CE selon directive Nr. 93/42 CEE
Date d'imposition du marquage CE: 14 juin 1998
as per EEC directive No. 93/42
Date of Imposition of EMI marking: 14th June 1998

INTEGRAL PROCESS

INTEGRAL PROCESS is certified
ISO 9001 : 2008 and ISO 13485 : 2003 (+AC : 2007)
by TÜV Rheinland Product Safety GmbH

INSTRUCTION MANUAL

IP-Set® ECG PREWIRED ELECTRODE STRIPS 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 IP-SET® ECG prewired electrode strips. No reference is made to a cardiological technique. The manufacturer declines any responsibility for medical problems resulting from improper use of these products.

Symbols used

	Please read both the instruction manuals for the **device** and the **IPC type INTEGRAL PROCESS ECG interface cable** and the instruction leaflet or user manual for the **ECG medical device**		At the end of its working life please follow attentively the current WEEE (Waste Electrical and Electronic Equipment) European directive		
	Single Use		Limits of temperatures storage and use		For Adults and children over 8 years old
LATEX	Does not contain latex	CE	CE marking – Complies with directive 93/42/EEC: applicable with effect from 14th June 1998		Not for neonates
	Keep in a dry place		Expiratory date		Not for paediatrics
	Manufacturing date	**RT**	Radiolucent application		For neonates
	Do not expose to direct sunlight				For paediatrics (young children between 1 and 8 years old)

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

- **The positioning of ECG electrodes can only be carried out by a health care specialist, familiar with proper placement and use.**
  The ECG electrodes can only be applied to undamaged and clean skin (not over open wounds, lesions, infected or inflamed areas)
- **After use always remove carefully the ECG electrodes so as not to damage the skin of the patient.**
- **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.**
  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 from other electromedical devices particularly the Electro Surgical Unit or Defibrillator.
- **IP-Set® cannot be used for more than one patient. IP-Set® cannot be sterilised.**
- **IP-Set® has to be used with maximum caution in a MRI environment**
- **Always read the instruction manual for the particular electromedical device and for the ECG interface cable before applying the devices to the patient.**

I – DESCRIPTION / FIELD OF APPLICATION

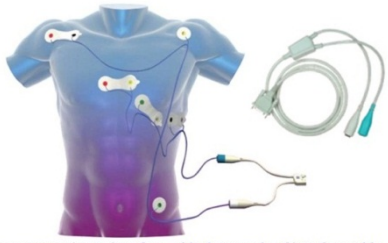
DEVICE DESCRIPTION

1. Presentation:

Instead of other marketed substantial equivalent ECG electrodes, Integral-Process electrodes are pre-wired and are offered as a full range of combinations covering all main types of application.

Each pre-connected harness enables a clean/easy positioning due to preset and adequate wire lengths and saves time. The harness is then connected to any type of electrocardiograph or monitoring system by an interface cable. This enables to keep the harness positioned on a patient between different hospital services and reconnect it to the different services' hardware if needed.

Monitoring specificity (diagnostic, coronary, intensive care, operating room, stress control), environment (X rays), and patient size (adult, pediatric, neo-natal), require different electrode numbers, electrode sizes, wiring lengths, and material composition (radio opacity). This leads to a complete family of 16 different pre assembled sets of electrodes as summarized on the next page.



Harness connection to interface cable & example of interface cable

2. Technical Description

2.1. IP-Set® Product

A set of disposable, single-use, pre-gelled ECG electrodes regrouped on one or two flat cables are placed to ease their positioning on the patient.
Electrode number and positioning design may vary according to the monitoring application.

Pre-gelled electrodes are made of a Ag/AgCl thin film on a carbon Eyelet construction with a sensor element area between 10 and 20 mm in diameter, and an adhesive part between 20 and 90 mm in diameter.

Lead wires are regrouped in a flat cable and are made of copper or carbon fiber (radiotranslucent).
Integral-Process has developed a specific set of jack/plugs to connect the harness to the interface cable.

2.2. Available Sets:

INTEGRAL PROCESS offers a full range of **IP-Set® ECG electrode strips** in its catalogue ***(COMM/DOCU001/027)*** which can be viewed and downloaded on the company's website at: ***www.integral-process.com***. The **intended use is mentioned clearly on the different packaging labelling: diagnostic, monitoring, neonates etc.**

2.3. Packaging:

- Each set / harness is packaged in one OPP/PE laminated pouch;	- Shipping cartons contain 12 boxes.
- Depending of the pouch size, 10 to 50 are supplied per box;	- Sets are supplied non-sterile.

In order to be able to identify more easily each ECG set reference is associated to a coloured graphic logo.
In case of several different IP-SET types being used in the same department, the coloured logo will help to save time and avoid errors.

IP-Set® ECG electrode strips are named as "**devices**" in the subsequent chapters of this instruction manual.

INSTRUCTION MANUAL

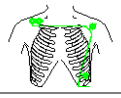
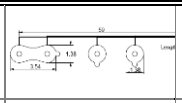
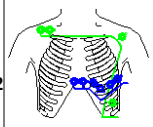
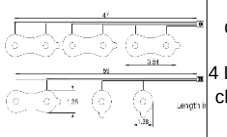
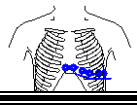
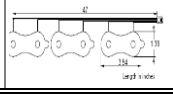
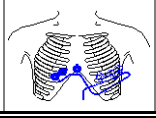
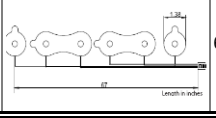
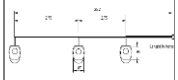
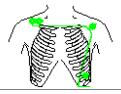
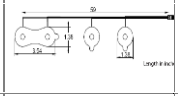
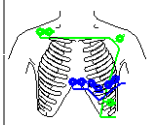
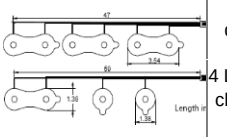
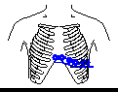
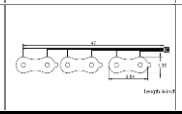
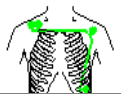
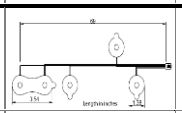
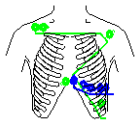
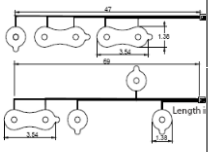
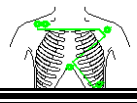
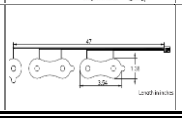
IP-Set® ECG PREWIRED ELECTRODE STRIPS for single-patient use

II – INTENDED USE / SUGGESTED INDICATION

There are several types of **IP-Set® ECG prewired electrode strips** offering different, complementary features and designed for taking an ECG **on a single patient**. Whether or not they are coupled, they thus allow the ECG signal to be taken from **1 (DII)** to **18 leads**.
They can be used in various different applications, always offering safe operation and maximum functionality. And they can be used on all type of patients (adult, paediatric or neonates), in all disciplines which require the taking of an ECG, according to the Physician's decision, e.g.
diagnosis, medium or long-term monitoring, stress tests, operating rooms, Emergency departments, Neonates department, transfering of patients between different departments, radiology, angiography and coronarography.

LIST OF REFERENCE NUMBERS (P/N) AND INTENDED USE (SUGGESTED APPLICATION)

CHART OF IP-SET® Electrodes sets (IEC colour coded leads)

	P/N / MODEL	Electrode's positioning	Artworks	Suggested/ Intended use	P/N / MODEL	Electrode's positioning	Artworks	Suggested/ Intended use
STANDARD APPLICATIONS	50500 IP-SET M3			4 Leads ECG (Monitoring)	50502 IP-SET 12			12 Leads diagnostic ECG 4 Limb's + 6 double chest's electrodes
	Not Marketed Item			6 chests Leads electrodes				
					IP-SET C			6 additional chest's electrodes
NEONAT PAEDIATRICS	50401 IP-SET N3			3 separate ECG Leads				
X-RAYS TRANSLUCENT APPLICATIONS	50600 IP-SET M3RT			4 Leads ECG (Monitoring	50602 IP-SET 12RT			12 Leads diagnostic ECG 4 Limb's + 6 double chest's electrodes
	50603 IP-SET 6VRT			6 chests Leads electrodes				
	50601 IP-SET M5			5 Leads ECG (Monitoring)	Not Marketed Item			12 Leads diagnostic ECG 4 Limb's & 1 +5 chest's electrodes
	50604 IP-SET 5VRT			5 chests lead electrodes				

MONITORING ⟸ DIAGNOSTIC

FIELD OF APPLICATION:

Each set comes with **repositionable pre-gelled contact electrodes**. They are only designed for application to **a single patient.** The innovative design of IP-Set® strips simplifies the electrodes positioning and avoids connection errors.

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 over open wounds, lesions, infected or inflamed areas)

The flat connecting cable has a specific connector at the other end which can only be connected to the electromedical device using an **IPC** type **INTEGRAL PROCESS ECG interface cable** ***(See catalogue COMM/DOCU 001/027)***.

III – INSTALLATION / USE

INSTALLATION:

Please follow these instructions for optimum installation and operation of the **devices**, and look at the electrodes placement shown on the packaging.

Example of taking the ECG signal with 12/18 leads

1. **Choose the appropriate device(s) for the measurement:**
   - ⇒ **ECG with 12 leads: ref. for the whole of the two devices: 50502**
   - ⇒ **Additional set for 18 leads: ref. : 50507**
2. **Place the device's or devices' electrodes corresponding to the site in question by following these stages:**

Preparing the patient:

- ⇒ Remove any hair by shaving if necessary,
- ⇒ First use an appropriate cleaning product (ethyl alcohol, ether, etc.) to clean the location where the electrode will be positioned on the patient.

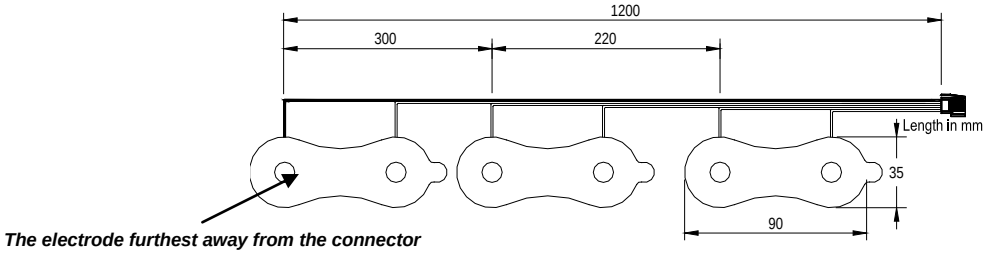
Placing the electrodes:

- ⇒ Remove the electrode's protective sheet.
- ⇒ Place the electrode on the site corresponding to the location designated by the colour or symbol.

N.B. - *Always start by positioning the device's electrode which is the furthest from the connector.*
- Proceed in the same way for each of the chosen device's electrodes to be positioned on the patient.

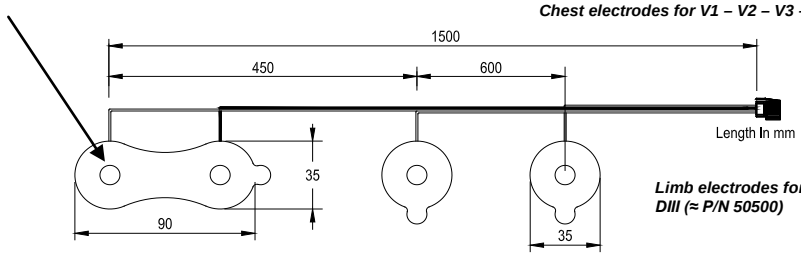
INSTRUCTION MANUAL

IP-Set® ECG PREWIRED ELECTRODE STRIPS for single-patient use



The electrode furthest away from the connector

Chest electrodes for V1 – V2 – V3 – V4 – V5 – V6 (are non marketed separately)

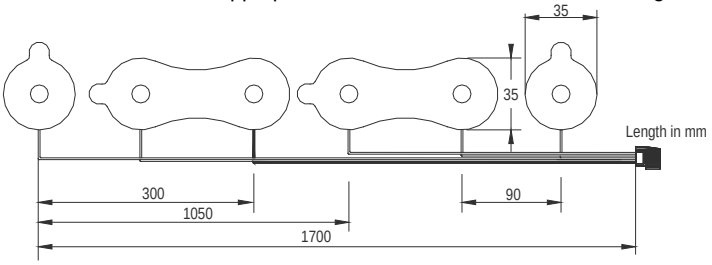


Limb electrodes for the standard ECG DI - DII – DIII (≈ P/N 50500)

P/N: 50502

3. **Placing devices' conductors:**
   - ⇒ Fix the **device's conductors** in order to avoid any undesirable traction on the electrodes
     (It is a good idea to fasten the device onto the patient using an adhesive plaster)
   - ⇒ Plug the **device's connector** into the appropriate **ECG interface cable** for the taking of the "standard" ECG.
   - ⇒ Plug the **device's connector** into the appropriate **ECG interface cable** for the taking of the "precordial" ECG.

   (See also the specific instruction manual for the particular IPC interface cable – COMM-DOCU 700/038)
4. **Proceed to record the 12 leads**
5. **Proceed to record the 6 additional leads**:
   - ⇒ Disconnect the plug from the device corresponding to the thoracic electrodes
   - ⇒ Plug the **50507 device's connector** into the appropriate **ECG interface cable** for the taking of the "additional" ECG.



Ref.: 50507

Device for the taking of the additional ECG (for example V3R, V4R, VE, V7, V8, V9)

⚠

   - ⇒ Proceed to record the additional **ECG** signals.
6. **Carefully remove the ECG electrodes so as not damage the skin of the patient.**

IV – PERFORMANCES / RELIABILITY / SAFETY / COMPATIBILITY / MECHANICAL INTEGRITY / SYMBOLS / ALLERGICITY

PERFORMANCES / RELIABILITY

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.
The test results have been authenticated by a notified Body **(LNE/Gmed technical report no. G011847 C2)**
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, European and/or National standards: (International standards **IEC 60601-1-1988 +A1:1991 & A2:1995 subclause 56.3** as required by **21CFR898)**
(American standard **AAMI/ANSI EC 12-2000 & EC 53-1998)**
(International standards ISO 14971, ISO 10993-1, ISO 10993-5 & ISO 10993-10)
(Radiolucent tests conducted according to ASTM F640)

The **devices** 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 cable for IP-Set® ECG prewired electrode strips**.
- 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 any risk of burning the patient while the electrosurgical unit is in operation as far as possible.

The **devices** have no accessible metal parts.
Their 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, measured in accordance with the recommendations of the current standards which are applicable to this product, do not exceed the authorised values. **(LNE/GMED technical report no. J021341-C2)**

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.

INSTRUCTION MANUAL

IP-Set® ECG PREWIRED ELECTRODE STRIPS for single-patient use

COMPATIBILITY:

In order to ensure compatibility between **devices**, use only the **specific IPC-type ECG INTEGRAL PROCESS cables** mentioned in the commercial documentation (***See catalogue COMM/DOCU 001/027***).

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

MECHANICAL and ELECTRICAL INTEGRITY:

In order to ensure the mechanical integrity of the **devices** (conductors, connectors, cable) and to reduce the risk of damage during use, **INTEGRAL PROCESS** has used high quality, highly reliable materials.
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 **72 hours.** Over this delay or in case of less adhesitivity or conduction defect, the **IP-Set® has to be replaced** if needed for reapplication.

ELECTRODES COLOUR CODES:

INTERNATIONAL COLOUR CODE (IEC)	
RA / RIGHT ARM: **RED**	LA / LEFT ARM: **YELLOW**
LL / LEFT LEG: **GREEN**	RL / RIGHT LEG: **BLACK**
V1: 4th intercostal space, right edge of the sternum: **RED**	
V2: 4th intercostal space left edge of the sternum: **YELLOW**	
V3: on the 5th rib between C2 and C4: **GREEN**	
V4: 5th intercostal space, left medioclavicular line: **BROWN**	
V5: between C4 and C6 on the front left axillary line: **BLACK**	
V6: on the left mid axillary line at C4 level: **VIOLET**	

ALLERGICITY:

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

V - MAINTENANCE / HYGIENE – STORAGE / PACKAGING

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 packaged either singly or in pairs in an aluminised plastic bag (sealed foil) available in boxes containing either 25 or 60 units, depending on their types and/or intended uses.
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.

VI – WARRANTY / LIABILITY

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.

CAUTION: FEDERAL LAWS (USA) RESTRICT THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

INTEGRAL PROCESS
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