Edwards

Dear Valued Customer,

This letter is a notice regarding the MRI compatibility rating that has been assigned to the following devices:

Device Name	Model Numbers
PreSep oximetry catheter	All Models
PediaSat oximetry catheter	All Models
VAMP system	All Models
VAMP Jr. system	All Models
VAMP Flex system	All Models
AVA HF catheter	All Models
AVA 3Xi catheter	All Models
AVA 3Xi introducer valve	All Models
Vantex CVC catheter	All Models
Multi-Med CVC catheter	All Models
IntroFlex catheter	All Models
Swan-Ganz pediatric catheter (oximetry without thermistor)	040F4, 040HF4, 015F4, 015HF4
Swan-Ganz flow directed catheter (all tip configurations)	111F7, 114F7, 115F7, 123F6

These devices have been determined to be “MR-safe” according to the classification method specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic resonance Environment*.

These devices are made entirely from nonmetallic, non-conducting, and nonmagnetic materials. None of these devices have materials that are affected by the electromagnetic fields generated during an MRI procedure. Accordingly, these devices present no known hazard when used in or on patients who are undergoing MRI procedures.

The cables which connect the oximetry catheters to monitors do contain metals and should be disconnected prior to performing the MRI procedure.

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

Sincerely,
Product Technical Support
Edwards Lifesciences

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.

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