User Manual

CLINIPORATOR 2
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1 INTRODUCTION

1.1 General Information

The instructions of the present manual pertain solely to the use of CLINIPORATOR EPS02 model, hereinafter referred to as CLINIPORATOR.

CLINIPORATOR shall be operated exclusively by a medical staff who received specific training and was instructed to correctly use the equipment.

Contact IGEA or IGEA’s authorized distributors to receive all relevant informations.

The instructions for the correct use of electrodes or medical devices necessary for treatment delivery are not dealt with in this manual. Before using the electrodes, it is necessary to consult the instruction sheets provided with them.

IGEA reserves the right to implement modifications or updates which will improve the performance of devices without changing the images or instructions found in this manual.

The Safety instructions found in the following pages are divided into Warnings and Cautions;

- Warnings are safety instructions that, if neglected, might lead to serious adverse events involving the patient, the operator, any other person or the environment.
- Cautions are safety instructions that, if neglected, might lead to undesired events, of marginal or negligible severity, that might involve the patient, the operator, any other person, or might cause failure to the device.

1.2 Intended Purpose of the Device

CLINIPORATOR is a medical device for electroporation.

Electroporation is a physical phenomenon occurring in the cell membrane as cells are exposed to an electric field with proper characteristics.

CLINIPORATOR delivers voltage pulses based on standard parameters or as specified by the operator, which are then applied to the patient using the approved type of electrodes.

The potential difference due to the pulses creates an electric field which acts on the cell membrane and induces an alteration which displays at macroscopic level an increased permeability of the membrane.

Molecules that normally do not go past the cell membrane either in diffusion or active transport, after electroporation can reach the intracellular environment.

Electroporation makes it possible, or rather increases the therapeutic effects of injected drugs, by temporarily increasing the cell membrane's permeability enabling the cells to absorb the injected substances.

Electroporation is the basis for electrochemotherapy (ECT)

The device shall not be used for different purposes other than those intended.
1.3 Indications for Use

CLINIPORATOR’s main indications of use are:

- Electroporation of tumour cells and local electroporation of subcutaneous and cutaneous metastasis independently from their source and from previous therapies,
- Electroporation of local skin tumours relapse,
- Electroporation of the human tissue,
- Electroporation of tumour tissue,
- Electroporation of tumour cells in bone tissue,
- Electroporation of cells in culture and tissues in animals.

Beside these main indications, CLINIPORATOR can be safely employed in pre-clinical or clinical investigations and in experimental trials that foresee the application of electrical pulses which the system is able to deliver as specified in this manual.

During electroporation of tumour tissue, it is recommended to follow the instructions indicated in “Standard Operating Procedures for Electrochemotherapy” (see reference 8. of section 3.5).

In other cases, it is recommended to follow validated treatment procedures.

1.4 Type of User and Patient

This device shall be operated by trained medical/scientific staff instructed on electroporation and on the correct use of the device. Please contact IGEA or its authorised distributors to receive proper training.

There are multiple types of patients, but in any case they are always patients suffering from pathologies which can be treated with electroporation, especially patients with tumours and/or metastasis who can benefit from electrochemotherapy.
2 GENERAL DESCRIPTION

2.1 System Components

CLINIPORATOR consists of a main unit characterised by:
- a control section called PC Panel made up of a terminal PC equipped with touch-screen on which the application that manages the system is installed,
- an incorporated radio section to automatically recognise the electrodes that can be used with the system,
- a power unit which generates pulses.

Some accessories are added to the main unit as an integral part of the system:
- a set of 2 Handles, that can be connected to the device through a connector, and allows the connection of CLINIPORATOR to some kind of electrodes (Figure 1 - Handle)
- the double control pedal (Figure 2), which allows the generation and delivery of electrical pulses

![Figure 1 - Handle](image1)

![Figure 2 – Double pedal](image2)

In order to perform the treatment, CLINIPORATOR must be used together with the ELECTRODES, disposable sterile medical devices approved by the manufacturer, specially designed for the application of treatment. The electrodes are not part of the system and are separately provided by request.

The CLINIPORATOR system is supplied with:
- 1 power supply connection cord
- 1 double control pedal
- 1 blue handle
- 1 green handle
- 1 user manual
- 2 replacement fuses

WARNING!

Only the usage of accessories provided by the manufacturer is recommended. The use of accessories, transducers and cables different from those indicated by the CLINIPORATOR manufacturer might cause an increase of electromagnetic emissions or a decrease of CLINIPORATOR electromagnetic immunity.
2.2 Description of the CLINIPORATOR Device

The main elements of CLINIPORATOR shown in Figure 3 are described below.

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adjustable PC Panel equipped with a touch screen</td>
<td>It displays a graphic interface and allows the operator to enter data and to select controls.</td>
</tr>
<tr>
<td>2</td>
<td>Display control buttons and PC Panel power-on light</td>
<td>The buttons regulate the display brightness and the audio level of the PC Panel speakers. The light found at the centre of button group indicates the turned on/turned off/stand by mode of the PC Panel (Figure 4).</td>
</tr>
<tr>
<td>3</td>
<td>Output connector for the connection to the handle / electrodes</td>
<td>It allows to connect the CLINIPORATOR to the handle (Figure 1) and/or electrodes.</td>
</tr>
<tr>
<td>4</td>
<td>Grip</td>
<td>It is used to facilitate the movement of the device.</td>
</tr>
<tr>
<td>5</td>
<td>Pedal connector, indicated by the wording &quot;Pedal&quot;.</td>
<td>It allows to connect the double control pedal in Figure 2 for consent and treatment delivery.</td>
</tr>
<tr>
<td>6</td>
<td>Wheels with locking lever</td>
<td>CLINIPORATOR is equipped with 4 wheels which facilitate the movement of the device. Each wheel is equipped with a locking lever which stop the wheel when lowered.</td>
</tr>
<tr>
<td>7</td>
<td>Front pocket and back pocket</td>
<td>The front pocket can contain the double pedal when the device is not in use and/or needs to be moved. The back pocket (not visible in Figure 3) can contain this manual.</td>
</tr>
<tr>
<td>8</td>
<td>Transponder detection area indicated by the symbol</td>
<td>An antenna for the automatic identification of the electrode is installed on the right side of the device. The operator should hold the package which contains the electrode close to this part in order to enable its use.</td>
</tr>
</tbody>
</table>
User interaction with CLINIPORATOR is similar to that of a PC; the operator dialogues with the device using the **PC panel** (Figure 4) equipped with touch-screen display. Data are entered by means of a virtual keyboard represented and controlled on the display, while the mouse functions by moving the finger on the screen just like a mouse pointer.

The PC Panel is equipped with input/output ports located in the lower part. These connections are used to connect the internal radio device (serial port) and the power unit found in the lower part of the system (USB port). A further USB port allows connection with the external devices necessary for data transfer, software update etc...

![Figure 4 – PC Panel front side and layout of connectors in the lower part](image)

**WARNING**

During patient treatment:
- the input/output ports must only be used to connect devices compliant with the IEC 60601-1 standard;
- only devices that are powered by the port itself - and that, therefore, are not connected to the power grid - must be connected to the USB ports, in addition to devices compliant with standard IEC 60601-1
- the LAN network connection port must not be used to transfer data.
The lower part of CLINIPORATOR contains the power unit which performs every activity that is closely related to administering and measuring the treatment.

The rear panel contains the elements shown in Figure 5, described in the following table:

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mains voltage monobloc</td>
<td>Monobloc composed of main switch, transformer, removable protection fuses and power socket.</td>
</tr>
<tr>
<td>2</td>
<td>Main electric switch</td>
<td>On/off switch.</td>
</tr>
<tr>
<td>3</td>
<td>Transformer and Support for protection fuses</td>
<td>Device which allows to select the voltage supply of CLINIPORATOR. Protection fuses are inserted in this part.</td>
</tr>
<tr>
<td>4</td>
<td>Power supply cord connector</td>
<td>Socket for the power supply cord connection.</td>
</tr>
<tr>
<td>5</td>
<td>Ventilation grids and fans</td>
<td>The system ventilation fans are placed behind the protection grids.</td>
</tr>
<tr>
<td>6</td>
<td>Data Plate</td>
<td>Data plate with technical data, information and warnings.</td>
</tr>
<tr>
<td>7</td>
<td>Connector for external synchronisation</td>
<td>It allows the connection to an external synchronisation device (e.g. QRS detection device).</td>
</tr>
</tbody>
</table>
3 SAFETY INSTRUCTIONS

3.1 Warnings

1. The device should only be used by a staff who received proper training and was instructed to correctly use the equipment. Please contact IGEA or its authorised distributors to receive proper training.

2. For electrical safety reasons CLINIPORATOR needs grounding. Use only power supply cords provided by the manufacturer or authorised suppliers. Make sure that the equipment is connected to a properly grounded mains system, and that the power supply cord plug is fully compatible with mains socket.

3. Before plugging the power supply cord to the mains, make sure that the power supply cords are not damaged. Replace the mains cords if they are damaged: they cannot be repaired.

4. Do not connect or disconnect the power supply cords from the equipment or from the mains with wet hands.

5. Internal parts of the CLINIPORATOR reach High Voltage (above 1000V). Do not open the device during use.

6. As applied part, use only disposable sterile electrodes approved by IGEA.

7. While treating the patient, avoid putting the applied part (electrode) on the ground by using, for example, an external measuring device like an oscilloscope.

8. Avoid penetration of liquids or dirt into parts of the device - such as plastic cover junctions - that could be hard to reach and clean. If necessary, cover the device's upper part with a suitable material.

9. Observe law prescriptions if the CLINIPORATOR is installed near devices that make use of flammable anaesthetic mixtures with oxygen or nitrous oxide or parts that have been connected to such devices and might contain flammable mixtures.

10. Electroporation treatment can cause sparks at the electrode. Treatment must not be performed if the concentration of flammable mixtures in the area is such that they could explode in the presence of sparks. If anaesthetic substances containing oxygen or nitrous oxide are used, a safe distance between pipes or parts containing the flammable mixture and the CLINIPORATOR or the area to be treated is required, as required by the standards. A mixture of the vapour of a flammable disinfection or cleaning agent with air can be treated as a flammable anaesthetic mixture with air, subject to national or local regulations.

11. Treatment may interfere with cardiac activity if applied to the chest, left arm, or abdominal cavity. It can cause atrial or ventricular fibrillation or other arrhythmias. We recommend the use of an R-wave detector to synchronize treatment with the refractory period of the cardiac cycle, unless there is reasonable certainty that the site to be treated is sufficiently far from the heart and the treatment can not interfere with the cardiac activity. Cardiac synchronization ensures that the pulses are delivered exclusively during the ventricular absolute refractory period to avoid the risk of ventricular fibrillation. If an atrial fibrillation event occurs, following impulse delivery, it should be treated in the most appropriate way.

12. The induction of ventricular fibrillation following delivery of treatment into the thoracic cavity is more likely if the patient has a history of cardiac cycle conditions that could lower the ventricular fibrillation threshold or affect the timing of the refractory period of the cardiac cycle.

13. If the R-wave detection device used to synchronize treatment with the cardiac cycle is not compatible with the CLINIPORATOR's input specifications, or if it is not reliable to identify the R-wave, the treatment impulses may be out of from the absolute refractory period of the cardiac cycle, exposing the patient to the possible risk of ventricular fibrillation or the onset of cardiac arrhythmias.
14. Operation of the ECG monitor may be temporarily interrupted after application of the treatment, such as after defibrillator discharge. If ECG signal monitoring is planned for patient safety reasons, verify proper monitoring of the ECG signal before and after application of the treatment. For monitoring heart signals, use only devices that are protected against defibrillator discharges.

15. Before beginning the treatment, always activate wheel locking levers and take the appropriate precautions to avoid device accidental movement or handle cable yanking during the treatment. Unexpected movements of the electrode could cause harm to the patient.

16. As indicated in section 8.1, it is advisable to carry out scheduled electrical safety tests and periodically check for correct operation of the device.

17. Use only protection fuses as specified in section 9.2 and as indicated on the data plate on the rear panel.

18. The present User Manual is a fundamental part of the CLINIPORATOR device and should always accompany the device. The operator must refer to this manual for the correct use of the equipment.

19. Make sure that the equipment connected to the patient and located next to the treatment area is protected from defibrillator discharge.

3.2 Cautions

1. Read thoroughly this Manual before operating the device. Contact the local supplier or manufacturer in case of doubt on the correct usage of the equipment.

2. Wear surgical gloves made of insulating material when delivering pulses and while holding the electrodes.

3. Do not use the handle without the electrode. Do not touch the electrode or the bushes of the handle with your fingers during the treatment.

4. The electrode connected to the device must always correspond to the code entered through the software interface. Disregarding this warning may result in undesirable effects including: ineffective treatment, unnecessary discomfort for the patient and possible slight complications in the healing of the treated area.

5. The safety and effectiveness of the treatment are not guaranteed if electrodes different from the ones approved and supplied by IGEA manufacturer or by an authorised dealer are used.

6. Unless there is a reasonable doubt that an area has been treated ineffectively, repeating a treatment on the same area is not advisable since it is not believed to increase treatment effectiveness. On the contrary, repeating the treatment on the same area would bring unnecessary discomfort to the patient and increase the risk of possible slight complications in the healing of the treated area.

7. Avoid short circuiting the electrodes when delivering treatment pulses.

8. Do not use worn out handles or handles whose cord, grip, pulse generator connector or electrode connector are damaged, or handles that have been tampered with.

9. Make sure that the mains power supply meets the instructions on the data plate on the rear panel and is able to supply the required power.

10. In case of suspected failure, do not use CLINIPORATOR and contact the manufacturer or the authorised supplier.

11. The PC Panel accepts only USB pen drive. Do not force the USB pen drive into the connector, rather check if it has been inserted properly.

12. Do not let the device get wet. Do not pour liquid on the unit.

13. Store CLINIPORATOR away from direct sunlight, heat sources or dust; in particular, do not expose the LCD display to direct sunlight for a long time.

14. Respect the operating and storing conditions as specified in section 9.3.

15. Do not block the aeration grids on the rear panel of the device. Periodically check that nothing is blocking the grids in order to have a correct ventilation of the internal circuits.

16. Do not hold the equipment with wet hands.
17. Avoid heavy shocks to the equipment during transport.
18. Avoid scratching the LCD screen of the Console. Follow the cleaning instructions described in section 8.3.
19. Before carrying out any cleaning of the system or of its parts, turn it off and disconnect the cord from the mains.
20. The device does not contain any parts that can be maintained by the user; repairs or maintenance that require the opening of the device must be carried out exclusively by the manufacturer or by personnel adequately trained and authorized in writing by the manufacturer. No modification of this equipment is allowed.
21. The replacement of fuses must be carried out only by qualified technical staff.
22. The Panel PC contains a back-up battery which, if not replaced correctly, could damage the Panel PC and eventually explode.
23. Pay attention to electrostatic discharge when touching the connectors of the PC Panel. Do not touch the connectors during treatment.
24. Since the device is equipped with an internal supply control system which stops the device putting it in safety mode and restarts the system in case voltage supply problems occurs, it is recommended to connect the CLINIPORATOR to a stable supply system.
25. While touching the patient, do not touch with bare fingers the RS232 connector on the rear of the monitor.
26. On switching on the device, check the cooling fans functionality.
27. In case of malfunction, wait at least 10 seconds before restarting the device, otherwise the self-test will not be completed successfully.

3.3 Contraindications and Warnings

There are contraindications for electroporation-based treatments using high voltage pulses. Such contraindications automatically become contraindications to use the equipment described in this manual.

For further information on possible contraindications of Electroporation-based treatments, please refer to the "Standard Operating Procedures for Electrochemotherapy" (see reference 8. of par. 3.5) or to any existing publications related to electroporation-based treatments.

Electroporation-based treatments are not recommended in the following cases:

- Treatments of lesions in precordial areas of the left hemithorax, in patients with a medical history of level > 2 cardiac arrhythmia.
- Treatments of lesions located near pace-makers, defibrillators, implanted electronic devices.
- Treatment of eyeball.
- Medical history of epilepsy
- When treating visceral areas, opencast, the use of cardiac synchronization (sec.5.7) to avoid interfering with the cardiac electric activity, is recommended.
- If the electroporation is associated to the delivery of drugs, refer to the contraindications related to the used drugs.
Warnings

When the electroporation is associated to the delivery of drugs, refer to the specific documentation related to the used drugs. The delivery of impulses can be associated with strong muscular contractions, therefore it is recommended to evaluate the use of an anesthesia with TOF (Train Of Four) = 0, especially in the treatment of deep, visceral or open-skinned lesions.

When treating lesions located in the head and neck area, it is recommended to:
- Consider using intraoperative imaging (i.e. echography) to avoid involuntary involvement of important structures.
- Carefully consider treating the rear part of the tongue and the hypopharynx. Electrochemotherapy might induce bleeding and tissue necrosis and cause adverse events to the patient.
- Define a precise strategy for post-treatment pain management, especially for the treatment of mucosa and tongue since the pain will be stronger in comparison to the normal cutaneous application.

In case of visceral opencast treatments, it is recommended the use of cardiac synchronisation (sec. 5.7) to avoid interferences with the electrical activity of the heart.

Pre-existing pathologies or concurrent pharmacological therapies - which lower the fibrillation threshold - might increase the risk that the treatment - especially if applied in the precordial area or in proximity of the heart - might provoke cardiac fibrillation (atrial or ventricular) or other arrhythmias.

In case of lesions near implanted metal parts, consider that the electric field delivered might be subject to change. It is also necessary to avoid any contact between electrodes and metal parts.

In case of lesions located close to breast implants, pay attention to the contact between pointed electrodes and implants.

3.4 Side Effects

Side effects of treatments based on high voltage pulses are reported in literature. Side effects may be related to the application of high voltage pulses or drugs and chemicals used together with the pulses. Side effects include:

- Involuntary muscle contraction at the time of the electric pulse, which stops immediately when the pulse train ends.
  The contraction of the muscle is painful. The painful muscular contraction can be managed by following the anaesthetic procedures indicated by the S.O.P. (see reference 8. of section 3.5).
- Slight skin burns sometimes have been observed when employing plate electrodes.
- Skin or mucosal exfoliation.
- Osteomyelitis, dysphagia, pharyngocutaneous fistulas, wounds breakdown can be ascribed to intravenous injection of bleomycin.

3.5 Small Bibliography


4 INSTALLATION AND START UP

4.1 System Location and Conditions of Use

As all electromedical devices, CLINIPORATOR necessitates specific precautions in regards to the electromagnetic compatibility (EMC) and must be installed and placed in a suitable location which follows the conditions specified in Section 9.3 and 9.9. Portable and mobile radio communication devices might influence the device operation. CLINIPORATOR must be used only in the operating room or in a medical clinic which meets the requirements provided by the regulations in force. The device is equipped with wheels which ensure an adequate movement. However, attention must be paid during its handling, since the equipment cannot move over obstacles higher than 10 mm. In this case - using the front grip - the device has to be tilted in order to lift the wheels. CLINIPORATOR must be installed leaving at least a 10 cm free space at the back of the device to allow ventilation. Do not use the equipment if the ventilation grids are blocked.

<table>
<thead>
<tr>
<th>WARNING!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connect CLINIPORATOR exclusively to a grounded mains system.</td>
</tr>
<tr>
<td>CLINIPORATOR must not be used in the presence of flammable mixtures.</td>
</tr>
<tr>
<td>CLINIPORATOR is not protected against liquid penetration. Do not use any part of the system as a surface support for containers with liquids.</td>
</tr>
<tr>
<td>Before beginning the treatment, always activate wheel locking levers and take the appropriate precautions to avoid device accidental movement or handle cable yanking during the treatment. Unexpected movements of the electrode could cause harm to the patient.</td>
</tr>
</tbody>
</table>

4.2 System Installation

CLINIPORATOR must be installed only by specialized IGEA staff. The parameters which allow the operators to access the system (username and password) are entered during the installation procedure. In this phase the system checks also the correct operation of the device.

4.3 Voltage Supply Selection

CLINIPORATOR allows the selection between two mains voltages: 115V and 230V. The voltage supply selector is in the monobloc on the rear panel.

In order to select the voltage supply, carry out the following steps:

1. make sure that the mains switch is in “O” position, i.e. turned off,
2. make sure that the power supply cord is disconnected,
3. open the voltage selector cover by using a slotted screwdriver,
4. pull out the red selector by using the slotted screwdriver,
5. place the voltage selector so that the indication of the select voltage is in the upper part,
6. place the selector back in monobloc and close the cover,
7. make sure that the small window on the cover shows the selected voltage,
8. reconnect the power supply cord.

### WARNING!
This operation must be carried out only by qualified technical staff.

#### 4.4 Operating the CLINIPORATOR Device

Connect the power supply cord to the proper socket of the rear panel (ref. 4 in Figure 5) and connect the plug to a socket with grounding. Connect the double control pedal connector to the designated socket (ref. 5 in Figure 3).

#### 4.5 Work Positions

During patient treatment, the expected work positions require the device to be outside of the sterile field, as shown in Figure 8.

It is recommended that the interaction with the device be performed by an operator while another takes care of electrode placement and treatment execution. The latter can initiate treatment via the activation pedal. The device is not sterile and can not be touched by the doctor who is in the sterile field; to introduce the device into the sterile field, it is recommended to cover it with a sterile transparent plastic sheet, without occluding the back slots necessary for ventilation.
4.6 System Start up

**WARNING!**

Start the device, wait for the completion of the automatic checks that the device performs at power up and check that it is functioning correctly, before preparing the patient for treatment. In particular, before subjecting him/her to anaesthesia or administer drugs for electrochemotherapy.

Turn on the device using the switch on the rear panel (ref. 2 of Figure 5). The system is ON when the switch is in "I" position and is turned off when the switch is in "O" position.

After turning on the system, the power supply green light in the centre of the monitor (Figure 4) turns on and the device loads the operating system.

If the monitor power supply green light does not turn on, check if the reset button - on the lower side of the monitor (Figure 4) - is not in OFF position.

At the end of the start-up process, the device selftest screen appears.
4.7 Selftest Screen

The system follows an automatic test during start up in order to check the correct operation of the device. In reference to Figure 10, the performed tests are the following:

1. System control to detect the drivers.
2. Checking the presence of radiofrequency transponder reader (RFID).
3. Checking the presence of FPGA card and programming it.
4. Testing the memory of the FPGA card.
5. Testing the overlength alarm.
6. Testing capacitor charge and discharge.
7. Treatment simulation with test of relay operation.
8. Information message on performed checks.

When a test is in progress, the corresponding coloured icon blinks while a message displayed in the dedicated area shows the operation status. When the test is passed, the icon stops blinking and the login screen is automatically displayed as in Figure 20.

**WARNING**

If the device shuts down unexpectedly during the selftest it could result in a fault.

If the device is rebooted and the problem persists, contact IGEA Customer Service.
During the selftest phase, any issues are flagged by an error message (an example is shown in Figure 11).

After pressing the confirmation button, a second message is displayed inviting the operator to insert a USB pen drive to save the error data by pressing the button or cancel the operation by pressing the button and proceed with the automatic shut down of the unit (Figure 12).

Pressing the button a dialog box appears on the screen informing the user of the search for the pen drive.
In the event that a USB pen drive is detected, a message appears informing the user of the beginning of the data copy and advises him not to remove the external media.

![USB pen drive scan](image1)

Figure 14 – USB pen drive scan

The message in Figure 15 appears when the Export phase is completed successfully. It is therefore possible to remove the USB pen drive and press the confirmation button.

![Log file export](image2)

Figure 15 – Log file export

Then the message to turn off the device is displayed when the confirmation button is pressed.

![Automatic turn off message](image3)

Figure 16 – Automatic turn off message
In the case of a pen drive that is not found or faulty, the message in Figure 17 appears, confirming that the shutdown procedure of Figure 16 is activated.

If an error is detected during the saving of the data, the message of Figure 18 is shown informing the user of the failure to save and the possibility of removing the USB support.

In the sole case in which the error diagnosed is related to the automatic recognition device of the electrode, the message shown in Figure 19 appears and the manual recognition procedure is enabled. Pressing the confirm button allows you to operate exclusively in manual mode, as described in paragraph 5.5. The self-test resumes from the point where it was interrupted.

In section 7.2, a complete list of error messages is shown.

**WARNING**

In case of automatic turn off during the autotest, wait for at least 10 seconds before restarting the device by pressing the turn on button. This will avoid the system to detect power supply errors in the selftest phase shown by the message “power supply failure”.

4.8 Login Screen

After passing the initial selftest, the system loads the Login screen (Figure 20), which shows the virtual keyboard with the necessary buttons to enter the requested data for accessing the system.

![Login screen diagram]

- **Field “Username”** (operator name)
- **Field “Password”** (keyword)
- **Confirmation button**
- **“Logout”** (disconnect) button
- **Alphanumeric keyboard**
- **Software distribution and manufacturer information**

After typing the username and password in the fields 1 and 2 by using the keyboard 5, if the credentials are correct, the confirmation button ✅ activates, and by pressing it, the operator can access the main menu.

Otherwise, an error window appears with retry message on it.

The login screen also allows to start the “shutdown” procedure of the device by pressing the button 4 (see section 4.9).

Press the button 6 to display a dialogue box with information on software distribution and on IGEA manufacturer (Figura 21 – Informations screen); by pressing the confirmation button ✅, the information window closes.

![Informations screen diagram]
4.9 Unit shutdown

To shut down the device, press the red stop button in Figure 20. A dialogue box appears (Figure 22) allowing the confirmation or interruption of the process.

When the system has completed the shutdown process, it shows the screen in Figure 23. Only at this stage the device can be turned off moving the rear panel switch (Figure 5 ref. ) in "O" position.

**WARNING**

Do not move the mains switch to turned off position (O) until the system has completed the shutdown procedure.

If it is necessary to restart the device, wait for at least 10 seconds before moving back the switch to turned on position (I).

Remove any USB pen drive connected to the device before restarting.
5 TREATMENT PERFORMANCE

5.1 Main Menu

After completing the login procedure, the application shows the main menu in Figure 24 which displays the access buttons for the different functions of the system:

1. ECT button (Electro Chemo Therapy), for ECT treatment access
2. Export button, for the exportation of archived treatment data
3. Logout button, which brings back the Login screen (Figure 20)
4. current date and time
5. software version information.

![Main menu screen](image)

**Figure 24 - Main menu screen**

5.2 System Time Setting

In the top-right area of the main menu (3 Figure 24) the current date and time are shown. The date cannot be modified. If the date is incorrect, please contact Igea Customer Service. However, the time can be modified.

Clicking on the time in the main menu, a time setting screen appears (Figure 25). To change the time press the setting buttons \( + \) at the left side of the time; to change the minutes press the setting buttons \( - \) to the right side of the minutes. To confirm the time and to go back to the main menu, press the confirmation button \( \checkmark \); to cancel the process and to go back to the main menu, press the “cancel” button \( \times \).
A dialogue window is displayed (Figure 26) with the message that the device will automatically shut down after pressing the confirmation button ✅.
5.3 Entering Patient Data

By selecting the ECT button from the Main Menu the user can access the Patient Data screen in Figure 27.

The Patient Data screen comprises a section dedicated to the patient's data, a section for notes, the “Logout” button (to go back to the main menu of Figure 24) and the Forward button (to go to the electrode selection).

The virtual keyboard which is needed for entering the required data is shown at the lower part of the screen.

In the top-left section the user can enter the following data of the patient:

1. Patient's family name: the field is mandatory and the system does not allow any actions if the field has not been filled out

2. Patient's name: the field is mandatory and the system does not allow any actions if the field has not been filled out

   IMPORTANT: It is permitted to use letters, numbers, and only the symbols "-" and "_". It is not permitted to use a number as the first character of the patient's name or surname.

3. Age

4. National insurance document number (i.e. health insurance card). IMPORTANT: It is not permitted to use symbols other than "-" and "_".

5. Operator

Data can be entered by typing the information on the keyboard after selecting the appropriate field.

In the section Notes, in the top-right area other additional information (for example notes related to the treated case) can be added.

The “Forward” button leads to the screen for the selection of the electrodes used for the treatment and activates (becomes green) only after filling out the required fields and .

Current time and data are shown in the top-right area of the screen.

When you return to this screen from the following pages, only the "Notes" field is editable. All the other fields are deactivated (grey) in order to preserve the information already entered.

WARNING!

The data inserted in the “Patient data” screen are collected for information use only and do not have any influence on the treatment settings.
5.4 Electrode Recognition

Before delivering treatment, it is necessary to follow the automatic recognition of the electrode or the electrodes that are intended to be used.

After selecting ECT from the Main Menu, the user has access to the Electrode Selection (Figure 28). The button allows the operator to go back to the Patient Data screen. The button allows the operator to go back to the main menu (Figure 24). The button activates only after recognising at least one electrode and allows to start the treatment. In the field help messages for operation request are shown.

To recognize the electrode the operator must:

1. press the “electrode selection” button, (Figure 28, 1). A dialogue box appears (Figure 29) informing the operator about the ongoing process of electrode recognition, which lasts about 10 seconds.
2. Bring the TAG placed on the electrode packaging close to the right part of the CLINIPORATOR, identified by the symbol ( ), and hold it in this position until the system recognises the electrode.

If the recognition is successful, a window (Figure 31) provides the code for the electrode recognised and the operator is asked not to move the packaging so "marking" can be completed.

This process is mandatory according to security obligations and allows the use of the same electrode for a single patient for 6 hours only.

To mark the electrode and to automatically configure the system for use, press the confirmation button ( ) without removing the packaging.

During the identification process, a dialogue box (Figure 32) informs that the operator should hold the TAG present on the packaging close to the antenna area ( ).

**WARNING!**
Interrupting the identification process can cause partial writing of information on the electrode and therefore the electrode might become unusable.
If the identification goes through, the system goes back to the “ELECTRODE SELECTION” screen in Figure 37, where the recognised and identified electrode has already been entered in the electrode list for use (Figure 37, ②).

If during the identification process the system detects an error, a dialogue box appears informing about the possible causes and the process is stopped. The following table shows the most common error messages that might be displayed.

<table>
<thead>
<tr>
<th>Error Message</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Error in electrode recognition” “Please check the tag position”</td>
<td>The electrode TAG was not held close (maybe not close enough) to the indicated position; this message may also appear during the recognition phase.</td>
</tr>
<tr>
<td>“Error selecting electrode” “Error reading electrode” “Error burning electrode”</td>
<td>An error occurred while trying to access the electrode data.</td>
</tr>
<tr>
<td>“Electrode validity time elapsed”</td>
<td>Attempt to use an already used electrode for the same patient after 6 hours from the first use.</td>
</tr>
<tr>
<td>“Electrode code is duplicated”</td>
<td>The electrode has an invalid or duplicate code and cannot be used for security reasons.</td>
</tr>
<tr>
<td>“Electrode has been changed”</td>
<td>The electrode was replaced during the automatic recognition phase.</td>
</tr>
</tbody>
</table>

It is possible to recognize and identify more than one electrode by repeating the above mentioned process. Otherwise, start the treatment by pressing the “forward” button in the bottom-right area which has now become active.

5.5 Non-recognition of the electrode

If the TAG on the electrode packaging is damaged or the packaging is improperly positioned, at the end of the automatic electrode recognition process the error message in Figure 33 is displayed.

By pressing the confirmation button the dialogue box is closed. Remember that, for this reason, the electrode packaging must be correctly positioned as seen in Figure 30.

If this process fails three times in a row, when the confirmation button is pressed again, the manual electrode security code entry screen appears as shown in Figure 35.
In the case where the selftest shows an electrode automatic recognition fault (see section 4.7) and, consequently, only the manual recognition procedure is allowed, the notice in Figure 34 will appear by pressing the "electrode selection" button (Ref. 6 in Figure 28).

Pressing the confirmation button again allows you to switch to the manual input mask of the electrode safety code as shown in Figure 37

If the detection fails three times in a row, at the next press of the confirmation button the manual input of the electrode safety code of Figure 37 is displayed.

By pressing the confirmation button again, the manual electrode security code entry screen is displayed as seen in Figure 35.

First, select the electrode that you want to use by clicking on the button 🔄 or 🔄.

Then, enter the 20-character code (ID CODE) found on the sticker located on the electrode bag in the 5 blank boxes using the alphanumeric keyboard.

Finally, confirm the settings by pressing the ENTER button; the system checks the coherence between the electrode selected and the security code entered. If the values entered are correct, the electrode code window becomes green and the confirmation button ✅ is activated, which allows you to move on to the "marking" phase. To cancel the process without identifying the electrode, press the button ❌.
5.6 Electrode selection

After identifying all the electrodes needed for the treatment through the process described in section 5.4, select the electrode to be used by pressing the indicator button placed to the right and to the left of the electrode image (Figure 37 ②), which could result enabled or not depending on the number of electrodes loaded, and then press the electrode image. At the end of the identification process, the last recognised electrode is the one displayed on the window, since it is automatically selected.

The selected electrode is identified through its code displayed against a green background. In the field ① are shown messages that suggest the operation that the user can perform.

At the same time in the upper part of the screen (Figure 37 ①) the treatment data associated to the electrode are shown.

- Number of delivered pulses.
- Amplitude (in volt) of pulses.
- Length (in microseconds) of pulses.
- Repetition frequency (in Hz).

These parameters cannot be modified in the ECT treatment mode.

Pressing the forward button ④, the treatment screen is shown (section 5.9).
5.7 ECG Synchronisation

Only in case of ECT treatments, CLINIPORATOR allows to synchronise pulses delivery with an ECG signal, in the following named “ECG sync”.

To be able to use this function, connect a "R-wave trigger" with the features indicated in the following section 5.8 to the appropriate connector located on the rear panel.

On the Electrode Selection screen (Figure 37), the button 🔄 will be displayed in order to perform this operation. In the beginning, this button is yellow indicating that the option is inactive.

By clicking on this button the window in Figure 39 appears with the message ‘Checking ECG signal’ together with a 10 seconds reverse count (1). Afterwards, the system responds on the ECG signal quality with two options:
Positive outcome: the dialogue box in Figure 40 shows that the test has been passed. By pressing on the confirmation button the window closes and the "ECG sync" button becomes active (green).

Negative outcome: it might be that the ECG signal has not been detected, the signal is disturbed or the signal is not appropriate. In these cases, a dialogue box (Figure 41) appears allowing the operator to repeat or cancel the process.

If, after receiving the ECG signal, the active button is clicked again (green), the "ECG sync" option is deactivated.

In this case a dialogue box shows the message "Warning ecg disabled" in Figure 42. By pressing the confirmation button the window closes and the "ECG sync" button turns yellow.
WARNING

Treatment may interfere with cardiac activity if applied to the chest, left arm, or abdominal cavity. It can cause atrial or ventricular fibrillation or other arrhythmias. We recommend the use of an R-wave detector to synchronize treatment with the refractory period of the cardiac cycle, unless there is reasonable certainty that the treatment site is sufficiently far from the heart and the treatment can not interfere with the cardiac activity.

Cardiac synchronization ensures that the pulses are delivered exclusively during the ventricular absolute refractory period to avoid the risk of ventricular fibrillation. If an atrial fibrillation event occurs, following impulse delivery, it should be treated in the most appropriate way.

5.8 Minimum Requirements for the ECG Synchronisation

To synchronize the pulse delivery with an ECG signal through the “ECG sync” function - which is only possible in case of ECT treatments, CLINIPORATOR should be connected to an external R-wave trigger recognized as a medical device in compliance with the MDD 93/42/EEC and subsequent modifications, CE marked and equipped with the following features:

- TTL or CMOS compatible output signal, in positive logic, length 150 ms. **Warning!** If the signal is in negative logic, the correct synchronism with the R wave is not guaranteed.
- capable of delivering a current of at least 15mA
- delay between R wave and trigger signal lower than 10ms
- RGU 174/U connection cable with a maximum length of 180cm that can be connected to the BNC socket on rear panel of the CLINIPORATOR
- protection against defibrillators discharge
- leakage current in the connection cable lower than 100 μA in normal conditions and lower than 500 μA in first failure conditions.

CLINIPORATOR synchronises with the leading edge of the trigger signal ensuring that the interval between the two consecutive triggers is more than 500ms; this means that the maximum allowed heart rate is 120 bpm

WARNING

If the R-wave sensing device used to synchronize treatment with the cardiac cycle is not compatible with the input specifications of the CLINIPORATOR, or if it is not reliable to identify the R-wave, treatment pulses could be delivered out of the period absolute refractory of the cardiac cycle, exposing the patient to the possible risk of ventricular fibrillation or the onset of cardiac arrhythmias.

The trigger signal must always correspond to an R wave.

If the treatment with CLINIPORATOR is carried out in the thoracic region, each wrong trigger can cause an extrasystole.

WARNING

CLINIPORATOR must be connected to a medical device for cardiac applications that meets the essential safety requirements defined in IEC 60601-1.
5.9 Treatment Screen

After identifying and selecting the electrode, the operator accesses the treatment screen (Figure 43).

The patient’s name and family name are shown in the top-left area while the treatment parameters associated with the electrode selected are in the top-right area.

For the ECT treatment only, in the lower part of the screen is displayed a timer (minutes/seconds) that can be activated by pressing the forward button. The timer starts a descending count starting from 8 minutes highlighted by a red background. Then the timer continues its count up to 99 minutes. The first 32 minutes are accompanied by a green background while the rest is yellow. The timer can be reset at any time by pressing the button which becomes active after the start up of the timer.
Pressing the icon \(\text{}\) activates the virtual keyboard that allows you to enter explanatory notes about the treatment performed.

Pressing the confirmation button \(\checkmark\) removes it by saving the entered data, pressing the button \(\times\) cancels the entered data.

Once started, the program waits until the operator selects the number of the nodule by pressing the increase/decrease buttons \(\PHA\) or charges the capacitors to start the treatment.

To charge the capacitors and accumulate energy press the charge button \(\text{}\), which is yellow at the beginning.

The ongoing charging process is graphically represented by a “battery” shown in the button \(\mathbb{1}\) that fills up progressively.

When the charging process is completed, the battery is completely full and the button turns green (Figure 45 \(\mathbb{1}\)). At this stage, the treatment can be delivered by acting on the double pedal for **activation** and **pulse** (Figure 2).

By pressing the **activation** pedal (white pedal in Figure 2) a 10 seconds reverse count starts and - until complete delivery of the treatment - the buttons \(\text{} \text{} \text{}\) in Figure 43 are replaced by the “abort” button \(\times\) in Figure 45. By pressing it the treatment is immediately interrupted; in this case the system provides the message "Treatment aborted by user" and proceeds to save the data of the treatment provided until the interruption.
The pedal *pulse* (Pulse) green pedal in Figure 2 must be activated within 10 seconds after pressing the pedal *activation* (Arm). Once the pedal has been pressed and the delivery of the treatment starts, the system sends an acoustic signal and the information about the system status shown in the status frame is updated (Figure 46 ①).

In case the pedal *pulse* is not pressed within 10 seconds, the treatment procedure will automatically be cancelled. If any treatment is delivered after 5 minutes the capacitors will automatically be discharged. In this case use the charge button (Figure 43 ③) or press the Arm pedal to recharge them and restart the treatment.

At the end of the treatment, the system sends a second acoustic signal and, as shown in Figure 47, inside the frame ② voltage and current waveforms are shown and the treatment counter is increased ③.
The background of the status frame is coloured according to the level of treatment “quality”:

- **Green** - successfully delivered treatment: average current higher than the minimum threshold expected for the selected electrode.
- **Yellow** - treatment to be evaluated: average current lower than the minimum threshold expected for the selected electrode. An acoustic signal notifies the user of the necessity of evaluating the treatment.
- **Red** – treatment with problems: null current and/or overload problems were detected. An acoustic signal notifies the user of the necessity of evaluating the treatment.

If the background is Yellow or Red, the current waveforms shown in the charts must be evaluated. If necessary, repeat the treatment that might have been not completely effective.

The system automatically restores the charging conditions after treatment delivery. As soon as the charge button turns green, CLINIPORATOR is ready to repeat the treatment. The background of the status frame remains coloured to show the quality level of the previous treatment. This until the ARM button is pressed or until the treatment session is quit.

With reference to Figure 43, the treatment phase can be quit in two different ways:

1. pressing the “Back” button, the system goes back to the page for selecting electrodes,
2. pressing the “Exit” button, the system goes back to the main menu.

In cases 2 the list of the recognised electrodes is reset and a dialogue box shows up asking the operator for confirmation (as shown in Figure 48).

In any case of abandonment, if the power part is charged, the system is discharged and a dialogue box informs the operator with this message “Discharging, please wait” (Figure 49).

If the system is not charged, the dialogue box does not appear.
5.10 ECG Synchronisation during the Treatment

Only in case of ECT treatments, in the treatment screen (Figure 43) the icon with the same symbol present in the electrode selection window and an explanatory message below it inform the operator about the synchronisation status with the ECG signal. The symbols are described below:

- Green background and "ECG sync" writing: ECG enabled and working
- Yellow background and "Disabled" writing: ECG disabled
- Red background and "ECG Noisy" writing: ECG enabled but with disturbed signal
- Red background and "ECG Lost" writing: ECG enabled but signal not detected
- Red background and "ECG BAD" writing: ECG enabled but with incorrect signal

In all the different phases of the treatment, the ECG status is monitored and for every status variation the corresponding symbol appears.

In case the icon appears with a red background, the detection of the pressure of the ARM pedal will be disabled and it will not be possible to deliver the treatment.

During application of the treatment, an anomaly on the ECG signal causes the temporary suspension of the treatment itself. If an "ECG Noisy" signal is detected, the software automatically resumes treatment delivery if the synchronization signal is restored within 3 seconds, but informs the user of the disturbance by displaying a message. If the ECG signal remains stable for at least 5 seconds after the noise is detected, the message will disappear, otherwise it will be displayed to indicate the presence of a disturbed ECG signal during which the CLINIPORATOR will try, if possible, to continue the treatment delivery. In the event that the disturbed signal protract over time and in other cases of abnormal ECG, the software proceeds to open the dialog box of Figure 51 with the following indications:

- message related to the detected anomaly;
- timer indicator with a 2 minute reverse count;
- “Resume” button and “Abort” button.
The “Resume” button is initially shown in grey (inactive) and is activated (green) only if the ECG signal becomes stable within 2 minutes. In this case, after pressing the above mentioned button the window closes and the treatment is resumed.

By pressing the “Abort” button the window closes and the ongoing treatment is interrupted, but the capacitors are not discharged. In addition, interrupted treatment data are saved. At the end of the countdown time, the status window confirms that the treatment has been interrupted and a dialog box displays the message “Treatment data saved successfully” (Figure 52) appears; by pressing the confirmation button the window closes and the treatment is interrupted, but the capacitors are not discharged. Also in this case the data of the interrupted treatment are saved.

Treatment delivery remains blocked until the correct ECG signal is restored or until cardiac synchronization is canceled.
5.11 Serious Errors of the Power Part during Operation

In the case of communication problems between the graphic interface and the power unit or in case of malfunction of the same, on the monitor appears a message that provides information on the causes of the problem (an example is shown in Figure 58).

The message of Figure 54 is then shown and, by pressing the confirmation key, the device turns off. Paragraph 7.2 lists the possible error situations and the related messages.

---

Figure 53 - Serious error in the power part

Figure 54 - Device shut down
5.12 Storing and Exporting Treatment Parameters and Waveforms

CLINIPORATOR automatically stores in a “treatment file” the treatment parameters and the waveforms resulting from delivery. Every file related to a treatment contains:

- data regarding the health facility
- data about the patient
- clinical data, if specified on the screen for the information on the treatment
- case information, if specified on the screen for information on the treatment
- treatment parameters
- measured values of the applied voltage
- measured values of applied current

The files are saved in CSV format and can be elaborated afterwards through commercial applications such as MS Excel 2003 or later, Open Office spreadsheet, etc...

The name of each file related to a treatment is made up of date, time, name and surname of the patient, treatment number and the treated nodule number. The system guarantees that the name is unambiguous.

The files can be exported out of the unit through a USB pen drive.

The “Export/Viewer” (Figure 55) archive screen can be accessed by pressing the Export button from the “main menu” (Figure 24) and allows to export the treatment data stored in the device by means of a USB pen drive so that these data can be processed also afterwards.

The files are archived in chronological order and the list of files can be navigated providing the date of the treatment (day, month, year).
The exportation process consists of three phases:

- selecting the date of the treatment data to be exported
- selecting the treatments
- exporting on a USB pen drive.

Regarding the numbering in Figure 55, the displayed elements are:

1. select year
2. select month
3. select day
4. selected date
5. treatment file list
6. file status
7. navigate the file list
8. select/deselect all files
9. export button on a USB pen drive
10. export checkbox for log files only for of all the treatment data files

Exit button.

The date can be selected in the upper part of the screen by selecting year 1, month 2, and day 3. It is not possible to select dates that are later in time in comparison to the date of the current operation.

As soon as a date is selected (displayed in 4), the 5 list on the right side of the screen is updated and shows the treatment files saved on the selected date.

File name display gives the following information:

- file status icon 6 (exported/to be exported)
- back up data (yyyymmddhhmmss – year, month, day, hour, minute, second)
- name and family name of the patient, corresponding to the patient's data records (see section 5.3)
- treatment number
- treated nodule number.

If the file list is too long to be entirely shown on the screen, it can be navigated using the up and "down" buttons. The list can be navigated “per pages”.

The operator selects the files to be exported by clicking on them. Click an already selected file to deselect it.

The buttons 7 select and deselect all the items of the list.

The files identified as “exported” can be selected and exported again.

Press the “Export log file” checkbox to start exporting the system log files. These files are copied in the USB pen drive together with the selected treatments.

Press the “Export all data” checkbox to start exporting all the treatment data stored in the archive. This procedure may take a few minutes depending on the number of treatments; the files are exported in a single compressed file (.zip), divided into folders by treatment date.

To exit the screen press the button.
By pressing the button 🔄, which is activated only after making a selection, the window in Figure 56 appears, informing the user that the device will calculate the space necessary to contain the files to be exported.

A subsequent message informs about the free space required for the USB pen drive.

Connect a USB pen drive and press the button ✅ to start the storage process. Press the abort button ❌ to interrupt the process. The selected files remain selected and marked as "not exported".
A message informs the user of the USB media scan.

If the pen drive is recognized, a dialog box informs the user that the media has been recognized and does not need to be removed until the procedure has been completed.

Once the storage process is completed, a dialogue box informs the operator that the USB pen drive can be removed. By pressing the confirmation button the dialogue box closes and the selected files in Figure 55 are deselected and marked as “exported”. In the only case the function “Export all data” is active, the files are not marked as exported since this is a back up function.

If an error occurs during the saving process, a dialogue box informs the operator about the possible causes of the problem. The process is interrupted and the selected files remain selected and “not exported”.

Figure 59 - Scansione

Figura 60 - Pen drive USB rilevata

Figure 61 – Export of the patient’s data successfully completed

Figura 62 – Error during data export
6 USE OF ELECTRODES

6.1 Electrodes

CLINIPORATOR must be used together with an applied part, approved by IGEA, the “Disposable sterile electrodes for IGEA electroporators”.

The electrodes specifically designed as applied parts of CLINIPORATOR, are stand alone medical devices, which can be ordered separately and are equipped with their own instructions for use.

All electrodes are disposable, i.e. each electrode can be used for only one patient during a single treatment session.

All the instructions on how to connect, use, protect after use and dispose the electrode are shown in the instruction sheets of the electrode and are not contained in the present manual.

<table>
<thead>
<tr>
<th>Type of Disposable sterile electrodes</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Series EPS**                       | **Needle electrode – hexagonal configuration.**  
The various models differ for needle length and for presence of partially insulated needles.  
To be used together with Handle IG0M915 (Green).  
**Needle electrode – linear configuration.**  
The various models differ for needle length.  
To be used together with Handle IG0M910 (Blue).  
**Plate electrode – linear configuration.**  
To be used together with Handle IG0M910 (Blue). |
| **Series NF**                        | **Finger Wearable electrodes.**  
The various models differ for needle length and for orthogonal or longitudinal needle position with respect to the thimble. |
| **Series NFD**                       | **Adjustable Needle electrodes – hexagonal configuration.**  
The exposure of the needles is adjustable in steps of 5 mm. The various models differ for needle maximum length and for presence of partially insulated needles.  
**Adjustable Needle electrodes – linear configuration.**  
The exposure of the needles is adjustable in steps of 5 mm. The various models differ for needle maximum length and for presence of partially insulated needles. |

IGEA reserves the right to introduce new parts used or discontinue existing models without the need for communication.
Some electrode models must be connected to CLINIPORATOR using the HANDLE supplied together with the CLINIPORATOR.

<table>
<thead>
<tr>
<th>Accessory Type</th>
<th>Description</th>
</tr>
</thead>
</table>
| Handle IG0M910 | **Blue Handle**  
Re-sterilizable handle for needle electrodes, EPS series, in linear configuration |
| Handle IG0M915 | **Green Handle**  
Re-sterilizable handle for needle electrodes, EPS series, in exagonal configuration |

The electrode for the treatment should be chosen according to the type of ECT or EGT treatment, the size of the lesions to be treated or their position:

- *the hexagonal arrayed needle electrodes* (series EPS/EPSA) are used for the treatment of big and deep lesions
- *the parallel row arrayed needle electrodes* (series EPS/EPSA) are used for the treatment of small and deep lesions
- *the plate electrode* (series EPS), made up of two stainless steel plates, can be used for the treatment of surface lesions without penetrating the skin
- *the wearable finger electrodes* (series NF/NFD) are used for the treatment of lesions in small anatomical cavities.

### 6.2 Handle for Connecting the Electrodes

Some electrode models must be connected to CLINIPORATOR using the Handle, accessory supplied together with CLINIPORATOR.

There are two handle models, the Blue and the Green one. They are both designed for multiple use and different patients and also for sterilisation using the methods described in section 6.2.2.

The two models are distinguished by both the handle color, blue and green, and the configuration of the electrical contacts at the end of the handle.

Each electrode can be connected to only one of the two supplied handle models according to the instruction sheet of the specific electrode. Some electrode models do not require any handle for the connection with CLINIPORATOR.

All the instructions detailed related to the cleaning, sterilization, care and substitution of the handle are described in the illustrative sheet furnished in endowment with the handle; read carefully the illustrative sheet of the handle before use.

### 6.2.1 Connecting/Disconnecting the handle to CLINIPORATOR

If the connection to the electrode requires the use of the handle, after having completed the electrode recognition procedure described in section 5.4, connect the handle compatible with the electrode to the proper front panel connector of CLINIPORATOR (reference 3 in Figure 3). Reference to Figure 63:
Align the arrow printed on the handle connector with the dot printed on the output connector of CLINIPORATOR.

Insert the connector in the socket and push until it is firmly connected.

To disconnect the handle from the CLINIPORATOR just hold the connector and take it out pulling it perpendicularly from the generator support but not in a strong way. Do not twist or bend the connector and never pull the electrode cable to pull out the handle.

6.2.2 Cleaning, Care and Recommended Replacement of the Handle.

All the instructions detailed related to the cleaning, sterilization, care and substitution of the handle are described in the illustrative sheet furnished in endowment with the handle; read carefully the illustrative sheet of the handle before use.

It is recommended to clean thoroughly the handle after each treatment session.

In particular if, during the session, it came in contact with blood or biological fluids, apart from regular cleaning, sterilisation is recommended.

Keep the part of the grip connecting the electrodes clean from dust or cleaning agents residues.

The handle can be cleaned using a soft fabric, moistened with water and surfactant detergent;

- avoid using partially halogenated or strong alkaline hydrocarbon-based detergents, ketone or very strong bases such as sodium hydroxide that could damage the handle.

WARNING!
The handle must be cleaned manually.

It is not allowed to use machine washers to disinfect the handle because it might compromise the operation of the connector and therefore the entire handle.

The handle can be sterilised in autoclave up to 20 times at 121°C for 15 min (caoutchouc cycle).

After many sterilisation cycles, the handle’s cable starts degrading; the manufacturer recommends handle’s replacement after 20 sterilisation cycles.

The colour of the cable may change after few sterilisation cycles, but this does not affect the safety and operation of the device.

Even if the handle has not undergone sterilisation, it is important to periodically check that the product is intact and replace it in the following cases:

- cable's sleeve is damaged
- electrode's link is less firm
- current waveforms present unusual spikes.
- the rib retaining the electrode - at the end of the handle’s grip - is worn out.

CAUTION
For patient's safety, it is important that the handles sheath maintains its insulating properties. Otherwise, the electrical current produced during treatment might not remain confined near the electrodes area and might involve the myocard. In such event, even very small currents might interfere with the hearth's electrical activity and might cause electrocution.

Do not use worn out handles, handles with damaged cable, grip or connector, or handles that have been tampered with.
The manufacturer is not responsible for consequences resulting from prolonged use of the handle beyond the duration herein specified, or resulting from the use of damaged, worn out or tampered handles. The warranty given by the manufacturer of CLINIPORATOR decays if damaged, worn out or tampered handles are used.

6.2.3 Handles Storage Instructions

The handles have to be kept in a dry, clean place, far from heat sources. Do not bend the cable too narrow, i.e. at a radius lower than 3 cm, since this could damage the wires inside.

6.3 Connecting the Electrode to the Handle and How to Use the Electrode

All the instructions related to:
- connecting the electrode to the handle
- correct electrode handling
- protecting electrode after use and electrode disposal

are shown in the instruction sheets of the electrode and are not contained in the present manual.

```
WARNING
Read carefully the instructions in the instruction sheet supplied together with the electrode, before using it with CLINIPORATOR.
```

To deliver a treatment with CLINIPORATOR it is important to follow the electrode recognition process; in this way CLINIPORATOR will automatically prepare itself to deliver a treatment that complies with the settings specified in the Standard Operating Procedures for the selected electrode.

The Manufacturer reserves the right to introduce new electrodes or discontinue the production of specific electrodes without notice.

It is recommended to make use exclusively of electrodes of the types approved by the CLINIPORATOR’s manufacturer and supplied by the CLINIPORATOR’s manufacturer itself or by the authorised distributors.

```
CAUTION
Using electrodes that are different from the ones approved and/or supplied by the CLINIPORATOR’s manufacturer or by an authorised distributor may be detrimental to treatment safety and efficacy.
```
7 TROUBLESHOOTING

7.1 Documented Problems and Solutions

<table>
<thead>
<tr>
<th>Failure</th>
<th>Possible causes</th>
<th>What to do</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINIPORATOR does not turn on</td>
<td>The unit is not connected to the mains voltage or the mains voltage socket is not working.</td>
<td>Check if the power supply cord is connected to the power supply group and to a proper and working mains (Figure 5, ⑥).</td>
</tr>
<tr>
<td></td>
<td>The fuses of the main switch are burned and need to be replaced</td>
<td>Replace the main switch fuses of the unit as shown in (section 8.4). ATTENTION! Only use fuses that have the same features as indicated in the device Data plate.</td>
</tr>
<tr>
<td>The LCD monitor does not turn on</td>
<td>The monitor has not been turned on</td>
<td>Press the power button at the bottom of the monitor (Figure 3).</td>
</tr>
<tr>
<td>Electricity does not pass from one electrode to the other when delivering pulses. (The message “Current too low” should also be displayed regularly)</td>
<td>The handle and/or the electrodes are not correctly connected to the unit.</td>
<td>Check the state of the CLINIPORATOR's connections with Handles/electrodes.</td>
</tr>
<tr>
<td></td>
<td>The handle/ electrode is damaged</td>
<td>Replace the handle/ electrode with a working one (see section 6.2.2).</td>
</tr>
</tbody>
</table>

If the problem persists even after the described checks, contact the dealer or the Customer Service of IGEA S.p.A.

7.2 Error Messages

<table>
<thead>
<tr>
<th>Error message</th>
<th>Possible causes</th>
<th>What to do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Already used for another patient</td>
<td>The electrode has already been used for another patient</td>
<td>Use a new electrode.</td>
</tr>
<tr>
<td>Bad ECG signal - Treatment aborted</td>
<td>ECG signal is noisy or absent for more than 120 seconds</td>
<td>Wait for the ECG signal to be restored, then repeat the treatment.</td>
</tr>
<tr>
<td>Bad parameter</td>
<td>The graphic interface displayed an error parameter</td>
<td>Try repeating the operation you were performing. If the problem persists, contact the Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Can't open serial device</td>
<td>The serial cable connection of RFID is disconnected</td>
<td>Check the serial cable connection of RFID and restart the device.</td>
</tr>
<tr>
<td></td>
<td>Software problem</td>
<td>Restart the device, if the problem persists, contact the Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Charge anomaly detected. Capacitors will be discharged and recharged.</td>
<td>The charging process of the high voltage pulse generator cannot be completed</td>
<td>Try to repeat the capacitors charge.</td>
</tr>
<tr>
<td></td>
<td>Hardware problem</td>
<td>Restart the device, if the problem persists, contact the Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Current is too low</td>
<td>The system detected a very low current between a couple of needles during the treatment.</td>
<td>Check the electrode position. It is recommended to repeat the treatment.</td>
</tr>
<tr>
<td></td>
<td>The electrode is disconnected from CLINIPORATOR</td>
<td>Check the electrode connection to the generator. Make the connection as required.</td>
</tr>
<tr>
<td></td>
<td>The handle is not correctly connected to the electrode (only for EPS series)</td>
<td>Check the connection between the handle and the electrode. Make the connection as required.</td>
</tr>
<tr>
<td></td>
<td>The cable / handle is damaged</td>
<td>Replace the cable / handle if possible, otherwise use a new electrode.</td>
</tr>
<tr>
<td>Error message</td>
<td>Possible causes</td>
<td>What to do</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>ECG bad</strong></td>
<td>The ECG leads were not positioned as expected.</td>
<td>Check if each ECG cable of the Synchronizer is connected to the correct ECG electrode (i.e. there is not a reversal of the leads). If the connections match check, if applicable, that the dip switches are correctly positioned. For instructions on the correct positioning of the dip switches, see the synchronizer manual.</td>
</tr>
<tr>
<td></td>
<td>The patient's cardiac activity is abnormal (e.g., nodal rhythm). In order to deliver the pulses, the rhythm must be sinus.</td>
<td>Check on the Anaesthesia monitors that the patient’s cardiac activity is really abnormal. If the track detected by the synchronizer is inaccurate, check the placement of the electrodes for the leads, otherwise interrupt the treatment.</td>
</tr>
<tr>
<td><strong>ECG signal lost</strong></td>
<td>The ECG cable is detached from the corresponding electrode placed on the patient.</td>
<td>Check the ECG cable-electrode connections. Reconnect the ECG cable to the corresponding electrode on the patient, if necessary.</td>
</tr>
<tr>
<td></td>
<td>The synchronizer does not generate any signal at the R wave.</td>
<td>Select a different Lead (refer to the user instructions of the synchronizer).</td>
</tr>
<tr>
<td></td>
<td>The width of the R wave detected by the synchronizer is not high enough.</td>
<td>Select a different Lead (refer to the user instructions of the synchronizer).</td>
</tr>
<tr>
<td></td>
<td>The ECG electrode is not attached to the patient.</td>
<td>Check the correct positioning of the ECG electrodes on the patient. Reposition / reattach the ECG electrode correctly, if necessary.</td>
</tr>
<tr>
<td></td>
<td>ECG electrodes are not positioned in the correct location.</td>
<td>Check the correct positioning of the ECG electrodes. Reposition the electrodes in the correct locations (for instructions on positioning the ECG electrodes, refer to the user manual of the synchronizer).</td>
</tr>
<tr>
<td></td>
<td>The patient's heart rate is less than 17 bpm.</td>
<td>Cliniporator delivers the pulses only if patient’s heart rate is above 17 bpm and below 120 bpm. Check on the Anaesthesia monitors that the heart rate is really below 17 bpm. If the heart rate detected by the synchronizer is inaccurate, select a different Lead (refer to the user manual of the synchronizer).</td>
</tr>
<tr>
<td></td>
<td>The synchronizer ECG cable is disconnected.</td>
<td>Check the connections between the ECG cable and the synchronizer connectors. Reconnect the cable if necessary.</td>
</tr>
<tr>
<td></td>
<td>The BNC coaxial cable, which connects the synchronizer to Cliniporator is disconnected.</td>
<td>Check the connection of the BNC cable to the synchronizer and to the pulse generator. Make sure that the BNC cable is connected to the synchronizer output labelled with &quot;ECG OUT&quot; if provided. Reconnect the cable, if necessary (for information on the connection with the synchronizer, refer to the user manual of the synchronizer).</td>
</tr>
<tr>
<td><strong>ECG signal is noisy</strong></td>
<td>The patient's heart rate is above 120 bpm.</td>
<td>In order for the generator to deliver the pulses, the patient’s heart rate must be above 17 bpm and below 120 bpm. Check on the Anaesthesia monitors that the heart rate is really above 120 bpm. If the heart rate detected by the synchronizer is inaccurate, select a different Lead (refer to the user manual of the synchronizer).</td>
</tr>
<tr>
<td></td>
<td>There is electrical interference on the ECG track.</td>
<td>If the interference is caused by the delivery of the treatment pulses, wait for the ECG trace to be restored following the completion of the delivery. If the interference is attributable to the simultaneous use of an electro-medical device (e.g. electrosurgery unit), stop using it and wait for the ECG trace to be restored. Otherwise check the positioning of the synchronizer cables and the correct connection to the patient.</td>
</tr>
<tr>
<td></td>
<td>ECG cables cross the connection cable of an electrical device (e.g., electrosurgical unit).</td>
<td>Check the relative positioning between the ECG cables and the electrical equipment cables. Reposition the electrical equipment cables as required or, alternatively, switch off the electrical equipment.</td>
</tr>
<tr>
<td></td>
<td>ECG cables cross the connection cable of an electrical device (e.g., electrosurgical unit).</td>
<td>Select a different Lead (refer to the user manual of the synchronizer).</td>
</tr>
<tr>
<td></td>
<td>The amplitude of the P wave detected by the synchronizer is high.</td>
<td>Select a different Lead (refer to the user manual of the synchronizer).</td>
</tr>
<tr>
<td></td>
<td>Muscular contractions are high.</td>
<td>Limit muscular contraction with muscular relaxation.</td>
</tr>
<tr>
<td>Error message</td>
<td>Possible causes</td>
<td>What to do</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>ECG signal not found</td>
<td>ECG signal not detected.</td>
<td>To solve the problem, check ECG electrodes position and connections.</td>
</tr>
<tr>
<td>Electrode code is duplicated</td>
<td>Attempt to use an electrode that is not approved by IGEA.</td>
<td>Replace the electrode with an electrode approved by IGEA.</td>
</tr>
<tr>
<td>Electrode validity time elapsed</td>
<td>More than six hours have passed since the electrode’s last use on the patient.</td>
<td>Replace the electrode with a new one.</td>
</tr>
<tr>
<td>Electrode was changed</td>
<td>The operator has changed the electrode between the recognition phase and the identification one.</td>
<td>Repeat the recognition of the electrode by not changing or moving the electrode between the recognition phase and the marking phase.</td>
</tr>
<tr>
<td>Error saving treatment data. Treatment has been completed correctly but data will be lost</td>
<td>Error during data treatment saving.</td>
<td>Continue with the treatment. If the problem persists, contact the Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Error while mounting USB pen drive</td>
<td>The USB device used is defective.</td>
<td>Replace the USB device.</td>
</tr>
<tr>
<td>Export completed with errors</td>
<td>Errors occurred during the data export process.</td>
<td>Check if the USB pen drive is correctly inserted and if it has enough free space. Disconnect the USB pen drive, boot the device and retry the operation. If the problem persists, contact the Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Incorrect password, please retry!</td>
<td>The password entered during login is incorrect.</td>
<td>Provide the correct credentials.</td>
</tr>
<tr>
<td>Not a valid electrode</td>
<td>Tag recognised as non valid.</td>
<td>Repeat electrode selection. If the problem persists, restart the device. If the problem persists, contact the Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Not allowed in this mode</td>
<td>Electrode code not allowed in the treatment mode chosen</td>
<td>The electrode chosen is not habilitated for EGT mode. Select only electrodes habilitated for EGT mode.</td>
</tr>
<tr>
<td>Not in proper state</td>
<td>The system tried to perform an operation at a wrong time</td>
<td>If the system works, continue using it. In any case, contact the Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Pedal pressed detected</td>
<td>Detected one or both pedals pressed during the self-test</td>
<td>Turn off the device, check if pedals are properly connected and not pressed and restart. If the problem persists, contact Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Please try to fix the ECG signal and press the retry button</td>
<td>The ECG synchronizer is turned off.</td>
<td>Turn on the ECG synchronizer.</td>
</tr>
<tr>
<td></td>
<td>The connection between the device and the ECG synchronizer is not correct.</td>
<td>Check that the connection between Cliniporator and the ECG synchronizer is correct (refer to the user manual of the synchronizer).</td>
</tr>
<tr>
<td></td>
<td>The ECG synchronizer works abnormally.</td>
<td>Switch the synchronizer off and on again. If the problem persists, contact the Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Timeout in electrode recognition</td>
<td>The RFID tag is not close enough to the relevant antenna.</td>
<td>Bring the electrode Tag closer to the antenna area and repeat the electrode recognition.</td>
</tr>
<tr>
<td></td>
<td>In the recognition phase the user does not position the RFID tag near the relevant antenna, or removes the RFID tag before the electrode recognition operation is completed.</td>
<td>Bring the electrode Tag close to the antenna area and repeat the electrode recognition by keeping the Tag in position for the entire duration of the operation.</td>
</tr>
<tr>
<td></td>
<td>The electrode RFID tag is damaged.</td>
<td>Recognize the electrode using the manual recognition operation. Contact Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td></td>
<td>Hardware / software problem.</td>
<td>Recognize the electrode using the manual recognition operation. Contact Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Timeout on arming pedal</td>
<td>The PULSE pedal pressure has been performed much later than the ARM pedal pressure.</td>
<td>The ARM and PULSE pedals must be pressed consequently within 10 seconds. If the problem persists, Contact Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Error message</td>
<td>Possible causes</td>
<td>What to do</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Too many tags found</td>
<td>The operator has approached the RFID antenna more than one electrode.</td>
<td>Repeat the recognition phase, placing a single electrode near the antenna.</td>
</tr>
<tr>
<td></td>
<td>The RFID transponder works abnormally or is damaged.</td>
<td>Contact Customer Service of IGEA S.p.A.</td>
</tr>
<tr>
<td>Treatment Failure: HV Overload</td>
<td>During treatment, the system detected a too high current between the two needles during the high voltage pulse delivery.</td>
<td>Check the electrode position. It is recommended to repeat the treatment.</td>
</tr>
<tr>
<td>Treatment timeout: aborted</td>
<td>The 10 second timeout between the ARM pedal activation and that of the PULSE pedal expired.</td>
<td>Press ARM again to start a new treatment.</td>
</tr>
<tr>
<td>Unknown username, please retry!</td>
<td>During the login, the username was not entered correctly</td>
<td>Provide the correct credentials.</td>
</tr>
<tr>
<td>USB driver error</td>
<td>The USB cable, coming from the power part, is disconnected from the relative USB port of the Panel PC.</td>
<td>Connect the USB cable, coming from the power part, to the USB port of the Panel PC. Then restart the device.</td>
</tr>
<tr>
<td>USB memory key not found or wrong</td>
<td>The USB pen drive is not inserted or is not inserted correctly.</td>
<td>Check that the USB pen drive is correctly inserted and repeat the data export operation (for instructions on the correct execution of the data export process see section 5.12).</td>
</tr>
<tr>
<td></td>
<td>The USB pen drive is defective.</td>
<td>Replace the USB pen drive, then repeat the data export operation (for instructions on the correct execution of the data export process see section 5.12).</td>
</tr>
<tr>
<td>Warning: electrode already selected</td>
<td>The electrode recognition is performed on an electrode already selected for the current treatment session.</td>
<td>Repeat the operation with a new electrode.</td>
</tr>
<tr>
<td></td>
<td>Hardware / software problem.</td>
<td>Contact Customer Service of IGEA S.p.A.</td>
</tr>
</tbody>
</table>
### 7.3 Unknown cause Error Messages

The error messages reported in this section relate to unforeseeable problems and therefore cannot be resolved by precise user action. In the presence of one of these messages, the user can restart the device and, if the problem persists, contact the Customer Service of IGEA S.p.A.

<table>
<thead>
<tr>
<th>Error message</th>
<th>Error message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bad configuration data</td>
<td>Error switching relays</td>
</tr>
<tr>
<td>Bad file type</td>
<td>Error updating ID repository</td>
</tr>
<tr>
<td>Bad parity</td>
<td>Firmware is corrupted</td>
</tr>
<tr>
<td>Bad serial params</td>
<td>FPGA error</td>
</tr>
<tr>
<td>Bad serial speed</td>
<td>FPGA init error</td>
</tr>
<tr>
<td>Bad stop bits</td>
<td>FPGA server in idle status</td>
</tr>
<tr>
<td>Bad word length</td>
<td>Hardware in a wrong state</td>
</tr>
<tr>
<td>Cannot reinit hardware. Idle</td>
<td>Hardware is in alarm</td>
</tr>
<tr>
<td>Cannot reinit hardware. Idle</td>
<td>HW communications error</td>
</tr>
<tr>
<td>Cannot reset HW</td>
<td>HW communications error. Idle</td>
</tr>
<tr>
<td>Cannot reset HW Idle</td>
<td>HV Failure: Overlength shutting down the machine</td>
</tr>
<tr>
<td>Can’t connect to FPGA server</td>
<td>HW in unexpected state (state=#)</td>
</tr>
<tr>
<td>Can’t reset ECG ABORT condition</td>
<td>Internal error (#)</td>
</tr>
<tr>
<td>Can’t test firmware integrity</td>
<td>Internal/Unknown error</td>
</tr>
<tr>
<td>Charge error in HV discharging</td>
<td>Invalid firmware version</td>
</tr>
<tr>
<td>Charge error in invalid state</td>
<td>No bitetag configured</td>
</tr>
<tr>
<td>Charge Timeout. Discharging…</td>
<td>No board found</td>
</tr>
<tr>
<td>Charging/Discharging error</td>
<td>No serial device configured</td>
</tr>
<tr>
<td>Error accessing ID repository</td>
<td>No serial params</td>
</tr>
<tr>
<td>Error burning electrode</td>
<td>Operation failed</td>
</tr>
<tr>
<td>Error charging HV</td>
<td>Overlength test failure</td>
</tr>
<tr>
<td>Error delivering treatment</td>
<td>Power supply failure: shutting down</td>
</tr>
<tr>
<td>Error discharging</td>
<td>Power switches failure: shutting down</td>
</tr>
<tr>
<td>Error discharging HV</td>
<td>RFID operation error</td>
</tr>
<tr>
<td>Error getting prompt</td>
<td>Shutting down the machine</td>
</tr>
<tr>
<td>Error holding HV charge</td>
<td>Switching not found</td>
</tr>
<tr>
<td>Error in electrode recognition</td>
<td>Syntax error</td>
</tr>
<tr>
<td>Error in memory test</td>
<td>Timeout in switching electrodes</td>
</tr>
<tr>
<td>Error in transceiver power off/on</td>
<td>Unrecoverable error</td>
</tr>
<tr>
<td>Error reading electrode</td>
<td>Unrecoverable error Shuting down the machine</td>
</tr>
<tr>
<td>Error reading electrodes list</td>
<td>The device will be shutdown. Wait 10 sec. before restarting the device.</td>
</tr>
<tr>
<td>Error resetting rfid transceiver</td>
<td>Watchdog timeout elapsed: shutting down</td>
</tr>
<tr>
<td>Error selecting electrode</td>
<td></td>
</tr>
</tbody>
</table>
8 MAINTENANCE

8.1 Routine Maintenance

Table 1 indicates the routine maintenance checks - recommended by the manufacturer - that the user has to perform to ensure the equipment correct operation.

In general it is not possible to carry out maintenance operations while the device is in use on the patient. If necessary, the pedal can be replaced, taking care to exit the treatment screen in advance. Handpieces and electrodes can be replaced without the need to restart the device.

<table>
<thead>
<tr>
<th>CHECK</th>
<th>FREQUENCY</th>
<th>PREVENTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handle replacement.</td>
<td>After 20 sterilisation cycles or if damaged.</td>
<td>Preventing the degradation of the performance of the Handles (After these sterilization cycles the mechanical properties of the cable begin to degrade).</td>
</tr>
<tr>
<td>Pedal inspection to check for cable abrasions, cuts or tampering, connector cracks or bended contacts, connector and pedal's sheath retention. If any of these are found, replace the pedal.</td>
<td>Periodically, according to the real frequency of use of the device.</td>
<td>Prevent breakdowns and consequent inability to deliver the treatment.</td>
</tr>
<tr>
<td>Power supply cord inspection to check for cable abrasions, cuts or tampering, plug bended contacts. If any of these are found, replace the power supply cord.</td>
<td>Periodically, according to the real frequency of use of the device.</td>
<td>Avoid electrical hazards or inoperativity of the device.</td>
</tr>
</tbody>
</table>

Table 1 – Routine maintenance

8.2 Periodical Preventive Maintenance

Table 2 shows preventive maintenance interventions recommended to ensure correct operation of the equipment. They must be performed by the manufacturer or by an authorized distributor in writing by the manufacturer. With the exception of the routine maintenance interventions indicated in the previous section, the device does not contain any component that can be repaired or replaced by the user technical support personnel.

<table>
<thead>
<tr>
<th>TEST/SERVICE</th>
<th>FREQUENCY</th>
<th>PREVENTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check the calibration and, if necessary, re-calibrate the device.</td>
<td>Every 24 months</td>
<td>Check that the device features always comply with the specifications.</td>
</tr>
<tr>
<td>Verification of compliance with EN60601-1 with regard to electrical safety.</td>
<td>Every 24 months</td>
<td>Preventing electrical hazards.</td>
</tr>
<tr>
<td>Replacement of the device's internal parts.</td>
<td>After 500 treatment sessions or 10 years</td>
<td>Prevent adverse events (marginal/minor severity class), maintain device’s features.</td>
</tr>
</tbody>
</table>

Table 2 – Preventive periodical maintenance

The manufacturer recommends to perform a periodical check every 24 months on the CLINIPORATOR in order to assess proper operation, calibration and electrical safety and for preventive maintenance. The manufacturer disclaims any responsibility for adverse events or damage, if the scheduled maintenance and the periodical check have not been performed on the unit by the manufacturer or the authorised local dealer. No modification of this equipment is allowed.
8.3 Cleaning
For the periodic cleaning of the device use a soft cloth slightly damped with water or sanitizing wipes (certified as a medical device). Do not pour water or other liquids directly on the device. Do not use alcohol, solvents or other aggressive products to clean the device! Using aggressive detergents may discolour or damage the coloured parts.

The screen can be cleaned with a soft cloth damped with water. Do not use spray products or aerosol on the screen to prevent liquids from entering the device and damaging the components.

8.4 Mains isolation
Unplugging the power cord from the wall socket is the primary mean for isolating the device from the supply mains. Beside this, unplugging the cord from the device is necessary, in order to be able to access the fuse compartment.

As a last possibility, the Mains switch is a suitable mean for isolating the internal circuits.

Acting on the button on the Panel PC has no effect as to isolation of any part from the mains voltage.

8.5 Fuses Replacement
The device is equipped with protection fuses; the fuse holder is located in the Power Supply Group on the rear panel (see section 2.2). To replace the protection fuses follow these steps:

- make sure that the mains switch is in “O” position, i.e. turned off
- disconnect the power supply cord from the generator
- open the voltage selector cover with a slotted screwdriver as shown in Figure64
- pull out the red selector by using the slotted screwdriver as shown in Figure64
- replace the fuses with new ones. The fuse type should correspond to the one indicated on the device's data plate
- place the fuse holder back in the Power Supply Group and close the cover
- reconnect the power supply cord.

**DANGER!** Use only fuses of the same type and with the same voltage and current as specified in the device's data plate.

**WARNING!** This operation must be carried out only by qualified technical staff.
8.6 Power Supply Cord Replacement

To replace the power supply cord use a 4mm Allen key. This procedure is described below:

- unscrew the screw which secures the cable clip to the rear panel of the device
- open the cable clip and remove it from the old cable
- apply it to the new cable, at a distance of 23 cm from the VDE plug tip
- secure the cable clip to the rear panel using the Allen screw, putting the star washer between the cable clip and the rear panel.

Figure 65 – power supply cord
9 TECHNICAL DATA

9.1 General Information
Manufacturer: IGEA S.p.A. Via Parmenide, 10/A 41012 Carpi (MO) Italy
Commercial name: CLINIPORATOR
Model: EPS02

9.2 Power Supply Specifications
Main switch voltage 115/230 VAC
Main switch frequency 50-60 Hz
Maximum power input 160 VA
Protection fuses 2 type T 2.5A 250V - 5 x 20 mm Breaking Capacity: 35A L

9.3 Environmental Conditions
Working conditions
Room temperature from 10 to 40 °C
Relative humidity from 30% to 75%
Atmospheric pressure from 700 hPa to 1060 hPa

Transport and Storage Conditions
Room temperature from -20 to 50 °C
Relative humidity from 10% to 90%
Atmospheric pressure from 500 to 1060 hPa

9.4 EN 60601-1 Classification
Protection against electrical risks CLASS I
Applied part class Defibrillation proof type BF applied parts.
Liquids penetration IPX0 – No special protection on the device.
At least IPX6 – Pedals.
CLINIPORATOR cannot be used in environments where there could be flammable anaesthetic mixtures as specified by the EN 60601-1 standards. A mixture of the vapour of a flammable disinfection or cleaning agent with air can be treated as a flammable anaesthetic mixture with air subject to national or local regulations.

9.5 Medical Device Directive Classification 93/42/EEC and 2007/47/EEC
Class IIa

9.6 Terms of Use
CLINIPORATOR is suitable for continuous use. However, it is recommended to turn off the device after every treatment session.

9.7 Technical Specifications
Dimensions (Width x Length x Height) 46 x 65 x 156 cm
Weight 52 Kg
Output channels 7
Switching interval between each needle pair <60 ms
Max. pulse energy (nominal) 20 J with HV pulses
9.8 High Voltage Pulses
The following table shows the maximum and minimum values for each parameter considered alone. The product of Number of pulses times Pulse duration must be less than 1000 µs.

<table>
<thead>
<tr>
<th>Number of Pulses</th>
<th>1 – 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Amplitude</td>
<td>100 - 1000V</td>
</tr>
<tr>
<td>Pulse Length</td>
<td>50 - 1000 µs</td>
</tr>
<tr>
<td>Rise Time</td>
<td>&lt;2 µs at 1000 V</td>
</tr>
<tr>
<td>Pulses Repetition Frequency</td>
<td>1 – 5000 Hz</td>
</tr>
<tr>
<td>Maximum Deliverable Current</td>
<td>20 A</td>
</tr>
<tr>
<td>Pulse Amplitude Accuracy</td>
<td>±5%</td>
</tr>
<tr>
<td>Pulse Length Accuracy</td>
<td>±2 µs</td>
</tr>
</tbody>
</table>

9.9 Electromagnetic Compatibility
CLINIPORATOR complies with the requirements of EN60601-1, EN60601-1-2.

Guidelines and Manufacturer declaration – electromagnetic emissions

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Guidelines – electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>CLINIPORATOR uses a radiofrequency device exclusively for internal functions. Its radio frequency emissions are very low and hardly cause interference with nearby equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>CLINIPORATOR can be used in the specific environment, from an electromagnetic point of view, represented by professional health facilities, where RF interference is under control. This includes operating rooms in hospitals, excluding the immediate vicinity of high-power equipment or radiofrequency surgical devices (including their cables), which are micro-environments with special emission characteristics, in which the intensity of electromagnetic disturbances is high. Screened rooms for magnetic resonance imaging are also excluded.</td>
</tr>
<tr>
<td>Harmonious emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Emissions of fluctuations of voltage/flicker IEC 61000-3-3</td>
<td>Compliant</td>
<td></td>
</tr>
</tbody>
</table>
### Guidelines and Manufacturer Declaration – electromagnetic immunity

**CLINIPORATOR** can be used in the electromagnetic environment specified below. The client or user of **CLINIPORATOR** should ensure that it is used in such environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level of IEC 60601</th>
<th>Compliance level</th>
<th>Guidelines – electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>during contact ± 6 kV in air ± 8 kV</td>
<td>during contact ± 6 kV in air ± 8 kV</td>
<td>The floors must be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be of at least 30%.</td>
</tr>
<tr>
<td>Transitory/sequence of fast electrical pulses IEC 61000-4-4</td>
<td>± 2 kV per lines of power supply ± 1 kV per lines of input/output</td>
<td>± 2 kV per lines of power supply ± 1 kV per lines of input/output</td>
<td>The mains voltage quality should be the same as that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Overvoltages IEC 61000-4-5</td>
<td>± 1 kV between phases ± 2 kV between phase/phases and ground</td>
<td>± 1 kV between phases ± 2 kV between phase/phases and ground</td>
<td>The mains voltage quality should be the same as that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage holes, short interruptions and voltage changes on lines of power supply input IEC 61000-4-11</td>
<td>&lt;5 % $U_T$ (&gt;95 % hole in $U_T$) per 0,5 cycles 40 % $U_T$ (60 % hole in $U_T$) per 5 cycles 70 % $U_T$ (30 % hole in $U_T$) per 25 cycles &lt;5 % $U_T$ (&gt;95 % hole in $U_T$) per 5 s</td>
<td>&lt;5 % UT (&gt;95 % hole in UT) per 0,5 cycles 40 % UT (60 % hole in UT) per 5 cycles 70 % UT (30 % hole in UT) per 25 cycles &lt;5 % UT (&gt;95 % hole in UT) per 5 s</td>
<td>The mains voltage quality should be the same as that of a typical commercial or hospital environment. If the CLINIPORATOR user requires a continuous operation during mains voltage interruptions, it is recommended to power the CLINIPORATOR with uninterruptible power supply or batteries.</td>
</tr>
<tr>
<td>Mains frequency magnetic fields (50/60 Hz) IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Mains frequency magnetic fields should have levels equal to those of a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: $U_T$ is the mains frequency in AC before applying the test level.

**NOTE 1**: Cliniporator has proven completely immune to overvoltages up to 1.5 kV between phase and ground, while overvoltages between 1.5 kV and 2 kV might cause the Panel PC to turn off. In this case, to restore the device operation, the operator must move the mains switch to turned off position (O), wait one minute, then move back the switch to turned on position (I).
Guidelines and MANUFACTURER Declaration – electromagnetic IMMUNITY

CLINIPORATOR can be used in the electromagnetic environment specified below. The client or user of CLINIPORATOR should ensure that it is used in such environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level of IEC 60601</th>
<th>Compliance level</th>
<th>Guidelines – electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF conducted</td>
<td>3 V eff from 150 kHz to 80 MHz</td>
<td>3 V</td>
<td>Portable and mobile RF communication devices should not be used nearer any part of CLINIPORATOR - including cables - than the recommended separation distance calculated by the equation applicable to the transmitter frequency. Recommended separation distance.</td>
</tr>
<tr>
<td>RF emitted</td>
<td>3 V/m from 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>RF conducted IEC 61000-4-6</td>
</tr>
</tbody>
</table>

where P is the maximum output transmitter value in watts (W) according to the transmitter manufacturer and d is the suggested separation distance in metres (m).

The fixed transmitters field intensities, determined by an electromagnetic analysis in loco\(^a\) should be lower than the compliance level for each frequency\(^b\) level.

Interference can occur near devices marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the separation distance for higher frequency interval applies.

NOTE 2: These guidelines might not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection of structures, objects and people.

\(^a\) The field intensities for fixed transmitters, such as radio telephones (mobile/cordless) and land mobiles base stations, amateur radio operator equipment, radio transmitter in AM and FM and TV transmitters cannot be foreseen theoretically with accuracy. To evaluate an electromagnetic environment caused by fixed RF transmitters, an electromagnetic analysis on site should be performed. If the field intensity measured in the location - where the [EM DEVICE or the EM SYSTEM] is used - exceeds the above indicated applicable compliance level, the operation of the [EM DEVICE or the EM SYSTEM] should be put on watch. If abnormal performances are registered, additional measures might be necessary, such as a different orientation or position of the [EM DEVICE or the EM SYSTEM].

\(^b\) The field intensity in the frequency interval from 150 kHz to 80 MHz should be less than [V1] V/m.
Recommended separation distance between portable and mobile radio communication devices and CLINIPORATOR

CLINIPORATOR should be used in an electromagnetic environment where the emitted RF interferences are under control. The client or user of CLINIPORATOR can help preventing electromagnetic interferences by maintaining a minimum distance between portable and mobile RF (transmitters) communication devices and CLINIPORATOR, as shown below, paying attention to respect the maximum output power of the communication devices.

<table>
<thead>
<tr>
<th>Maximum Output nominal transmitter power W</th>
<th>Separation distance from transmitter frequency m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>From 150KHz to 80MHz</td>
</tr>
<tr>
<td></td>
<td>1.2 x √P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters set at a maximum output power level not indicated above, the suggested separation distance d, in metres (m) can be estimated using the applicable transmitter frequency equation where P is the maximum transmitter output power level in watts (W) as determined by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for higher frequency interval applies.

NOTE 2: These guidelines might not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection of structures, objects and people.

The following cables may affect the compliance of the device with the applicable electromagnetic compatibility regulations. The table indicates the type of cable and the maximum length for which the electromagnetic compatibility has been verified:

<table>
<thead>
<tr>
<th>Cable</th>
<th>Type</th>
<th>Maximum length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Supply cable</td>
<td>Not shielded</td>
<td>3 m</td>
</tr>
<tr>
<td>Electrodes connection cables</td>
<td>Not shielded</td>
<td>3 m</td>
</tr>
<tr>
<td>Pedal cable</td>
<td>Not shielded</td>
<td>2.0 m</td>
</tr>
<tr>
<td>Synchronisation cable (ECG-Sync)</td>
<td>Shielded</td>
<td>1.8 m</td>
</tr>
</tbody>
</table>

WARNING! Use of this device near other equipment should be avoided as it may cause malfunctions. If such use is necessary, this device and the other equipment should be monitored to ensure that they work without malfunction.

WARNING! The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased immunity of this device to electromagnetic disturbances and cause malfunctions.

WARNING! Portable telecommunications equipment (including peripheral devices such as antenna cables and external antennas) should not be used at a distance of less than 30 cm (12 inches) from any part of the CLINIPORATOR, including cables specified by the manufacturer, otherwise degradation of this device.

CLINIPORATOR is able to detect a possible degradation of its performances beyond the limits considered acceptable, with particular reference to a degradation in the amplitude or duration of the pulses supplied.

In the event that, due to electromagnetic disturbances, these treatment parameters are compromised, the device will notify the operator of the presence of error conditions and will automatically interrupt the treatment, it will be brought into safety conditions and, in some cases, may require the restart and repetition of the initial self-test.

However, error conditions may arise, even if they are not related to alterations in machine performance. Their appearance does not necessarily imply that the performance of the machine has deteriorated or has been influenced by electromagnetic disturbances.
CLINIPORATOR includes an RFID device that has the following characteristics:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenna</td>
<td>Loop type; area &lt; 0.05 m²</td>
</tr>
<tr>
<td>Frequency band</td>
<td>13.553 – 13.567 Mhz</td>
</tr>
<tr>
<td>Maximum power of RF</td>
<td>&lt; 60 dBuA/m at 10 m</td>
</tr>
<tr>
<td>signal</td>
<td></td>
</tr>
<tr>
<td>Modulation</td>
<td>Backscatter ASK</td>
</tr>
<tr>
<td>Transmission standard</td>
<td>ISO 15693</td>
</tr>
<tr>
<td>ERP</td>
<td>1.32 uW</td>
</tr>
</tbody>
</table>

The transmitting antenna is normally off and is activated only when the menu of selection is displayed on the screen.

9.10 End of Life Disposal

The end of life disposal of CLINIPORATOR does not cause any risk for environment or the personnel, provided that the device and the electrical parts given as accessories are disposed in accordance with the national regulation in force for the disposal of electric or electronic equipment.

9.11 Essential performances

In accordance with EN 60601-1, "essential performance" is defined as the performance of a clinical function for which loss or degradation beyond the limits specified by the manufacturer is deemed to pose an unacceptable risk.

The essential performances of CLINIPORATOR, identified by the manufacturer according to this definition, are the control of the energy delivered during the treatment. It has been estimated that uncontrolled energy delivery above 60 Joules would expose the patient to a risk deemed unacceptable.

To ensure the maintenance of essential performances it is necessary to carry out the checks and preventive maintenance interventions described in paragraph 8.2.

The verification of the essential performances requires the measurement, through an oscilloscope equipped with a suitable high voltage probe, of the amplitude (V) of the supplied pulses and of the duration (L) of the pulses. The following specifications must be respected:

- \( V \leq 1.1 \times V \text{ nominal} \) (e.g. \( 1.1 \times 730 \text{ V} = 803 \text{ V} \));
- High Voltage Pulse: \( L \leq 2.48 \text{ ms} \)
## 10 SYMBOLS

### 10.1 Standard Symbols Used

The following symbols, used in CLINIPORATOR or its separable parts comply with international standards.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
<th>Where it appears</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Protective ground connection" /></td>
<td>Protective ground connection</td>
<td>On every protective ground connection.</td>
</tr>
<tr>
<td><img src="image" alt="Warning, electricity" /></td>
<td>Warning, electricity</td>
<td>On every external or internal part of the device where there is a potentially dangerous High Voltage.</td>
</tr>
<tr>
<td><img src="image" alt="Open: when a switch is pressed in this position, the device is turned off." /></td>
<td>Open: when a switch is pressed in this position, the device is turned off.</td>
<td>Printed on the main switch</td>
</tr>
<tr>
<td><img src="image" alt="Closed: when a switch is pressed in this position, the device is turned on." /></td>
<td>Closed: when a switch is pressed in this position, the device is turned on.</td>
<td>Printed on the main switch</td>
</tr>
<tr>
<td><img src="image" alt="The generator and all its parts need to be disposed according to the local laws for electronic device disposal." /></td>
<td>The generator and all its parts need to be disposed according to the local laws for electronic device disposal.</td>
<td>Printed on the data plate</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
<td>Printed on the data plate and on the pedal</td>
</tr>
<tr>
<td><img src="image" alt="Defibrillator-proof type BF applied part." /></td>
<td>Defibrillator-proof type BF applied part.</td>
<td>Printed on the front cover of the generator near to the output connector</td>
</tr>
<tr>
<td><img src="image" alt="Federal Communications Commission." /></td>
<td>Federal Communications Commission.</td>
<td>Printed on the data plate</td>
</tr>
<tr>
<td><img src="image" alt="European Conformity mark with the identifying number of the Notified Body." /></td>
<td>European Conformity mark with the identifying number of the Notified Body.</td>
<td>Printed on the data plate</td>
</tr>
<tr>
<td><img src="image" alt="Generator and accessory model identification or inventory code" /></td>
<td>Generator and accessory model identification or inventory code</td>
<td>Printed on the data plate, and on accessories</td>
</tr>
<tr>
<td><img src="image" alt="Serial number: indicates the serial number of the generator" /></td>
<td>Serial number: indicates the serial number of the generator</td>
<td>Printed on the data plate and on the label placed on the display</td>
</tr>
<tr>
<td><img src="image" alt="Indicates the batch number" /></td>
<td>Indicates the batch number</td>
<td>Printed on handle cable</td>
</tr>
<tr>
<td><img src="image" alt="Upper temperature limit" /></td>
<td>Upper temperature limit</td>
<td>Used to indicate the maximum temperature that should be set when accessories are sterilized.</td>
</tr>
<tr>
<td><img src="image" alt="Do-not-push symbol. The device may overbalance if pushed against an obstacle or with locked wheels." /></td>
<td>Do-not-push symbol. The device may overbalance if pushed against an obstacle or with locked wheels.</td>
<td>On the data-plate label and on device's sides.</td>
</tr>
<tr>
<td><img src="image" alt="Consult operating instructions" /></td>
<td>Consult operating instructions</td>
<td>Close to RFID reader antenna</td>
</tr>
<tr>
<td><img src="image" alt="Refer to instruction manual" /></td>
<td>Refer to instruction manual</td>
<td>On the data-plate label and close to the ECG Sync connector</td>
</tr>
<tr>
<td><img src="image" alt="xx Kg" /></td>
<td>Indicates the weight of the Device</td>
<td>On the data-plate label</td>
</tr>
</tbody>
</table>
10.2 Non Standard Symbols

The following are custom symbols, which are also used on CLINIPORTA TOR or its separable parts.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
<th>Where it appears</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="RFID antenna" /></td>
<td>RFID reader antenna</td>
<td>Printed on the side cover of the generator to indicate the area in which the RFID reader antenna is located.</td>
</tr>
<tr>
<td><img src="image" alt="Fuses" /></td>
<td>Fuses: the value of protection fuses is indicated beside this symbol</td>
<td>Printed on the data plate</td>
</tr>
<tr>
<td><img src="image" alt="Electrical source" /></td>
<td>Electrical source: the features of the electrical source used for the generator power supply are indicated beside this symbol</td>
<td>Printed on the data plate</td>
</tr>
<tr>
<td><img src="image" alt="Double control pedal" /></td>
<td>Double control pedal</td>
<td>Printed on the front panel beside the connector</td>
</tr>
<tr>
<td>20 x</td>
<td>Number of times the action can be repeated</td>
<td>Printed on the handle cable, it indicates the number of times it is guaranteed that the handle supports the sterilization process.</td>
</tr>
<tr>
<td><img src="image" alt="Exposure time" /></td>
<td>Exposure time</td>
<td>Printed on the handle cable, it indicates the validated sterilization process duration.</td>
</tr>
</tbody>
</table>
11 WARRANTY AND MANUFACTURER'S LIABILITY

IGEA manufacturer is responsible for the safety, trust and performance of the equipment only if:

1. The installation of the system is carried out by a qualified technician authorised by the manufacturer.
2. Modifications, repairs and software or hardware updates are done only by the manufacturer or by authorised and qualified staff.
3. The system was not opened or tampered with by the operator or by non authorised persons.
4. The system and its parts are used in compliance with the user instructions of the present manual.
5. The equipment and its parts still have all the protection devices applied by the manufacturer except for the particular cases anticipated and described in this manual.
6. Remote connection to the unit is in compliance with the procedures described in this manual by IGEA.
7. The operator regularly performs each checking procedure and/or equipment calibration according to what is written in this manual.
8. Only software applications supplied or authorised in writing by the manufacturer have been installed or loaded on the system.
9. The system shows the original configuration set up by the manufacturer.

The warranty is valid only for the restoration of the complete operation of the system and does not cover any side effects such as loss of data or other damage arising from improper use or negligence.

For information or updates, contact the local distributor or manufacturer:

IGEA S.p.A. - Via Parmenide 10/A - 41012 Carpi (MO), Italy
Phone +39 059.699600 Fax. +39 059.695778
E-mail : info@igeamedical.com;
Technical support: support.oncology@igeamedical.com
ANNEX 1 - EC CERTIFICATE

EC CERTIFICATE
Certificate No 1289/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

IGEA SPA
41012 CARPI (MO) - VIA PARMENIDE 10/A (ITA) - Italy

manages the factories of:
41012 CARPI (MO) - VIA PARMENIDE 10/A (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:
Electroporation devices and related accessories
Type ref. EPS02
Trade mark IGEA

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 6 of Annex II.

Reference to IMQ files Nos:
10AJ00224; 10EL0044; COMEDCONMHDM120058654-01; DM15E0379144-01;
DM16-E000283.

Notified Body notified to European Commission under number: 0051.

Date: 2010-02-04
Updated: 2016-05-02
Substitution Date: 2015-02-04
Expiry Date: 2021-05-01

IMQ S.p.A. - I-20138 Milano
Via Olmantino 43
tel. +39 0259731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the “Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC”. This is a translation of the Italian text, which prevails in case of doubts.