



Index

1. Description and field of use.....	2
2. Cliniporator ²	2
Console Unit.....	2
Power Unit.....	2
Accessories: Handles	3
Sterile single patient's electrodes	3
3. Technical data.....	4

1. DESCRIPTION AND INTENDED OF USE

Cliniporator² 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].

Cliniporator² 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 Cliniporator² measures the voltage and current wave forms applied and display them in real time.

The treatment data are stored inside an archive.

2. CLINIPORATOR²

Cliniporator² is constituted by:

- Console Unit: allow the operator to insert data patient, select the appropriate electrode and perform the ECT treatment.
- Power Unit: power generator for electric pulse delivering.
- Handles: allow the connection with the electrodes.



CONSOLE UNIT

Features	
Operative system	Linux – Kernel 2.6.25
Display	17" X VGA Touch screen resistive - resolution 1280 x 1024 pixels
Electrical supply	115/230 VAC
Radiofrequency Identification	RFID reader/writer of the electrode

POWER UNIT






FEATURES	HIGH VOLTAGE	LOW VOLTAGE
Pulses number	0 ÷ 10	0 ÷ 10
Pulses amplitude	[100 ÷ 1000] Volt	[20 ÷ 200] Volt
Pulses length	[50 ÷ 1000] µs	[1 ÷ 200] ms
Rise up time	< 3 µs a 1000 Volt	< 3 µs a 200 Volt
Pause between pulses	100µs ÷ 1s	[1 ÷ 2000] ms
Pulses repetition frequency	[1 ÷ 5000] Hz	[1 ÷ 5000] Hz
Maximum supplied current	20 Ampere	5 Ampere
Pulse amplitude precision	±5%	±5%
Pulse length precision	±1 µs	±1%
Pause between high and low voltage pulses	1 – 2000 ms	

ACCESSORIES: HANDLES

CODE	ASPECT	DESCRIPTION
H20066CC		Cliniporator ² handles enable the electrodes to be connected to the power unit. Two models of handles are available. They can be sterilized 20 times in autoclave caoutchouc cycle a [121°C, 15 minutes]. Sterilization process performed not according to the specifics above mentioned, can wear down the handles and jeopardize the effectiveness as stated by the manufacturer (IGEA S.p.A.), which declines any responsibility.
H266CC99		

STERILE SINGLE PATIENT'S ELECTRODES

Cliniporator² must be utilized together with single used sterile device "Electrode for electroporation EPS series" manufactured by IGEA. The electrode is the applied part. Electrode allows the pulse delivering to the tissues.

CODE	ASPECT	DESCRIPTION
N – 10 – HG		Needles [N], 10 mm length [10] hexagonal configuration (H), green handle [G]
N – 20 – HG		Needles [N], 20 mm length [20] hexagonal configuration (H), green handle [G]
N – 30 – HG		Needles [N], 30 mm length [30] hexagonal configuration (H), green handle [G]
N – 10 – 4B		Needles [N], 10 mm length [10], linear configuration (4), blue handle [B]
N – 20 – 4B		Needles [N], 20 mm length [20], linear configuration (4), blue handle [B]
N – 30 – 4B		Needles [N], 30 mm length [30], linear configuration (4), blue handle [B]
P – 30 – 8B		Plates [P], 30 mm length [30] linear configuration [8], blue handle [B]
F-05-OR		Finger configuration [F], with orthogonal needles [OR] 5 mm length [05]
F-10-OR		Finger configuration [F], with orthogonal needles [OR] 10 mm length [10]
F-05-LG		Finger configuration [F], with longitudinal needles [LG] 5 mm length [05]
F-10-LG		Finger configuration [F], with longitudinal needles [LG] 10 mm length [10]

3. TECHNICAL DATA

Manufacturer	IGEA S.p.A. Via Parmenide 10/A Carpi, Modena, Italy. Company with certified Quality System ISO 9001 and ISO 13485
Model	EPS02
Product name	Cliniporator²
Field of use	Tissue electroporation
Certifications	Cliniporator ² complies with electrical safety standards IEC 601-1, 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.
Registration to RDM	Number:295232
Physical specifications:	Dimensions [width x length x height]: 43cm x 53cm x 147 cm Weight: 49 kg
Technical specifications	<ul style="list-style-type: none"> ▪ Output: 7 ▪ Commutation interval for each couple of needle > 60 ms ▪ Maximum Energy delivered per pulse [nominal]: 20 J High voltage regime; 200 J in low voltage regime.
Power supply specifications	<ul style="list-style-type: none"> ▪ Mains Voltage: 115/230 VAC ▪ Mains frequency: 50 / 60 Hz ▪ Maximum input power: 160 VA
Operating conditions	<ul style="list-style-type: none"> ▪ Room temperature: 20°C to 30°C ▪ Relative humidity: 30% to 75% ▪ Atmospheric pressure: 700 hPa to 1060 hPa
Electromagnetic compatibility	Complies with the relevant directives for electromagnetic compatibility of medical equipment EN60601-1, EN60601-1-2.
Transportation and storing conditions	<ul style="list-style-type: none"> ▪ Room temperature: -40°C to +70 °C ▪ Relative humidity: 10% to 90% ▪ Atmospheric pressure: 500 to 1060 hPa
Classification	<ul style="list-style-type: none"> ▪ IEC 601-1 Classification <ul style="list-style-type: none"> ▪ Protection against electrical risks: Class I ▪ Protection against electric shock: BF ▪ CEE 93/42 Classification: Hazard class IIa