MRI safety information

Non-clinical testing has shown that the "Intracranial Pressure and Catheter System" is "MR conditional". A patient with this product can be safely scanned in an MRI system meeting the following conditions:

- static magnetic field of 1.5 - 3 Tesla with
- maximum spatial field gradient of 2,300 G/cm (23 T/m)
- maximum force product of 38,000,000 G^2/cm (38 T^2/m)
- theoretically estimated whole body averaged (WBA) specific absorption rate (SAR) < 2 W/kg (Normal Operating Mode).

Under the scanning conditions defined above, the "Intracranial Pressure and Catheter System" is expected to produce a maximum temperature rise of less than

- 2.8 °C (2 W/kg, 1.5 Tesla) with an ambient temperature increase of approximately 1.1 °C (2 W/kg, 1.5 Tesla)[1]
- 2.7 °C (2 W/kg, 3 Tesla) with an ambient temperature increase of approximately 0.8 °C (2 W/kg, 3 Tesla)[2]

after 15 minutes of continuous scanning.

In non-clinical tests, the image error generated by the product is around 70.9 mm for the product family worst case[3] when the image is generated using a gradient echo pulse sequence and a 3 Tesla MRI.

WARNINGS according to the MRI safety information

- Patient injuries can occur if the conditions for safe use in rooms designated as MRI environments are not observed.
- Never exceed a maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg during MRI measurement (Normal Operating Mode).
- The ICP probe must be disconnected from the Spiegelberg ICP monitor before it is brought into rooms designated as MRI environments.
- Make sure that all components of the EVD set used with the ICP probe are "MR Safe" or "MR Conditional" at 1.5 or 3 Tesla.
- Do not bring probe accessories (stylet, 8, dura opener, 9, drill, 10+11, and Allen wrench, 12) into the MRI environment.
- Spiegelberg ICP monitors must never be brought into rooms marked as MRI environments.

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[1] RF-related temperature increase for probe 3PS (REF: SND13.1.63/FV535P); worst case on behalf of the whole "Intracranial Pressure and Catheter System" under the aforementioned scanning conditions

[2] RF-related temperature increase for Silverline® ventricular drainage catheter with cranial bolt (REF: EVD30.014.02); worst case on behalf of the whole "Intracranial Pressure and Catheter System" under the aforementioned scanning conditions