



## IC-2A Ventilator MR Information

Non-clinical testing has demonstrated the IC-2A adult/pediatric MRI ventilator is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla
- Spatial gradient field of 262-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning
- MR image quality may be 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.
- Additional requirements:

The IC-2A must be used with the BMD MR-conditional stand, and the stand's wheels that have integral wheel locks must be locked.

Do not place the IC-2A & stand closer than one foot away from the MR bore (do not place the IC-2A inside the MR bore).

If using supply gas cylinders and regulators, use only MR-conditional aluminum gas cylinders and regulators (observe manufacturer's published MR-conditional requirements).

Attested by

A handwritten signature in black ink, appearing to read 'Ken Close', written over a horizontal line.

Kenneth Close  
Manager of Regulatory Affairs  
Bio-Med Devices, Inc.



### **MVP-10 Ventilator MR Information**

Non-clinical testing has demonstrated that the MVP-10 infant MRI ventilator is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla
- Spatial gradient field of 472-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning
- MR image quality may be 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.
- Additional requirements:

The MVP-10 must be used with the BMD MR-conditional stand, and the stand's wheels that have integral wheel locks must be locked.

Do not place the MVP-10 & stand closer than one foot away from the MR bore (do not place the MVP-10 inside the MR bore).

If using supply gas cylinders and regulators, use only MR-conditional aluminum gas cylinders and regulators (observe manufacturer's published MR-conditional requirements).

Attested by

A handwritten signature in black ink, appearing to read 'Ken Close', written over a white background.

Kenneth Close  
Manager of Regulatory Affairs  
Bio-Med Devices, Inc.