Microstim EMC

EN 60601-1-2:2007
There appears no evidence of full or partial compliance to the standard or a sufficiently documented justification for partial/non-compliance.

Rationale for device being unable to be tested, is apparently (BSI) not unique to the device, and does not constitute a rationale for non-test. No obvious solution was offered by a test house other than that explained (remote control which may affect EMC). The only way to test EMC is to have an operator or a robot in the EMC room. The device remains an electromechanical device which is also itself susceptible to EMI.

We also know the pulses are sent down unscreened ECG wires so some interference is almost guaranteed. The Microstim DBS generates high voltage stimuli with pulse width of 200 μs in four modes of operation. User manual DOCID 17089. These pulses are only generated for a short time when the battery is activated.

It is alleged “BSI” that the device generates EMI through demonstrated interference with a pacemaker. This is not proven. The placement of electrodes was never divulged by the complainant and is assumed that the electrodes were located at the Ulnar nerve.

This happened in the early days of nerve location and regional anaesthetics and the Microstim could have used lying on the chest.

It was initially designed to be handheld.

It is very likely that interference to the pacemaker could have been caused by signal conductivity. Bear in mind ECG electrodes are also usually placed on the limbs or on the chest.

The product was deigned pre-EMC legislation, but was tested clinically under severe EMC conditions i.e. Operating Theatres and use of Surgical Diathermy.

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