



**Instructions for Use
Nova 1Tx32Rx
Head Coil 7T Clinic
for use with the
Siemens MAGNETOM Terra MR Scanner**

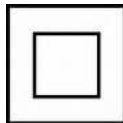
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Nova Medical REF : 1893279**

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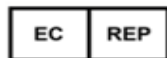
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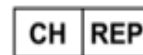
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Importer (only for EEA – European Economic Area):



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Siemensstrasse 3
91301 Forchheim
Germany

Importer (only for Switzerland):



Siemens Healthineers International AG
Hinterbergstr. 14
6312 Steinhausen

Introduction:

The Nova 1Tx32Rx Head Coil 7T Clinic is a unique product set which provides the transmit capability of a volume coil with the sensitivity of a whole-brain receive array on the Siemens MAGNETOM Terra 7T MRI scanner platform. Careful design of the volume coil provides a high efficiency transmit field while featuring circuitry to enable its use with a thirty-two channel receive array which provides cortical and central brain sensitivity as well as the capability of highly accelerated acquisition in any imaging plane.

Based upon our well-known 1Tx32Rx Head Coil, the Nova 1Tx32Rx Head Coil 7T Clinic has been specifically adapted for use with the new Siemens MAGNETOM Terra MRI scanner. It specifically includes a CE mark for clinical use in Europe. Electrically the coil remains the same, though features a new tray which allows the coil to rest 2cm lower in the patient table. Additionally, the SAR management of the MAGNETOM Terra will allow improvements in SAR performance with higher number of slices allowed with power intensive sequences.

The coil consists of the following parts:

- Transmit Volume Coil
- 32 Channel Receive-only Head Array
- Tray that is used for placement of the coil onto the patient bed of the scanner

Accessories:

- Mirror
- Phantom Holder
- Cushions

Indications for Use:

Used in the Siemens MAGNETOM Terra System, the 7T 32-channel Head Coil is intended to be used as a diagnostic imaging device to produce transversal, sagittal, coronal, and oblique images of the internal structure of the body. The images produced reflect the spatial distribution of protons exhibiting magnetic resonance.

When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Intended Users:

Users of this device are Radiologist and radiologist technicians.

Intended Patient Target Groups:

Patients weighing greater than 30kg who are undergoing MRIs, for which transversal, sagittal, coronal and oblique images of the internal structure of the body are to be produced.

Clinical Benefits:

- Improved diagnosis in comparison to MRI without head coil or similar technology.
- Improved depiction of the anatomical structures of the head.

Safety:

The Nova 1Tx32Rx Head Coil 7T Clinic has been designed for maximum subject 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.

Contraindications:

- 1) ***Do not use with patient(s) who have implanted metallic objects located above the level of the neck.***
- 2) ***Do not use with patient(s) with external conductive hardware such as EEG electrodes, electrical stimulation devices, jewelry, or other conductive bodies in the neck or head region.***
- 3) ***Do not use with children or patients weighing less than 30kg***

 **Warnings:**

In particular, observe the following before using the product.

- 1) 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
- 2) Do not use coil if it is wet.
- 3) Do not use unapproved cables or adapters for coil hook up.
- 4) Do not modify or alter coil configuration files
- 5) Do not use this product with scanners other than the 7T Siemens MAGNETOM Terra MR Scanner- Never attempt use with on a 1.5T or 3T scanner. Additionally, this coil is not compatible with older Siemens 7T MR scanners.
- 6) Always use hearing protection in form of foam earplugs or other suitable hearing protection equipment.
- 7) Repairs to this product may only be performed by Nova Medical Inc. or by a representative authorized by Nova Medical
- 8) Do not use transmit coil with any other components than the provided receive-only thirty-two channel array
- 9) Do not use receive-only thirty-two channel array with any other components than the provided transmit coil.
- 10) Higher SAR limits with MAGNETOM Terra: the SAR management with the MAGNETOM Terra is different and allows higher average power levels. While the power levels used are within IEC regulations, the safety of non-Nova provided coil accessories may change with the new scanner.
- 11) In cases of unusual patient anatomy (e.g. hydrocephalus, large surgical resections of brain tissue) or serious underlying health conditions which can impair thermoregulatory capacity (e.g. circulatory impairment, febrile states) it is recommended to use the "Normal Operating Mode". Use caution when using "First Level Controlled Operating Mode" under these conditions as this presents additional RF heating risks to the patient.

Important: Both the array and volume coil have been designed for use as a package together. Modification for use with other coils will void warranty and is done so at the entire risk of the operator. Neither, Nova Medical or its personnel will be held for liable damages resulting from such unauthorized use of either portion of the coil set.

NOTICE: The 1Tx32Rx Head Coil 7T Clinic has been configured for improved SAR performance on the Siemens MAGNETOM Terra MR Scanner when using the “First Level Controlled Operating Mode”. Any user generated heating test data done with previously released research version will need to be repeated for this new product set. Do not change the SAR configuration for the previously released Nova 1Tx32Rx Head Coil as this may lead to coil damage and subject injury.

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.

Installation Instructions

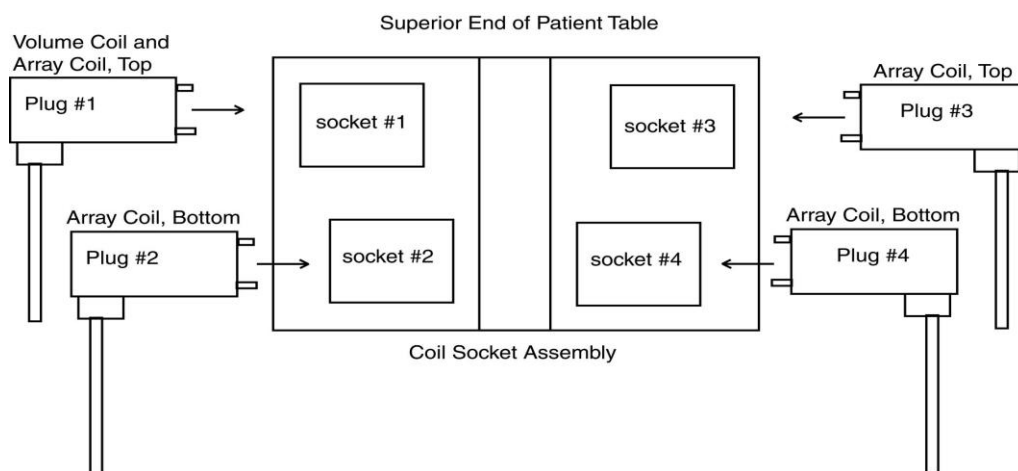
Siemens Healthcare will perform the steps required to install the Nova 1Tx32Rx Head Coil 7T Clinic onto their MR Scanner system.

Operation:

Connecting Coils:

Place the Nova 1Tx32Rx Head Coil 7T Clinic on patient table. Slide coil backwards so that coil holder fits against the Siemens provided foam padding at the back portion of the patient table.

Connect the four plugs into the Siemens patient table as below:



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

For subject positioning, first slide back volume coil and then slide back top half of array. 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, the subject mirror can be inserted onto its mounting rail and positioned for optimum viewing location. To insert mirror, loosen locking screw and slide mirror mounting bracket onto the mirror mounting rail.

NOTE: Do not attempt to completely remove mirror locking screw as a lock ring prevents this operation – it is only necessary to loosen this screw to slide mirror bracket onto the mounting rail.

Once the array coil has been set up, slide volume coil over array coil. The volume coil should be brought to its maximum forward position. If needed, the volume coil can be locked into place with screws at either side of coil.

HELPFUL HINT: for subjects with large heads, use 5mm foam pad. Slightly tucking chin to chest also will improve head clearance. In some cases, it may be necessary to push top portion of array coil back about 1cm to allow extra room for head (though always slide volume coil fully down over array coils and head to provide best transmit performance).

Landmark subject with alignment lights on the isocenter mark present on the top of the volume coil.

Typical use of the coils would be to use the volume coil for transmit and the array for receive. This provides maximal sensitivity and capability for accelerated parallel imaging. In this mode, all thirty-two array channels can be used for receive. However, the system can be used with the volume coil for both transmit and receive. This is useful for many applications such as shimming, scouting, and other operations which require a more uniform receive field.

-> To select all thirty two elements for array-receive, select “AC” icon on the console interface.

-> To select Volume Coil for receive, select “VC” icon on console.

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.

HELPFUL HINTS REGARDING SETTING TRANSMIT VOLTAGE: In some cases system will “miss” proper transmit voltage setting. If system does not converge upon a transmit voltage or converges on a very high transmit voltage (e.g. 350V), then manual setting of the transmit voltage should be done. B1 mapping is the preferred method of setting the transmit voltage, though for most heads a transmit voltage for 90 degree flip at center of the brain might run 200-220V.

To remove subject from coil, follow the reverse procedure as patient setup. This includes sliding volume coil backwards (unlocking it if necessary), moving top half of array coil backwards, and having subject slowly raise their head.

Disconnecting coils:

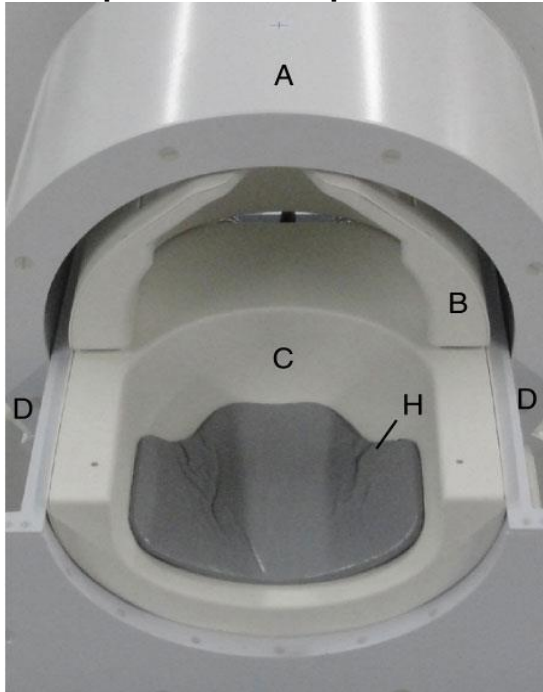
Disconnect all four cables going to patient bed.

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

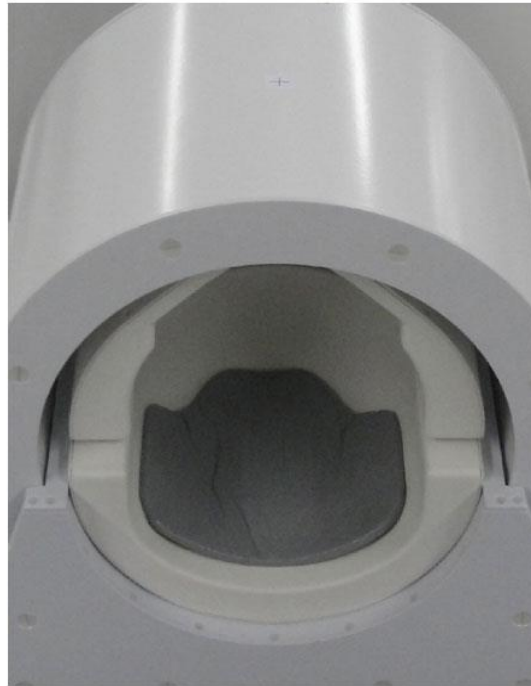
Carefully remove coils from patient bed and store in a safe place

 **NOTE: USE CAUTION when lifting coils since they weigh about 15kg total. Lift coil with two hands.**

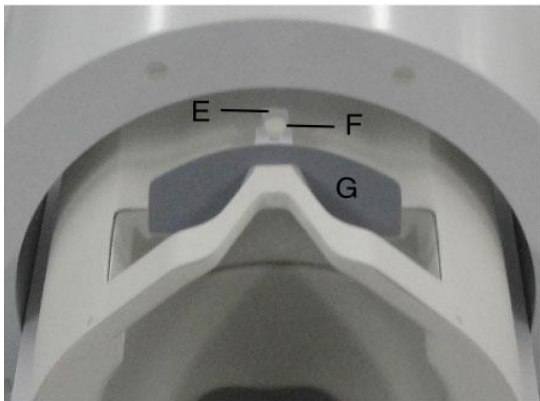
Description Coil Components:



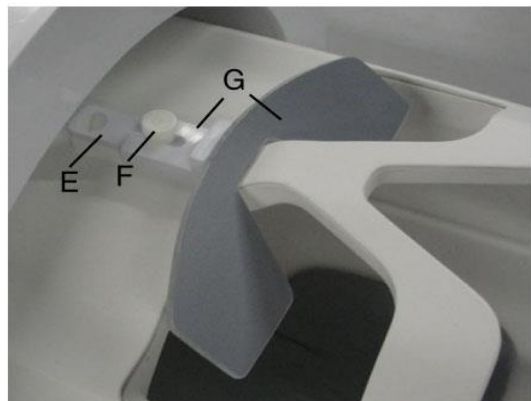
Volume Transmit, 32ch Array Coil
Open for Subject Positioning



Volume Transmit, 32ch Array Coil
Closed for Subject Imaging



Subject Mirror For Rear Projection
of visual stimuli



Detail, mirror assembly

LEGEND:

A: Volume Transmit Coil

B: Array Coil, Top Half

C: Array Coil, Bottom Half

D: Volume Coil Locking Screws

E: Mirror Mounting Rail

F: Mirror Locking Screw (loosen, do not remove, to position or insert mirror)

G: Subject Mirror with Mounting Bracket

H: Foam Pad

Troubleshooting:

Problem: Scanner reports coil file error

- 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 fully extended, image reception from top elements will not be good.
- Check to make sure that all array coil elements have been selected.

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 not be affected by reconstruction FFT scale factors.

Problem: High Transmit Voltage required

- Make sure all connections are properly made.
- Check patient landmark is correct and that the volume coil has been fully extended over subject's head. Operating the volume coil without fully extending it over subject's head will lead to a large decrease in transmit efficiency.
- In some cases, it may be worth trying a manual setting of the transmit voltage. In general, transmit voltage setting between subjects should only vary by about ten to fifteen percent.

Problem: Contrast Variations in Images:

The circularly polarized transmit B1 produced by a volume coil is markedly affected by the presence of the human head. These effects have been well described and include a pronounced increase in the B1 field strength in the center of the head ("center brightening"). Less well known, is the significant loss of B1 field in the more inferior brain structures. These "anti-nodal" patterns are particularly noticeable in the deep temporal lobes. Additionally, depending upon head shape and size, there can be some right-left asymmetry in the transmit fields in the more inferior portions of the brain. All of these transmit field variations become particularly noticeable with sequences that require precise flip angles.

While other approaches may eventually be useful, a well-built highly efficient circularly polarized volume coil offers the advantages of simplicity, reliability and the inherent safety of well described field patterns.

Some suggestions that may be helpful in overcoming 7T field effects:

- Check Transmit Voltage calibration. For more inferior portions of brain, additional transmit voltage may be required to compensate for variations in transmit field caused by head and volume transmit coil.
- Check head position in coil – tilting of head to right or left may worsen field distortions.
- If available, consider the use of adiabatic or semi-adiabatic transmit pulses.

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 damage the surface of the coil housings. Although the electronic circuitry is protected against moisture, liquids should not be allowed to get into the device. Do not immerse the device in water or cleaning solution.

Maintenance:

The Head Transmit Coil and Array coils have no user serviceable parts. Under no circumstances should the coils be opened and user repair attempted.

Service/Repair:

The Nova 1Tx32Rx Head Coil 7T Clinic 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 Nova 1Tx32Rx Head Coil 7T Clinic 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 hPa and <1060 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), it is recommended that the coil be allowed to achieve equilibrium to the conditions listed in A) for a period of not less than 24 hours before use.

Packing and Repacking for Transport:

The product requires no special unpacking instructions: remove clamps holding box cover, remove foam 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. 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: (1) 978-988-5553
Fax: (1) 978-988-5556

Disposal:

At the end of the product's lifetime, the Nova 1Tx32Rx Head Coil 7T Clinic 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:

Nova 1Tx32Rx Head Coil 7T Clinic: Volume Transmit Coil Component

	PARAMETER	VALUE	UNITS
1.0	General Specifications		
1.0	Coil Type	Actively Detunable High Pass Volume coil for receive array coils	
1.2	Compatibility	Siemens MAGNETOM Terra 7T Whole-Body MRI Scanners	
1.3	Application	High Sensitivity Neuro- Imaging/fMRI/Spectroscopy	
2.0	Electrical Specifications		
2.1	Resonant Frequency, nominal	297.18	MHz
2.2	RF Element number	16	-
2.3	RF Element type	flat 2.5cm width	-
2.4	RF Element Length	20	Cm
2.5	RF Element Cylinder Diameter	30.5	Cm
2.6	Cavity Shield Type	Slotted, EPI compatible	-
2.7	Shield Diameter	37	Cm
2.8	Field Polarization	Circular	-
2.9	Maximum Peak Power	8	kW
2.10	Interface	Quadrature TR Switch with Integrated preamplifier, includes multiplex switch and adapter for 8 array receive channels	
2.11	RF and bias connections	Avanto style 7T Siemens connector	
2.12	Detuning method	Active PIN diode circuits	
2.13	Bias, Tuned mode	-31V @0mA	
2.14	Bias, Detuned mode	0.7V @200mA	
3.0	Mechanical Specifications		
3.1	Physical Inside Diameter	29.5	Cm
3.3	Physical Outside Diameter	37.5cm	Cm
3.4	Physical Length	27.5	Cm
3.5	Materials	FR4, PVC, Polycarbonate	
3.5	Mounting	Sliding tray compatible with Siemens MAGNETOM Terra 7T Whole-Body Patient Table	

Specifications (continued):

Nova 1Tx32Rx Head Coil 7T Clinic: 32 Channel Receive Array Coil Component

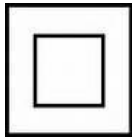
	PARAMETER	VALUE	UNITS
1.0	General Specifications		
1.1	Coil Type	Thirty-Two Channel Whole-Brain Receive-only Array	
1.2	Compatibility	Siemens MAGNETOM Terra 7T Whole-Body MRI Scanners	
1.3	Application	High Sensitivity Neuro-Imaging/fMRI/Spectroscopy	
2.0	Electrical Specifications		
2.1	Element Geometry	Top half: four radially gapped columns of four elements Bottom: four radially gapped columns of four elements	
2.2	Coil Resonant Frequency (Nominal)	297.18	MHz
2.3	RF Element Construction	Flexible PC board trace with distributed capacitance	
2.4	Detuning Circuitry	High Power active+ one passive + fuse detuning circuits for each coil element	
2.5	Detuning Bias Voltage	100mA @ <10V x 24 pin lines	
2.6	Isolation Active Detuned State (measured with two isolated loops)	>30	dB
2.7	RF and bias connections	Three Avanto style connectors + interconnect to Volume Coil Interface	
2.8	Coil Interface	Includes Preamplifiers, bias multiplexers, and protection circuitry.	
3.0	Mechanical Specifications		
3.1	Coil shape	Close fitting head former inside cylindrical case, housing splits open for subject positioning.	
3.2	Materials	Urethane, FR4, PVC, Ultem 1010	
3.3	Physical Outside Housing Width	25.5	cm
3.4	Physical Inside Housing Width	18.0	cm
3.5	Physical Inside Housing Height	22.0	cm
3.6	Coil Physical Length	31	cm
3.7	Mounting	Compatible with Siemens MAGNETOM Terra 7T whole-body MRI scanner with Nova Medical Volume Transmit Coil	

Appendix I: Explanation of symbols

The following symbols are used on the coil and in user documentation. These are their meanings:



Body Floating (BF) type Applied Part



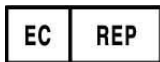
Double Insulated



Read Operating Instructions



Do not dispose in trash; follow disposal instructions in user manual



Authorized Representative



Swiss Authorized Representative



Catalog Number



Serial Number



Manufacturer



Date of Manufacture



0197

CE Mark



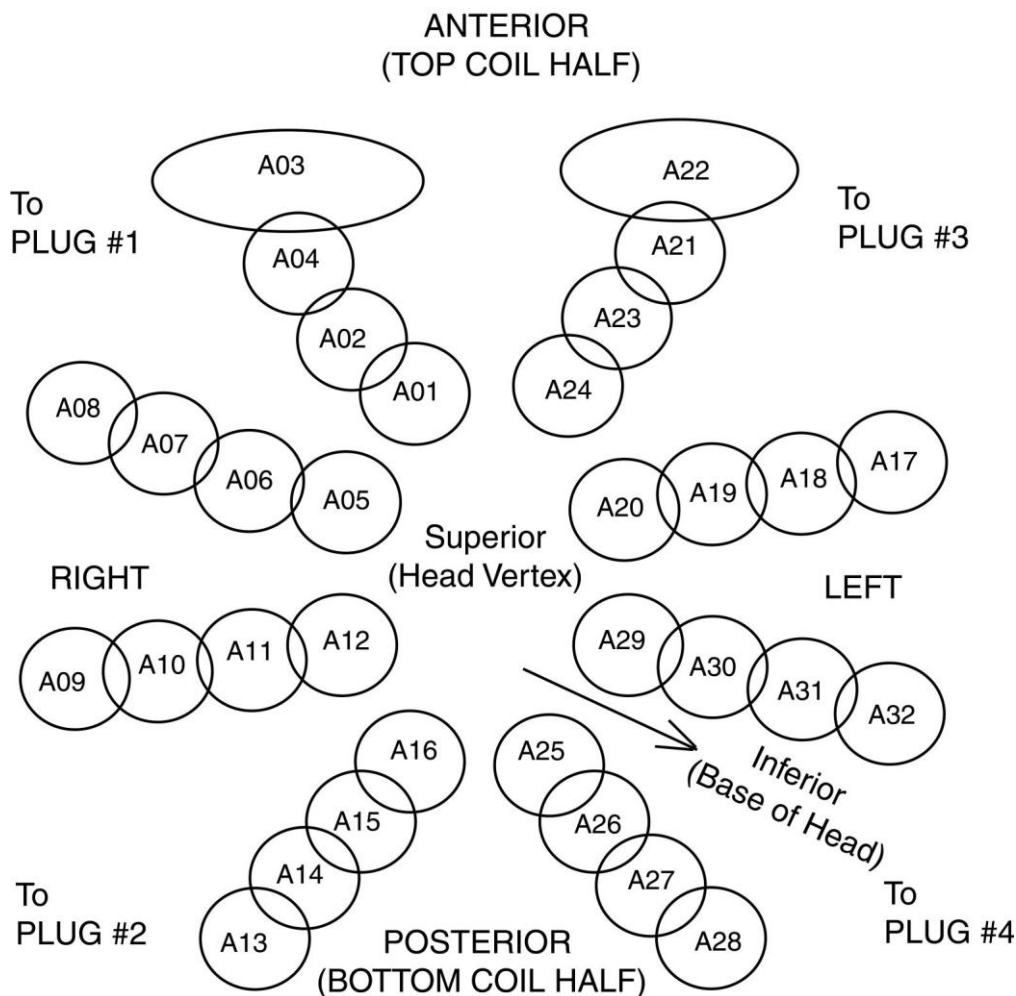
Medical Device



This symbol identifies the Importer

Appendix II: Nova 1Tx32Rx Head Coil 7T Clinic

Element Layout: Axial View from Front of Coil



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

Receive channel for element A01 preamp (Plug#1, channel #1) is multiplexed with the volume coil preamp. When the VC element is selected on the user console, this first receive channel carries signal from volume coil preamp. When the AC element is selected on the user console, this first receive channel carries signal from the A01 receive coil preamp.