Nova Medical, Inc.

Instructions for Use
Nova 2Tx32Rx
32 CH Head Coil for
General Electric 7T MR System

GE Part #: 5799571-2
Nova Medical REF : 4318932

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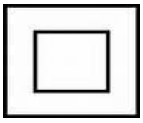


℞ Only

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⚠ **Caution: Federal law (USA) restricts this device to sale, distribution, and use by or on the order of a physician.**

This device is distributed by GE Medical Systems LLC.

Introduction:

The Nova Medical 2Tx32Rx 7T Head coil (Model No. 4318932) is a unique product set which provides the transmit capability of a volume coil with the unsurpassed sensitivity of a whole brain receive array on the General Electric 7T MR system. Careful design of the volume coil provides a high efficiency transmit field while featuring circuitry to enable its use with the high-performance thirty-two channel receive array. The optimized design of the thirty-two channel receive array provides superb cortical and central brain sensitivity as well as the capability of highly accelerated acquisition in any imaging plane.

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

Included Accessories:

- Mirror
- Cushions

Indications for Use:

Used in the GE 7T MR System, the 2Tx32Rx 7T 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 2Tx32Rx 7T 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.

⚠ Contraindications:

1) Do not use with patient(s) who have implanted metallic objects.
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 GE Medical Systems 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 GE 7T MR System
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.

⚠ ***WARNING: Both the array and volume coil have been designed for use as a package together. Use with unapproved 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.***

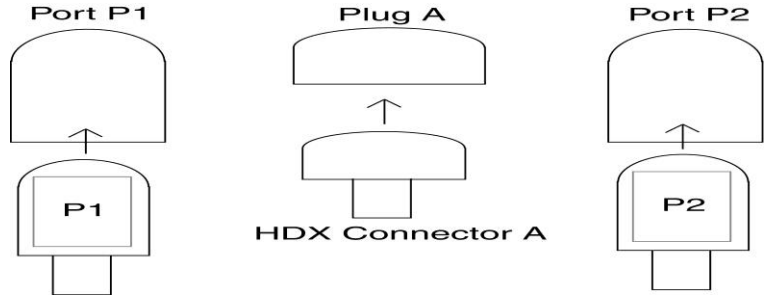
Note to user and/or patients: Any serious incident that has occurred in relation to this device should be reported to Nova Medical and/or the competent authority of the Member State in which the user and/or patient is established.

Operation:

Connecting Coils:

Place the transmit coil with array insert on patient table. Connect the coil plugs into the General Electric 7T MR system 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 all three coil cables to the patient bed. Failure to connect all channels of array coil may result in coil damage and/or unsafe operation.

IMPORTANT: Use caution when sliding volume coil and receive coil components to avoid trapping fingers between sliding parts.

Function:

Port P1- Rx Port A – Transmit Port P2 – Array Rx

Patient Positioning:
First place the 2T32Rx coil on the patient table and slide back volume coil

Step 1:

Place Coil on Patient Table

Step 2:

Slide back Volume Coil

Next 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.

Step 3:

Slide back top half of array

Step 4:

Position Head into bottom half

Slide top portion of array over the head. Push downward lightly and it will click into position at its fully forward position. If desired, the patient 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 setup, 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.

Step 5:

Step 6:

HELPFUL HINT: For patients with large heads, use 5mm 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 (though always slide volume coil fully down over array coils and head to provide best transmit performance).

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

Step 7:

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, choose the coil labeled "Head 32ch" on the console interface.

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. This includes sliding volume coil backwards (unlocking it if necessary), moving top half of array coil backwards, and having patient slowing raise their head.

Disconnecting coils:

Disconnect all three cables going to patient bed.

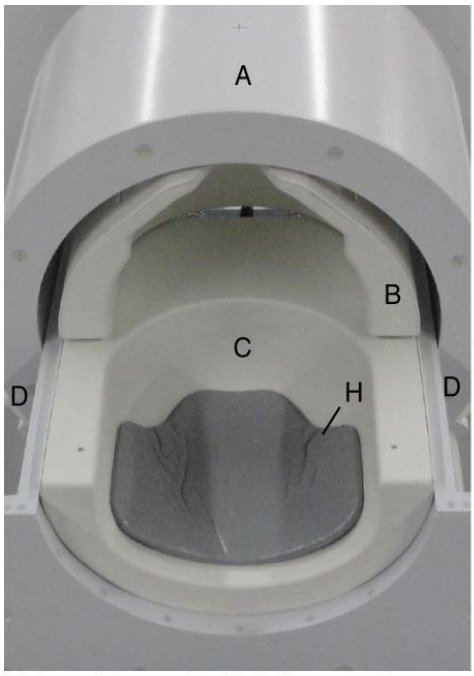
NOTE: Turn both handles on the P-Port Plugs 1 and 2 to the red "open" position before removing these connectors.

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

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

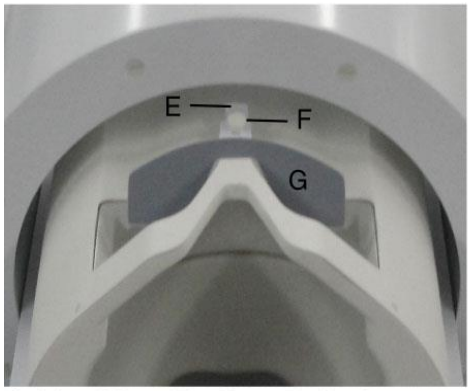
NOTE: USE CAUTION when lifting coils since they weigh about 15kg (35lbs.) total.

Description Coil Components:

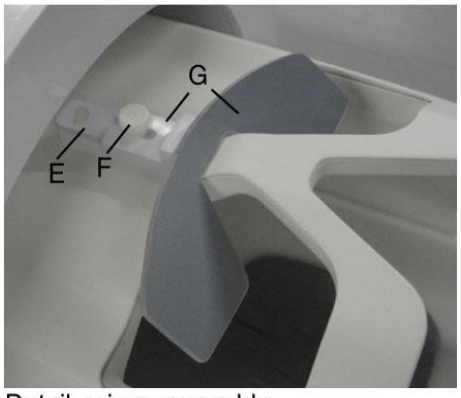


Volume Transmit, 32ch Array Coil
Open for Subject Postiioning

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 Mouting Rail
F: Mirror Locking Screw (loosen, do not remove, to position or insert mirror)
G. Subject Mirror with Mounting Bracket
H. Foam Pad

The Array Coil Top/Bottom halves are applied parts.

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.

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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.

Problem: High Transmit Gain required

- Make sure all connections are properly made.
- Check patient landmark is correct, and that the volume coil has been fully extended over patient's head. Operating the volume coil without fully extending it over patient's head will lead to a large decrease in transmit efficiency.
- In some cases, it may be worth trying manual setting of the transmit gain.

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 quadrature 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 Gain calibration. For more inferior portions of brain, additional transmit power 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:

The coil can be cleaned with a paper towel or towelette wetted with an appropriate (e.g. nationally approved) alcohol based disinfectant. We do not recommend the use of iodine containing disinfectants as these will stain the coil surface. Do not use any rough or abrasive detergents which could dissolve the surface of the housing. Although the electronic circuitry is protected against moisture, take care that liquids do not enter the device. Do not immerse the device.

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.

If necessary, the coils can be cleaned with a moist cloth. *Do not immerse in water or use harsh solvents on the coil as this may cause potential coil damage.*

Service/Repair:

The Nova 2Tx32Rx 7T Head Coil has no user serviceable parts. Under no circumstances should the coils be opened, and user repair attempted.

Please contact your GE representative with questions regarding service of the coil.

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^{o}C and <26^{o}C (>50^{o}F and <78^{o}F)
Humidity (non-condensing) >30% and <70%
Altitude: <3000m

B) Non-operating Conditions (Storage and Transport)
Temperature: >0^{o}C and <40^{o}C (>32^{o}F and <104^{o}F)
Humidity (non-condensing): >20% and <90%
Barometric Pressure: >500hPa and <1060hPa

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.

Please contact your GE representative with questions regarding the return transport of the coil.

Disposal:

Please contact your GE representative with questions regarding the disposal of the coil.

Specifications:

Nova 2Tx32Rx: Volume Transmit Coil Component
For General Electric 7T Whole-Body MRI Scanners

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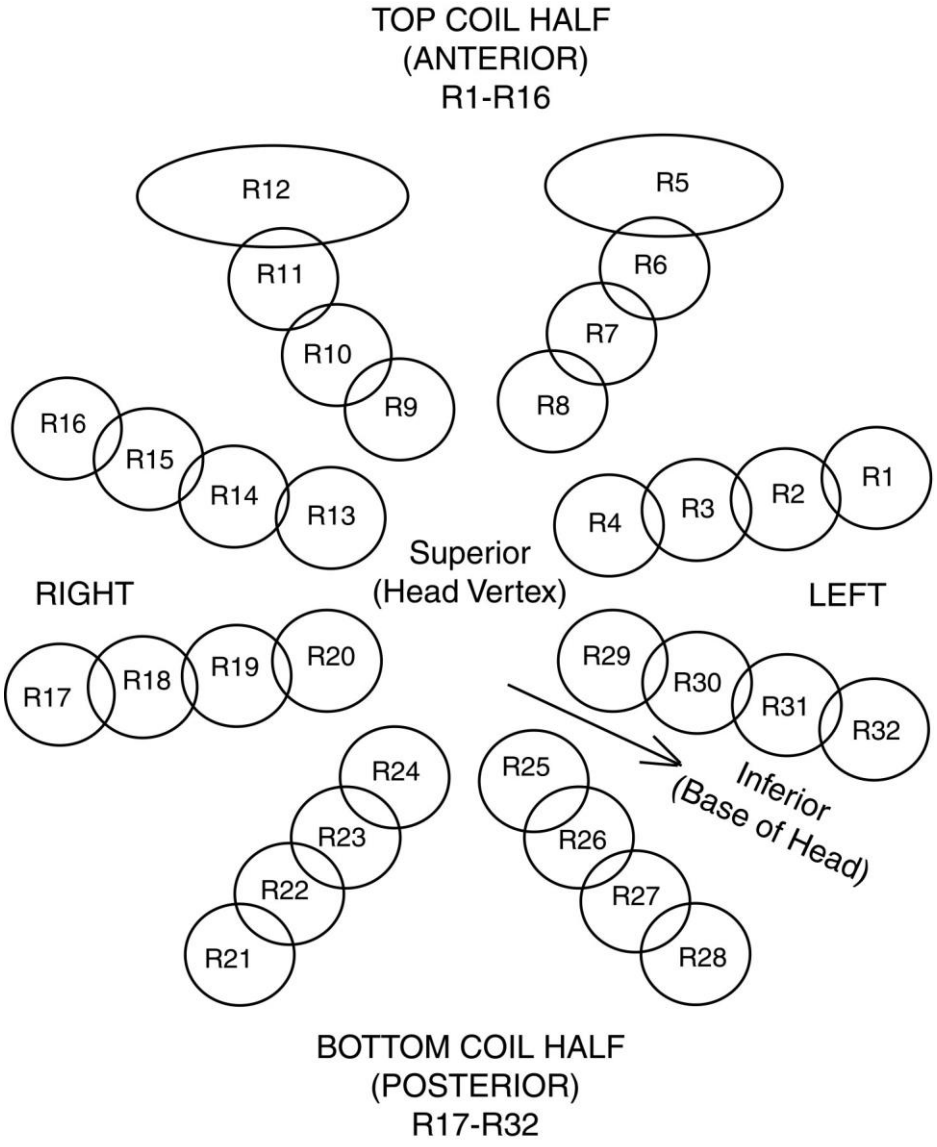
	PARAMETER	VALUE	UNITS
1.0	**General Specifications**		
1.1	Coil Type	Actively Detunable High Pass Volume coil for surface and array receive coils	
1.2	Compatibility	7T General Electric 7T Whole-Body MRI Scanners	
1.3	Application	7T Whole Brain Imaging, fMRI, and spectroscopy in TR mode or with Nova Medical receive-only insert arrays.	
2.0	**Electrical Specifications**		
2.1	Resonant Frequency, nominal	298.2	MHz
2.2	RF Element number	16	-
2.3	RF Element type	flat 2.5cm width	-
2.4	Cavity Shield Type	Slotted, EPI compatible	-
2.5	Field Polarization	Circular	-
2.6	Loaded VSWR	< 1.5:1, typical head load	-
2.7	Loaded to Unloaded Q ratio	> 2:1 (inside shielded 60cm bore)	-
2.8	Maximum Peak Power (@298.2MHz)	3.2	kW
2.9	Maximum Average Power	20	W
2.9	Interface Electronics (separate box mounted on coil tray)	Dual TR Switches with integrated preamplifiers. Includes bias driver for volume coil detuning.	
2.10	RF and bias connections	8ch ODU connector Port A (RF power and +15V supply) and P-Port connector (P1) (RF receive, +10V, and coil bias)	
2.11	Detuning method	Active PIN diode circuits	
2.12	Bias, Tuned mode	+15V @0mA	
2.13	Bias, Detuned mode	-0.7V @200mA	
3.0	**Mechanical Specifications**		
3.1	Physical Inside Diameter	29.2	Cm
3.3	Physical Outside Diameter	37.5	Cm
3.4	Physical Length	28.5	Cm
3.5	Materials	Urethane, FR4, PVC, Polycarbonate, (all UL94VO rated)	
3.5	Mounting	Sliding tray compatible with the General Electric 7T Whole-Body Patient Table	

Specifications(continued):

Nova 2Tx32Rx Thirty-Two Channel Array Coil Component

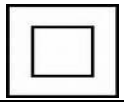
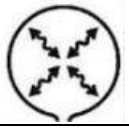
	PARAMETER	VALUE	UNITS
1.0	**General Specifications**		
1.1	Coil Type	Thirty-Two Channel Whole-Brain Receive-only Array	
1.2	Compatibility	7T General Electric Whole-Body MRI Scanners with Nova Medical Volume Transmit Coil	
1.3	Application	High Sensitivity Neuroimaging /fMRI/spectroscopy	
2.0	**Electrical 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)	298.2	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	150mA @1V detuned, -5V @0mA tuned	
2.6	Isolation Active Detuned State	>30	dB
2.7	RF and bias connections	P-Port Plug connector (P2), using channels 1-32 (RF receive, bias, and +10V)	
2.8	Coil Interface (inside coil housing)	Includes preamplifiers and bias distribution network.	
2.9	Preamplifier Gain	29db +/-1.5db (50ohm)	
2.10	Input Reflection Coefficient	Gamma > 0.9, <0.98 @298Mhz	
2.11	Preamplifier Power	15mA typical, <20mA max @ 10V, <640mA total, fused at 1A	
3.0	**Mechanical Specifications**		
3.1	Coil shape	Close fitting head former inside cylindrical case, housing splits open for patient positioning.	
3.2	Materials	Urethane, FR4, PVC (all UL94VO rated)	
3.3	Physical Housing Width	25.5	cm
3.4	Physical Inside Housing Width	18.2	cm
3.5	Physical Inside Housing Height	22.2	cm
3.6	Coil Physical Length	31	cm
3.7	Mounting	Compatible with Nova Medical Volume Transmit Coil Tray	

Appendix I: Element Layout for the 7T Nova Medical Model Nova 2Tx32Rx 32ch Array Component



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
	Follow Instructions for Use
	Caution is necessary when operating the device and/or the situation described needs operator awareness or operator action to avoid undesirable consequences
	Do not dispose in trash; follow disposal instructions in user manual
	RF Coil: Transmit and Receive
	Catalog Number
	Serial Number
	Manufacturer
	Date of Manufacture
	CE Mark
	Temperature Limits
	Locked (Closed) Position
	Unlocked (Open) Position

MD	Medical Device
℞ Only	Prescription use Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician

Instructions for Use Revision History
NMIFU_2Tx

Rev. 0	2019-08-12
Rev. 1	2019-11-20
Rev. 2	2020-04-17
Rev. 3	2021-01-20
Rev. 4	2021-11-30
Rev. 5	2022-04-14
Rev. 6	2023-04-10