Edwards

Dear Valued Customer,

This letter, originally published in November 2010, is a notice regarding the MRI compatibility rating that has been assigned to the following devices:

- FloTrac sensor
- TruWave disposable pressure transducer

These devices have been determined to be “MR-conditional” according to the classification method specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic resonance Environment*.

This MR Conditional rating has been achieved under the following test conditions:

- Testing conducted under a static magnetic field of up to 3-Tesla
- Highest spatial gradient field of 720-Gauss/cm or less

These devices and their associated cables are not intended for use inside the bore of the MR system and should not be in contact with the patient during the MR procedure.

The devices listed above do not contain any ferrous metals that are dangerous in an MRI, but they do contain other metals that could produce signal artifacts. The transducers should be kept out of the field of view during imaging.

If you have any additional questions, please do not hesitate to contact the Edwards Lifesciences Technical Support Department at 800-822-9837 (USA) or 949-250-2500 (outside the USA).

Sincerely,
Product Technical Support
Edwards Lifesciences
1-800-822-9837

For professional use. CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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