

APPENDIX A

510(k) SUMMARY

K961842

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## 510(k) Summary

1. **Model Name:** MRT-35A  
**Device Name:** Magnetic Resonance Device Accessory  
**Trade/Proprietary Name:** MRT-35A Upgrade 8.5CD
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:** 26 April 1996

### 5. DEVICE DESCRIPTION

The 8.5CD Upgrade for MRT-35A adds a new sequence and software enhancements to the existing MRT-35A software version.

#### 5A. DEVICE CHARACTERISTICS:

The following describes the MRT-35A system with the 8.5CD Upgrade.

Type of magnet	Superconductive
Static Field	0.35 Tesla
Type of RF Coil	Not applicable
Data Acquisition Mode	2D Multislice, Multiecho, 3DFT
Pulse sequences	Spin echo, Inversion recovery, Fast spin echo, Cardiac Gated, Partial Flip, Matched Bandwidth, 3D, inplane presaturation, Spectre, Angiography, <b>2D Time-of-Flight</b> .
Reconstruction Technique	2 Dimensional Fourier 3 Dimensional Fourier 3 Dimensional Slice shift, Oblique, MIP for Angio
Display Matrix:	512x512
Slice Selection method:	Selective gradient, "slab" select slice encode for 3D
Acquisition Matrix:	256x32 to 256x256 in steps of 1
Image Acquisition Time:	3 seconds for fluoro acquisitions typical, 6 minutes for 4 NEX FSE typical
Pre and Post Processing:	No baseline correction except for data conjugation of Advanced Fourier Imaging, Post processing filtering
Number of slices:	64 for 3D acquisitions, protocol file limit of 256 slices
Slice Orientation:	unrestricted
Spacing:	gapless imaging

### 5A.1 New Hardware and Hardware Changes

Version 8.5CD does not change the configuration of hardware for the MRT-35A.

### 5A.2 New Software Features

Version 8.5CD does not introduce new software features to the MRT-35A.

### 5A.3 New Sequences and Sequence Changes

#### 5A.3.1 2D Time of Flight(TOF) sequence

The 8.5CD upgrade provides a 2DTOF sequence. 2DTOF includes optional walking presat (superior or inferior) to reduce the signal from adjacent tissue due to motion. The user interface for sequence selection and parameter specification common to other sequences is supported for 2DTOF also. There is no exceptional change in the manner that 2DTOF is selected when compared to pre-existing sequences. Acquisition orientation is restricted to transaxial orientation only. The sequence will not support oblique orientations nor gated acquisitions.

#### 5A.3.2 Sequence specification summary

The new 2DTOF sequence, with its identification parameters, is given below. With the exception of this additional sequence, there is no change to the sequence software.

Seq #	Sequence Type	TE	Flow Comp	Min Thick 8.5CD	Difference from 8.0CD
27	2D ANGIO TOF	12	FC	2.0mm	NEW

## 6. SAFETY PARAMETERS

Maximum static field strength:	0.35 Tesla
Rate of change of magnetic field:	6.83 Tesla/sec Axial 6.69 Tesla/sec Transverse
Radio frequency power deposition:	0.34 W/kg
Acoustic Noise levels:	L-peak: 101.6 db (peak impulse sound pressure) L-eq: 86.5 db (time integral of a-weighted sound pressure)

**7. IMAGING PERFORMANCE PARAMETERS**

Specification volume	10 Cm dsv for head coil 20 Cm dsv for body coil
Signal to noise:	Sample phantom images and clinical images were presented for all new sequences. Signal-to-noise ratios for each phantom image was given. Clinical studies were presented for all new sequences.
Uniformity in three orthogonal planes	Not Applicable
Slice Profile in three orthogonal planes	Not Applicable
Geometric Distortion in three orthogonal planes	Not Applicable
Slice Thickness	0.8 mm to limits of FOV and sequence.
Interslice Spacing	0 mm minimum

**8. Intended Use**

Anatomical Region:	Head, body, extremity, spine, neck, TMJ, Knee
Nuclei excited:	Hydrogen
Diagnostic Use:	2D and 3D imaging, Contrast Media, MR Vascular Imaging

**9. Equivalency Information**

8.5CD Upgrade for MRT-35 is substantially equivalent to the 8.0CD Software release for MRT-35. Similarity and/or differences between this device and the predicate device are summarized below.

**HARDWARE ENHANCEMENTS**

8.5CD has no hardware component differences from the preceding MRT-35A upgrade, 8.0CD.

**SOFTWARE ENHANCEMENTS**

Technical	Clinical
<b>Improved Image Reconstruction for FSE</b> Image reconstruction software is provided to further reduce subtle acquisition artifacts previously found in TE=20 Fast Spin Echo (FSE) sequences.	Image quality is improved for Fast Spin Echo TE=20 (4 and 7 echo).

**SEQUENCE ENHANCEMENTS**

Technical	Clinical
<b>2D Time-Of-Flight (TOF) Sequence</b> A new 2DTOF sequence is provided with optional pre-saturation bands that are user selected.	Allows image acquisitions of vascular structures with reduced motion artifacts.