

ENGLISH

REUSABLE ELECTRODES FOR ECG IN SILVER CHLORIDE

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

DIRECTIONS FOR USE

INDICATIONS:

Surface ECG recording.

For a description of the model, refer to the information on the envelope.

PRELIMINARY NOTES

Normally a surface ECG (at rest or during stress) consists of 12 leads: 3 limb bipolar recordings, 3 limb unipolar recordings and 6 precordial unipolar recordings. Therefore, 10 electrodes, 4 for the unipolar and bipolar derivations and 6 for the precordial derivations have to be placed on the patient. The following GIMA electrodes are available:

Cod. 33364

Clamp electrodes for limbs, with sensor coated with Silver Chloride (Ag / AgCl), and universal attachment held in place by an elastic mechanism

Cod. 33365 - 33368 - 33369

Silver silver chloride suction chest electrodes with universal connection provided with rubber balls. After their positioning on the skin surface, rubber balls must be squeezed to improve adherence. These chest electrodes are used for precordial recording at rest.

In case of rest ECG the electrodes are positioned as follows:

- Upper limbs: about 10 cm above the wrists on the internal forearm face.
- Lower limbs: about 10 cm above the malleolus on the internal leg face.
- Precordials: (V1) 4th left intercostal space at the right parasternal line. (V2) 4th left intercostal space at the left parasternal line. (V3) halfway between V2 and V4. (V4) 5th left intercostal space at the midclavicular line. (V5) 5th left intercostal space at the anterior axillary line. (V6) 5th left intercostal space at the midaxillary line.

In case of a stress test, to avoid ECG noises caused by limbs movements, limb electrodes must be positioned on the back of the patient. The precordial electrodes must be positioned as follows:

- Right arm electrode: on the right shoulder-blade.
- Left arm electrode: on the left shoulder-blade.
- Right leg electrode: lowest intercostal space on the right posterior axillary line.
- Left leg electrode: lowest intercostal space on the left posterior axillary line.

INSTRUCTIONS

Clean the skin surfaces with a cotton flock soaked with ether. Spread conductive paste on the above described skin areas with an amount

enough to ensure a complete adherence of the metallic plate. In precordial areas shave hairs if necessary. Put electrodes on the so treated area.

To ensure a stable position of the plate electrode, insert its special support in a hole of rubber belt, then place the belt around the limb and close it on the support choosing the most effective tension.

To connect the electrodes insert the plug of the patient cable in the socket of the electrode connection cable.

POSITIONING

Suction chest electrode (precordial derivations): place the electrode on the wished point by squeezing the rubber ball. Squeeze the rubber ball and press the electrode until a good adherence of the chest on the skin is obtained, then release the rubber ball.

Clamp electrode (peripheral derivations): place the clamp so that the conductive plate adheres on the skin of the arm or of the leg on the points previously selected.

Plate electrode: insert the special connection of the electrode in one of the holes of the rubber belt, roll the belt around the limb and fasten it on the electrode connection using the hole which gives enough tension.

ATTENTION

European and American standards use the following colours to identify patient cable leads:

• EUROPEAN STANDARD:

right arm: **RED** – left arm: **YELLOW**
right leg: **BLACK** – left leg: **GREEN**.

• USA STANDARD:

right arm: **WHITE** – left arm: **GREEN**
right leg: **BLACK** – left leg: **RED**.

WARNING

• A non sterile device is supplied.

- ECG devices and connection cables which will be connected to GIMA electrodes must be in accordance with regulations in force.
- Devices must be connected and activated by qualified personnel.
- Do not spread the electroconductive paste on wounded or scarred skin.

- Do not use Code 33365 - 33368 - 33369 for monitoring during cardioversion and / or defibrillation procedures as the trace recovery time after discharge may exceed 10 seconds.

Code 33364 can be used during cardioversion and / or defibrillation procedures because it has characteristics for which the recovery time of the trace is less than 10 seconds, as indicated in the standard EN 60601-2-25 "Electro-medical devices: standard particular for the safety of electrocardiographs".

- Specific for Code 33364: During cardioversion and / or defibrillation procedures it is advisable to insert the filters for the Base Line Restorer on the electrocardiograph.

- Specific for Code 33364: After each electrocardiographic investigation, carefully clean with non-abrasive materials to avoid damaging the surface of the electrodes

Do not use these electrodes for short or medium monitoring (monitoring during surgical procedures, Holter recording).

- The electrodes are in accordance with the biocompatibility ISO10993-1.

CLEANING / DISINFECTION

To clean the electrodes, cleaning and disinfecting detergents commonly suitable for surgical devices are suggested. For Codes 33365 - 33368 - 33369, for example, products based on benzalkonium chloride can be used. Before using these cleaning products read carefully their instructions. After cleaning wash with water.

N.B. Do not use ultrasonic cleaners. Don't use removers, don't sterilize with steam. It possible to clean with ethyl alcohol with concentration less than 10%.

PRODUCT LIFE

The Silver Silver chloride (Ag/AgCl) coating of electrodes is obtained with a galvanic proceeding. The silver silver chloride could be removed by a not suitable cleaning (for example by abrasive systems) and this could cause the registration of a non suitable ECG signal. In this case eliminate the products.

- Clamp electrode: intensive and protracted use eventually deteriorates the flexible part (spring).
- Suction electrodes: in presence of chaps on the rubber ball or failure to adhere to the skin, replace the rubber ball.

STORAGE

The product should be stored in its original packaging in rooms with ambient conditions of temperature and relative humidity, as specified on the package label. The overlap of weights on the packaging may damage the product.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

WASTE DISPOSAL

Waste coming from hospitals must be disposed of in accordance with regulations in force.

	IT Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso GB Caution: read instructions (warnings) carefully FR Attention: lisez attentivement les instructions (avertissements) DE Achtung: Anweisungen (Warnungen) sorgfältig lesen ES Precaución: lea las instrucciones (advertencias) cuidadosamente PT Cuidado: leia as instruções (avisos) cuidadosamente		IT Dispositivo medico conforme al regolamento (UE) 2017/745 GB Medical Device compliant with Regulation (EU) 2017/745 FR Dispositif médical conforme au règlement (UE) 2017/745 DE Medizinprodukt im Sinne der Verordnung (EU) 2017/745 ES Producto sanitario conforme con el reglamento (UE) 2017/745 PT Dispositivo médico em conformidade com a regulamentação (UE) 2017/745
	IT Conservare al riparo dalla luce solare GB Keep away from sunlight FR À conserver à l'abri de la lumière du soleil DE Vor Sonneneinstrahlung geschützt lagern ES Conservar al amparo de la luz solar PT Guardar ao abrigo da luz solar		IT Conservare in luogo fresco ed asciutto GB Keep in a cool, dry place FR À conserver dans un endroit frais et sec DE An einem kühlen und trockenen Ort lagern ES Conservar en un lugar fresco y seco PT Armazenar em local fresco e seco
	IT Leggere le istruzioni per l'uso GB Consult instructions for use FR Consulter les instructions d'utilisation DE Gebrauchsanweisung beachten ES Consultar las instrucciones de uso PT Consulte as instruções de uso		IT Dispositivo medico GB Medical Device FR Dispositif médical DE Medizinprodukt ES Producto sanitario PT Dispositivo médico
	IT Codice prodotto GB Product code FR Code produit DE Erzeugniscode ES Código producto PT Código produto		IT Non sterile GB Non-sterile FR Pas stérile DE Nicht steril ES No estéril PT Não estéril
	IT Numero di lotto GB Lot number FR Numéro de lot DE Chargennummer ES Número de lote PT Número de lote		IT Data di scadenza GB Expiration date FR Date d'échéance DE Ablaufdatum ES Fecha de caducidad PT Data de validade
	IT Fabbricante GB Manufacturer FR Fabricant DE Hersteller ES Fabricante PT Fabricante		IT Limite di temperatura GB Temperature limit FR Limite de température DE Temperaturgrenzwert ES Límite de temperatura PT Limite de temperatura
	IT Data di fabbricazione GB Date of manufacture FR Date de fabrication DE Herstellungsdatum ES Fecha de fabricación PT Data de fabrico		IT Limiti di umidità GB Humidity limit FR Limite d'humidité DE Feuchtigkeitsgrenzwert ES Límite de humedad PT Limitação de humidade
	IT Latex free GB Latex free FR Sans latex DE Ohne Latex ES Sin látex PT Isento de látex		IT Unique device identify GB Unique device identifier FR Identification unique de l'appareil DE Eindeutige Geräteidentifikation ES Identificación única del dispositivo PT Identificação exclusiva do dispositivo
	IT Rappresentante autorizzato in Svizzera GB Authorized Representative in Switzerland FR Représentant autorisé en Suisse DE Bevollmächtigter Vertreter in der Schweiz ES Representante autorizado en Suiza PT Representante Autorizado na Suíça		IT Rappresentante autorizzato nel Regno Unito GB Authorized Representative in the UK FR Représentant autorisé au Royaume-Uni DE Autorisierter Vertreter im Vereinigten Königreich ES Representante autorizado en el Reino Unido PT Representante Autorizado no Reino Unido

REF 33364 - 33365 - 33368 - 33369

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