

263

SYNOPSIS

Doc: MHD 07 (12991) IS/ISO/TS 10974: 2018 - Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

Scope:

This standard is applicable to implantable parts of active implantable medical devices (AIMDs) intended to be used in patients who undergo a magnetic resonance scan in 1,5 T, cylindrical (circular or elliptical cross-section) bore, whole body MR scanners operating at approximately 64 MHz with whole body coil excitation

The scope is limited to AIMDs that do not use sensing functions or to AIMDs that are programmed not to use sensing functions to affect therapy delivery during an MR scan

a) Salient features of content:

The tests that are specified in this standard are type tests that characterize interactions with the magnetic and electromagnetic fields associated with an MR scanner. The tests can be used to demonstrate device operation according to its MR Conditional labelling. The tests are not intended to be used for the routine testing of manufactured products

c) Type/grades/classes, if any covered in the standard: Nil.
