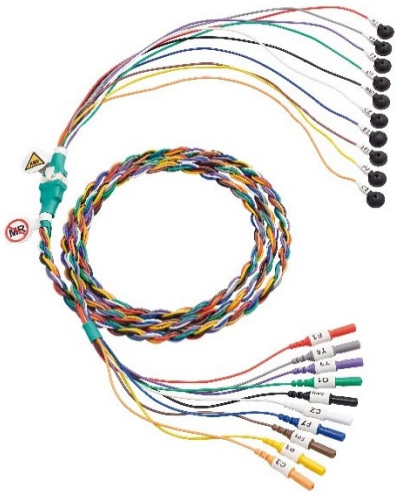
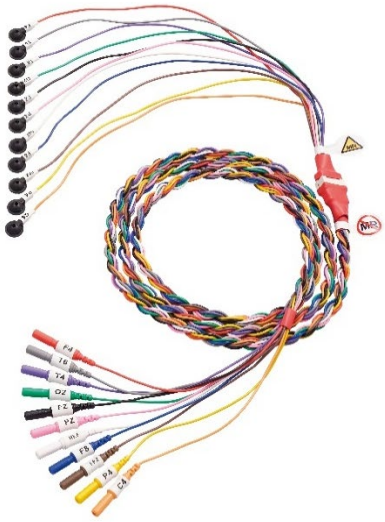
CUP ELECTRODE MRI CONDITIONAL





Description

The cup electrode set is suitable for MRI tests ensuring safety conditions. For ICU the system has the advantage to avoid to remove the electrodes from patients' skin thanks to the easy disconnection of multipolar connector. These electrodes must be used with their dedicated connection cable.

UMDNS 17554

Materials

Electrode	AgAgCl
Material in contact with the skin	AgAgCl
Lead wire	Cu/Sn with PVC jacket
Connector	CuZn with PE jacket
Packaging	PP
Lead wire	Cu/Sn with PVC jacket
Connector	Touch Proof 1,5 mm DIN 42802

Safety

Biocompatibility *(UNI EN ISO 10993)*	Yes
Latex	No
Phthalates	No

Specifications

Generic code	DCCCCPE-XX
Electrode diameter	10 mm
Electrodes number	From 21 to 27
Recording Area	78 mm^2
Cable length	100 cm

Environment

RoHS II	✓
REACH	✓

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MRI Safety information

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.

MRI staff

The Conductive Plastic Electrodes 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 Conductive Plastic Electrodes are constructed of non-magnetic material including some noble metals that are well established as being compatible in the MR environment (copper, silver, gold).

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 1.5-T and 3.0-T
- Maximum spatial gradient magnetic fields of 2,000 gauss/cm (20T/m) or less
- Transmit body or 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 1.5-T and 3.0-T MRI system.

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 or Head Coil Tx With Head Coil Rx
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.