ADVANCED MRI FOR DBS: INTERNAL UCSF PROTOCOL

3T **BRAIN** MRI with DBS implant

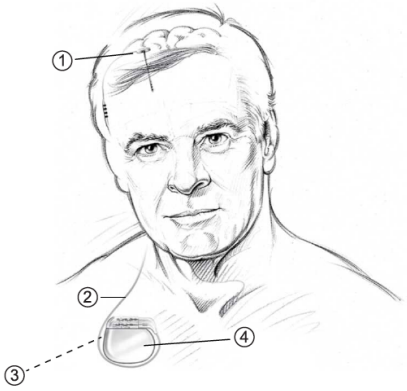

Figure 1. *Medtronic DBS System components.*

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.*

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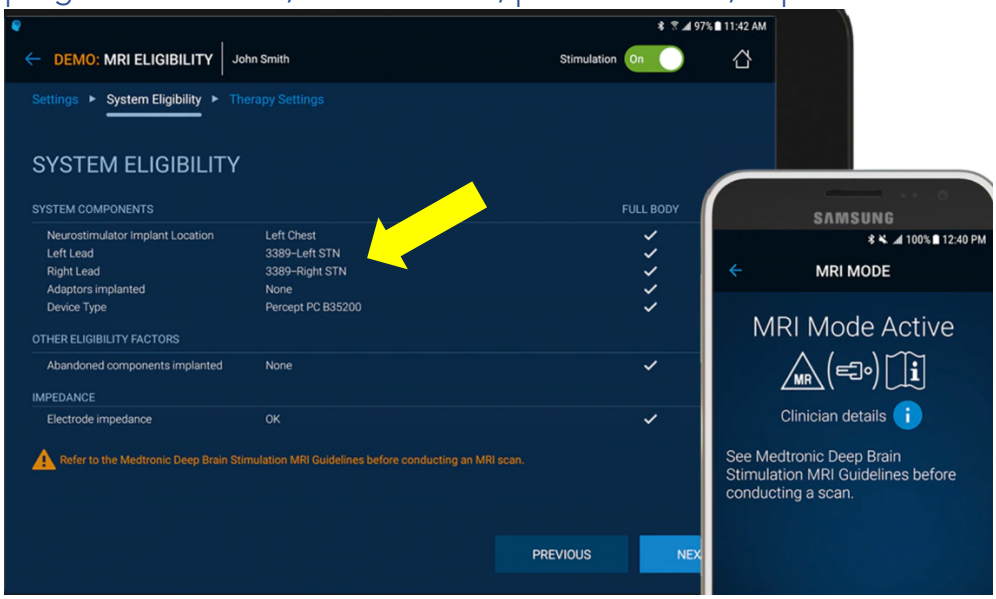
IN CONSENT ROOM (~30 mins):

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	
clinician review MRI eligibility report with patient: a. confirm patients name	
b. review report date; since report date, ask patient if they've had a fall, physical trauma, DBS revision surgery, or major changes to settings	
c. confirm neurostimulator(s) listed on report are correct by reviewing the programmer screen, serial number, patient ID card, implant location 	
d. confirm **bipolar** therapy settings to be used (by group name or letter)	
check for short or open circuit: ▪ 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 troubleshot based on information code and Medtronic Technical Services, do not 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: ▪ can hear and speak to us in between the loud sounds, and notify us to stop the scan during the loud sounds by squeezing the ball ▪ may feel heating at the neurostimulator site during the MRI. If it causes discomfort → squeeze ball → scan will be stopped ▪ may feel tugging and/or vibration 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 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	
set first level controlled operating mode	
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 **bipolar** 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 2nd fMRI; check in with patient; **do not bring patient programmer (smartphone) in scanner room**	
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.*