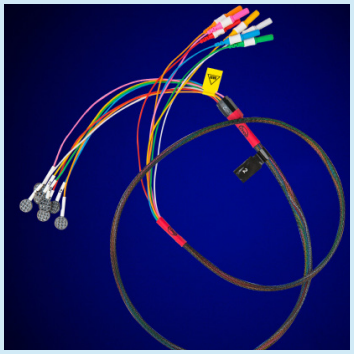





Rhythmlink's MRI & CT Technical Specifications and Clearance Information

Updated 2021

Rhythmlink®

Guide Overview

Clearance Overview - Instructions for Use - Contacts for Q&A

Deep & Slim Cup, Webb™,
PressOn™, Quick Connect System™
& Sticky Pad™ Surface Electrodes

MR Conditional*/CT Slim Cup, Deep Cup and Webb™ Electrodes for the 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.

MRI 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 4ºC or less after 15 minutes of continuous scanning.

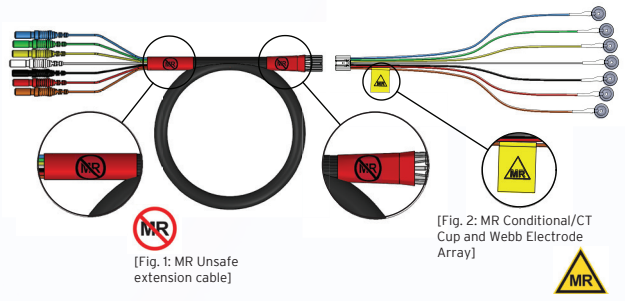
In non-clinical testing, the image artifact caused by the device extends less than 2.5 mm from the MR Conditional/CT Cup and Webb Electrodes when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

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

The included extension cables are MR Unsafe. Remove all extension cables before entering an MR environment.



[Fig. 1: MR Unsafe extension cable]

[Fig. 2: MR Conditional/CT Cup and Webb Electrode Array]

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.

**Multiple Patents Pending*

MR Conditional*/CT Disposable Slim EEG Cup Electrodes

Intended Use
The MR Conditional/CT Disposable EEG Cup Electrode is 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 provided non-sterile for Single Patient Use Only and may remain on the patient in a MR 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 Disposable Slim EEG Cup 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 Cup Electrode using Weaver Ten20 conductive paste. MR Conditional/CT Disposable Slim EEG Cup Electrodes are only approved for use with Weaver Ten20 conductive paste. Collodion may be used if desired. Remove all extension cables before entering an MR environment. When finished, remove electrodes and clean application sites.

MRI Safety Information
Non-clinical testing has demonstrated that the MR Conditional/CT Disposable Slim EEG Cup Electrode [Fig. 2] is MR Conditional in configurations of 2 to 48 electrodes. These electrodes can safely remain on a patient during a MR scan for 15 minutes under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient field of 4,000 gauss/cm [40T/m] or less
- Maximum whole-body averaged specific absorption rate of 2 W/kg in the Normal Operating Mode
- **Remove extension cables [Fig. 1] before entering an MR environment. They are MR Unsafe.**

Under the scan conditions defined above, the MR Conditional/CT Disposable Slim Cup EEG Electrode is expected to produce a maximum temperature rise of less than 2ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the Slim Cup Electrode extends less than 2 mm from the Slim Cup Electrode when imaged with a gradient echo pulse sequence and a 3 T MRI system.

RF Induced Heating Information
1.5 Tesla Systems: In non-clinical testing with a 1.5 Tesla Intera, Philips Medical Systems MR system (Software: Release 12.6.1.4 2012-05-22) the MR Conditional/CT Slim Cup Electrode produced a temperature rise of ≈ 0.7ºC in a static phantom with a background temperature increase of ≈ 0.1ºC at a software-displayed head averaged (HA) specific absorption rate (SAR) of "<3.9" W/kg (≈ 2.1 W/kg in a phantom calorimetric test) for 15 minutes of continuous MR scanning with transmit/receive body coil. The local SAR shall be < 0.9 W/kg for using the MR body coil.

3.0 Tesla Systems: In non-clinical testing with a 3 Tesla Magnetom Trio, Siemens Medical Solutions MR system (Software: Numaris/4 syngo MR B17) the MR Conditional/CT Slim Cup Electrode produced a temperature rise of ≈ 1.5ºC in a static phantom with a background temperature increase of ≈ 0.4ºC at a software-displayed head averaged (HA) specific absorption rate (SAR) of "3.5" W/kg (≈ 3.2 W/kg in a phantom calorimetric test) for 15 min. of continuous MR scanning with transmit/receive body coil. The local SAR shall be < 1.3 W/kg for using the MR body coil.

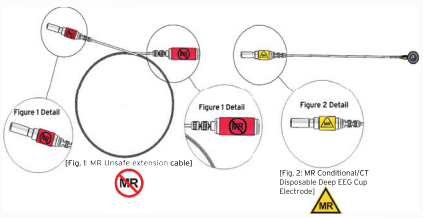
The MR Conditional/CT Disposable Slim EEG Cup Electrode, dual and multiple configuration [2 to 48 electrodes] have not been tested in simultaneous combination with other devices.

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	0.43 mm	0.90 mm
Test object diameter	1.39 mm	1.47 mm

The included extension cables are MR Unsafe. Remove all extension cables before entering an MR environment.



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.

**Multiple Patents Pending*

MR Conditional*/CT Disposable Deep EEG Cup Electrodes

Intended Use
The MR Conditional/CT Disposable EEG Cup Electrode is 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 provided non-sterile for Single Patient Use Only and may remain on the patient in a MR 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 Disposable Deep EEG Cup 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 Cup Electrode using Weaver Ten20 conductive paste. MR Conditional/CT Disposable Deep EEG Cup Electrodes are only approved for use with Weaver Ten20 conductive paste. Collodion may be used if desired. Remove all extension cables before entering an MR environment. When finished, remove electrodes and clean application sites.

MRI Safety Information
Non-clinical testing has demonstrated that the MR Conditional/CT Disposable Deep EEG Cup Electrode [Fig. 2] is MR Conditional in configurations of 2 to 48 electrodes. These electrodes can safely remain on a patient during a MR scan for 15 minutes under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient field of 4,000 gauss/cm [40T/m] or less
- Maximum whole-body averaged specific absorption rate of 2 W/kg in the Normal Operating Mode
- **Remove extension cables [Fig. 1] before entering an MR environment. They are MR Unsafe.**

Under the scan conditions defined above, the MR Conditional/CT Disposable Deep EEG Cup Electrode is expected to produce a maximum temperature rise of less than 2ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the Cup Electrode extends less than 4 mm from the Cup Electrode when imaged with a gradient echo pulse sequence and a 3 T MRI system.

RF Induced Heating Information
1.5 Tesla Systems: In non-clinical testing with a 1.5 Tesla Intera, Philips Medical Systems MR system (Software: Release 12.6.1.4 2012-05-22) the MR Conditional/CT Deep Cup Electrode produced a temperature rise of ≈ 0.7ºC in a static phantom with a background temperature increase of ≈ 0.1ºC at a software-displayed head averaged (HA) specific absorption rate (SAR) of "‹3.9" W/kg (≈ 2.1 W/kg in a phantom calorimetric test) for 15 min. of continuous MR scanning with transmit/receive body coil. The local SAR shall be ‹ 0.9 W/kg for using the MR body coil.

3.0 Tesla Systems: In non-clinical testing with a 3 Tesla Magnetom Trio, Siemens Medical Solutions MR system (Software: Numaris/4 syngo MR B17) the MR Conditional/CT Deep Cup Electrode produced a temperature rise of ≈1.5ºC in a static phantom with a background temperature increase of ≈ 0.4ºC at a software-displayed head averaged (HA) specific absorption rate (SAR) of "3.5" W/kg (≈ 3.2 W/kg in a phantom calorimetric test) for 15 min. of continuous MR scanning with transmit/receive body coil. The local SAR shall be ‹ 1.3 W/kg for using the MR body coil.

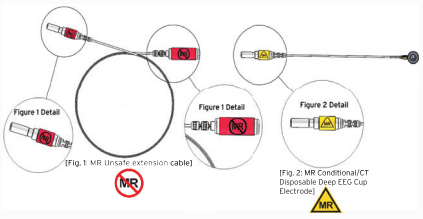
The MR Conditional/CT Disposable Deep EEG Cup Electrode, dual and multiple configuration [2 to 48 electrodes] have not been tested in simultaneous combination with other devices.

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

The included extension cables are MR Unsafe. Remove all extension cables before entering an MR environment.



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.

**Multiple Patents Pending*

MR Conditional*/CT Disposable EEG Webb** Electrodes

Intended Use
The MR Conditional/CT Disposable EEG Webb Electrode is intended for use in the recording of the Electroencephalography [EEG], Evoked Potentials [EP] or as a Ground or Reference in an EEP or EP recording. This device is provided non-sterile for Single Patient Use Only and may remain on the patient in a MR 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 Disposable EEG 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 an MR environment.

Instructions for Use
Clean application site. Apply Webb Electrode using Weaver Ten20 conductive paste. MR Conditional/CT Disposable EEG Webb Electrodes are only approved for use with Weaver Ten20 conductive paste. Collodion may be used if desired. Remove all extension cables before entering an MR environment. When finished, remove electrodes and clean application sites.

MRI Safety Information
Non-clinical testing has demonstrated that the MR Conditional/CT Disposable Webbed EEG Electrode [Fig. 2] is MR Conditional in configurations of 2 to 48 electrodes. These electrodes can safely remain on a patient during a MR scan for 15 minutes under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient field of 4,000 gauss/cm [40T/m] or less
- Maximum whole-body averaged specific absorption rate of 2 W/kg in the Normal Operating Mode
- **Remove extension cables [Fig. 1] before entering an MR environment. They are MR Unsafe.**

Under the scan conditions defined above, the MR Conditional/CT Disposable Webb EEG Electrode is expected to produce a maximum temperature rise of less than 2ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the Webb Electrode extends less than 3 mm from the Webb Electrode when imaged with a spin echo pulse sequence and a 3 T MRI system.

RF Induced Heating Information
1.5 Tesla Systems: In non-clinical testing with a 1.5 Tesla Intera, Philips Medical Systems MR system (Software: Release 12.6.1.4 2012-05-22) the MR Conditional/CT Webbed Electrode produced a temperature rise of ≈0.7ºC in a static phantom with a background temperature increase of ≈0.1ºC at a software-displayed head averaged (HA) specific absorption rate (SAR) of "‹3.9" W/kg (≈ 2.1 W/kg in a phantom calorimetric test) for 15 min. of continuous MR scanning with transmit/receive body coil. The local SAR shall be ‹ 0.9 W/kg for using the MR body coil.

3.0 Tesla Systems: In non-clinical testing with a 3 Tesla Magnetom Trio, Siemens Medical Solutions MR system (Software: Numaris/4 syngo MR B17) the MR Conditional Webbed Electrode produced a temperature rise of ≈1.5ºC in a static phantom with a background temperature increase of ≈0.4ºC at a software-displayed head averaged (HA) specific absorption rate (SAR) of "3.5" W/kg (≈ 3.2 W/kg in a phantom calorimetric test) for 15 min. of continuous MR scanning with transmit/receive body coil. The local SAR shall be ‹ 1.3 W/kg for using the MR body coil.

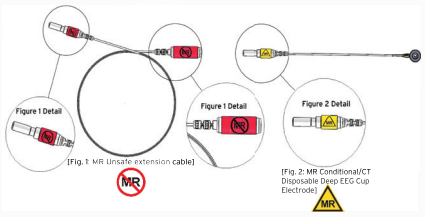
The MR Conditional/CT Disposable EEG Webb Electrode, dual and multiple configuration [2 to 48 electrodes] have not been tested in simultaneous combination with other devices.

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	0.72 mm	1.50 mm
Test object diameter	2.05 mm	2.40 mm

The included extension cables are MR Unsafe. Remove all extension cables before entering an MR environment.



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.

**Multiple Patents Pending*

* Disposable Webbed EEG Electrodes US Patent No. D 644,738 and European Patent Registration Number 001893751-0001. and multiple patents pending.

With the growth of the use of MR technology, the U.S. Food & Drug Administration [FDA] recognized the need for a consensus on standards of practice, and the FDA sought out ASTM International [ASTM] to achieve them. Working with key stakeholders, Committee F04 of ASTM developed F2503, Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. These practices have been put in place for Rhythmlink's MR Conditional*/CT electrodes.

Rhythmlink's MR Conditional/CT Electrodes have been cleared by the FDA and have demonstrated to be both safe and effective for their intended use. These electrodes can remain safely on the patient during MR imaging under specific conditions. Our Slim Cup, Deep Cup, Webb™ and PressOn™ Electrodes incorporate a proprietary design which has undergone extensive computer simulations and real world testing to assess its safety and efficacy.

MR Conditional*/CT Disposable PressOn™ Electrode

Intended Applications
The MR Conditional/CT PressOn Electrode is intended for use in the recording of the Electroencephalography [EEG], Evoked Potentials [EP] or as a Ground or Reference in an EEP or EP recording. This device is provided sterile for Single Patient Use Only and may remain on the patient in a MR environment under specific conditions.

Sterilization
Sterilized by Ethylene oxide.

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. Product is sterile unless packaging is opened or damaged.

MR Conditional/CT PressOn 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 an MR environment.

Packaging - Each Pouch Contains:
1 MR Conditional/CT PressOn Electrodes

1 MR Unsafe Extension cable

General Information
- MR Conditional/CT PressOn electrodes are supplied sterile, intended for single patient use and are disposable.
- The MR Conditional/CT PressOn EEG leads can be connected to any commercially available EEG equipment.
- MR Conditional/CT PressOn electrodes should only be used by trained or skilled personnel under the direction of a physician.
- MR Conditional/CT PressOn electrodes are approved for prolonged usage.
- Follow hospital guidelines for application and dispensing of the MR Conditional PressOn electrode.

Storage
Keep the package away from sunlight. Store at 8-40ºC [46-104ºF].

Warnings
- Electrodes are only approved for recording.
- Electrodes should be applied only to normal healthy skin.
- The skin, shape and type of electrodes may affect the safety and effectiveness of electrical recording.
- The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical recording.
- You should contact the manufacturer of the electrical recording device if you do not know if the electrodes can be used with the recording device.

Precautions
- The long-term effects of cutaneous electrodes for electrical recordings are unknown.
- Keep electrodes out of the reach of children.
- Use caution if electrodes are applied over areas of skin that lack normal sensation.

MRI Safety Information
Non-clinical testing has demonstrated that the MR Conditional/CT PressOn Electrode [Fig. 2] is MR Conditional in configurations of 2 to 48 electrodes. A patient with this device can be safely scanned in an MR system under the following conditions:
- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient field of 4,000 gauss/cm [40T/m] or less
- Maximum whole-body averaged specific absorption rate of 2 W/kg in the Normal Operating Mode
- **Remove extension cables [Fig. 1] before entering an MR environment. They are MR Unsafe.**

Under the scan conditions defined above, the MR Conditional/CT PressOn Electrode is expected to produce a maximum temperature rise of 2.0ºC at 1.5 T and 1.4ºC at 3 T after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the MR Conditional/CT PressOn Electrode extends less than 2 mm from the MR Conditional/CT PressOn Electrode when imaged with a gradient echo pulse sequence and a 3 T MRI system.

RF Induced Heating Information
1.5 Tesla Systems: In non-clinical testing the MR Conditional/CT PressOn Electrode, [in configurations of 2 to 48 electrodes] produced a temperature rise of less than 2.1ºC **[with a background temperature increase of 0.7ºC]** at a maximum head/whole body averaged specific absorption rate [SAR] of 2.1 W/kg assessed by calorimetry for 15 min. of **continuous** MR scanning **with whole body coil** in a 1.5 Tesla Intera Philips [Software: Release 12.6.1.4 2012-05-22] MR Scanner.

3.0 Tesla Systems: In non-clinical testing the MR Conditional/CT PressOn Electrode, [in configurations of 2 to 48 electrodes] produced a temperature rise of less than 2.2ºC **[with a background temperature increase of 0.5ºC]** at a maximum head/whole body averaged specific absorption rate [SAR] of 3.2 W/kg assessed by calorimetry for 15 min. of **continuous** MR scanning **with whole body coil** in a 3 Tesla Magnetom Trio Siemens [Software: Numaris/4, syngo MR A30] MR Scanner.

The MR Conditional/CT PressOn Electrode, dual and multiple configuration [2 to 48 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	0.95 mm	1.81 mm
Test object diameter	1.56 mm	1.85 mm

The included extension cables are MR Unsafe. Remove all extension cables before entering an MR environment.

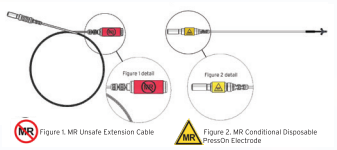


Figure 1. MR Unsafe Extension Cable

Figure 2. MR Conditional Disposable PressOn Electrode

Instructions for Use


1. Open the MR Conditional/CT PressOn electrode's sterile pouch and remove the electrode applicator from the pouch. One electrode is contained within each applicator.

2. Using your thumb and index finger, press tabs that secure the applicator's cap and pull the cap upward to remove. MR Conditional/CT PressOn electrode is visible and ready to be launched. Discard the cap.

3. Place applicator, electrode end down, onto the site chosen for the electrode's placement. If necessary, part patient's hair at the electrode placement site to ensure the MR Conditional/CT PressOn is touching the skin prior to launch. The applicator should be oriented so that the electrode end is resting on the skin so the applicator's plunger is facing up.

4. Using two fingers on the finger pads of the applicator, press the plunger downward toward the skin with light to moderate pressure to launch the electrode. When the plunger is completely depressed the electrode is deployed. If properly launched the teeth should be equally embedded under the skin. Discard the electrode applicator.

5. If any teeth did not properly engage the skin, remove the electrode *[see step 9]*, discard it and insert a new electrode.

6. Connect the electrode to commercial EEG equipment per manufacturer's instructions.

7. Dispose of MR Conditional/CT PressOn applicator according to standard biomaterial handling protocols.

8. During prolonged monitoring, check the electrode insertion site regularly for any signs of infection, reddening or discharge. Replace electrode, as needed.

9. To remove a MR Conditional/CT PressOn electrode, grasp the electrode's wire within 1-2 centimeters of the electrode site, then pull quickly upward away from the skin. Pull in a direction perpendicular to the skin until the electrode pulls free. Discard all used electrodes per hospital guidelines.

10. Minor capillary bleeding may be present once an electrode has been removed. Should this occur, press a sterile cotton pad on the site and hold until bleeding has stopped.

11. Dispose of electrodes in a medical sharps container according to standard biomaterial handling protocols.

**Multiple Patents Pending*

MR Conditional* Sticky Pad™ Surface Electrode

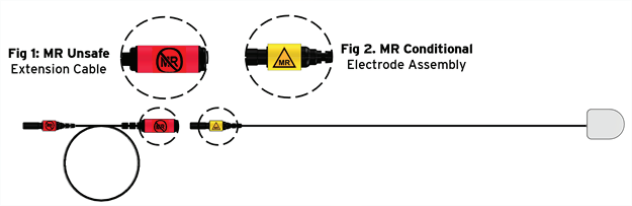
Intended Use
The Rhythmlink MR Conditional Sticky Pad Electrode is intended for use with recording, monitoring, and stimulation equipment in the study of biopotentials such as Electroencephalograph (EEG), Surface Electromyography (EMG), or Nerve Conduction Evoked Potential Signals (EP). This device is 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
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 mm2	.99 mm
Test object diameter	1.77 mm3	.55 mm

The included extension cables are MR Unsafe. Remove all extension cables before entering an MR environment.

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