Position Statement and Practice Guidance

Audiological assessment and hearing aid provision for patients with a programmable ventriculo-peritoneal (PVP) shunt

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General foreword

This document presents Practice Guidance by the British Society of Audiology (BSA). This Practice Guidance represents, to the best knowledge of the BSA, the evidence-base and consensus on good practice, given the stated methodology and scope of the document and at the time of publication.

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Comments on this document are welcomed and should be sent to:

British Society of Audiology
Blackburn House,
Redhouse Road
Seafield,
Bathgate
EH47 7AQ
Tel: +44 (0)118 9660622

bsa@thebsa.org.uk
www.thebsa.org

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Authors

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Key Authors:

John E FitzGerald	Norfolk & Norwich Universities Hospital NHS Trust
Guy Lightfoot	ERA Training & Consultancy Ltd
Siobhan Brennan	University of Manchester; Sheffield Teaching Hospitals
Verity Hill	University Hospital of Coventry
Soumit Dasgupta	Alder Hey Children's NHS Foundation Trust, Liverpool
John Day	Betsi Cadwaladr University Health Board, North Wales

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- Declaration of interests by the authors: None declared

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Shared Decision-Making

It is implied throughout this document that the service user should be involved in shared decision-making when undertaking audiological intervention, receiving subsequent information and understanding how it will impact on the personalisation of care. Individual preferences should be taken into account and the role of the clinician is to enable a person to make a meaningful and informed choice. Audiological interventions bring a variety of information for both the clinician and the patient which can be used for counselling and decision-making regarding technology and anticipated outcomes.

Contents

1. Abbreviations

FDA	Food and Drug Administration (American Government Agency overseeing safety including medical devices)
G	Gauss (a measure of magnetic field strength; 1 G = 0.1mT)
mT	milli-Tesla (The SI unit of magnetic field strength)
PTA	Pure-tone audiometry
PVP Shunt	Programmable ventriculo-peritoneal Shunt
SI unit	The International System of units

2. Introduction

2.1 Background and aims

A ventriculo-peritoneal (VP) shunt is a surgically implanted device in the ventricle of the brain which can be fitted to patients of all ages as a treatment for hydrocephalus to drain excess CSF from the brain to another part of the body. There are two types of commonly used VP shunts: Programmable shunts (PVP shunts) and non-programmable shunts (non-PVP shunts). PVP shunts have a magnetically adjustable valve placed under the skin, which is often on or near the mastoid bone to allow the shunt to be adjusted by an external control magnet if required. Appendix 1 lists some common makes.

However the magnetic valve is also susceptible to other external magnetic fields and if activated inadvertently by an external magnetic field this can trigger the shunt to adjust, cause a change in intracranial pressure which in turn may lead to a life threatening situation. The magnetic field strength[1] required to adjust the valve setting varies between different types of PVP shunts. Some adjustable valves can be readjusted by relatively weak fields. A study by Zuzak et al., 2009 found the Strata valves could be readjusted by magnetic fields ranging from 0.4mT to 13.8mT with a median of 4.7mT and the Codman Hakim valves by magnetic fields ranging from 2.4mT to 153mT with a median of 30.5mT. Newer valves (Polaris, ProGAV, ProSA, and Certas) have mechanisms intended to prevent accidental readjustments, even in MRI machines (up to 3T).

Non-PVP shunts are not susceptible to this risk.

[1] The strength of a magnetic field can be measured as magnetic flux density (B), which represents the number of magnetic field lines penetrating an area (1m^2) perpendicular to it. The unit of magnetic flux is the Tesla.

Manufacturers of all PVP shunts recommend caution around external magnetic fields and that all products with magnets are kept at least 5cm from the implant site. This is because magnetic field strength decreases significantly with a small change in distance. For example a decorative refrigerator door magnet may have a magnetic field strength of 100 mT at the magnet surface, but 0mT at 5cm, an iPad smart cover 206mT at its surface and 0.13mT at 5cm. This is supported by the FDA who suggest keeping products that contain magnets at least 2 inches (5.08cm) from the PVP shunt valve.

Given the above, any magnetic field generated by an audiological device or equipment that reaches the PVP shunt programming levels (when measured at 0mm distance) poses a risk.

This position statement aims to highlight the potential risks posed by audiological equipment and hearing aids to patients with PVP shunts and to provide recommendations to minimise such risks.

2.2 Scope

The previous version of this document provided examples of magnetic field strengths emitted by some audiological equipment and highlighted potential risks posed by hearing aids and hearing aid ancillary devices to patients with PVP shunts. This current document does not set out to provide details for specific equipment and what is safe or not safe. Readers are advised to consult with both PVP shunt manufacturers to identify safe levels of magnetic flux for specific shunts and with audiological equipment suppliers/hearing aid companies to establish magnetic field strengths emitted by specific equipment.

3. What audiology procedures pose a potential risk to the operation of a PVP shunt and how can the risk be avoided?

Earphones (supra-aural and circum-aural), insert earphones, ear muffs/cups, bone conductor transducers, otoacoustic emission probes, tympanometer transducers, conventional hearing aids, bone osseointegrated hearing devices and cochlear implants, all contain magnets which emit an external magnetic field (even when not in use) and their use should therefore be considered with caution when dealing with a patient with a PVP shunt. This should apply to all audiology clinics; for example, including adults and children seen for hearing assessment and rehabilitation, hearing therapy and those seen in vestibular assessment clinics which may also use similar transducers. Evidence from the literature that earphones and other devices can influence PVP shunts is presented in Appendix 2.

Previous versions of this guidance presented magnetic field strength measurements from a range of commonly used transducers in Audiology departments. These measures imply that earphones have the potential to affect a PVP shunt if positioned directly over the site of the shunt, but do not pose a risk if kept 5cm from the shunt at all times. As this is unlikely to be possible for the testing of an ear on the side of a shunt, the use of such earphones on the side of a shunt must be considered a risk.

The B71 and B72 bone conduction transducers do not reach the median levels at which the PVP shunts referenced in this document are triggered but given some shunts were adjusted by levels as low as 0.4mT the margin of safety is small so this guidance currently adopts a cautious approach.

All conventional hearing aids emit a magnetic field, and both the specific internal components and other ancillary equipment they are used with should be considered in relation to the potential risk to alter the performance of a PVP shunt.

Pierson et al (2017) showed that some osseointegrated hearing aids the magnetic field strength at 5cm did not represent any risk to PVP shunt operation, but others had a considerably higher magnetic field strength and additional caution was required. It is not advised that a single approach is adopted when using these devices.

The magnetic discs used in cochlear implants have a high magnetic field strength at their surface and some at 2cm.

Where the presence of a PVP shunt restricts the ability to achieve a comprehensive audiological assessment or compromises the ability to provide optimal amplification this needs to be discussed with the patient / carer and the neurosurgical team.

4. Recommended action

4.1 Audiology assessment

Prior to audiology assessment all subjects should be asked if they have a PVP shunt and which make and model it is. If they do have a PVP shunt the following is advised unless the tester is certain the make and model is not prone to magnetic field strengths emitted by the transducers being used. In other words, the following transducers should not be used unless specific reassurances have been received from the transducer manufacturer that it is safe to do so.

Do not place the following transducers on or near the ear with the PVP shunt valve, unless these have been validated as safe by the manufacturer;

- Supra-aural or circum-aural earphones (this also includes AABR earcups)
- Bone conductors[2]
- Otoacoustic emission probes
- Tympanometer transducers

[2] For adult PTA the bone conductor can be placed on the forehead, as long as this is 5cm from the mastoid with the PVP shunt and correction factors applied as defined in BS EN ISO 389-3. For newborn ABR diagnostic testing the forehead placement is not recommended as there are no known correction values for a forehead bone conduction placement and the effect on threshold determination is unknown.

Ear inserts can be used, but a cautious approach is recommended by keeping the transducer part at least 5 cm from the mastoid containing the shunt valve at all times.
Bone conduction testing can be performed on the ear contralateral to the PVP shunt valve.

Babies with a PVP shunt should not undergo newborn hearing screening and should be referred directly to the local Audiology service for ABR testing using inserts.

Children with a PVP shunt should not undergo school hearing screening with earphones and should be referred directly to the local Audiology service for testing using inserts.

4.2 Hearing aid fitting

Services should seek manufacturers' advice regarding the magnetic field strengths emitted by the range of hearing aids they prescribe, with particular attention to hearing aid ancillary equipment, such as magnetic switch activators.

Prior to hearing aid fitting all subjects should be asked if they have a PVP shunt. If they do, the following is advised:

- Avoid a hearing aid fitting (conventional, osseointegrated or cochlear implant) to the side with the shunt valve if possible.
- Explore options to re-locate the hearing aid where viable.
- Consult with the specific shunt manufacturer and hearing aid manufacturer to identify the safe level of magnetic field strength and to establish the potential risk.
- Do not implant a Sophono osseointegrated hearing aid on the side of a PVP shunt
- If a decision is taken to proceed with an osseointegrated hearing aid or cochlear implant on the same side as a PVP shunt it should be at least 5 cm from the shunt valve.

4.3 Recommended action if a transducer with a potential to affect a PVP shunt setting has been placed near the site of the shunt.

Inform the patient or carer that there is a possibility that the shunt settings may have been affected by placing the transducer/hearing aid near the shunt. They will be familiar with the symptoms of shunt malfunction to look out for (see appendix 3) and if they experience any symptoms they should be advised to see their neurosurgical team immediately. Contact the neurosurgical team as soon as the error is realized and follow their advice.

If there is uncertainty about which type of shunt a patient has, a cautious approach should be adopted and the advice regarding PVP shunts should be followed.

4.4 Suppliers

Manufacturers of equipment used in any audiology assessment and rehabilitation clinic, including hearing aids and associated worn equipment, should routinely provide information on magnetic field strengths. This requirement should also feature in procurement of equipment by services and agencies.

Appendix 1. Common manufacturers of PVP shunts

Codman-Hakim and the Codman Certas ™ programable valve (Codman Integra)
Strata adjustable valve (Medtronic Neurologic Technologies)
Polaris adjustable valve (Sophysa)
Miethke proGAV (Aesculap Inc)
Sophy adjustable valve (Sophysa)

Appendix 2. Evidence from the literature that earphones and other devices affect PVP shunts

In *in vitro* experiments, Spader et al (2015) demonstrated that Apple earbuds, Beats by Dr. Dre, and Bose QuietComfort Acoustic Noise Cancelling earphones all reprogrammed the Strata™ II and Codman-Hakim PVP shunts at 0mm to the shunt valve when the earphones were rotated 180° on the valve. The Bose earphones reprogrammed the valves when brought into contact with them. However above a distance of 5cm none showed magnetic field strengths above the manufacturers' recommended levels. Zuzak et al (2009) demonstrated that magnetic toys could alter the settings on Strata and Codman valves.

A case report of a Programmable Strata™ II valve being maladjusted by a hands-free wireless communication device worn by a nurse in a hospital environment when it was inadvertently brought close to a baby's head demonstrates the potential dangers of external magnetic fields influencing programmable shunt valves (Fujimura et al 2018).

Appendix 3. Common symptoms with PVP shunt malfunction

Vomiting with little or no nausea.
A constant, unrelieved headache.
Vision problems, such as blurry, double vision, or loss of vision.
Irritability.
Fatigue.
Personality changes (not acting like your normal self).
Loss of coordination or balance.
Swelling, redness, or both, along the shunt path.
A bulging soft spot on an infant's head.
Difficulty waking up or staying awake.
Decrease in school performance.

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