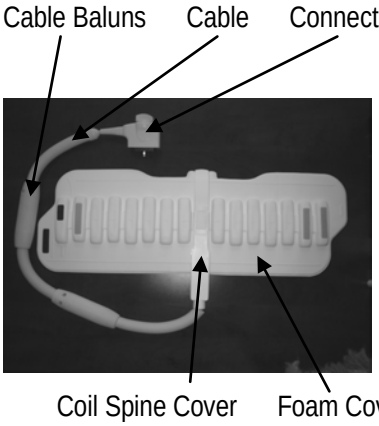
16ch Flex SPEEDER Large Coil

MJAJ-227A

1. The NeoCoil Flex SPEEDER Large Coil Product components:
    a. Flex Coil
    b. Operation Manual

2. System Parts and Materials:



Patient contact Parts and Materials:

a. Coil Spine Cover: Polycarbonate
b. Coil Foam Cover: Dartex

3. Ratings:
    a. Power supply: power supply for preamp
        1. Voltage:12 +/- 0.2 VDC
    b. Class of Device: Class II
    c. Type of applied part: BF Applied Part
    d. EMC Standard: IEC 60601-1-2+Amd.1

4. Coil Dimensions:

Component	Dimensions (W x L x H)	Weight
16ch Flex SPEEDER Large Coil	31cm x 73cm x 5cm	1.6kg
16ch Flex SPEEDER Large Cable with Connector	107.5cmx40cm	N/A (included in coil weight)

*Cable size is not included in above measurements.

5. Principle of Operation

Connecting the RF coil to the magnetic resonance imaging apparatus (hereafter MRI), the RF coil and the region of interest of the patient is sent to the center of the center of MRI magnet, and RF magnetic field is exposed to the patient with predetermined timing. The RF coil receives the magnetic resonance signal emitted by hydrogen nuclei (proton) in the patient body with built in surface coils while decoupling the magnetic coupling to the magnetic field exposed using RF decoupling circuits. The signal acquired is amplified by an amplifier built in the coil and transferred to the MRI apparatus via a connector, processed by a computer in the MRI, and reconstructed into cross sectional images of the patient.

6. Intended Use:

To be used in conjunction with Toshiba Magnetic Resonance Scanners with DL96 connectors to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck and spine that can be interpreted by a trained physician.

7. Pharmaceutical Affairs Law Requirements:

3 dB Bandwidth: Δf

Center Frequency shift: $\Delta f0$($\Delta f0=fc-f0$, $f0=63.78MHz$)

Coil Impedance: Z(at 63.78MHz)

8. Environmental Conditions
    a. Operating conditions
        Temperature: 16 to 24 degree C
        Humidity: 40 to 60 RH%
        Atmospheric pressure: 700 to 1060 hPa

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9. Use Case, Work flow

The outline of operation procedure is as follows.

(1) Turn on the power supply of the MRI system and execute pre-operation checks

(2) Place the system standard mats on the couchtop, and set the patient on the couchtop

(3) Secure the coil to the patient with pads or mats

(4) Place the patient and coil so that the target region is at the center of the magnetic field

(5) Operate the MRI system, and obtain the tomographic images

(6) Confirm the finish of scanning, and remove the coil and pads from the patient, and take down the patient from the couch

(7) Remove the coil connector from the MRI system

(8) Clean the coil and pads if necessary

(9) Keep the coil and pads in the shelf in the scan room

10. Application:

Applicable MRI Scanners:

Vantage Titan MRI Scanner

Production Distributor: Toshiba Medical Systems

Applicable Coil System:

16ch Flex SPEEDER Large MJAJ-227A

Production Distributor: Toshiba Medical Systems

11. Safety Information

⚠WARNING:Do not allow the hook surface of hook-and-loop fasteners to come into contact with the patient.

Hook-and-loop fasteners are used on this coil and on pads and mats to facilitate immobilization using belts. Scraping the hook surface (on the coil, pad, or mat) of these fasteners against the patient's skin may result in injury to the patient. Be careful when handling items with hook-and-loop fasteners.

When wrapping the coil around the head, avoid overlap as this could restrict the patient's breathing.

Safety Information Continued

⚠CAUTION:1.Do not allow the RF coil or RF coil cable to come into contact with the gantry inner wall.
Confirm that the RF coil main unit and RF coil cable are at least 5 cm away from the gantry inner wall when applying the coil to the patient. Otherwise, the coil may be damaged. If a damaged coil is used for scanning, burn injury to the patient may result.

2.Do not route the coil cable along the bore surface in the circumferential direction. Heating of the coil cable may result.
If it is necessary to route the cable in the lateral direction, route it on the couchtop.

3.Do not scan the patient with the convex pad removed. Poor image quality may result.

4.Remove from the couchtop all RF coils that are connected to the connector port on the gantry and RF coils that are not connected to the connector ports on the couchtop.
If an RF coil that is not used for scanning is present on the couchtop, a high-frequency induction current loop may form, resulting in burn injury to the patient. In addition, the devices may be damaged.

5.Confirm that the connector of this coil is connected to the connector port before starting scanning. If scanning is performed with the coil connector not connected to the connector port, the coil may be damaged or abnormal heating may result.

6.Do not perform scanning with the cable of this coil routed in a U shape. The coil may be damaged or abnormal heating may result.

7.If image quality becomes temporarily abnormal but recovers immediately without intervention, continue scanning but pay close attention to the results. Report the phenomenon to your Toshiba service representative.

8.When securing the coil to the patient, ensure that positioning and retention force do not cause discomfort.

9.In the unlikely event that a coil creates smoke, sparks, or makes an unusually loud noise, or if the patient requires emergency assistance:

Stop the scan if one is in progress

Remove the patient from the scan room if medical treatment is necessary.

10. To prevent strangulation, do not wrap the strap around the patient's neck.

*Above safety information are extracts from Operator's Manual. Please see operation manual.

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12. Storage, Durability, and Parts:

    a. Storage and transportation

    Temperature:-10 to 50 degree C

    Humidity: 20 to 95 RH%

    Atmospheric pressure: 700 to 1060 hPa

    b. Durability

    Estimated durability of 6 years when specified quality check is performed per operation manual.

    c. Parts

    There are no service or replacement parts on the Coil product.

13. Maintenance and inspection:

    Maintenance and inspection should be conducted in order to ensure that the rated safe operation and performance levels of the product are maintained. Maintenance and inspection are the customer's responsibility.

    1. Daily Checks
    2. Periodic Checks
    3. Image Quality Check Procedure

14. Packaging:

    Custom-designed carton

    Product is packed as one unit.

15. Production Distributor and Supplier:

    a. Production Distributor:

    Toshiba Medical Systems Corporation
    1385, Shimoishigami, Otawara-Shi
    Tochigi-Ken 324-8550, Japan

    b. Manufacturer:

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