



English

MR Conditional/CT Cup and Webb* Electrodes

Disposable EEG Cup/Webb Quick Connect System™

Intended Use

The MR Conditional/CT Cup and Webb Electrodes are intended for use in the recording of the Electroencephalography [EEG], Evoked Potentials [EP] or as a Ground or Reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in a MRI environment under specific conditions.

Caution

Federal [USA] law restricts this device to sale by or on the order of a physician and it should only be used in compliance with accepted industry standards. RhythmLink International, LLC is not responsible for injury, infection or other damage resulting from the use or misuse of this product.

MR Conditional/CT Cup and Webb Electrodes are for professional use only and should only be used in compliance with accepted industry standards. **The included extension cables [Fig. 1] are MR Unsafe.** Remove all extension cables before entering a MR environment.

Instructions for Use

Clean application site. Apply electrode using Weaver Ten20 conductive paste. MR Conditional/CT Cup and Webb Electrodes are only approved for use with Weaver Ten20 conductive paste. Collodion may be used if desired. *At least two (2) electrodes, per array, must be applied to the patient for use in the MR environment. Remaining electrodes can either be left unattached or can be removed by cutting the electrode wire flush to the connector.* Remove all extension cables before entering an MR environment. When finished, remove electrodes and clean application sites.



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To view a list of symbol definitions found on packaging and instructions for use, please visit Rhythmink.com/symbols.
Rhythmink® is a registered trademark of RhythmLink International, LLC.

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MR Safety Information



Non-clinical testing has demonstrated that the MR Conditional/CT Cup and Webb Electrodes Array [Fig. 2] is MR Conditional in configurations of 2 to 40 electrodes, using 1 to 4 arrays. These electrodes can safely remain on a patient during a MR scan meeting the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial field gradient of 4,000 gauss/cm [40T/m]
- Maximum MR system reported whole-body averaged specific absorption rate [SAR] of 2 W/kg and whole-head averaged SAR of 3.2 W/kg
- Quadrature driven transmit body coil only
- Maximum active scan time of 15 minutes

Under the scan conditions defined above, the MR Conditional/CT Cup and Webb Electrodes are expected to produce a maximum temperature rise of 4°C or less after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends less than 2.5 mm from the MR Conditional/CT Cup and Webb Electrodes when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

The MR Conditional/CT Cup and Webb Electrodes have not been tested in simultaneous combination with other devices.

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this device.

MR image artifacts can affect the device surrounding on each side from the device surface as follows:

Worst-case artifacts of	Spin Echo	Gradient Echo
Test object length	1.46 mm	2.11 mm
Test object diameter	2.22 mm	2.46 mm

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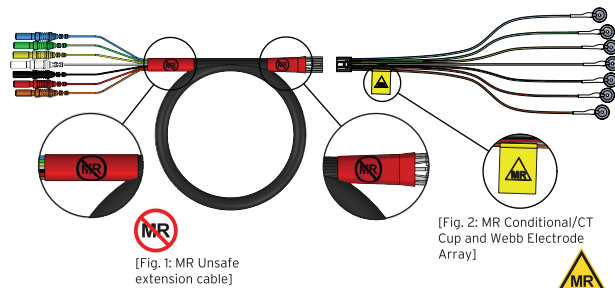


Diagram is representative, arrays consist of up to 10 electrodes per array.

The appearance of the MR Quick Connect extension cable is a trademark of RhythmLink.

Avoid prolonged or repeated exposure to substances containing acetone or ethyl acetate. These solvents can damage the electrode and may lead to premature product failure.