Safety Information 011/22

Issue date
25 November 2022

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
Medicine
Nursing and Midwifery
Sleep Laboratories
Respiratory Departments
All medical and surgical services
Paediatrics
Biomedical Engineers
Staff caring for patients at home on CPAP/BiPAP

Content reviewed by:
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Philips Respironics CPAP and bi-level masks containing magnets

Situation

Following consultation with the Therapeutic Goods Administration (TGA), Phillips is conducting an Urgent Product Defect Correction (RC-2022-RN-01171-1) of Respironics patient interface devices (face and nasal masks) that contain magnets.

These magnets have the potential to cause harm to patients with metallic implants, devices, or foreign bodies insitu, as they may interfere with the functioning of devices or induce the movement/dislocation of metallic material.

The below masks use magnets to secure the mask on patients receiving CPAP or bi-level therapy. The following Philips masks are affected:

Amara View Full Face Mask	DreamWisp Nasal Mask	DreamWear Full Face Mask	Wisp and Wisp Youth Nasal Mask	Therapy Mask 3100 NC/SP

Background

Magnets with a magnetic field strength of 400mT are used in the masks. This has the potential to interfere with medical implants, medical devices, and foreign bodies in patients.

To date there have been no incidents reported in Australia; however, internationally there have been 14 reported cases of patient harm.

The current labelling on these devices has warnings related to magnets.

Assessment

The use of the mask is **contraindicated** for patients and their household members, caregivers, and bed partners that have implanted devices that may be affected by magnets, including but not limited to:

- Pacemakers
- Implantable cardioverter defibrillators (ICD)
- Neurostimulators
- Magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher (i.e. neck and head)
- CSF (cerebral spinal fluid) shunts (e.g. ventriculo peritoneal shunt)
- Aneurysm clips
- Embolic coils
- Intracranial aneurysm intravascular flow disruption devices
- Metallic cranial plates, screws, burr hole covers, and bone substitute devices
- Ocular implants (e.g. glaucoma implants, retinal implants)

- Certain contact lenses with metal
- Implants to restore hearing or balance that have an implanted magnet (such as cochlear implants, implanted bone conduction hearing devices, and auditory brainstem implants)
- Magnetic denture attachments
- Metallic gastrointestinal clips
- Metallic stents (e.g. aneurysm, coronary, tracheobronchial, biliary)
- Implantable ports and pumps (e.g. insulin pumps)
- Hypoglossal Nerve Stimulators
- Devices labelled as MR (magnetic resonance) unsafe
- Magnetic metallic implants not labelled for MR or not evaluated for safety in a magnetic field
- Metallic splinters in the eye

Planned updated contraindications and warnings on labels will strengthen messaging about potential interference.

Clinical Recommendations

- The affected masks should be kept at least 15cm away from a metallic implant(s) or device(s), which includes patients, their household members, caregivers, and/or bed partners.
- No action is required for patients, household members, caregivers, and bed partners who do not have any contraindications.
- Risk assess patients who use affected face/nasal masks to determine if they have any of the listed contraindications.
- Advise patients using the affected magnetic masks to STOP if they have any of the listed contraindications, and consult their prescriber/supplier. In the interim, switch to a non-magnetic mask if available, for continuation of therapy. Patients should dispose of the mask that has magnets after an alternative is obtained.
- Inform patients of the potential risk of magnetic interference when they are prescribed/supplied a mask with magnetic properties. Clinicians should distribute information about all masks with magnets to patients commencing therapy or during review (a Fact Sheet is under development by the Agency for Clinical Innovation).
- Patients should be advised to contact their prescriber/supplier for more information on non-magnetic mask options.

A copy of the Philips FAQ can be found here for further information.

Required actions for the Local Health Districts/Networks

- Distribute this Safety Information to all relevant clinicians.
- Ensure there is a process for risk assessment and escalation for patients who are using these devices.
- Provide families/carers with information and education on safe management and use of affected devices, as required.
- Report any incidents associated with these devices into ims+ and TGA.