



**Instructions for Use
3T 32 Channel Head Coil for
General Electric Discovery MR750
MRI Scanners
Model #: 3832016**

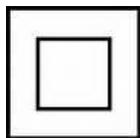
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Revision <14> 2023-06-30

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Introduction:

The Nova Medical 3T 32 Channel Head Coil is a unique product which provides high sensitivity and excellent parallel imaging performance on the General Electric 3T MR750 MRI scanner platform. The close-fitting element geometry provides SNR improvements of 2-3X in brain cortex while allowing ASSET acceleration factors of up to 4X along any imaging axis. This combination allows the extremely fast acquisition of ultra-high resolution anatomic and fMRI data sets.

The Nova Medical 3T 32 Channel Head Coil may also be referred to as 3T 32 CH Head Coil.

The coil consists of the following applied parts:

- 32 Channel Head Coil
- Tray that is used for placement of the array onto the patient bed of the scanner

Accessories:

- Mirror
- Foam Cushions

Intended Use:

The Nova Medical 3T 32 Channel Head Coil is a non-implantable magnetic resonance receive-only head coil intended for diagnostic patient imaging when used in conjunction with a GE 3T Discovery MR750 MRI Scanner to produce images and/or spectra of a human head for medical diagnosis purposes.

Indications for Use:

The Nova Medical 3T 32 Channel Head Coil is to be used in conjunction with a GE Magnetic Resonance (MR) Scanner to produce images and/or spectra of the head, that when interpreted by a trained physician yield information that may assist in diagnosis.

- Model # 3832016 is used with the GE 3T Discovery MR750 MRI Scanner

Intended Users:

Users of this device are Radiologist and radiologist technicians.

Intended Patient Target Groups:

The Nova Coil is intended for all patients requiring MRI scanner of the head in 3T environment.

Clinical Benefits:

Improved diagnosis in comparison to MRI without head coil or similar technology.

Safety:

The Nova Medical 3T 32 Channel Head Coil has been designed for maximum patient safety. In particular, the coil set includes multiple different circuits to assure safe operation.

It is essential to follow the safety instructions in the 'Instructions for Use' of all equipment and systems being used.

In particular, observe the following before using the product:

- Before every use of this product make sure that the housing, connecting cables, and plug contacts are intact. If defects are discovered, the product must not be used. If any physical or other damage is discovered or malfunctions occur, do not use device. Notify Nova Medical Inc. without delay
- Do not use coil, if coil is wet.
- Do not use unapproved cables or adapters for coil hook up.
- Do not modify or alter coil configuration files
- Do not use this product with scanners other than the GE 3T Discovery MR750 MR System - Never attempt use with on a 1.5T or 7T scanner.
- Always use hearing protection in form of foam earplugs or other suitable hearing protection equipment.
- Repairs to this product may only be performed by Nova Medical Inc. or by a representative authorized by Nova Medical Inc.

Contraindications:

MRI is contraindicated when these specific patient conditions exist:

- Patient(s) who have implanted metallic objects including but not limited to cardiac pacemakers, implanted defibrillators, neurostimulators, bio-stimulation devices, pumps, orthopedic joint prostheses, metallic foreign bodies (e.g., shrapnel, bullets, ferro-metallic machining debris).
- Patient(s) with external conductive hardware such as EEG electrodes, electrical stimulation devices, jewelry, drug eluting patches (e.g., nicotine, fentanyl) or other conductive objects on their bodies.
- Patient(s) with excessive tattoos.

Caution: Federal law (USA) restricts this device to sale by, or on the order of, a physician/healthcare professional.

Note to user and/or patients: Any serious incident that has occurred in relation to this device should be reported to Nova Medical and/or the competent authority of the Member State in which the user and/or patient is established.



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Installation Instructions

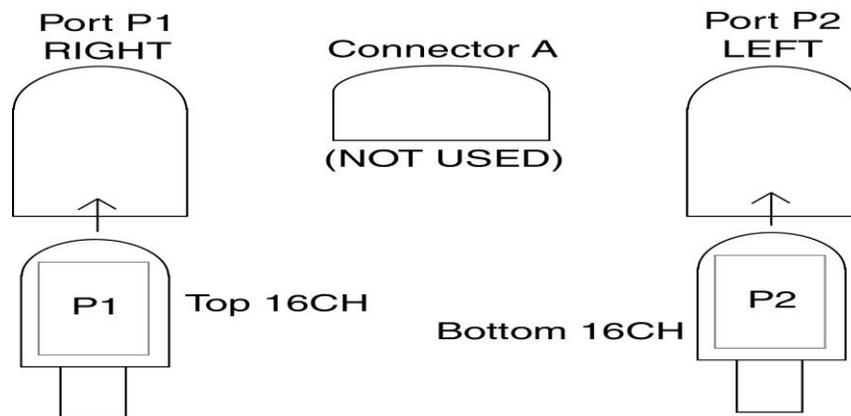
Before operating coil, be sure to install the proper coil file database entries. As these files and installation methods depend upon the operating system version, please check with Nova Medical and/or your GE representative to obtain the latest information.

Operation:

Connecting Coils:

Place head array coil with array on patient table. Two “feet” extrusions are present on either side of tray and should fit into the slots in the patient table. This ensures the coil remains firmly in position. Connect the coil plugs into the General Electric MR750 patient table as below:

NOTE: Make sure plugs P1 and P2 are in red “open” position before inserting into patient table, then turn handles to green “closed” position to lock these connectors into place before using coil.



IMPORTANT: Always connect both coil cables to the patient bed. Failure to connect all channels of array coil may result in coil damage and/or unsafe operation.

For patient positioning, first slide back top half of array. The detents on the coil travel may require the front of top coil half to be minimally lifted by 1-2mm to allow backwards travel. Depending upon head size and patient comfort, place either thin (6mm) or thick (12mm) foam pads in array coil. Head should be positioned so that it fits comfortably inside bottom half of array coil. For best results, make sure head is fully inserted into coil – a large gap between top of head and coil will reduce coverage and sensitivity. Slide top portion of array over head. Push downward lightly and it will click into position at its fully forward position. If desired, adjust mirror as needed for optimum viewing angle.

HELPFUL HINT: For patients with large heads, use 6mm foam pad. In some cases, it may be necessary to push top portion of array coil back about 1cm to allow extra room for head. This has minimal impact on coil performance.

Scan as with any other coil. The coil set should be compatible with all standard sequences that can make use of thirty-two channels for receive.

To remove patient from coil, follow the reverse procedure as patient setup by sliding top half of coil backwards (may require lifting front edge of top half 1-2mm), moving mirror out of the way if needed, and having patient remove head from coil.

Disconnecting coils:

Disconnect both cables going to patient bed.

NOTE: Turn both handles on the P-Port Plugs 1 and 2 to the red “open” position before removing these connectors.

IMPORTANT: BE SURE TO DISCONNECT ALL PLUGS FROM PATIENT TABLE BEFORE REMOVING COILS FROM PATIENT TABLE. ATTEMPTING TO REMOVE COIL BEFORE IT IS DISCONNECTED CAN LEAD TO CABLE AND COIL DAMAGE

Cable holders on either side of tray can be used to secure cables for convenience.

Carefully remove coils from patient bed and store in a safe place

NOTE: USE CAUTION when lifting coil since it weighs about 8kg. Lift coil using both handles.

Troubleshooting:

Problem: Scanner reports coil file error

- Check to be sure proper coil database entries are installed on scanner. These depend upon scanner system software. Without database entries correctly installed, the coil will not work
- Check that all connections are made properly. In particular check to make sure that each plug is connected to its respective socket.

Problem: Poor image SNR:

- Check that patient landmark is correct and that the head is fully extended into the array coil.
- Check to see that top half of array is extended fully forward. If this portion is not extended over head, image reception from top elements may suffer.

Problem: Image “White-out” of high intensity areas on receive-coil images:

- This is caused by FFT scale factors that are too large. Setting of proper FFT scale factors is a highly complex issue that depends upon a number of factors. In some cases, reducing FFT scale factors on individual coil channels may help minimize this problem.
- Try using raw data files (e.g. not the processed DICOM images). These should be not affected by reconstruction FFT scale factors.

Problem: Patient’s head doesn’t fit into coil.

- The coil has been designed to fit >95% of typical adult heads. We have had relatively few cases reported to us of patients whose heads were too large to fit inside the array coil. Large heads may benefit from the use of thinner foam cushions. Also having patient slightly tuck chin downwards may be required on patients with large facial structures.

Problem: My headphones don’t fit; how can I present audio data to a patient?

- The Nova Medical 3T 32 Channel Head Coil has been optimized for coil performance which requires placing coil elements close to the head. Consequently, many standard headphones won’t fit inside the coil. A number of solutions are available including earbud style headphones, foam ear inserts with thin acoustic tubes, ultra-flat headphones, among others. Please check with Nova regarding the current status of compatible products.

Important: Always use some form of suitable hearing protection to prevent scanner noise from causing patient hearing loss.

Problem: Minimal Improvement in Image Quality on Anatomic Images

- Depending upon resolution and voxel size, many standard anatomic sequences have excellent image quality and may not show dramatic benefit of increased coil sensitivity. In many cases, it is only with very high-resolution images (e.g. 512x512 matrix, 1-2mm slices, and higher acceleration rates) that real benefit can be seen with improved coil performance. We often recommend increasing in-plane spatial resolution by 30-50% with our coil. For cortical regions, even higher resolutions can be used. If it is desired to leave resolution unchanged, the parallel imaging performance of the Nova Medical 3T 32 Channel Head Coil can be used to significantly shorten image acquisition times with ASSET, ARC, and other such techniques. In general, acceleration rates of up to 4X can be achieved along any imaging axis.

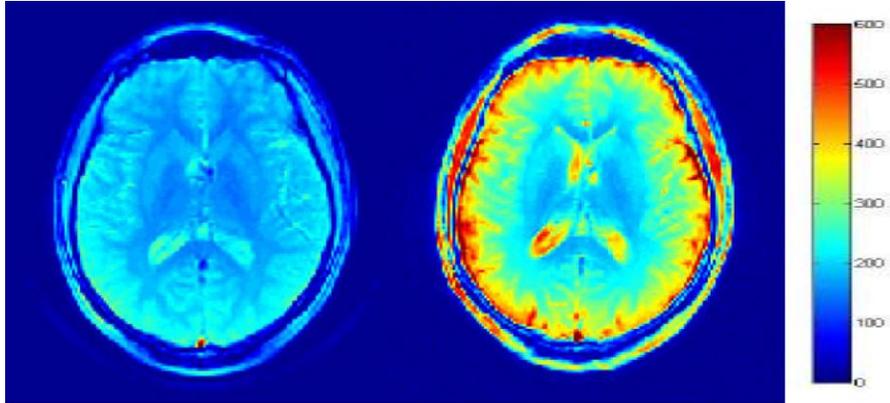
Problem: Minimal Improvement in fMRI data with Coil

- The temporal stability of fMRI datasets is affected by many factors and the inherent coil performance is often not a limiting factor for comparatively large voxel sizes. In particular, large 5x5x5mm voxels may see very little benefit. It is only with smaller voxel sizes such as 2x2x2mm as can be achieved by multi-slice techniques where a marked performance benefit is demonstrated. If you wish to acquire more modest resolution fMRI data, we recommend increasing the ASSET factors to allow faster image acquisition with reduced susceptibility to B0 distortion artifacts.

Problem: Reduced Central SNR in comparison with standard GE 8ch array

- Image SNR depends upon many factors only some of which involve the coil. In particular, very high SNR images (SNR>500) can be affected by other parameters such as digital image noise, post-processing, and other factors not related to coil performance. Nova generally recommends doing SNR comparisons at a SNR of around 50 in the center of the image. This is particularly important with the Nova Medical 3T 32 Channel Head Coil where the SNR depends strongly on position and can reach very high values in the periphery.
- As a quick check on coil performance, run a lower SNR scan (e.g. 512x512, 2mm slice, GRE, 25deg flip, full matrix acquisition) on a suitable phantom such as the MRS sphere. Measure signal intensity in center and divide by <standard deviation> of background noise in region where it is uniform and not affected by artifacts. Compare results between coils. This should show that 8ch array and Nova Medical 3T 32 Channel Head Coil are approximately equal in the center of the phantom.
- In general, all good coil designs will have similar central SNR but the Nova Medical 3T 32 Channel head Coil should have up to 2-3X SNR improvement in cortex over the standard 8ch array. In addition to having better SNR, the Nova Medical 3T 32 Channel Head Coil has much better parallel imaging performance and allows acceleration along any axis.

SNR Comparison with standard 8CH GE Head Coil



Note 2-3X SNR improvement in cortex, modest central improvement
Source: Tom Lu, University of California, San Diego

Cleaning and Disinfection:

A moistened cloth can be used to clean the product using water or commercially available cleaning and disinfection solutions (e.g. alcohol-based). Do not use any rough or abrasive detergents, which could dissolve the surface of the housing or varnish. Although the electronic circuitry is protected against moisture, liquids should not be allowed to get into the device. Do not immerse the device.

Maintenance:

If the product is/are subjected to normal use and cleaning, no maintenance is necessary.

Service/Repair:

The 3T 32 Channel Head Coil has no user serviceable parts. Under no circumstances should the coils be opened, and user repair attempted.

Repairs may only be performed by Nova Medical Inc. or by a representative authorized by Nova Medical Inc.

The user of the product is not entitled to perform repairs. If this happens, Nova Medical Inc. does not accept any liability for the operability of the product or for any consequential damage or injury, especially such caused to patients, staff, equipment or third parties.

Prior to returning the product for servicing the product should be cleaned and disinfected following the instructions for use.

Storage and Transport Environment:

When the unit is not in use, it is recommended that the unit be kept within the controlled humidity and temperature conditions of the MR scan room. This will assure proper operating conditions for immediate use of the coil

For storage outside the MR scan room it is recommended that the following ranges not be exceeded

A) Operating Conditions (Allows Immediate use of Product)

Temperature: $>10^{\circ}\text{C}$ and $<26^{\circ}\text{C}$ ($>50^{\circ}\text{F}$ and $<78^{\circ}\text{F}$)

Humidity (non-condensing) $>30\%$ and $<70\%$

Altitude: $<3000\text{m}$

B) Non-operating Conditions (Storage and Transport)

Temperature: $>0^{\circ}\text{C}$ and $<40^{\circ}\text{C}$ ($>32^{\circ}\text{F}$ and $<104^{\circ}\text{F}$)

Humidity (non-condensing): $>20\%$ and $<90\%$

Barometric Pressure: $>500\text{ hPa}$ and $<1060\text{hPa}$

If the product has been outside of the conditions listed in A), the product should be allowed to achieve equilibrium to these conditions before use.

If the product has been kept outside of the conditions listed in B), the coil should be allowed to achieve equilibrium to the conditions listed in A) for a period of not less than 24hrs before use.

Packing and Repacking for Transport:

The product requires no special unpacking instructions: remove box cover, remove excess packing material, lift product out of box, and remove remaining protective foam covering.

It is strongly recommended that the original packing materials be kept and used in the situation that the unit needs to be transported back to Nova Medical. The wooden crate with cover clamps, interior foam cushioning, and accessory foam covering will protect the coil against the rigors encountered in domestic and international shipping.

IMPORTANT: To minimize chance of damage, be sure unit is secure within the wooden shipping container. If necessary, add cushioning as required to stabilize the unit within its container. Additionally, ensure that box cover is firmly in place

If the original packing materials have been lost or damaged, please contact Nova Medical at the following address for appropriate transport instructions:

Nova Medical, Inc.
150 West Street Suite 201
Wilmington MA 01887 USA
Phone 978-988-5553
Fax 978-988-5556

Disposal:

At the end of the product's lifetime, the Nova Medical 3T 32 Channel Head Coil Model # 3832016 should be shipped back to Nova Medical for proper disposal and recycling.

This service is offered free of charge.

The disposal address is:

Nova Medical, Inc.
Attention: Coil Disposal
150 West Street Suite 201
Wilmington MA 01887 USA

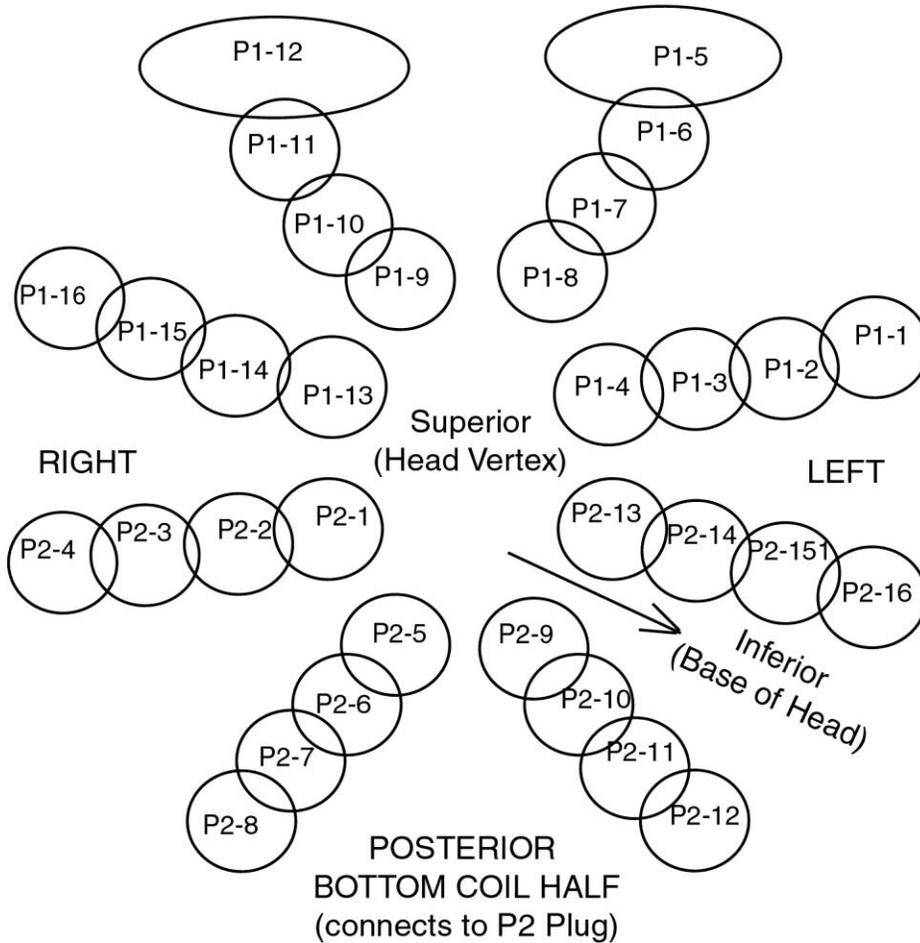
Specifications:

Model # 3832016 3T 32 Channel Head Coil

	PARAMETER	VALUE	UNITS
1.0	General Specifications		
1.1	Coil Type	32 Channel Whole-Brain Receive-only Array	
1.2	Compatibility	GE 3T Discovery MR750 MR System	
1.3	Application	High Sensitivity Neuroimaging/ fMRI/spectroscopy	
2.0	Electrical Specifications		
2.1	Element Geometry	Top half: four columns of four elements each Bottom: four columns of four elements each	
2.2	Coil Resonant Frequency (Nominal)	127.75	MHz
2.3	RF Element Construction	Flexible PC board trace with distributed capacitance	
2.4	Detuning Circuitry	High Power active+ one passive detuning circuit for each coil element	
2.5	PIN Bias Voltage and current	+130mA body transmit, -5V @0mA receive	
2.6	Isolation Active Detuned State	>30	dB
2.7	RF and bias connections	P1,P2 MR750 ODU connectors, each using channels 1-16	
2.8	Coil Interface (inside coil housing)	Includes preamplifiers, MR750 style connectors, bias distribution network.	
2.9	Preamplifier Gain	28.5db +/-1.5db (50ohm)	
2.10	Preamplifier Power	+10V, total current less than 600mA	
3.0	Mechanical Specifications		
3.1	Coil shape	Close fitting head former inside cylindrical case, housing slides open for patient positioning, tray included to affix coil to patient bed	
3.2	Physical Inside Dimensions	Designed to fit > 95th percentile head size	
3.2	Coil Width	44	cm
3.3	Coil Length	38.2	cm
3.4	Coil Height	29.25	cm

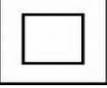
Appendix I: Element Layout for the Nova Medical 3T 32 Channel Head Coil Model #: 3832016

ANTERIOR
TOP COIL HALF
(connects to P1 Plug)



Note: Depending upon imaging plane, some elements may be out of plane and show low signal intensity.

Appendix II: Explanation of Symbols

Symbol	Explanation
	Body Floating (BF) type Applied Part as defined in International Standard
	Double Insulated
	Read Operating Instructions
	Do not dispose in trash; follow disposal instructions in user manual
	European Authorized Representative
	Catalog Number
	Serial Number
	Manufacturer
	Date of Manufacture
	CE Mark
	Medical Device
	This symbol identifies the importer

	Temperature Limits
	Locked (Closed) Position
	Unlocked (Open) Position
Rx only	Prescription use Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician

Appendix III: Quality Checks – Testing Coil Signal to Noise Ratio (SNR)

In order to assure that the coil is in working order, we recommend periodically checking the coil SNR by the following tests.

Procedure:

- 1) Start New Exam
- 2) Coil setup: Place coil on patient table in its normal imaging position (e.g. locks in slots on patient table sides). Connect coil plug(s).
- 3) Place 6mm foam cushion pad on bottom half of coil.
- 4) Place 3.0 TLT sphere (GE Model 2359877) on foam cushion pad so it rests in bottom half of coil. Coil should rest within a few mm of the superior portion of bottom coil. Slide top half of coil fully over the bottom half.
- 5) Landmark on center of TLT sphere.

Measurement Parameters: (select scan plane as axial and frequency direction as R/L for first image sequence). For Sagittal select frequency direction as S/I and Coronal as R/L)

Patient Name	None
Patient ID	Nova test
Patient Weight	111 lbs
Patient Position	Supine
Patient Entry	Head First
Coil Mode	Not applicable
Pulse Sequence	Spin Echo, 2D
Pulse Sequence Options Selected	Extended dynamic range
Scan Plane Orientation	Axial
Direction of Frequency Encoding	R/L (axial)
Frequency	512
Phase	512
Field of View	25 cm
Phase FOV	1
Slice Thickness	2mm
Sequence Repetition (TR)	1000ms
Echo Delay Time(TE)	30ms
Number of Averages	1
# of slices	1
Spacing	0
NEX	1
Bandwidth	12.5kHz
Shim	Auto
RF Drive Mode	Quadrature
Intensity Correction	None
Intensity Filter	None
Phase Correct	Off

Wait at least 10 minutes before scanning to allow coil and phantom to come to equilibrium

4) Run AutoPrescan, then press scan.

5) After image collection, window and level the resulting image. Place four rectangular ROIs of approximately 625mm² in the corners of the image. Be sure to avoid any residual ghosting artifacts and make sure each ROI is fully within the noise region. Place a ROI of size approximately 18600mm² in the center of the phantom.

6) Average the standard deviations of the four background regions, and divide this number by 0.71 to determine the average image noise level.

Then divide the mean of the fifth large ROI by the noise to calculate SNR.

Example:

ROI1: 7.9

ROI2: 7.8

ROI3: 8.1

ROI4: 8.0

ROI5: 810

Mean STD: $(7.9+7.8+8.1+8.0)/4 = 31.2/4 = 7.95$

Image Noise: $7.95/0.71 = 11.2$

SNR (axial) = $810/11.2 = 72.3$

7) This test should be repeated for the coronal and sagittal planes. For sagittal plane use frequency readout S/I and Coronoal use R/L

Specification: SNR measured by this method should exceed 50 and is typically higher depending upon scanner specifics.

If SNR is low, we suggest repeating the measurement and making sure that the background ROIs are free from ghosts and artifacts.

It is recommended to measure the SNR values for the axial, sagittal, and coronal planes when first installing the coil. In this fashion, there is baseline data for the product. For quality assurance, the measurement set can be repeated at intervals depending upon site specifics. We generally would recommend at least the axial measurements be repeated on a monthly basis and the results recorded.

Figure 1: Coil and Phantom Setup. A) shows proper position of phantom, B) shows coil top portion fully forward and in the correct location for imaging.

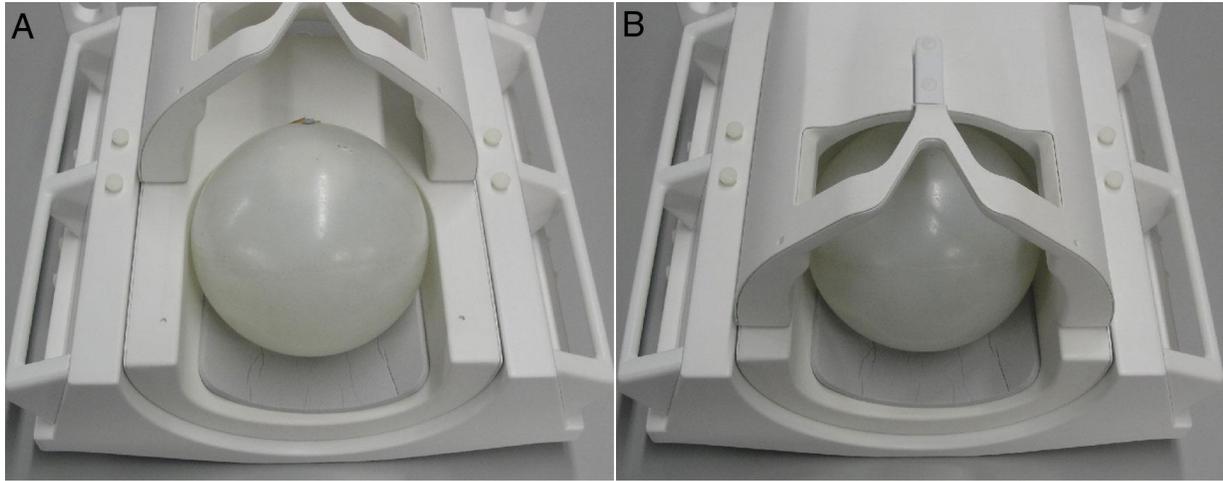
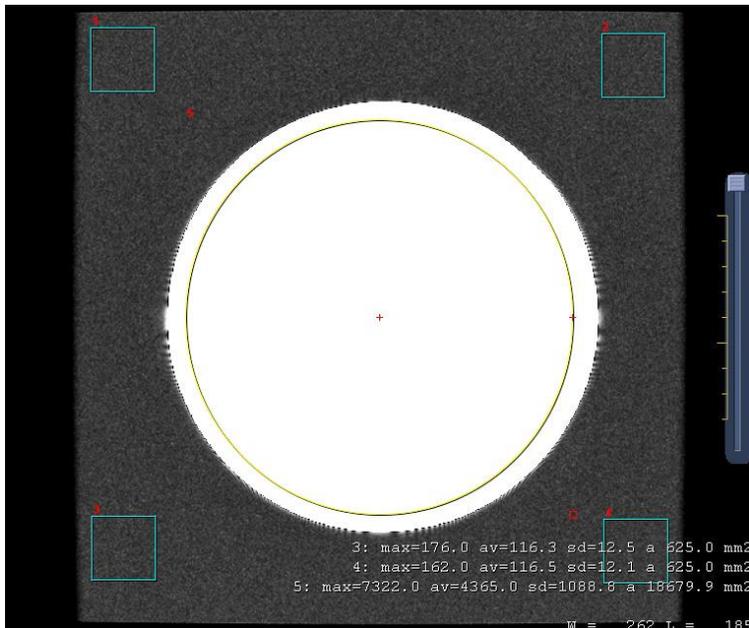


Figure 2: Noise ROI placement. Place four ROIs in corners of image avoiding ghosting or other artifacts. Be sure that they fully reside in the noise region. Place fifth ROI in center of phantom image. This should have an area of roughly 18,600 mm².



References:
NEMA MS-6-2008(R2014), MS-1-2008(R2014)