MRI Generic Implant Safety Policy (GISP): Detailed review

Title: Cerebrospinal Fluid (CSF) Shunt Valves

Executive summary

Date detailed review completed: *'not important for now, these are placeholders as a reminder that this should be set. Will likely be recorded in document quality system if available or set by local board'*

Date of current review: 04/09/2020

Date of next review: Annually/ pending new information.

Version code: *'as per comment above'*

Introduction

Generic benefits of generic implant safety policies for MRI

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Ensuring the safety of patients undergoing MRI is of paramount importance. An appreciable portion of the population has medical implants or devices and in many cases an individual patient may have multiple implants. Identifying every patient implant can be difficult for a number of reasons and the purpose of the GISP's is to review specific categories of implants such that general statements of safety can be made. Key benefits of GISP's are as follows:

- Facilitates scanning when implant information is not readily available.
- Speeds up scanning when implant information takes some time to obtain.
- Avoids unnecessary cancellations.
- Reduces resources required to obtain and evaluate specific implant information

Generic risks of generic implant safety policies for MRI

'Generic text to be added, ignore for now'' (This may come out of this document on webpage)

It should be noted that generic implant safety policies and their use are not without risk. Some of the risks involved are listed below

- Newly developed unsafe implant
- Previously unrecognised unsafe implant
- Failing to identify a specific patient implant has the potential to mis-identify an implant due to some misunderstanding
- Updated safety information that adversely changes the safety status of an implant might take some time to filter through to the GISP

Clinical context of the 'insert implant / device category'

'Briefly outline the clinical use of the implant/device category. This might include but is not limited to: details of the function of the implant or device, implant procedure, implant materials commonly used, clinical cohorts where the device is typically used'

Cerebrospinal Fluid (CSF) shunts are implanted to treat patients with hydrocephalus [1] – a condition which results in the accumulation of CSF in the ventricles of the brain affecting 4-6 people per 1000 [2]. Shunt systems aid in restoring the balance of CSF. A basic shunt system comprises of a proximal ("ventricular") catheter which is connected to a distal catheter via a one-way pressure valve (see Fig. 1). The proximal catheter enters the ventricle space through a burr-hole in order to suction out excess CSF. The remaining parts of the shunt system are subcutaneously implanted and therefore entirely extracranial. The distal catheter extends from the valve to an absorption site, such as the peritoneal space/abdominal cavity (as in Fig. 1), pleural space or right atrium, where it is reabsorbed. More than 95% of catheters use medical grade silicone, a few polyurethane or intracranial metal tubes [3]. The shunt valve directs the flow of CSF away from the brain and regulates the pressure and flow rate [4]. Typical placement of the shunt valve is on top of the head or just behind the ear [1].

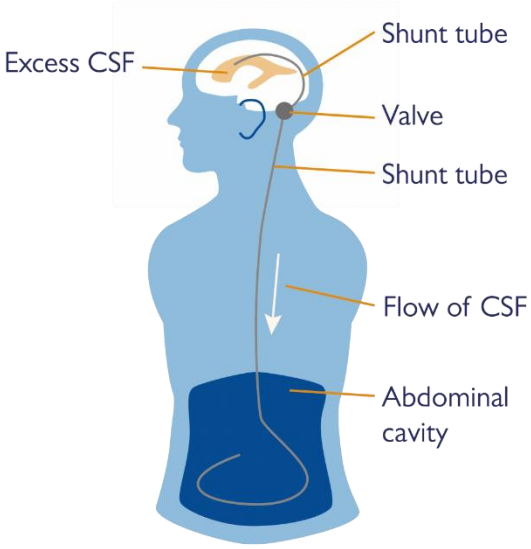


Figure 1. A basic shunt system [32].

A wide range of shunt designs and configurations exist [5] [3] [6]. A bewildering multitude of shunt components, secondary to the shunt valve and catheters, are offered by various manufacturers. Internal accessories include reservoirs, siphon control devices/gravitational units, connectors, pumping chambers and filters [6].

Reservoirs/pumping chambers can be felt through the skin and are located in the proximal part of the shunt system or may be a part of the valve design. They allow fast access to ventricular CSF for diagnostics and for therapy, e.g., perform ICP measurements or inject drugs into the brain.

Connectors are made of plastic or stainless steel and are short pieces of tubing used to connect catheters (i.e., in the distal part of the shunt system due to the long length of catheter that may be required) or connect catheters with valves/internal accessories (see Fig. 2).

Figure 2. Different types of connectors used in shunt systems [6].

The siphoning effect means that some shunt valves will result in overdrainage of CSF when the patient is in the upright position. Anti-siphon devices (other synonyms include siphon control device (SCD) or gravitational unit/valve) have been developed to circumvent this complication and similar to reservoirs, may be included in the valve design or as a standalone internal accessory.

Many different designs of shunt valves exist which reflects efforts, throughout the 1900s and into the 21st century, to overcome shunt complications and improve treatment results. Essentially there are two different types of shunt valves: fixed/mono-pressure ("non-programmable") and adjustable ("programmable").

Fixed pressure valves drain at a pre-defined rate (low, medium or high pressure) which is defined by the opening pressure of the valve [5]. If this opening pressure is not suitable, there will be over or under-drainage of CSF and a neurosurgeon will have to surgically revise the shunt valve [7]. Programmable valves mitigate this invasive procedure by allowing the neurosurgeon to non-invasively adjust the valve setting using an externally applied (magnetic) programming tool. The tool utilises a

strong magnetic field and thus shunts of this valve type can be susceptible to environmental magnetic fields – patients are typically asked to stay away from sources of magnetic fields such as magnetic toys [8]. These valves must be re-adjusted by a clinician requiring the patient to make a routine appointment with their implant clinician [1]. The appearance of programmable valves on a skull X-ray will manifest differently for different types and can help inform the valve setting.

Unlike non-programmable CSF shunts, programmable valves comprise of magnetic components which communicate with the external device to alter the valve settings.

Typical implant materials for programmable CSF shunts include stainless steel, tantalum and titanium.

Outline the challenge / issue from a MRI unit context in dealing with the 'implant / device category'

'Briefly outline the challenge MRI units may face when patients present with these implants'

The challenge which MRI units may face when patients present with a CSF shunt valve is determining whether the valve is programmable or non-programmable which will affect the circumstances under which an MRI scan can proceed.

Hypothesis

'You may wish to make a statement here which you can later refer back to in regard to your initial impression on the general MRI safety status of this implant category'

- Programmable CSF shunt valves are MRI Conditional up to 3T; non-programmable CSF shunt valves are generally deemed MR Safe or MR Conditional up to 3T.
- The catheter system (comprising of a proximal and distal catheter), included in the design of CSF shunt systems to divert excess CSF away from the brain to an absorption site through the shunt valve, do not contain any metallic components and are therefore always MR Safe.
- All external accessories to a CSF shunt valve (e.g. programming tools used to adjust valve settings, tools used to make pressure measurements/ evaluation of CSF) are considered MR Unsafe and thus prohibited from entering the MR Environment.

Aim

The aim is to provide a detailed review from all available sources in regard to the MRI safety status of both programmable and non-programmable CSF shunt valves. This is with a view to creating the basis to inform subsequent risk assessments on this topic. This will in-turn be used as the basis for guidance and safety policies to be used by Radiology staff to inform decisions on performing MRI scans on patients with these implants or devices.

Methods

A range of MRI safety resources will be reviewed with the aim of gathering as much information as possible in regard to the MRI safety status of programmable and non-programmable CSF shunt valves. As far as possible, detail should be included on search terms used and time periods reviewed such as to allow provenance of the information to be established and if necessary, replicated or audited at a later date.

Results

Review of MRI implant safety databases

'Review the MRIsafety.com website for an overview of the safety status of the implant category of concern as well as recording publications discussing incidents or injuries as a result of the implant category under review.

A review of www.mrisafety.com highlights the following:

- Number of MR Unsafe CSF shunt valves: 1 non-programmable
- Number of MR Conditional CSF shunt valves: 17 programmable and 1 non-programmable
- Number of MR Safe CSF shunt valves: 19 non-programmable
- Number of MR Unsafe internal accessories: Cerebral ventricular shunt tube connector (type unknown)

The search terms used to capture the above number of CSF shunt valves includes: "shunt valve", "pressure valve", "adjustable valve", "shunt system", "gravitational valve", "programmable valve". These implant devices are listed under the safety topic "*Cerebrospinal Fluid (CSF) Shunt Valves and Accessories*." The website recognises the many different types of CSF shunt valves exist and that those containing magnetic components, i.e. programmable valves, must be scanned under specific safety guidelines.

All programmable CSF shunt valves fall under MR Conditional scanning up to 3T for which the conditional statements vary according to whether the valve settings must be checked pre- and post-MRI.

All non-programmable valves, with the exception of the *CODMAN Hakim Precise Pressure Valve, Sophysa monopressure valve* and the *Holter Valve (Holter Co.)*, are labelled as MR Safe owing to the absence of magnetic and/or metallic components. The MR conditions of the *CODMAN Hakim Precise Pressure Valve* match those of the *Codman Hakim Programmable valve* except there is not requirement for pre and post MRI checks:

- MRI can be performed at any time after implantation
  - Use an MR system with a static magnetic field of 3-T or less
  - Use an MR System with a spatial gradient of 720 gauss/cm or less
  - Limit the exposure to RF energy to a whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes (per pulse sequence)
- MR image quality may be compromised if the area of interest is relatively close to the device. Distortion may be seen at the boundaries of the artifact. Therefore, optimization of the MR imaging parameters may be necessary.

The *Holter Valve (Holter Co.)* is a non-programmable valve which has been labelled as MR Unsafe to which the work of Go *et al* [7] has been referenced and is discussed in the "Review of the peer reviewed literature" section of this GISP.

The *Hakim Valve* is a non-programmable valve which appeared on mrisafety.com in Jan 2020 as MR Unsafe but has since been removed from the list.

The work of New *et al* [9] has been referenced to the MRI Unsafe labelled unnamed ventricular shunt tube connector and is discussed in the "Review of the peer reviewed literature" section of this GISP.

Review of manufacturer implant information

'Include here information on manufacturer implant documentation such as the MRI safety statements from the instructions for use (IFU) documents.'

4 major company manufacturers of CSF programmable and non-programmable shunt valves include: Aesculap (Tuttlingen, Germany), Codman (Raynham, Massachusetts), Medtronic (Minneapolis, Minnesota) and Sophysa (Orsay, France).

Medtronic Non-Programmable Valves:

"Non-adjustable valves such as Delta™ and CSF-Flow Control Valves do not contain any metal materials. They are considered MR Safe in accordance with ASTM F2503."

Integra LifeSciences Non-Programmable Valves:

Codman Hakim Precision Fixed Pressure valve: "*The valve unit contains components made from titanium and 316L stainless steel. When tested with MRI magnets of up to 1.5 Tesla, the valve produced an insignificant amount of force and torque. This shunt system, as with other implants containing metallic components, may produce an artifact during MRI. The requesting physician must determine whether the location of the artifact will affect the area of interest."*

For all other fixed pressure valves on the current Integra LifeSciences website (Contour Flex Hydrocephalus Valve, Integra DP Valve, Ultra VS Valve, Pudenz Valve, Mishler & On/Off Valve), the following statement is made about the composition of the valves: *"made of materials that are known not to interfere with CT scans or MRI imaging."*

Aesculap-MIETHKE Non-Programmable Valves:

On the Aesculap website, the company state that all their MIETHKE valve "*are made using titanium. Titanium was selected because of its excellent MRI and bio-compatibility*."

Sophysa, Orsay Non-Programmable Valves:

Sophysa currently advertise 2 mono-pressure valves: The Sophy Mini SM1 and the Pulsar. The Pulsar is stated to be a "*Burr-Hole type, non-metallic membrane valve, safe for MRI."* For the Sophy Mini SM1, the company states: *"It has the small size, the shape of the Sophysa Adjustable Valves and is made of the same material."* The Sophysa Adjustable Valves are MR Conditional up to 3T.

Review of the peer reviewed literature

'Review the peer reviewed scientific literature for evidence of publications relating to the MRI safety status of the implants of concern as well as publications discussing incidents or injuries as a result of the implant under review.

The most current review on CSF shunts and technologies was conducted in 2018 [2] which gives results from a PubMed literature search as well as company brochures and websites, covering both previously and currently available programmable and non-programmable shunt valves. This review states that, for fixed differential pressure valves: "*The benefits are a lack of components that may impact MRI*." Furthermore, notes that the PS Medical Delta, the Codman Hakim Precision Valve and the Aesculap MIETHKE are the most commonly used non-programmable valves. The Codman Hakim Precision Valve (DePuy Synthes) has been noted for its difficulty in determining the valve pressure setting and frequent requirement for adjustment hence is less common compared to variable pressure valves.

Fixed differential pressure (non-programmable) valves first came into clinical use in the 1950s, the shunt design typically containing a ball and flat metal spring mechanism [2]. The first shunt was manufactured by John Holter in 1955 – the Holter Shunt (Holter Co.) [10]. The Holter shunt is a non-programmable valve (listed on mrisafety.com) that has shown "weaker ferromagnetism" when compared with neurosurgical aneurysm clips under 1.5T MRI safety testing in the 1989 study conducted by Go et al [7]. This is the only evidence, to date, in the literature to explain the MR Unsafe labelling of this shunt type. Suggested in the paper by Boockvar et al [11], the Holter Shunt may also go by the name of Spitz-Holter – Spitz being the neurosurgeon who provided John Holter with the criteria to engineer the first ever shunt. MRI scanning of this shunt valve has been documented on the internet and is considered in the "*Internet Search"* section of this detailed review. The radiology of the Spitz-Holter shunt has also been discussed in a 1973 article in the British Journal of Radiology which states that this valve was "probably most widely used" [12]. X-rays are provided which show the construction of the valve and the case where the valve may be combined with a Rickham reservoir – lending itself the name "Rickham-Holter valve".

The Hakim shunt (non-programmable) was also tested by Go et al [7] and was also described, with the Holter shunt, as exhibiting "weaker ferromagnetism". New et al [9] had also tested the ferromagnetic properties of the Hakim valve in a prior study (year of 1983). Testing was conducted at 0.147T and 1.44T – no measurable ferromagnetism was recorded.

Papers, which report patient case studies on unusual long-term shunt-valve complications pertaining to the Holter valve and Hakim valve, reveal the proximal parts of the two types of valve are metallic and connected by a silicone casing [13] [14] [15]. According to source [15], newer Holter type valves exist which are *"completely covered with plastic"* suggesting a non-metallic design. A Holter valve for adults, a Holter valve for children and a Hakim valve for adults are mentioned in source [14] along with their X-rays.

Other fixed differential pressure valves (non-programmable) reported in the literature include the Holter-Hausner valve (Codman Shurtleff, Randolph, Mass., USA) and Heyer-Schulte (Heyer-Schulte del caribe, McGraw Park, Ill., USA) which were implanted in the 1980s and 1990s [16] – there is no information in the literature relating to their MRI safety. However, clinical evidence exists which suggests these devices (along with other Holter type valves) are safe to scan and has been mentioned in the "Empirical Evidence" section of this detailed review.

To cover every possible internal accessory would be impossible but there are sources of information which summarise the typical shunt components and their material composition [6] [5] [17]. The most utilised material in a shunt system is silicone rubber but other materials may be used and are detailed in Table 1.

Biomaterial	Shunt part
Silicone Elastomer	Catheters, valve housings, suture clamps, siphon devices
Polypropylene/ Polysufone/ Nylon/ Polyethersulfone	Valve housing/seats, needle stops, connectors, reservoirs
Ruby/Sapphire	Valve pins, balls, seats
Titanium/ Stainless Steel	Valve housings, needle stops, springs
Tantalum	Radiopaque markers
Barium	Radiopaciofier

Table 1. Biomaterials typically used to manufacture CSF shunt valves/ accessories [6] [5] [17].

Table 1 highlights that the material which poses an MRI safety related risk is stainless steel. Depending on the alloy, stainless steel can have magnetic properties and therefore pose an unacceptable risk in the MRI Environment. New *et al*. [9] conducted testing on an unnamed right angle stainless steel ventricular shunt tube connector at 0.147T and 1.44T (see Fig 3a). The result was "measurable ferromagnetism" – no further details or quantification was provided. This shunt component has been labelled MRI Unsafe on mrisafety.com (as detailed in section "Review of MRI implant safety databases"). Other testing, at 1.5T, has highlighted a ventricular shunt catheter with metal connector (Cordis Co., Miami, FL, USA) to exhibit "evident" ferromagnetism and "slight" image distortion (see Fig 3b) [7]. Again, no further details or quantification was provided.

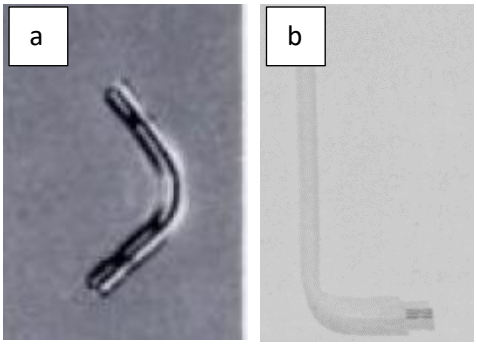


Figure 3. (a) Right angle stainless steel ventricular shunt tube connector. (b) Ventricular shunt catheter with metal connector (Cordis Co., Miami, Fl, USA).

No further evidence in the literature can be found to suggest that other components of shunt systems would be contraindicated in the MRI Environment. However, radiographic visualisation may falsely allude to internal accessories being comprised of metal because of their radiopaque appearance. Catheters, and similarly reservoirs, are two examples of internal accessories which may be impregnated with radiopaque material (e.g., barium) or have radiopaque markers (e.g., tantalum) added for ease of radiographic visualisation [5].

This section of the detailed review has not highlighted any patient incidents/injuries relating to the MR scanning of a non-programmable CSF shunt valves.

The aforementioned review paper [2] provides information on the following programmable valves: Codman Hakim Programmable Valve, the Medtronic Strata Valve, the Sophy Programmable Pressure Valves and the ProGAV (Aesculap MIETHKE). The first programmable valve introduced into clinical practice were the Sophy programmable valves in the 1980s which contain micromagnets of cobalt-samarium. These shunts are currently advertised as being resistant to magnet strength up to 3T – this may be explained by the ability to always be able to interrogate the valve settings and subsequently reprogram the valve after MRI induced change to its settings [18] [19] [20]. Testing of the Sophy valve model SM8 has shown that its settings changed at 5mT when exposed to a homogeneous static magnetic field [21].

The Codman Hakim Programmable Valve and the Medtronic Strata Valve both incorporate a ball and magnetic rotor into their design. The CODMAN Hakim Programmable Valve (also named the Programmable Codman Medos Shunt) specifically consists of a ruby ball and 316L flat stainless-steel spring. Adjustment of the opening pressure is achieved by raising the spring on a spiral polyethersulfone staircase using an external handheld magnetic device. The Codman Hakim valve can be scanned at no more than 3T MRI but the valve must be immediately readjusted post MRI to prevent adverse complications such as altered valve setting or permanent disability of the valve [18] . A drastic change in valve setting can be detrimental to the patient resulting in, e.g. subdural hematoma. In one paper, testing of the Codman Hakim programmable valve found it to only be affected in a non-homogeneous field at 15mT – the current manufacturer IFU for this shunt valve states that the valve setting should be verified after the MRI procedure [22]. The same recommendation for immediate readjustment post MRI is given for the Medtronic Strata Valve [20] [19] – this valve includes two

adjustment tools used for pre-operative and post-operative adjustment. The Medtronic Strata II programmable valve and the Codman Hakim programmable valve has been tested in close proximity to magnetic toys which demonstrated that the external magnetic field was sufficient to induce adjustments in the valve setting [23].

The Miektke ProGAV valve differs from other programmable valves in its unique design and possible implantation site [2]. The valve consists of an adjustable unit and then a separate compartment that houses a non-adjustable gravitational Shunt Assistant. This shunt device can be implanted in the chest as opposed to the head so long as the Shunt Assistant is positioned parallel to the longitudinal axis of the body to minimise/eliminate siphoning effects. Testing of the ProGAV has shown that the valve settings are not altered by multiple exposure to 3T MRI [4] and was deemed MR safe in another study [24] owing to its brake mechanism – this avoids unintended readjustments to the pressure level due to exposure of external magnetic fields.. These results are reflected in the current manufacture IFU which does not ask for valve settings to be checked post-MRI [25].

It has been recognised that programmable shunts may be categorised according to whether the design includes a locking mechanism - this has important safety implications relating to its use in MRI [10]. A key difference between programmable shunt valves of older and newer models is an in-built locking mechanism which prevents adjustments to the valve settings by external magnets other than the programmer device provided by the manufacturer – 2nd generation programmable shunt valves have this functionality incorporated into their design. 1st generation programmable shunt valves have no locking mechanism. This locking mechanism thus explains why some programmable shunt valves do not suffer MRI induced setting alterations such as the ProGAV with its brake (locking) mechanism. Table 2, extracted from [10], lists 1st (no locking mechanism) and 2nd generation (include locking mechanism) programmable shunt valves which have been tested at 3T MRI: the 1st generation shunt valves experienced changes in valve settings after repeated 3T MRI exposure but no change to the programming mechanism. The valve settings of the 2nd generation shunts were not altered by the repeated MRI exposure and the ability to be reprogrammed was retained. All the valves mentioned in Table 2, except the Sophysa Polaris, have been previously discussed in this section. The secure valve settings of the Sophysa Polaris have been demonstrated in several published reviews [19] [26] [23] but the current manufacture IFU still requires pre and post MRI checks [27].

The manufacturer Aesculap (Miethke) have introduced a programmable shunt assistant, ProSA, which may be implanted alone or in addition to a fixed differential pressure valve. The ProSA has been developed to resolve overdrainage of CSF in shunt-dependent patients when in the upright position by impeding CSF flow to a prescribed opening pressure range. The authors in [28] demonstrated the ProSA to be MR Conditional up to 3T with no unintended changes in valve settings and no impairment of the brake mechanism – this brake mechanism is also incorporated into the design of the ProGAV

Valve	Locking mechanism (Y/N)	Manufacturer's information
Codman Medos®	N	Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham, MA, USA
Medtronic Strata® NSC	N	Medtronic, Inc., 710 Medtronic Parkway, NE Minneapolis, MN, USA
Codman Certas®	Y	Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham, MA, USA
Sophysa Polaris®	Y	Sophysa USA Inc., 760 West 16th St., bldg. N, Costa Mesa, CA, USA
Miethke proGAV®	Y	Aesculap AG, Am Aesculap-Platz, 78532 Tuttlingen,

Table 2. List of externally programmable shunt valves [10].

previously mentioned. The ProSA is composed of small embedded permanent magnets, like all other CSF shunt technology, which lost their functional capability at 7T MRI.

Metallic induced artefact is a concern for both non-programmable and programmable CSF shunts which are of metallic design. The maximal area of metallic artefacts (cm^2) has been reported for the following programmable shunt valves: Codman Medos (Hakim), Medtronic Stata, Codman Certas, Miethke ProGAV and Sophysa Polaris [10]. The results showed that T1-weighted spin-echo sequences produces the least artefact whilst Gradient echo sequences produced the greatest artefact. Metal artefact has also been attributed to the Hakim and Holter (non-programmable) valve as demonstrated by New et al [9] and Go et al who showed the result was image distortion appearing as dents in the forehead [7], respectively. For all shunt valves of metallic design, the location of the artefact should be considered with respect to the area of interest.

Review of the SMRT MR Technologist mail base

'Review the SMRT MR Technologist mail base for evidence of incidents or injuries as a result of the implant under review and also any information on the MRI safety status of this implant type'

Discussions on the SMRT MR Technologist mailbase are mostly concerned with non-programmable CSF shunts – the emails noted here are from 2008 and 2011.

In 2008, a shunt valve from 1972 was queried:

"We have a pt with a VP shunt from 1972. The shunt was subsequently trimmed back to the dura in 1992. The shunt appears to be non-metallic except the tip. Of course no OP report available. No programmable valve or connector seems apparent. Can shunt's like this with

just the tip being metallic be safely scanned on 1.5 or is this still a big red flag? Also pt's family claims he had an MRI some yrs back w/o being able to tell us where it was done."

The response to this was a paper which references the Hakim Valve [9] and a paper which references the Holter valve [7] – these has been discussed in the Peer Literature Review section of this detailed review.

In 2011, a discussion was held around the Codman Hakim Precision Valve:

"The information I need is to show that "Codman Hakim precision valve with right angle reservoir and Siphonguard, operating pressure 70+/- 10mm H2O fixed pressure, Ref No 82-5483 serial NG6715" is not only MRI safe, but is not of the programmable type and therefore we can go ahead and scan this patient."

Dr Frank Shellock responded with:

"According to Mr. Matthew King at Codman, "This valve system is essentially identical to the programmable valve only without programming mechanism. Materials and configurations are otherwise identical. Thus there is no need for re-programming after exposure in MR."

The materials for the Codman Hakim Programmable valve have been discussed in the Peer Literature Review section of this detailed review.

The Holter valve has gained much interest on the mail base over recent years, discussions from 2008-2015 are presented here:

"…we just caught a Rickham-Holter Shunt (SS) from Codman # 82-1621 in a 34 year old patient. According to Codman, these have not been MRI safety tested and they sent me a company memo stating they don't recommend scanning."

There was no response to this email.

"…The pt has a Holter valve Ventriculo-Peritoneal Shunt, placed for hydrocephalus in 1977. We don't have any surgical reports but a neurologist said its safe to scan and is compatible. What do you think about scanning this pt?... We don't have any other information on this implant."

There was no response to this email.

"*60yr old sedated pt came for Mri Brain w/wo…she has a Holter 70 shunt, 25 yrs ago, that is all op report said. Pt had a brain Mri 2 yrs ago on 1.5 tesla Mri…no artifact from shunt."*

To which Frank Shellock replied:

"is it holter or holter type?... Some of these holter-shunts are nonmetallic. Do you have an x-ray to assess?

...If no "artifact", perhaps it is nometallic?"

In response to another query regarding Holter valves, Frank Shellock states there is one type of Holter valve which is MRI Unsafe:

"*I have a patient scheduled for an MRI Abdomen on a 1.5 magnet using a Speeder Coil by Toshiba. The patient underwent an operation in 1985 and had a VP Shunt placed due to*

hydrocephalus and MR. I have obtained the report from the procedure and it only states she has a "Holter Valve" and "AcuFlow Catheter". After researching "Holter Valve" I see there are many, some safe, some conditional…Should I have any reservations about putting this patient into the MRI room/machine?"

Frank Shellock replied with:

"*At least one is UNSAFE… This is a matter for your radiologist."*

No additional information on CSF shunts could be found on the MRI Safety Facebook page which has not already been covered in this review.

Review of the UK MRI mail base

'Review the MRI Physics JISCMAIL mail service for evidence of incidents, injuries as a result of the implant under review and also any information on the MRI safety status of this implant type'

On the UK MRI mail base, the MRI safety of a Spitz-Holter 1963 shunt was questioned in 2014:

"Does anyone know if these early shunts are MR safe? Holter type valves contraindicated at a couple of sites in the US. Would these be the same things?"

http://www.rahxray.com/files/mri-ordering-guide-012808.pdf

http://www.theradiologygroup.net/forPatients/MRI-prohibited-items.php

The links attached in the email are no longer accessible. One responder commented on the MR Unsafe labelling of this shunt device on mrisafety.com:

"Mrisafety lists one type of holter shunt as being mr unsafe. Attached is the reference they refer to. There is several conversations on the mrtechnologist list (you may have seen these already) regarding Holter shunts of this era with reference to potential ferromagnetic components and the need to determine the ferromagnetic nature of these components prior to scanning."

The Codman Certas Valve is another shunt which had been questioned – there was no response to this email on the mail base:

"I would be keen to here of anyone's experience with the Codman Certas Plus shunt valve. The device is described as 'MR resistant to 3 T', but in the MR safety advice (attached for info) it states that the valve setting should be verified after the MR procedure. This makes me question the point of the 'MR resistant' statement.

… If you scan these shunts, does your institution perform post MR checks, or do you have enough confidence / experience not to?"

Internet Search

'Summary of information found as a result of a general internet search, please record search terms and web browser used'

Web browser: Google Search

Search terms: "Spitz-Holter", "shunt", "MRI safety"

Paediatric Neurosurgeons and Neuropaediatricians at the University of Leipzig have provided information on their website about the radiologic identification of VP shunt valves and adjustment where they share their own experiences regarding the MRI scanning of the Spitz-Holter shunt valve: *"we have no negative experience with MRI scans with up to 1.5T even in valves older than 25 years"* [29]. An x-ray of the Spitz-Holter valve is provided and may be compared to the image of the Holter shunt provided by Go et al – the two valves look identical. There is no evidence in the literature or through a general internet search to suggest this shunt valve may be safely scanned at field strengths above 1.5T.

Web browser: Google Search Images

Search terms: "Hydrocephalus", "shunting"

A slideshow presentation on "Hydrocephalus and Neuro Shunting", created for sales training in April 2001 [30], provides a history of the treatment for hydrocephalus – this helps to understand what shunts were available, from what year they were implanted and under what company they were manufactured. These slides are shown in *Fig* 1. Whilst MR safety information was not provided in this presentation, the following non-programmable valves were noted to contain metal and therefore potentially ferrous:

- Phoenix Holter-Hausner Cruciform-Slit valve: Stainless Steel Inlet Adapter and Outler Adapter.
- Cordis Hakim Valve (Standard) System: Stainless Steel Spring (Ball and cone valve mechanism) and stainless-steel valve seat.
- Cordis Hakim (Paediatric) System: Stainless steel valve housing and stainless-steel spring.
- Codman Non-programmable Hakim Valve: Stainless steel pressure inducing flat spring and stainless-steel adjustable fulcrum. Titanium base plate.
- Codman Denver Shunt: Stainless-steel reservoir base
- Holter Valve, Elliptical: stainless-steel inlet & outlet adapter, stainless steel inlet & outlet valve, stainless steel helix wire.
- Radionics Proximal Slit valve: 316L stainless-steel slit valve housing.

The presentation also illustrated how a shunt may be implanted which clearly shows how the valve may be positioned within a patient – this is shown in *Fig.* 2.

Figure 1. Historical Treatment of Hydrocephalus. Extracted from online slideshow presentation [30].

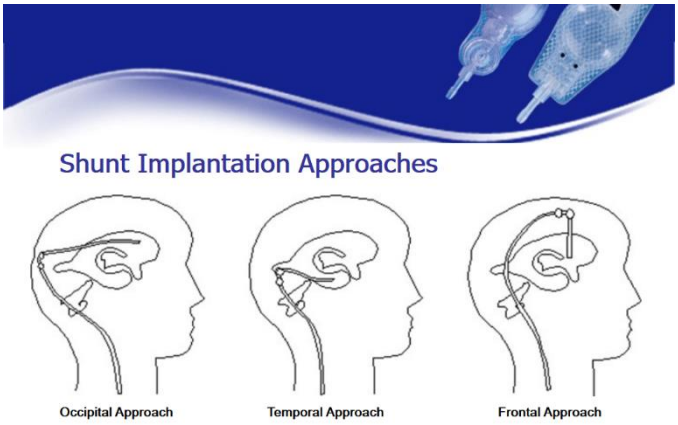


Figure 2. Positioning of shunt valve for the different shunt implantation approaches. Extracted from online slideshow presentation [30].

Web Browser: Google Search

Search terms: "shunt", "valve", "MRI"

The Neurosurgery Education and Training School - All India Institute of Medical Sciences provide a pdf lecture on "Shunt Technology" which covers material composition of shunts and MRI artefacts [17]. The information contained within these slides on the materials which shunts are typically made from is consistent with Table 1. The pdf highlights the Chhabra shunt as another valve which contains a stainless-steel sleeve and balls.

With regards to MRI artefact, images for patients with a Codman Hakim Programmable Valve (CHKV) and Medtronic Strata valve are provided which estimate the effective radius of the artefact from the scalp – this is shown in *Fig. 3*.

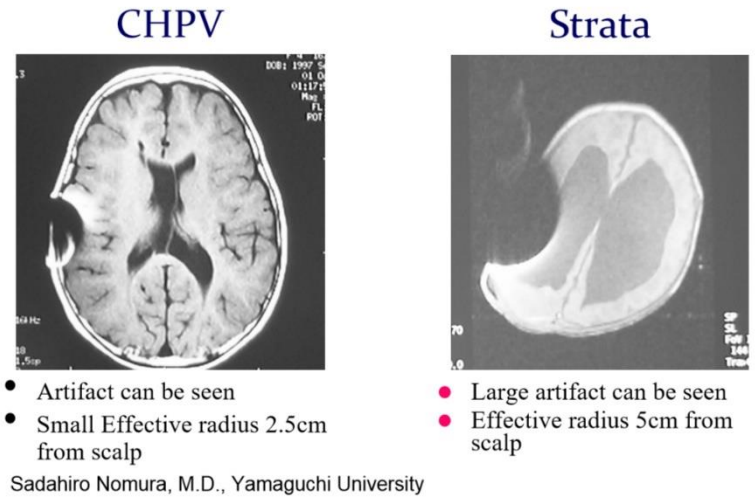


Figure 3. MRI artefacts produced by programmable shunts. Extracted from online presentation [17].

Summary of locally implanted devices *'Optional section'*

'The aim of the generic implant safety policies is to be exactly that, generic. That is, the policy should hold true throughout the world. However, in some circumstances, it may be desirable to insert a local caveat or to capture information on a local context. For example, if a notable exception is recorded for a particular device in general terms, one may wish to record information on local implants alone such as to form the basis of a locally defined decision-making pathway. On the other hand, some health boards (perhaps the larger ones) may find it difficult to get a handle on locally implanted devices and to establish robust processes for ongoing assessment of such devices, thus, this section may be deemed undesirable.'

Empirical evidence

'This section is included to capture data and experience from real world use and knowledge of clinical MRI in patients with these implants i.e. whilst a formal documented policy may not have been in place previously, sites and persons may have considerable experience in scanning patients with these devices. This real world, practical experience should not be ignored. The expectation here is that MRI modality leads may be able to contribute a great deal of useful information in this section.'

Yale-New Haven Hospital, Department of Diagnostic Radiology Policy and Procedure Manual, MRI Safety Manual

The Yale-New Haven Hospital MRI Safety Manual consider programmable shunts – the procedure flowchart included in this manual is shown in the Appendix of this Detailed Review. This hospital site appears to scan all non-programmable CSF shunts generically – differentiating from programmable shunts using X-rays when shunt type is unknown.

Sheffield Teaching Hospital NHS Foundation Trust – MRI Programmable Shunt Valve Policy

Sheffield Teaching Hospitals NHS Foundation Trust have an MRI Programmable Shunt Valve Policy which is also included in the Appendix of this Detailed Review. This policy considers specific manufactures of programmable shunts and highlights those that need pre and post MRI checks.

NHS GG&C MRI Physics Implant Database:

Review of the NHS GG&C MRI Physics Implant Database highlighted types of Holter Valve have been scanned with no incidents recorded. This clinical evidence is also in agreement with the evidence provided by the University of Leipzig, noted in the "Internet Search" section of this detailed review.

Anecdotal data

'This section is included to capture data from any resource which does not have a strong scientific basis, this might include but is not limited to: anecdotal patient or radiography reports, unverified statements e.g. as noted on safety message boards or mailing lists. The expectation is that MRI modality leads may be able to contribute information in this section.'

An incident resulting from an MRI-Induced Programmable Valve Setting Alteration was shared on a radiology website [31]**:**

A patient implanted with the Medtronic Strata Valve underwent a 1.5T MRI scan. The axial T2-weighted image shows no ventricular dilation and the valve settings were not checked post-MRI scan. The following day, the patient was minimally responsive – symptomatic of recurrent hydrocephalus. An X-ray of the shunt revealed an alteration to the pressure setting from 0.5 (pre-MRI) to 2.5 (post-MRI) and was assumed to be the result of exposure to the powerful magnetic field of the MRI scanner. An axial CT obtained the day after the MRI shows signs of ventricular enlargement owing to underdrainage of CSF. This is shown in *Fig.* 4 below.

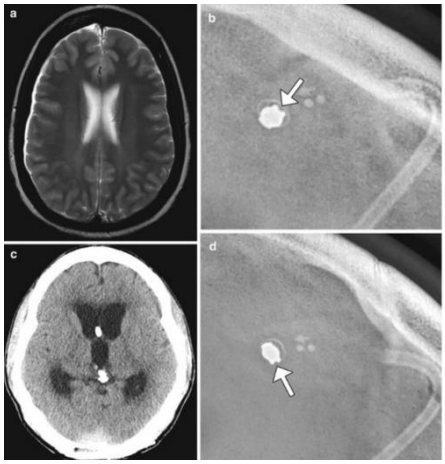


Figure 4 (a). Axial T2-w MRI shows no ventricular dilation. (b) X-ray of shunt pre-MRI shows valve setting at 0.5. (c) Axial CT acquired post-MRI (next day) shows acute massive hydrocephalus. (d) X-ray of shunt post-MRI shows increase in valve setting to 2.5.

Email from the company Sophysa confirming implant time period for the first programmable CSF shunt valve:

Re: Tr : first adjustable valve - when and where

MPrudhomme@sophysa.com

You replied to this message on 23/07/2020 09:32.

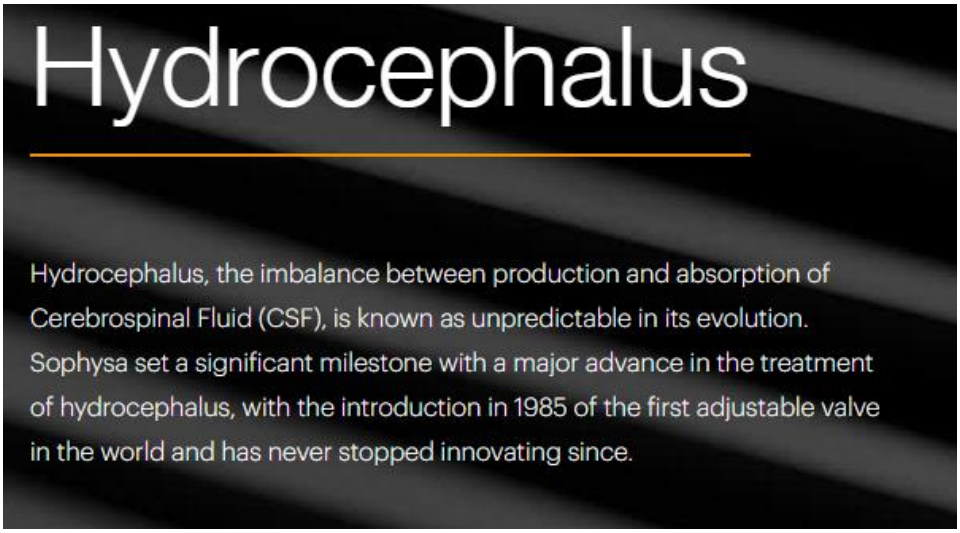
Sent: Thu 23/07/2020 09:20
To: STACE, Rebecca (NHS HIGHLAND)

Good morning,
The Sophy valves were indeed the first adjustable valves on the market, and soon after the codman-hakim came.
I do not have the exact date of the first surgery but for sure it was not before1984.
Best regards

Marion PRUD'HOMME, PhD
Global Product Manager
Sophysa SA
Siège – 5 rue Guy Moquet – 91400 Orsay, France
Production - Technopôle TEMIS – rue Sophie Germain – 25000 Besançon, France
Mobile: +33 (0)7 71 44 83 37
Email: mprudhomme@sophysa.com I www.sophysa.com

SOPHYSA
At the heart of the brain

At a later date following this email conversation, the official Sophysa website states they were the first manufacturer to introduce programmable shunt valves on the market [32]. A screenshot of their statement is shown below:



Summary of risks from implant associated with static field, RF and imaging gradients

'From the evidence gathered above, summarise the perceived risks of the implant category in the context of the MRI hardware, including considerations for different magnetic field strengths up to and including 7T'

CSF shunts may contain magnetic components (specifically programmable valves) and/ or metallic components (in some cases, this may be both programmable and non-programmable valves). Shunt valves which contain permanent magnets and are metallic (i.e. programmable valves), are at risk of movement of the device, changes to the programmed settings, demagnetisation and/or permanent damage to the device [4]. As with all metallic implants, artefacts and RF heating are also of concern. If the valve settings are altered by the MRI scan and this is not rectified by re-programming the device, the patient's health may be compromised, resulting in under – or over- drainage of CSF. Furthermore, demagnetisation and/or RF heating can result in the inability to interrogate and/or re-program the device post-MRI [10].

MRI testing of the programmable shunt assistant ProSA (Aesculap, Miethke) at 7T [28] implies that current shunt technology would be MR Unsafe at higher field strengths above 3T and thus CSF shunt technology may have to be made non-magnetic or devices redesigned somehow for safe scanning at higher tesla clinical MRI.

Consideration of risks, specific to this implant category

'Here we record information on risks specific to this implant category, this may include but is not limited to notable exceptions, the potential for misunderstandings between the implant category under consideration and other devices and the potential for new unsafe devices of this type to be released'

There is the risk of incorrectly categorising a patient's CSF shunt and/or incorrectly identifying the type of shunt valve – CSF shunts may be programmable or non-programmable of which, a range of make/models and configurations exist.

A patient's CSF shunt may have been implanted with other internal accessories (i.e., components other than the one-way shunt valve and proximal and distal catheters). This detailed review has highlighted that the risk of confusing reservoirs, impregnated with radiopaque material, with metal components that an observer may believe to be potentially MRI Unsafe or MRI Conditional and therefore have reservations about scanning the patient.

This detailed review has highlighted an unnamed right angle stainless steel ventricular shunt tube connector to be MRI Unsafe (labelled on mrisafety.com). Additionally, review of the literature has highlighted a ferromagnetic ventricular shunt catheter with metal connector.

Discussion (optional)

'If there are points worthy of discussion, in particular, matters pertaining to limitations of the review process or method, these may be included here. However, this section may be surplus in many instances'

Conclusion

'Summarise the above into a concise closing statement. You may wish to refer back to your hypothesis at this point. You may also wish to highlight the conclusion and any notable exceptions or salient points from empirical experience. The conclusion here will likely be very close to the executive summary at the beginning of the detailed review'

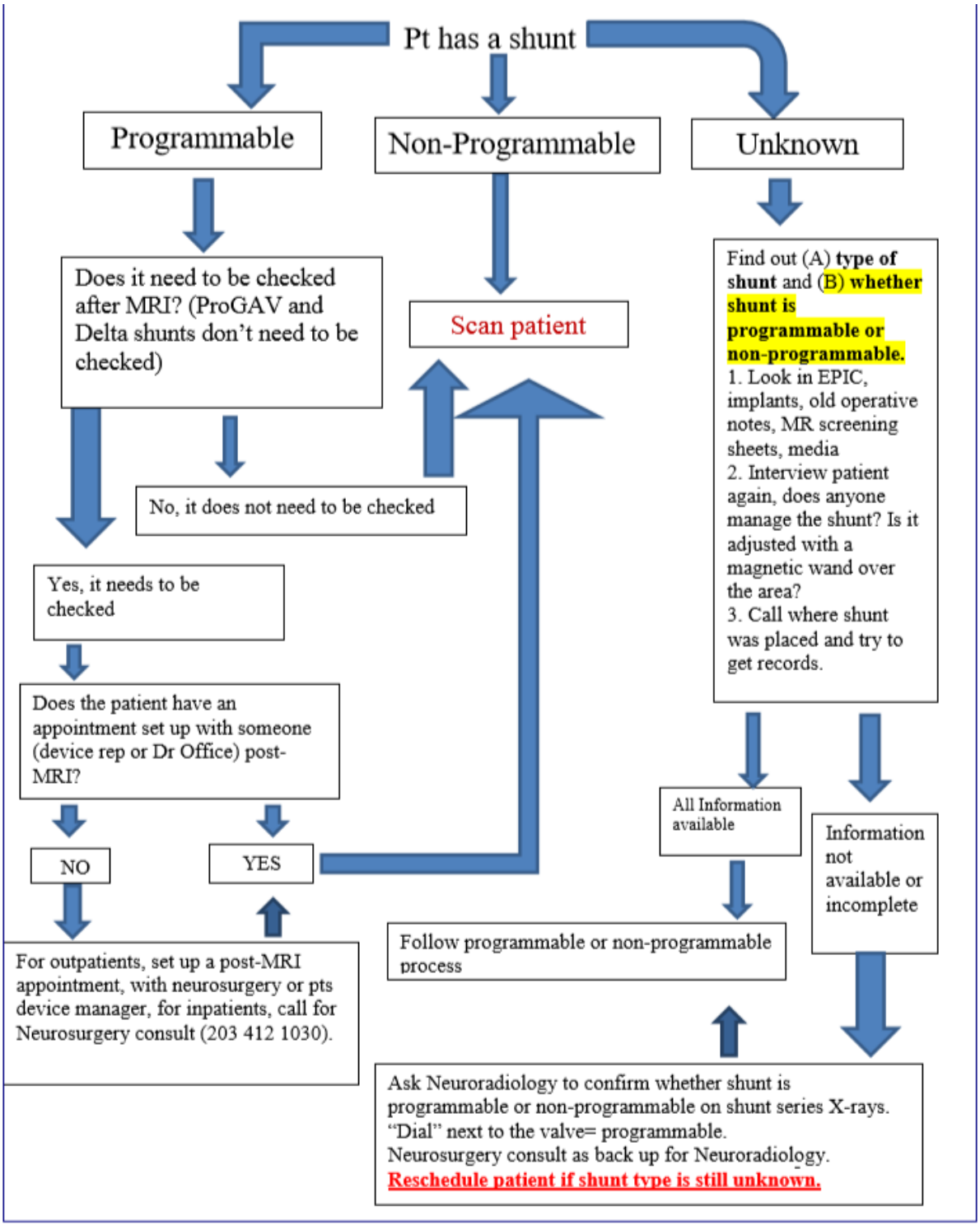
No injury/incident has been reported in the literature, nor online, regarding MRI scanning of patients with non-programmable (fixed pressure) shunt valves. The majority of non-programmable valves are non-metallic in design and contain no magnetic active components and thus are accepted MRI Safe at

1.5T. However, there are non-programmable CSF shunt valves which are MRI Conditional (e.g., Codman Hakim Precise fixed pressure valve and the Sophysa Sophy Monopressure valve) and MRI Unsafe (older models of the Holter valve and the Hakim valve). Given this detailed review has not highlighted any injuries/incidents related to the MRI scanning of patients with non-programmable shunt valve systems in addition to the empirical evidence that variations of the Holter valve have been scanned safely both locally (NHS GG&C) and internationally (University of Leipzig, Germany) at 1.5T, a generic scanning policy seems acceptable for this implant category. Furthermore, internal accessories which have been listed in this detailed review (reservoirs, pumping chambers, connectors, filters, gravitational units/siphon control devices/anti-siphon devices) should not be excluded from this generic scanning policy. Whilst there are two known ferrous accessories (unnamed right angle stainless steel ventricular shunt tube connector and the Cordis ventricular shunt catheter with metal connector), their level of ferromagnetic mass is poorly described. Moreover, these accessories are implanted extracranially and would exhibit far less ferromagnetism compared to programmable shunt valves which are all known to be MRI Conditional up to 3T. If an internal accessory is nominated which does not fit under the list of known components detailed in this review, it's MRI safety status should be investigated.

All CSF shunts identified as programmable are MRI conditional and thus make/model should be identified in order to inform of safe scanning conditions. The main concern with this shunt category is MRI induced alteration to the valve settings – it is important to identify if a patient's programmable valve requires the valve settings to be checked pre and post MRI. Those programmable valves known to have an in-built locking mechanism are designed to be resistant to MRI-induced setting changes however the manufacture IFU should be consulted prior to scanning to determine whether pre and post MRI checks are required. All Miethke manufactured valves do not require pre and post MRI checks; Sophysa Polaris and Codman Certas Plus are two examples of valves with in-built locking mechanisms that do require pre and post MRI checks.

Appendix

1. Yale-New Haven Hospital MRI Safety Manual – Programmable Shunt Policy



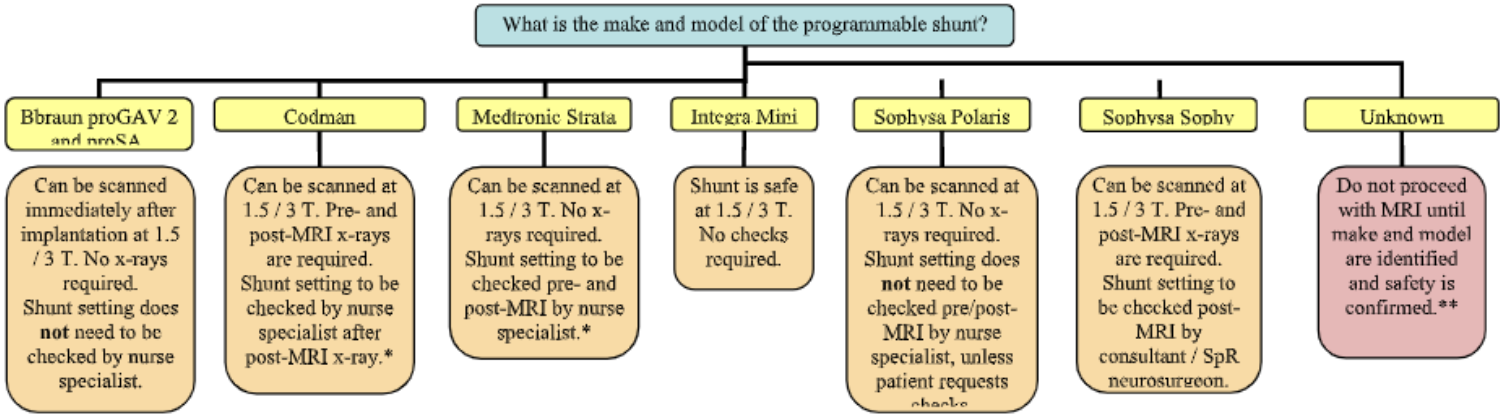
2. Sheffield Teaching Hospitals NHS Foundation Trust – MRI Programmable CSF Shunt Valve Policy

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

a. MRI Programmable CSF Shunt Valve Policy

i.

This policy describes the action to be taken in the event that a patient requiring an MRI scan has a programmable CSF Shunt Valve. This policy must be reviewed annually to ensure that any new implants meet the same conditions.



Sheffield Teaching Hospitals NHS
NHS Foundation Trust

(2) To limit the spatial gradient position the patient so that the shunt remains approximately central on the table as the patient is slowly moved into the scanner.
(3) To minimise heating each sequence should only be planned once the last has finished, and the scanner must be kept in normal mode.

* Nurse Specialist to record pre & post MRI shunt setting on patient's EDMS record.

** Once the make and model are identified, if the shunt has not been fitted at STHFT and is not one of the shunts described above the company representative will be required to confirm settings of the device.

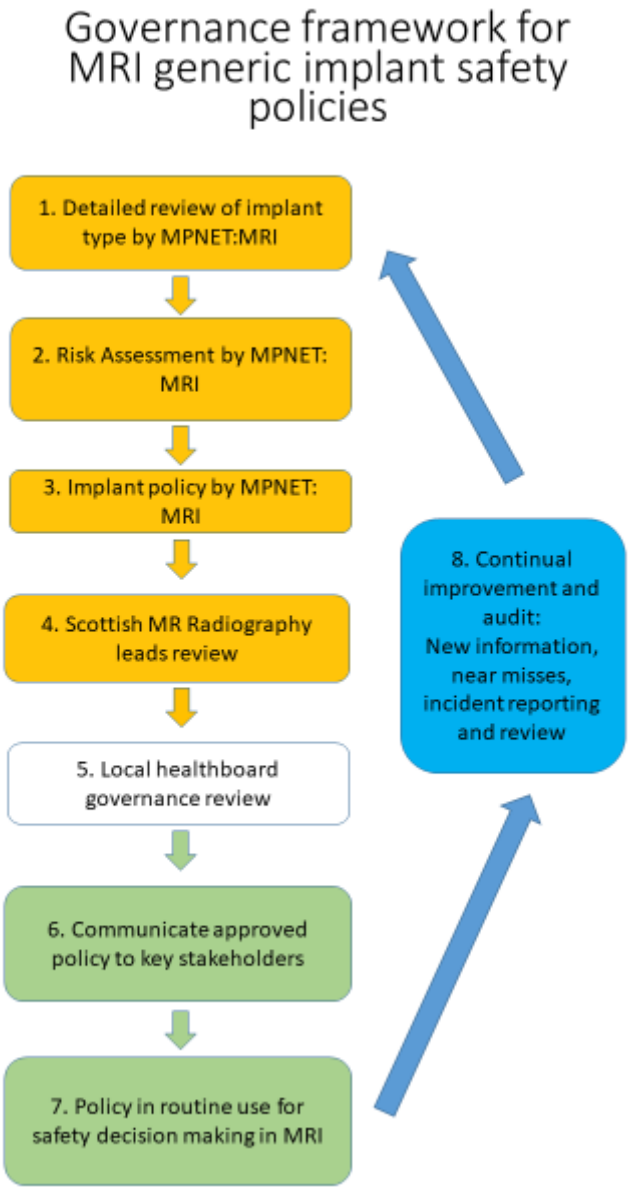
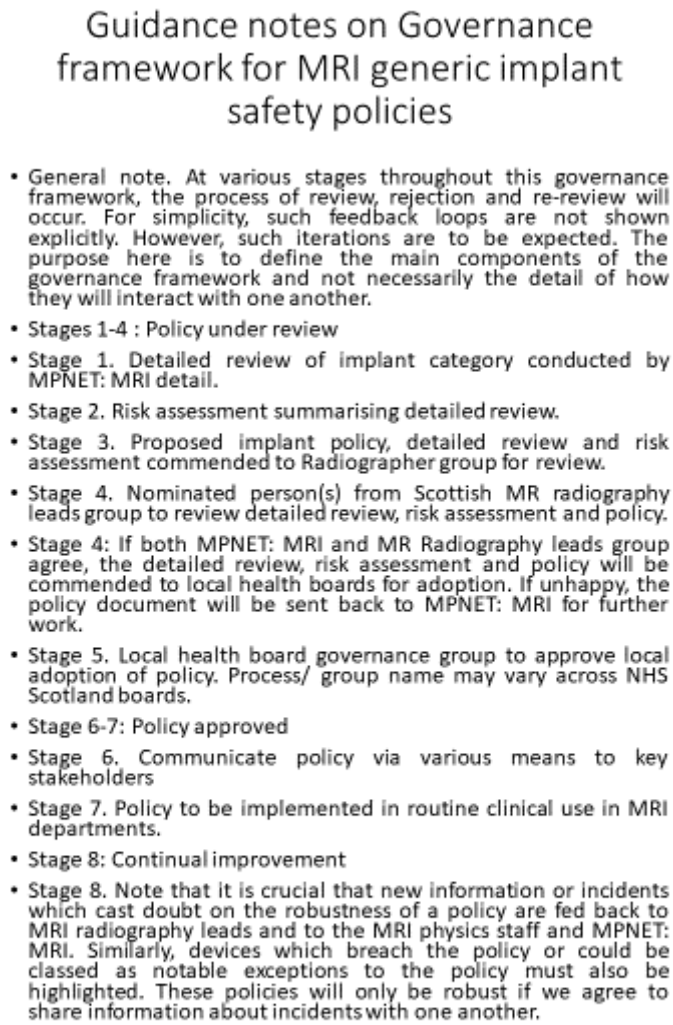


Figure AX: Governance Framework for Generic Implant Safety Policies, creation to deployment



Guidance notes on Governance framework for MRI generic implant safety policies

- General note. At various stages throughout this governance framework, the process of review, rejection and re-review will occur. For simplicity, such feedback loops are not shown explicitly. However, such iterations are to be expected. The purpose here is to define the main components of the governance framework and not necessarily the detail of how they will interact with one another.
- Stages 1-4 : Policy under review
- Stage 1. Detailed review of implant category conducted by MPNET: MRI detail.
- Stage 2. Risk assessment summarising detailed review.
- Stage 3. Proposed implant policy, detailed review and risk assessment commended to Radiographer group for review.
- Stage 4. Nominated person(s) from Scottish MR radiography leads group to review detailed review, risk assessment and policy.
- Stage 4: If both MPNET: MRI and MR Radiography leads group agree, the detailed review, risk assessment and policy will be commended to local health boards for adoption. If unhappy, the policy document will be sent back to MPNET: MRI for further work.
- Stage 5. Local health board governance group to approve local adoption of policy. Process/ group name may vary across NHS Scotland boards.
- Stage 6-7: Policy approved
- Stage 6. Communicate policy via various means to key stakeholders
- Stage 7. Policy to be implemented in routine clinical use in MRI departments.
- Stage 8: Continual improvement
- Stage 8. Note that it is crucial that new information or incidents which cast doubt on the robustness of a policy are fed back to MRI radiography leads and to the MRI physics staff and MPNET: MRI. Similarly, devices which breach the policy or could be classed as notable exceptions to the policy must also be highlighted. These policies will only be robust if we agree to share information about incidents with one another.

Figure AY: Notes on Governance Framework for Generic Implant Safety Policies

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'Include any relevant references used throughout this detailed review here'

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