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IlsanDong-gu, Goyang-si,Gyeonggi-do, Korea, 10355

User's Guide

VIVA combo RF System
With
Coagulation Electrode

(ST-UM-15E(US) Rev.3)

Only the certified medical doctors, capable of conducting surgical treatment with special techniques should use the described equipment in this user's guide. The purpose of this user's guide is to present the way to use the radiofrequency lesion generator and the electrode of STARmed Co., Ltd.

Rx only

Caution

- Federal law restricts this device to sale by or on the order of a physician.

Equipment covered in this manual
VIVA combo RF System with coagulation electrode
Part No. VCS10
Effective date November 22, 2018

Notices

Manufactured for:
STARmed Co., Ltd.
(Jungsan-dong, Daebang-Triplaon Business Tower), B-dong, 4F & 12F, 158, Haneulmaeul-ro,
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Website
www.STARmed4U.com

Product Warranty

Warranty is for one year.

The company will repair this product for free during the warranty period, one year from the date of purchase, when there is malfunction or product defect that may have been a result of normal transportation and use.

Repair is charged in the following cases.

- Malfunction resulting from natural calamity such as fire, earthquake, fall etc.
- Malfunction resulting from inappropriate move of the product and user's negligent use after installation
- Malfunction resulting from unlawful renovation or repair
- Defect or malfunction occurring after the warranty period expires
- Malfunction resulting when user neglects the warning specified in this user's guide
- Replacement of consumable parts such as battery due to inevitable wear and tear resulting from use

Safety Warning

Danger
- Indication of the hazardous situation that could result in death, serious injury, or permanent impairment.

Warning
- Indication of the hazardous situation that could result in minor or moderate harm to a body structure.

Caution
- Precaution that describes an unsafe situation that could cause equipment damage or product malfunction.

Important
- Information on the proper use, storage, and maintenance of the product.

Table of Contents

1. System Overview

Caution

- Use this equipment only after reading warning, cautions and information on the product's usage.
- Use other accessories related to this equipment only after reading the warnings, cautions, and information on the product's usage. The user's guide for the electrode is provided separately.

1.1. Cautions for Electric Safety

Radiofrequency lesion generator

The equipment is designed for the safety and effectiveness of performance, but it is also important how user utilizes the equipment. Read the user's guide before operating the RF Lesion generator for tissue ablation during surgical procedures and the pump.

Caution

- User should not disassemble the equipment. Inquire with the STARmed on how to prevent electric shock.
- Disconnect the device from the power line before cleaning or performing maintenance
- Electrical medical equipment requires special precautions regarding EMC. The product needs to be installed according to EMC requirements.
- The VCS10 should not be used adjacent to or stacked with other equipment.

Warning

General

- DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
- DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
- When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.
- Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
- If the device is argon enhanced, you should include warnings and recommendations regarding gas embolisms.
- If the instrument is reusable, you should also include a warning that visual inspection alone may not be sufficient to ensure that the insulation is intact.
- DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.
- ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.

- DO NOT USE with hybrid trocar systems, i.e., a combination of metal and plastic, when using monopolar active components. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems.
- Prior to increasing the intensity, check the adherence of the neutral electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections.
- If the device uses a neutral electrode and does not have a CQM, you should include a warning that loss of safe contact between the neutral electrode and the patient will not result in an alarm.
- If the device uses a neutral electrode and does have a CQM, you should include a warning that loss of safe contact between the neutral electrode and the patient will not result in an alarm unless a compatible monitoring neutral electrode is used.
- Do not use on patients with cardiac pacemakers or other active implants.
- This equipment outputs energy that can exert physical harm.
- This equipment must only be connected to a grounded power supply.
- Be cautious not to connect any conductive items to a patient except for grounding pads.
- Connect this equipment to a grounded power supply. The user or patient could be injured due to electric shock if a grounded power supply isn't used.
- Modification of this equipment is not allowed.
- Do not use this equipment at a place that is vulnerable to explosion and/or where there is flammable material.

Caution

- The intensity should be set as low as is necessary to achieve the desired effect.
- Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.
- A time interval of approximately five minutes is required (after a coagulation procedure) to stabilize the equipment before the next procedure is started.
- Instructions that indicate the output power should be set as low as possible for the intended purpose.

Peristaltic pump

Warning

- Stop the pump immediately and remove the power cord if the pump becomes wet.
- User should not disassemble the equipment. Inquire with STARmed on how to prevent electric shock.
- Do not use this pump at a place that is vulnerable to explosion and/or where there is flammable material.

1.2. Caution for General Safety

VIVA combo RF Generator is radiofrequency generator for the cautery of the local tissue concerning the electrode's tip due to the radiofrequency current. This equipment is safe from the electric danger and it obtained the permit based on the Medical Equipment Law.

VIVA combo RF System was certified as appropriate by the IEC 60601-1, IEC 60601-2-2, IEC 60601-1-2. This is a Class 1 Type BF medical device.

Warning

- The risk of ignition by combustible gas or material at the time of electrosurgery is very high. Thus, if possible, do not place the equipment near combustible materials before the electrosurgery. Avoid using combustible anesthetic drugs, nitrogen oxide, and oxygen on the thorax or head when conducting treatment. Do not place these items near the equipment.
- Remove combustible materials used for cleaning and/or removing contaminants before conducting the radiofrequency treatment. Combustible materials remaining on the patient's body could cause a dangerous situation. There is risk of ignition even when the equipment is used normally.

Radiofrequency lesion generator with coagulation electrodes

Warning

- All electrodes from STARmed Co., Ltd. are recommended for use only with STARmed radiofrequency lesion generators. Please inquire with STARmed on the use of the VIVA, star, and Octopus radiofrequency electrodes.
- VIVA combo RF Generator's Maximum output voltage is 275Vp-p. Use the accessories with rated voltage above 275Vp-p.
- A warning indicating failure of hf surgical equipment could result in an unintended increase of output power.

Caution

- When fitting the tube into the pump's head, check the exact location after confirming the tube's measurement. Then, secure the tube by pulling on the lever so that the tube will not deviate during use.
- Always use the STARmed inflow-outflow tubing set. Use a new tubing set for each patient.
- Use only non-flammable agents for cleaning and disinfecting.
- Allow any flammable agents used for cleaning or disinfecting to evaporate before the electrosurgery.
- Information indicating, there is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina

Warning

- When radiofrequency output is suspected, even after the button on the front panel or foot switch is pressed to stop the radiofrequency output, press the main power switch located on the equipment's rear panel immediately to stop the power. Then, remove the electrode's connector from the RF generator. Stop using the equipment and request service.
- Use this equipment only at a place where emergency electric power is supplied, or use it with an UPS (Uninterruptible Power Supply) to prepare for the risk of power failure while operating the equipment.

Caution

- There may be a defect with the grounding pads or electrode cable connection if the radiofrequency output comes out too low or when the output does not come out after starting the electrosurgery. Do not increase the radiofrequency output before identifying the root cause. Confirm that the grounding pads are attached to the patient's skin correctly after a patient moves or changes posture.
- The radiofrequency lesion generator and pump may cause electromagnetic wave obstruction in other equipment even when it is operating normally. Place the other equipment as far away as possible if electromagnetic wave obstruction is generated.
- Electrodes and probes used for monitoring and imaging can disrupt the radiofrequency current. To avoid unintentional burns, place all other electrodes and probes as far away as possible from the grounding pads and the area to be treated. The use of needle injected monitoring electrodes is prohibited.

Grounding Pad

Warning

- Attaching the Grounding pads correctly at the appropriate part is crucial for the safe and effective use of this equipment, as well as to avoid grounding pad burns.
- Read the Instruction for Use (IFU) that is included with all electrodes from STARmed Co., Ltd for the correct grounding pad usage. The IFU includes the information on the preparation of the grounding pads, location for attachment, inspection, and removal.
- When using a single electrode, attach two grounding pads. It is necessary to attach four grounding pads when using multi electrodes. The radiofrequency current gets distributed more evenly when the grounding pads are attached to a wider area. This can also help prevent heat generation within the pad. The distance between each attached pad and cautery lesion should be made as equal as possible to prevent burning.
- Be careful not to overheat the grounding pads during ablation.
- Avoid air bubbles by carefully attach the grounding pads completely onto a patient. Remove body hair from the grounding pad area if necessary.

Coagulation Electrode

Warning

- Use caution after removing the electrode from the package to avoid contamination. Avoid applying excessive force to the electrode to prevent damage before use.
- Check whether there is groove or crevice in the electrode's insulation and/or cable before using the electrode. The radiofrequency current may leak out if there is an insulation

defect. This means that the amount of current that flows at the electrode's tip can decrease, and there is high possibility that burning may result in an unintended area.
- The measurement of the body's temperature through the electrode may be inaccurate even when the pump is turned off. The coolant's temperature is bound to decrease due to the circulation when the pump is being operated.
- When using the CONTINUANCE mode, adjust the settings so that the stable performance is maintained, and that the radiofrequency output can increase slowly.

Caution
- Conduct periodical performance and safety tests for the reusable cables and accessories.

Note
- Problem may result when the supplementary accessories are used once.
- Conduct periodical test of the accessories at all times, and record the results.

1.3. Surgical treatment cautions

Warning

- A standard biopsy procedure is required to place the coagulation electrode to the part that is subject to cautery.
- It is necessary to use the diagnosis image to predicate the tissue necrotic area.
- Pre-clinical training is required for the doctors by appropriate literature or education in order to use the electrode of RF Lesion generator for tissue ablation during surgical procedures.

Caution

- The equipment's performance is important to obtain safe and effective coagulation results, but the operator's skill is a significant factor as well. Please read all instructions on how to use the radiofrequency lesion generator and pump. Please provide this user's guide to operating and/or maintenance users.

Important

- If VIVA combo RF generator is affected by an electrostatic discharge(ESD) or power surge, the PC connection may get disconnected. If that happens, the PC linked program should be connected again.
- The electrode should only be used with STARmed Co., Ltd. products.

1.4. Intended Use

The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.

1.5. Contraindications

There is a risk that error may result due to the radiofrequency current on patients who have pacemakers and other active implants. Do not use the radiofrequency lesion generator and electrode on these patients.

1.6. Complications

The following types of complications may result due to the use of the radiofrequency lesion generator and electrode.

- tumor recurrence
- burn due to the over-heating of the surgical equipment
- dangerous situation due to the unskilled equipment control
- cross-infection or complications due to the re-use of the inappropriate electrode
- ascites/diarrhea
- bleeding of the coagulated part
- ventricular fibrillation

1.7. Intended PATIENT Population

a) Age : Not limited
b) Weight : > 2.5kg
c) Health: Do not use on patients that have active implants.
d) Patient's state: The patient is not the device user.

1.8. Intended USER PROFILE

Considerations		Requirement description
Education	Minimum	● Medical doctor who has medical license.
	Maximum	● N/A
Knowledge	Minimum	● Knowledge of the side effects or complications due to the error of medical device. ● Clinical expertise with appropriate literature or training
	Maximum	● N/A
Language comprehension	Minimum	● Understand the manual ● Understand the meaning of the abbreviations.
	Maximum	● N/A
Experience	Minimum	● Procedure performance and specific technology training ● Device usage and safety training
	Maximum	● N/A

1.9. Intended Conditions of Use

Considerations		Requirement description
Environment	General	● Only for professional use ● Use at the operating room in the hospital ● Keep the accuracy of output when function is operating. ● No inflammable materials. ● Connect electrode to peristaltic pump with activating coolant. ● Use only after installing the device on a flat surface ● An electrode from a different device shall be located far away
Frequency of use		● Use for a maximum of 30 minutes. ● The power cycle is 10 seconds on / 30 seconds off.
Mobility		● The device can be transported inside of hospital operating rooms.

1.10. Operating Principle

The RF generator works at 500kHz. The frequency flows to the electrode's tip and then is applied to the tissue. Frictional heat occurs and causes the ions to move from the negative pole to the positive pole and from the positive pole to the negative pole forty to fifty thousand times per second. Tissue necrosis is the principle that occurs by using heat generated from the tissue impedance.

1.11. Essential Performance

Essential performance of this equipment are as followings;
- Accuracy of output control setting
- Monotonicity of output control setting
- Accuracy of maximum output voltage

1.12. System description

The VIVA combo RF system consists of an RF generator, Peristaltic pump, cables, and accessories. This VIVA combo RF Lesion generator is designed to coagulate local tissue through a coagulation electrode.

Radiofrequency power is supplied and controlled with maximum of 200 Watt. Power, impedance, current and temperature are monitored. The temperature of the electrode's tip is monitored for charring.

Power, impedance, current and temperature are stored through a PC software program after connecting the communication terminal of the rear panel of the RF generator with the PC via the communication cable.

Applied Part

Grounding pads, Electrode tip

Components

1. VIVA combo RF Generator
2. coagulation electrode set (optional: supplied separately)
3. Peristaltic pump
4. foot switch (1 tier: blue) (optional): RF ON/OFF button function
   - Total Length : 4.1m±10, SN Series
5. foot switch (2 tier: blue/yellow) (optional): RF power adjustment function
   - Total Length : 4.1m±10, SN Series
6. power cable
   - Total Length : 1.8m±10
7. USB communication cable
   - Total Length : 1.9m±10, USB A B Type
8. CD (user's guide, PC linked monitor program, USB driver)
9. equipotential earthing cable
   - Total Length : 2.1m±10, MC POAG Series
10. user's guide
11. Bluetooth radio communication module (optional)
12. Power supply cord
    - 125 V~,10 A SJT, 18 AWG, "Hospital Grade"

Caution

- Other cables and accessories may negatively affect EMC performance.

1.13. Preparations before Use

Radiofrequency lesion generator

1. Check the rated voltage is correct for the equipment before connecting the power.

Caution
- The equipment may be damaged if it is not connected to the correct voltage.

2. Warning: To avoid risk of electric shock, this equipment must only be connected to a power supply with protective earth.
3. Avoid using the equipment at an unsanitary or flammable place.
4. Power on, Power off Procedure
   4-1. Before Surgery
   1) Connect the power cable to the RF generator
   2) Press the power switch
   3) Check the main menu
   4-2. After Surgery
   1) The output is stopped
   2) Press the power switch
   3) Disconnect the power cable from the RF Generator

Peristaltic pump

1. Connect the power cable to the pump's rear part.
2. Warning : To avoid risk of electric shock, this equipment must only be connected to a power supply with protective earth.

Electrode tubing set connection

Preparation materials:
- Coolant container (3L capacity)
- Cooled IV bag (1 – 3L)

1. Make sure that the IV bag is sufficiently cooled before the treatment.
2. Use the saline solution as coolant before the treatment.
   Note: 2L coolant is appropriate for a 12 minute-long treatment. The pump's flow rate is appropriately 100ml/min.
3. The coolant temperature is indicated on the generator when the coolant is connected and circulating through the pump. The cooling temperature is normally less than 20℃. When the cooling temperature is over 25℃, ensure that the coolant's temperature is maintained by placing the IV bag into the coolant's storage container.

Grounding pads inspection

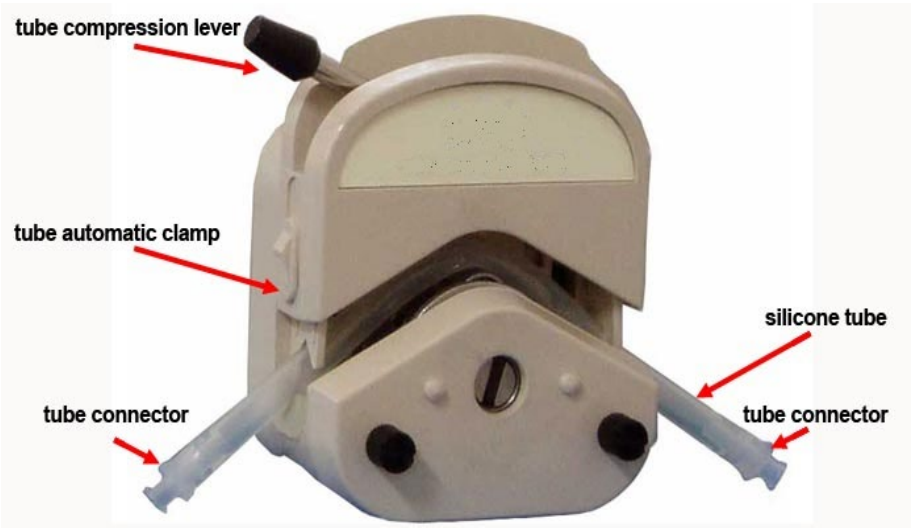
1. When attaching the grounding pads to the patient's thigh, please make the pads are firmly attached without air bubbles or irregularity.
2. There is a risk of burning when the grounding pads are not completely attached to the patient's thigh. Double-check the location and attachment of the grounding pads.
3. Connect the grounding pads with the ground Plate connector (P9532-EXT). Then, plug the grounding connector to the generator's front panel.

Checking RF electrode and tubing set

Connect the electrode and the tubing set in the following sequence:
Note: Confirm that the power cables for the generator and the pump are connected.
[VP01]

1. Place the IV bag above the patient and equipment to allow the air in the IV bag to elevate upward.
2. Pull the tube's compression lever indicated in the following photo in a counterclockwise direction.
3. Place the pump's tube in the roller that is located inside of the pump's head. Adjust the tube so that the left and right parts of the tube are similar in length.
   Note: Check that the coolant's flow direction is set in the correct direction of the pump's head. Check the direction of the arrow on the front of the pump.
4. Pull down the roller head's cover by pushing the tube compression lever to the very end towards the right side up to 180°. Check to make sure the tube is tight and placed correctly.

[Location for the pump diagram]

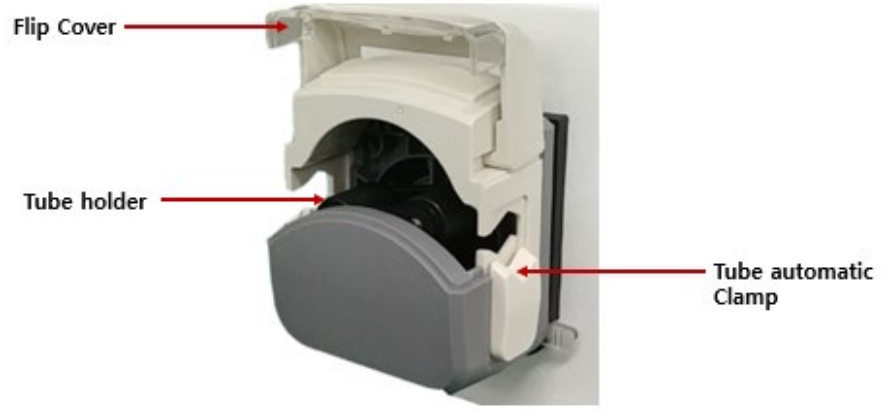


5. Push the input tube's spike into the inside of the saline solution bag while the input tube's roller clamp is temporarily closed.
6. Place the ends of the output tube in the water container after connecting the output tube to the electrode's coolant outflow connector.
7. Open the Input tubing's roller clamp.

[VP01-1]

1. Saline solution bag is located at a higher part, and maintain so that the air in the saline solution bag elevates upward.
2. Up the flip cover indicated in the following photo in a up direction.
3. Place the pump tubing at the roller located at the inside of the pump head. Adjust so that the length of the pump tubing is similar, left and right, and fit in.
   Note: Check the direction of the coolant flows to set the direction for the rotation of the pump head in an appropriate manner. Check the direction of the arrow on the pump's indication part in the front
4. Down the flip cover and Check the state of tube fixation.

[Location for the pump diagram]

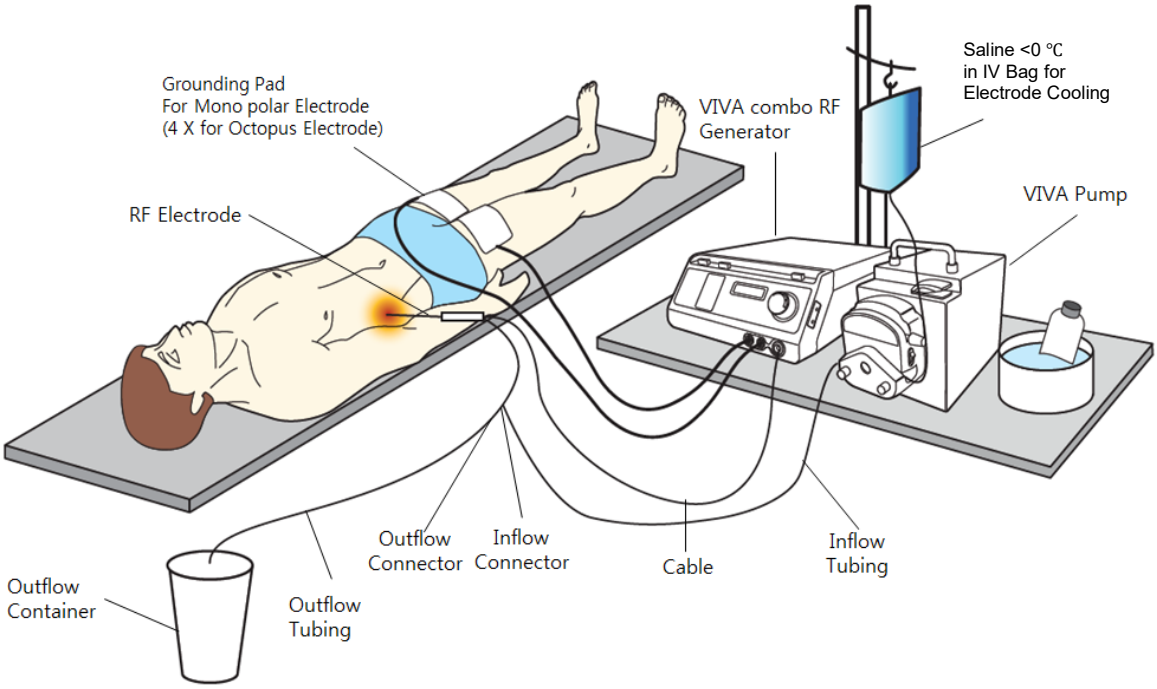


5. Push in the Input tubing's spike into the inside of the saline solution bag while Input tubing's roller clamp is closed temporarily.
6. After connecting the Output tubing to the electrode's coolant outflow part connector. Place the ends of the Output tubing in the water container.
7. Open the Input tubing's flip cover.

Warning

- star RF Electrode and tubing set are sterilized products for disposable use. Re-sterilization and re-use are prohibited.
- Stop using the electrode if the patient's body temperature is not indicated on the screen of the generator after all the preparations are completed, after the electrode is inserted into the human body, and before the radiofrequency ablation starts. After starting the pump, the lowered temperature in combination with the coolant's temperature is displayed.

1.14. System Connection Diagram

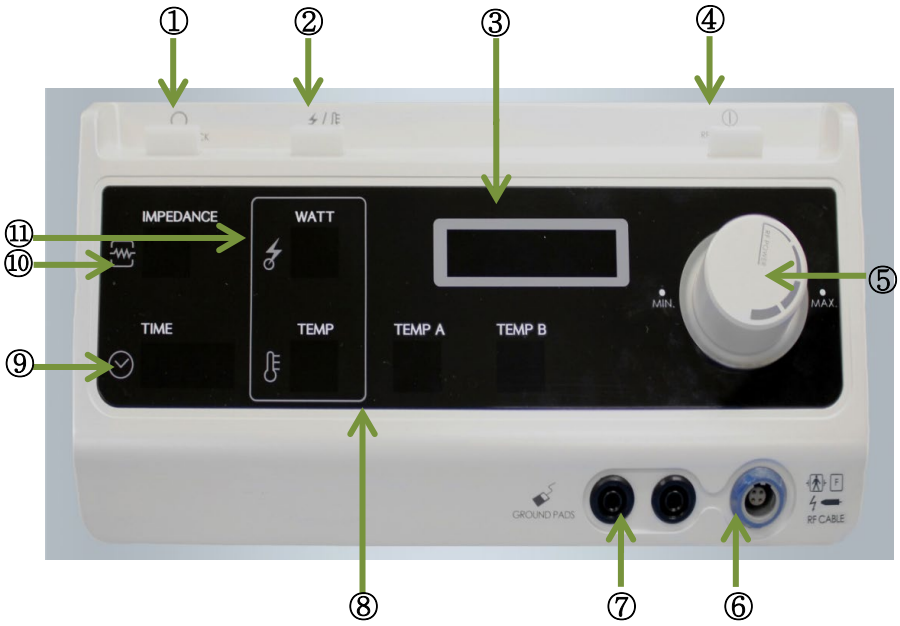


2. Radiofrequency Lesion Generator

Caution

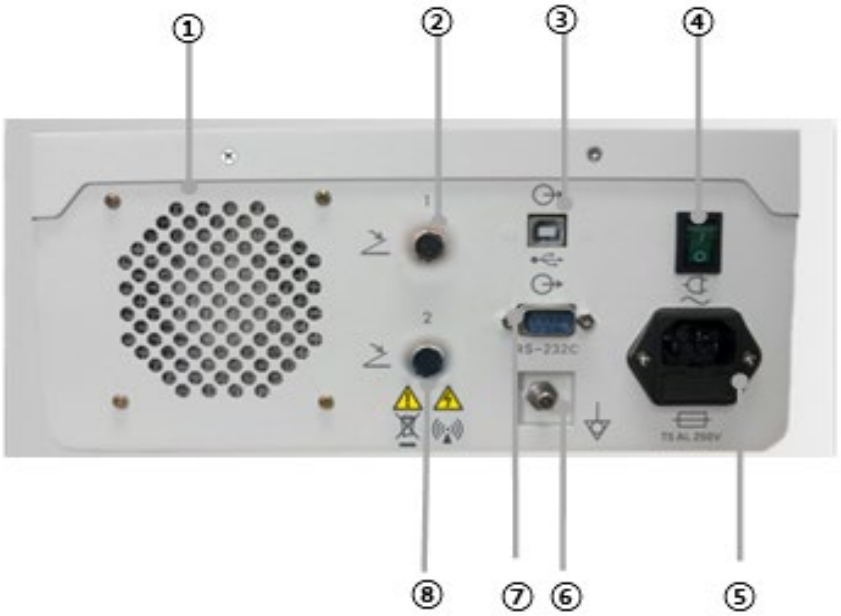
- Use the equipment only after reading the warnings, cautions, and information on the product's usage.
- Use other accessories related to this equipment only after reading the warnings, cautions, and information on the product's usage. The user's guide for the electrode is provided separately.

2.1. Description of generator's front panel



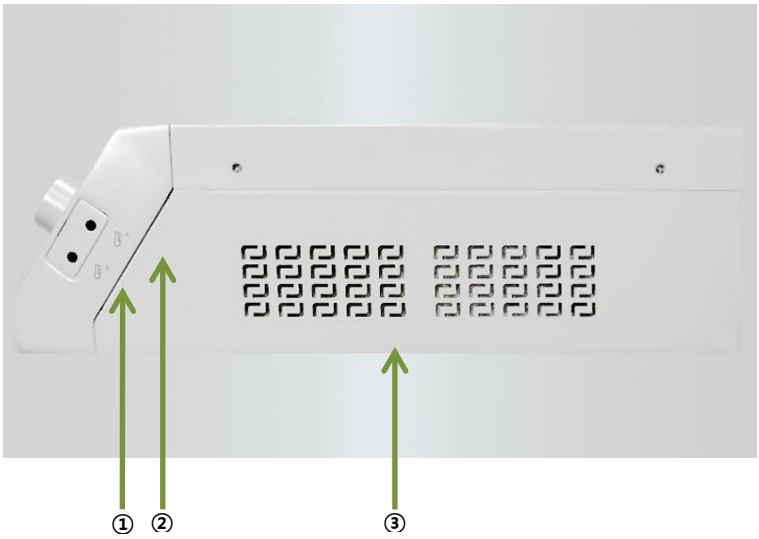
No.	Feature Name	Function
1	OHM/RESET button	Measures the impedance of targeted tissue from the active tip.
2	MODE button	Mode selected (General, Continuance, Auto, Temperature) button
3	Part for indicating the operation status	Indicates the menu setting concerning equipment operation, and indicated status including the power, impedance, temperature, time.) at the time of operation. Refer to the explanation on the main screen
4	RF START/STOP button	Pressing this button turns the RF output ON and OFF.
5	RF POWER control dial	Adjusts the RF output power.
6	RF CABLE connector	These are the electrosurgical electrode couplers for the RF output. The electrode's cable is connected here.
7	GROUND PADS connectors	These are the couplers for the RF current to be released from the RF electrode. The grounding pad's cable is connected here.
8	Display the temperature values	Measures the temperature of targeted tissue from the active tip.
9	TIME LAP	Indicates the lap time for a RF ablation.
10	Display the IMPEDANCE values	Indicates the resistance value of the targeted tissue at the time of RF output.
11	Display the RF POWER values	Indicates the actual amount of radiofrequency power that is supplied to the electrode and targeted tissue.

2.2. Description of generator's rear panel



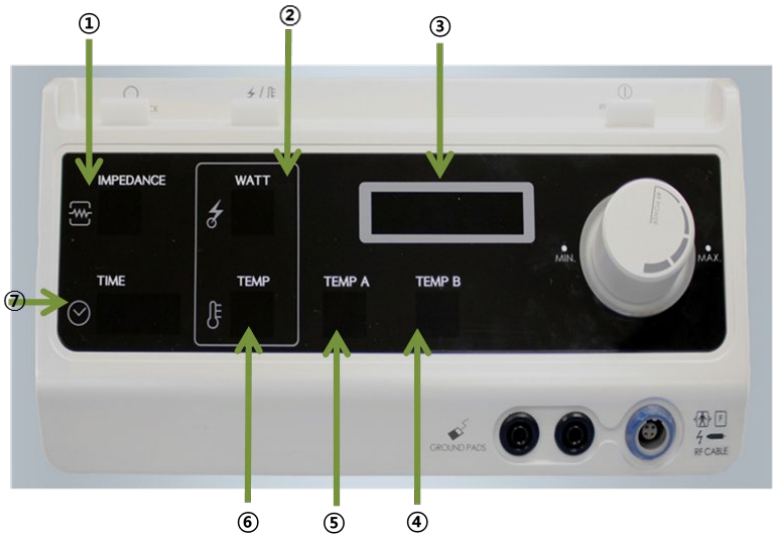
No.	Feature Name	Function
1	Ventilation hole	Hole for cooling down the inside of the system
2	Foot switch connector (upper part)	Foot switch pedal connected with this part that offers the same function as that of the RF ON/OFF button function
3	Data communication connector	Connecting part for the serial communication with PC, and it monitors the generator' operation state (power, current, impedance, temperature, time etc.) from a PC.
4	Power switch	Turns on/off the main power supply
5	Fuse/power code connection socket	Power is supplied to the generator by coming into contact with the power code. Includes the fuse box where two fuses are connected.
6	Equipotential grounding terminal	Equipotential grounding coupler for making the equipment and electric potential the same besides the main frame
7	RS-232C Data communication connector	Equipped with RS-232 Serial communication module in the device's Tablet PC operating conditions such as power, current, impedance, temperature, time should be monitored.
8	Foot switch connector (lower part)	Foot switch pedals connected with this part that offer the same function as that of the RF power control dial function. (yellow (-), blue (+))

2.3. Description of generator's side panel



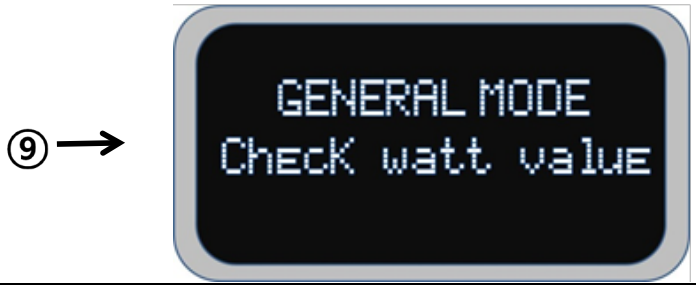
No.	Feature Name	Function
1	Temperature sensor connector B	Used to measure the temperature of the procedure part
2	Temperature sensor connector A	Used to measure the temperature of the procedure part
3	Ventilation hole	Hole for cooling down the inside of the system

2.4. Main screen



No.	Feature Name	Function
1	IMPEDANCE	Indicates the resistance value of the targeted tissue at the time of RF output.
2	RF POWER-LAP	Indicates the actual amount of radiofrequency power that is supplied to the electrode and targeted tissue.
3	MODE	User setting mode is displayed
4	TEMP-B	Temperature measured at the temperature sensor connector B displays the value.
5	TEMP-A	Temperature measured at the temperature sensor connector A displays the value.
6	TEMP	Indicates temperature at the active tip of electrode
7	TIME-LAP	Indicates the lap time for a RF ablation.

8	System message 1	Indicates message when the resistance value is too high or when the state of grounding pads, electrode connection are faulty



9	System message 2	Indicates message when RF output is 0 (General Mode only).

10	System message 3	Indicates message when the temperature is too high.

11	System message 4	In temperature mode, in case of not reaching the setting figure, continuing unexpected impedance and coming out power output continuously under the setting temperature, this message appears .

2.5. Usage

50W RF OUT (AUTO Mode)

A) The initial values are set with 50W, 12 minute-long automatically when press the AUTO Mode button on the generator's front panel. AUTO button lights up with blue color.
The initial value can be set up the desired output value with the RF POWER control dial. The range of Initial value is from 5W to 100W in units of 5W and it is indicated on a Segment, VFD display screen.
B) The RF output starts when RF STAR/STOP button is pressed on.
C) RF output is increased with 10W for every one minute. When 12 minutes lapse by, light of the button is turned off automatically, and the RF output is stopped.
D) Light of the button is turned off and the RF output is stopped when the RF START/STOP button is pressed on even during the use before 12 minutes lapse by.

Caution

- Read the user's guide for this equipment prior to the treatment and use the equipment afterwards.

E) Stepwise RF output is changed to pulsing RF output when the first RF pause (Roll-off) after increases 10W for every minute, starting with the 50W output before the first RF pause (Roll-off).

RF OUT (General Mode)

A) Set the desired output value with the RF POWER control dial. Output changes in units of 5W and it is indicated on a Segment, VFD display screen.
B) Press on the RF START/STOP button and it is lit up with blue color. RF output starts with pulsing format. Output can be adjusted with the RF power control dial. Lapsed time is indicated on the of Segment, VFD display screen.
C) The RF output is stopped and light is turned off when the RF START/STOP button is pressed on during use.
D) RF output with the General Mode and the initial output value, set initially
E) After RF output for 12 minutes, the alert sound plays three times at 2-second intervals.

CONTINUANCE RF OUT

A) Set the desired output with the RF power control dial after pressing on the CONTINUANCE Mode button. Output changes in units of 5W and appears on the Segment, VFD indication screen. CONTINUANCE button gets lit up.
B) Lit up when the RF START/STOP button is pressed on, and the RF output starts.
C) Output can be adjusted with the RF power control dial during the operation.
D) Light of the button is turned off and the RF output is stopped when the RF START/STOP button is pressed on during operation.

TEMPERATURE MODE

A) TEMPERATURE MODE, press the MODE button to enter
B) On the Segment, VFD screen '* set temp' in the presence of the phrase is marked with RF POWER control dial to set the desired temperature. The temperature change in degrees 5 and appears on the Main screen.
C) RF POWER setting and press to dial. On the Segment, VFD screen '* set watts' phrase will be displayed and the RF POWER control dial is set to the desired output. POWER is a 5W unit changes the display appears on the Main screen.
D) After pressing the dial to set the temperature of the Segment, VFD to check the set temp.
E) The RF output starts when RF STAR/STOP button is pressed on.
F) Temperature monitoring channel sees the temperature of the procedure part

OHM/CHECK

A) Press on the OHM/CHECK button of the generator's front panel.
B) Impedance value is indicated on the Segment, VFD display screen when the button is pressed on continually, and the screen goes back to the standby status ('---') state when the button is released.

Operation and storage of PC linked monitor program

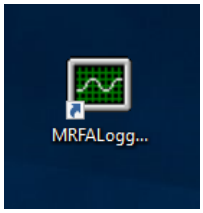
No.	Feature name	Function
1	Start monitoring	Connect or Disconnect a USB Serial communication between your PC and RF Generator.
2	Path	To set a folder which the log files will be saved to.
3	ID	To set a id
4	Auto/Manual Stop	Indicates the status of the monitoring of the output data
5	Setting Icon	To set Display Configuration you would like to be displayed
6	RF Output Graph	Display graph and output value measured on the active tip of electrode at the time of RF output
7	TIME-LAP	Indicates the lap time for a RF ablation.
8	RF Output Value	Indicates output value measured on the active tip of electrode at the time of RF output

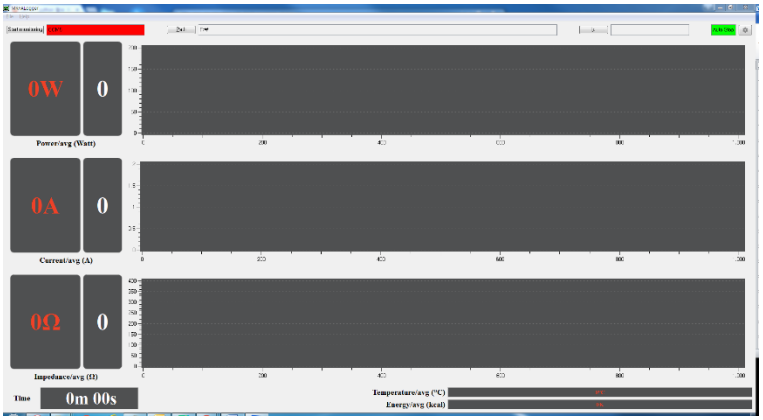
1) Connect the generator with computer which has the monitoring viewer program by using cable that can carry out the USB communication.

Caution

- Must connect the generator with the computer where the software is installed before running the software by USB communication cable.

2) Execute by double clicking the 'MRFALogger' shortcut icon or the MRFALogger.exe in the folder of the path where software is installed.





3) Select the computer with the searcher concerning the communication port setting (sequence: Diagram 1 → 2→ 3) for the communication between the generator and computer. Then, when the mouse's right button is pressed on, and when the management in the indicated menu is selected and executed, computer management is executed as shown on Diagram 1. When the device manager is selected among the indicated menu, the device list which the computer is using is indicated. Check the current communication port by clicking on the port (COM and LPT) among the indicated device list.

(Example: COM1 or COM2 or USB Serial Port (COM5))

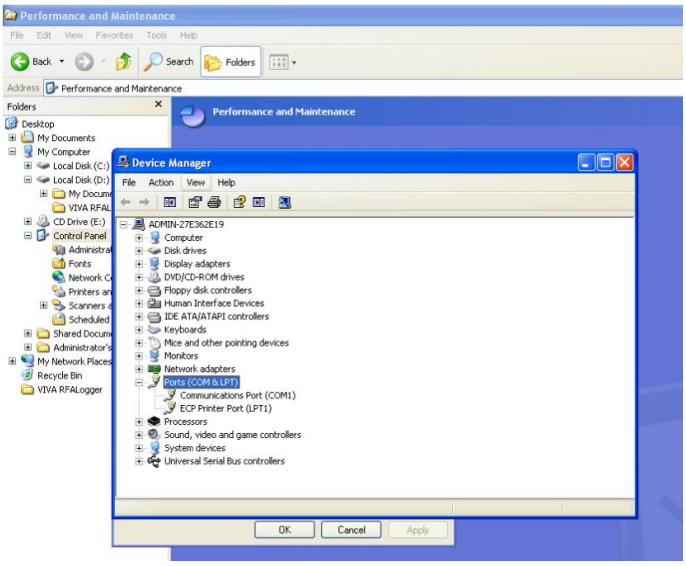


Diagram 1

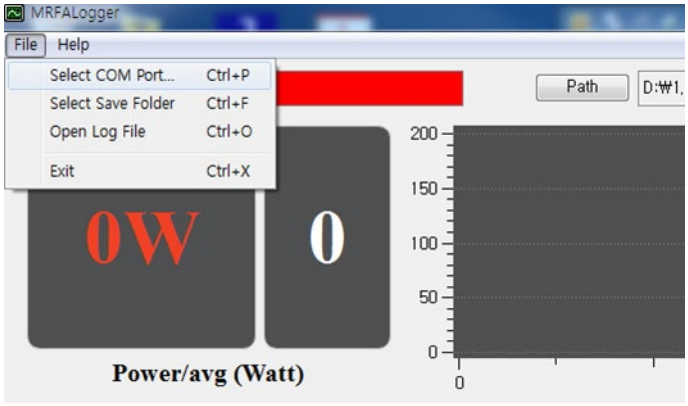


Diagram 2

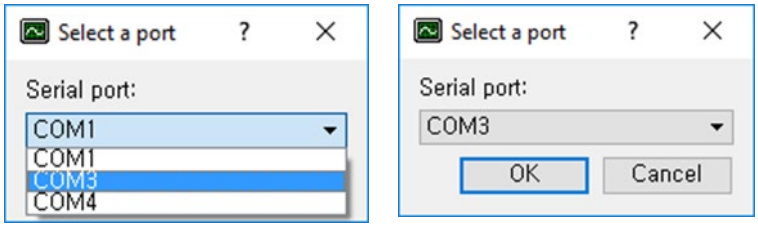


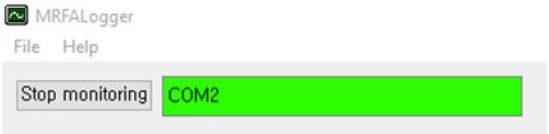
Diagram 3

Caution

- Depending on your PC, USB communication could be disconnected. In that case, set the USB communication port again.

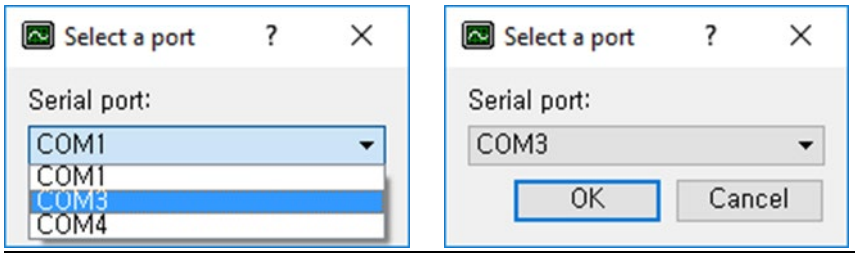
4) USB Serial Port

Select and execute the port menu to set up the communication port that is currently in use.
Click 'Start monitoring' or File – Select COM Port to activate a monitoring viewer program.
When completed, the background color of the USB port box is changed to green.



When disconnection or click 'Stop monitoring' button, the background color is red.

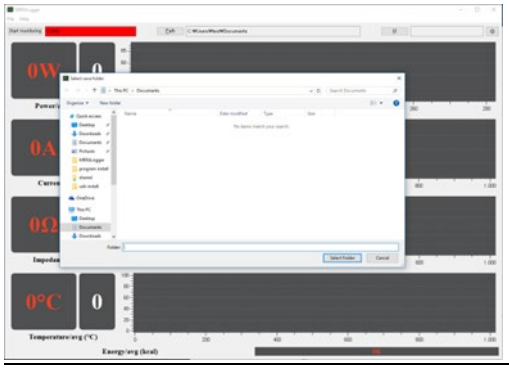
If the message shows 'No Port', 'Select a port' dialog is displayed automatically to set USB Serial port



In the "Serial port' drop-down box, select the USB serial number which start with lower number.
Press 'OK' to connect a USB serial communication between PC and VIVARF Generator.
Press 'Start monitoring' button again for ready to use.

5) Path

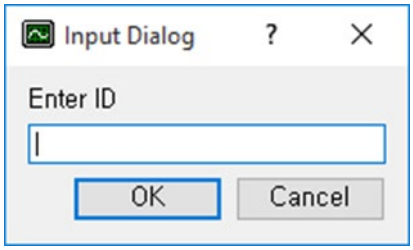
Select 'Select Save Folder' under File menu or Click 'Path' button. Select folder to store log files that is created automatically for every VIVARF Generator operation. And the file name is applied into
'week_month_day_hour_minute_second_year_record.txt' format.
(example : Fri_Jan_09_19H_14M_01S_2015_record.txt)
If Id is set, the log file name is extended with Id, the file name format is assigned below.
– 'ID_week_month_day_hour_minute_second_year_record.txt' format
(example : STARmed_Fri_Jan_09_19H_14M_01S_2015_record.txt)



Press 'Choose' to select the saving folder then the address box is updated automatically.

6) Id

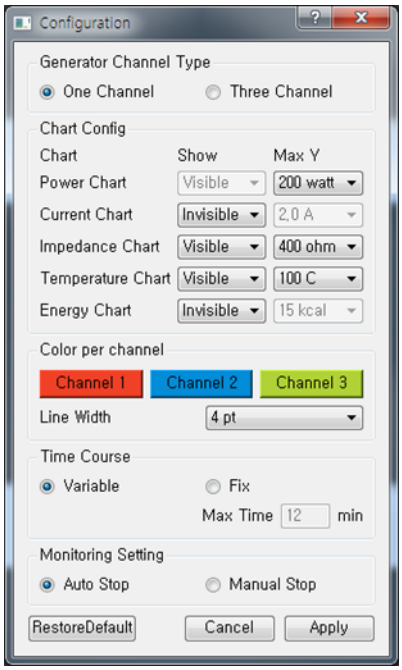
You may need to specify log file name to distinguish patient's information.
Click 'Id' button and Input characters.



If Id is set, the log file name is extended with Id, the file name format is assigned below.
- 'ID_week_month_day_hour_minute_second_year_record.txt' format
(example : STARmed_Fri_Jan_09_19H_14M_01S_2015_record.txt)

7) Display Configuration

Set Display Configuration you would like to be displayed.



(1) Generator Channel Type :
- One Channel : The display for only one channel electrode generator.
- Three Channel : The display for three channel electrode generator.
(2) Chart Config :
- Show : Selection of the display for each parameters
- Max Y : Adjustment of the amplitude for each parameters
(3) Color per Channel : Set the colors of output value and line of graph.
- Line Width : Set line width of graph.
(4) Time Course :
- Variable : Set to enable automatic the time axis resizing.

- Fix : Set the time axis limits to range from 1 to 99

(5) Monitoring Setting :

- Auto Stop : Redraw the graph every time whenever the RF output starts.
- Manual Stop : Draw the graph to be continuous even if RF output restarts.

(6) RestoreDefault : To choose the default setting.

(7) Cancel : Escape without setting.

(8) Apply : Apply user setting.

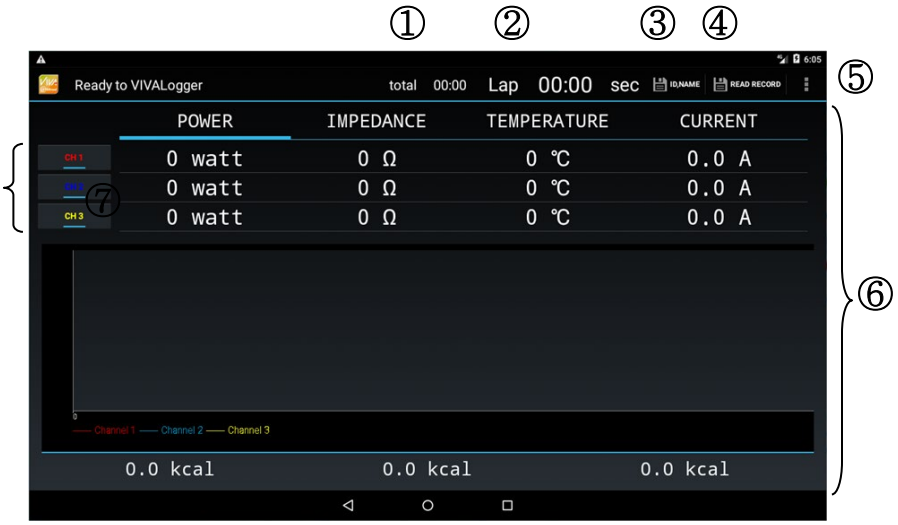
Operation and Storage of the Tablet PC linked Monitoring Software (VIVALogger)

1) Install APK

Before you can install it on your tablet, you will need to make sure that third-party apps are allowed on your device. Go to Menu > Setting > Security > and check Unknown Sources to allow your table to install app.

(1) You can download VIVALogger_Version.apk file on your PC and transfer it on the tablet.
(2) Open VIVALogger_Version.APK to install on your device.
(3) The app will begin installing on your device, and then VIVALogger icon will be visible when you open the app drawer.

2) Usage



① total : Indicates the total time for a procedure.
② Lap : Indicates the lap time for a RF ablation.
③ ID,NAME : You may need to specify log file name to distinguish patient's information. The file name is applied into 'name@week_month_day_hour_minuate_second_year_record.txt' format
▶ name@Wed_Mar_16_11H_32M_30S_2016_record.txt
And you can see file list using 'READ RECORD'
④ READ RECORD : To read log files that is created automatically for every RF output.

⑤ Configuration  :

- Setting Serial : Bluetooth setting_

'Scan for devices' retrieves already discovered or known devices that are nearby.
Select a Bluetooth device connecting to the tablet.
Once the correct code is entered there will be a notification that the Bluetooth is successfully paired with the tablet. (Default paring code is 1234)

- Write Info : Write information
- About : Display version of VIVALogger
- Quit : app quit

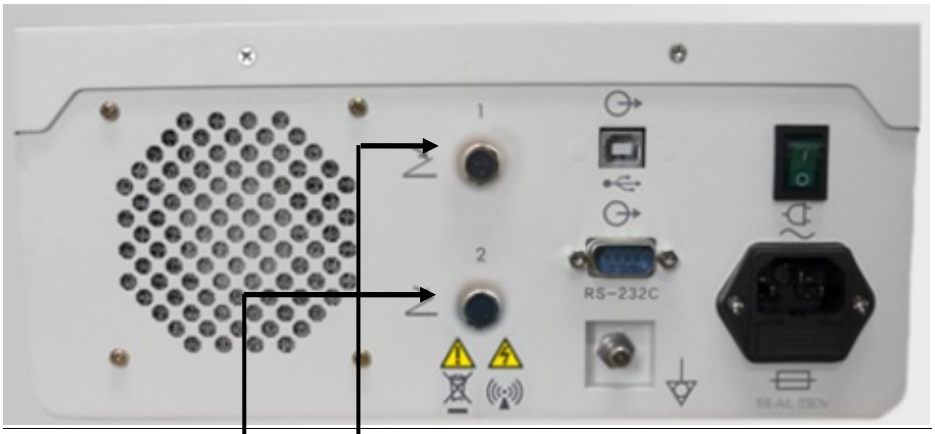
⑥ POWER, IMPEDANCE, TEMPERATURE, CURRENT : Displays the RF graph for selected RF Parameter.

⑦ CH1, CH2, CH3 : Determine whether or not selected channel is visible.

3) Move log files by USB
You can use a USB cable to move log files between your computer and tablet
With a USB cable, connect your device to PC
On your device, tab the 'USB for ..' notification.
On your PC, open File Explorer. and search for your Android device
Look for 'viva' folder at your device's internal storage.
You can see log files in 'viva' folder and Drag and drop files between your device and PC

Foot Switch Installation and Operations Guide

☞ Foot switch is an optional product accessory.



Single Foot Switch

Double Foot Switch

☞ Connect the foot switch. Then, tighten the screws.

A) Single Foot Switch.

The foot switch pedal offers the same function as the RF START/STOP button function.

Note : Press the switch for more than 1 second to start the RF output.

The Single foot Switch has the same function as the RF START/STOP Button

B) Double Foot Switch.

The foot switch pedals offer the same function as the RF POWER control dial function.
Note : (Yellow (-5W), blue (+5W))

Press the Yellow pedal to reduce output.
(Pressing and holding the pedal decreases output quickly.)

Press the Blue pedal to increase output.
(Pressing and holding the pedal increases output quickly.)

Double Foot Switch is the same function as the dial at front panel.

2.6. Explanation of Symbols

RF Generator

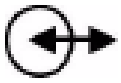
DEFIBRILLATION-PROOF TYPE BF APPLIED PART

Floating return (high frequency)

Warning, electricity

General warning sign

Footswitch input jack



Signal input/output port

Refer to instruction manual/booklet

Equipotentiality

Indicates rotational direction of increase (for output control and set output)

RF START /STOP

Non-ionizing electromagnetic radiation

Serial number

Manufacturer

Date of manufacture

Power on

Power off

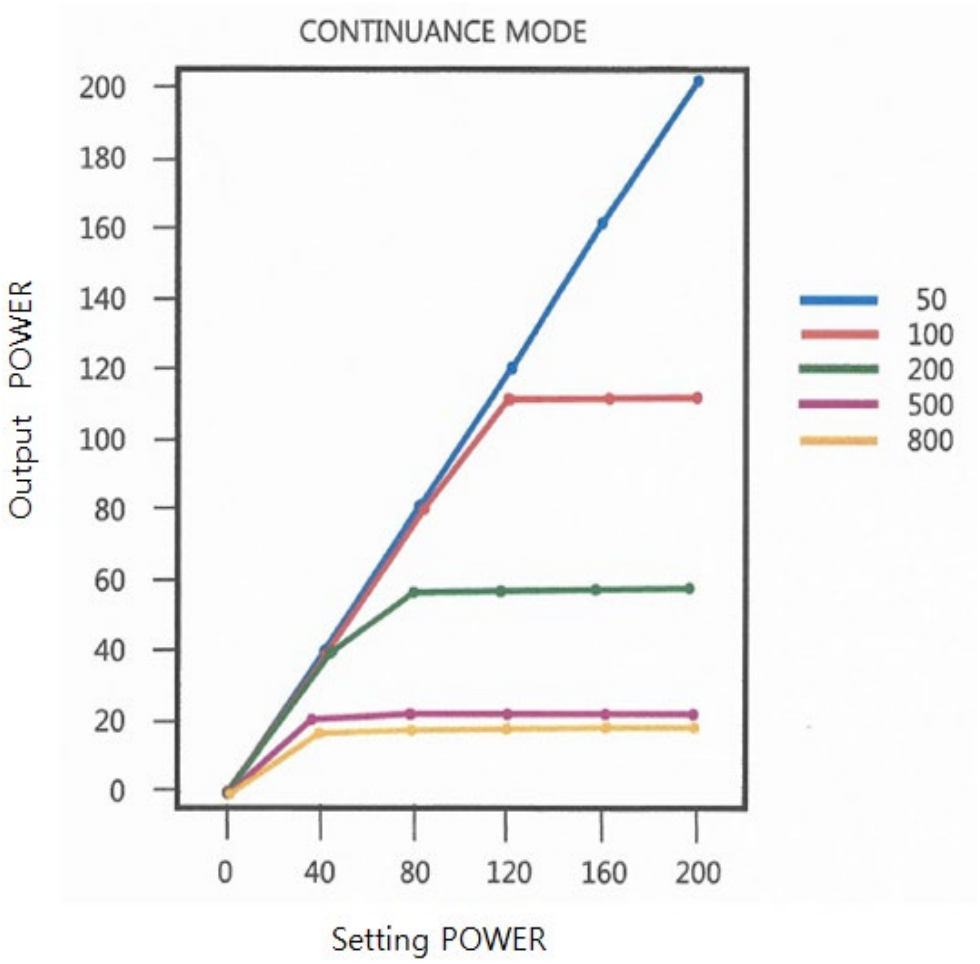
Caution: Federal law restricts this device to sale by or on the order of a physician.

Box

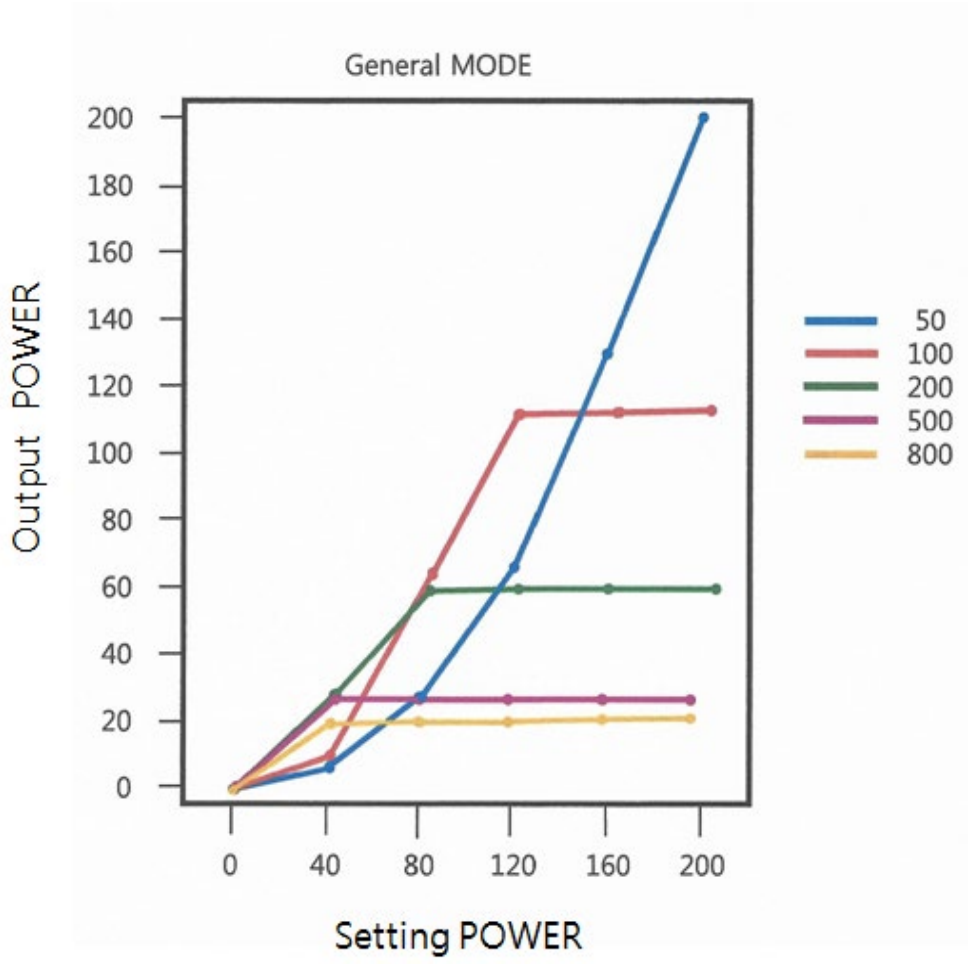
Symbol	Meaning
	To indicate that the transport package shall be kept away from rain and in dry conditions.
	To indicate that hooks shall not be used for handling the transport package.
	To indicate correct upright position of the transport package.
	To indicate that the contents of the transport package are fragile and the package shall be handled with care
	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature ofthe items themselves.

2.7. Generator Output Power Characterization

CONTINUANCE MODE



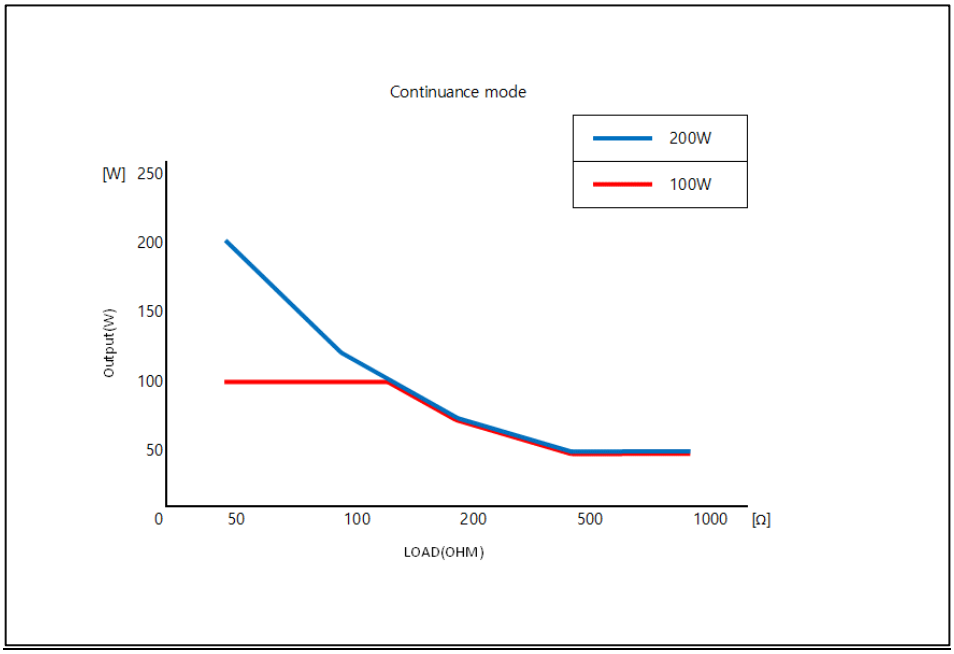
GENERAL MODE



* Graphical Displays of Auto Mode and Temperature Mode are same with Graphical Display of Continuance Mode.

Diagram of power output data

(1) 200W(Maximum output current : 2A)



2.8. Radiofrequency Lesion Generator Specifications

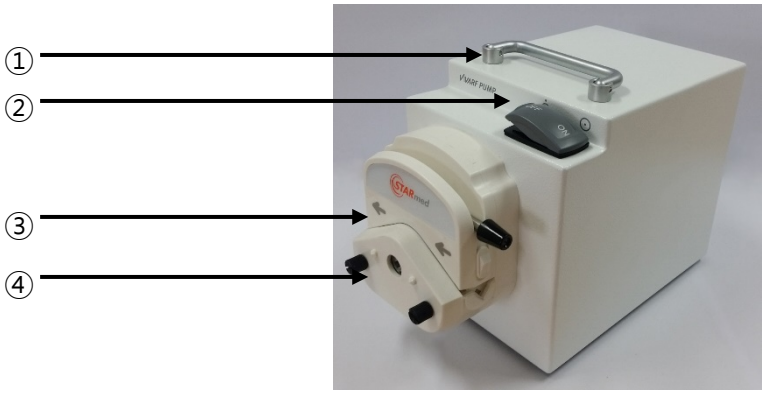
Rated power	
Voltage range:	100 – 240 V~
Maximum input voltage:	250 V~
Maximum input power:	450 VA
Fuse capacity:	F 5AH 250 V
Power frequency:	50/60 Hz
Impedance measurement	
Range:	10 – 800 ohms
Resolution:	1 ohm
Accuracy:	10 – 50 ohms ±10 ohm 51 – 300 ohms ±15% 301 – 800 ohms ±30%
Radiofrequency output	
Watts:	0 – 200 watts max output @ 50 ohm
Accuracy:	±20%
Resolution:	1 watt
Frequency:	480 kHz±10%
Drive on time:	30minutes max.
Temperature measurement	
Range:	5°C – 95°C
Resolution:	1°C
Accuracy:	±5°C
Operating environment	
Clean, dry area	
Temperature	15°C – 40°C
Humidity:	15 – 80% relative, non-condensing
Atmospheric Pressure:	800 – 1060 hPa

3. Peristaltic Pump

Caution

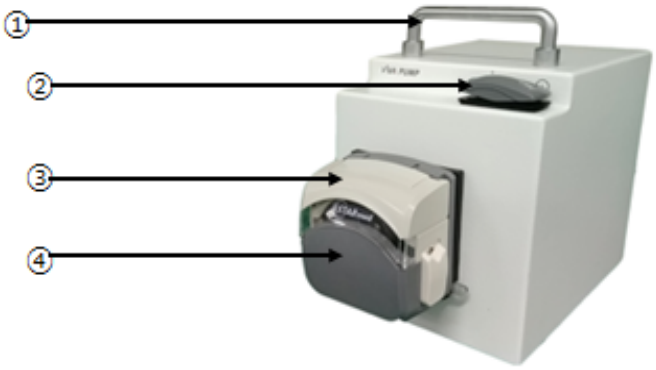
- Use this Peristaltic pump only after reading the warnings, cautions, and information on the product's usage.
- Use other accessories related to the Peristaltic pump only after reading the warnings, cautions, and information on the product's usage.

3.1. Description



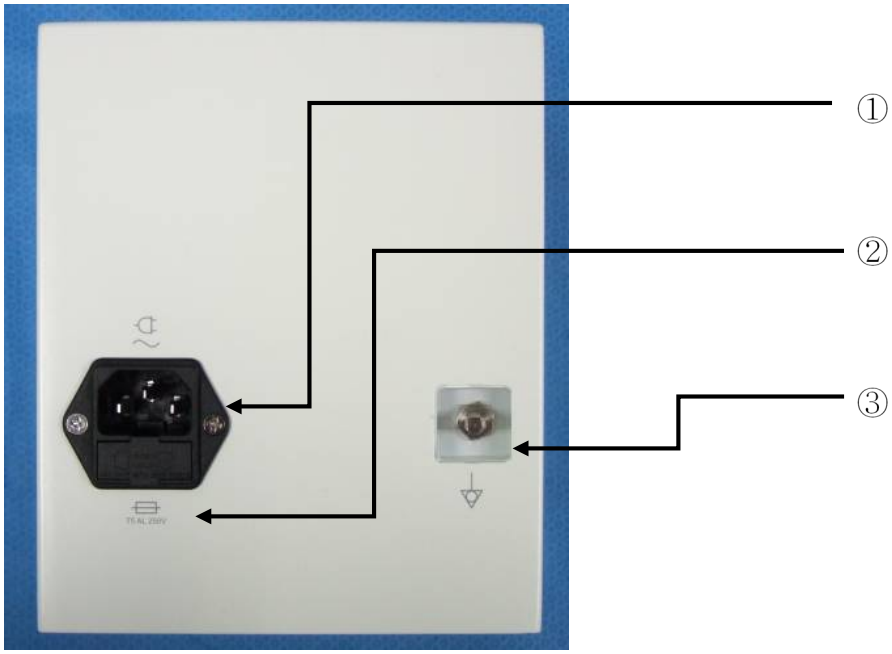
VP01

Description of the pump front part and control part		
No.	Feature Name	Function
1	Handle	Handle that use for moving of pump
2	Power Switch	Switch that starts and stops the operation of the pump roller
3	Tube compression lever	Maintains proper contact status between the pump tubing and roller Clamps that are located at the two sides fix the location of tubing
4	Roller head	Body of revolution composed of the rollers that press down on the pump tubing to push and squeeze out the coolant



VP01-1

Description of the pump front part and control part		
No.	Feature Name	Function
1	Handle	Handle that use for moving of pump
2	Power Switch	Switch that starts and stops the operation of the pump roller
3	Flip cover	Maintains proper contact status between the pump tubing and roller Clamps that are located at the two sides fix the location of tubing
4	Roller head	Body of revolution composed of the rollers that press down on the pump tubing to push and squeeze out the coolant

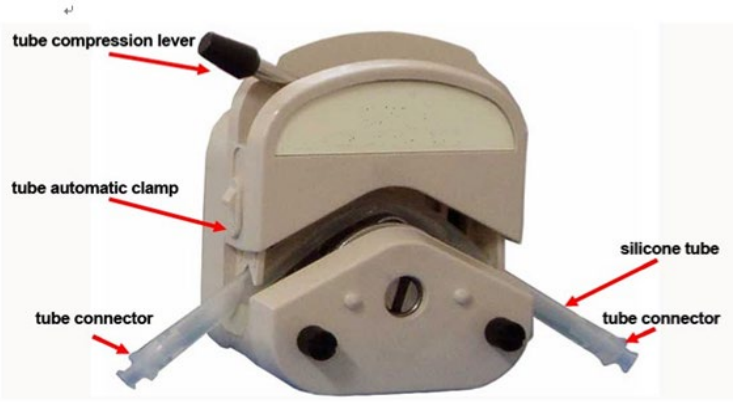


Description of the pump's rear part		
No.	Feature Name	Function
1	MAINS INLET	AC Power cable coupler
2	FUSE box	Two fuses attached
3	EQUIPOTENTIAL GROUND	Equipotential coupler for making the equipment besides the main frame and the electric potential, the same

3.2. Preparations

Mounting the pump tubing inside of the front part(VP01)

Lift up the cover by pushing the TUBE COMMPRESSION LEVER to the left.
Mount the tubing to the inner side of the roller head. When mounting, mount the tubing by lifting up the TUBE AUTOMATIC CLAMP.
Lift down the roller head cover by pushing the TUBE COMMPRESSION LEVER to the right side to the very end, 180° and check the tube fixation status.



Mounting the pump tubing inside of the front part(VP01-1)

Lift up the cover by pushing the flip cover to the up.
Mounting the pump tubing inside of the front part
Mount the tubing to the inner side of the roller head.
Push the flip cover to the down side and check the tube fixation status.

Caution

- Use the sterilization pump tubing provided in the electrode set.
- To prevent contamination, do not reuse disposable pump tubing after using it.

3.3. Explanation of symbols

Caution

Equipotentiality

Power on

Power off

3.4. Peristaltic pump specifications

Rated power	
Input voltage	100 – 240 V~
Frequency	50/60 Hz
Consumption power	80 VA (max.)
Flow rate (when using while connecting to the electrode tubing set)	
Flow rate :	load = 80ml or higher (no load = 120 ml or higher)
Dimension	
Size (w x h x d)	193 * 160 * 135 mm
Weight	4 Kg
Operating Environment	
Clean, dry area	
Temperature:	15°C – 40°C
Humidity:	15 – 80% relative, non-condensing
Atmospheric Pressure:	800 – 1 060 hPa

4. RF Electrode

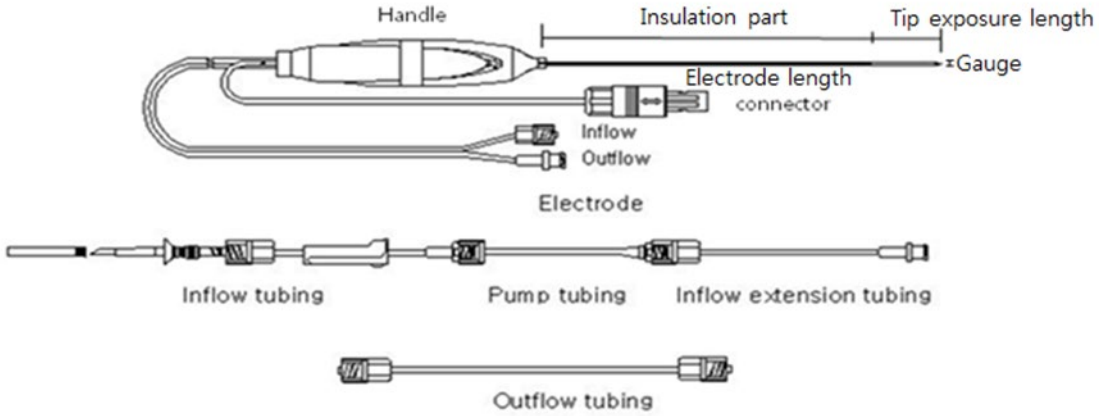
Caution
- Use RF Electrodes only after reading warning and caution messages and information on the usage first.
- Use other accessories related to this RF Electrodes only after reading information on the usage, and warning and cautioning messages first. The guide related to electrode is provided separately.

4.1. Description

Sterile single-use RF coagulation electrode is intended for coagulation of tissue during percutaneous and intraoperative surgical procedures.
RF electrode is a disposable medical device and reuse is not allowed.

star RF Electrode (mono polar)

star RF Electrode (Fixed type)



No.	Art. No	Electrode length	Tip exposure length	Gauge	Note
1	17-15s30F	150	30	17	
2	17-20s30F	200	30		

(Unit: mm)

4.2. Treatment Guidelines – Ablation of Tissue

Gauge	Tip Exposure Length (mm)	Time (min.)	Target Watt	Width	Length	Depth	Volume
17	30	12	60	3.10	4.21	3.21	**22.25**
			120	3.51	4.12	3.35	**25.34**
			200	3.51	4.33	3.39	**26.95**

Note

- Ablation Zone is dependent upon tissue status, type, temperature and humidity.
- Testing was performed in healthy ex vivo bovine temperature 23.6 ℃, humidity 27% liver.
- Ablation zone may vary in clinical circumstance.

5. Technical Reference

Caution

- Use generator only after reading warning and caution messages and information on the usage first.
- Use other accessories related to this generator only after reading information on the usage, and warning and cautioning messages first. The guide related to electrode is provided separately.

5.1. Device Classification

Classification as per IEC60601-1, the manufacturer describes the VIVA combo RF generator as:

Type of protection against electric shock:	Class I
Degree of protection against electric shock:	Generator -> Type BF Defibrillator Protected
	Pump -> Not applicable
Degree of harmful ingress of water:	Ordinary no-waterproof
Mode of operation:	Continuous use with intermittent Loading
Degree of safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide:	Not suitable for use

5.2. Storage and management after use

Management method after using the generator (PC for monitoring viewer)

A) Turn off the power switch of the generator's rear part, and separate the accessories from it.
B) Separate the power code from the power outlet on the wall.
C) To store, keep the proper temperate from 10 – 40°C.
D) Cleaning method: Use 70% isopropyl alcohol solution to wipe off the generator's panel. However, there should be no moisture remaining in the electrode coupler.

Storing method

A) Store it in the place that is free from the effects of the atmosphere that includes air pressure, temperature, humidity level, wind, sunlight, salinity, ion etc.
B) Be careful to ensure safety against vibration, shock etc. (at the time of transport, and move)
C) Do not store at the place where chemicals are stored, or where gas might be generated.
D) Do not store it at the place where is close to the water.
E) Gather together the accessories such as code and connectors after cleaning them well.

Transportation and Storage Environment	
Clean, dry area	
Temperature:	-40°C – 40°C
Humidity:	0% – 87%, including condensation
Atmospheric Pressure:	800 – 1 060 hPa

5.3. Equipment Waste and Management

Discard
Please call or Consult your local STARmed representative for supporting.

5.4. Cleaning and Disinfection

The RF Lesion generator for tissue ablation during surgical procedures with coagulation electrode's reusable components may be cleaned with mild cleaning solutions, such as 70% isopropyl alcohol. Care should be taken to keep moisture out of the connectors. Store both units and accessories in a clean, dry, and non-corrosive atmosphere. The generator, pump, and accessories are designed to withstand all normally encountered environmental conditions (see "RF Generator Specifications" and "Pump Specifications").

The coagulation electrode kits are for SINGLE USE ONLY. Do not clean or re-sterilize products prior to use. Do not attempt to reuse coagulation electrodes and grounding pads.

Caution

- Do not sterilize RF Lesion generator for tissue ablation during surgical procedures or pump. Sterilization will destroy the unit's electronic components.

5.5. Maintenance and Service

The RF lesion generator and pump are not user serviceable, and both units should be returned to STARmed authorized service center if any problems arise. To ensure accuracy of unit outputs and displays, the annual inspection of the unit is recommended by official process. Please call your local STARmed representative for support in detail.

This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The RF Lesion generator for tissue ablation during surgical procedures is designed to be durable medical equipment. However, physical impact, such as dropping the unit, may result in damage and subsequent injury to the patient or operator. If the generator or pump is subjected to impact, discontinue use and immediately return the generator or pump to STARmed for evaluation.

The pump generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does not cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving devices.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Caution

- You must replace the tubing sets with each patient use.
- Remove tubing after each coagulation RF electrode procedure to minimize risks and to prevent contamination
- RF Generator check is must be maintained by qualified and trained personnel.

5.6. EMC Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The **VIVA combo RF Generator (VCS10)** is intended for use in the electromagnetic environment specified below. The customer or the user of the VIVA combo RF Generator (VCS10) should assure that it is used in such an environment.		
	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The **VIVA combo RF Generator (VCS10)** uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The **VIVA combo RF Generator (VCS10)** is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption, and	< 5 % UT (> 95 % dip in UT)	< 5 % UT (> 95 % dip in UT)	Mains power quality should be that of a typical commercial or hospital environment. If the user

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
voltage variations on power supply input lines IEC 61000-4-11	for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	of the VIVA combo RF Generator (VCS10) requires continued operation during power mains interruptions, it is recommended that the VIVA combo RF Generator (VCS10) be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U is the A.C. mains voltage prior to application of the test level.			

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bandsa 10 Vrms 150 kHz to 80 MHz in ISM bandsa	3 Vrms 150 kHz to 80 MHz outside ISM bandsa 10 Vrms 150 kHz to 80 MHz in ISM bandsa	Portable and mobile RF communications equipment should be used no closer to any part of the VIVA combo RF Generator (VCS10), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1,17\sqrt{P}$ $d=1,2\sqrt{P}$

Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	d=1,2√P 80 MHz to 800 MHz d=2,3√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meteres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range .[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1 At 80MHz and 800MHz, the higher frequency range applies. Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. [b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges. [c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VIVA combo RF Generator (VCS10) is used exceeds the applicable RF compliance level above, the VIVA			

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
combo RF Generator (VCS10) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VIVA combo RF Generator (VCS10). [d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			