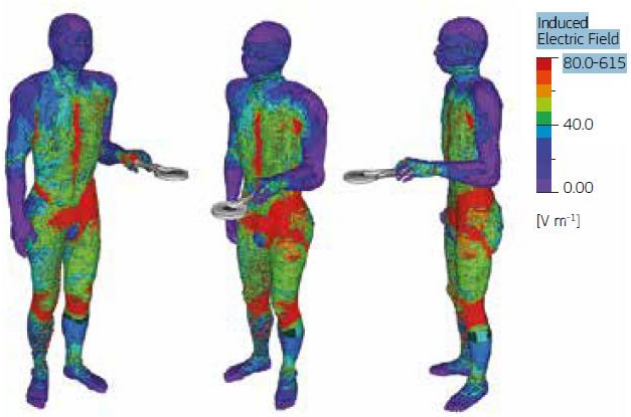
CASE STUDY 3: TRANSCRANIAL MAGNETIC STIMULATION (TMS)

A transcranial magnetic stimulation (TMS) device intentionally produces pulses of electromagnetic fields for the purpose of inducing currents in the brain, and can be used in a number of applications (e.g. brain stimulation and behaviour research).

Typical TMS devices consist of a main unit producing a high current pulse and a handheld stimulation coil. Energy is stored in large, high voltage capacitors and these capacitors discharge into the coil using a thyristor, capable of switching large currents; pulsing can be rapid or several seconds apart.

Two coil designs are in widespread use and are used at the University; the circular coil and figure-of-eight coil (although other coil designs exist).



Typical EMF Exposure Profile for the Researcher/Operator

The coil is placed close to the participant/patient's head, and an electromagnetic pulse or series of pulses will be generated to induce currents in the patient's brain. The probe may be fixed in position or, more often than not, held in position by the Researcher.

The images on the left show a distribution of the induced electric field in the human model from exposure to the TMS coil when standing with the coil held 30 cm from the body.

The Researcher (and the participant) will be exposed, in the short-term, to high levels of EMF. Therefore, a number of operational controls are required to eliminate and reduce risks, principally risks which could adversely affect those at *"Particular Risk".*

TMS 'Figure of 8' Coil

Equality Statement:

It is recognised that exclusion of those with medical devices or implants from participating, operating or observing use of the TMS may occur where there is a risk. All effort should be made to support those at risk to observe use of the TMS.

Hazard - EMF Exposure From:	Risk to Any Person	Persons at Particular Risk	General Controls
a) Direct Effects: There is a likelihood that Exposure Limit Values will be exceeded (short-term) in the Researcher and the Participant b) Indirect Effects: Interference with Implanted Devices, effect on Expectant Mothers c) Indirect Effects: Potential for electromagnetic interference with sensitive medical devices	TMS Operator & Participant	YES Expectant Mothers, interference with Implanted Devices SEE BELOW	**<u>TMS Operator</u>** ***See below for Persons at Particular Risk*** i. See Manufacturer's advice regarding: ❖ EMF exposure taking into account different handling positions TMS Operator uses during procedure ❖ Provision of a diagram detailing exposure in various Operator positions ❖ Suitable signage for general area and TMS Equipment ii. General Controls to consider: ❖ Mount TMS on remote device so TMS Operator can stand further away from the probe during procedures ❖ Fit physical access controls to entry door eg SALTO, Key Pad ❖ Post required Warning Strong Magnetic Fields signs on the entrance door ❖ Display Warning / Prohibition Signs on entrance door and TMS equipment for people wearing AMIDs and Expectant Mothers ❖ Provide information, instruction and training to those affected, includes operators and those being treated ❖ Arrange inspections and maintenance with a competent person as required ❖ Keep records eg all maintenance, authorised operators, training

Hazard - EMF Exposure From:	**Risk to Persons at Particular Risk**	**ADDITIONAL CONTROLS: Persons at Particular Risk**
d) Indirect Effects of TMS: Interference with Active Medical Implanted Devices (AMIDs), effect on Expectant Mothers	**Consider persons:** Have any implanted medical devices, both passive and active, and those who wear Expectant Mothers	As General Controls above **PLUS** i. **NEVER** treat persons fitted with AMIDs ii. **PROHIBIT** Expectant Mothers and **PROHIBIT** persons fitted with AMIDs from: iii. Operating the equipment iv. Remaining in the room during treatment (unless outside of the EMF zone) v. Person to seek advice regarding precautions from their Medical Consultant and advise their Line Manager / Supervisor if precautions recommended vi. Line Manager / Supervisor to prepare individual Risk Assessment if precautions recommended by Medical Consultant can be put into place vii. Line Manager / Supervisor to assess new TMS equipment, or if adjustments to the existing TMS machines are made with the person concerned viii. Person concerned to seek further advice from their Medical Consultant if necessary ix. Line Manager / Supervisor to review Risk Assessment and associated procedures e.g Signs, Safe Operating Procedures as required