

Governance & Training:

- update local fetal monitoring and training policies to include RF risks and mitigation measures
- ensure competency training includes RF risks and mitigation for all CTG users

Operational Controls:

- 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 (consult the Instructions for Use and/or contact the manufacturer)
- ensure equipment is maintained appropriately by EBME/Clinical Engineering

- ensure proper cleaning of base stations, charging racks and transducers is carried out by Maternity Services
- limit access to RF channel settings where appropriate. Ensure access to a wired CTG system as a backup in the event of signal drop out or crossover

Explanation of identified safety issue

CTG is a standard method of monitoring fetal well-being by recording fetal heart rate (FHR) and uterine contractions during pregnancy and labour. Traditionally, CTG uses wired ultrasound and pressure sensors placed on the maternal abdomen. Wireless cardiotocography represents an evolution of this technology, enabling the same physiological measurements without tethering the pregnant woman to bedside equipment, thereby allowing greater freedom of movement during labour.

Wireless CTG systems sometimes operate using shared RF telemetry channels. If multiple devices operate within range using the same channel, signal crossover or interference may occur. For example, signal crossover or interference may occur between rooms on the same floor, between floors, during patient transfers or where devices are moved between clinical areas.

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.

Evidence from incident reports and stakeholder feedback has identified the following risks:

- **signal crossover:** devices capturing fetal heart rate from a different device where devices are operating on the same RF channel and are an insufficient distance apart
- **incorrect or inconsistent readings:** differences between displayed and actual fetal heart rate
- **signal persistence:** continued recording after transducers are removed
- **environmental effects:** RF interference can be influenced by building structure and layout
- **user and maintenance factors:** improper docking, insufficient cleaning after use or incorrect configuration

These combined factors can lead to misinterpretation of CTG traces, potentially resulting in inappropriate clinical decisions and harm.

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:

- NHSE Patient Safety
- Devolved Administrations: Scotland, Wales and Northern Ireland
- NHSE Chief Midwifery Information Officer
- NICE
- Clinical Engineering Network