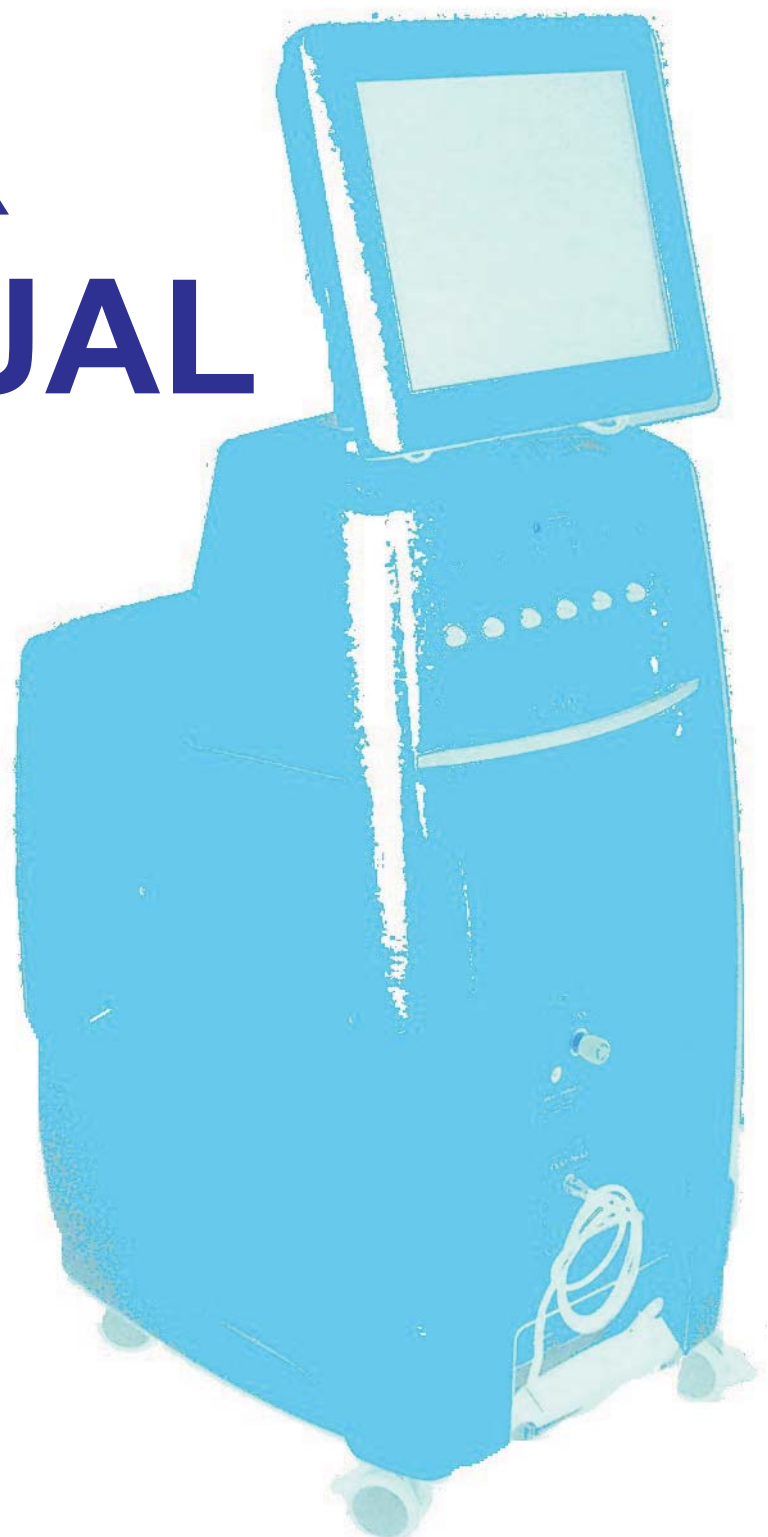


HVP-VG

USER MANUAL



HVP-VG Treatment Manager Application version 1.x

Read thoroughly this manual before operating the unit: the present manual is fundamental part of the HVP-VG custom electroporator device and should always accompany the device.

The HVP-VG shall be operated exclusively by personnel who received specific training.

RESEARCH ONLY – NOT FOR HUMAN USE

HVP-VG – Treatment Manager Application version 1.x

This manual consists of 27 pages

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1 SAFETY INSTRUCTIONS

1.1 Warnings

1. The HVP-VG has a BF class applied part. Do not ground it while applying a treatment (e.g. when using an external measurement device like an oscilloscope).
2. Internal parts of the device reach High Voltage (above 1000V). Do not open the unit!
3. For electrical safety the device needs grounding. Use only the supply cord supplied by the manufacturer or one equivalent. Make sure to connect the unit to a properly grounded mains system, and that the power supply cord is fully compatible with mains sockets.
4. Before plugging the unit to the mains, make sure that mains power supply cord is not damaged. Replace in case of damage: mains cords cannot be repaired.
5. Do not connect or disconnect the device from the mains with wet hands.
6. Observe mandatory prescription for installation of the HVP-VG in the vicinity of devices that make use of flammable anaesthesia mixtures with oxygen or nitrous oxide and parts that are connected to such devices and might contain flammable mixtures.
7. In case flammable anaesthesia mixtures with oxygen or nitrous oxide are employed, it is required to observe mandatory prescription when placing tubing or parts that might contain flammable mixtures in the vicinity of the HVP-VG or in the vicinity of the area to be treated.
8. Whenever necessary, replace mains fuses only with spare fuses specified on the **Data Plate**, which is on the rear part of the device.
9. The present User Manual is fundamental part of the HVP-VG device and should always accompany the device. Operators must refer to this manual for correct information on the use of the device.
10. Read thoroughly this User Manual before operating the unit. Do not hesitate to contact the manufacturer in case of doubt on the correct use of the unit.
11. Wear latex surgical gloves when holding the electrodes and while delivering pulses.
12. Avoid short circuiting the electrodes when delivering pulses.
13. Do not use the HVP-VG if suspecting malfunction. Contact the manufacturer.
14. Avoid any liquid enter the unit.
15. Store and install the unit away from direct sunlight, heat sources, dust; in particular, do not expose the display to direct sunlight for long time.
16. Respect environmental operating and storing conditions.
17. Do not obstruct aeration grids, which are on the rear part of the unit. Verify periodically that nothing is obstructing the grids, in order to allow a correct ventilation of the internal circuits.
18. Avoid shocks to the equipment during transport.
19. Avoid scratching the display. Follow cleaning instructions.
20. Before carrying out any cleaning of the system or of its parts, power it off and disconnect the cord from the mains.

2 GENERAL DESCRIPTION

The unit consists of a computer that runs a graphic user interface and a power part controlled its own control logic. The user interacts with the device by means of the touch-screen incorporated in the display and a double pedal.

The computer communicates with the control logic of the power part by means of an optically isolated USB communication.

The unit incorporates also a RFID identification card, connected to the computer by a RS-232 cable.



Figure 1. General Description

1. User Interface Computer, Display and Touch screen
2. Display regulation controls
3. Treatment Output sockets (High Voltage)
4. Handle
5. Emergency STOP button
6. Stop button status indicator
7. Pedal connector
8. Double pedal
9. Front pocket (it can room the double pedal)
10. Wheel brake (on each wheel).
11. USB optically isolating cable
12. Storage space
13. Synch TTL Input (e.g. ECG synch)
14. Trigger TTL Output (e.g. to trigger scope acquisition)
15. Data Plate label
16. Mains Cord
17. Rear pocket (it can room the mains cord and the User Manual).



Figure 2. Rear Panel

1. Strain relieve screw (unscrew to replace mains cord)
2. Ventilation grids
3. Synch Input (e.g. ECG synch)
4. Trigger Output (e.g. to trigger scope acquisition)
5. Mains fuses' drawer
6. Mains Switch
7. Mains cord plug
8. Data plate label



Figure 3. Connection under the User Interface Computer

1. Free USB connector
2. External PS2 Keyboard connector
3. External Mouse Connector
4. Connector to USB optically isolating cable
5. RS232 connector to RFID card
6. User Interface Power Switch

3 INSTALLATION AND START UP

3.1 System location

The HVP-VG must be installed and operated in an environment that respects the operating conditions specified in Paragraph 7.4.

The HVP-VG must be installed in a way that its ventilation grids are free. Care must be taken to avoid items (e.g. dust covers) to occlude them.

WARNING!

The unit needs grounding. The supplied *Mains Cord* can ensure proper grounding only if connected to properly grounded mains system, through suitable mains sockets.

WARNING!

Observe mandatory prescription for installation of the HVP-VG in the vicinity of devices that make use of flammable anaesthesia mixtures with oxygen or nitrous oxide and parts that are connected to such devices and might contain flammable mixtures.

3.2 Installation instructions

For correct and safe installation of the HVP-VG, it is recommended to follow carefully the instructions below:

- Connect the *Mains Power Supply Cord* to the plug placed at the *Power Unit's* back. Connect the plug to a grounded mains outlet.
- Make sure the *USB optically isolating cable* as well as the serial cable for the RFID card are connected below the *User Interface Computer* as illustrated below:
- Turn ON the equipment, acting on the *Mains Switch* at the back of the unit. The unit is ON when the mains switch is pressed in "I" position. It's OFF when pressed in "O" position.

3.3 External Keyboard and mouse connection

It is possible to connect an external PS2 keyboard and/or mouse to the connectors placed under the *User Interface Computer* (see Figure 3).

3.4 Unit's Start Up

- Switch the *Mains Switch* at the back of the unit to "I" position.
- Wait until the first screen of the *Treatment Manager Application* appears.

3.5 Unit's Shut-Down


- Exit the *Treatment Manager Application*.
- Wait until the message "It's now safe to turn off your computer" appears.
- Turn off the unit, moving its *Mains Switch* to the "O" position.


3.6 Touch screen user interface

The touch screen user interface behaves similarly to a mouse, with the basic difference that it is sufficient to touch the point where the cursor should go in order to move it to the desired position.

Touching the graphic controls equals to a single left-click with the mouse.

Double tapping on an icon or control equals to a double left-click with the mouse, although it

might be easier to use the  key of the virtual keyboard. Should a **right click** be necessary,

just hold the finger on the desired point for a few seconds, or use the  key of the virtual keyboard.

More precise interaction can be achieved using a thin, **not sharp** object.

ATTENTION! Hard, sharp, pointed objects may scratch the screen.

4 GRAPHIC SOFTWARE INTERFACE DESCRIPTION

4.1 Startup screen

At start-up the system runs a start-up sequence of tests. If it completes successfully then it loads automatically the *Treatment Manager Application* and displays its *First Screen*, else it displays an error message, a close window then operative system's desktop.

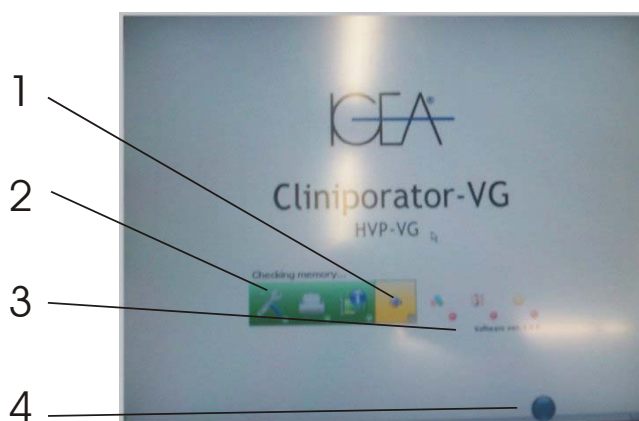


Figure 4. Start-up screen

1. Running Test
2. Passed Test
3. Software version
4. Click to start on-Screen virtual keyboard whenever needed

4.2 Information Screen

The *Information Screen* is shown automatically after system's start up test. It allows to enter information that will be stored in an xml file, after the treatment, along with data measured during the treatment.

The Patient ID is the only mandatory field that needs to be entered before proceeding to treatment.

This screen has also the shut-down button to close the application and shut down the unit.

The screenshot shows the 'Information' screen of the IGEA HVP-VG Electroporator. The screen is divided into several sections: 'Patient information' (Name, ID number, Age), 'Clinical data' (Clinical indication, Targeted area), 'Case information' (Procedure date, Physician name, Case notes), and 'Institution' (Address, Contact info, Logo). At the bottom, there is a 'Shut-down' button and a 'Next' button. Numbered callouts point to specific elements: 1. Patient Name text box, 2. Patient's ID number text box, 3. Patient's Age selector, 4. Clinical Indications text box, 5. Lesion size selectors, 6. Unit Shut-down button, 7. Procedure date indicator, 8. Physician's Name text box, 9. Case Notes text box, 10. Institution's data indicator, 11. Institution's logo, 12. Next button.

Figure 5. The *Information* screen.

1. Patient **Name** text box.
2. Patient's **ID number** text box. This is the only mandatory field
3. Patient's **Age** selector
4. **Clinical Indications** text box.
5. Lesion size selectors.
6. Unit **Shut-down** button. Closes the *Application* and shuts down the unit.
7. **Procedure date** indicator. The date is set automatically by the system.
8. Physician's **Name** text box.
9. **Case Notes** text box. Allows adding case or treatment specific information.
10. **Institution's data** indicator. The content of this field can be customised to display the data of the institution that owns the unit. By default it shows unit's manufacturer information.
11. **Institution's logo**. The image can be customised to display the logo of the institution that owns the unit. By default it shows unit's manufacturer logo.
12. **Next** button. Tap here once filled in the required fields, to proceed to the next screen.

4.3 Probe Selection

The *Probe selection* screen allows setting how many probes will be used. Choosing *Bipolar probe*, the unit sets for using a bipolar probe, with fixed treatment parameters. Choosing *Custom*, it is required to enter the number of probed that are foreseen and it will be possible to set treatment parameters as needed.

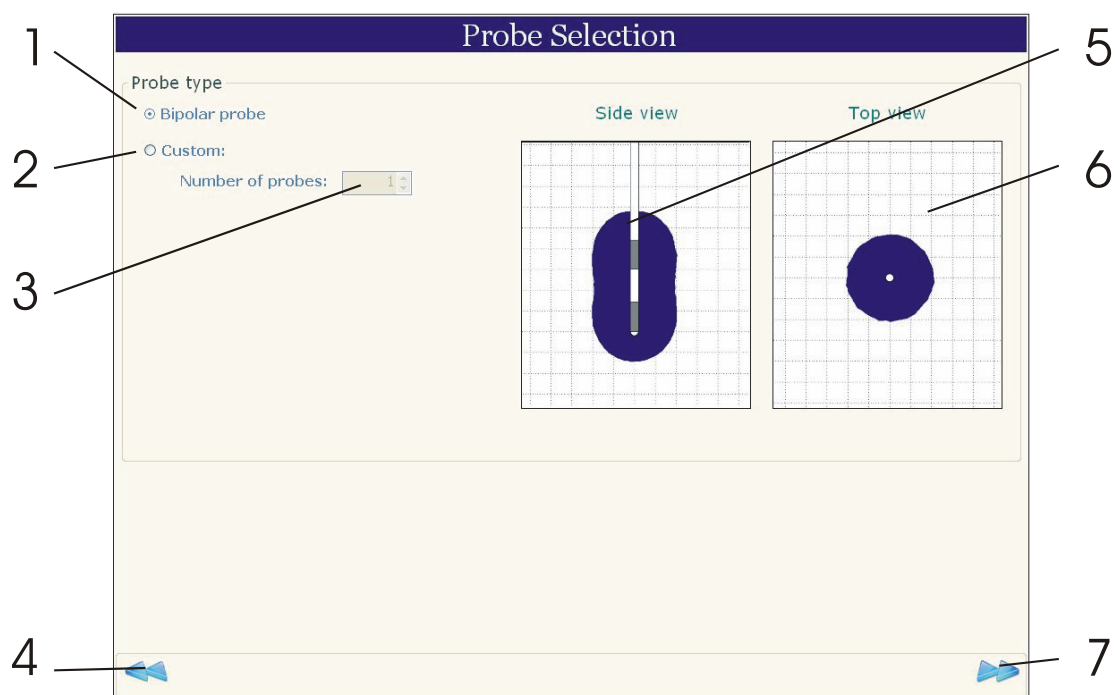


Figure 6. The *Probe selection* screen.

1. **Bipolar probe** selector. Selecting this option allows to use only a bipolar probe (or two probes) with fixed treatment parameters.
2. **Custom treatment** selector. Selecting this option allows up to six probes, and treatment parameters can be set as needed.
3. **Number of probes** selector. Enter how many probes are to be used.
4. **Back** button. Goes back to the *Information* screen (i.e. the first screen).
5. **Side view** representing the electric field distribution for a bipolar probe.
6. **Top view** representing the electric field distribution for a bipolar probe.
7. **Next** button. Leads to the next screen.

4.4 The *Probe Placement Process* screen

The *Probe Placement Process* consists of activities that are indeed performed on the patient (i.e. probe application at the treatment site) and activities to be carried out on the graphic user interface, in order to instruct the unit with the required treatment parameters.

When using more than two probes, treatment parameters are likely to vary between probe couples, besides the user has the freedom to choose how to pair the probes for the treatment.

The Graphic user interface provides a grid that facilitates the probe placement process and helps keeping univocal association between the probes that are applied to the patient and their representation on the user interface.

Under the grid there are as many numbered circles as the required probes (the number of required probes has been set in the previous screen). Each numbered circle represents a probe.

The numbers on the circles correspond to the numbers of the treatment output sockets; therefore each circle represents the probe connected to the corresponding treatment output socket.

To benefit from the graphic tool, the user should position the numbered circles on the grid in a way that resembles as close as possible how the probes are placed at the treatment site. This way, once completed the probe placement process, the user looking at the grid will have a picture of the treatment site and it will result easier to choose probe pairs to be used for the treatment, and assign correctly treatment voltage according to probe distance and the required electric field.

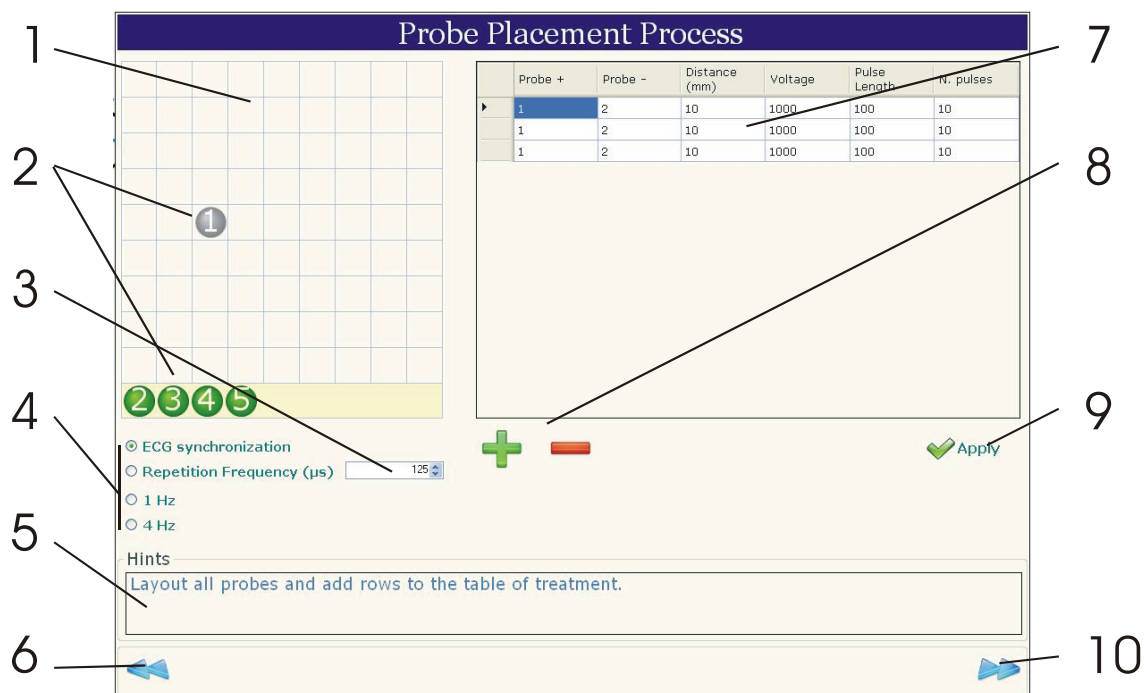


Figure 7. The Probe Placement Process screen

1. Grid where to reproduce actual probe placement
2. Numbered circles representing the probes. Tap on the circle then tap in the position corresponding to where the probe is actually placed.
3. Repetition period, expressed in microseconds. Enter here the time that must elapse between each pulse start in the treatment pulse sequences. The repetition period is the sum of pulse length and pause between the end of a pulse and the start of next pulse within the pulse sequence. The repetition period is also the inverse of the pulse repetition frequency. E.g. 8 kHz pulse repetition frequency corresponds to 125 us, 1 kHz pulse repetition frequency corresponds to 1000 us.
4. Pulse repetition options:
 - **ECG synchronization**: each pulse is delivered synchronously with an external triggering signal that must be supplied through the ECG synch input.
 - Custom **Repetition period**: pulses will be spaced according to the specified timing.
 - **1 Hz** standard repetition frequency: pulses within each pulse sequence will be repeated at 1 Hz (i.e. one per second).
 - **4 Hz** standard repetition frequency: pulses within each pulse sequence will be repeated at 4 Hz (i.e. four per second, one every 250 ms, or 250000 us).
5. Hints text box. This text box suggests the user what he's expected to do.
6. **Back** button. Goes back to previous screen.
7. Treatment parameters table (see below).

8. Add and Remove a treatment sequence buttons. The + button adds a new line in the treatment parameters table; the - button removes the selected line from the treatment parameters table. In order to proceed to treatment it is necessary to add at least one line.
9. **Apply/Edit** button. This button shows the “Apply” label while the table is in editing mode and the values can be changed. Once all needed values have been entered tap on the Apply button to confirm them. The button then will show the “Edit” label. To change the entered values or add/remove lines from the table, tap on the button and enter edit mode. The label will change to “Apply”. It is not permitted to leave the screen and proceed to the treatment while the table is in edit mode. It is required that the user taps on the **Apply** button. If treatment parameters violate the constraints specified at paragraph 4.4.2, when tapping on the **Apply** button the corresponding table’s row will colour red and it won’t be possible to proceed to treatment unless the violation is removed.
10. **Next** button. Leads to the next screen.

4.4.1 The *Treatment Parameters* table

The treatment consists of pulse sequences that are applied between probes. Each row of the table corresponds to a pulse sequence.

Pulses are characterised by the following parameters:

- The probes between which it is applied a voltage difference. It is possible to specify which probe will be the positive probe (**Probe +**) and which probe will be the negative probe (**Probe -**), with respect to each other (i.e. no probe is grounded; both probes are separated from ground). Obviously Probe + must differ from Probe - .
- **Distance** between probes in mm. This information is used by the software only to calculate a voltage-to-distance ratio, which is often used in order to provide a single number that is somehow related to the electric field that is created in the tissues during the treatment.
- **Voltage**, in volts. Corresponds to the pulsed voltage difference that will be applied between the probes.
- **Pulse length**, in microseconds. It is the pulse duration, i.e. for how long it is applied the voltage difference for each pulse. This parameter is common to all pulses of the sequence and to all pulse sequences. I.e. to all table rows. If it is changed in one row, the same value is applied to all rows.
- **Number of pulses**. It specifies how many pulses make the pulse sequence.
- The **Pulse Repetition Period** or the **Pulse Repetition Frequency**, which are two equivalent ways to express the time between each pulse start, within a pulse sequence. This parameter is ignored when the pulses have to be synchronous with the external triggering signal (i.e. ECG synchronisation option)
- The **time interval between pulse sequences**. This parameter is fixed, since it is a physical constraint that depends on the hardware, and it is **6 seconds**. When the ECG synchronisation option is set, the next pulse sequence will start at the first valid triggering pulse after this time has elapsed.

To change parameters’ values just tap on the required box in the table and type the required value or use the on-screen keyboard arrows to change it.

The following table shows additional information about the treatment parameters.

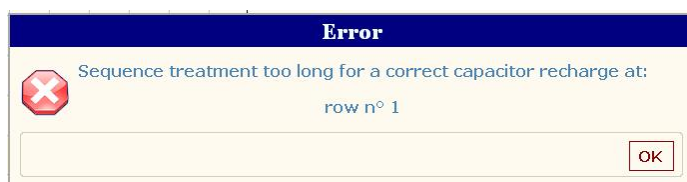
Parameter	Min value	Max value	Step	Default value
Probe +	1	6	1	1
Probe -	1	6	1	2
Distance (mm)	1	30	1	10
Voltage (V)	500	3000	100 ⁽¹⁾	1000
Pulse Length (us)	50	1000	10 ⁽¹⁾	100
N. pulses	1	100	1	1

⁽¹⁾ Can be set to other values using the keyboard.

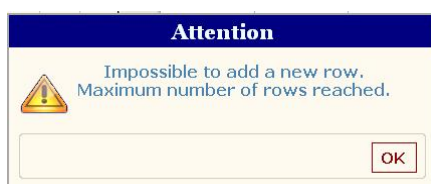
4.4.2 Treatment parameters constraints

There are the following constraints between treatment parameters:

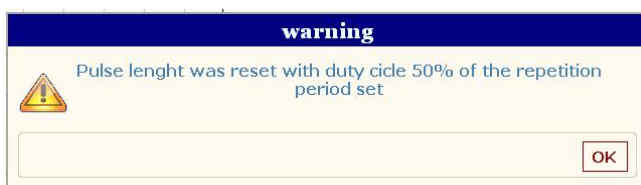
- 1 In each pulse sequence: number of pulses x pulse length \leq 2000 us (i.e. 2 ms).
If treatment settings violate this rule, i.e. the treatment sequence is too long, it is necessary to reduce either the number of pulses in the treatment sequence or their length.



- 2 The maximum number of treatment pulse sequences is 10. If more treatment sequences are needed, just command additional treatment applications, varying treatment settings as needed.



- 3 The duty cycle: Pulse Length / Pulse Repetition period x 100 \leq 50%, i.e. pulse length cannot exceed half of the pulse repetition period. If treatment settings violate this rule, the system will automatically reduce the pulse length to the half of the pulse repetition period. As an alternative, the user may comply by increasing the pulse repetition period (i.e. reducing the pulse repetition frequency).



If the constraints are not respected, when tapping on the **Apply** button of the *Probe Placement Process* screen, an error message appears, indicating which constraint has been violated and the numbers of table's rows to be corrected. Rows violating the constraints will be coloured red.

4.5 The Pulse Generation screen

The treatment starts by applying a test pulse per each treatment sequence. The test pulse is a single pulse with fixed 100 us duration and amplitude that varies with the voltage set for the treatment pulse sequence. Namely its voltage is 1/10 of the set voltage for the treatment

sequence, with a minimum of 200 V, i.e. when the treatment voltage is below 2000 V, the test pulse has 200 V amplitude

After applying the test pulse the system evaluates the voltage and current measured during the pulse, uses this measurement to foresee what current is expected during the treatment, and allows to proceed to treatment only if the estimated current is below 45 A. Else it gives a current-too-high warning.

If the current measured during the test pulse is very low the system gives a too-low-current warning, nevertheless it allows proceeding to treatment.

After the test pulse, if it is possible to proceed to treatment, the system automatically charges the internal capacitors to a voltage that guarantees the required pulse amplitude.

Once the capacitors are charged, the user can command the treatment pressing first the left pedal (arm) then the right pedal (pulse). The system signals to the user when it is ready to accept the left or the right pedal.

The right pedal must be pressed within 10 seconds after the left pedal.

As the treatment starts, the system provides an audible indication in the form of a single long beep. While the treatment is in progress the system emits two short beeps after every treatment sequence. When the treatment ends it emits two long beeps.

Once the treatment has ended, the system shows on the screen the voltage and current waveforms measured during the treatment, then it automatically discharges the internal capacitors.

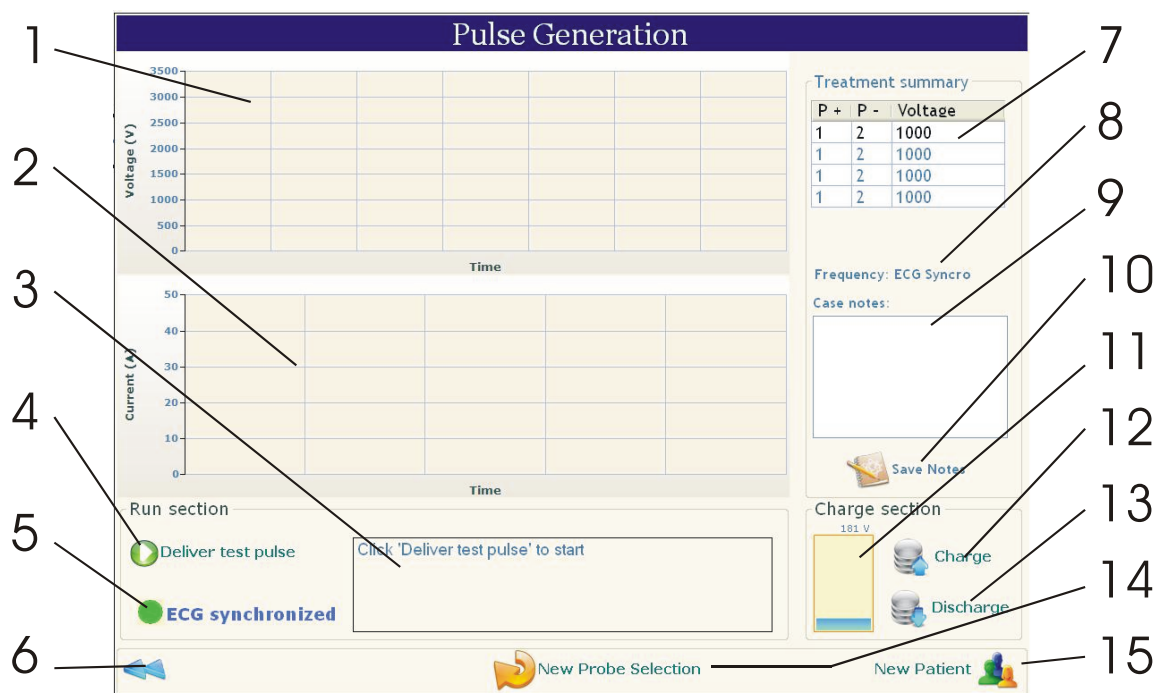


Figure 8. Pulse Generation screen

1. **Voltage** waveform graph. Once the treatment is completed, it shows the measured voltage waveform. Tapping on the waveforms zooms on the corresponding pulse sequence.
2. **Current** waveform graph. Once the treatment is completed, it shows the measured current waveform. Tapping on the waveforms zooms on the corresponding pulse sequence.

3. **System status** and instructions indicator. Informs the user about system status and provides instructions on what the user is expected to do.
4. **Deliver test pulse** and **Abort** button. Tap to send the pre-treatment test pulse(s). This button becomes the **Abort** button while the pre-treatment test or the treatment itself is running. The **Abort** button can be used to interrupt the treatment. No data will be saved.
5. **ECG synchronised** indicator. When in synchronous treatment delivery mode, shows whether the system senses a valid triggering signal on the ECG synch input: GREEN = valid triggering signal, YELLOW: momentary loss of triggering signal, RED: triggering signal has been absent for more than 15 seconds.
6. **Back** button. Goes back to previous screen.
7. **Treatment summary** table. Shows the selected probes and voltage for each treatment sequence. While the treatment is in progress, the rows of this table may change colour: YELLOW indicates that the system measured a very low current while applying the corresponding treatment pulse sequence; RED indicates that the corresponding treatment pulse sequence has been interrupted due to high current.
8. **Frequency** indicator. Shows what treatment frequency, or period had been selected, or whether the system works in synchronous treatment delivery mode.
9. **Case notes**. The user may add case notes in this field. The notes will be saved in the last treatment application file (only if the user taps on the Save Notes button).
10. **Save notes** button. Saves the Case notes in the last treatment application file.
11. **Capacitors charge** indicator. Shows capacitors' charge status and the voltage the capacitors are charged at. The indicator is "full" when the capacitors are charged to their maximum voltage.
12. **Charge** button. Allows to command capacitors' charge if they have been discharged. The button is enabled only if the capacitors have been discharged.
13. **Discharge** button. Allows to command capacitors' complete discharge. It is recommended to discharge capacitors if the treatment will not be applied shortly. Capacitors will be automatically discharged after 5 minutes of inactivity. The button is disabled when the capacitors are fully discharged.
14. **New Probe Selection** button. It's a shortcut to the *Probe Selection* screen, to apply another treatment to the same patient, using a different probe.
15. **New Patient** button. It's a shortcut to the *Information* screen (i.e. the first screen), from where it is possible to start the procedure for treating another patient, or to shut down the unit. The information entered in the *Information* screen is cleared when tapping on this button.

4.6 The On-screen keyboard

The On-screen keyboard appears automatically each time the user may need to type in a text field or enter a value. It is possible to force the keyboard to appear, by tapping on its icon (which is always on top of the screens).



Figure 9. On-screen keyboard icon.


When the keyboard overlaps useful information, it is possible to iconize it tapping the key: . If the user shuts down the keyboard tapping on the red button, it is not possible to restore it anymore, unless re-starting the system.



Figure 10. The on-screen keyboard

1. Reduce keyboard to icon
2. **DO NOT TAP this key** – Shuts down keyboard until next system re-start.
3. Right mouse button's menu.
4. Up and Down arrows can be used for changing parameters' values faster.

4.7 Stored Treatment Data

At the end of each treatment application, the system automatically saves on the hard disk a file with all data entered in the *Information* screen, and the waveform measured during the treatment. The files are given names made by the current date and time, followed by patient's name. When exiting the Treatment Manager application, before shutting down the unit, the system asks whether to export the files on a USB key.

Any time it is possible to take the stored treatment information out of the unit:

- Complete all treatments foreseen in the present date.
- before exiting the Treatment Manager application connect a USB flash disk to the free USB port
- Tap the shut-down button on the Information screen
- Follow the instructions for saving the files on the flash disk.

The files are zipped on the flash disk in a zipped file with the name of the present date.

ATTENTION!

Take care the flash disk not to have a file with the same name, or this will cause loss of data.

Once the files have been exported to a flash disk, a zipped back-up copy is kept on the hard disk, unless the files are exported a second time in the same day, in which case the backup zipped file will be overwritten.

4.8 Emergency Treatment Interruption

Besides the Abort button of the graphic user interface, which acts at software level, and which is the recommended normal way to interrupt a treatment, it is possible to interrupt via hardware the treatment, by pressing the emergency STOP button, on the front of the unit.

As well as the Abort button, this button makes the patient be disconnected from the high voltage power part. If high voltage is present on the capacitors, after pressing the emergency STOP button the unit may need to be re-started.

ATTENTION!

If the STOP button is latched it is not possible to charge the capacitors.

To release the STOP button, rotate it clockwise.

When the *STOP* button is latched the *STOP Button Status Indicator* is OFF.

5 TROUBLESHOOTING

5.1 Documented Problems and Solutions

Malfunction	Possible Reasons	What to do
Generator does not turn on	Unit unplugged from the mains or mains outlet not powered.	Check that the Mains Power Supply Cord is connected to unit's power supply group and that it is connected to a suitable Mains outlet. Check that mains' outlet is actually powered.
	Blown unit's mains fuses	Replace unit's mains fuses. ATTENTION! Replace only with fuses having identical characteristics, as indicated on the data plate.
The <i>Computer</i> does not turn on	The <i>Computer</i> is OFF.	Press the switch below the <i>Computer</i> .
System not able to charge/discharge.	STOP button latched	Twist the stop button clockwise, to release it. NOTE: When the STOP button is latched the STOP Button Status Indicator is OFF.
No current during the pulse sequence.	Probe disconnected.	Check that all probes are connected to the unit.

5.2 Error Messages

Message	Possible Reasons	What to do
Current too low between probes: {X}-{Y} Verify probes connection. Proceed to treatment?	During the pre-pulse the system detected a too low current between two probes	Check the probes connection or the probes placement. Reposition the probes.
Error while uploading treatment parameters	The systems had a problem during transfer of treatment parameters	Insert the treatment parameters again. Reboot the device to let the startup auto-test check the device.
Hardware failure	The system detected excessive current and failed.	Reboot the device to let the startup auto-test check the device.
Impossible to add a new row. Maximum number of rows reached.	The user tried to add more rows than the maximum allowed number to the Treatment Parameters table.	Additional treatment sequences must be set and commanded as a separate treatment application.
Pulse length was reset with duty cycle 50% of the repetition period set	Set pulse length exceeded the half of the Pulse Repetition period (i.e. duty cycle > 50%.	The system corrects the problem decreasing pulse length to 50% of the Pulse Repetition period. As an alternative, the user may increase the Pulse Repetition period and restore the required pulse length.
Reading error from USB3FPGA	Communication problem with the Console and Power Unit	Reboot the device to let the auto-test check the device.

Message	Possible Reasons	What to do
The current measured between probes {X}-{Y} exceeds limits. Check the probes and the values.	During the pre-pulse the system detected excessive current between two probes	Reposition the probes. Decrease the voltage between the probes.
Sequence treatment too long for a correct capacitor recharge at: row n° x	Number of pulses and pulse length in the specified treatment sequence exceed the constraint.	Decrease number of pulses in the specified treatment sequence or pulse length.
Time expired	The 10 seconds timeout between the activation of the ARM foot pedal and the PULSE foot pedal is elapsed.	Press again the ARM foot pedal to restart with a new treatment sequence.
Unable to charge/discharge	The system detected a problem during the charge or discharge of the capacitors.	Confirm that the STOP button is not engaged. Try to charge and discharge the capacitors. (Section 6.4).
Unable to complete treatment: charge failure	The system detected a charge fail during the treatment.	Reboot the device to let the startup auto-test check the device.
Unable to deliver a correct pulse	The system detected a too long pulse.	Reboot the device to let the startup auto-test check the device.
Warning! Low current between probes ({X}-{Y})	During the treatment a low current has been detected between two probes	Confirm probe connections It is recommended to repeat the treatment between probes in question.
Warning! treatment aborted between probes {X}-{Y} due to high current	During the treatment, excessive current was detected between two probes.	The system stopped the pulse delivery only between the selected probes. It is recommended to repeat the treatment between such probes.

6 MAINTENANCE

6.1 Preventive Maintenance and Periodical Verifications

The following table indicates periodical checks and preventive maintenance the user is recommended to carry out.

Test/Service	Time interval	Rationale
Inspection of Mains cords	12 months	Electrical Safety
Replacement of mains fuses	18 to 24 months	Prevent fuse blowing during treatment.

The following table indicates periodical checks and preventive maintenance for which the user should submit the unit to the manufacturer.

Test/Service	Time interval	Rationale
Calibration verification and re-calibration if needed	24 months	Maintain device performance within specifications.
Replacement of Hard Disk Drive	54 months	Prevent failure.
Replacement Power Part's internal parts	500 treatment sessions or 10 years	Prevent failure.

6.2 Cleaning

To periodically clean the device, use a soft, lint-free 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 paint.

Computer's screen can be cleaned with a soft cloth dampened with water. Do not use spray or aerosol products on the screen.

6.3 Mains Selection and fuse replacement

The device has the capability to select the mains to use it in US (115V) or in Europe (230V). Mains selection is made inserting the fuse holding drawer in the required direction.



Figure 10-1: Power Supply Group hosting the mains selector.

To select the correct Mains Value do the following:

- Make sure that the Mains Switch is on “O” position, i.e. switch-off position.
- Disconnect the Mains Power Supply Cord from the generator.
- Open the cover of the mains selector/fuse holder using a flat-bladed screwdriver.
- Pull out the fuse holding drawer, using a flat-bladed screwdriver, acting on the groove at its top. Do not lever on its sides because they may break
- Replace the fuses contained in the fuse holding drawer with new ones of the same type specified on the Data Plate Label.
- Reposition the fuse holding drawer in a way that the required voltage (115V or 230V) is read correctly (not reversed).
- The windows on the cover must show the selected mains value.
- Reconnect mains cords.

CAUTION!

This operation must be carried out by qualified technical personnel.

WARNING!

Use exclusively protection fuses of the type, current and voltage values specified by the manufacturer and indicated on the Device Plate Label.

7 TECHNICAL DATA

7.1 General information

Manufacturer: IGEA S.p.A.
Via Parmenide 10/a
41012 Carpi – MO
Italy
Model: HVP-VG

7.2 Power Supply Specifications

Mains Voltage: 115/230 VAC
Mains Frequency: 50/60 Hz
Maximum Input Power: 280 VA

7.3 Protection Fuses on the Mains:

2 fuses type T 4A 250V - 5 x 20 mm

7.4 Environmental conditions

7.4.1 Operating conditions

Room Temperature: 10 to 40°C
Relative Humidity: 30% to 75%
Atmospheric Pressure: 700 to 1060 hPa

7.4.2 Transport and storing

Room Temperature: -40 to +70 °C
Relative Humidity: 10% to 90%
Atmospheric Pressure: 500 to 1060 hPa

7.5 Classification:

FOR RESEARCH ONLY - NOT FOR HUMAN USE

7.5.1 EN 60601-1 Classification:

Protection Against Electric Shock

CLASS I

Degree of Protection Against Electric Shock

BF applied part

Ingress of Liquids:

IPX0 - No special protection.

Safety degree in the presence of flammable anaesthetic mixtures with air, with oxygen, or with nitrous oxide:

The HVP-VG is NOT SUITABLE to be employed within the regions where flammable anaesthetic mixtures may be present, specified by EN 60601-1.

7.5.2 EEC 93/42 Classification

Hazard class: Class IIb

7.6 Use conditions:

The HVP-VG is suitable for continuous operation.

Nevertheless it is suggested to shut down the device at the end of each treatment session.

7.6.1 Mechanical specifications (without packaging):

Approx. Dimensions (width x length x height): 60 x 70 x 160 cm
Approx. Weight: 70 kg

7.7 Technical Specifications










Number of Probe Outputs	6
Number of Pulses	1 to 100
Pulse Amplitude	500 to 3000V
Pulse Length	50 - 1000 μ s
Pulse Repetition Frequency	1-8000 Hz
Dwell between pulse sequences	6 s
Pulse Amplitude Precision	$\pm 3\%$
Pulse Length Precision	$\pm 2 \mu$ s
Maximum Current	50 A

7.8 Radiofrequency Identification

Module type: RFID reader/writer Soltec model KIT33039
FCC ID: WAKSK33039.

8 SYMBOLS

All the symbols used on the HVP-VG are in conformity with CEI 62-5 Directives.

Symbol	Meaning	Where it appears
	Defibrillation-proof type BF applied parts.	Printed on the <i>Data Plate</i> , on unit's back panel.
	Protection Ground Outlet	Marks protection ground chuck inside the device
	Dangerous High Voltage	Marks every part inside the device where a dangerous High Voltage potential difference might be present, except mains voltage.
	Caution: indicates that the user should read the accompanying documentation in order to understand and/or use correctly the part marked by the symbol	On the LCD Display.
	Open: when a mains switch is pressed in the position marked by this symbol, the device is switched off.	Printed on mains switch.
	Closed: when a mains switch is pressed in the position marked by this symbol, the device is switched on.	Printed on mains switch.
	Alternating Current: indicates the kind of current required to be supplied to the device.	Printed on the data plate.
 	HVP-VG and all its parts should be disposed off according to local regulation for disposal of electronic devices. FCC symbol, indicates that the device contains a part complying with USA's Federal Communication Commission Standards for the kind of equipment and classification.	Printed on the data plate. Printed on equipment Data Plate on Power Unit's back

9 END OF LIFE DISPOSAL

Life-end disposal of electronic devices in general entails hazard to the environment.

It is recommended to dispose of the HVP-VG device in accordance with local regulation for the disposal of electrical or electronic equipment, as an alternative the Device may be returned to the manufacturer.

FOR RESEARCH ONLY - NOT FOR HUMAN USE

