**INSTRUCTION MANUAL**

**NEONATAL AND PAEDIATRIC ECG PREWIRED ELECTRODES SETS for single-patient use**

Please read carefully the following information
Failure to observe these precautions may lead to serious medical problems.

**Important note:**
This insert is designed to provide guidance on the use and handling of the Neonatal ECG prewired electrode sets. No reference is made to a cardiacological technique. The manufacturer declines any responsibility for medical results resulting from improper use of these products.

**Symbols used**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Single Use</td>
</tr>
<tr>
<td>✒</td>
<td>Limits of temperatures storage and use</td>
</tr>
<tr>
<td>🌞</td>
<td>For Adults and children over 8 years old</td>
</tr>
<tr>
<td>☀</td>
<td>Does not contain latex</td>
</tr>
<tr>
<td>🌿</td>
<td>CE marking – Complies with directive 93/42/EEC: applicable with effect from 14th June 1998</td>
</tr>
<tr>
<td>🏱</td>
<td>Not for neonates</td>
</tr>
<tr>
<td>🌲</td>
<td>Keep in a dry place</td>
</tr>
<tr>
<td>🕒</td>
<td>Expiratory date</td>
</tr>
<tr>
<td>☑</td>
<td>Not for paediatrics</td>
</tr>
<tr>
<td>🏗️</td>
<td>Manufacturing date</td>
</tr>
<tr>
<td>🔥</td>
<td>Radiolucent application</td>
</tr>
<tr>
<td>⚠️</td>
<td>For neonates</td>
</tr>
<tr>
<td>🌞</td>
<td>Do not expose to direct sunlight</td>
</tr>
<tr>
<td>🔥</td>
<td>For paediatrics (young children between 1 and 8 years old)</td>
</tr>
</tbody>
</table>

The classification rules may vary from one country to another. According to the European directive 93/42 (annex IX) or the Australian MD regulation, the ECG electrodes are Class I products. According to USA/FDA and Canada/CMDCAS regulations, the ECG electrodes are Class II products.

- The positioning of ECG electrodes can only be carried out by a health care specialist, familiar with proper placement and use.
- No skin prep is required or recommended. It is important to have skin as clean and dry as possible for proper attachment.
- The ECG electrodes can only be applied to undamaged and clean skin (not on open wounds, lesions, infected or inflamed areas).
- For removal saturate surface of lead with water, gently peel away from skin as you swab with water so as not to damage the skin of the baby.
- Always read the instruction manual for the particular electromedical device and for the ECG trunk cable before applying the neonatal ECG prewired electrodes set to the patient.

**PLEASE NOTE:**
INTEGRAL PROCESS may not be held liable for any incidents which might occur to the patient, to the user and to any other persons in the area which might be caused by the presence of dangerous electrical currents or electromagnetic fields from other electromedical devices particularly the Electro Surgical Unit or Defibrillator.

- In the operating room, ensure that all parts of the device are outside of the operating area. This is done in order to reduce any risk of burning the patient while the electrosurgical unit is in use and always as far away from the patient as is possible to minimize any risk.
- The neonatal ECG prewired electrodes sets are designed to withstand repeated defibrillation shocks.
- The neonatal ECG prewired electrodes set cannot be used for more than one patient. They cannot be sterilised.
- The neonatal ECG prewired electrodes set has to be used with maximum caution in a MRI environment.
- INTEGRAL PROCESS may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.

**I – DESCRIPTION / FIELD OF APPLICATION**

**DESCRIPTION:**

1. **Presentation**
   Set of three prewired and pre-gelled ECG Electrodes for the monitoring of newborn babies and small children. The electrodes are repositionable on the same patient and are designed to be used for at least 48 Hours.

2. **Technical Description**

   2.1. **ECG Electrode for neonates and pediatrics**
   Pre-gelled electrodes use a solid hydrogel and are made of an Ag/AgCl 100 microns thin film on a carbon Eyelet construction with a sensor element area of 10 mm in diameter, and an adhesive part of 22x25 mm in size. The duration of use is more than 48 hours.
   The lead wires are 60 cm in length and are made with a carbon conductor having a great mechanical resistance.
   The maximum absorption of X rays is due to the Ag/AgCl film, it is less than 4 mm of water (or 5 mm of soft tissues) for X rays having an energy of 80 kEV for which opacity tests conducted according to the american standard ASTM F640.

   2.2. **Available Sets:**
   INTEGRAL PROCESS offers two types of neonate and paediatric ECG electrode sets in its catalogue (COMM/DOCU 100008 B - 2011) which can be viewed and downloaded on the company’s website at: [www.integral-process.com](http://www.integral-process.com). One set is equipped with 1,5 mm security plugs, the other with 4mm plugs.

   2.3. **Packaging:**
   - Each set of three electrodes are in one OPP/PE laminated pouch;
   - 50 sets are supplied per box (150 electrodes);
   - Shipping cartons contain 12 boxes (1800 electrodes);
   - the sets which are supplied are non-sterile.
The two types of ECG electrodes for neonates and paediatrics are designed for taking a one lead ECG on a single patient. They can be used in paediatrics' monitoring applications, always offering safe operation and maximum functionality, in medium and long time use on newborn, young or premature babies.

The neonates and paediatrics ECG electrode sets are named as "devices" in the subsequent chapters of this instruction manual.

### FIELD OF APPLICATION:
Each set comes with repositionable pre-gelled contact electrodes. They are only designed for application to a single patient. The electrodes offer simple and quick positioning.

The positioning of ECG electrodes should be carried out by a health care worker, familiar with proper placement and use.

The ECG electrodes should be applied to intact, clean skin (not on open wounds, lesions, infected or inflamed areas)

The ends of the paediatrics ECG electrodes leadwires are designed to be connected either to a security paediatric trunk cable, or to a 3 leads ECG cable bananas.

Examples are proposed on the website of INTEGRAL PROCESS [www.integral-process.com](http://www.integral-process.com) (See the catalogue COMM/DOCU 100/008 B - 2011).

### INSTALLATION / USE:
Please follow these instructions for optimum installation and operation of the devices, and look at the electrodes placement shown on the packaging and follow the instructions below.

1. **Place the electrodes corresponding to the site in question by following these stages:**
   - **Preparing the patient:**
     - No skin prep is required or recommended. The skin must be clean and dry per hospital protocol. It is important to have skin as clean and dry as possible for proper attachment. Moisture, oils or lotions adversely affect the adhesion of hydrocolloid. **DO NOT USE ALCOHOL.**
   - **Placing the electrodes:**
     - Remove the electrode’s protective sheet.
     - Place the electrode on the site corresponding to the area designated by the colour or symbol.

2. **Placing devices’ conductors:**
   - Fix the devices’ conductors in order to avoid any undesirable traction on the electrodes
   - Plug the device’s connector into the appropriate ECG cable for the taking of the ECG.
   - (See also the specific instruction manual for the particular ECG cable)

3. Proceed to monitor the ECG lead
4. For removal saturate surface of lead with water, gently peel away from skin as you swab with water so as not to damage the skin of the baby.

### PERFORMANCES / RELIABILITY / SAFETY / COMPATIBILITY / MECHANICAL INTEGRITY / ALLERGICITY

The devices are inspected both during and at the end of the manufacturing process according to a technical protocol drawn up in line with current standards and regulations of this type of product. They have also undergone clinical testing and assessments.

**SAFETY:**
- The devices are designed and manufactured to meet current recommendations based on the general and special specifications of the relevant current International and/or European standards:
  - (International standards IEC 60601-1 & 60601-2-25 / 60601-2-27)
  - (International standards ISO 14971, ISO 10993-1, ISO 10993-5 & ISO 10993-10)
  - (Radiolucent tests conducted according to ASTM F640)

The devices used are part of the "applied part" to the patient as defined by the IEC 60601-1 International safety and essential performance standard. The safety class, the type of protection (BF, CF), the degree of protection against electric shocks from the devices are closely linked to those of the electro-medical device to which it is connected.

- Please read the instructions for the electromedical device before applying the ECG prewired electrode sets.
- The devices are sensitive to electromagnetic fields. So it is a good idea to remove these sources of radiation to a safe distance from the devices.
- In the operating room, ensure that all or part of the device is outside of the operating area. This is done in order to reduce as much as possible any risk of burning the patient while the electrosurgical unit is in operation.
- The neonatal ECG prewired electrodes sets are designed to withstand repeated defibrillation shocks. They have no accessible metal parts.
- The use of prewired ECG electrodes in an RMI environment may lead currents in the conductor of the cables and then could cause the patient to suffer burns.

The device's use in the surgical operating room requires additional precautions for application by ensuring that the ECG electrodes are outside of the operating area.

Low frequency leakage currents are below authorised values and are measured in accordance with the recommendations of the current standards which are applicable to this product.

### PLEASE NOTE:
INTEGRAL PROCESS may not be held liable for any incidents which might occur to the patient, to the user and to any other persons caused by the presence of dangerous electrical currents coming from the electromedical device.

![Image](https://via.placeholder.com/150)

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**NEONAT AND PAEDIATRIC ECG PREWIRED ELECTRODES SETS for single-patient use**

<table>
<thead>
<tr>
<th>P/N</th>
<th>MODEL</th>
<th>Electrode's positioning</th>
<th>Atworks</th>
<th>Suggested/ Intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>50554IP</td>
<td>PAED</td>
<td>Yellow</td>
<td>Atworks 01</td>
<td>ECG trois voies pour surveillance monitorée</td>
</tr>
<tr>
<td>50555IP</td>
<td>PAED</td>
<td>Yellow</td>
<td>Atworks 02</td>
<td>ECG trois voies pour surveillance monitorée</td>
</tr>
</tbody>
</table>
INTEGRATION MANUAL

NEONAT AND PAEDIATRIC ECG PREWIRED ELECTRODES SETS for single-patient use

COMPATIBILITY:
In order to ensure compatibility between devices, use only the compatible ECG INTEGRAL PROCESS cables mentioned in the commercial documentation (see catalogue COMM/DUCO 001/029B – 2011/2012).

On the company’s website (www.integral-process.com), INTEGRAL PROCESS offers its customers a downloadable document with technical details on the device’s compatibility.

MECHANICAL and ELECTRICAL INTEGRITY:
INTEGRAL PROCESS has used high quality, highly reliable materials to ensure the mechanical integrity of the devices (conductors, connectors, cables) and to reduce the risk of damage during use.

The devices are designed to withstand repeated defibrillation shocks. Adherence to the conditions of storage and use is crucial in order to keep the device’s characteristics at an acceptable level. The device must not be used after the expiry date shown on its packaging. The electrodes are repositionable. The maximum application time to the skin of the patient should not exceed 48 hours. Over this delay or in case of less adhesitivity or conduction defect, the ECG Electrodes have to be replaced if needed for reapplication.

ALLERGICITY:
The materials used to manufacture INTEGRAL PROCESS devices have been subjected to allergy tests. These tests have not shown the presence of any products which might trigger an intolerable allergic skin reaction. (Report NAMSA no. 04C_40861_02 – 04T_51183_01 – 04C_40861_01, etc.) For certain patients, it cannot be totally excluded that a skin irritation might occur at the point of contact between the electrode and the skin.

HOW TO HANDLE:
SPECIAL CONDITIONS:
- Do not use a device or part of a device if there is any risk to the patient (e.g. damaged insulating material).

PREVENTIVE MAINTENANCE:
- You must ensure that the expiry date shown on the protective wrapper is still valid, after this date INTEGRAL-PROCESS can no longer guarantee that the device will work properly.
- The conditions for the storage of these devices must be adhered to. (See chapter II of this instruction manual)

CORRECTIVE MAINTENANCE:
- There is no corrective maintenance for this product.

HYGIENE:

Please note:
The device must not be used for more than one patient.
The device cannot be sterilised.

STORAGE:
The storage conditions for the devices are as follows:
- Ambient temperature: 5 to +38°C (+40 to +100°F)
- Relative humidity: 40 to 90% (no condensation)
- Atmospheric pressure: 500 to 1060 hPa (mbar) (7.25 to 15.37 psi/14.8 to 31.39 inHg)
- Expiry date: as shown on the packaging

PACKAGING:
The devices are packed by three in an aluminised plastic bag (sealed foil) available in boxes containing 50 units (150 electrodes). When they are not in use, devices of this kind must be stored in their original packaging in order to prevent any damage which might reduce their service lives, performances and/or safety levels. The time limit of the use of the device is shown on its packaging.

INTEGRAL-PROCESS can only guarantee that the device will work properly if it is used and stored under the conditions described in these instructions and if it has not suffered any apparent mechanical damage and if the expiry date for its use is valid.

INTEGRAL-PROCESS guarantees that the device complies with the specifications of the current safety and performance standards applicable to it. The class and type of protection (BF, CF) against electric shocks are defined by the type of electromedical device to which the devices are connected.

Please note:
Always read the instruction manual for the particular apparatus before applying the devices.
INTEGRAL PROCESS may not be held liable for any incidents which might occur in the event of any failure to adhere to the rules of installation and use mentioned in this instruction manual.