DO'S AND DONT'S OF DBS IMPLANTS

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Electromagnetic Interference

- Electromagnetic interference (EMI) is a field (electrical, magnetic, or a combination of both) that is generated by various types of equipment or environmental devices found in medical, work, and home environments

- Potentially could interfere with implanted system

Environmental EMI- Examples

Safe from Interference

- Computer
- Cell Phone
- Household appliances
- High Voltage Power Lines (Normal Interaction)
- Communication Equipment (Normal Interaction)

Probable Interference

- Theft Detectors
- Security Gates
- Arc Welders
- High Voltage Power Lines (Service Personnel)
- Induction Furnaces
- Communication Equipment (Service Personnel)

Medical Environment Examples

- MRI
- CT scan
- Diathermy/ Therapeutic Ultrasound
- Dental Procedures
- Lithotripsy
- Radiotherapy
- rTMS, DCS
- X-ray, Ultrasound

Currently available Implants in INDIA

MRI interaction with DBS

- **Heating –** The RF field induces voltages onto the lead system that can produce significant heating effects at the lead-electrode-tissue interface or at the location of any breaks in the neurostimulator lead system. This can result in a thermal lesion
- **Magnetic field interactions –** The magnetic material of an implanted system may exert force, vibration, and torque effects due magnetic fields produced by an MRI scanner. Patients may feel a mild tugging or vibration sensation at the site of the device implant.
- **Induced stimulation –** The gradient magnetic and RF fields produced by an MRI scanner induce energies onto an implanted lead system that could potentially cause unintended stimulation. This can occur even if only a lead or extension is implanted.
- **Effects on neurostimulator function –**MRI may affect the neurostimulator operation and programming. Parameters will need to be reprogrammed if the MRI causes a POR (power-on-reset) of the neurostimulator. Programmed parameters are retained for Activa RC and PC

Is MRI Safe?

DBS patients may undergo brain 1.5 Tesla (T) MRI, though all RF pulse sequences must result in a displayed estimated average head specific absorption rate (SARH) of 0.1 W/kg or less and have a gradient dB/dt field of 20 T/s or less.

1995-2007, 249 pts underwent 445 scans, Kansas Univ.

Head coil

Max dB/dt 10.43T/s

For non DBS scans SAR -range 0.89 W/kg to 3.13 W/kg

For DBS scans SARS of 0.68 W/kg

No brain adverse event or IPG malfunction reported

Nazzaro, et al. International Journal of Neuroscience, 120, 176–183, 2010

MRI safety

Zrinzo et al.
262 MRI (including 15 with IPG)
No adverse event
SAR <0.4W/kg and dB/dT <20T/s
4000 MRI exams-2 hardware failure, 1 temporary and 1 permanent complication
MRI is safe

Zrinzo et al, WORLD NEUROSURGERY 76 [1/2]: 164-172, 2011

MRI safety -3T!!!???

Boutet et al (2019)

102 cases

fMRI

1.5 and 3T MRI

SAR for 3T 0.221 to .397 W/kg

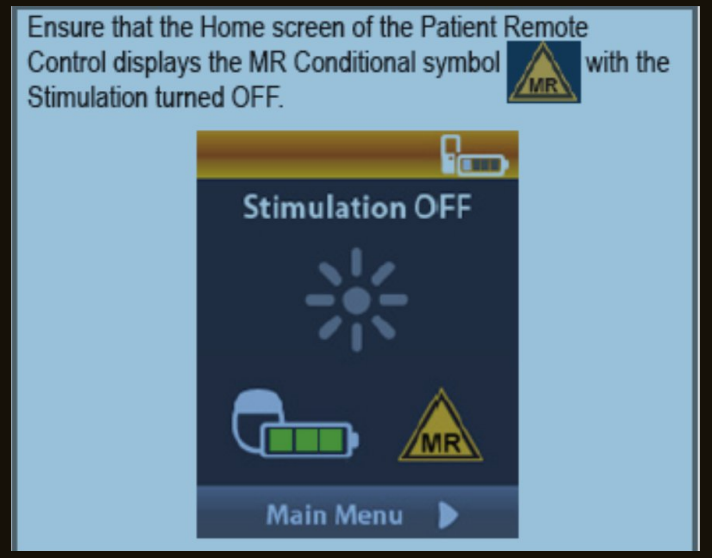
B1+RMS = 1.16 to 1.4μT

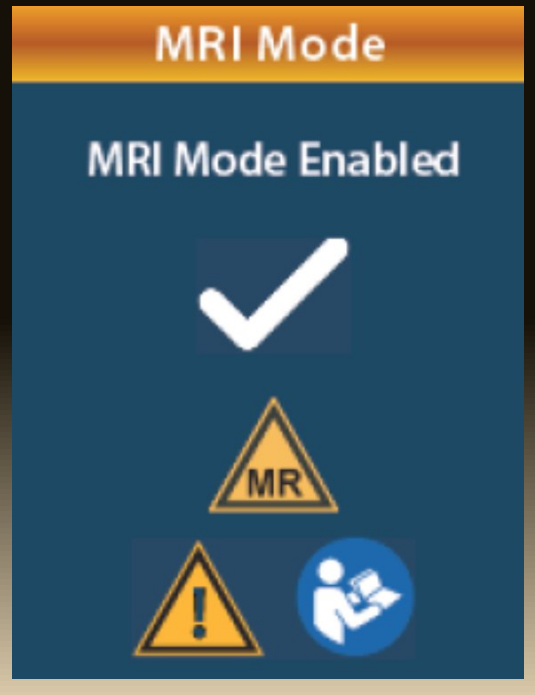
No adverse events

Boutet et al, Radiology 2019; 293:174–183 •

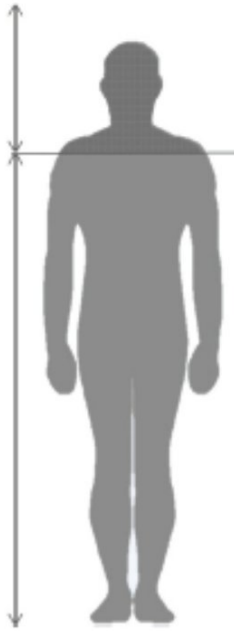
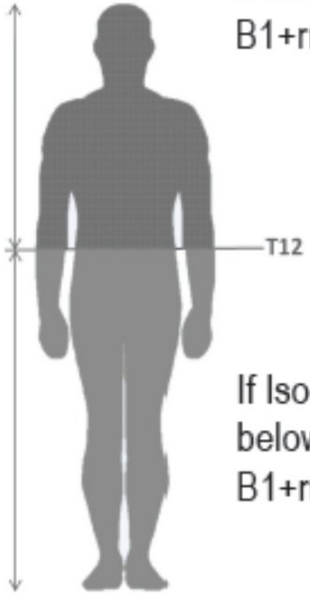
Scanning recommendations for Boston IPG

- 1.5 T
- Max spatial field gradient of 4,000 gauss/cm
- Cumulative scan time 30 min (or gap of 60 min)
- Pt. to be supine or prone
- MRI mode to be enabled prior to MRI
- Stimulator should be fully charged
- No adaptors!!





Boston scientific recommendation

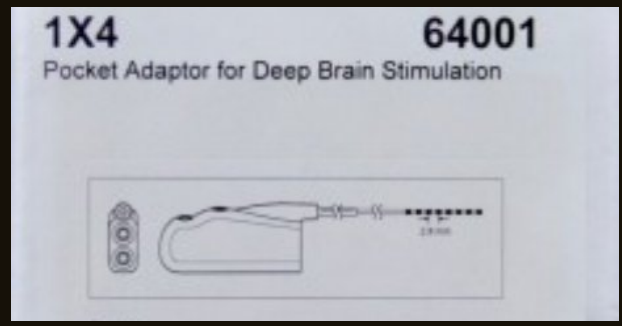
	Full System with DB-2201 Standard Lead	Full System with DB-2202 Cartesia Directional Lead
Head Transmit/ Receive Coil	 B1+rms ≤ 2.0 µT	
Full Body Transmit/ Receive Coil	 If Isocenter above T5 B1+rms ≤ 1.5 µT If Isocenter at T5 or below T5 B1+rms ≤ 2.0 µT	 If Isocenter above T12 B1+rms ≤ 1.2 µT If Isocenter at T12 or below T12 B1+rms ≤ 2.0 µT

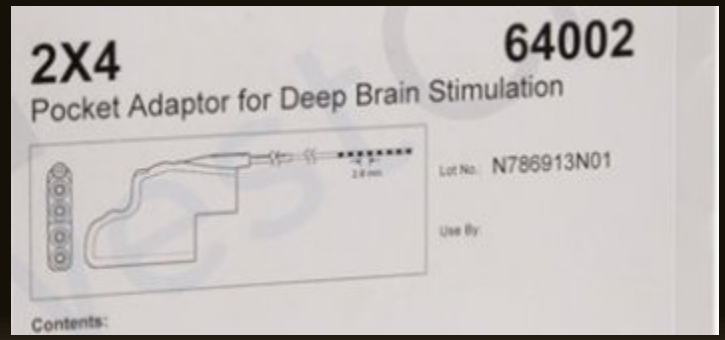
If B1+rms is not available SAR ≤ 0.1kg

Medtronic recommendations

MRI cannot be performed

- Soletra Model 7426 Neurostimulator
- Kinetra Model 7428 Neurostimulator
- Activa SC Model 37602 Neurostimulator
- Model 64001 and Model 64002 pocket adaptors implanted with any DBS system
- Do not perform MRI if impedance <250 in bipolar setting and >2000 in unipolar setting





Medtronic recommendation

DBS systems that are full-body eligible must comply with a specific set of conditions.

DBS systems that are full-body eligible:	
Neurostimulator models	37612 Activa RC, 37603 Activa SC, 37601 Activa PC
Pocket adaptor	No pocket adaptor can be implanted with the DBS system.
Lead-only systems	Fully-implanted leads (ie, leads that are internalized and capped)
System integrity	No open or short circuits

DBS systems that do not satisfy full-body eligible conditions are considered head-only eligible systems.

DBS systems that are head-only eligible:	
Neurostimulator models	37602 Activa SC, 7428 Kinetra, 7426 Soletra
Pocket adaptor	**Any** DBS system that is implanted with a pocket adaptor.[a]
Lead-only systems	Partially-implanted leads (ie, leads that are externalized)
System integrity	No open or short circuits

Medtronic recommendation

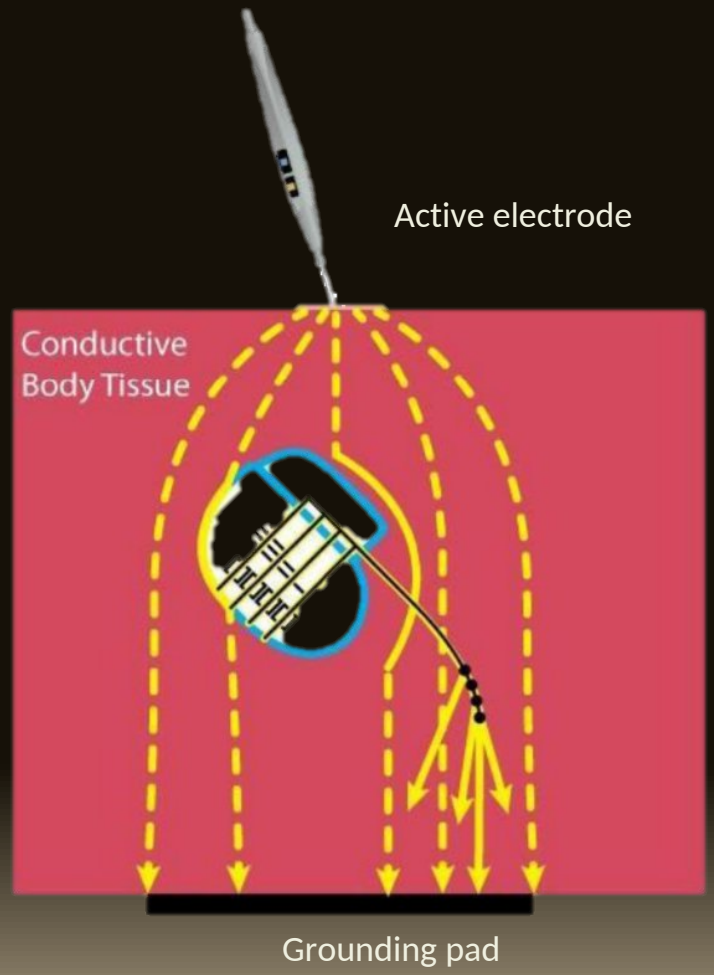
- Check impedance
- Switch off the IPG if unipolar settings
- If Bipolar settings the therapy can be kept ON
- Do not perform MRI if body temperature is above 38C
- Do not cover patient with blankets
- In supine or prone position only

Image artifacts

- Avoid using the body receive coil if possible. Use a local receive-only coil instead.
- Use imaging sequences with stronger gradients
- Use higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for the read-out axis that minimizes the appearance of in plane distortion.
- Use spin echo or gradient echo MR imaging sequences with a relatively high data sampling bandwidth.
- Use a shorter echo time for gradient echo technique, whenever possible.
- **Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted neurostimulator**

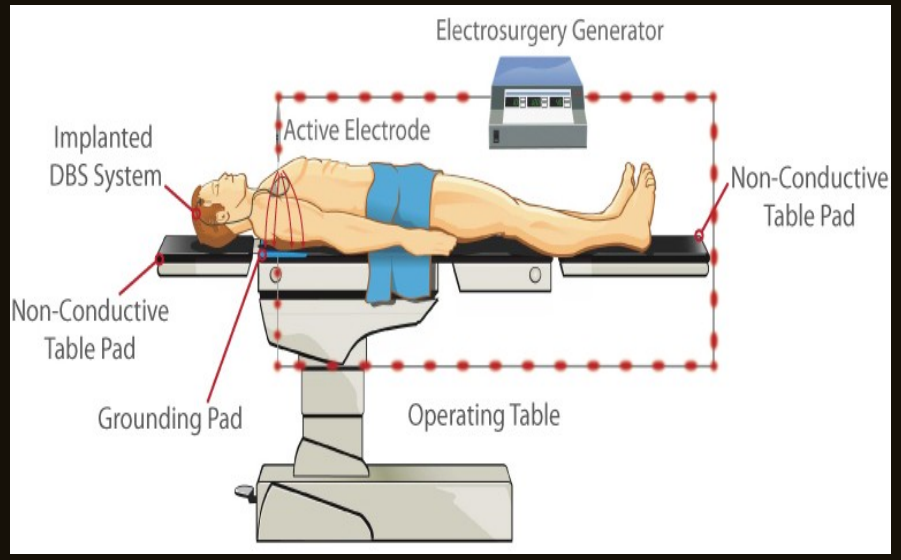
Surgical diathermy

- IPG works as a conducting device
- Two cases have been reported of permanent damage
- Nutt et al : Dental diathermy
- Medtronic database: Scoliosis surgery
- We have one patient that we know underwent cardiac surg

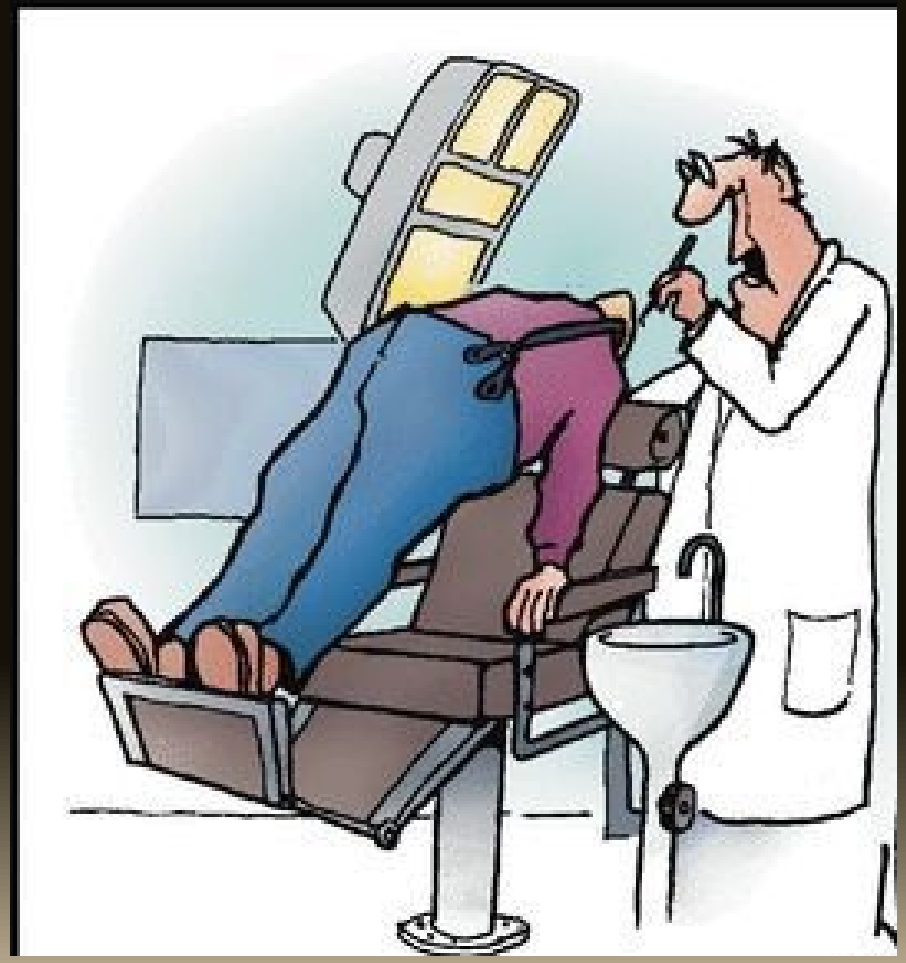


Surgical diathermy

- Use only bipolar cautery
- If unipolar cautery is necessary:
  - Use only low-voltage mode
  - Use the lowest possible power setting
  - Keep the current path (ground plate) as far away from the INS as possible.
  - Do not use full-length operating room table grounding pads
  - Keep the implanted IPG and lead system out of the conductive path
  - Keep the electrocautery current flow perpendicular to a line drawn between the neurostimulator case and lead electrodes.
- **After using electrocautery, confirm that the neurostimulator is functioning as intended.**



Dental Procedures



Listed as possible EMI

DBS

6 cm Extension wire, 15 cm from lead and 25 cm from pt programmer. Rx time 20 min

Kojima Y, Anesth Prog 63:95–104 2016

Electric motors found in dental handpieces, light-curing units (both battery powered and corded), endodontic heat carriers, apex locators, and electrosurgical units all generate some degree of EMI. Only electrosurgery units produce EMI disturbances that may possibly adversely affect the function

James, Anesth Prog 63:95–104 2016

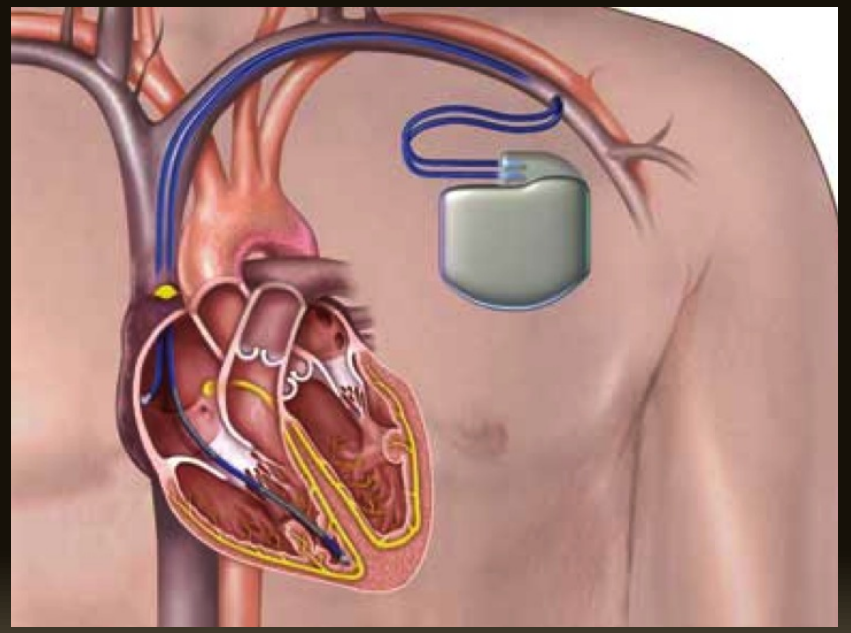
Dental Procedures

Recommendations

Common dental devices and equipment, except electrosurgery, produce minimal EMI in dental practice. Exercise care and keep potential sources of EMI as far away from implants as possible

Dual pacemaker

- No contraindication to having two pacemakers
- Should be separated as far as possible
- Discuss with the cardiologist before the implant
- Set the DBS to bipolar mode
- If unipolar mode is essential, observe the patient for few days in ICU for cardiac issues
- If ICD device is used, the vector of discharge should be away from DBS.

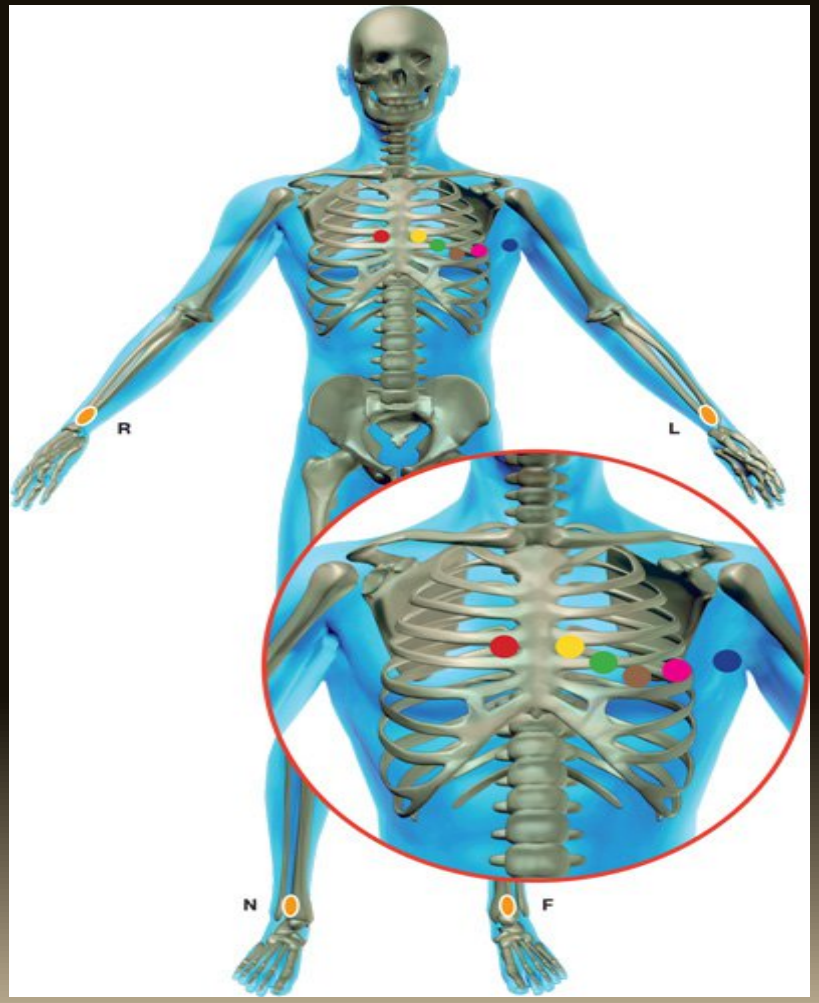


Defibrillator

- Position defibrillation paddles as far from the neurostimulator.
- Position defibrillation peddles perpendicular to the implanted neurostimulation-lead system.
- Use lowest clinically appropriate energy output (watt seconds).
- Set the IPG to 0 volt
- Confirm neurostimulation system function following any external defibrillation.

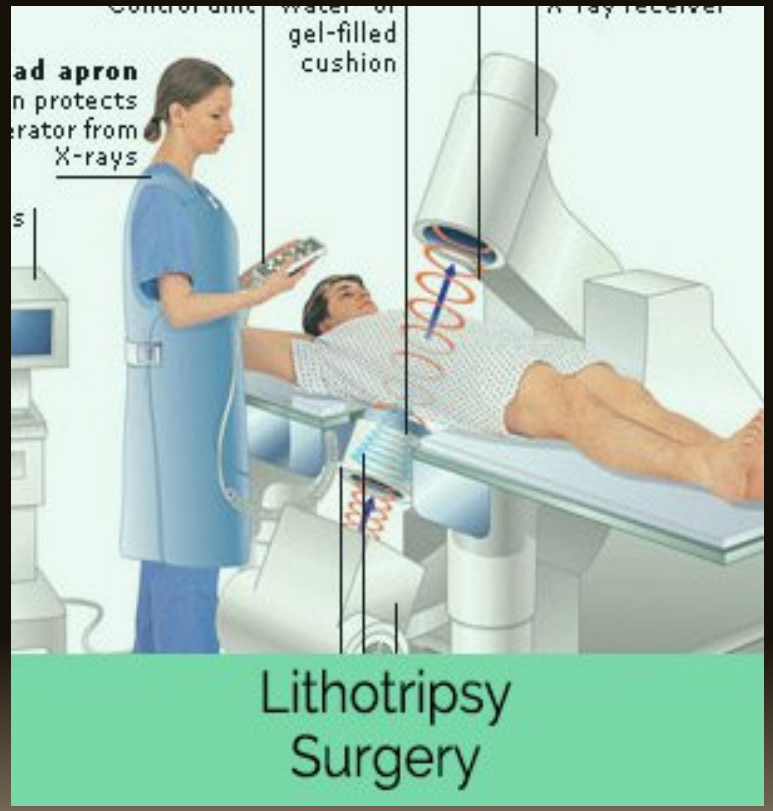
One case of lesioning following defibrillator use reported by Yamamoto

ECG



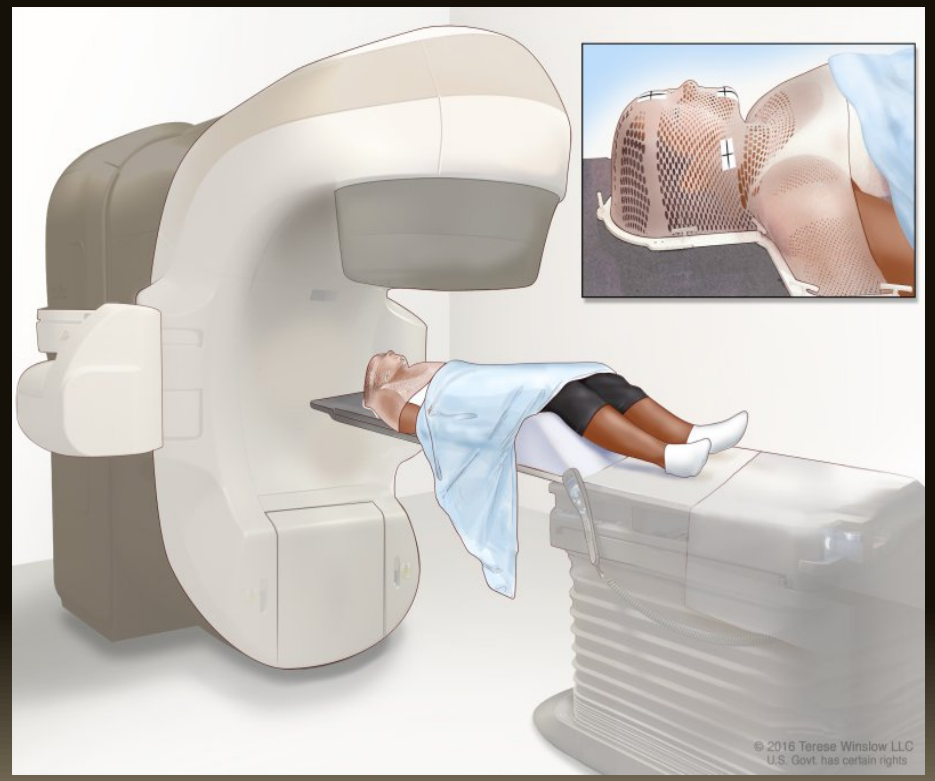
- Neurostimulators interferes with ECG tracing. Repositioning the ECG leads away from the pacemaker can rectify this interference.
- Even if artifacts are seen in ECG, IPG can be switched off for a while.

Lithotripsy



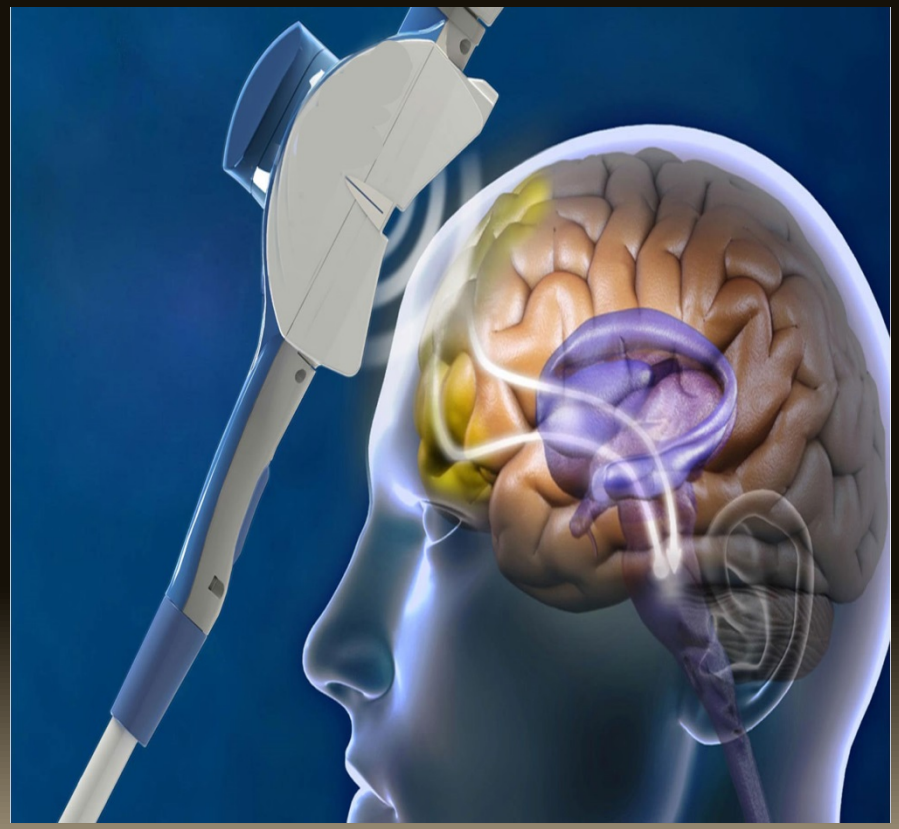
- Lithotripsy – Use of high output an ultrasonic device, such as electrohydraulic lithotriptor, is not recommended for patients with implanted neurostimulation system.
- There will be no damage to the patient, but exposure to high output frequencies may result in damage to the circuits.
- If lithotripsy must be done, do not focus the beam near the neurostimulator.

Radiation Therapy



- High radiation sources, such as cobalt-60 or gamma radiation, should not be directed at the neurostimulator.
- If patient requires radiation therapy, lead shielding should be used over the stimulator to prevent its damage. Any device damage due to radiation may not be immediately detectable.

Transcranial stimulation



safe use of transcranial magnetic stimulation, have not been established with stimulators.

Computed Tomography (CT Scan)

- No need to turn the implant off as long as the IPG is NOT in the direct beam of the ionizing radiation.
- If the INS is in the direct beam, turn it off or consider planning the scan as to avoid it.
  - If you do not turn it off the patient may experience unintended stimulation or unusual sensations.
- Device may POR

Theft detectors

Patients should not pass through the scanners used in Airport security or at the entrances of buildings including hand held scanners.

Activity Restrictions

- Avoid activities that put undue stress on implanted system (examples)
- Hyperbaric Chambers/Scuba Diving
  - Do not enter chambers more than 2.0 ATA (Medtronic) and 2.5ATA (Boston)
  - Do not dive below 10 m

After you have left

IPG has to be explanted after death, before cremation

No need to explant the lead or extension

DO'S & DON'TS:

1) **Patient Activities:**
Close proximity to high levels of electromagnetic interference (EMI) may cause a Neurostimulator to switch On or Off. The system may also unexpectedly cease to function due to normal battery depletion or other causes. For these reasons, the patient should be advised about hazardous activities that would be potentially unsafe if their movement disorder unexpectedly returns.

2) **Electromagnetic Interference:**
Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause a neurostimulator to switch On or Off. Sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. Also, severe EMI can permanently erase the neurostimulator serial number, causing "????" to be displayed in place of the serial number.

Some sources of EMI strong enough to interfere with Neurostimulator operation in a home or occupational environment include the following:

- Commercial electrical equipment (arc welders, induction furnaces, resistance welders)
- Communication equipment (microwave transmitters, power amplifiers, high-power amateur transmitters)
- High voltage power lines, which may generate enough EMI to interfere with Neurostimulator operation if approached too closely
- Theft detectors and screening devices

Other sources of EMI in a home or occupational environment unlikely to interfere with Neurostimulator operation include the following:

- Home appliances that are properly grounded and in good working order.
- Cellular phones.

3) **Component Disposal:**
If explanting a system component, please the remember the following guidelines:

- Do not incinerate the Neurostimulator, explosion can result if a Neurostimulator is subjected to incineration or cremation temperatures.
- Return all explanted components to Medtronic for analysis and safe disposal.

4) **Medical Enviornment:**
Most routine diagnostic procedures, such as fluroscopy and x-rays, are not expected to affect system operation. However, the following precautions should be noted.

a) Diathermy: The effects of diathermy on patients with an implanted neurostimulation system are unknown. Use of diathermy directly over an implanted lead or Neurostimulator is not recommended since internal components may be damaged.

b) Effects on Other Medical Devices: The neurostimulation system may affect the operation of other implanted devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate devices responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system may be necessary to optimize the patient's benefit from each device.

Electrocautery: Electrocautery can cause temporary suppression of Neurostimulator output and/or reprogramming of the Neurostimulator. If use of electrocautery is necessary, turn off the Neurostimulator to avoid damage to the Neurostimulator and keep the current path (ground plate) as far away from the Neurostimulator and lead as possible. The use of bipolar cautery is recommended.
It can also interfere with ECG tracing. Repositioning the ECG leads away from the pacemaker can rectify this interference.

External Defibrillators: Safety for use of external defibrillatory discharges on patients with neurostimulation systems has not been established. External defibrillation may damage a Neurostimulator.

If external defibrillation is necessary and the situation permits, follow these precautions to minimize current flowing through the neurostimulator and lead-extension system:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the implanted neurostimulator-lead system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm neurostimulation system function following any external defibrillation.

High Radiation Sources: High radiation sources, such as cobalt 60 or gamma radiation, should not be directed at the neurostimulator. If a patient, requires radiation therapy in the vicinity of neurostimulator, place lead shielding over the device to prevent radiation damage.

Lithotripsy: Use of high output an ultrasonic device, such as an electrohydraulic lithotriptor, is not recommended for patients with an implanted neurostimulation system. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be sued, do not focus the beam near the neurostimulator.

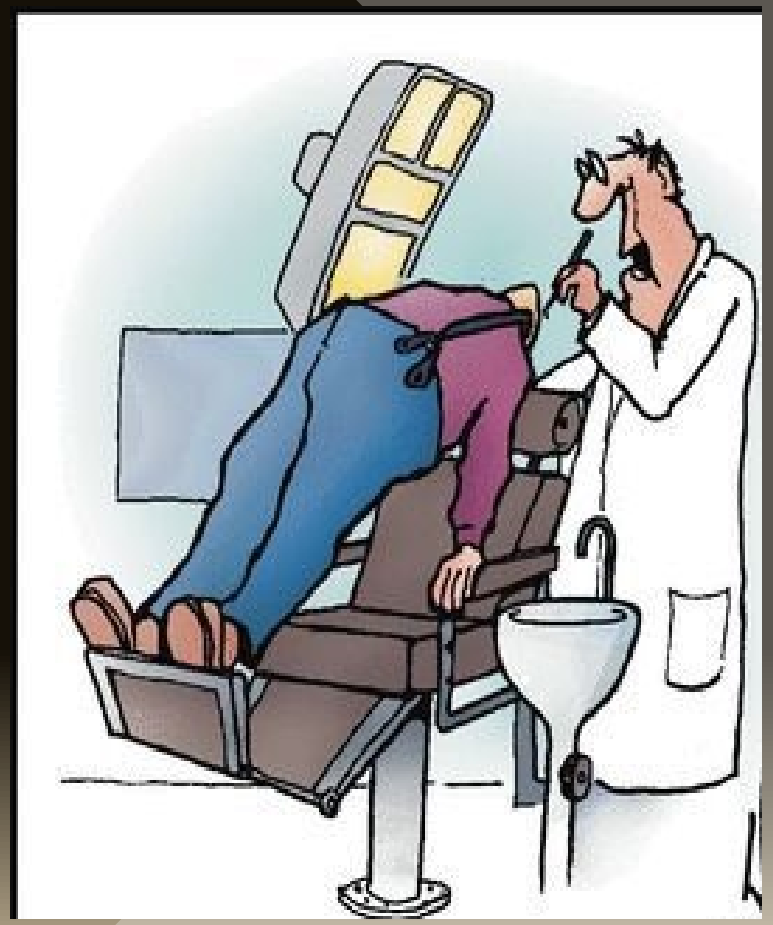
Magnetic Resonance Imaging: Patients with an implanted device should not be exposed to the electromagnetic fields produced by magnetic resonance imaging (MRI). Use of MRI may potentially change the neurostimulator settings, activate the device, or induce voltages in the neurostimulator and/or lead. An induced voltage through the neurostimulator or lead may cause uncomfortable, "jolting," or "shocking" levels of stimulation. Additionally, MRI may dislodge or heat the lead. Any of the above effects may potentially injure the patient. Patients exposed to the electromagnetic fields generated from an MRI should be closely monitored, and programmed parameters verified upon cessation of MRI.

Tell your dentist where your neurostimulator is implanted, so he or she can take precautions with dental drills and ultrasonic probes used to clean your teeth. These devices should not be used directly over the implant site.

Thank you

www.neurologicalsurgery.in

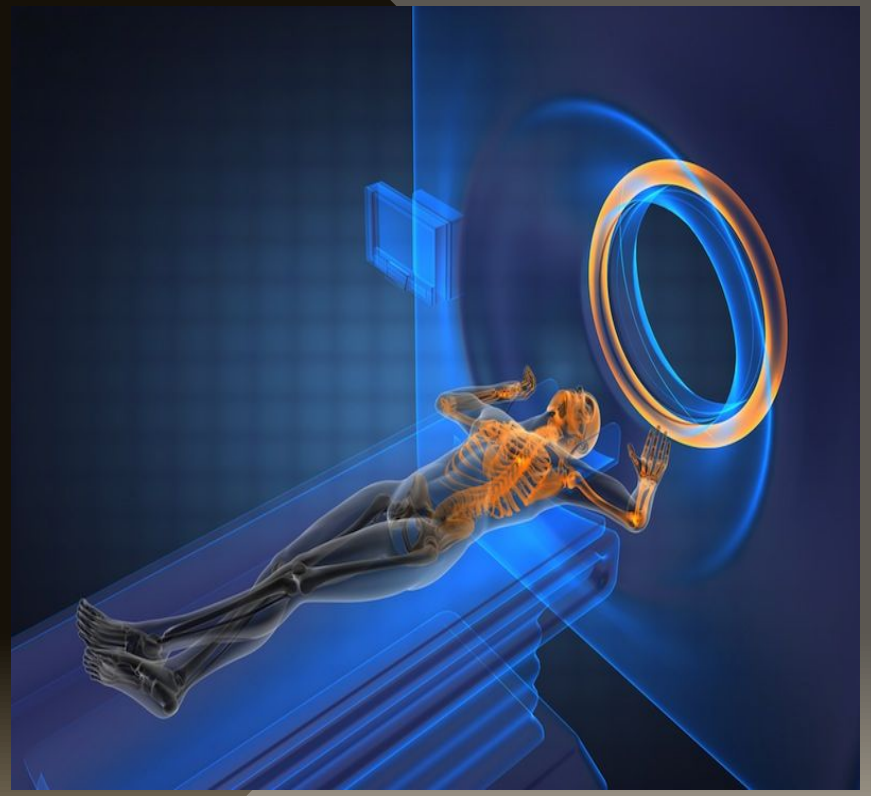
Patients should avoid arc welders, induction furnaces, microwave transmitters, power amplifiers, high voltage power lines, which may generate enough electromagnetic interference with neurostimulator.



10. **Dental procedures-**

- Tell your dentist where your neurostimulator is implanted, so he or she can take precautions with dental drills and ultrasonic probes used to clean your teeth.

- These devices should not be used directly over the implant site.



MRI- Patients with Boston Vercise should not be subjected to MRI to avoid damage to device and patient.

Now, MRI compatible Boston IPG are available .

Activa-PC and Activa-RC IPG are compatible with 1.5 T MRI once the device is swiched OFF (stimulation should be 0 with bipolar lead settings), settings should be checked after the procedure .

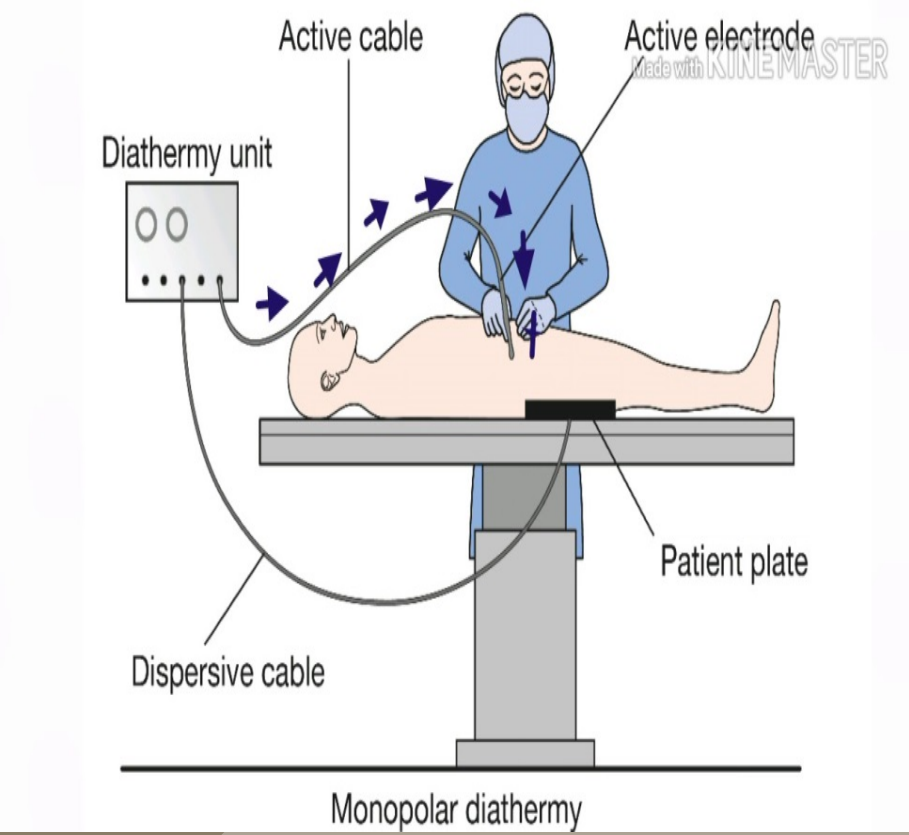
Instructions for Use

- Use only bipolar cautery
- If unipolar cautery is necessary:
  - Use only low-voltage mode
  - Use the lowest possible power setting
  - Keep the current path (ground plate) as far away from the INS as possible.
  - Do not use full-length operating room table grounding pads
  - Keep the implanted INS and lead system out of the conductive path
  - Keep the electrocautery current flow perpendicular to a line drawn between the neurostimulator case and lead electrodes.
- After using electrocautery, confirm that the neurostimulator is functioning as intended.

- **MRI exposure may results in**:

1. Dislodgement of implanted components.
2. Heating of contacts or other system components, causing permanent tissue lesioning.
3. Damage to stimulator’s electronics.
4. Current induction in DBS system may cause unpredictable levels of stimulation.
5. Distortion of the disgnostic image.
6. Personal injury or even death.

- Patients exposed to electromagnetic fields should be closely monitored, and programmed parameters verified upon cessation of MRI.



6. **Diathermy**- Shortwave, microwave and/or therapeutic ultrasound diathermy should not be used. Stimulator may be critically damaged by the diathermy use.

- Diagnostic ultrasonography are safe in these patients.