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ADVANCED MRI FOR DBS: INTERNAL UCSF PROTOCOL

3T BRAIN MRI with DBS implant

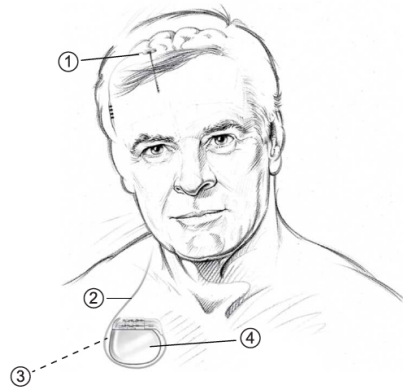


Figure 1. Medtronic DBS System components.

- ① Lead and burr hole cover
- ② Extension
- ③ Pocket adaptor (not present in all implanted systems)
- ④ Neurostimulator

STUDY GOAL: To study the underlying mechanisms of implantable deep brain stimulation (DBS), by evaluating fMRI data collected while therapy is ON, OFF, or in cycling mode.

TARGET POPULATION: Parkinson's Disease, Obsessive-Compulsive Disorder, Dystonia

SCANNER/FREQUENCY: GE 3T MR750 at UCSF Byer's Hall; 0-3 scans per month

SAFETY STATEMENT: The study will be conducted in accordance with FDA guidelines for imaging device B35200. See www.medtronic.com/mri and enter device '35200' to access original safety requirements. No off-label imaging will be performed.

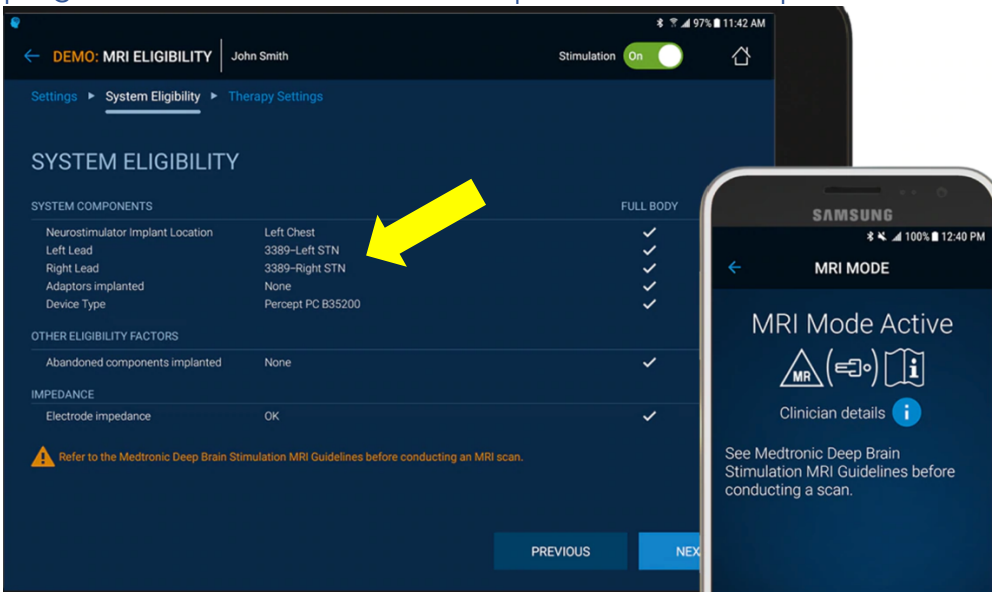
SAFETY PERSONNEL: PI, Neurologist or Psychiatrist (versed in DBS and disorder), Radiologist or Physicist (versed in MR safety), MRI technician, Nurse

PRIOR TO ARRIVAL:

Step	Done?
pre-screen patient with MRI screening form	
fill DBS MRI eligibility form for signing by physician; submit to MRI facility*	
request scanner time; pend apex order for signing; update wiki	
patient meets with clinician for clinical assessment; bipolar therapy setting evaluated during visit will be used during MRI	
ask patient to arrive with patient programmer, patient ID card, and implant devices charged (if applicable)	

*confirms full-body system eligibility for 3T scanner. See www.medtronic.com/mri and enter device '35200' to access form.

IN CONSENT ROOM (~30 mins):

Step	Done?
have patient fill and sign MRI screening form	
review exam details and risks with patient; consent/HIPPA if not already	
confirm current medications and time since last dose	
<p><u>clinician</u> review MRI eligibility report with patient:</p> <ol style="list-style-type: none"> confirm patients name review report date; since report date, ask patient if they've had a fall, physical trauma, DBS revision surgery, or major changes to settings confirm neurostimulator(s) listed on report are correct by reviewing the programmer screen, serial number, patient ID card, implant location 	
	
<ol style="list-style-type: none"> confirm <u>bipolar</u> therapy settings to be used (by group name or letter) 	
<p>check for short or open circuit:</p> <ul style="list-style-type: none"> measure monopolar impedance between each electrode and neurostimulator, and bipolar impedance between all electrode pairs > 2000 ohms = possible open circuit for monopolar impedance < 250 ohms = possible short circuit for bipolar impedance if open or short circuit verified and cannot be troubleshoot based on information code and Medtronic Technical Services, <u>do not</u> scan 	

PRIOR TO GOING INTO SCAN ROOM (~30 mins):

Step	Done?
have patient change and remove metal objects; keep patient programmer (smartphone) accessible but do not bring in scanner	
take patient temperature; do not perform MRI if body temperature > 100 °F	
remind patient that they: <ul style="list-style-type: none">▪ <u>can hear and speak to us</u> in between the loud sounds, and <u>notify us to stop the scan</u> during the loud sounds by squeezing the ball▪ <u>may feel heating</u> at the neurostimulator site during the MRI. If it causes discomfort → squeeze ball → scan will be stopped▪ <u>may feel tugging and/or vibration</u> of the neurostimulator. If it causes considerable discomfort → squeeze ball → scan will be stopped	
set device to MRI mode and first bipolar therapy setting for scan; if therapy will be off or in cycling mode remind patient that their symptoms may return abruptly	
have neurologist (or psychiatrist) quickly assess patient symptoms; iPad may be used to record patient responses, mainly OCD patients	

DURING SCANNING (30 mins of active scan time):

Scanner requirements for Medtronic Percept PC (B35200)

- MRI scanner manufacturer: any
- MRI system type: 3T horizontal cylindrical system; H-imaging; 128 MHz
- Maximum spatial field gradient: 20 T/m (2000 gauss/cm)
- RF coils: whole body transmit coil (integrated transmit coil) with any receive coil
- RF power: B1+rms ≤ 2.5 μT; SAR ≤ 1.0 W/kg
- Operating mode: first level controlled
- Maximum gradient slew rate: 200 T/m/s or less
- Active scan time limits: do not exceed 30 minutes during a 90-minute window

Note: 3T systems may using two transmit channels (or fewer) may operate in Multichannel-2 or CP configurations. Systems with >2 transmit channels have not been studied, but such systems could be operated in CP or MC-2 configurations if available.

Step	Done?
have patient lie in scanner in supine position; do not use blankets for warmth; do not provide audio or visuals (unless task-based fMRI is being	

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performed. Task will be explained to patient and equipment will be set up prior to scan)	
load in patient information for scan via accession number	
load "Morrison_DBS" protocol from Adult Brain; confirm total scan time is 30 minutes or less	
<u>set first level controlled operating mode</u>	
run localizer* and review artifacts of DBS components; check in with patient	
run T1* considering artifacts when selecting FOV; check in with patient	
run fMRI* copy FOV from T1; check in with patient	
remove patient from scanner room by detaching bed	
have clinician program next <u>bipolar</u> therapy setting; if therapy will be off or in cycling mode remind patient that their symptoms may return abruptly.	
reattach patient to scanner and run 2 nd fMRI; check in with patient; <u>do not bring patient programmer (smartphone) in scanner room</u>	
remove patient from scanner, exam is complete	

* Monitor SAR window throughout

* Specific sequence parameters:

- T1: typical parameters, 1x1x1mm resolution (4 min)
- fMRI T2*w EPI: 2.5x2.5x3mm resolution, 2500/20ms TR/TE, 150 time points (5 min x N runs)

FOLLOWING SCANNING:

Step	Done?
have clinician reprogram patient's original therapeutic setting and reassess for potential AE	
review the final T2*-weighted fMRI images for potential AE	
push T1 and last fMRI scan to PACs for read → anonymize the scan* → push all data to MB_RESEARCH	
Coordinator calls patient one week after scan to check in	

***how to anonymize the data:** when everything is done transferring over, highlight the patient exam number and on the RIGHT side of the scanner look for TOOLS TAB. (see pics in binder). This will create a duplicate study, but it will give it a random ANON #. Wait for all sequences to finish, then go to the EDIT PATIENT TAB. Erase all the lines of PHI, and only put in PD### (or OCD###) in the name and MRN area. Enter your name as person making the change. Click on ACCEPT. When you have the new anonymized study, (same Exam #), push everything to AW-MB, and to RESEARCH.