

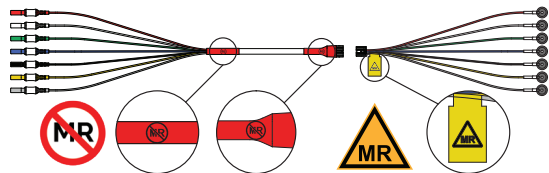
# INSTRUCTIONS FOR USE

## MR Conditional / CT Cup Electrodes



Part Number	Numbers	Length (m)	QTY	Type
302934-000-039	1-12	1.0	12	Single
302934-000-059	1-12	1.5	12	Single
302934-000-078	1-12	2.0	12	Single
302934-000-098	1-12	2.5	12	Single
302933-000-039	1-24	1.0	24	Single
302933-000-059	1-24	1.5	24	Single
302933-000-078	1-24	2.0	24	Single
302933-000-098	1-24	2.5	24	Single
302932-000-039	1-28	1.0	28	Single
302932-000-059	1-28	1.5	28	Single
302932-000-078	1-28	2.0	28	Single
302932-000-098	1-28	2.5	28	Single

## MR Conditional / CT Array Electrodes



Part Number	Numbers	Length (m)	QTY	Type
302931-000-039	25	1.0	3	Array
302931-000-059	25	1.5	3	Array
302930-000-039	27	1.0	3	Array
302930-000-059	27	1.5	3	Array

**Intended Use and Indications For Use**

The MR Conditional/CT Cup Electrodes and Arrays are intended for use in the recording of the Electroencephalogram (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in an MRI or CT environment under specific conditions.

**Intended Users**

The MR Conditional/CT Cup Electrodes and Arrays are for professional use only and should be used in compliance with accepted industry standards.

**Intended Patient Population**

Adult patients only.

**Operating Instructions**

1. Clean skin at electrode site.
2. Apply Ten20™ conductive paste to the electrode cup (do not overfill). Only Weaver Ten20™ is approved for use with the MR Conditional/CT Cup Electrodes.
3. Attach the electrode cup to the scalp.
4. Secure electrode with gauze or tape; apply head wrap if needed.
5. Connect the lead wire of the extension cable to the monitoring device.
6. Before MRI or CT imaging, disconnect and remove extension cables. Reconnect extension cables after scanning.
7. After monitoring, remove the electrode from the skin.
8. The electrodes are disposable and must be disposed of according to local hospital procedures.

**WARNING!**

Extension cable used during an MR scan may heat or dislodge causing burns or other serious injury. Disconnect the extension cable from the electrodes before MR imaging procedures. Refer to MRI Safety Information for more information.

**CAUTIONS**

1. Using damaged or defective electrodes, cables, or connectors can cause electric shock, burns, or data loss.
2. If the device is dropped before use, carefully check it for any signs of damage, or wear. Replace when worn or damaged.
3. Do not try to modify or repair the device yourself. Unauthorized changes may affect how the device works or make it unsafe.
4. Prolonged electrode application may increase the risk of skin irritation; regularly inspect the patient's scalp and do not leave electrodes in place longer than clinically necessary to prevent skin injury
5. This product is for single patient use only. Do not reuse or attempt to clean or sterilize it. Reuse may lead to infection or other health risks.
6. Federal law (USA) restricts this device to sale by or on the order of a physician.

**MRI Safety Information**



**MR Conditional**

A patient with the "MR Conditional / CT Cup Electrodes" or "MR Conditional / CT Array Electrodes" may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Condition of Use/Information
Device Names	MR Conditional / CT Cup Electrodes and MR Conditional / CT Array Electrodes
Static Magnetic Field Strength (B0)	1.5 T, 3 T
Static Magnetic Field Strength (B0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	40 T/m (4,000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Polarization	Circular Polarized (CP)
RF Transmit Coil	Integrated Whole Body Transmit RF coil
RF Receive Coil	Any receive RF coil may be used
<b>MR System (RF) Operating Modes or Constraints</b>	<b>Device-specific RF Operating Conditions</b>
Whole-Body Averaged SAR	<b>1.5 T:</b> 2 W/kg (Normal Operating Mode) <b>3.0 T:</b> 2 W/kg (Normal Operating Mode)
Head SAR	<b>1.5 T:</b> 3.2 W/kg (Normal Operating Mode) <b>3.0 T:</b> 3.2 W/kg (Normal Operating Mode)
Scan Duration	60 minutes of continuous RF exposure (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The image artifact caused by the device extends less than 4.7 mm from the MR Conditional/CT Cup Electrodes when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system. Some manipulation of scan parameters without exceeding SAR limits above may be needed to compensate for the artifact.