User Manual: Ives MR Conditional Cup Electrodes

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Indications for Use (IFU)

The Ives MR Conditional Cup Electrodes are intended for use in the general recording and monitoring of the electroencephalography (EEG), evoked potential (EP) as well as ground and reference related to the EEG and EP recording.

The Cup Electrodes are intended to be left in place during MR imaging at 1.5T and 3T as well as during CT scanning.

The extension cable must be disconnected from the Ives MR Conditional Cup Electrodes before scanning and MUST remain disconnected throughout the entire MR scan. EEG or EP should not be recorded throughout the entire the CT and MR imaging.

Initial patient set-up with MRI Conditional EEG electrodes

Follow the steps below for initial patient set-up with MRI Conditional EEG electrodes.

Step	Action
1	Inspect the electrode set for any mechanical problems.
2	Prep scalp location as per established lab guidelines.*
3	Fix EEG electrodes to scalp as per established lab guidelines.*
4	Orient tails of electrodes and lead wires pointing to the head apex as per Figure 1 (see page 3).
5	Install electrode gel as per established lab guidelines.*
6	Wrap or do not wrap head and electrodes as per established lab guidelines.*
7	Gather EEG electrode lead wires at apex and install "Blue-Sponge" as per Figure 2 (see page 2) or leave for nurses to install prior to transporting patient to imaging.

* We are not aware of any counter indications or negative feedback related to skin prep, electrode fixation, electrode gel, or head wrap over 10 years of experience from over 200 hospital sites using these electrodes.

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Nurse preparation of patient prior to transport for imaging

The following procedure is for nurse preparation of patient prior to transport for imaging.

Step	Action
1	Disconnect the electrode set from the recording Harness, as there should be no connections to the electrode set during imaging.
2	If not installed, install "Blue-Sponge" to keep the EEG electrode leads straight, the connectors clear of the scalp and centered to the top of the head. The "Blue-Sponge" can also be used as an indicator to the Imaging Technologist that these electrodes are the set that is established as being MR Conditional. See Figure 2 (see page 2).
3	Communicate with Imaging Technologists that the patient is being sent with MR Conditional EEG electrodes in-place.

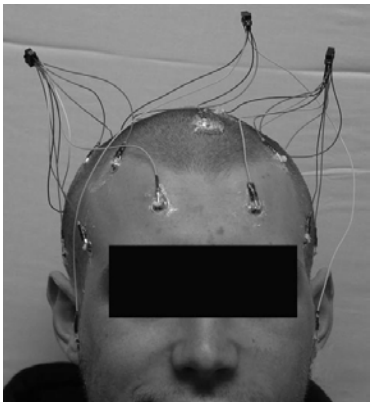
Imaging Technologist preparation of patient prior to imaging

The following procedure is for Imaging Technologist preparation of patient prior to imaging.

Step	Action
1	Confirm that the patient has the MR Conditional electrodes in place.
2	Confirm that the connectors and EEG electrode leads are situated at the apex of the patient's head.
3	Place the patient in the MR keeping the electrode leads and connectors at the apex of the head.

Figure 1 and Figure 2

The figures below show proper electrode set-up.

Figure 1	Figure 2
	

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Cleaning	Use warm water with a soft brush and detergent to remove all foreign material. Dry electrodes with paper towel and store them by hanging in the air. Do **not** store electrodes in a plastic bag.
Disinfection	Use 20% bleach solution or other commercial liquid solution recommended by your institution. Do **not** soak longer than recommended in disinfection solution instruction. **DO NOT SOAK** (even in water) electrodes for any extended length of time as this will cause deterioration on the lead/electrode junction. Again, dry electrodes with paper towel and hang in air to dry for storage.
Sterilization	If sterilization is required by your laboratory's protocol, you will need to follow procedures and recommendations of your institution.
Storage between use	Hang electrodes in air. Do **not** store them in a sealed bag.
MRI staff	The Conductive Plastic Electrodes (CPE) have been designed for MR compatibility based on years of MR and EEG electrode experience at more than 200 institutions ever since 1993 (Ives et al, 1993). The CPEs are constructed of non-magnetic material (plastic, Teflon, carbon) including some noble metals that are well established as being compatible in the MR environment (copper, silver, gold). The electrodes are placed on the patient's scalp by an EEG technologist based on symmetrical 10% and 20% (standard EEG 10-20 locations) over the measured head. There is no concentration of electrodes as they are evenly spaced over the entire scalp (see Figure 1 on page 2). The electrodes are all placed on the surface of the scalp. It is well known and has been shown that the major contribution to RF heating is the antenna effect related to the lead length relative to the 1/8 wave length of the RF, which is 4ft at 1.5T and 2ft at 3T (Balasubramanian et al, 2017). Therefore, the lead wires are designed to be between 6" and 11" in length, depending on the 10-20 site and connection into a small plastic mass connector located at the vertex of the head. The connectors are held at the top of the head by a simple sponge which keeps these connectors off of the scalp by about 2". The sponge ensures that the EEG lead wires are contained at the isocentre of the head and thus the bore of the magnet. The short staggered length leads keeps the leads as straight as possible without forming any coils. The sponge also draws and holds all the leads to the apex of the patient's head and thus maintains the connectors and lead terminations to the center of the bore and keeps them away from the surface of the coil. In this application there should not be anything connected to these connectors and they should appear similar to the photo shown in Figure 2 (see page 2).

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MRI staff, (continued)

Over the intervening years since 1993 more than 200 Hospitals/Institutions (all Harvard teaching hospitals, most hospitals in Philadelphia, Chicago, Phoenix, etc.), have internally cleared these electrodes to be left in place during routine imaging at 1.5T and 3T. They internally tested and cleared these electrodes based on "word-of-mouth," other groups' experiences and/or some published papers (Mirsattari et al, 2004; Vulliemoz et al, 2009).

We can provide you with contact information if this would help in establishing experience and protocol details.

With Respect to Imaging Diagnostic Quality:

Based on published, peer reviewed, clinical imaging studies (CT, 1.5T and 3T), the imaging artifact caused by the device extends only a few millimeters (if at all) from the surface of the Conductive Cup. The electrodes affects mainly skin and in the extreme bone but does not affect the quality of the diagnostic image of the brain. See references below. For CT: Abend et al., 2016; Das et al., 2009; Vulliemoz et al., 2007 & 2009. For 1.5T: Das et al., 2009; Mirsattari et al., 2004. For 3T: Vulliemoz et al., 2007 & 2009.

MR Condition Statement:

Allowable imaging zone	Head/neck
Allowed patient position	Head first supine
Static field strength	3T OR 1.5T
RF Coil Type	Body transmit coil
RF Coil Mode	CP mode only
MRI operating mode	Normal
Head Average SAR	≤3.2W/Kg
B1rms	≤2.0μT

! Body Imaging: safety has not been verified and may cause injury.

Localized imaging of extremities such as the foot, ankle and knee can be performed safely where the Ives electrodes are **not** within the transmit RF field of the RF transmit coil.

In non-clinical testing, the (Ives MR Conditional cup electrodes, based on 21 electrodes with lengths varying from 6" to 11") produced a temperature rise of less than 5°C at a maximum head averaged specific absorption rate (SAR) of 3.2 or 2μT B1rms, for 10 minutes of MR scanning in 1.5T and 3T field strength scanners (details below).

Tested MR Conditions:

- Heating of 21 EEG electrodes evaluated when placed at standard EEG 10-20 sites.
- Heating evaluated on a realistic head phantom.
- Heating evaluated at 1.5T and 3T.

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MRI staff, (continued)

Specific Conditions Evaluated:

a. Electrode wire position controlled with sponge (normal);

b. Electrode wires under the head (single-fault condition);

c. Scanning centered on the nasion (isocentre scanning for the head);

d. Scanning centered on the neck (nasion 100mm from isocentre).

The amount of RF-induced heating varies between electrodes; it is typically maximal at T6 and Fp2 but limited to 1-4°C in each of the tested cases.

Non-Clinical Testing:

Non-clinical testing has demonstrated that the Ives MR Conditional Cup Electrodes is MR Conditional and can safely remain on the patient during an MR scan under the following conditions:

- Static magnetic fields strength of 1.5T and 3T
- Maximum spatial gradient magnetic fields of 2,000 gauss/cm (20T/m) or less
- Transmit body and head coil, quadrature driven
- 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
- Under the scan conditions defined above, the Ives MR Conditional Cup Electrodes is expected to produce a maximum temperature rise of less than 5ºC after 15 minutes of continuous scanning.
- The extension cable must be disconnected from the Ives MR Conditional Cup Electrodes before scanning and must remain disconnected throughout the entire MR scan.

In non-clinical testing, the image artifact caused by the device extends approximately 3 mm from the Ives MR Conditional Cup Electrodes when imaged with a gradient echo pulse sequence and a 1.5T and 3T MRI system.

Conclusions:

These observations strongly suggest that skin heating is highly unlikely to approach unsafe levels (refer to CEM43), given that skin temperature under the electrodes will not exceed 30 °C.

NOTE: We have subjected these electrodes to 1.5T and 3T environments to demonstrate that these electrodes are MR Conditional under very limited and specific conditions as all possibilities (manufacture, model, bore size, Tx, Rx combinations) cannot be addressed; particularly, in lieu of new developments, MR techniques and sequences, etc. Please review our specific testing conditions. If your conditions are significantly different than our stated conditions and if your MR group has concerns, then you may want to perform some further internal testing to evaluate your specific MR Conditions.

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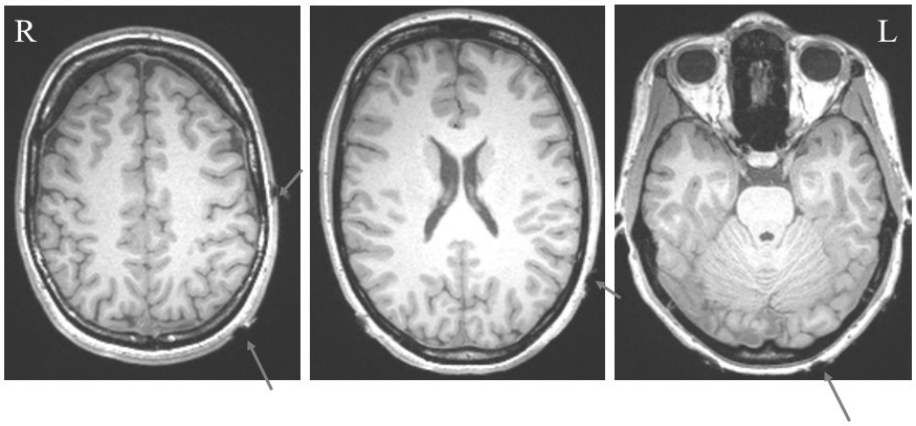
MRI Imaging

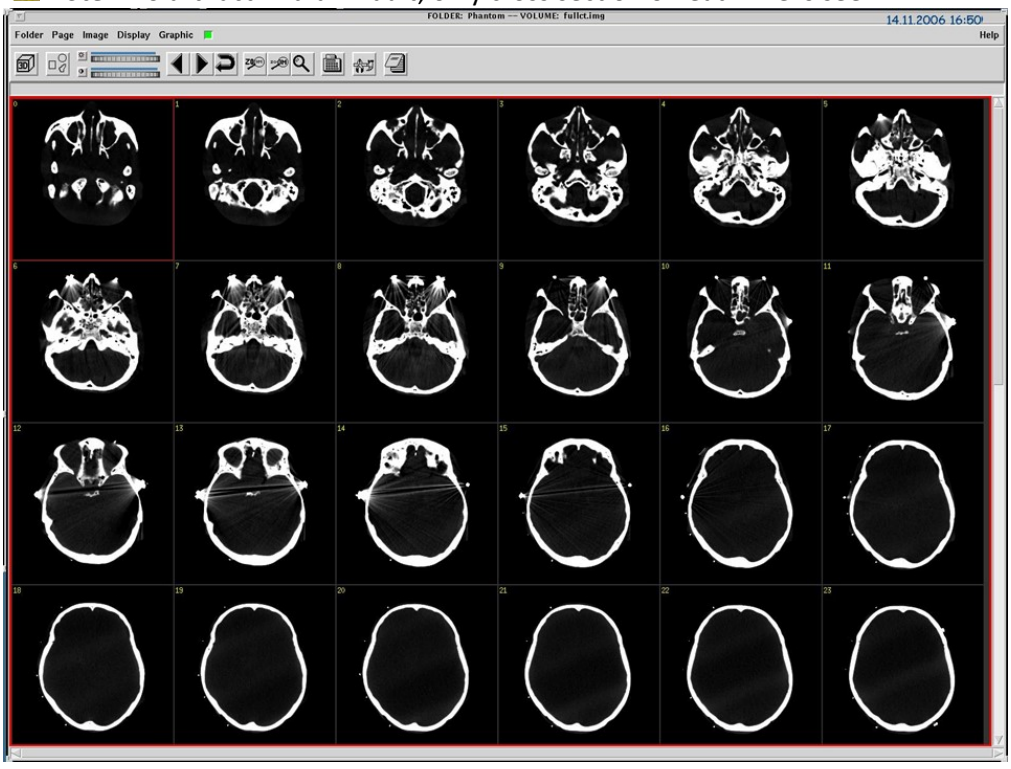
Electrode Types: Conductive Plastic @ left, some artifact
Gold Cup @ right, some artifact
Subdermal Wire@ frontal, no artifact
Arrows indicate location of electrode artifact at 3T



CT Imaging

CT of 3 electrode types on phantom. Gold cup around eye area show "star-burst" artifact. Conductive plastic on right-side and subdermal wire electrode on left-side.

Note: No artifact in brain vault; only cross section of lead wire is seen.



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