



TECHNOLOGY FOR CLINICAL BIOPHYSICS

User's Manual

Cliniporator System Prototype

Control Unit Model: CC01

Power Unit Model: PU01

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User's Manual

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2 INTRODUCTION

2.1 Features

The Cliniporator Prototype is an electroporation device designed for use on tissue samples and in animal trials.

It offers the following features:

- **Pulse Generation** - Generation of pulse sequences characterised by high voltage electroporating pulses and low voltage “electrophoretic” pulses.
- **Pulse Measurement** – Measurements and recording of voltage and current pulses in time
- **Pulse Control** - Real time control of pulse shape for optimisation of electroporation and minimal tissue damage.
- **Archive Management** – Storing of patient and treatment information for analysis and future retrieval
- **Graphic User Interface** – Easy interaction and system operating through friendly user interface

3 SAFETY INSTRUCTIONS

3.1 Warnings


1. The design and manufacturing of the Cliniporator Prototype aimed to produce a safe device. Nevertheless it is still a prototype and not all issues which can assure safety, according to the present standards and regulations, have been addressed yet.
2. Because of the above reasons it is not recommended to employ this Cliniporator Prototype in clinical trials on human patients.
3. Wear latex surgical gloves when holding the electrodes and delivering pulses.
4. Generally, avoid touching the metal parts of the electrodes when they are connected to the device (although it is unlikely to be harmful).
5. Both the Cliniporator Console and the Cliniporator Power units need to be connected to the protective earth of the mains. This is assured if you use the supplied power supply cords (given the electrical plant protective earth).
6. *Do not use the Cliniporator Prototype if suspecting malfunction.*
7. If suspecting malfunction contact the manufacturer
8. Internal parts of the device reach High Voltage (above 1000V). Do not open the console and power unit cases!

3.2 Cautions.

1. Take particular care to avoid short circuiting the electrodes when delivering pulses.
2. Be sure capacitors are completely discharge before powering off the power unit.
3. Disconnect from the mains both the Console and the Power Unit before cleaning any part of the system.

4 INSTALLATION PROCEDURE AND SET UP

For correct and safe installation of the *Cliniporator System Prototype*, is recommended carefully to follow the instructions below:

- Extract the console from its package avoiding excessive shocks or jolts.
- place the equipment still closed by the hard protection cover on a plane surface clean, dry and sufficiently large to house the whole system
- unscrew the black knob placed on the upper part of the protection cover until the cover is completely released from the base
- lift the protection cover and take it out of the working area
- connect a mains supply cord to the socket placed on the back of the **Cliniporator Console**, then connect the plug to a mains outlet with protective earth.
- connect the mouse/keyboard adapter to the corresponding connector placed on the back of the console and identified by the symbol .
- Connect the mouse cable to the proper connector of the adapter, as illustrated in Figure 1.
- connect a mains supply cord to the socket placed on the back of the **Cliniporator Power Unit**, then connect the plug to a mains outlet with protective earth.
- Power ON the system acting on the mains switches placed on the back of the Console and of the Power Unit close to the sockets for the power supply cord. The units are ON when the mains switches are pressed in I position. They are OFF when pressed in O position.

4.1 Mouse and External Keyboard Connection

It is possible to connect an external keyboard and/or mouse of PS/2 type to the Cliniporator Console. For this purpose connect the keyboard to the mouse adapter as illustrated in Figure 1.

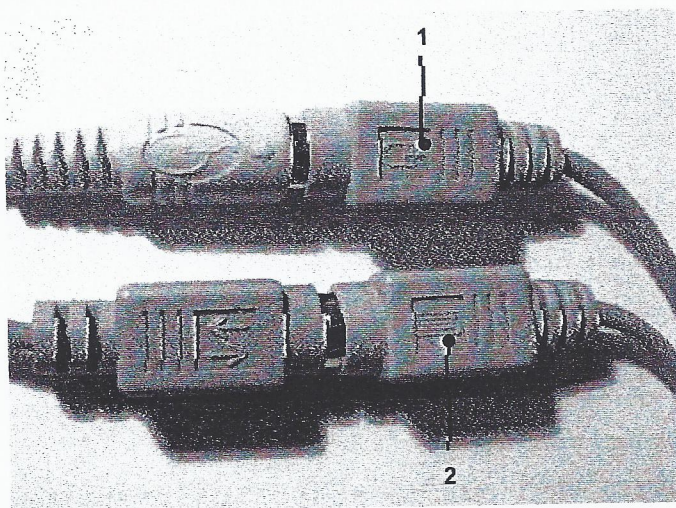


Figure 1. Connection of the mouse (1) and of an external keyboard (2).

4.2 Intranet connection

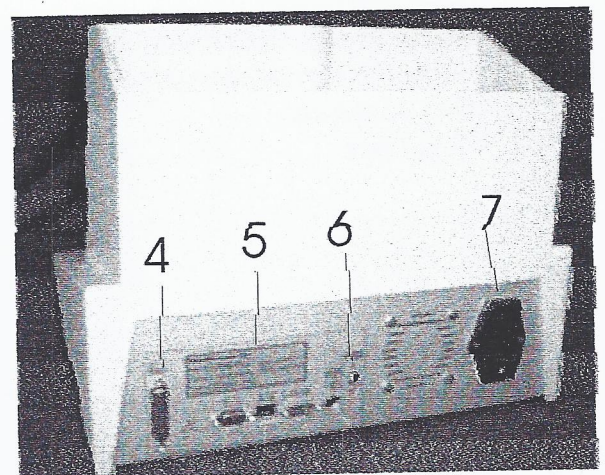
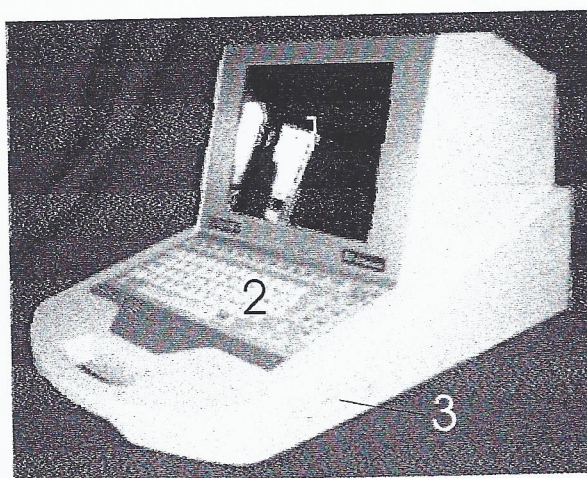
Connect an ethernet cable (not supplied) to the ethernet port on the rear of the console. Contact the Network administrator of your Local Area Network for setting up the Network Connection.

5 CLINIPORATOR – SYSTEM DESCRIPTION

5.1 System Components

Quantity	Component
1	Console
1	Power Unit
1	Console hard cover
2	Mains supply cord
1	Serial communication cable
1	Connection cable for keyboard and PS/2 external mouse
2	Spare protection fuses
1	External Serial Mouse
1	User's and maintenance manual
1	Installed Software Licence Agreement

5.2 Cliniporator Console Description



8 9 10 11

Figure 2. Cliniporator Console

1. LCD Monitor
2. Internal Keyboard
3. Floppy Disk Unit
4. Parallel Port
5. Data Plate
6. Keyboard Selection Switch

7. Mains Switch, Power Supply cord connector and Mains Fuses
8. External Monitor connector
9. Ethernet Connector (LAN)
10. Serial Port Connector
11. Mouse and Keyboard adapter connector

5.3 Cliniporator Power Unit Description

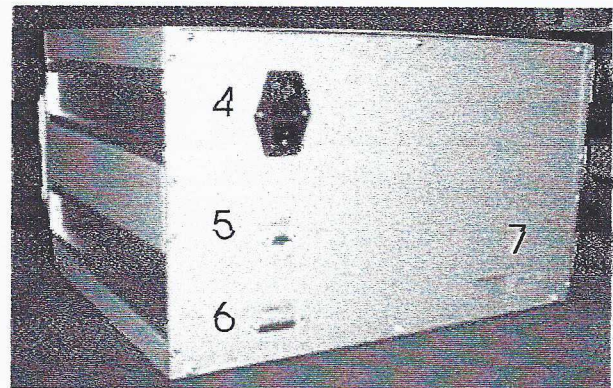
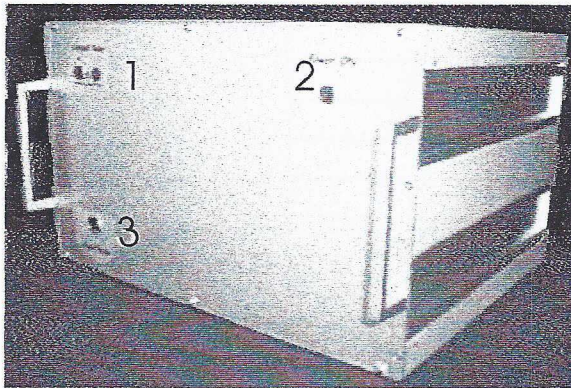


Figure 3. Cliniporator Power Unit.

1. Output Pulse 4mm safety sockets
2. Power ON indicator
3. Pedal connector
4. Mains Switch, Power Supply cord connector and Mains Fuses
5. Serial Communication connector
6. D25 connector
7. Data Plate

5.4 Graphic Interface Description

5.4.1 Cliniporator Main Screen

The **Cliniporator Main Screen** (see Figure 4) is loaded automatically at system start up.

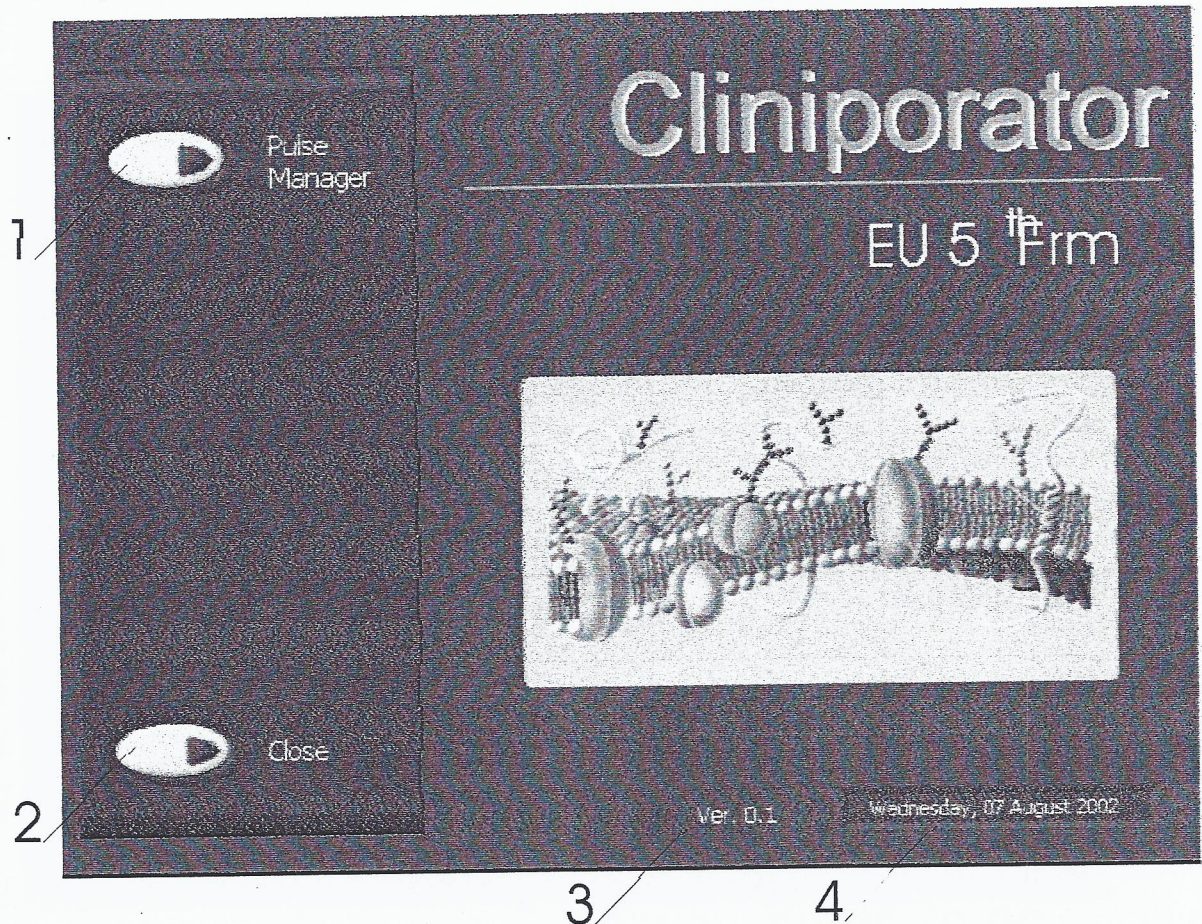


Figure 4. The Cliniporator Main screen.

1. **Pulse Manager** button. Leads to the **Pulse Manager** screen.(3.3.2)
2. **Close** button. Closes the **Cliniporator Main Screen**, shuts down the Cliniporator Prototype application and returns to Windows 2000 operating system.
3. Current software version
4. Current date

5.4.2 Pulse Manager

5.4.2.1 Pulse Manager – Sequence Scope

Pulse Manager Screen (see Figure 5) presents:

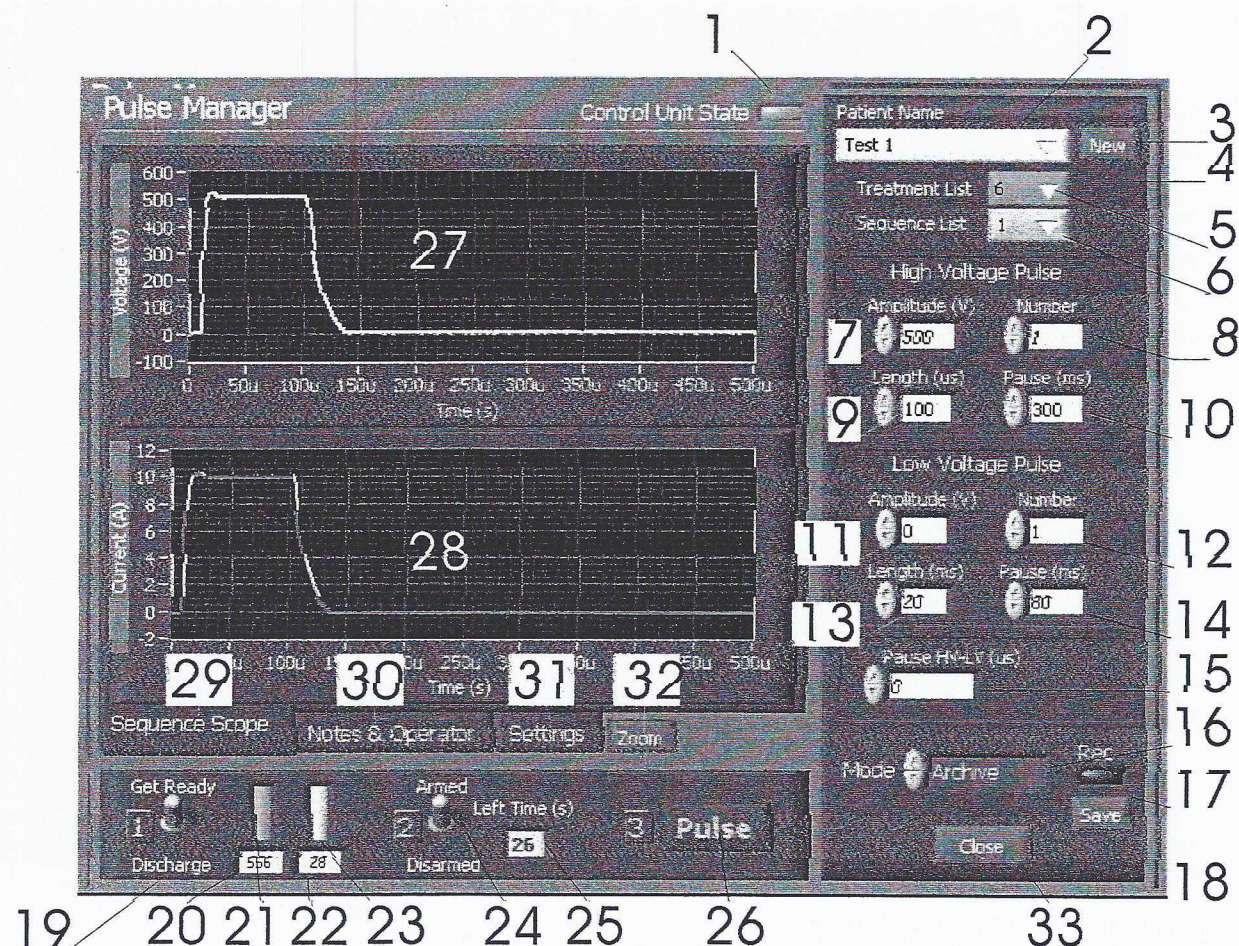












Figure 5. The Pulse Manager Screen.

1. **Control Unit State** **Control Unit State** indicator.
2. **Patient Name** drop-down list of the patients in the current archive. Patients are listed by family name in alphabetical order. Click on a name from the list to select the patient.
3. **New** button. Opens **Patient Data** window (3.3.2.1).
4. **Next** button. Appears only in **Recording Mode**. Starts another treatment to which next pulse sequences will be assigned.
5. **Treatment List** (drop-down) of the treatments the selected patient (displayed in **Patient Name**) underwent. Patient treatments are listed by date. Click on a patient treatment record to select the treatment.
6. **Sequence List** (drop-down). Allows to select a pulse sequence from the selected patient

treatment, which will be displayed on the graphs.

7. **High Voltage Pulse Amplitude** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 10V. Minimum allowed value is 1V. Maximum allowed value is 1100V.
8. **High Voltage Pulse Number** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 1. Maximum allowed value is 20. Minimum allowed value is 1.
9. **High Voltage Pulse Length** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 10us. Maximum allowed value is 200us. Minimum allowed value is 10us.
10. **High Voltage Pulse Pause** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 10 ms. Maximum allowed value is 3000 ms. Minimum allowed value is 500ms.
11. **Low Voltage Pulse Amplitude** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 1V. Maximum allowed value is 200V. Minimum allowed value is 0V.
12. **Low Voltage Pulse Number** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 1. Maximum allowed value is 20. Minimum allowed value is 1.
13. **Low Voltage Pulse Length** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 10ms. Maximum allowed value is 400ms. Minimum allowed value is 0 ms.
14. **Low Voltage Pulse Pause** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 10 ms. Maximum allowed value is 3000 ms. Minimum allowed value is 1 ms.
15. **Pause HV-LV** setting box. Type in the box or click on  to increase/decrease the displayed value. Minimum step is 10 us. Maximum allowed value is 20000 us. Minimum allowed value is 0 us.
16. **Pulse Manager Mode**. Click on  to change the **Pulse Manager** working mode. There are two possible working modes: **Archive Mode** and **Recording Mode**.
17. **Rec Indicator**. It is green when in "Recording" Mode.
18. **Save** button. Saves the last sequence.
19. **Get Ready/Discharge** switch. Prepares the machine for the treatment.
20. **High Voltage Capacitors digital** indicator. Displays the voltage present on the High Voltage capacitors in volts.
21. **High Voltage Capacitors status** indicator. Indicates whether the High Voltage capacitors are discharged, being charged or already charged to the necessary voltage.
22. **Low Voltage Capacitors digital** indicator. Displays the voltage present on the Low Voltage

capacitors in volts.

23. **Low Voltage Capacitors status** indicator. Indicates whether the Low Voltage capacitors are discharged, being charged or already charged to the necessary voltage.
24. **Armed/Disarmed switch**. Appears only when the machine is ready for the treatment.
25. **Time Remaining box**. Indicates the time remaining for starting the pulse sequence, before the "Pulse" Button is automatically disarmed.
26. **Pulse button**. Appears when the Armed/Disarmed switch is in Armed position. Starts pulse delivery sequence with parameters that have been set.
27. **Voltage Pulse** graph display.
28. **Current Pulse** graph display.
29. **Sequence Scope** tab button. Click on **Sequence Scope** tab button switches the to **Sequence Scope View**. (Figure 5).
30. **Notes and Operator** tab button. Click on **Notes and Operator** tab button switches to **Notes and Operator Tab View** (Figure 7).
31. **Settings** tab button. Click on **Settings** tab button switches to **Settings Tab View** (Figure 8)
32. **Zoom** button. Leads to the **Sequence Pulse Analysis Screen**. (Figure 10).
33. **Close** button. Closes the current **Pulse Manager** screen and returns to **Cliniporator Main Screen**

5.4.2.2 Patient Data Window



The screenshot shows a 'Patient Data' window with the following fields and callouts:

- 1**: Points to the 'Family Name' label.
- 2**: Points to the 'Given Name' label.
- 3**: Points to the 'Birth Day' section, which includes 'Day' (2), 'Month' (4), and 'Year' (1960) fields.
- 4**: Points to the 'Sex' label.
- 5**: Points to the 'Close' button.
- 6**: Points to the 'Save' button.

The window also contains a 'Family' text box, a 'GivenName' text box, and a 'Male' dropdown menu for sex.

Figure 6. The Patient Data Window

Patient Data window (Figure 6) presents:

1. **Family Name** text box. Type patient family name.
2. **Given Name** text box. Type patient first name.
3. **Birth Day**. Insert patient birth day by setting patient's day, month and year of birth. Click on  to increase/decrease the displayed values of birth **Day**, **Month** and **Year**.
4. **Sex Male/Female**. Click on  to set the patient sex.
5. **Close** button. Closes the **Patient Data** window and returns to the **Pulse Manager Screen**.
(NOTE: Data are lost if not saved).
6. **Save Data** button. Adds the patient data as inserted above to the **Patient List** and stores it in the current Working Archive.

5.4.2.3 Notes and Operator Tab View

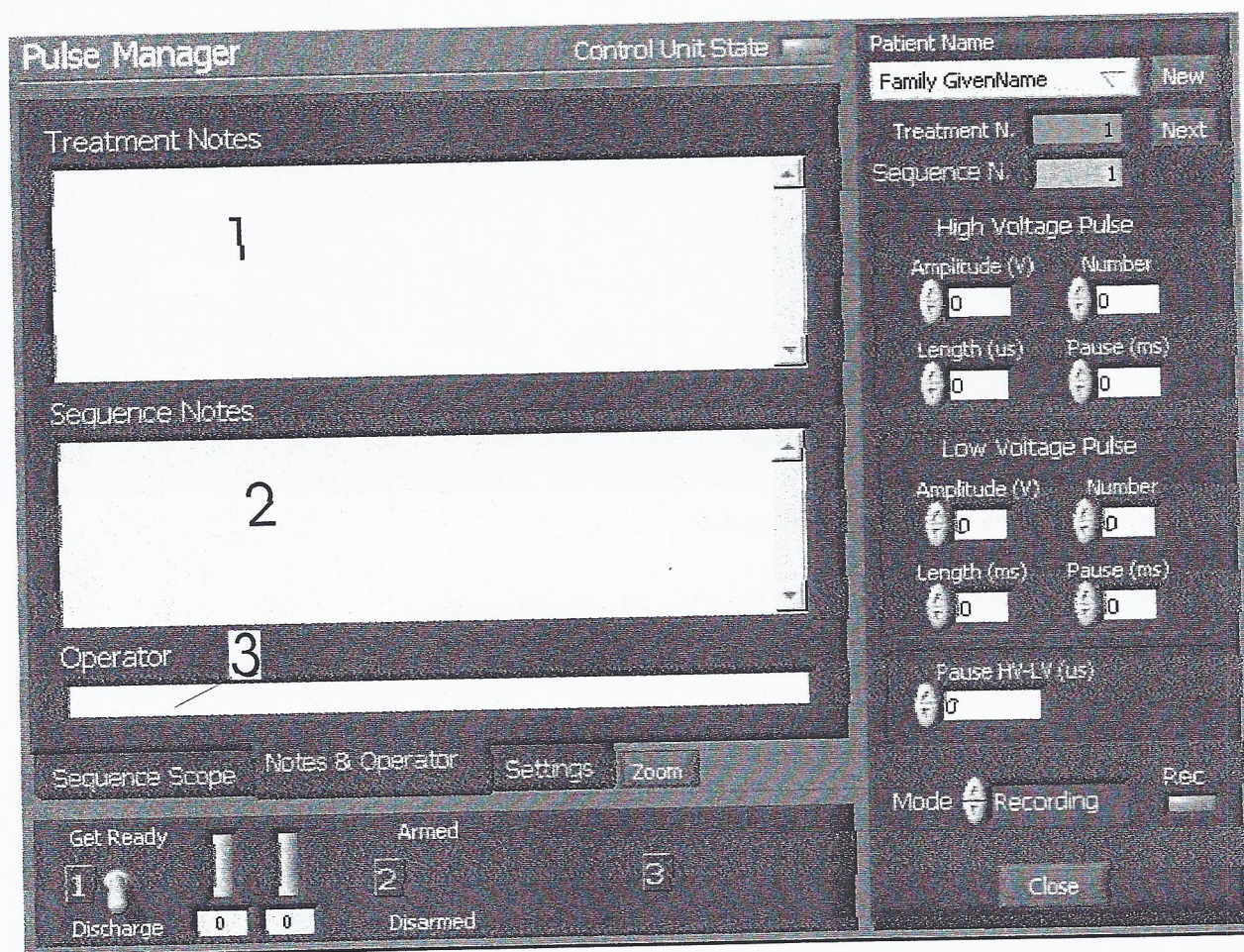


Figure 7. The notes and operator tab.

The **Notes and Operator Tab** presents three text fields that may be optionally filled (Figure 7):

1. **Treatment Notes** text field. The stored annotations concern the whole treatment.
2. **Sequence Notes** text field. The stored annotations concern only the single sequence being delivered.

3. **Operator** text box. To insert the name of the operator who is performing the treatment.

5.4.2.4 Settings Tab View

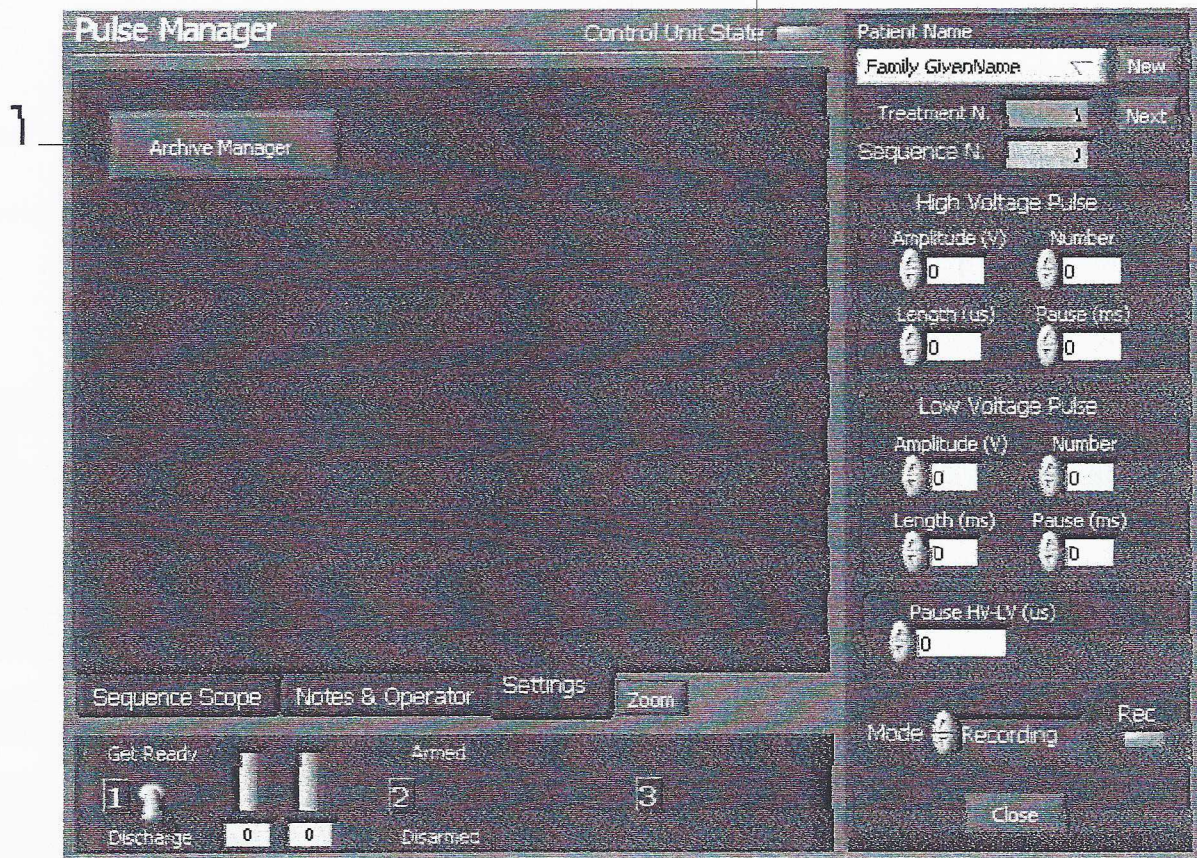


Figure 8. The Pulse Manager Settings Tab

The Pulse Manager Settings Tab View (Figure 8) presents:

1. **Archive Manager** button. Leads to the Archive Manager screen (3.3.3)

5.4.3 Archive Manager

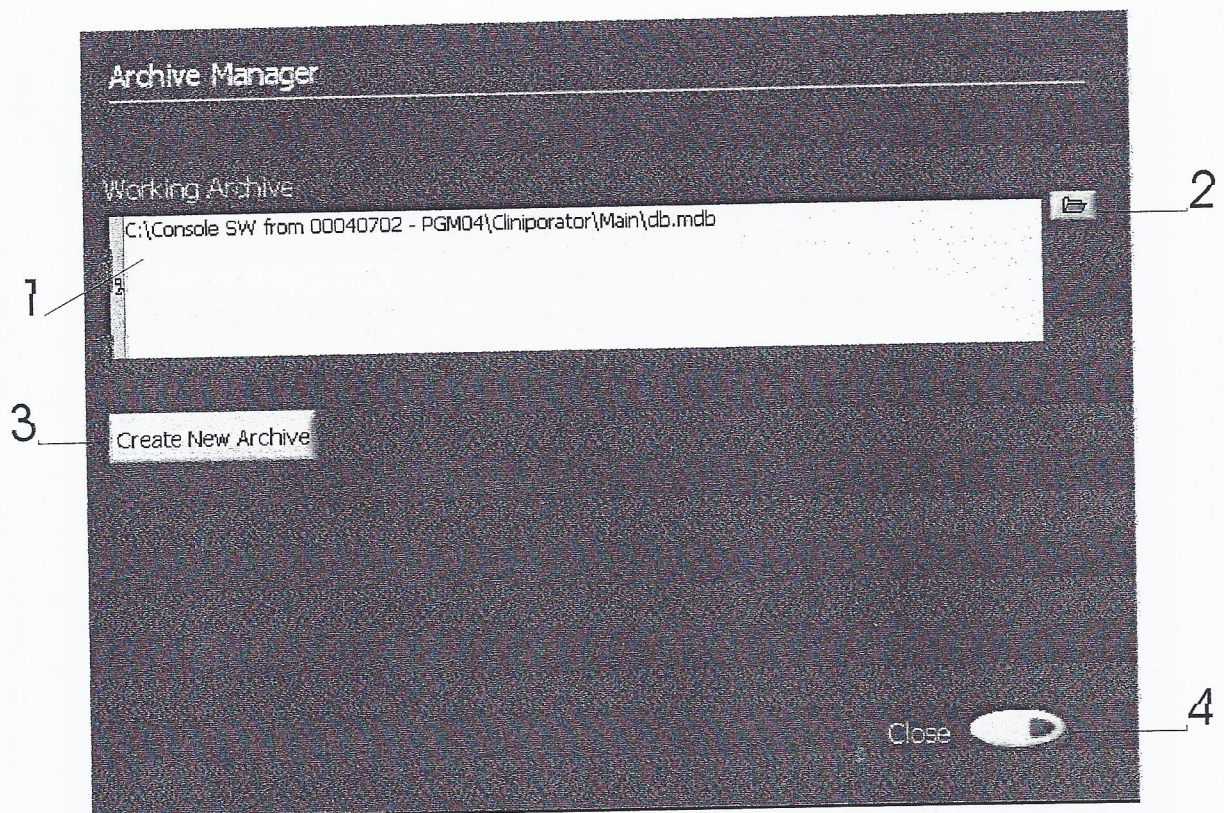


Figure 9. The Archive manager window.

Archive Manager screen (Figure 9) presents:

1. **Working Archive.** Displays the current working archive.
2. **Browse button.** Opens standard Windows **Open file** browser window.
3. **Create New Archive buttons.** Opens standard Windows **Save file** browser window.
4. **Close button.** Closes the current **Archive Manager** screen and returns the Pulse Manager screen.

5.4.4 Sequence Pulse Analysis Screen

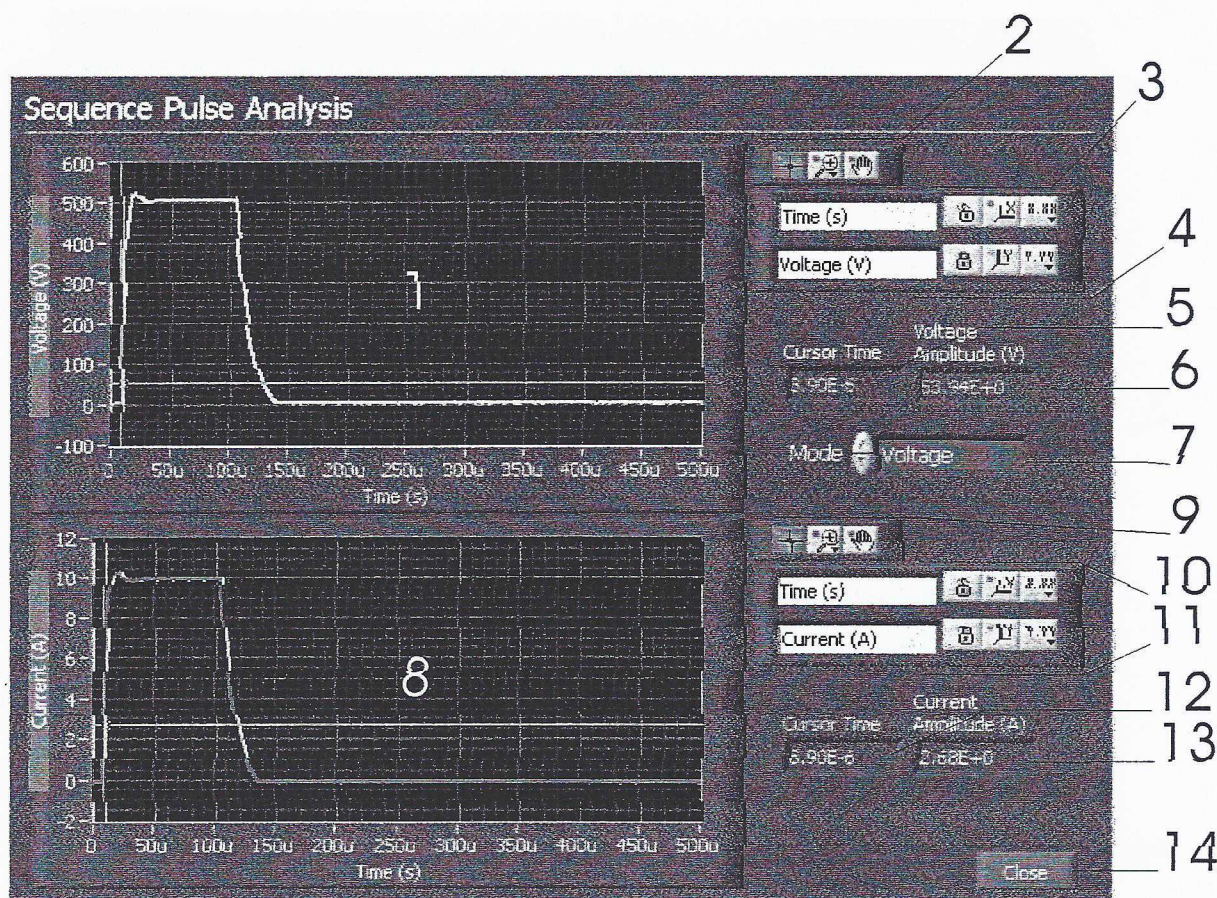


Figure 10. The Sequence pulse analysis Screen.

Sequence Pulse Analysis Screen (Figure 10) presents:

1. **Voltage Pulse Graph** display.
2. **Voltage Pulse Graph tools.** Click on a button to select the tool:

- Cursor Drag
- Zoom
- Graph Drag

3. **Voltage Pulse Graph X-Axis tools.** Include:


X-Axis Label text box.


Autoscale X-Axis buttons. Click to auto-scale the X-Axis. The **Lock** button toggles automatic auto-scale activation.


X-Axis button. Displays X-Axes properties menu. Allows setting X-Axis format, precision, mapping mode, colour, grid, and other scale and label properties.

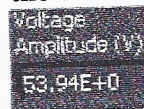
4. **Voltage Pulse Graph Y-Axis tools.** Include:

 **Y-Axis Label** text box.

 **Autoscale Y-Axis** buttons. Click to auto-scale the Y-Axis. The **Lock** button toggles automatic auto-scale activation.


 **Y-Axis** button. Displays Y-Axes properties menu. Allows setting Y-Axis format, precision, mapping mode, colour, grid, and other scale and label properties.

5.  **Voltage Graph Time Cursor** box. Displays the current position of the cursor in the Time axis.

6.  **Voltage Amplitude.** Displays the current position of the cursor in the Voltage axis.

7. **Current Pulse Graph** display.

8. **Current Pulse Graph** tool bar. Click on a button to select the tool:


 **Cursor Drag**


 **Zoom**

 **Graph Drag**

9. **Current Pulse Graph X-Axis tools.** Include:

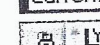
X-Axis Label text box.


 **Autoscale X-Axis** buttons. Click to auto-scale the X-Axis. The **Lock** button toggles automatic auto-scale activation.


 **X-Axis** button. Displays X-Axes properties menu. Allows setting X-Axis format, precision, mapping mode, colour, grid, and other scale and label properties.


10. **Current Pulse Graph Y-Axis** tool bar. Includes:


 **Y-Axis Label** text box.

 **Autoscale Y-Axis** button. Click to autoscale the Y-Axis. The **Lock** button toggles automatic autoscale activation.

 **Y-Axis** button. Displays Y-Axes properties menu. Allows to set Y-Axis format, precision, mapping mode, colour, grid, and other scale and label properties.

11.  **Voltage Graph Time Cursor** box. Displays the current position of the cursor in the Time axis.

12.  **Current Amplitude** box. Displays the current position of the cursor in the Current axis.

13. **Waveform Analysis Mode Selection.** Click on  to change the Waveform Pulse Analysis mode. There are 2 Analysis Modes: voltage-and-current or conductance-and-current. See also Paragraph 6.7.1.
14. **Close button.** Closes the **Sequence Pulse Analysis** screen and returns to the **Pulse Manager** screen. Figure 5

6 SYSTEM START UP AND OPERATION

6.1 System Start Up

Turn the Console ON, pressing on I position the mains switch, positioned on the back of the Console.

Turn the Power Unit ON, pressing on I position the mains switch, positioned on the back of the Power Unit.

Wait until the Cliniporator Main screen appears (see Figure 4).

To proceed click the Pulse Manager Button. The **Control Unite State** indicator (Control 1 on Figure 5) turns green, showing that Console and Power Unit are communicating correctly through the serial cable.

6.2 Working Modes

The Pulse Manager has two working modes: Recording Mode and Archive Mode. Pulse Manager recording mode is the working mode for pulse generation and visualisation of the measured waveforms just after treatment delivery.

Pulse Manager Archive Mode allows to view information concerning previous treatments, like treatment parameters and notes, and to analyse previously recorded waveforms. The working mode is selected acting on the control 16 of Figure 5.

6.3 Treatment and sequence meaning

A sequence is made by one ore more pulses the system delivers automatically according to the settings. All pulses of the same sequence are delivered on the same place (e.g. the same tumor, or the same part of the tumor).

A sequence is composed of at least one High Voltage electroporating pulse, followed by none, one ore more Low Voltage electrophorating pulses. All High voltage pulses of the sequence are equal and equally spaced in time. Similarly all Low Voltage pulses are equal are and equally spaced in time.

A treatment is a set of sequences delivered one after the other on the same patient, in the same treatment session, but generally not in the same place.

Delivering a treatment composed of several sequences is the fastest way to repeat the delivery of the same pulse sequence on different locations e.g. on different tumors or different parts of a tumor, or even on different samples or animals. However all the sequences are assigned to the same patient.

It is possible to modify any of the parameters characterising each pulse sequence within the same treatment.

6.4 Treatment delivery

To deliver a treatment do the following:

- 1) Select the working archive and select the patient from the patient list (or create a new patient).
- 2) Set or retrieve the parameters describing the pulse sequence
- 3) Be in Recording Mode
- 4) Deliver and save all sequences, adding Notes or the name of the operator if desired.

To pass to a new treatment either select another patient or increase the treatment number, press the "Next Button" (control 12 of Figure 5).

At the end follow the Shut Down Procedure (Paragraph 6.8).

6.4.1 Patient selection and management

To select a patient from the current archive, act on the control 12 of Figure 5.

To change the working archive or add a new patient, proceed as described in paragraph **6.6-Archive management**.

After a patient is selected the screen presents the patient name, and the default next number for treatment and pulse sequence according to the patient treatment records.

6.4.2 Pulse parameters meaning

High Voltage Pulse Amplitude: The amplitude of the High Voltage electroporating pulse(s), expressed in Volts.

High Voltage Pulse Number: The number of High Voltage electroporating pulses.

High Voltage Pulse Length: The duration of the High Voltage electroporating pulse(s), expressed in microseconds (us).

High Voltage Pulse Pause: The time between subsequent high voltage pulses, expressed in milliseconds (ms). This parameter is ignored if there is only one High Voltage Pulse.

Low Voltage Pulse Amplitude: The amplitude of the Low Voltage electrophorating pulse(s), expressed in Volts.


Low Voltage Pulse Number: The number of Low Voltage electrophorating pulses.

Low Voltage Pulse Length : The duration of the Low Voltage electrophorating pulse(s).

Low Voltage Pulse Pause: The time between subsequent Low Voltage pulses, expressed in milliseconds (ms). This parameter is ignored if there is none or one Low Voltage Pulse.

Pause HV-LV : The time between the end of the last High voltage pulse, and the start of the first Low Voltage Pulse expressed in microseconds (us). This parameter is ignored if there are no Low Voltage pulses.

6.4.3 Setting the parameters describing the pulse sequence

To set the parameters describing the pulse sequence type in the text boxes or use the control  to set the desired values. Parameters minimum and maximum limits and incrementation steps are specified in paragraph 5.4.2 .

6.4.4 Retrieving pulse parameters from previous pulses

It is possible to copy from previously delivered pulses the parameters defining the pulse sequence. To do this pass to archive mode and select the archived pulse sequence. Moving back to recording mode the parameters describing the previously delivered pulse sequence remain in the corresponding fields, and therefore define the pulse sequence that will be delivered next.

6.4.5 Pulse Sequence Delivery

Once the sequence parameters are set, to deliver the pulse sequence do the following:

Click the **Get Ready/Discharge** switch to move it up to "Get Ready" position. And wait while the system accumulates on capacitors the energy necessary to complete the pulse sequence. The High Voltage capacitor and Low Voltage capacitor status indicators (numbers 21 and 14 of 5.4.2.1 Table of Contents). Progressively colour green, from bottom to top. Once all necessary energy is stored, the **Armed/Disarmed** switch appears.

Click the "**Armed/Disarmed**" switch, to move it up to "Armed" position. The **Start** button appears.

1. Click the **Start** button to deliver the pulse sequence.

Once the sequence is delivered, the measures waveforms are transferred from the Power Unit to the Console and the user is prompt to save them in the archive.

After engaging the "Start" button, the pulse sequence must be started (clicking the "Start" button) within 30 seconds. After this time elapses, the "Armed/Disarmed" lever goes down to "Disarmed" position. And the "Start" button disappears. To deliver the pulse sequence move it up to "Armed" position again.

After 5 minutes that the capacitors remain charged but no pulse sequence is delivered, the "Get Ready/Discharge" switch is moved back to "Discharge" position. And the capacitors are automatically discharged. To deliver the pulse sequence move it up to "Get Ready" position again.

The **Sequence Scope** tab of the Pulse Manager initially displays blank graphs.

When a treatment pulse sequence is applied, the **Pulse Manager-Sequence Scope** screen automatically displays the measured **Voltage** and **Current** waveforms, in the upper and lower graph respectively.

6.4.6 Notes & Operator

It is possible to add Additional information concerning the whole treatment (like diagnosis or annotations) or concerning each pulse sequence composing the treatment. They are saved in the

database along with the measured waveforms.

A special field is reserved to indicate the operator performing the treatment.

Select the Notes & Operator tab of the Pulse Manager and fill in the desired fields (see also Figure 7).

Note: Notes & Operator information has to be inserted before saving the waveforms.

6.5 Waveform Storage

6.5.1 Storing Waveforms immediately after the pulse

Once the pulse sequence is completed, the following window appears, displaying the information that will be stored in the current archive along with the waveforms.

The image shows a software window titled "Sequence Summary". Inside, there is a section titled "LV amplifier test". Below this, there are two columns of parameters. The left column is for "High Voltage Pulse" and the right column is for "Low Voltage Pulse". Each column has five input fields. At the bottom of the window, there is a question "Do you want to save current sequence?" with "Yes" and "No" buttons.

Sequence Summary	
LV amplifier test	
Treatment N. 8	Sequence N. 1
High Voltage Pulse	Low Voltage Pulse
HV Amplitude (V) 10	LV Amplitude (V) 0
HV Number 1	LV Number 1
HV Length (us) 10	LV Length (ms) 0
HV Pause (us) 500	LV Pause (ms) 1
Pause HV-LV (us) 0	
Do you want to save current sequence?	
Yes No	

Figure 11. The Sequence Summary Window

If all fields are correct, press the button "Save" to save the measured waveforms and displayed information.

Press the button "Cancel" to go back to the Pulse Manager. It will be possible to save the

measured waveforms and all the related information later on.

To add or change the displayed notes or operator, press "Cancel", and select the Notes and Operator Tab from the Pulse Manager. (See 6.4.6).

6.5.2 Storing waveforms from the Pulse Manager Screen

If the waveforms shown in the Voltage and Current Graphs have not been saved yet (e.g. they have not been saved immediately after delivering the pulse sequence), to save them click the "Save Button" on the Pulse Manager screen (18 at page 3).

6.6 Archive management

The Cliniporator Prototype offers the possibility to operate with several archives stored on the hard Disk of the console.

6.6.1 Working Archive Selection

To select or change the working archive, that is the archive where treatments are being stored or retrieved from, do the following:

From **Pulse Manager Screen** (See Figure 5) select the **Settings** tab. And click the **Archive Manager** button to access the **Archive Management** screen.

To locate and set the archive you want to work with, click the **Browse** button. A standard Windows **Open** file browser appears. Browse the hard Disk to locate the desired Archive. Once the working archive is set, use the Close button to confirm the change and exit the **Archive Management** screen.

6.6.2 Creating a new Archive

To create a new archive click the **Create New Archive** button. A standard Windows **Save** file browser appears. Browse on the Hard Disk the folder where to create the new archive. Type the name of the new Archive. Click the "Save" button to confirm the creation of the new archive or "Cancel" to quit.

To set the new archive as the working Archive, use the procedure for changing the working archive described above.

6.6.3 Treatment Information Retrieval

To retrieve stored information and waveforms from the Archive, do the following:

Select the archive containing the desired waveform or information as the working Archive.

Select the desired Patient in the drop-down **Patient List**.

As a result of the selection the drop-down **Treatment List** presents a list of the treatments the patient underwent, ordered by date.

Select the desired treatment.

Select the desired Pulse Sequence from the drop-down **Sequence List**.

Additional information about the selected patient treatment: name of the operator, diagnosis and annotations can be viewed clicking the **Notes and Operator** tab button of the Pulse Manager.

6.6.4 Creating a new patient

To add a new patient to the working Archive do the following:
From the Pulse Manager Screen, click on the **New** button. The **Patient Data** window appears.
Insert all patient information: Name, Family Name, Sex, Birthday.
After typing into the fields press the "enter" key of the keyboard or click into a different field.
To add the patient to the current archive, once all information is input, press the "**Save Data**" button. The button is not enabled until all necessary information is inserted.
To quit the screen without saving click the **Close** button

6.6.5 Operating on Archives

At present the software of the Cliniporator Prototype does not include features to modify the *information stored into the archive*. For this purpose it is necessary to use commercial software applications for archive manipulation (E. g. Microsoft ® Access TM).

6.7 Waveform Analysis

The Pulse Manager –Sequence scope screen (see Figure 5) displays either the last delivered pulse sequence or the pulse sequence just retrieved from the archive. Besides, the sequence defining parameters show the values that had been set, to deliver the pulse sequence.

To analyse in detail the selected pulse sequence use the **Zoom** button. The **Sequence Pulse Analysis** screen appears, as described in Figure 10 of paragraph 5.4.4.

The **Sequence Pulse Analysis** screen offers tools to analyse the displayed waveforms. All features are described in the paragraphs below.

The **Close** button on the **Sequence Pulse Analysis** screen closes that screen and returns to the **Pulse Manager** screen.

6.7.1 Voltage, Current and Conductance

The cliniporator prototype measures the voltage and current delivered during the pulse sequence and calculates the ratio between the measured current and the measured voltage, which is named *conductance*.

The graphs visualise either the measured voltage and current waveforms or the calculated conductance waveform and the current waveform.


See also Paragraph 8.2 - Current limitations.

Select the desired combination acting on the control:

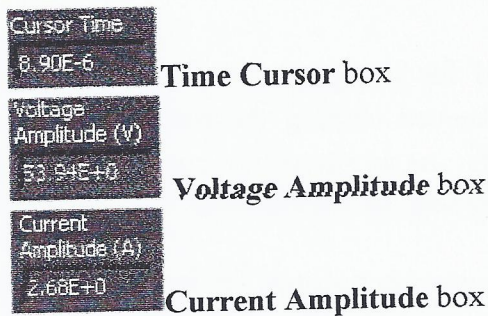


6.7.2 Cursor measurement


A cursor can be moved along the voltage and current waveforms. In each graph the cursor position is displayed in the **Time Cursor** box. It represents the time elapsed from the beginning of the acquisition. The **Voltage Amplitude** box shows the voltage measured at the given time. The **Current Amplitude** box shows the measured current at the given time.

To change the position of the horizontal or the vertical cursor click the **Cursor Drag tool** button  (when selected appears in dark grey colour). Then position the mouse cursor on the graph *cursor and drag it to the desired position*. Note that the mouse cursor changes its shape when is

placed upon the graph cursor.





6.7.3 Zoom


To zoom the waveforms select the **Zoom** tool button  (when selected appears in dark grey colour).


Then from the popping up panel select one of the zoom functions.


Zoom functions allow to:

Zoom in the entire graph: Select the **Zoom In** tool  and click on the graph location where you would like to centre the graph window. Having the Zoom In tool selected, the waveform enlarges every time you click on the graph.


Zoom out the entire graph: Select the **Zoom Out** tool  and click on the graph location where you would like to have the centre the graph window. Having the Zoom Out tool selected, the waveform shrinks every time you click on the graph.

Zoom an area of the graph: Select **Graph Area Zoom**  tool and drag a rectangle around the area you would like to enlarge.



Stretch Vertically: Select **Stretch Vertically Area Zoom**  tool and, moving vertically, drag an horizontal strip that includes the area you would like to enlarge. The X-scale will not change.



Stretch Horizontally: Select **Stretch Horizontally Area Zoom** tool  and, moving horizontally, drag a vertical strip that includes the area you would like to enlarge. The Y-scale will not change.

6.7.4 Graph drag

Graph drag allows seeing with the same resolution the pulse behaviour beyond the graph view. To drag the pulse graph select the **Graph Drag** tool button  (when selected appears in dark grey colour). Then position the mouse cursor on the point where the graph should be dragged from, with a click grasp the point (the mouse cursor changes its shape) and drag it in the desired direction.



6.7.5 Scale setting and autoscale

By default X and Y scales are automatically adjusted for the graph to display the whole waveforms. Automatic scaling can be activated or removed clicking the button . When autoscaling is removed the lock on the button is open: . As an alternative, autoscaling can be set or removed right clicking the graph area and selecting or de-selecting the "autoscale" property.

X and Y axes can be singularly auto-scaled clicking the **Autoscale buttons**:  for the X axis and  for the Y axis. These buttons adapt automatically the scale but don't affect the auto-scale setting. When autoscale is set, the LED on the button icon becomes green.

To set a particular upper or lower limit of the X and Y scales, click on the maximum or minimum values of the scales and type the desired value. The graph scale is automatically adjusted accordingly.

6.7.6 Axes settings

To set X and Y axes format, precision, mapping mode, colour, grid and other scale and label properties, use the **X-Axis** button  and **Y-Axis** button .

6.7.7 Graph Export

Graphs can be exported to other applications. Right click on the graph area and select the "Copy" command. The graph is copied to the clipboard and can be pasted into another application (e.g. a document).

6.8 Shut Down Procedure

Before Exiting the Pulse Manager, Discharge capacitors moving down the "Get Ready/Discharge" lever (Control 13 of Figure 5).

Click the Close button to close the Pulse Manager screen and return to the Cliniporator Main Screen.

Click the Close Button of the Cliniporator Main screen to to quit the cliniporator application and move to the operative system.

Shut down the Console clicking on the Windows "Start" Button, selecting "Shut Down" and confirming.

Wait until the message "It's now safe to turn off your computer" appears.

Turn off the Console turning the Mains switch on the rear to O position.

Turn off the Power Unit turning the Mains switch on the rear to O position.

NOTE: If you click the Pulse Manager "Close" button while the capacitors are still charged, the Pulse Manager does not close. Instead, the "Get Ready/Discharge" lever is moved to discharge

position. Once the capacitors are discharged click again the "Close" button to quit the Pulse Manager.

7 TROUBLESHOOTING

7.1 Documented Problems

Malfunction	Possible Reasons	What to do
Keyboard not working	Wrong keyboard selection External keyboard disconnected	1. Check that the switch on rear panel is in the correct position (INT = console keyboard. EXT = external keyboard plugged to the mouse-keyboard adapter)
Mouse not working	Wrong connection	1. Check if it is to the right connector of the mouse adapter
System does not get ready to generate pulses	Power unit OFF or disconnected from console.	1. Check the power unit is ON (Green Light on front panel) 2. Check that the serial communication cable is plugged both to the Console and to the Power Unit and that the retaining screws are screwed in
No pulse delivery	Electrodes disconnected or hardware failure	1. Check that the electrodes are connected to the Power Unit. 2. Contact Manufacturer

7.2 ASSISTANCE:

For assistance please contact:

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Email: pmmargotti@igea.it

Tel. +39 059 699600

Fax. +39 059 695778

Address:

IGEA S.r.l.
Via Parmenide 10/a
41012 Carpi – MO
ITALY

8 TECHNICAL DATA

8.1 Pulse Characteristics

8.1.1 High Voltage Pulse

Maximum HV Output	960-1000V
Minimum HV Output	50-80V
Maximum Current to the load	16-16.5 A
Maximum HV repetition frequency	2 Hz
Maximum HV Pulse Interval	3000ms
Minimum HV Pulse Interval	500ms
Maximum HV Pulse Length	200 us
Minimum HV Pulse Length	30 us

8.1.2 Low Voltage Pulse

Maximum LV Output	160-200V
Minimum LV Output	20-50V
Maximum Current to the load	16-16.5 A
Maximum LV repetition frequency	1 kHz
Maximum LV Pulse Interval	3000ms
Minimum LV Pulse Interval	1ms
Maximum LV Pulse Length	20 ms
Minimum LV Pulse Length	0 us

8.2 Current limitations

8.2.1 Measurement

Presently the Power Unit measures and transmits to the Console only the first 5 milliseconds from the beginning of the first pulse of the sequence. The remaining part of the low voltage pulse and other eventual high voltage pulses are not measured.

8.2.2 Pulse amplitude accuracy

Output pulse amplitude differs less than ± 15 V from the set value, when the set value is in the range 160-850 V for the High Voltage part and less than ± 5 V when the set value is in the range 40-120V for the Low Voltage part.

Above 850V for the High Voltage and 120 V for the Low Voltage, the set pulse values produce in facts pulses of lower amplitude. Nevertheless, the same pulse settings produce the same output within ± 15 V for the High Voltage and ± 5 V the Low Voltage).

9 MAINTENANCE AND SERVICE

9.1 Cleaning

9.1.1 Control Unit Cleaning

- To clean periodically the device use a soft cloth dry or slightly dampened with water. **Do not pour water or any other liquid** directly on the device, **do not use alcohol or solvents or other aggressive products** to clean the device! The use of aggressive detergent products can discolour or damage the covering of the case.
- The dirt remaining between the keys of the keyboard can be removed with a small vacuum cleaner (reduced power).
- The screen can be cleaned with a soft cloth dampened with water. Do not use spray or aerosol products directly on the screen to avoid that the liquid penetrates inside damaging the components.

9.1.2 Mouse Cleaning

If the pointer moves with difficulty or irregularly, or the small ball does not move freely inside the device, it is necessary to clean it.

To clean the mouse follow these indications:

1. Switch the Console and Power Unit off, following the procedures described.
2. Disconnect the mouse cable from the Console.
3. Turn the mouse upside-down in order to have the lower part turned up-wards.
4. Remove the cover of the small ball of the mouse rotating in an anticlockwise direction.
5. Take the small ball out of the mouse.
6. Use a wad of cotton soaked with isopropyl alcohol (slightly abrasive) to clean the small ball; before cleaning the small ball wring out the wad of cotton to eliminate the alcohol in excess.
7. Dry the small ball with a clean cloth which does not leave residues on it.
8. Blow inside the small ball holding space to remove possible dust residues from the inside.
9. Clean the rollers contained in the holding space with a wad of cotton and a detergent for heads or another similar product (non oily).
10. Replace the small ball in its holding space and close the cover again.
11. While power is off, connect the mouse cable to its adapter.

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