NISSHA MEDICAL TECHNOLOGIES

ECG ELECTRODE WITHOUT LEAD MR RADIOLUCENT DISPOSABLE ECG MEDICAL SENSORS

Magnetically induced displacement force and torque:

Safe for static magnetic fields of 1.5 T and 3 T with Static magnetic field gradient $|\nabla B| \leq 25$ T/m (extrapolated) Static magnetic field gradient product |B|. $|\nabla B|$ not determined.

RF heating: single configuration has been tested by scanning with a 1.5 Tesla Intera Philips and a 3 Tesla Magnetom Trio Siemens MR System. No leads have been tested for RF heating interation.

Theorical estimated WBA-SAR \leq 2 W/kg (1.5 and 3 T, single electrode, no leads connected) with maximum continuous RF scan duration of 10 minutes for MR scans with transmit/receive body coil (recommended WBA SAR is based on theoretical extrapolation to maintain localized temperature increase \leq 4°C based on data from in-vitro testing and human computational modeling).

General notice: the whole body averaged (WBA) software display SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed. Measurement inaccuracies and additional safety margins should be taken into account.

No RF heating testing, other than 1.5 and 3 Tesla, was performed.

Gradient Magnetic fields: stimulation level of ≈74% (3 Tesla Magnetom Trio Siemens) and parameter PNS = 47% (1.5 Tesla Intera Philips) were used during RF heating tests. No tests have been performed regarding possible nerve or other tissue stimulation.

The "Electrodes for ECG" have not been tested in simultaneous combination with other devices.

MR image artifacts: MR image quality is compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this device.

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EU REPRESENTATIVE / IMPORTER:

Nissha Medical Technologies SAS 25 Boulevard de la Paix 95800 Cergy, France +33 1 39 72 66 66

MANUFACTURER:

Graphic Controls Acquisition Corp. d.b.a. Nissha Medical Technologies 400 Exchange Street Buffalo, NY 14204 USA HS.NisshaMedical.com

VML096 Rev E. 05/2021

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