



# Medical Devices Safety Update

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## Preventable alarm issues remain a major source of adverse event reports

Failure to generate alarms, inaudible alarms, or failure to trigger alarms continue to be major sources of adverse event reports received by the TGA.

One Australian hospital, in consultation with the TGA, recently undertook a review into its use of cardiocotographs (CTGs) following the death of a foetus.

The review found that a number of these devices in use at the facility had their alarms disabled.

A TGA investigation noted that a number of CTG devices on the market could have their default alarm settings to off or disabled. This would mean that if a situation warranting clinical attention developed, no clinical alarms would be generated to warn the clinician.

The TGA is continuing to investigate this issue and encourages hospitals and health professionals to review and test alarm generation capability and settings of all devices monitoring life-critical function.

### Advice for health workers and facilities

Health workers and facilities should:

- regularly test alarms on devices that monitor critical physiological parameters
- review the alarm settings of devices periodically to ensure they are correct and suit your needs

- review training and educational opportunities available to staff regarding alarms
- increase staff awareness of the implications of muting alarms and changing alarm settings
- avoid exclusive reliance on audio alarms
- be aware that some manufacturers have factory default alarms set to “off” or “technical alarms only” – these could cause a risk to users and patients if not reviewed
- be aware that issues can happen due to a defect with the device, especially with the speakers, an incorrect alarm setting, users muting the device or setting it off accidentally
- report any missed alarms or adverse events to the TGA.

### Advice for manufacturers and sponsors

Manufacturers and sponsors should:

- check that the default settings of their devices are designed and tested from the perspective of safety and that it needs to conform to Essential Principles.
- review the ability of users to mute alarms permanently
- report alarm-related issues to TGA
- ensure their post-market process appropriately trigger corrective and preventative action and correct any issues early
- ensure corrective action and recalls address all devices, not just newly manufactured units.

Medical Devices Safety Update is the medical devices safety bulletin of the Therapeutic Goods Administration (TGA)

## Review into cochlear implants and magnetic resonance imaging safety

The TGA has received a number of adverse event reports relating to cochlear implants and magnetic resonance imaging procedures.

Cochlear implants are small electronic devices that are used to stimulate the auditory nerve to provide a sense of sound to someone with profound hearing loss.

A cochlear implant has multiple parts including external parts consisting of a microphone and auditory processor as well as a transmitter. Other parts of the implant are located under the skin, including the receiver. The electrode or electrode array is inserted into the cochlea and stimulates the auditory (hearing) nerve. Magnets in both the internal and external parts of the implant allow them to connect and remain in place.

The TGA had received 18 Device Incident Reports relating to MRI safety and cochlear implants as of 9 March 2018. These reports concerned issues relating to the device's internal magnet dislodgement and reversal, subsequent surgeries to replace magnets, and pain and discomfort experienced by patients undergoing MRI while the internal device magnet is in situ.

Magnets in both the external and internal components of cochlear implants hold them in place.

### TGA actions

The TGA sought advice from the Advisory Committee on Medical Devices in February 2017

regarding the risks associated with MRI scans and patients with cochlear implants.

A post market review was conducted on all cochlear implants supplied in Australia to assess the current procedures and advice related to MRI scans and cochlear implants.

The TGA is currently working with sponsors of cochlear Implants to update the Instructions for Use and associated product materials. The materials provided with the cochlear implant should address and advise users and clinicians about the risks when having an MRI scan with a cochlear implant.

Any decision to authorise an MRI scan remains a medical decision balancing the risk of damage to the implant and possible pain and discomfort against the benefit of information provided by the scan.

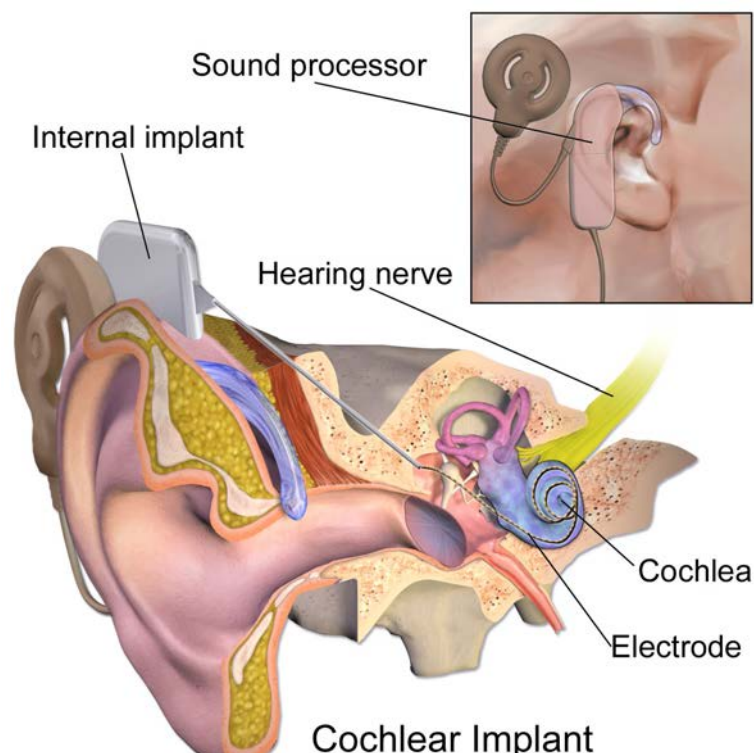


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## NHS cylinder alert

The United Kingdom's National Health Service (NHS) has issued a safety alert about risks associated with newer designs of oxygen cylinders.

The TGA has received reports relating to fire, leakage and broken valves and regulators but none for the [reported UK issues](#).

The NHS said insights from local investigations prompted the following advice for facilities to focus on: prioritising training for staff groups and clinical areas where the risk is high; reinforcing theoretical training with regular opportunities to practise operating the cylinder controls; linking safe operation of cylinder controls with other key safety issues, including fire hazards and how long a full cylinder will last; and placing laminated guides close to the point of use.

## Recent safety alerts

Below are TGA safety alerts relating to medical devices published since the last edition of *Medical Devices Safety Update*.

[Rite Aid Mini Digital Temple Touch Thermometer:](#)

Recall - potential risk of harm for children who access the button battery

[Puritan Bennett 980 Series Ventilator:](#) New suspension - Medtronic Puritan Bennett 980 Series Ventilator

[Therakos Cellex Photopheresis System:](#) Update: Therakos Cellex Photopheresis System Safety advisory – risk of blood clots

[TGA actions after review into urogynaecological surgical mesh implants:](#) Update - Stress Urinary Incontinence (SUI) mid-urethral slings



### What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies

- device interactions
- user/systemic errors

Suspected adverse events or near misses can be reported directly to the TGA:

- **online** at [www.tga.gov.au](http://www.tga.gov.au) (click 'Report a problem')
- **by emailing** [iris@tga.gov.au](mailto:iris@tga.gov.au)
- **by mail** to IRIS, TGA, PO Box 100, Woden ACT 2606
- **by fax** to 02 6203 1713

For more information about reporting, visit [www.tga.gov.au](http://www.tga.gov.au) or contact the TGA's Medical Devices Branch on 1800 809 361.

For the latest information from the TGA, subscribe to the TGA Safety Information email list via the TGA website

For correspondence or further information about Medical Devices Safety Update, contact the TGA's Medical Devices Branch at [iris@tga.gov.au](mailto:iris@tga.gov.au) or 1800 809 361

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