Rhythmlink

English

MR Conditional* Sticky Pad™ Surface Electrode

Intended Use

The Rhythmlink MR Conditional Sticky Pad Electrode is intended for use with recording, monitoring, and stimulation equipment in the study of biopotentials such as Electroencephalograph (EEG), Surface Electromyography (EMG), or Nerve Conduction Evoked Potential Signals (EP). This device is non-sterile, single-use only, and may remain on the patient in a MRI environment under specific conditions.

Intended Applications

EEG [Electroencephalography], EP [Evoked Potentials], IONM [Intraoperative Neurophysiological Monitoring], ICU [Intensive Care Unit], NCS [Nerve Conduction Studies], LTM [Long Term Monitoring], PSG [Polysomnography] and Ambulatory.

Caution

Federal [USA] law restricts this device to sale by or on the order of a physician. Rhythmlink International, LLC is not responsible for injury, infection or other damage resulting from the use or misuse of this product.
MR Conditional Sticky Pad Surface Electrodes are for professional use only and should only be used in compliance with accepted industry standards. The included extension cables are MR Unsafe (Fig 1). Remove all extension cables before entering a MR environment.

Storage

Keep the package away from sunlight. Store at 10-40°C [50-104°F]

Instructions for Use

Select appropriate Sticky Pad electrode. Remove excess hair, oils and dirt. Prep application site, remove Mylar backing from electrode and place on application site. Apply pressure to center of electrode and move to edges. **Remove all extension cables before entering a MR environment.** When finished, remove by pulling directly on electrode, not the cable. Remove remaining hydrogel with clean, soapy water. This product is single-patient use only. Discard electrode after use.

MRI Safety Information

Non-clinical testing has demonstrated that the MR Conditional Sticky Pad Surface electrodes (Fig 2) are MR Conditional in configurations of 2 to 48 electrodes. These electrodes can safely remain on the patient during a MR scan meeting the following conditions:

Static magnetic field of 1.5 or 3.0 Tesla

Maximum spatial field gradient of 25,000 gauss/cm [250T/m]

Maximum MR system reported, whole-body averaged specific absorption rate [SAR] of 2.0 W/kg

Maximum 15 min of continuous scanning (i.e., per pulse sequence)

Under the scan conditions defined above, the MR Conditional Sticky Pad electrodes are expected to produce a maximum temperature rise of 3.1°C or less after 15 minutes of continuous scanning (i.e., per pulse sequence) when aligned parallel to the static magnetic field.

In non-clinical testing, the image artifact caused by device extends less than 3.55mm from the MR Conditional Sticky Pad electrode when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

The MR Conditional Sticky Pad 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	1.78 mm	2.99 mm
Test object diameter	1.77 mm	3.55 mm

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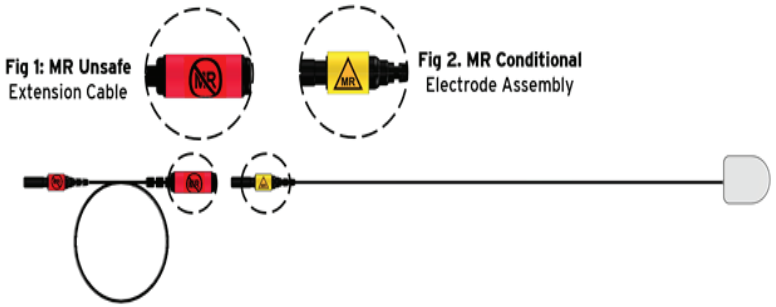

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Rx Only

To view a list of symbol definitions found on packaging and instructions for use, please visit Rhythmlink.com/symbols.

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