Safety Benefits of an Advanced Acceleration Technology and an Implant Interface in Scanning a Complex MR Conditional Implant

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Background

Recently, three new Advanced Acceleration Technologies (AATs) have been released clinically, Simultaneous Multi-Slice (SMS), Compressed Sense (CS) and AI-based Deep Learning (DL). Each of these techniques offers the promise of decreased acquisition time, without negatively impacting image quality, and potentially improving it [1]. Another recent tool on some MRI scanners is the "implant interface" which allows the MR Operator to limit the outputs of the imaging gradients (dB/dt) and the radiofrequency field (SAR, B_{1+RMS}). Patients frequently present for MRI with complex MR Conditional implants. One such MR Condition is cumulative scanning time.

Methods

A patient with a Deep Brain Stimulator (DBS) (Medtronic Activa PC 37601) was referred for multiple sclerosis (MS) brain and MS C-spine scan to a Philips Ingenia Ambition X 1.5T MRI scanner. There are many MR Conditions associated with this implant [2], which include limiting B_{1+RMS} to ≤ 2.0 μT, and total acquisition to ≤ 30 minutes scanning time. A prospective phantom study was carried out to investigate steps to be taken to adhere to the MR Conditions utilising the on-board Implant Interface (ScanWise Implant).

Results

An imaging protocol was developed by a multi-disciplinary team to allow both body regions of the patient to be scanned while adhering to the 30 minutes cumulative acquisition time limit and B_{1+RMS} limit.

Table 1:
Key scanning parameters before and after adaption to adhere to the MR Conditions of a Deep Brain Stimulator.

		Routine sequences with CS		ScanWise Implant applied to routine sequences with CS	
	Sequence	TA (mm:ss)	B_{1+RMS} (μT)	TA (mm:ss)	B_{1+RMS} (μT)
MS Brain	SmartBrain	00:18	1.09	00:18	1.09
	cs_3D_Brain	03:02	1.03	03:02	1.03
	T2W_TSE	**02:46**	**2.56**	**06:05**	**2.00**
	DWI_og	00:42	1.43	00:42	1.43
MS C-Spine	SURVEY SAG	**00:38**	**2.22**	**00:47**	**2.00**
	SURVEY COR	**00:38**	**2.22**	**00:47**	**2.00**
	T2W_TSE upper	**02:02**	**3.67**	**07:14**	**2.00**
	mFFE (neuro/ortho)	**04:37**	**2.54**	**05:02**	**1.99**
	STIR_long TE Sag	**02:29**	**3.60**	**06:41**	**2.00**
	Σ	**17:12**		**29:33**	

The parameter changes made by ScanWise Implant were analysed and in this instance had minimal or no effect on image quality. The changes were similar to those recommended by an experienced MR Safety Expert to achieve the B_{1+RMS} condition, without unduly increasing the scanning time and maintaining image quality and contrast.

Conclusion/Discussion

An acquisition protocol was developed to allow a DBS patient to have both a brain and C-spine MRI in under 30 minutes. This was primarily enabled by the current protocols being very short in acquisition time due to the MRI centre embracing CS technology. As well as offering advantages in speed of acquisition and resolution gain, AATs may have the added benefit of making it easier to adhere to the cumulative scanning time limit MR Condition of many complex implants. CS and DL may also assist in meeting RF-related MR Conditions.

ScanWise Implant was a useful tool for this MR Conditional implant. It is important to verify that the sequence alterations suggested by an implant interface do not affect image quality or image contrast or unduly affect other parameters, e.g., total scan time.

The patient has yet to be scanned due to DBS battery issues but a subset of the modified sequences were acquired for another DBS patient referred for routine brain imaging and verified by a Neuroradiologist to be of similar image quality as non-adapted scans.

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https://www.medtronic.com/uk-en/healthcare-professionals/therapies-procedures/neurological/deep-brain-stimulation/mri-information.html

Effectively-MR Conditional cardiac implantable electronic devices

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Background. Many patients with non-MR Conditional cardiac implantable electronic devices (CIEDs) are denied MR, for example mismatched systems where pulse generator and lead(s) are MR Conditional but from different manufacturers. Strickland et al. 'believe that patients with cardiac devices should no longer be disadvantaged and have the same access to MRI scanning in the NHS as everyone else', and this includes 'legacy non-MRI Conditional devices if pre-defined protocols are followed [1]'. There is growing evidence that non-MR Conditional CIEDs can be scanned without incident [2,3,4,5]. Non-MR Conditional CIEDs must be scanned off-label, for which the MHRA guidelines recommend a patient specific risk assessment and written informed consent obtained by a clinician [6]. The joint British society consensus recommendations for MR imaging for patients with CIEDs [7] provides a comprehensive list of non-MR Conditional CIED scenarios and assigns risk categories to each scenario. We aimed to widen access to MR for patients with non-MR Conditional CIEDs via an extension to our existing standard operating procedure (SOP) for MR Conditional devices, that treats low risk (as defined by [7]) CIEDs as effectively-MR Conditional (e-MR Conditional), as defined below.

Methods. A limited number of non-MR Conditional CIED scenarios with MR Conditional pulse generators have been defined as e-MR Conditional, see figure 1. Patients with e-MR Conditional CIEDs do not follow the patient specific risk assessment and consent procedure in [6], instead an over-arching risk assessment for the e-MR Conditional CIED service was agreed between cardiology and radiology, and a patient information sheet (PIS) was created to inform each patient that their CIED is treated as e-MR Conditional. The extended SOP was introduced in February 2023. Its impact on non-MR Conditional CIED referrals was assessed.

1. The lead models are not MR CONDITIONAL or are MR UNLABELLED (legacy leads). 2. Lead lengths are not known and/or the lead length is MR UNLABELLED (untested). 3. The leads (or pin plug) are produced by a different manufacturer to the pulse generator (mismatched system). 4. Lead (or pin plug) details are incomplete, or pin plug model is unknown. 5. CIED components (pulse generator and/or leads) that were implanted <6 weeks ago*. 6. Unmet patient/landmark position exclusion zone for the requested examination. 7. Unmet condition due to the presence of additional implanted device(s).

Figure 1. List of CIED scenarios that are defined as effectively-MR Conditional. *if clinically urgent.

Results.

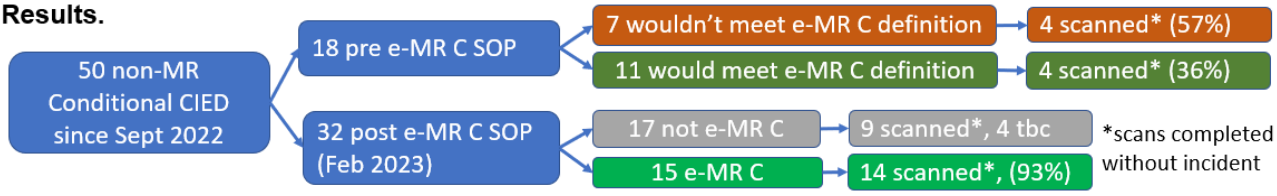

Figure 2. Non-MR Conditional CIED patients, pre and post introduction of e-MR Conditional SOP

Discussion. The SOP has increased the proportion of low-risk non-MR Conditional devices scanned and raised awareness about the possibility of scanning non-MR Conditional CIEDs more widely. The SOP has added benefit for urgent referrals by speeding up the pre-checking process.

Conclusion. The effectively-MR Conditional SOP has simplified the safe scanning of patients with a specific subset of low-risk non-MR Conditional CIEDs, widening access to MR for these patients.

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Implementing *effectively*-MR Conditional CIED scanning: A radiographer's perspective

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Aims and/or Background: MRI is one of the fastest growing imaging modalities with many diagnostic and treatment pathways increasingly dependent on MRI [1]. The implantation rates of cardiac devices are increasing. Currently half a million people in the UK have cardiovascular implantable electronic devices (CIEDs) and over 40,000 new CIEDs are implanted per year [2]. Many CIEDs have MR Conditional labelling, but due to the extensive and expensive safety testing that devices require to attain certification as MR Conditional, many older device configurations and multi-manufacturer systems have not been tested in the MR Environment and are thus classed as MR Unlabelled. This may lead to many centres rejecting MRI requests and such patients being disadvantaged [3]. It is reported that only half of the MRI units in the UK scan MR Conditional CIEDs [4]. At Blackpool Teaching Hospitals NHS Foundation Trust, we have scanned MR Conditional CIEDs for a number >15 years, but only began scanning MR Unlabelled systems regularly in 2022, initially under patient-specific risk assessments. With support from the Trust MR Safety Experts, we have now extended our MR Conditional SOP to permit low risk, non-MR Conditional scenarios as defined by Bhuva *et al* [3] to be treated similarly to MR Conditional systems; these were given the label of effectively-MR Conditional or e-MR Conditional systems. The aim of this service will be to increase access to MR for patients with MR Unlabelled CIEDs and to reduce delays in scanning.

Historically, within the radiography and wider MR community there has been hesitance and trepidation when scanning MR Unlabelled devices, particular CIEDs. When scanning these devices, it can be a worrying endeavour for the MR Operator and one that is often met with resistance from out of date thinking or lack of knowledge. It is important to offer this service, but it is also important to understand the impact on the department and the additional training and support that is required. This abstract provides a radiographer's perspective of a newly established service, focusing on the key role a radiographer plays in it, how it impacts wider radiographic and cardiology teams, communication with patients, and the additional training and education required to deliver the service safely and efficiently.

Methods: This work will present the authors personal experience having taken on a key role in establishing the service, including communicating the new service to patients who had previously been told they could not have an MR scan and to other healthcare professionals, including referring clinicians, cardiac physiologist, and radiologists, who are unfamiliar with the scanning of MR Unlabelled CIEDs. Recommendations on training requirements will be provided.

Results: Information on the local procedure will be presented, including the steps taken to inform and educate referrers, radiologists, cardiac physiologists, and radiographers on the new service. To date, all patients with CIEDs that have been identified as e-MR Conditional have benefited from an MR scan, indicating it has been effectively communicated to all involved. Key learning from communicating the new service to other healthcare professionals and patients will be presented.

Discussion: Establishing a e-MR Conditional service has many benefits for patients, but it's essential that all staff involved in the service understand the scope of the service and how to effectively communicate this with other healthcare professionals and patients. Effective communication across multi-disciplinary teams is key to the success of the service, with potential to bring equity of access to MRI for patients with many MR Unlabelled CIEDs.

Conclusion: The established service is working well and key learning points to assist others to set up such a service will be presented.

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Technical safety assessment of non-CE/UKCA-marked MR pulse sequences

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Background. Non-CE/UKCA-marked MR pulse sequences (e.g. home-built MR pulse sequences) do not have the same guarantees of safety provided by the scanner manufacturer as CE/UKCA-marked MR pulse sequences. There is, therefore, a requirement to conduct a risk assessment for using non-CE/UKCA-marked MR pulse sequences and take suitable precautions to minimise the risk (IPEM 2022). There is, however, no standard framework for conducting such a risk assessment (Tong 2022), unlike other areas of MR development such as experimental radiofrequency hardware where guidelines have been published (De Zanche 2022). The aim of this work was to formally assess the technical safety aspects of non-CE/UKCA-marked MR pulse sequences.

Methods. A risk assessment was conducted for use of non-CE/UKCA-marked MR pulse sequences on scanners from one manufacturer (Siemens Healthineers, Erlangen, Germany) at a single institution. Control measures were identified and implemented to mitigate the risks.

Results. Table 1 lists the hazards and proposed control measures that were identified in the risk assessment. Figure 1 shows the results of an image orientation test for one non-CE/UKCA-marked MR pulse sequence.

Hazard	Information and control measures
Exceeding international electrotechnical commission (IEC) safety limits for gradient/radio-frequency (RF) exposure during MRI scanner operation.	□ Siemens scanners conduct continuous monitoring, which is independent of the pulse sequence. The system will abort the sequence if IEC safety limits are exceeded for gradient stimulation or RF exposure. □ Developers of non-CE/UKCA-marked MR pulse sequences must provide evidence that a non-CE/UKCA-marked sequence has passed unit tests for specific absorption rate (SAR) pulse energy and SAR measurement time. □ Individual consideration will be given before using non-CE/UKCA-marked MR pulse sequences in patients with implant-specific SAR limits.
Damage to hardware.	□ Siemens specify critical frequency ranges, which must be avoided for each model of MR scanner. □ Siemens sequences do not use echo spacings in these frequency ranges. □ Developers of non-CE/UKCA-marked MR pulse sequences must provide evidence that the echo spacings used in the sequence do not lie within these critical ranges.
Incorrect orientation of outputs.	□ Siemens does not provide a guarantee of image fidelity for images produced using non-CE/UKCA-marked MR pulse sequences. □ Image fidelity for non-CE/UKCA-marked MR pulse sequences will be assessed as described in the department's SOP for assessment of orientation using non-CE/UKCA-marked MR pulse sequences.
Inadvertent use of non-CE/UKCA-marked MR pulse sequences in situations where use has not been approved.	□ Unless otherwise agreed, imaging sequences from non-CE/UKCA-marked MR pulse sequences must include an agreed phrase ("not_for_clinical_use" for home-built MR pulse sequences) at the beginning of the sequence name. This step is included to alert the operator to the status of the sequence.
Inadvertent transfer of images produced using non-CE/UKCA-marked MR pulse sequences to other users/institutions.	□ Unless otherwise agreed, images from non-CE/UKCA-marked MR pulse sequences must be 'soft deleted' from patient studies the hospital's picture archiving and communication system (PACS) by the researcher or delegated person.
Acoustic noise.	□ MR scanners are capable of generating high levels of acoustic noise in ordinary operation as a CE/UKCA-marked system. All patients and volunteers are given hearing protection (earplugs and headphones) during scanning in order to reduce acoustic noise below acceptable levels. Non-CE/UKCA-marked MR pulse sequences are not expected to produce substantially higher levels of acoustic noise, and the existing hearing protection is therefore expected to be adequate. Importantly, the magnetic field gradients are already driven at maximum strength and switching speed in certain imaging sequences in ordinary operation as a CE/UKCA-marked system, suggesting that the highest levels of acoustic noise are already encountered.

Table 1: Hazards identified and control measures put in place.

Discussion. The control measures identified from the risk assessment are straightforward to implement and do not impede developmental work. The framework presented here facilitates development of novel acquisition and reconstruction methods, whilst maintaining equivalent standards of safety for protection of patients, volunteers and the scanner hardware. A limitation of this work is that it only considers MR scanners from one manufacturer. However, some aspects are considered to be vendor-agnostic and relevant more generally. Since the scope of this work was limited to assessing the technical safety aspects, additional work would be required to assess the clinical aspects prior to any intended clinical use.

Conclusion. A risk assessment identified hazards associated with use of non-CE/UKCA-marked MR pulse sequences and appropriate control measures were put in place. The authors hope that sharing our practice may assist other centres conducting similar assessments.

Key words. Pulse sequences; risk assessment; safety.

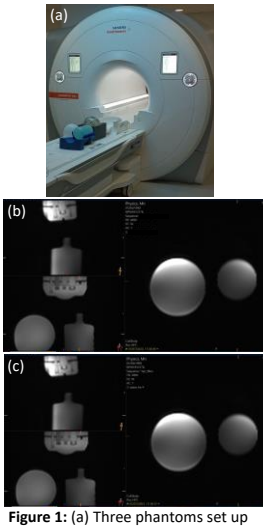

Figure 1: (a) Three phantoms set up for orientation test. (b) Multi-planar reformat (MPR) of axial images acquired using non-CE/UKCA-marked MR pulse sequence. (c) MPR of axial images acquired using a similar MR pulse sequence from the manufacturer's library (CE-marked).

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Update on clinical imaging national error reporting analysis and learning system

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Background

The value of incident and near miss reporting and the associated learning is well appreciated in the UK radiotherapy community. In 2007 a dedicated incident learning system was established for UK radiotherapy providers.

Since its implementation over 90,000 radiotherapy incidents and near miss events have been coded using published radiotherapy taxonomies, submitted, analysed and shared for learning through a series of publications by UKHSA. This initiative is undertaken in partnership with the wider radiotherapy community and is acknowledged nationally and internationally for improving patient safety in radiotherapy.

To date there is no national reporting and learning system specifically intended to analyse and learn from incidents in diagnostic imaging, MRI and nuclear medicine in the UK.
The Clinical Imaging Board (CIB) recognised the need for such a system for diagnostic imaging and agreed this work would be taken forward by UKHSA, who would co-ordinate the project with input from the professional bodies.

Methods

UKHSA has established a multidisciplinary working party to take this work to a national level. The incident classification and pathway coding system first developed for the CIB has been reviewed to mirror the patient pathway from referral to reporting, rather than focussing on the IR(ME)R duty holders of referrer, practitioner and operator. The coding taxonomy has been expanded to include the modalities of MRI and molecular radiotherapy and the associated guidance further developed to explain how to classify incidents and near miss events.

In order to minimise the burden on clinical departments, UKHSA plan to extract relevant incident data from existing systems such as National Reporting and Learning System (NRLS) and Learning From Patient Safety Events (LFPSE) and newly developed systems such as Once for Wales. Individual departments in Northern Ireland, Scotland and the Independent Sector will also have the opportunity to submit data directly to UKHSA. Providers will need to add the relevant incident codes to their local incident management system, for example Datix, prior to submission to UKHSA.

Results

The submitted incident data will be analysed by UKHSA. Results and learning will be published in regular reports on the gov.uk website. This will provide opportunities for clinical departments to learn from a greater pool of data, supporting a reduction in the magnitude and probability of incidents. As the system becomes established and more departments contribute data, this will allow local comparison of local incidents with the national picture.

Conclusion

Sharing learning from clinical imaging incident data at a local, national and international level is essential to maximise opportunities to improve patient safety. By presenting at this MR safety update, UKHSA hopes to raise awareness of this work at an early stage and encourage clinical departments to contribute their data to this national patient safety initiative.

Title of Study: Variations in SAR and B1+rms with anatomical position on a Siemens Sola MRI scanner.

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Background.

It may be necessary to restrict radiofrequency (RF) power deposition while MRI scanning patients with certain implants or off-label / MR unlabelled items. This is often achieved by restricting whole body specific absorption rate (SAR) levels. Similar sequences may produce very different whole body SAR measurements dependent on the body area being scanned, although RF deposition over an implant within the RF field may be very similar. B1+rms is another measure of RF power deposition which is less dependent on patient parameters[1,2]. This investigation aims to compare SAR and B1+rms values to each other at different anatomical locations for similar pulse sequences to ensure the most appropriate RF power limitation is used for a particular scenario.

Methods.

A series of phantoms, positioned adjacent to each other along the scanner couch, were scanned on a 1.5 T Siemens Magnetom Sola MRI scanner. The table was positioned so that the positioning markings on the head coil were at isocentre. Turbo spin echo sequences were acquired, and SAR and B1+rms values recorded.

The table was then moved in 5 cm increments, until it was a total of 80 cm from the starting position. Identical imaging sequences were acquired and SAR and B1+rms values were recorded at each table position.

Additionally, SAR and B1+rms values were recorded for specific sequences acquired in patients undergoing clinical brain, neck, breast, prostate, and knee examinations on a Siemens Magnetom Sola scanner. At least five patients were included for each anatomical area. SAR and B1+rms were corrected for changes in imaging parameters.

Results.

Phantom results show that SAR varied with table position, provided the patient is registered as being positioned head first supine. If the patient was registered feet first supine, then SAR remained constant regardless of table position (figure 1). B1+rms remained constant at all table positions.

In clinical patients, SAR also varied with table position. There was a lower variation in B1+rms measurements than in SAR measurements for the same sequence in the same anatomy (figure 2).

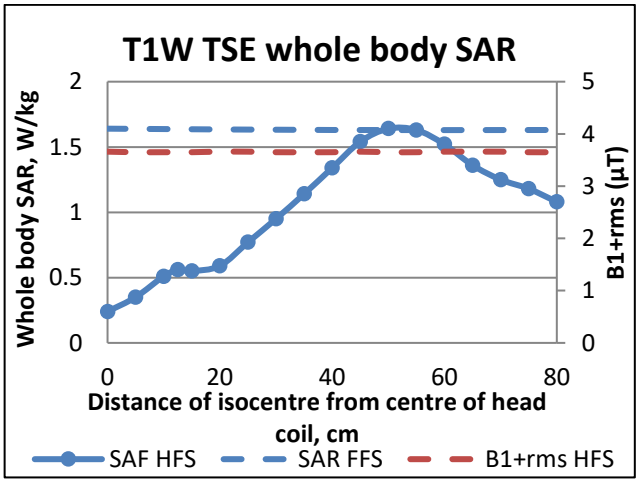

Figure 1: Measured whole body SAR and B1+rms at different table positions.

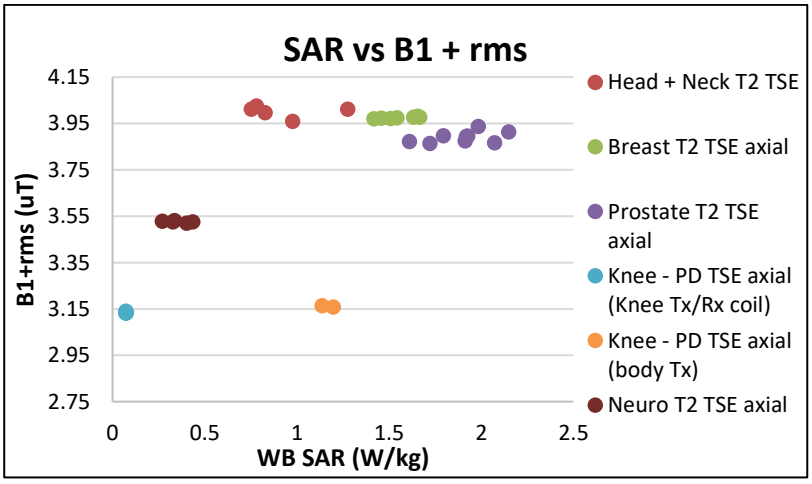

Figure 2: Measured SAR and B1+rms values in different anatomies, showing much higher variation in SAR than B1+rms.

Discussion.

Different SAR values can be obtained with the same B1+rms value, depending on anatomical area imaged and patient height. If SAR is used to limit RF deposition, differing amounts of RF power will be deposited depending on the anatomy being imaged. This has implications when scanning implants with tight RF power deposition limits. B1+rms varies significantly less with body area being scanned and should be considered when setting low RF heating protocols.

Conclusion.

Whole body SAR as a means to reduce RF exposure to implanted items should be treated with caution especially for more superior scanning regions.

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