

***EURODEFIPADS<sup>®</sup>***

***FIAB<sup>®</sup>***

**CE**  
2797

- IT** ELETTRODI MULTIFUNZIONE MONOUSO EURODEFIPADS®
- EN** DISPOSABLE MULTIFUNCTION ELECTRODES EURODEFIPADS®
- FR** ÉLECTRODES MULTIFONCTIONS À USAGE UNIQUE EURODEFIPADS®
- DE** MULTIFUNKTIONS-EINWEGELEKTRODEN EURODEFIPADS®
- NL** MULTIFUNCTIONELE WEGWERPELEKTRODEN EURODEFIPADS®
- ES** ELECTRODOS MULTIFUNCIONALES DESECHABLE EURODEFIPADS®
- PT** ELÉTRODOS MULTIFUNÇÃO DESCARTÁVEIS EURODEFIPADS®
- RU** МНОГОФУНКЦИОНАЛЬНЫЕ ОДНОРАЗОВЫЕ ЭЛЕКТРОДЫ EURODEFIPADS®
- EL** ΗΛΕΚΤΡΟΔΙΑ ΠΟΛΛΑΠΛΩΝ ΛΕΙΤΟΥΡΓΙΩΝ ΜΙΑΣ ΜΟΝΟ ΧΡΗΣΗΣ EURODEFIPADS®
- SV** MULTIFUNKTIONELLA ELEKTRODER FÖR ENGÅNGSBRUK EURODEFIPADS®
- HR** VIŠENAMJENSKE ELEKTRODE ZA JEDNOKRATNU UPOTREBU EURODEFIPADS®
- PL** ELEKTRODY WIELOFUNKCYJNE JEDNORAZOWEGO UŻYTKU EURODEFIPADS®
- CS** JEDNORÁZOVÉ MULTIFUNKČNÍ ELEKTRODY EURODEFIPADS®
- HU** EGYSZERHASZNÁLATOS TÖBBFUNKCIÓS ELEKTRÓDÁK EURODEFIPADS®

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## DISPOSABLE MULTIFUNCTION ELECTRODES EURODEFIPADS®

### OPERATING INSTRUCTION

#### CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

#### IMPORTANT

The product is intended for use in non-sterile environment by authorized personnel only. Before using the product, the user should deeply understand these instructions.

#### DESCRIPTION

The disposable multifunction electrodes *FIAB EURODEFIPADS*® are constituted by a pair of adhesive pads provided with gels and direct connection to cables and defibrillators which may be used in place of the manual reusable paddles [1].

#### PACKAGING

Each pair of FIAB disposable multifunction electrodes is packaged in sealed envelopes of opaque material suitable to protect the gel from light and moisture. Envelopes are included in the carton sales package along with a copy of the operating instructions.

#### INDICATIONS

The disposable multifunction electrodes *FIAB EURODEFIPADS*® are indicated for:

- Transthoracic external defibrillation.
- Transthoracic synchronized cardioversion.
- Transthoracic ECG Monitoring.
- Temporary transthoracic cardiac pacing (non-invasive).

FIAB disposable multifunction electrodes allow the user to effectively operate in the treatment of rhythm disorders related to the above-mentioned applications, without the risk of accidental electrocution related to the use of normally available reusable paddles.

#### CONTRAINDICATIONS

- FIAB disposable multifunction electrodes for adults are generally contraindicated in patients younger than 8 years old [2] (weighing less than 25kg [3][4]), but can be used if the size of the chest allow it, taking care that one pad do not come in contact with the other one. Follow the operating instructions of the defibrillator for energy to be delivered.
- The use of FIAB disposable multifunction electrodes in versions for adult or adult/paediatric is generally contraindicated in patients aged less than 12 months (weighing less than 10kg).
- The use of FIAB paediatric disposable multifunction electrodes is generally contraindicated in patients older than 8 years old [2] (weighing more than 25kg [3][4]);
- Do not apply on skin that shows signs of irritation or injury.

#### MODE OF USE

External Defibrillation and synchronized cardioversion: the FIAB disposable multifunction electrodes are able to transfer to the patient the electrical energy supplied by the defibrillator up to a maximum value of 360J in the adult version [1], of 300J for adult/paediatric unic version and of 100J in the paediatric version [5].

The depolarization of the critical mass of the myocardium, which is essential for the success of the therapy, is only possible if it is crossed by a current of appropriate intensity: the active surface of the electrodes is optimized for this purpose. It is therefore appropriate, in addition to a targeted selection of the positioning sites, to apply the adhesive pads in such a way that their contact surface with the skin is maximum. The choice of power to supply is at the discretion of the operator.

In paediatric applications the Guidelines for cardiopulmonary resuscitation recommend a supply of energy of 2-4J / kg; the recommended starting level is of 2 J / kg and it is preferable not to exceed 100J in order to avoid burns [5].

**ATTENTION** FIAB disposable multifunction electrodes can withstand up to 50 defibrillation shocks.

**ATTENTION** Do not supply a shock with manual metal paddle above the disposable electrode pads or ECG electrodes.

Non-invasive transthoracic pacing: FIAB disposable multifunction electrodes can be used for non-invasive transthoracic pacing. To minimize the threshold of pacing it is appropriate to apply the adhesive plates in the manner described above. It is also necessary to have a good understanding of the equipment you want to use and follow the manufacturer's instructions.

**ATTENTION** It is good practice to replace FIAB disposable multifunction electrodes after 8 hours, checking, in case of prolonged pacing (greater than 30 minutes), the skin of the patient for signs of irritation.

**ATTENTION** Replace FIAB disposable multifunction electrodes after 30 minutes if the supplied pulses are monophasic and longer than 20ms.

ECG monitoring: FIAB disposable multifunction electrodes can also be used for ECG monitoring.

**ATTENTION** If the tracing is not sufficiently clear, use an ECG patient cable, if it is present, and a separate set of ECG electrodes.

## MODE OF APPLICATION

- The multifunction electrodes can be applied to the patient even in the mere suspicion that a severe arrhythmic disease may develop.
- The points where it is possible to apply the adhesive electrodes are listed in "PLACEMENT AND POLARITY".
- Uncover the chest and prepare the skin. Remove excessive hair [1]. Slightly abrade the skin surface to reduce the contact impedance. Avoid applying the adhesive pad on the nipple or breast tissue [6].
- Remove any residue (dirty, greasy and debris), using non-flammable cleaners. Finally, make sure the application sites are clean and dry.
- Open the package and remove multifunction electrodes.
- Gently remove the protective liner, starting from the tab to expose the adhesive and conduction areas.
- In case of multifunctional electrodes with clips remove the protective support.
- Apply the adhesive pads one-to-one starting with one side and pressing progressively over the entire surface to avoid the formation of air bubbles and ensure complete adhesion to the skin. Keep the adhesive pads well separated one from the other and be careful not to overlap them with other objects (ECG electrodes, cables, transdermal patches, clothing etc.) [7][8].
- Do not reposition the adhesive pads once applied. If the position must be changed, remove and replace with new multifunction electrodes.
- To remove the adhesive plate without irritating the patient's skin, lift an edge and gently pull back. Hold at the same time the skin with the other hand.
- For multifunctional electrodes without clip: connect the electrodes to the defibrillator or the adapter cable by following the instructions for use of the defibrillator.
- For multifunctional electrodes with clips: connect the clip to the cable of the defibrillator for the correct polarity, observing the instructions for use of the defibrillator.
- For on demand pacing, separately connect ECG monitoring electrodes.

## POSITIONING AND POLARITY

The international guidelines indicate various placements as equally effective for the treatment of atrial or ventricular arrhythmias [1][5].

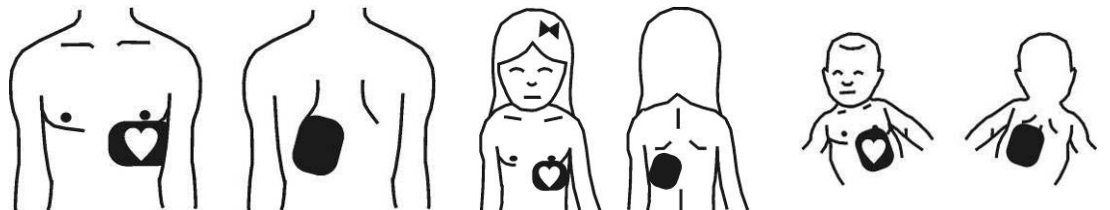
The following figures show the application sites commonly used and recommended by most manufacturers of defibrillators. Choose the most appropriate points of application of the therapy according to manufacturer's instructions for use of the defibrillator to be used.

For ease of placement and for training purposes, the anterior-lateral side (Fig.1) is preferred for arrhythmias defibrillation and cardioversion; the anterior-posterior side (Fig.2) is more common in hemodynamics and in transthoracic pacing and recommended in case of use of electrodes for adults on pediatric patients.

Fig.1  
 • Defibrillation  
 • Cardioversion  
 • Pacing  
 • Monitoring (it provides a track Lead II)



Fig.2  
 • Pacing  
 • Monitoring  
 • Defibrillation  
 • Cardioversion



To maintain the proper signal polarity, apply the electrode pads in the indicated positions (the apex is identified by the symbol of the heart). However note that for the purpose of the therapy, it is not relevant which electrode pad (apex / sternum) is placed in one of the two positions [2].

Regarding the polarity of the electrodes in unique version adult/pediatric, follow the directions on the labels of the electrode pad (according to the instructions of the manufacturer of the defibrillator to be used).

### SIDE EFFECTS

- Plate adhesive may cause light cutaneous irritation.
- The prolonged transthoracic stimulation or the repeated administration of defibrillation shock may cause more or less noticeable skin reddening according to the supplied energy.
- A lack in adhesion and/or air presence under the electrode may cause burnings.

### PRECAUTIONS AND WARNINGS

- Use the product only on defibrillators brands indicated on the labels.
- Check that the product is compatible with the specific model of defibrillator intended to be used.
- Read the instructions for use of the defibrillator, with particular attention on the placement of multifunction electrodes, their polarity and the power to be supplied.
- In paediatrics and for some models of automatic defibrillators the use of specific reducing power devices or the adoption of special precautions may be required. Always pay a special attention to energy levels set on the defibrillator and that can be delivered to the paediatric patient (see section "MODE OF USE").

#### ATTENTION



Do not use paediatric multifunction electrodes marked with the symbol shown beside with automatic defibrillators.



Paediatric multifunction electrodes marked with the symbol shown beside are indicated for use with automatic defibrillators.

- The electrode choice should be based on the evaluation of chest size and weight of the patient. Paediatric electrodes used beyond the specified energy limit may cause also major skin burns; on the contrary the extended active surface of adult electrodes may jeopardize the therapy when used for pediatric treatment.
- After an extended period of transthoracic pacing the ability to detect the evoked ECG signal can be reduced. In this case it is necessary to provide for the collection of the evoked signal by a separate set of ECG electrodes.

- Replace the multifunction electrodes after 24 hours from their application on the patient's skin.
- Check the expiration date on the package. Do not use after this date.
- Do not use multifunction electrodes if removed from the envelope for more than 24 hours. The adhesive pads are to be applied within 30 minutes after removal of the protective coating.
- Check that the packaging is intact: do not use the product otherwise.
- Do not use the multifunction electrodes if the gel is removed from the support or if it is ripped, torn or dry. Any discoloration localized on gel or on conductive foil does not affect the functionality of the product.
- Do not use the multifunction electrodes if during removal of the protective coating the product is damaged (eg. the insulating coating of the contact has detached or there are tears in the foam support and/or in the electrode).
- Do not bend, do not cut and do not squash the adhesive pads.
- Do not use the multifunction electrodes if the connector, the cable or the clips appear to be damaged.
- Check on the operating instructions of the defibrillator at which safety distances the devices (surgeon's electric knife, RF ablaters, diathermy equipment, mobile phones, etc.) that emit strong electromagnetic interferences must be placed. Position the defibrillator / electrode system at a distance of at least one and a half times the recommended separation distances.
- To prevent accidental damage from electric shock, ensure that during discharge operators are not in contact with the electrode pads, with the patient, or with conductive parts close to the patient.
- When defibrillators are used near oxygen sources or other flammable gases, use extreme care to avoid risk of fire or explosion.
- The product neither is sterile nor can be sterilized.
- The product is disposable. For use on a single patient. Discard after use.

### **POTENTIAL COMPLICATIONS**

There are no complications related to the use of multifunction electrodes.

**ATTENTION:** The defibrillator discharge may cause irregularities in the operation of an implanted pacemaker/defibrillator [1]; apply the multifunction electrodes at a distance of at least 8cm [9]. After defibrillator discharge check its operation.

**ATTENTION:** If the chosen energy level is insufficient the success of therapy may be jeopardizing. On the contrary, higher levels may modify the enzyme structure without actual evidence of myocardial damage.

### **PRODUCT LIFE AND STORAGE**

Check the expiration date printed on the package.

The product should be stored in its original packaging in rooms with environment conditions of temperature and relative humidity, specified on the label. The storage at extreme temperatures must be limited to short periods (24 hours at -30°C or +65°C). Prolonged storage at extreme temperatures can shorten the life of the product.










**ATTENTION:** The overlap of weights on the packaging could damage the product.

### **DISPOSAL**

Refuses deriving from health structures must be disposed in according to the regulation in force.

### **WARRANTY AND LIMITATIONS**

FIAB S.p.A. guarantees that the product complies with Directive 93/42/EEC. No responsibility may be ascribed to the Manufacturer who shall not be held liable for medical costs, direct or indirect damage due to lacking function or malfunction of the above product, when used differently from the instruction for use. We recommend to report opportunely any malfunction or defect of the product to FIAB Quality Assurance Service.

|           |  |  |  |  |  |  |  |  |  |
|-----------|---|---|---|---|---|--|---|---|---|
| <b>IT</b> | Conformità Europea  | Prodotto da   | Numero di Catalogo  | Numero di Lotto   | Numero pezzi per confezione   | Data di Produzione   | Usare entro il  | Limiti temperatura  | Temperatura operativa   |
| <b>EN</b> | European Conformity   | Manufactured by   | Catalogue Number  | Batch number  | Pcs. per box/pack   | Production date  | Use before  | Temperature limits  | Operating temperature limits  |
| <b>FR</b> | Conformité Européenne   | Produit par   | Numéro de catalogue   | Numéro de Lot   | Numéro de pièce par emballage   | Date de production   | Utiliser avant le   | Limites de température  | Température de fonctionnement   |
| <b>DE</b> | CE Prüfzeichen  | Erzeugt von   | Katalognummer   | Postennummer  | Stück/ Packung  | Erzeugungsdatum  | Verwendbar bis  | Temperaturbegrenzungen  | Betriebstemperatur  |
| <b>NL</b> | Europese conformiteit   | Geproduceerd door   | Catalogusnummer   | Partijnummer  | Aantal artikels per verpakking  | Productiedatum   | Te gebruiken binnen   | Temperatuur limieten  | Temperatuur limieten  |
| <b>ES</b> | Conformidad Europea   | Fabricado por   | Número de catálogo  | Número de Loto  | Piezas por bolsa o paquete  | Fecha de producción  | Usar antes de   | Límites de temperatura  | Límites de temperatura de funcionamiento  |
| <b>PT</b> | Conformidade Europeia   | Fabricado por   | Número de Catálogo  | Número de Grupo   | Unidades por embalagem  | Data de Fabrico  | Usar antes de   | Limites de temperatura  | Limites da temperatura de funcionamento   |
| <b>RU</b> | Соответствие нормам ЕС.   | Изготовитель  | Номер по каталогу   | Номер партии/изделия  | Кол-во в коробке/упаковке   | Дата изготовления  | Использовать до   | Ограничения по температуре  | Пределы рабочей температуры   |
| <b>EL</b> | Ευρωπαϊκή συμμόρφωση.   | Κατασκευασμένο από  | Αριθμός καταλόγου   | Αριθμός λαχειοφόρου αγοράς  | Τεμάχια ανά κουτί/πακέτο  | Ημερομηνία παραγωγής   | Να χρησιμοποιηθεί πριν από  | Όρια θερμοκρασίας   | Όρια θερμοκρασίας λειτουργίας   |
| <b>SV</b> | Överensstämmelse med EG-direktiven  | Tillverkad av   | Artikelnummer   | Satsnummer  | Antal per låda/förpackning  | Tillverkningsdag   | Används innan   | Temperaturgränser   | Temperaturgränser för användning  |
| <b>HR</b> | Usklađenost s EU zahtjevima   | Proizvođač  | Kataloški broj  | Broj serije   | Komada u kutiji/pakiranju   | Datum proizvodnje  | Rok valjanosti  | Granice temperature   | Granice radne temperature   |
| <b>PL</b> | Zgodność Europejska   | Wyprodukowany przez   | Numer katalogu  | Numer partii  | Liczba sztuk w opakowaniu   | Data Produkcji   | Używać w terminie do  | Wartości graniczne temperatury  | Temperatura operacyjna  |
| <b>CS</b> | Evropská shoda  | Vyrobena v  | Katalogové číslo  | Šarže   | Kusů v krabici/balení   | Datum výroby   | Použitelné do   | Meze teploty  | Meze provozní teploty   |
| <b>HU</b> | Az (EU) rendeletnek való megfelelés   | Gyártó  | Katalógus száma   | Batch kód   | Mennyisége darabok  | Gyártás dátuma   | használatá által  | Hőmérséklet korlátozás  | Üzemi hőmérséklet   |



|                                |  |                                |  |                                       |                           |  |  |  |
|--------------------------------|--|--------------------------------|--|---------------------------------------|---------------------------|--|--|--|
|                                |  |                                |  |                                       |                           |  |  |  |
| Limiti di Umidità              | Tenere al riparo dalla luce solare         | Teme l'umidità                 | Attenzione leggere attentamente la documentazione allegata | Consultare le istruzioni d'uso        | Non riutilizzare          | Non contiene LATTICE di gomma naturale         | Compatibile con Corpuls3 (Defib-Unit con pad riutilizzabili)                         | Non usare con Corpuls3 con Defib-Unit SLIM               |
| Humidity limits                | Keep away from sun light                   | Keep away from humidity        | Warning: read the enclosed documentation                   | Consult instructions for use          | Do not reuse              | Latex free                                     | Compatible with Corpuls3 (Defib-Unit with reusable pads)                             | Do not use with Corpuls3 with Defib-Unit SLIM            |
| Limites d'humidité             | Protéger des rayons du soleil              | Craindre l'humidité            | Attention lire attentivement la documentation ci-jointe    | Consulter les instructions            | Ne pas réutiliser         | Ne contient pas de latex de caoutchouc naturel | Compatible avec Corpuls3 (Defib-Unit avec pad réutilisables)                         | Ne pas utiliser avec Corpuls3 avec Defib-Unit SLIM       |
| Feuchtigkeitsbegrenzungen      | Vor Sonne schützen                         | Vor Feuchtigkeit schützen      | Warnzeichen: lesen Sie die Beschreibung                    | Gebrauchsanweisung lesen              | Einmalgebrauch            | Latexfrei                                      | Kompatibel mit Corpuls3 (Defib-Unit mit wiederverwendbaren Pads)                     | Nicht mit Corpuls3 mit Defib-Unit SLIM verwenden         |
| Vochtigheidsgrens              | Tegen zonnelicht beschermen                | Niet bestand tegen vochtigheid | Let op, lees zorgvuldig de bijgesloten documentatie        | Lees eerst de instructies             | Niet her te gebruiken     | Bevat geen natuurrubber                        | Compatibel met Corpuls3 (Defib-Unit met hergebruikbaar pad)                          | Niet gebruiken met Corpuls3 met Defib-Unit SLIM          |
| Limites de humedad             | Mantener lejos de la luz solar             | Mantener lejos de la humedad   | Alerta: lea la documentación adjunta                       | Consulte las instrucciones de uso     | No reutilizar             | Libre de látex                                 | Compatible con Corpuls3 (Defib-Unit con pad reusables)                               | No usar con Corpuls3 con Defib-Unit SLIM                 |
| Limites de Humidade            | Manter protegido da luz do sol             | Teme a humidade                | Atenção, ler atentamente a documentação incluída           | Consultar instruções de utilização    | Não reutilizar            | Não contém látex de borracha natural           | Compatível com Corpuls3 (Defib-Unit com placas reutilizáveis)                        | Não usar com Corpuls3 com Defib-Unit SLIM                |
| Ограничения по влажности       | Оберегать от солнечных лучей               | Оберегать от влаги             | Внимание: прочитайте прилагаемую документацию              | Обратитесь к инструкции по применению | Не использовать повторно  | Не содержит латекса                            | Совместим с Corpuls3 (Defib-Unit с многоразовыми пластинами)                         | Не использовать с Corpuls3 с Defib-Unit SLIM             |
| Επίπεδα Υγρασίας               | Μακριά από φως                             | Μακριά από υγρασία             | Προειδοποίηση  | Συμβουλευτείτε τις οδηγίες χρήσης     | Να μην ξαναχρησιμοποιηθεί | Χωρίς λάτεξ                                    | Συμβατό με Corpuls3 (Defib-Unit με pad επαναχρησιμοποιήσιμα)                         | Δε χρησιμοποιείται με Corpuls3 με Defib-Unit SLIM        |
| Fuktighetsgränser              | Skyddas mot solljus                        | Skyddas mot väta               | Varning: läs den bifogade bruksanvisningen                 | Läs bruksanvisningen                  | Endast för engångsbruk    | Latexfri                                       | Kompatibel med Corpuls3 (Defib-enhet med återanvändbar dyna)                         | Använd inte med Corpuls3 med Defib-enhet SLIM            |
| Granice vlažnosti              | Držati podalje od izvora sunčevog svjetla  | Držati na suhom mjestu         | Upozorenje: proučite priloženu dokumentaciju               | Pročitajte upute za upotrebu          | Za jednokratnu upotrebu   | Ne sadrži latex                                | Kompatibilan sa Corpuls3 (Defib-Unit sa papučicom za višestruku primjenu)            | Ne upotrebljavati sa Corpuls3 sa Defib-Unit SLIM         |
| Wartości graniczne wilgotności | Przechowywać z dala od światła słonecznego | Chronić przed wilgocią         | Uwaga dokładnie przeczytać załączoną dokumentację          | Zapoznać się z instrukcją użytkowania | Nie używać ponownie       | Nie zawiera LATEKSU z gumy naturalnej          | Kompatybilny z Corpuls3 (Defib-Unit z podkładkami wielokrotnego użytku)              | Nie używać z zastosowaniem Corpuls3 z Defib-Unit SLIM    |
| Meze vlhkosti                  | Uchovávejte mimo sluneční záření           | Uchovávejte v suchu            | Varování: čtěte přiloženou dokumentaci                     | Věnujte pozornost návodu k použití    | Nepoužívejte opakovaně    | Bez latexu                                     | Kompatibilní s Corpuls3 (Defibrilační jednotka s opakovaně použitelnými elektrodami) | Nepoužívejte s Corpuls3 a defibrilační jednotkou SLIM    |
| páratartalom korlátozás        | Tartsa távol a napfénytől                  | Tartsa szárazon                | Vigyázat, konzultáljon kiséző dokumentumokat               | Consult használati utasítás           | Ne használja újra         | Nem tartalmaz természetes gumi latex           | Kompatibilis a Corpuls3-zal (Defib-egység újrafelhasználható párnákkal)              | Ne használja a Corpuls3-szal Defib-Unit SLIM készülékkel |



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