MR COMPATIBILITY DECLARATION

Audio Technologies Srl, as manufacturer of the medical devices named "Prosthesis for Otosurgery", hereby declares as follows:

Our prosthesis have been tested in a specific study (Prof. Dr. Alberto Spisni - "Tests for MR SAFE Certification of Audio Technologies implants" - University of Parma, Italy) in which it was found that they do not undergo any displacement nor temperature variation after been exposed to magnetic field of 3 Tesla.

The above-mentioned study, excerpt in the attachment below, was conducted on the worst cases (therefore heavier and more ferromagnetic) of each model of prosthesis.

All prosthesis codes starting with the following ref. code:

SPL

TAP

TPL

INCUS

are therefore compatible with magnetic resonance exam up to 3 Tesla.

Gossolengo, 14th December 2022

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audio TECHNOLOGIES

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Parma, 11th January 2011

TESTS FOR "MR SAFE" CERTIFICATION OF AUDIOTECHNOLOGIES IMPLANTS.

In order to establish if the implants produced by "Audio Technologies" can be declared **"MR safe"** according to the current terminology[1], we have carried out the following tests:

TEST 1. Exposition of the implants to a static horizontal magnetic field of 3.0 Tesla, *Figure 1.*

Figure 1 shows the GE 3T MR Imager with the superconducting magnet used for the tests. It is visible the cylindrical structure, parallel to the ground and empty inside, where the implants to test are introduced.

Procedure: each implant, placed on a Petri dish, is introduced in the pore of the magnet where the magnetic field reaches a strength of 3 Tesla. The orientation of the pore, that is 50 cm in diameter, is parallel to the ground. See *Figure 1*.
The implants are place on the mobile bed that is then moved inside the cylinder in a position corresponding to a field strength of 3 Tesla. In this case the implant is laying on the surface of the Petri dish that is placed on the bed, thus parallel to the ground.
The Petri dish is then rotated inside the magnet pore to test the effect of different orientations of the implant with respect to the magnetic field direction.
In the absence of interaction, the implant must follow the rotation of the Petri dish when the it is rotated. Alternatively, if sensible to the magnetic field, the implant will not follow the rotation of the Petri dish, when it is rotated, in order to maintain its alignment with respect to the magnetic field.
TEST 2. Exposition of the implants to a static vertical magnetic field of 9.39 Tesla (*Figure 2*) and test of their degree of interaction with the magnetic field itself.

Figure 2 shows the structure of a super-conducting magnet of the type used for the tests. It is visible a central cylindrical structure that is empty inside, allowing to introduce the implants to test. The implants inside the cylinder where locate in a position corresponding to the black region in the bottom part which is the centre of the magnet where the field strength is 9.39 Tesla.

Procedure: the test consisted in introducing the implants, hanging by a thin cotton thread, inside the magnet cylindrical pore (the orientation of the pore is perpendicular to the ground and has a 5 cm diameter) down to the centre of the magnet where the magnet field reaches a strength of 9.39 Tesla. See *Figure 2*.
Then was observed if the implants remained still in the pore central position, in other words, equidistant from the magnet wall or if the implants were attracted by the magnetic field against the wall. In the absence of interaction, the implant must remain still. If the implant is sensible to the magnetic field it will be attracted against the wall.

Table 1 reports the implants that have been tested:
the ones that can be safely exposed to a static magnetic field of up to 3 Tesla have been termed "**MR 3T safe**" and the ones exposed to a static magnetic field of 9.39 Tesla were termed "**MR 9T safe**".

Prof. Alberto Spisni

Table 1 - The results obtained for the implants exposed to the static magnetic field of 3 and 9.39 Tesla

CATALOG NUMBER	STATIC MAGNETIC FIELD 9.39T	STATIC MAGNETIC FIELD 3T
AME 07.20.85	*n.d.*	MR 3T safe
AME 07.20.105	*n.d.*	MR 3T safe
PAP 07.15.450	MR 9T safe	MR 3T safe
PAP 07.47	MR 9T safe	MR 3T safe
PAP 07.50	MR 9T safe	MR 3T safe
PAP 07.53	MR 9T safe	MR 3T safe
PAP 07.66.225	MR 9T safe	MR 3T safe
SPL 03.04	MR 9T safe	*n.d.*
SPL 03.10.700/S	MR 9T safe	MR 3T safe
SPL 03.13.500	MR 9T safe	*n.d.*
SPL 03.19.550	MR 9T safe	*n.d.*
SPL 03.26	MR 9T safe	MR 3T safe
SPL 03.27.500	*n.d.*	MR 3T safe
SPL 03.29/S	MR 9T safe	MR 3T safe
SPL 03.31.450	MR 9T safe	*n.d.*
SPL 03.35/S	MR 9T safe	MR 3T safe
SPL 03.43.500	*n.d.*	MR 3T safe
SPL 03.45.575	MR 9T safe	MR 3T safe
TAP 07.35	MR 9T safe	*n.d.*
TAP 07.42	MR 9T safe	*n.d.*
TAP 07.46	MR 9T safe	*n.d.*
TAP 07.52	*n.d.*	MR 3T safe
TAP 07.55	*n.d.*	MR 3T safe
TAP 07.58	MR 9T safe	MR 3T safe
TAP 07.61.525	*n.d.*	MR 3T safe
TAP 07.63	*n.d.*	MR 3T safe
TPL 04.00.12 CF	MR 9T safe	*n.d.*
TPL 07.02	MR 9T safe	*n.d.*
TPL 07.07(700)	MR 9T safe	*n.d.*
TPL 07.51	MR 9T safe	MR 3T safe

n.d. : not determined

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