MRI Safety Physics Case Review:

Assessment & Scanning of an MR Conditional Spinal Cord Stimulator with Low SAR Conditions

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Joint AAPM – COMP Meeting July 2020

Initial email requests to the MRI team

Initial request from scheduler in clinics

Hello,

Please advise if this patient's implants are MRI safe.

Vendor Implant	Model	Implanted	Explanted
Medtronic Coronary Stent	Unknown	11/5/14	4/28/16
SJM Octrode Lead (Trial) (x2)	3086	2/16/18	
SJM Swift Lock Anchors	1192	3/2/18	
SJM Octrode Lead (x2)	3186	3/2/18	
SJM Proclaim 7 Elite IPG	3662	3/2/18	

What is needed to begin assessment?

- Patient information
- Requested exam
- Device vendor & model number(s)
  - IPG and leads
- Implant date
- Lead location
- Still functional?
- Other implants in patient

Initial response from MRI Supervisor

Team,
Please hold off on scheduling this patient. This patient has an implanted St. Jude's Proclaim Elite Neuro Stimulator, which happens to be one of the more restrictive type of neuro-stimulators for MRI imaging. We have prior imaging for this patient, but none after the implant.

Dr. Stafford,
The orders are for an MRI of the Lumbar Spine and MRI of the Pelvis. From what I can tell this device is conditional for *only* Head and Extremity imaging.

Please advise

“Trust … but verify”

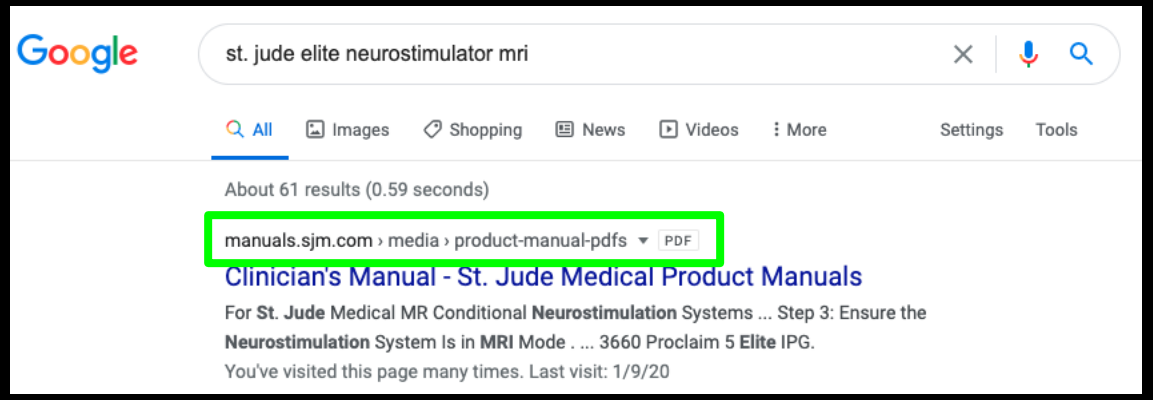

Table 1. Approved models and implant locations for an MR Conditional neurostimulation system

Component	Model	Location of Implanted Component
IPG	3771 Protégé MRI IPG	Upper buttock, low back, midline, flank, or abdomen
	3660 Proclaim 5 Elite IPG	
	3662 Proclaim 7 Elite IPG	
Lead*	3186 Octrode 60-cm lead	Lead tip in the epidural space between the T7 and T12 vertebrae
	3228 Penta 60-cm lead	
Lead anchor	All St. Jude Medical models	All locations

* Multiple MR Conditional lead models may be implanted.

Problem:

Outdated manual on vendor manual site accessible by Google

Table 2. MRI equipment and scanning requirements

	Scan Region	
	Head scans	Extremity scans
Scan region (isocenter)	Head only Use head transmit-receive coil only.	• Lower extremities: all except hip • Upper extremities: wrist only Use extremity transmit-receive coil only.
Patient position	Supine, patient's arms must be at his or her sides for head scans	Supine, patient's arm must be at his or her side for upper extremity scans
MRI system type	1.5-T closed-bore, horizontal field orientation	1.5-T closed-bore, horizontal field orientation
Gradient slew rate	Maximum gradient slew rate of ≤ 200 T/m/s per axis	Maximum gradient slew rate of ≤ 200 T/m/s per axis
Spatial gradient	Maximum spatial gradient of 30 T/m (3000 G/cm)	Maximum spatial gradient of 30 T/m (3000 G/cm)
RF coil	RF transmit-receive head coil (quadrature only)	RF transmit-receive extremity coil (quadrature only)

“Trust … but verify”

(manuals.sjm.com)

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MRI Procedure Information, MR Conditional Neurostimulation Systems, Clinician's Manual [PDF 0.84MB] (EN)

Order a paper copy

Protégé MRI™ IPG, 16 CH, Rechargeable, IPG, 5.3Ah, DRG, Lead Anchor, Butterfly, Lead Anchor, Long, Octrode Lead Kit, 60cm Length, Penta 3mm Lead, 60 cm, Pro More

3771ANS, 3664ANS, 1105ANS, 1106ANS, 3186ANS, 3228ANS, 3772ANS, 3856ANS, 3874ANS, 3875ANS, 1192ANS, 1194ANS, MN10450-50A, 3660, 3662 More

Effective Begin Date 9/11/2019

RevisionType:

Whenever possible, use the vendor manual site directly to obtain the most recent IFU for device assessment.

Table 2. Approved models and implant locations for an MR Conditional neurostimulation system

Component	Model	Location of Implanted Component
IPG	3660 Proclaim™ XR 5 IPG	Upper buttock, low back, midline, flank, or abdomen
	3662 Proclaim™ XR 7 IPG	
	3771 Protégé MRI™ IPG	
	3772 Prodigy MRI™ IPG	
	3664 Proclaim™ DRG IPG	Upper buttock, low back, flank, or abdomen
Lead*	3186 Octrode™ lead, 60 cm	Lead tip in the epidural space between the T7 and T12 vertebrae
	3228 Penta™ lead, 60 cm	
	MN10450-50 lead, 50 cm	Lead tip in the epidural space between the T10 and S2 vertebrae
	MN10450-50A lead, 50 cm	
Lead anchor	All Abbott Medical models	All locations

* Multiple MR Conditional lead models may be implanted. Extensions are untested and are therefore considered MR Unsafe.

Note: change in model NAME, not model NUMBER

Table 3. RF field requirements (see Table 4 for additional scanning requirements)

IPG Model	Lead Model	Scan Region	RF Coil	RF Power (SAR)	Notes and Warnings
Proclaim XR 3660 3662	Octrode 3186	Any body part	Body RF transmit coil (quadrature only) with any receive coil	Whole body SAR ≤ 0.8 W/kg	**WARNING:** Personnel knowledgeable in MR safety should be involved to optimally plan the scan and actively monitor specific absorption rate (SAR) levels during the scan. Ensure the scanner displays SAR prospectively. Exceeding these SAR limits could increase the risk of excessive heating of implanted components. **NOTE:** To allow the MRI scanner to estimate the SAR, ensure that you enter the patient's body weight accurately into the scanner. **WARNING:** Before an MRI scan, determine the patient's body

injury.

NOTE: The SAR requirements will be met if the scanner is in normal operating mode.

Looks like scanning torso is a possibility.

<0.8 W/kg is low, but can manage via modification of the MR protocol/acquisition.

Time to gather information and more fully assess MR conditions.

Assessment: Review and interpret the IFU

Table 3. RF field requirements (see Table 4 for additional scanning requirements)

IPG Model	Lead Model	Scan Region	RF Coil	RF Power (SAR)	Notes and Warnings
Proclaim XR 3660 3662	Penta 3228	Any body part	Body RF transmit coil (quadrature only) with any receive coil	Whole body SAR ≤ 0.1 W/kg	**WARNING:** Personnel knowledgeable in MR safety should be involved to optimally plan the scan and actively monitor SAR levels during the scan. Ensure the scanner displays SAR prospectively. Exceeding these SAR limits could increase the risk of excessive heating of implanted components. **NOTE:** To allow the MRI scanner to estimate the SAR, ensure that you enter the patient's body weight accurately into the scanner. **WARNING:** Before an MRI scan, determine the patient's body temperature. If the patient has a fever, you should not perform an MRI scan.

Table 4. Additional scan requirements (see Table 3 for device- and lead-specific scanning requirements)

MRI system type ✓	1.5-T cylindrical-bore magnet, horizontal field orientation	**WARNING:** Only use 1.5-T cylindrical-bore magnet, horizontal field orientation MRI systems. Other MRI systems, such as 1.0-T and 3.0-T machines or vertical field orientation machines, have not been tested and could cause device damage and excessive heating of implanted components, which could result in serious patient injury.
Gradient slew rate ✓	Maximum gradient slew rate of ≤ 200 T/m/s per axis	**WARNING:** Do not use gradient slew rates greater than 200 T/m/s because they have not been tested and could increase the risk of induced stimulation or heating of the neurostimulator.
Spatial field gradient ✓	Maximum spatial field gradient of 30 T/m (3000 G/cm)	
Patient position ✓	Supine, patient's arms must be at his or her sides	**WARNING:** Any prone patient positions or "superman" positions (where the patient's arm is raised above his or her head) are excluded and have not been tested.
Total active scan time (RF on-time)	• 30 minutes total of active scan time per session • 30-minute wait between sessions	**WARNING:** Exceeding the active scan time limit increases the risk of excessive heating, which could result in serious patient injury.

Appendix A: Patient Eligibility Form for MRI Scans

Complete this form to help you determine the eligibility of a patient with an implanted neurostimulation system for an MRI scan.

If the answers to all of the following questions are "Yes," consult the MRI procedures manual for complete information on conducting an MRI scan. If the answer to any of the questions is "No," do not perform the scan. If "Unsure," contact the patient's physician or Technical Support for help.

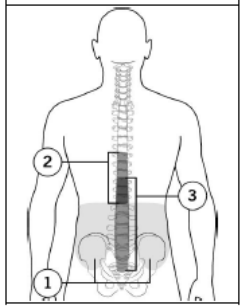
WARNING: Scanning patients who have other MR Conditional devices is acceptable as long all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it. If you are unclear what implants are present, perform an X ray to determine the implant type and location.

NOTE: Before conducting an MRI scan, always ensure that you are using the most recent version of these MRI procedures. Contact Technical Support or get the most recent version online at **medical.abbott/manuals**. For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

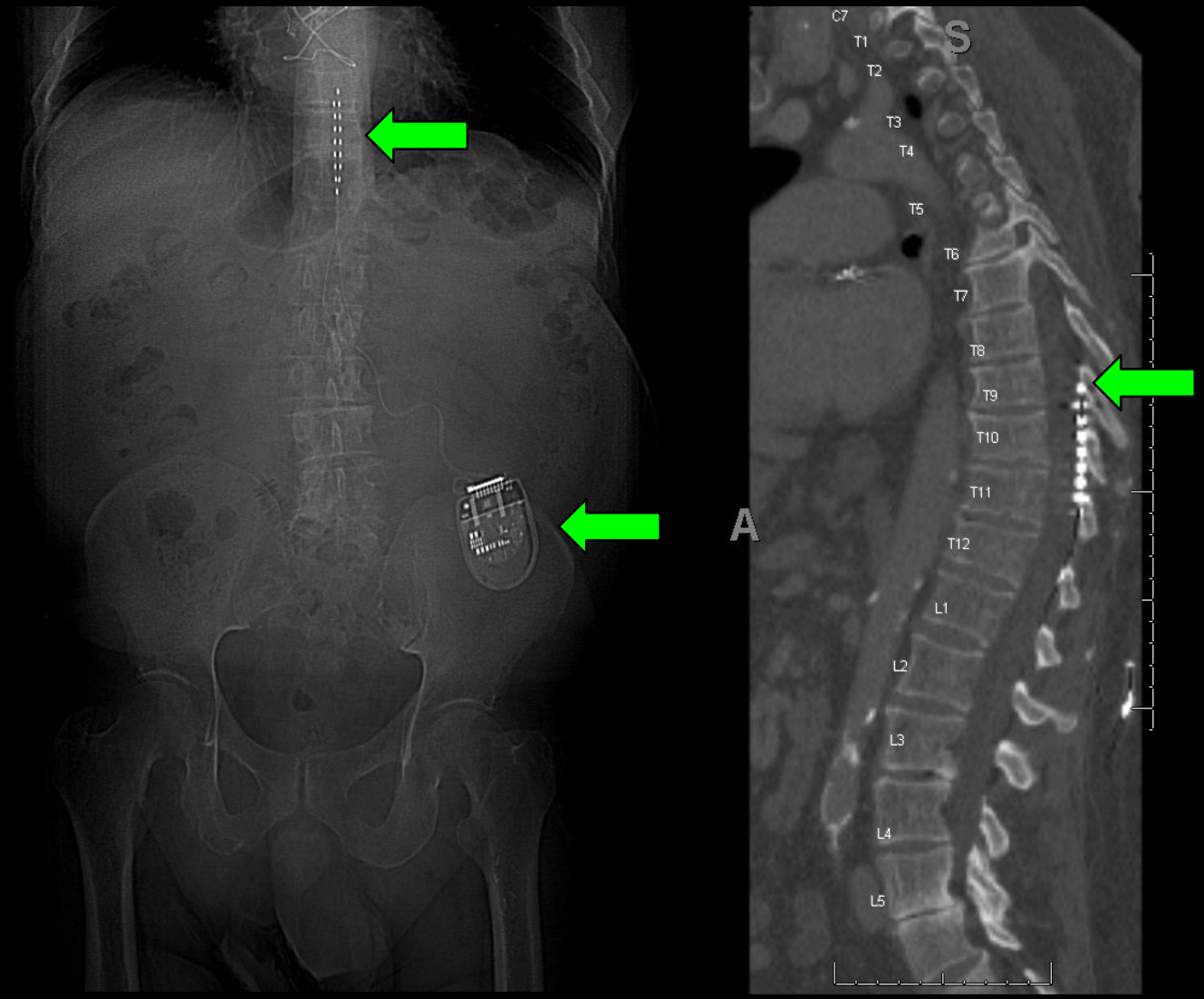
Patient's name			
Physician's name and contact information (office name, address, phone number)			
Date of eligibility assessment			
IPG model	✓	**IPG location**	?
Lead model/models	✓	**Lead location/locations**	

Eligibility Factor	Yes	No	Unsure
1. Does the patient have IPG and lead models that are MR Conditional? (See the patient's ID card for IPG and lead models.)	✓		
2. Are the MR Conditional components the only neurostimulation components implanted?	✓		
3. Identify the location of the implanted components (including lead tips) and mark them on the diagram to the right. Is the IPG within zone 1, and are the Model 3186 or 3228 leads within zone 2 or the Model MN10450-50 or MN10450-50A leads within zone 3?	?		
4. Is only one IPG implanted?	✓		
5. Is the patient free of broken or abandoned neurostimulation devices?	?		
6. Does the intended scan region meet the conditions of use for the RF coil that will be used?	✓		
7. Did you confirm the patient does not have a fever (Proclaim XR IPG Models 3660 and 3662, and Proclaim DRG IPG Model 3664 only)?	Day of Scan		
8. Is the IPG set to MRI mode?			

Approved Implant Locations
Zone 1, IPG location: Upper buttock, low back, midline (except Model 3664), flank, or abdomen
Zone 2, lead tip location: T7–T12 (Models 3186 and 3228)
Zone 3, lead tip location: T10–S2 (Models MN10450-50 and MN10450-50A)



Assessment: Review and interpret the IFU



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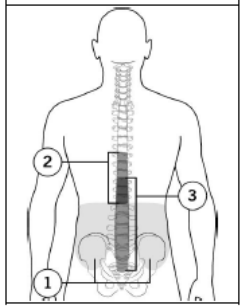
Patient's name			
Physician's name and contact information (office name, address, phone number)			
Date of eligibility assessment			
IPG model	✓	**IPG location**	✓
Lead model/models	✓	**Lead location/locations**	

Eligibility Factor	Yes	No	Unsure
1. Does the patient have IPG and lead models that are MR Conditional? (See the patient's ID card for IPG and lead models.)	✓		
2. Are the MR Conditional components the only neurostimulation components implanted?	✓		
3. Identify the location of the implanted components (including lead tips) and mark them on the diagram to the right. Is the IPG within zone 1, and are the Model 3186 or 3228 leads within zone 2 or the Model MN10450-50 or MN10450-50A leads within zone 3?	✓		
4. Is only one IPG implanted?	✓		
5. Is the patient free of broken or abandoned neurostimulation devices?	?		
6. Does the intended scan region meet the conditions of use for the RF coil that will be used?	✓		
7. Did you confirm the patient does not have a fever (Proclaim XR IPG Models 3660 and 3662, and Proclaim DRG IPG Model 3664 only)?	Day of Scan		
8. Is the IPG set to MRI mode?			

Approved Implant Locations
Zone 1, IPG location: Upper buttock, low back, midline (except Model 3664), flank, or abdomen
Zone 2, lead tip location: T7–T12 (Models 3186 and 3228)
Zone 3, lead tip location: T10–S2 (Models MN10450-50 and MN10450-50A)



Physicist recommendations after initial assessment

Device: Stimulator – spinal cord stimulator (SCS)
IPG Model: SJM 3662
Lead Model: 3186 (x2 implanted at T8 per Abbott technician on phone)

Procedure: Pelvis + L-spine w/wo contrast (surgical planning)

The following recommendations apply only to imaging of the above anatomical region with the specified components:

Note: This is a LOW SAR exam and requires a priori coordination to adapt the acquisition to meet timing and SAR requirements.
- **Need radiologist input and patient specific customization on protocol**
- **Need time on scanner to develop and test protocol**

As always, please ***read attached vendor IFU*** for complete scanning procedure guidance prior to scanning patient.

Complete patient eligibility form prior to scanning patient (below information assumes patient meets eligibility for scan location)

Procedure considerations:
- Device needs to be charged.
- Patient needs to bring programmer to put system into MRI mode.
- Need to assess patient for broken leads

Technical MR Safety conditions:

Field: **1.5T**
Max SFG: **OK** for all current clinical scanners (<30 T/m)

RF: **Body transmit with phased-array receive**

SAR : **≤0.8 W/kg**
Note: SAR limit less than Normal Operating Mode

Timing: **30 min active scan (with 30 min between sessions)**

Note: Due to low SAR and abbreviated scan time, to scan patient on-label, need:
- **radiologist assistance in modification of protocol**
- **physicist preparation & testing of patient specific protocol**
- **physicist supervision of protocol execution**

Gradients (dB/dt): Normal Operating Mode
OK for all current scanners (<200 T/m/s)

Artifacts: Near IPG. Likely to have distortion and fat saturation difficulty in pelvis and L-spine.

Positioning: Supine with arms at sides
Monitoring: Visual & audible (if possible) patient monitoring.

If decision is made to proceed, can review prior OSF MRI in pelvis and spine (prior to implant) to help assess SAR and design protocol.

Planning & Scanning: Review → Patient specific plan → Scan

Routine L-Spine (100 lbs) (Active Scan time: 46.9 min)

Series (#)	WB SAR (W/kg)	Time (sec)	PSD	Series Description
1	0.31	29.4	GR	3Pl Loc
2	*0.31*	*29.4*	*GR*	*3Pl Loc*
3	*0.83*	*105.7*	*SE*	*Sag 48 FOV*
4	*0.31*	*29.4*	*GR*	*3Pl Loc*
5	*1.32*	*280.4*	*SE*	*Sag T1*
6	0.97	264.2	SE	Sag T2
7	1.66	286.4	SE	Ax T1 TOP
8	1.72	210.0	SE	Ax T1 BOT
9	0.88	395.6	SE	+C Sag T1
10	0.96	405.9	SE	+C Ax T1
11	*1.00*	*390.6*	*SE*	*+C AxT1 BOT*
12	*0.90*	*389.9*	*SE*	*+C Cor T1*

Routine Pelvis (93 lbs) (Active Scan Time: 34.3 min)

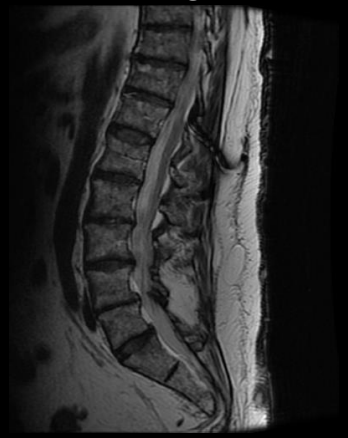
1	*0.02*	*16.3*	*GR*	*3Pl Loc*
2	*0.03*	*16.3*	*GR*	*3Pl Loc*
3	*1.83*	*157.1*	*SE*	*Cor T1*
4	*1.19*	*312.0*	*SE*	*Cor T2*
5	1.73	115.4	SE	Ax T1
6	*1.30*	*234.0*	*SE*	*Ax T2*
7	*1.98*	*276.0*	*SE*	*Sag T1 Sacrum*
8	*1.80*	*285.0*	*SE*	*Ax T1 Sacrum*
9	*0.15*	*432.0*	*EP*	*Ax DWI*
10	1.25	215.3	SE	+C Ax T1

L-Spine + Pelvis (Review)

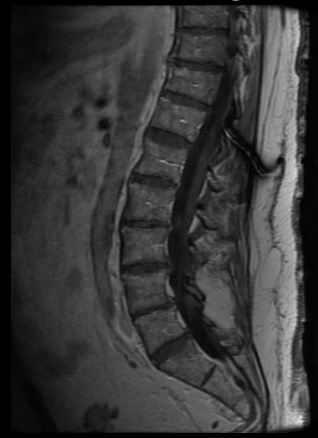
Total Active Scan Time: 81.2 min
Maximum SAR: <2 W/kg
Scanner: Various 1.5T

Planning & Scanning: Review → Patient specific plan → Scan

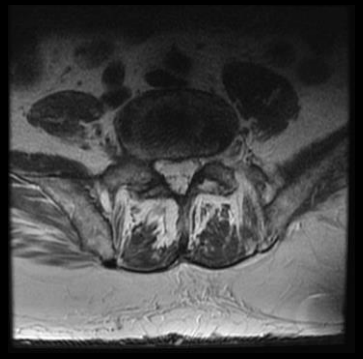
Ser 2: Sag T2



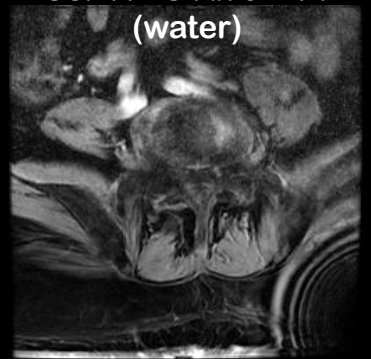
Ser 6: +C Sag T1



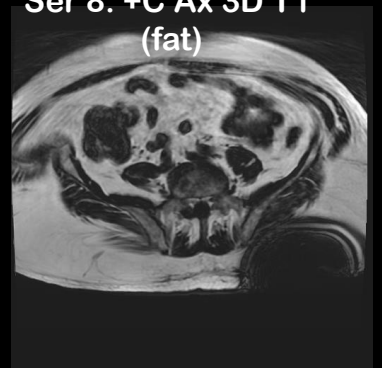
Ser 5: Ax T2



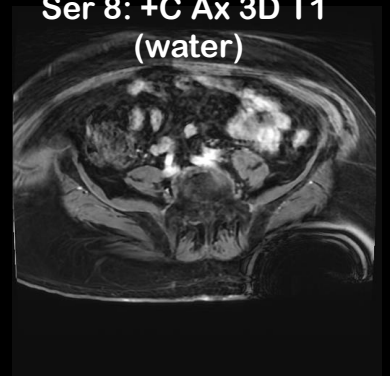
Ser 7: +C Ax 3D T1 (water)



Ser 8: +C Ax 3D T1 (fat)



Ser 8: +C Ax 3D T1 (water)



Series (#)	WB SAR (W/kg)	Time (sec)	PSD	Series Description	Notes (SAR Reduction)
1	0.20	21.9	GR	3Pl loc	Single localizer for both
					Focused series acquisitions => drop series
2	0.67	231.2	SE	Sag T2	Refocus → 130°; Spatial SAT → Weak
3	0.23	109.6	GR	Ax 3D T1 Dixon	FSE → GRE
5	0.65	250.7	SE	Ax T2	T1→ T2; Refocus → 130°; Spatial SAT → Weak
6	0.54	325.5	SE	+C Sag T1	Refocus → 130°; Spatial SAT → Weak
7	0.23	109.6	GR	+C Ax 3D T1 Dixon	FSE → GRE
4	0.30	148.6	GR	Ax 3D T1 Dixon	FSE → GRE
8	0.30	148.6	GR	+C Ax 3D T1 Dixon	FSE → GRE

Low SAR L-Spine + Pelvis (Scan)

Total active scan time:	22.4 min	versus <30 min
Maximum SAR:	<0.7 W/kg	versus <0.8 W/kg
Scanner:	1.5T GE Optima 450W [Low SAR Mode + dB/dt NOM]	

Summary

- Increased number of stimulators with a wide range of varying MR safety conditions on market
- Physicist must be diligent in obtaining and verifying necessary information for assessment
  - scan conditions and SAR vary as a function of IPG, lead, transmit RF coil selection and anatomical landmark
- Low SAR and restricted active scan time requirements may be met by using low SAR acquisition techniques and making the protocol more specific to the indication for the exam
  - at the same time, must be aware that other imaging techniques may answer the question with less risk, less artifacts and less disruption

THE UNIVERSITY OF TEXAS
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Thank you for your time!

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