

## 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 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 shaves 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.

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

**REF** 33364 - 33365 - 33368 - 33369

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