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## 1. DESCRIPTION AND INTENDED USE OF CLINIPORATOR

Cliniporator, model EPS02, is the most advanced device for tissues electroporation.

Electroporation is a physical phenomenon inducing an alteration in the structure of cells membrane obtained exposing cells to an intense but short electric field; this alteration of the cell membrane produces an increase in its permeability. As a consequence of the electroporation the molecules that usually cannot enter the cell membrane, neither through diffusion nor through active transport, can reach the cytoplasm. Electroporation is the principle Electrochemotherapy [ECT] is based upon as well as the transfer of gene materials into cells [EGT].


Cliniporator enables the application of electroporation applying high and low voltage electric pulses that allow the intracellular transfer of molecules not or little permeant the cell membrane. During the electroporation procedure the Cliniporator measures the voltage and current wave forms applied and display them in real time. The treatment data are stored inside an archive.

Cliniporator is constituted by:

- a control section called Console which, through a graphical interface, allows to insert data patient, select the appropriate electrode and perform the treatment;
- a Power Unit which generates pulses;
- an incorporated radio section to automatically recognise the electrodes that can be used.









CONSOLE FEATURES		
Operative system	Linux	
Display	17" XVGA Touch screen resistive - resolution 1280 x 1024 pixels	
Electrical supply	115/230 VAC	
Radiofrequency Identification	RFID ISO15693	
POWER UNIT FEATURES	HIGH VOLTAGE	LOW VOLTAGE
Pulses number	1 ÷ 10	1 ÷ 10
Pulses amplitude	[100 ÷ 1000] Volt	[20 ÷ 200] Volt
Pulses length	[50 ÷ 1000] µs	[1 ÷ 1000] ms
Rise up time	< 2 µs a 1000 Volt	
Pause between pulses	[1 ÷ 2000] ms	
Pulses repetition frequency	[1 ÷ 5000] Hz	
Maximum supplied current	20 Ampere	5 Ampere
Pulse amplitude precision	±5%	±5%
Pulse length precision	±2 µs	±1%
Pause between high and low voltage pulses	1 – 2000 ms	
ECG signal Synchronization through Norav 1200T (Optional) or a device with same characteristics.		


## 2. ACCESSORIES

CODE	APPEARANCE	DESCRIPTION
IG0M910 (BLU) IG0M915 (GREEN)		The handle (two different models) allows the connection with some of the sterile disposable electrode. <b>The handle tolerates up to 20 sterilisation cycles in autoclave [caoutchouc cycle, minimum of 15 and maximum of 20 minutes at 121°C].</b> Process performed not according to the specifics above mentioned, can wear down the handles and jeopardize the effectiveness as stated by the manufacturer, which declines any responsibility.

### 3. STERILE SINGLE PATIENT'S ELECTRODES

Cliniporator must be used together with Electrodes, single used sterile devices manufactured by IGEA. The electrode is the applied part of Cliniporator and allows the pulse delivering to the tissues.

Model	Series EPS, Needle Electrode	Description
N – 10 – HG		Needle length <b>10</b> mm, <b>hexagonal</b> configuration, to be used with <b>green handle</b>
N – 20 – HG		Needle length <b>20</b> mm, <b>hexagonal</b> configuration, to be used with <b>green handle</b>
N – 30 – HG		Needle length <b>30</b> mm, <b>hexagonal</b> configuration, to be used with <b>green handle</b>
N – 10 – 4B		Needle length <b>10</b> mm, <b>linear</b> configuration, to be used with <b>blue handle</b>
N – 20 – 4B		Needle length <b>20</b> mm, <b>linear</b> configuration, to be used with <b>blue handle</b>
N – 30 – 4B		Needle length <b>30</b> mm, <b>linear</b> configuration, to be used with <b>blue handle</b>
Model	Series EPS, Plates Electrode	Description
P – 30 – 8B		Plates length <b>30</b> mm, <b>linear</b> configuration, to be used with <b>blue handle</b>
Model	Series EPSA, Adjustable Needle Electrode	Description
H-30-ST		Hexagonal configuration ( <b>H</b> ), Needle length adjustable in steps of 5mm, 30 mm maximum length ( <b>30</b> ), Standard not insulated needles ( <b>ST</b> )
H-40-IN		Hexagonal configuration ( <b>H</b> ), Needle length adjustable in steps of 5mm, 40 mm maximum length ( <b>40</b> ), Insulated needles ( <b>IN</b> )
L-30-ST		Linear configuration ( <b>L</b> ), Needle length adjustable in steps of 5mm, 30 mm maximum length ( <b>30</b> ), Standard not insulated needles ( <b>ST</b> )
L-40-IN		Linear configuration ( <b>L</b> ), Needle length adjustable in steps of 5mm, 40 mm maximum length ( <b>40</b> ), Insulated needles ( <b>IN</b> )
Model	Series NFD, Wearable Finger Electrode	Description
F-15-NO		Orthogonal configuration, Needle length <b>15</b> mm
F-10-NL		Longitudinal configuration, Needle length <b>10</b> mm
F-20-NL		longitudinal configuration, Needle length <b>20</b> mm
Model	Series EGPS, Expandable Electrode	Description
E-L2-00-S4-2		Expandable Electrode ( <b>E</b> ), shaft diameter 5 mm ( <b>L</b> ), shaft length 20 cm ( <b>2</b> ), zero divergence ( <b>00</b> ), square needle configuration ( <b>S</b> ), maximum needle exposure 40 mm ( <b>4</b> ), active part length 20 mm ( <b>2</b> ).
E-L2-02-S2-2		Expandable Electrode ( <b>E</b> ), shaft diameter 5 mm ( <b>L</b> ), shaft length 20 cm ( <b>2</b> ), 2° divergence ( <b>02</b> ), square needle configuration ( <b>S</b> ), maximum needle exposure 20 mm ( <b>2</b> ), active part length 20 mm ( <b>2</b> ).
E-X2-00-S4-2		Expandable Electrode ( <b>E</b> ), shaft diameter 10 mm ( <b>X</b> ), shaft length 20 cm ( <b>2</b> ), zero divergence ( <b>00</b> ), square needle configuration ( <b>S</b> ), maximum needle exposure 40 mm ( <b>4</b> ), active part length 20 mm ( <b>2</b> ).
E-X2-03-S2-2		Expandable Electrode ( <b>E</b> ), shaft diameter 10 mm ( <b>X</b> ), shaft length 20 cm ( <b>2</b> ), 3° divergence ( <b>03</b> ), square needle configuration ( <b>S</b> ), maximum needle exposure 20 mm ( <b>2</b> ), active part length 20 mm ( <b>2</b> ).

Model	Series EGPS, Expandable Electrode	Description
E-L5-00-S4-2		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 50 cm (5), zero divergence (00), square needle configuration (S), maximum needle exposure 40 mm (4), active part length 20 mm (2).
E-L5-02-S2-2		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 50 cm (5), 2° divergence (02), square needle configuration (S), maximum needle exposure 20 mm (2), active part length 20 mm (2).
E-L2-10-SA-B		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 20 cm (2), 10° divergence (10), square needle configuration (S), maximum needle exposure 25 mm (A), active part length 15 mm (B).
E-L5-10-SA-B		Expandable Electrode (E), shaft diameter 5 mm (L), shaft length 50 cm (5), 10° divergence (10), square needle configuration (S), maximum needle exposure 25 mm (A), active part length 15 mm (B).
E-X2-10-SB-B		Expandable Electrode (E), shaft diameter 10 mm (X), shaft length 20 cm (2), 10° divergence (10), square needle configuration (S), maximum needle exposure 15 mm (B), active part length 15 mm (B).

#### 4. TECHNICAL DATA

Manufacturer	IGEA S.p.A. Via Parmenide 10/A Carpi, Modena, Italy Quality System certified ISO 13485
Model	EPS02
Product name	Cliniporator
Field of use	Tissue electroporation
Certifications	Cliniporator complies with electrical safety standards EN 60601-1, complies with the requirements of the European directives for medical devices 93/42/CEE and 2007/47/CEE and it is marked CE0051 under the control of the Notification Body IMQ.
Italian Medical Device Register CND Classification	Registration Number: 295232/R K0299: Electrosurgery devices - others
Dimensions	[width x length x height]: 46cm x 65cm x 156 cm
Weight:	52 kg
Technical specifications	<ul style="list-style-type: none"> <li>▪ Output: 7</li> <li>▪ Commutation interval for each couple of needle &lt; 60 ms</li> <li>▪ Maximum Energy delivered per pulse [nominal]: 20 J High Voltage; 200 J Low voltage</li> </ul>
Power supply specifications	<ul style="list-style-type: none"> <li>▪ Mains Voltage: 115/230 VAC</li> <li>▪ Mains frequency: 50 / 60 Hz</li> <li>▪ Maximum input power: 160 VA</li> </ul>
Operating conditions	<ul style="list-style-type: none"> <li>▪ Room temperature: 10°C to 40°C</li> <li>▪ Relative humidity: 30% to 75%</li> <li>▪ Atmospheric pressure: 700 hPa to 1060 hPa</li> </ul>
Electromagnetic compatibility	Complies with requirements of Standard EN60601-1, EN60601-1-2.
Transportation and storing conditions	<ul style="list-style-type: none"> <li>▪ Room temperature: -20°C to +50 °C</li> <li>▪ Relative humidity: 10% to 90%</li> <li>▪ Atmospheric pressure: 500 to 1060 hPa</li> </ul>
Classification	<ul style="list-style-type: none"> <li>▪ EN 60601-1: Class I, BF</li> <li>▪ MDD 93/42 CEE: IIa</li> </ul>