

JUN 28 1996

510(k) Summary

SUMMARY OF SAFETY AND EFFECTIVENESS

MRT-50A/150A SOFTWARE UPGRADE 12.0 and MRT-150A SOFTWARE UPGRADE 12.1

1. **Model Name:** MRT-50A/MRT-150A
Device Name: Magnetic Resonance Device Accessory
Trade/Proprietary Name: MRT-50A/150A Upgrade 12.0, MRT-150A Upgrade 12.1
2. **Establishment Registration:** #2936923
3. **Name and Address:** TOSHIBA AMERICA MRI, INC.
280 Utah Avenue
South San Francisco, CA 94080

Contact Person: Steven M. Kay
(714) 730-5000
4. **DATE OF SUBMISSION:** March 27, 1996
5. **DEVICE DESCRIPTION**
The Software Version 12.0/12.1 Upgrade for the MRT-50A/MRT-150A adds new sequences and software enhancements to the existing MRT-50A/150A software version. Version 12.1 also adds a new hardware to increase the number of slices available for FastSE sequences.
6. **DEVICE CHARACTERISTICS:**
The V12.0/12.1 product is an upgrade to the MRT-50A/150A software release V11.9. V12.0/12.1 includes hardware upgrades, software changes and new sequences. The hardware upgrade in V12.1 increases the number of slices available for FastSE sequences. Version 12.0 software changes provide improved FastSE sequences and Multislab MRA. Version 12.1 software changes provide improved Fat Suppression sequences and STC Imaging.
7. **SAFETY PARAMETERS**

	<u>MRT-50A</u>	<u>MRT-150A</u>
Maximum static field strength: There are no changes to B0	0.5T	1.5T
Rate of change of magnetic field: There are no changes to dB/dt	7.5T/sec, $\tau = 1000\text{ms}$	7.5T/sec, $\tau = 1000\text{ms}$
Radio frequency power deposition: S.A.R. remains below the cleared levels.	0.3W/kg max SAR	0.8W/kg max SAR
Acoustic Noise levels:	80 dB	105 dB worst case 85 - 100 dB typical

Acoustic noise data was measured in accordance with NEMA guidelines.

510(k) Summary (cont'd)

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8. IMAGING PERFORMANCE PARAMETERS

	<u>MRT-50A</u>	<u>MRT-150A</u>
Specification volume:	Head: 14cmX14cmX14cm Body: 125mm diameter cross section X 250mm long	10cm dsv 20cm dsv
Signal to noise ratio:	Sample phantom images and clinical images were presented for all new sequences. Signal-to-noise ratios for each phantom image were given. Clinical studies were presented for all new sequences.	
Uniformity in three orthogonal planes:		Unchanged
Slice Profile in three orthogonal planes:		Unchanged
Geometric Distortion in three orthogonal planes:		Unchanged
	V12.0 and V12.1 do not change the gradient system, especially with regard to linearity. It is the gradient linearity that affects geometric distortion.	
Slice Thickness:		Not Applicable
Interslice Spacing:		Not Applicable

9. INTENDED USE

Anatomical Region:	Head, Body, Extremity, Spine, Neck, TMJ, and Heart
Nuclei excited:	Hydrogen
Diagnostic Use:	2D/3D Imaging, MR Angiography

10. EQUIVALENCY INFORMATION

Version 12.0/12.1 Upgrade for the MRT-50A/150A is substantially equivalent to the V11.9 Software release for the MRT-50A/150A. The 510(k) submission for V11.9 received FDA clearance on January 26, 1995 (K941864). Some of the scanning techniques require that the Super Performance Package be installed on the MRI system. Version 11.1 with the Super Performance Package was cleared for the MRT-50A in K924808. Version 11.1 was cleared for the MRT-150A in K914012. The MRT-150A with the Super Performance Package received market clearance in K925286.

Version 12.0/12.1 provides an improved selection of FastSE sequences, adds the FastIR technique and improves the performance of the Vascular Imaging Package. All safety and effectiveness attributes remain essentially unchanged.