User's Guide

RF lesion Generator

with

Coagulation Electrode

(ST-UM-15E Rev.0)

Only the certified medical doctors, capable of conducting surgical treatment using 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.

Caution

This product can be sold only to the medical professional or based only on their request in accordance to the Medical Devices Law.

Equipment covered in this manual

RF lesion generator with coagulation electrode

Part No.

Effective date December. 2013

Notices

Trademark acknowledgements

.

Manufactured for:

STARmed Co., Ltd.

(Jungsan-dong, Daebang-Triplaon Business Tower), B-dong, 4F, 158, Haneulmaeul-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea

TEL: +82(506)-816-3546

FAX: +82(506)-816-4546

Internet address

www.STARmed4U.com

Product warranty

Warranty is for one year.
The company repairs this product for free during the warranty period, one year from the day of purchase when there is malfunction or product defect that may have resulted during normal transport and use.
Standard for the compensation such as repair and exchange should comply with the “Regulation for the Consumer Compensation for Damages” posted by the Economic Planning Board.
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

This warranty is effective only in Korea.
You must present the certificate of warranty when requesting repair.
Please keep this certificate of warranty since this is not re-issued.

Safety warning

Danger
Indication of the high risk situation which may result in death or severe injury if neglected
Warning
Indication of the hazardous situation that may result in minor or moderate injury that is not too severe if neglected
Caution
Indication of the dangerous situation that may damage the product
Important
Indication of the matters on the proper use, storage and maintenance of the product

1.System overview

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

Caution for electric safety

Radiofrequency lesion generator

The equipment design is important 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 and the pump.

Caution

Danger of electrocution

User should not disassemble the equipment. Ask the STARmed on how to prevent electric shock.

Disconnect the device from the power line before cleaning or maintenance

Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information

The VCS10 should not be used adjacent to or stacked with other equipment, IF stacked use is necessary, the VCS10 should be observed to verify normal operation in the configuration in which it will be used.

Until press the stop button between the RF output of the set time, the output of the electrode will continue. Use carefully during using the device

Warning

Hazardous electrical shock

This equipment can be used only by the proven medical doctor who qualified to use the equipment.
Those who have Pacemakers transplanted cannot use this equipment, and should not be near the equipment within 4 meters.
This equipment outputs the energy that can exert physical effect.

Risk of burn

Do not use it near the objects such as metallic cart, bed and(or) hanger etc. that can conduct electricity.

Equipotential earthing

Connect this equipment with the power outlet in hospital for grounding. When protective grounding is unable, user or patient could cause to be injured due to electric shock.

Caution

Appropriate interval (approximately five minutes) for the next procedure is required to stabilize the equipment after coagulation procedure.
Caution required so that the maximum output does not get discharged continually for at least six minutes at the time of radiofrequency output.
Instructions indicating the output power should be selected as low as possible for intended purpose.

Peristatic pump

Warning

Hazard of electrocution

If pump becomes wet due to the tube leakage or flooding, stop immediately the pump operation and take out the main power code.

User should not disassemble the equipment. To prevent electric shock, please inquire with the STARmed.

This equipment outputs the energy that can exert physical effect.

This pump cannot be used at a place that is vulnerable to explosion and where there is inflammable material.

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 Generator was certified as appropriate by the EN60601-1, EN60601-2-2, and this is the medical equipment of the ClassI Type BF type.

warning

Risk of ignition by combustible gas or material at the time of electrosurgery is very high. Thus, please remove the combustible ignition material before the electrosurgery. Avoid using combustible anesthetic drug, nitrogen oxide and oxygen on the thorax or head when conducting treatment. If these were used, remove before using this equipment.

Remove combustible material used for cleansing, removing contaminant and adherence before conducting radiofrequency treatment. If there is combustible material still remaining on the patient's body, this could be dangerous. Be careful of the danger of ignition due to the endogenous gas. Materials such as cotton wool, wool and gauze adhere to the oxygen. Thus, there is risk of ignition resulting from flame even when the equipment is used normally.

Radiofrequency lesion generator with coagulation electrodes

warning

RF coagulation electrode is recommended for the STARmed radiofrequency lesion generator. Please inquire the company on the use of the radiofrequency electrodes made in STARmed Co., Ltd.
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 in the pump tube into the head, check the exact location after confirming the tube's measurement. Then, fixate by pulling on the lever so that the tube will not deviate during use.

Use the STARmed inflow-outflow tubing set always, and replace for each patient.
Recommendation on the use of non-flammable agents for cleaning and disinfections wherever possible
Instructions indicating, flammable agents for cleaning, disinfecting, or as solvents of adhesives shall be allowed to evaporate before application of hf surgery
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 at the front part or foot switch is pressed on to stop the radiofrequency output, press on the main power switch located at the equipment' rear part immediately, to stop the power. Take out the power so that the electrode connector gets separated from the equipment. Stop using the equipment and request service.

Use this equipment at place such as the hospital operation room where the emergency electric power is supplying or use it with UPS (Uninterruptible Power Supply) in order to prepare for the risk of power failure while operating equipment.

Caution
When the radiofrequency output comes out too low or when the output does not come out, after setting normally, this means that there is a defect when it comes to the Grounding pads or electrode cable connection. Do not increase the radiofrequency output before identify the root causes accurately. Check again whether the Grounding pads come into contact with the patient's skin correctly, when the patient's posture changes or moves.
Radiofrequency lesion generator and pump may cause electromagnetic wave obstruction in other equipment even when it is operating normally. When electromagnetic wave obstruction is generated, place the other equipment as far as possible. Re-connect the power plug to the other power that is separated. Request service.
Electrode and probe for the monitoring, magnetic pole, and equipment for imaging can flow the radiofrequency current. To minimize the danger of burn, place other equipment' electrode and probe as far as possible form the affected area to cautery and Grounding pads. Use of the monitoring electrode of the needle injection format is prohibited.

Grounding pads

warning

Attaching the Grounding pads correctly at the appropriate part is crucial for the safe and effective use of this equipment, but it is particularly important for the pad part's burn.
Read the instruction for use that is included in the RF coagulation electrode kit made by STARmed on how to use the Grounding pads. It includes the information on the preparation of the Grounding pads, location for attachment, inspection and removal. Use of the P9532 Grounding pads that is provided by the STARmed and that satisfies the ANSI/AAMI specs requirement (HF18) is recommended.

When using one RF coagulation electrode kit made by STARmed, attach two Grounding pads. When using more electrodes, then it is necessary to attach four Grounding pads. The wider the area mass of the area for the Grounding pads attachment, radiofrequency current gets distributed even more, which can prevent the heat generation in the pad. Distance between each attached pad and cautery lesion should be made as same as possible to prevent the burn resulting from the concentration of the radiofrequency current. Refer to the user's guide that is provided.

Be careful about the question of Grounding pad's overheating when conducting cautery.

To prevent the incident burn due to the contact between patient's skin and skin, place gauze pad in the part where there is contact between the skin and skin in an appropriate manner.

Coagulation Electrode

Before using the electrode, you must check whether there is groove or crevice in the electrode insulation part and cable. In case of the insulation defect concerning the electrode or cable, radiofrequency current may leak out, which means that the amount of current that flows at the electrode's end can decrease, and there is high possibility that the burn may result in the unintended part.

Even when the pump stops to operate, measurement of the body temperature through the electrode may be inaccurate. When the pump is operated once, coolant's temperature is bound to decrease due to the circulation.

When using the CONTINUANCE mode, adjust so that the stable performance is maintained when using it and so that radiofrequency output can increase slowly.

Caution

Conduct periodical performance and safety test for the reusable cables and accessories.

Note: Problem may result when the supplementary accessories are used once.

Note: Conduct periodical test of the accessories at all times, and record the results.

Caution during surgical treatment

warning

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.

Caution

Equipment' performance is important to obtain safe and effective coagulation results, but operator's skill is a significant factor as well. Please read how to use the radiofrequency lesion generator and pump. Please provide this user's guide to operating and(or) maintenance user(s).

Important

If VIVA combo RF generator is affected by ESD, surge or burst, PC connection might be disconnected. In that case PC linked program should be set connection port once again.
Electrode is used only the product of STARmed Co.,Ltd.

Purpose for the product use

Radiofrequency lesion generator and electrode are the equipment that is used for tissue coagulation and hemostasis using radiofrequency current through the percutaneous, laparoscopic and intraoperative surgical treatment.

Contraindications

There is a risk that error may result due to the radiofrequency current when it comes to the patients who get transplanted with the Pacemakers and Cardioverter/Defibrillators that are used to put into the body. Thus, do not use the radiofrequency lesion generator and electrode.

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

Intended PATIENT population

a) Age : Not limited
b) Weight : > 2.5kg
c) Health: Use for the patient with liver cancer, thyroid cancer, lung cancer, kidney cancer, in patients with lesions of Use. Do not use the patient implanted Pacemakers, Cardioverter, Defibrillators
d) Country :
e) The patient condition : The patient is not device user. Condition is not relevant, unless the patient is excited.

Intended USER PROFILE

Considerations		Requirement description
Education	Minimum	• Medical doctor who has medical license.
	Maximum	• N/A
Knowledge	Minimum	• Knowledge of the side effect or complications due to the error of medical device. • Clinical expertise according to the education of the proper article or education
	Maximum	• N/A
Language understanding	Minimum	• Understand the manual(in Korean, in English) • Understand the meaning of abbreviation.
	Maximum	• N/A
Experience	Minimum	• Training of performance procedure and specific technology. • Training about use method in order to device safety and performance.
	Maximum	• N/A

Intended conditions of use

Considerations		Requirement description
Environment	General	• Not for family use, it is professional • Use at the operating room in the hospital. • Keep the accuracy of output when function is operating. • No inflammable materials. • Use to connect between electrode and peristaltic pump that use coolant. • Use after install the device on the flat plate. • The electrode of other device shall be located far away from the prove.
Frequency of use	• When use 1 time and 12 minutes, can be use maximum 30 minutes. • It is discontinuity. The duty cycle is 30 sec on/ 30 sec off.	
Mobility	• The device can be transported inside of hospital operating rooms.	

Operating principle

It is a RF generator surrounding 500kHz, its frequency shall be flowed to electrode tip and then apply to the tissue, the frictional heat would be occurred when an ion do move from the negative pole to the positive pole and from the positive pole to negative pole for forty thousand times to fifty thousand times for 1sec. The tissue necrosis is the principle that occurred by using heat generated from the tissue impedance.

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

Description of System

The VIVA combo RF system consists of an RF generator, peristaltic pump, cables, and accessories. This VIVA combo RF lesion generator is designed to coagulation of the local tissue through the coagulation electrode for RF lesion generator.

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

Power, resistance, current and temperature enables storing through PC software program after connecting the communication terminal of the rear part of RF generator with the PC with the communication cable.

Components

1. VIVA combo RF lesion Generator
2. Coagulation electrode set (optional :supplying separate)
3. electrode conversion cable (optional)
4. Peristaltic pump(optional)
5. Foot switch (1 tier/blue) (optional): RF ON/OFF button function
6. Foot switch (2 tier/blue/yellow) (optional): RF power adjustment switch function
7. Power cable (2ea)
8. USB communication cable
9. CD (user's guide & PC linked monitor program & USB driver)
10. Equipotential earthing cable
11. user's guide

Preparations before use

Radiofrequency lesion generator

1. Check the rated voltage that suits the equipment, and connect the power.

Caution
Equipment may be damaged when not suited to the equipment' rated voltage.

2. Connect the power cable to the grade AC Power supply in hospital.
3. Prepare rated fuse for reserve.
4. Avoid using at unsanitary or inflammable place.

Peristatic pump

1. Connect the power cable to the pump's rear part.
2. Connect the power cable to the grade AC Power for hospital.

Electrode tubing set connection

Preparation materials:

• Coolant container (3L capacity)
• Cooled sterilized saline solution bag (1~3L)

1. Cool enough off the sterilized saline solution bag sufficiently before the treatment.
2. Use the coolant saline solution before the treatment.
   Note: 2L coolant is appropriate for the 12 minute-long treatment. Pump's flow rate is appropriately 100ml/min. Accordingly, 1.2liters/12min coolant is consumed. About 3L coolant is appropriate for two 12 minute-long treatment.
3. When the coolant connected to the pump circulates in overall, coolant temperature is indicated in the generator. Temperature of the Indicated coolant is normally less than 20℃. When the temperature of the Indicated coolant is over 25℃, ensure that the coolant's temperature is maintained low by placing the saline solution bag into the storing container.

Grounding pads inspection

1. When attaching Grounding pads to the patient's thigh, please make the pads firmly adhesive without air bubbles or irregularity.
2. When the Grounding pads do not get adhered to the patient's thigh completely, there is a risk of burn. Thus, check the state of adherence.
3. Connect the Grounding pads with the Ground Plate connector (P9532-EXT). Then, plug into the function grounding connector that is located at the main frame's front part.

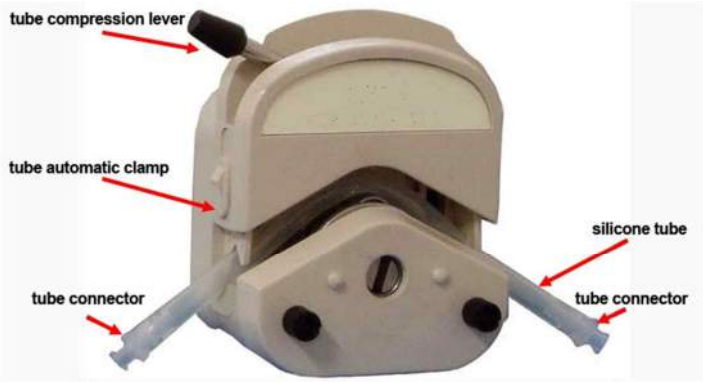
Checking RF electrode and tubing set

Connect the electrode and the tubing set in the following sequence:

Note: Check whether main frame equipment and pump's power are connected.

1. Saline solution bag is located at a higher part, and maintain so that the air in the saline solution bag elevates upward.
2. Pull the tube compression lever indicated in the following photo in a counter clock-wise 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. Pull down the roller head cover by pushing the lock lever to the very end towards the right side up to 180°. Check the state of tube fixation.

[Location for the pump diagram]



5. the 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 roller clamp.

Warning

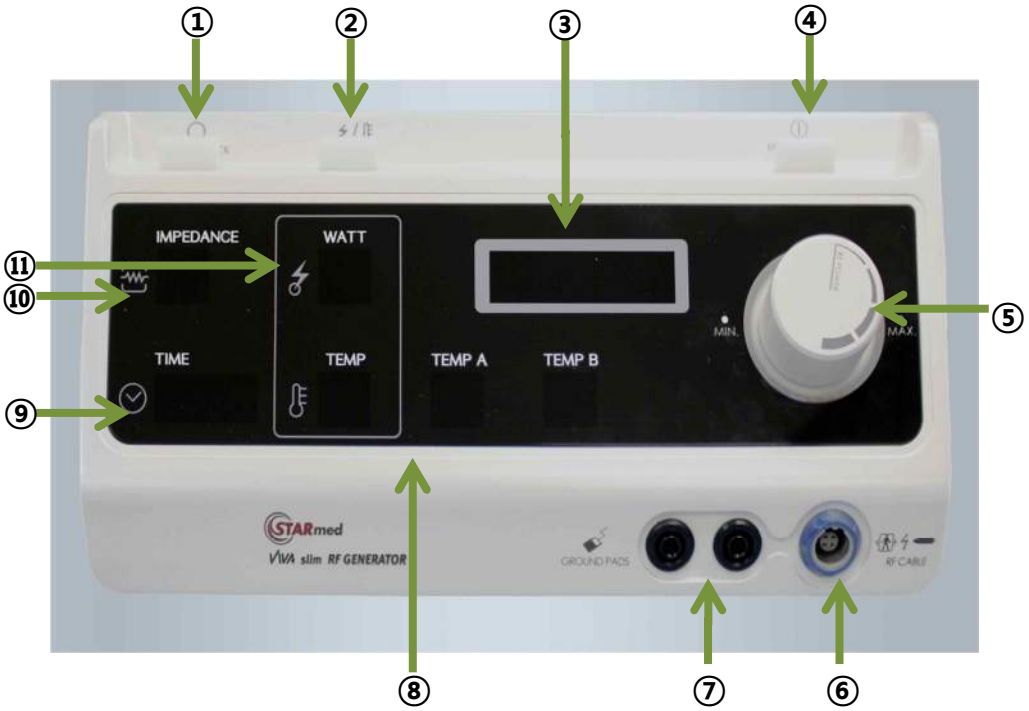
VIVA combo RF electrode and tubing set are sterilized products for disposable use. Re-sterilization and re-use are prohibited.

Stop using it if the body temperature is not indicated on the Segment, VFD display panel of generator after all the preparations are completed, after the electrode is inserted into the human body, and before the radiofrequency is created. After the pump operation, the lowered temperatures up to the coolant's temperature scope are indicated.

2. Radiofrequency lesion generator

Caution
Use equipment only after reading the information on the warning, caution and correct usage.
Use other accessories related to this equipment only after reading information on the usage, and warning and caution first. User guide related to electrode is provided separately.

Description of front part on main frame

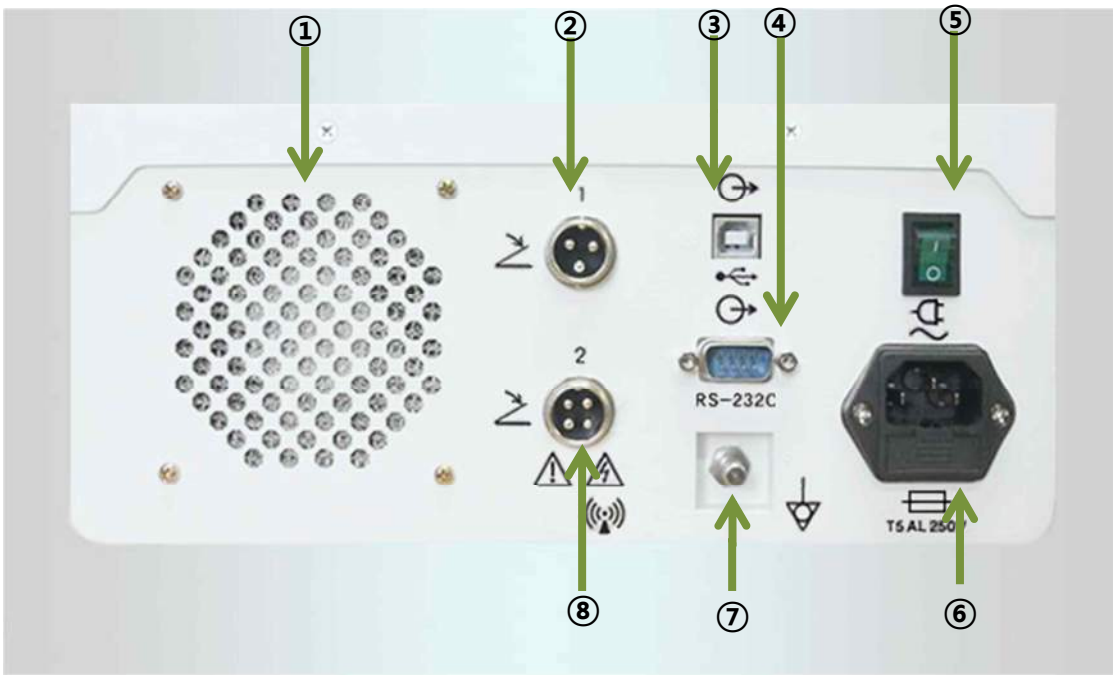


[Diagram for the main frame's front part]

Description of the adjustment part at the front part

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 frame's screen
4	RF START/STOP button	The setting power is generated when General button is on only. The RF output value will be adjusted by the RF power control dial while operating. (General Mode) When Auto Mode is on, which starts 50watts and increases 10 watts every minute automatically until the first RF pause, and then it will be pulsing RF output. Initial value is from 5W to 100W in units of 5W and it is indicated on a Segment, VFD display screen.(The maximum value is 200W) When the CONTINUANCE Mode is on, RF output is generated continuously with the setting value and it will be adjusted by using the RF power control dial.
5	RF POWER control dial	Adjusts the RF output power. (AUTO mode is an exception)
6	RF CABLE connector	This is electrosurgical electrode coupler for the RF output.
7	GROUND PADS connectors	Those are couplers to connect with the cables of the grounding pads that receive the RF current released from RF electrode.
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.

Rear part of main frame

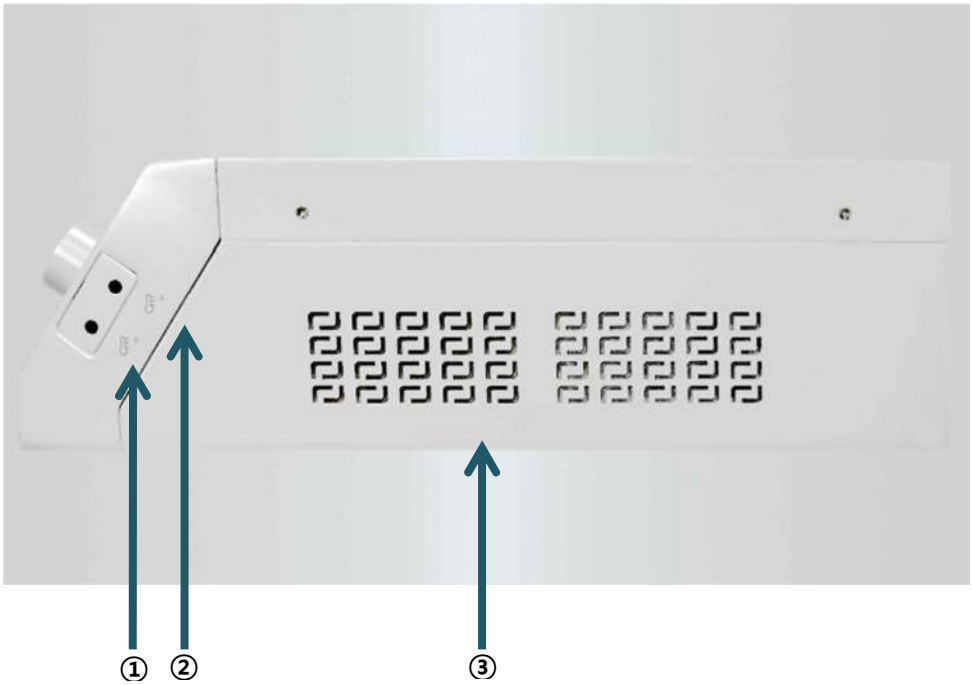


[Diagram of the main frame's rear part]

Description of the main frame's rear part

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	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 * This module is only used in domestic.
5	Power switch	Turns on/off the main power supply
6	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.
7	Equipotential grounding terminal	Equipotential grounding coupler for making the equipment and electric potential the same besides the main frame
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 (+))

Side part of main frame



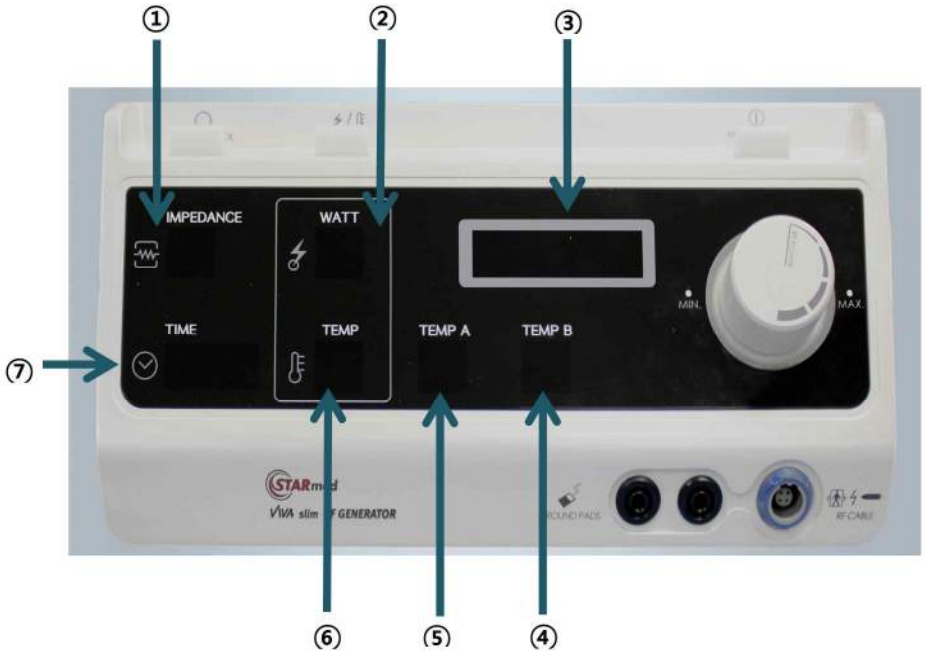
[Diagram of the main frame's side part]

Description of the main frame's rear part

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

Main screen

[Diagram of the Screen]



Description of the Segment, VFD *screen's indication parts*

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	Safety alarm1	Indicates message when the resistance value is too high or when the state of grounding pads, electrode connection are faulty

9	Safety alarm2	Indicates message when RF output is 0 (General Mode only).

10	Safety alarm3	Indicates message when the temperature is too high.

Usage

(1) 50W RF OUT (AUTO Mode)

A) The initial values are set with 50W, 12 minute-long automatically when press the AUTO Mode button on main frame. 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. Alarm is triggered every three minutes. 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).
[Diagram of the output]

(2) 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
[Diagram of the output]

E) After RF output for 12 minutes, the alarm rings three times at 2-second intervals.

(3) CONTINUANCE RF OUT (for Track ablation)

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.

(4) 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 front panel display.

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 front.

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.

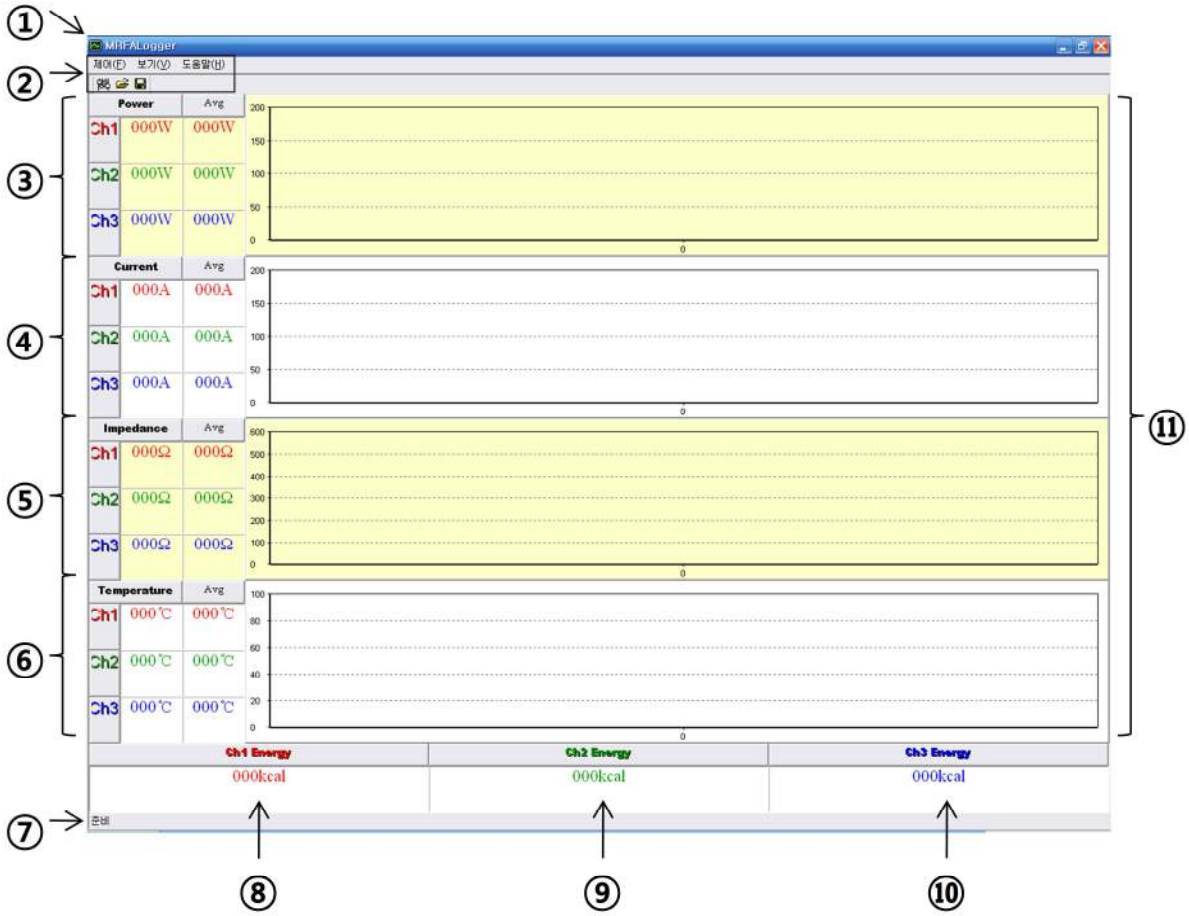
F) Temperature monitoring channel sees the temperature of the procedure part

(5) OHM/CHECK

A) Press on the OHM/CHECK button of the main frame.

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.

(6) Run and storage of PC linked monitor program



[Diagram of the software]

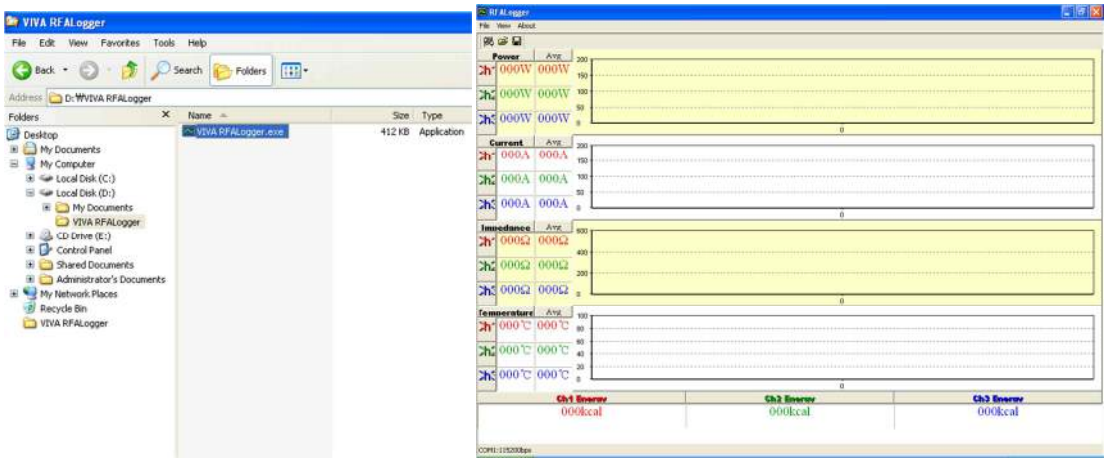
Description of the program screen indication

No.	Feature name	Function
1	Program title indication part	Indication for the program's title
2	Menu part	Setting up of the communication with the generator, document storing and the version information etc.
3	Power value indication part	indicates amount of power that is approved to the electrode at the time of RF output
4	Current value indication part	indicates amount of current that is approved to the electrode at the time of RF output
5	Impedance value indication part	Indicates the measured impedance value at the targeted tissue at the time of RF output
6	Temperature value indication part	indicates temperature value measured on the active tip of electrode at the time of RF output
7	program status indication part	Indicates program's current status, communication setting, name of the document storing
8	Total amount of approved energy	Indicates the total amount of energy that is approved
9	No use	
10	No use	
11	Status graph indication part	Status of the power, current, impedance and temperature is indicated by graphs

A) 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.

B) Execute by double clicking the VIVA RFALogger.exe in the folder of the path where software is installed.



C) 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 (COM6))

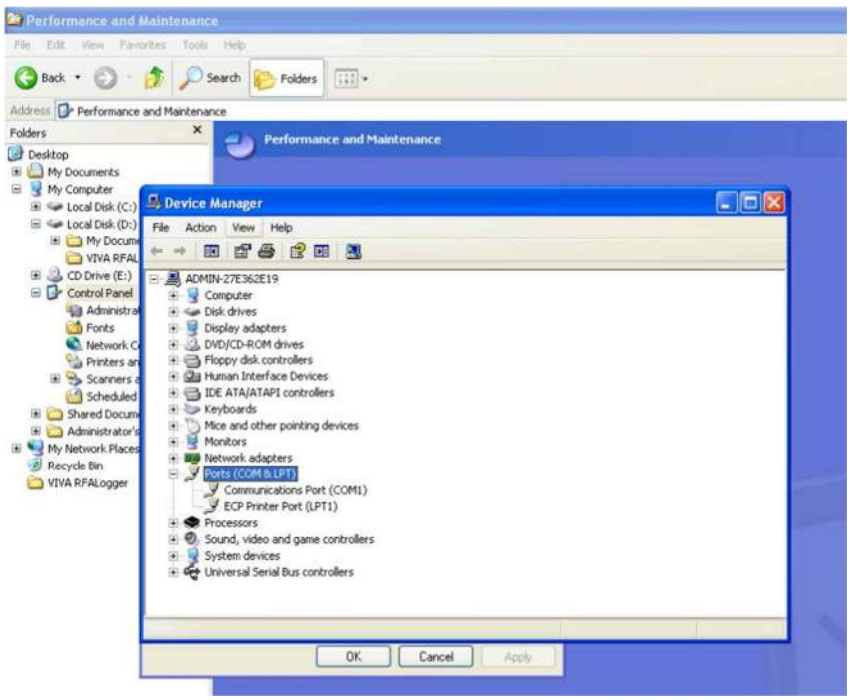


Diagram 1

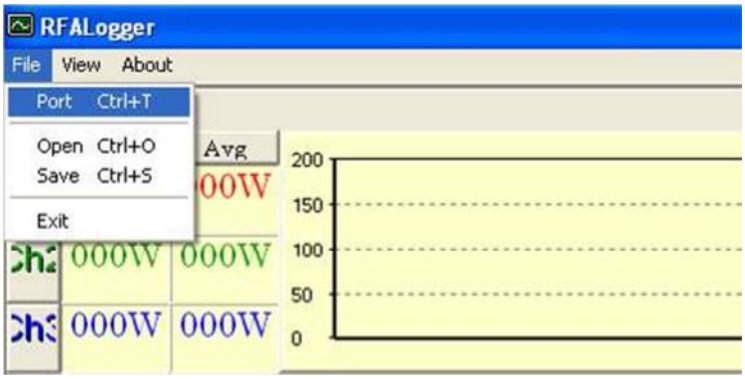


Diagram 2

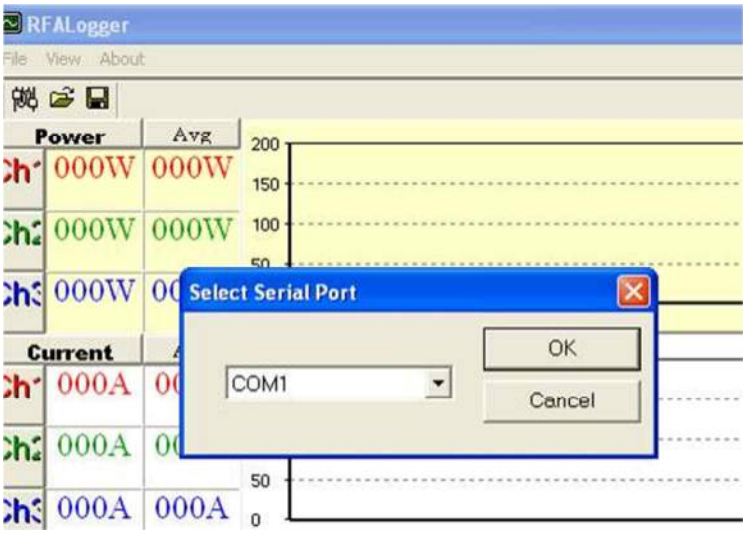


Diagram 3

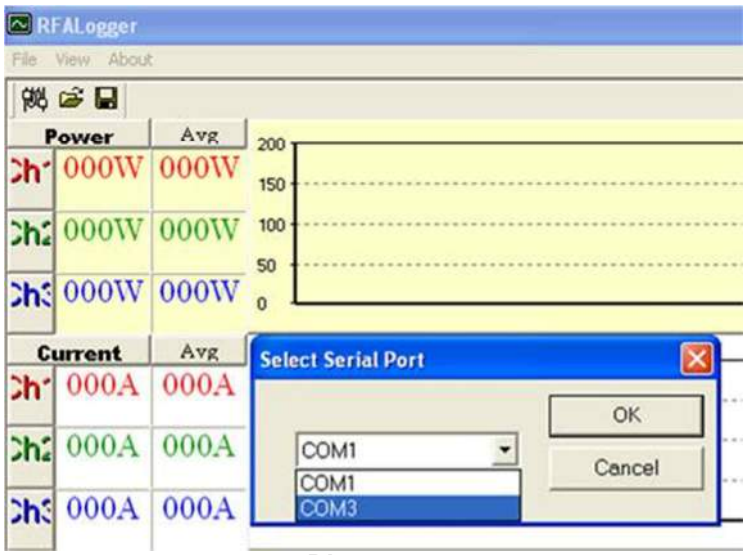


Diagram 4

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

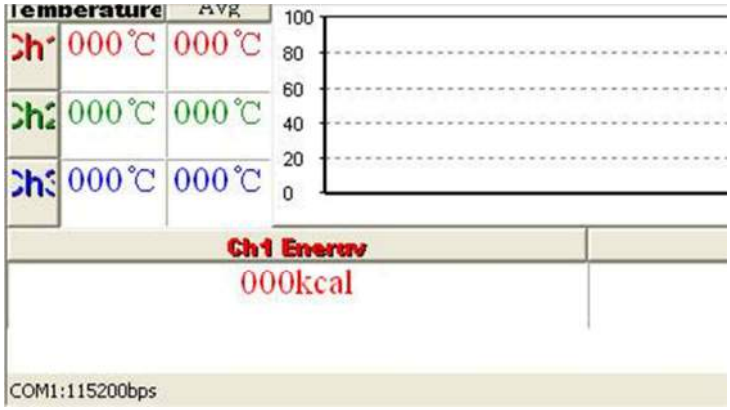


Diagram 5

Select and execute the port menu to set up the communication port that is currently in use.
When completed, setting status of the communication port and communication speed that are set currently are indicated on the program status indication line as shown on Diagram 5.

D) Setting up the path and the file name of the document to store (sequence: Diagram 6 → 7)

Diagram 6

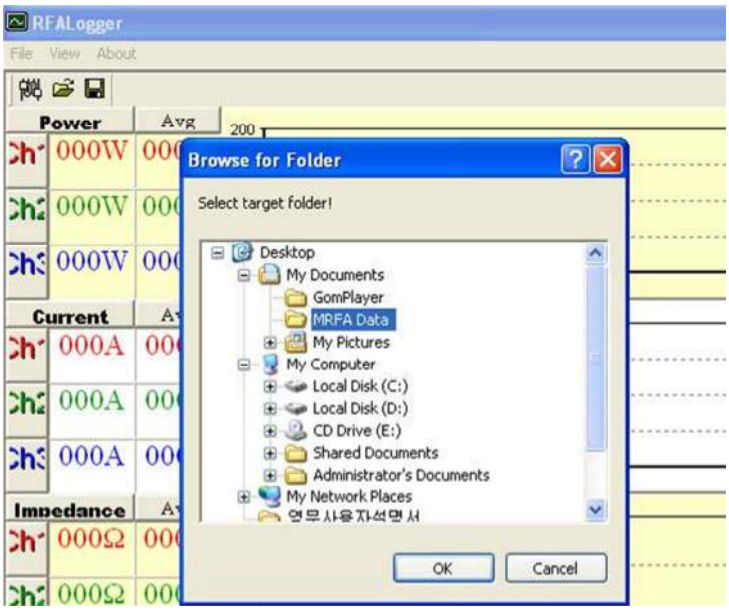


Diagram 7

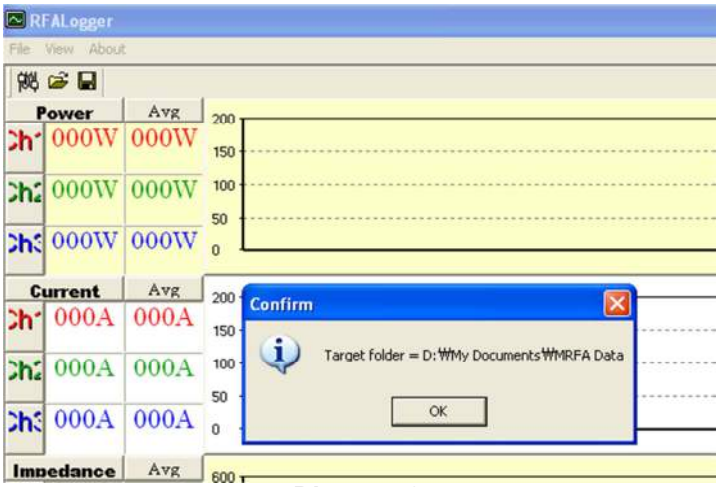


Diagram 8

When you execute the Save menu to open up the storage dialog box, 'Browse for folder' is indicated. Then, select a folder to store file and input the file name. Path of the file stored is indicated as shown on Diagram 8 and then, when you click 'OK' button, it will be completed.

☞ Caution: file name to be saved is created automatically for every VIVA combo RF generator operation, and the file name is applied into 'day of the week_month_day_hour_minute_second_year_record' format.
(Example: Fri_Jan_09_19H_14M_01S_2008_record)

E) After complete the setting for path of file, set up the operation mode, RF power value and operation time etc on VIVA combo RF Generator. Then, press on the 'RF ON' button on the generator. VIVA RFALogger is executed automatically while the generator is running. Values of the power, current, impedance, temperature and energy are transmitted from the generator, and they are indicated and executed as shown on Diagram 10.

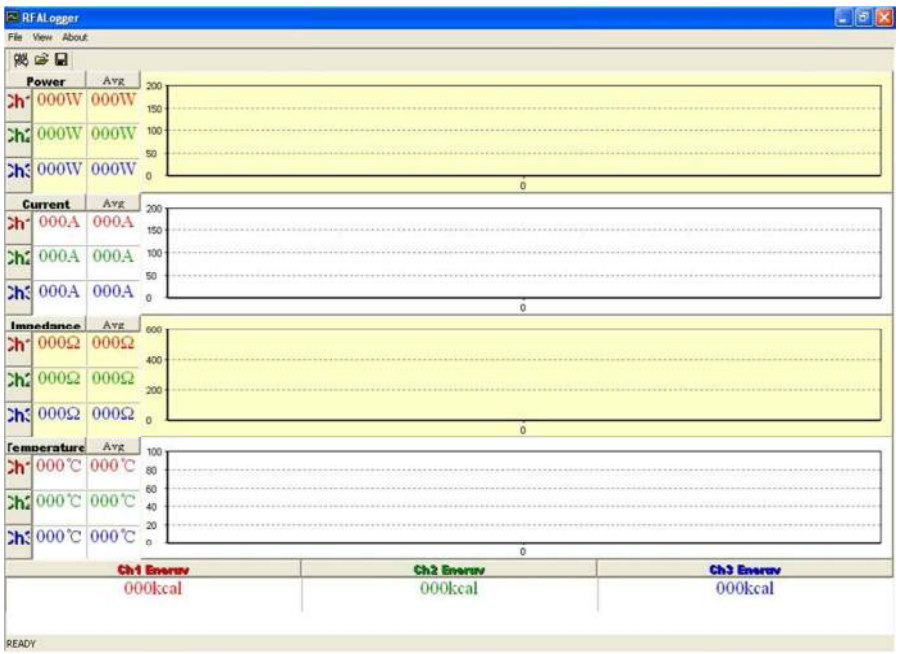


Diagram 9

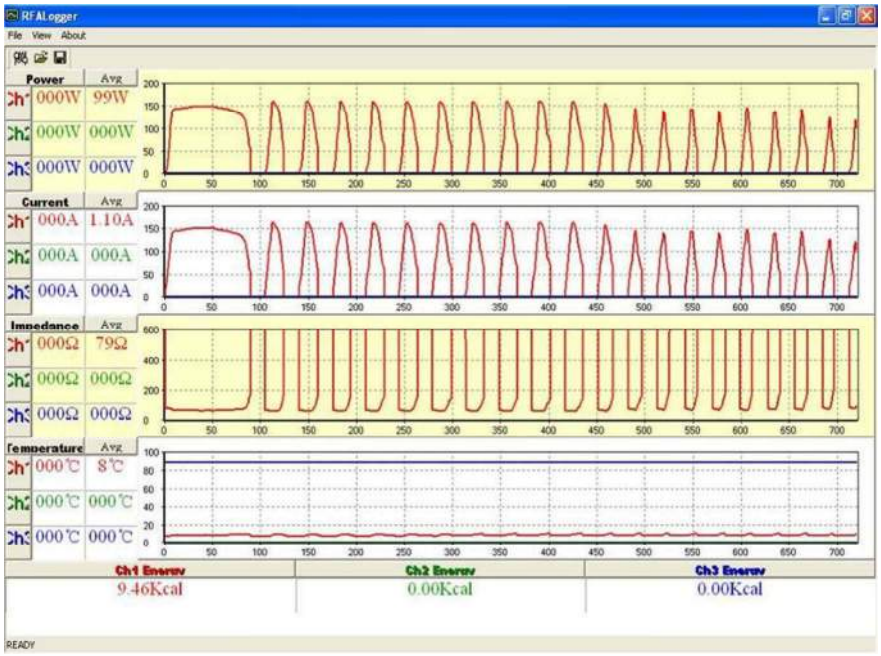


Diagram 10

F) Open the saved document

As shown on Diagram 11 and 12, select the Open menu and search the file which you want to open, and then select and execute it.

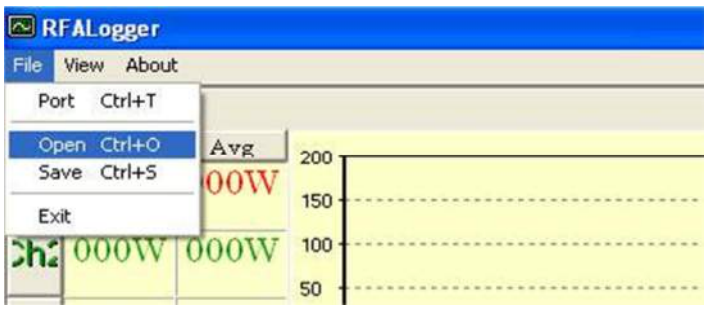


Diagram 11

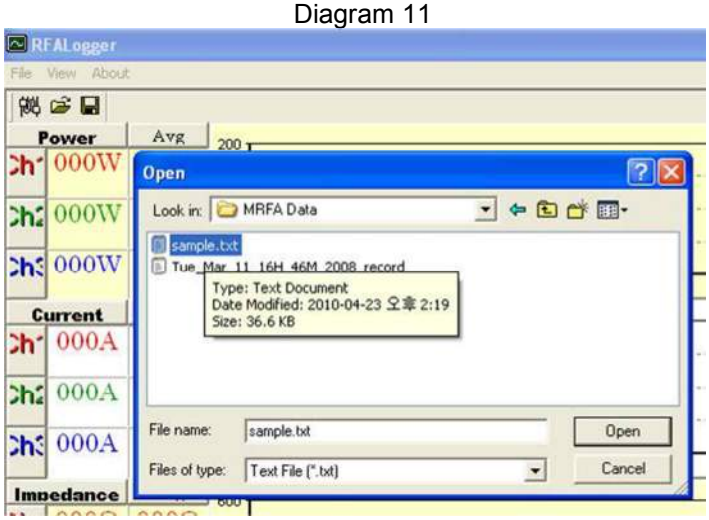


Diagram 12

G) Indicate information on the program version

As shown on Diagram 13, select and execute the About menu. You can check the version of program.

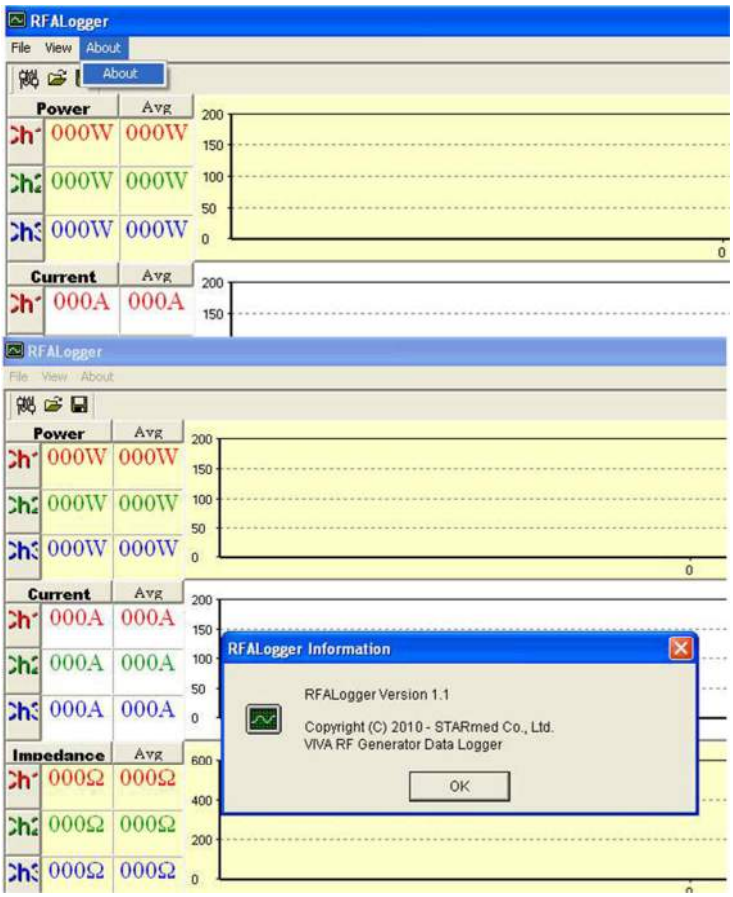


Diagram 13

H) End of the PC linked monitor program
As shown on Diagram 14, select and execute the File menu. When you execute Exit, the PC linked monitor program will be close.

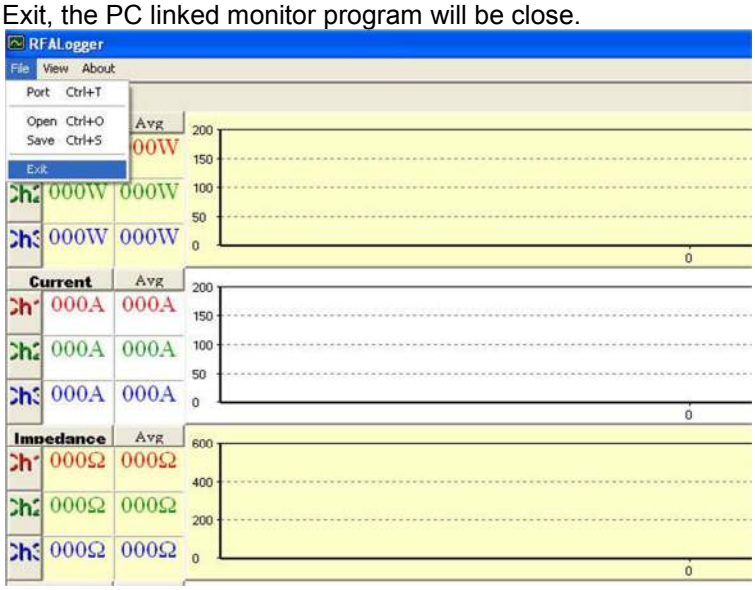
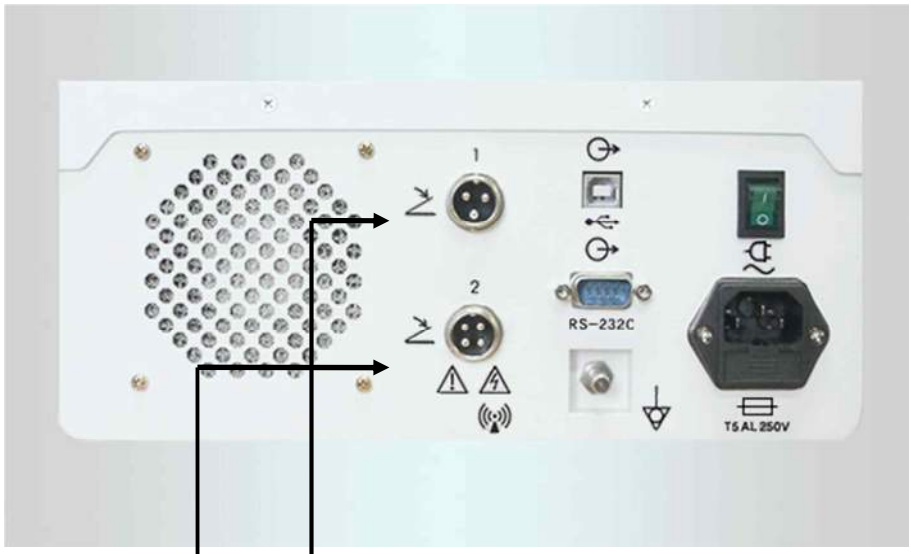


Diagram 14

(7) Foot switch installation and operations guide

☞ **Foot switch is a product accessory**.



Single Foot Switch

Double Foot Switch

☞ **Connect the foot switch then tighten the screws.**

A) Single Foot Switch.

Foot switch pedal connected with this part that offers the same function as that of the RF START/STOP button function.

☞ **Press the switch more than 1 second to start RF out.**

Single Foot Switch is the same function as the RF START/STOP Button

B) Double Foot Switch.

Foot switch pedals connected with this part that offer the same function as that of the RF power control dial function.

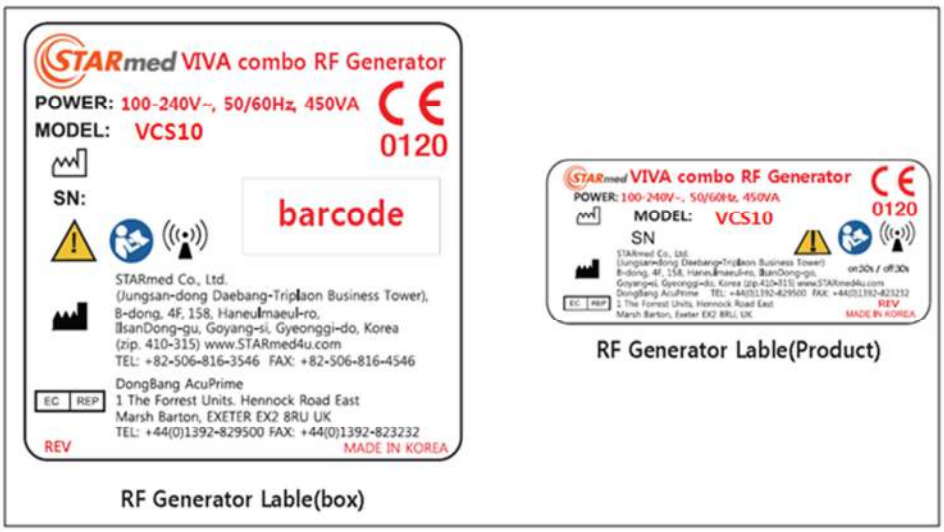
☞ (Yellow (-5W), blue (+5W))

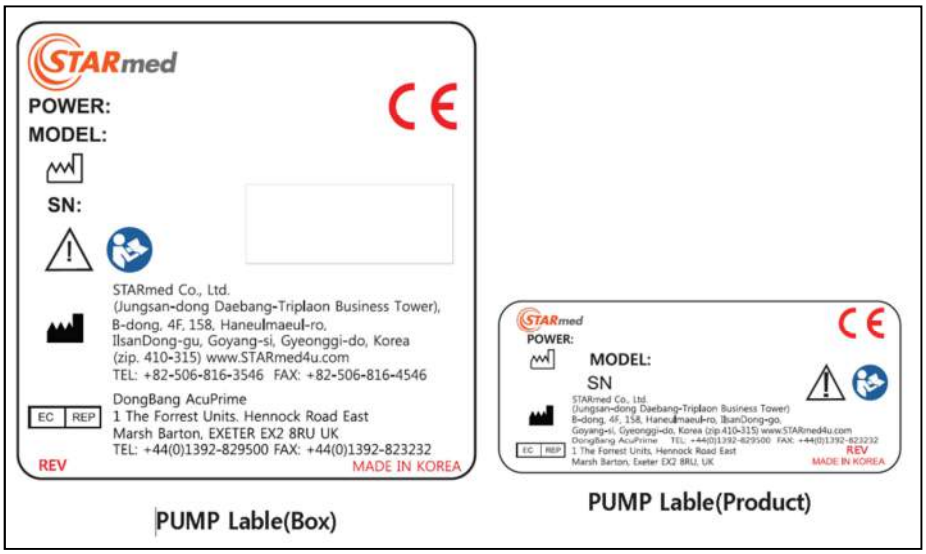
Yellow pedal press to reduce output.
(Press and hold the switch output goes down quickly.)

Blue pedal press to increase output.
(Press and hold the switch output goes up quickly.)

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

Labeling


STARmed VIVA combo RF Generator
POWER: 100-240V~, 50/60Hz, 450VA
MODEL: VCS10
0120
SN:
barcode
STARmed Co., Ltd.
(Jungsan-dong Daebang-Triplaon Business Tower),
B-dong, 4F, 158, Haneulmaeul-ro,
IlsanDong-gu, Goyang-si, Gyeonggi-do, Korea
(zip. 410-315) www.STARmed4u.com
TEL: +82-506-816-3546 FAX: +82-506-816-4546
DongBang AcuPrime
EC REP
1 The Forrest Units. Hennock Road East
Marsh Barton, EXETER EX2 8RU UK
TEL: +44(0)1392-829500 FAX: +44(0)1392-823232
REV
MADE IN KOREA
RF Generator Lable(box)
STARmed VIVA combo RF Generator
POWER: 100-240V~, 50/60Hz, 450VA
MODEL: VCS10
0120
SN
RF Generator Lable(Product)


STARmed
POWER:
MODEL:
SN:
STARmed Co., Ltd.
(Jungsan-dong Daebang-Triplaon Business Tower),
B-dong, 4F, 158, Haneulmaeul-ro,
IlsanDong-gu, Goyang-si, Gyeonggi-do, Korea
(zip. 410-315) www.STARmed4u.com
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DongBang AcuPrime
EC REP
1 The Forrest Units. Hennock Road East
Marsh Barton, EXETER EX2 8RU UK
TEL: +44(0)1392-829500 FAX: +44(0)1392-823232
REV
MADE IN KOREA
PUMP Lable(Box)
STARmed
POWER:
MODEL:
SN
REV
MADE IN KOREA
PUMP Lable(Product)

Explanation of symbols

RF generator

Type BF protection against electric shock, defibrillator protected

Floating return (high frequency)

Warning: Dangerous voltage/no user-serviceable parts inside

Footswitch input jack

Signal input/output port

Attention: Consult user's/Operator's guide

Equipotential ground

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

RF START /STOP

Non-ionizing electromagnetic radiation

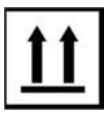
Serial number

Manufacturer

Date of manufacturer

Box

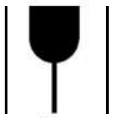
Handle with care



This side up

Package keep dry

Stacking limit



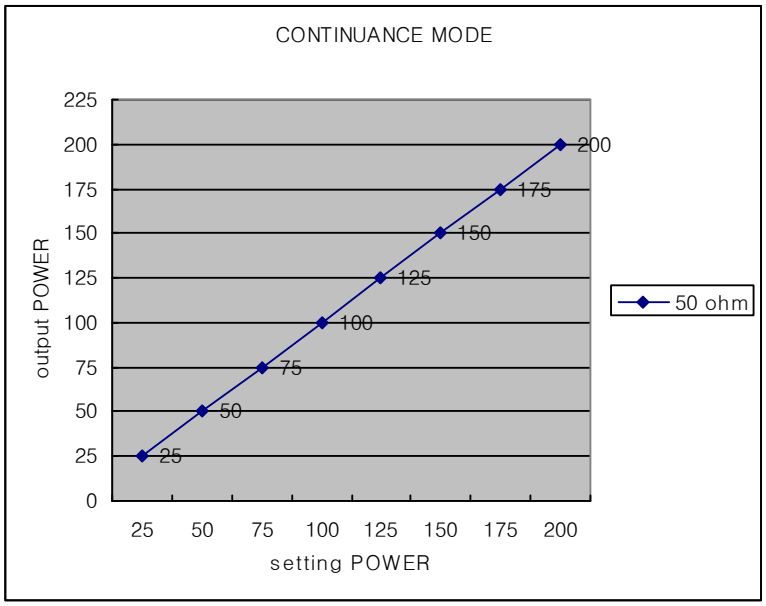
Fragile

Manufacturer

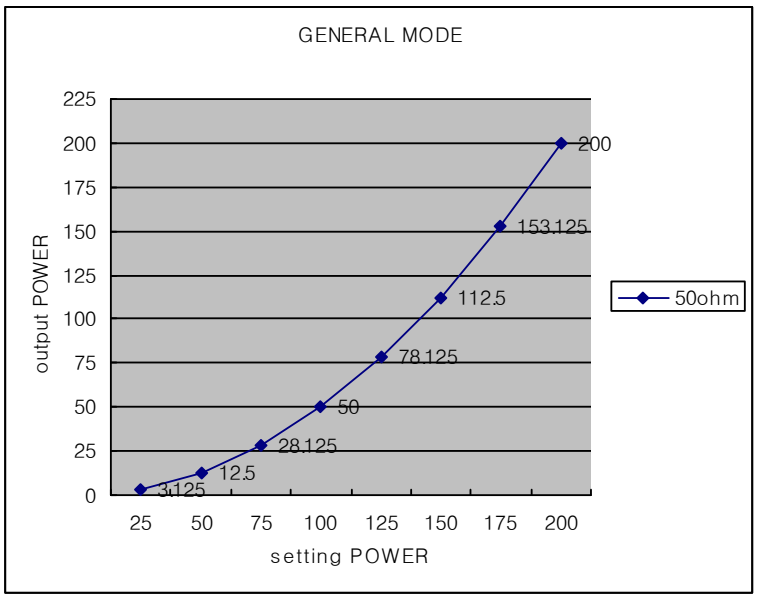
No use hook

Generator output power characterization

(1) CONTINUANCE MODE



(2) GENERAL MODE



* For more information about the RF power, refer to the service manual

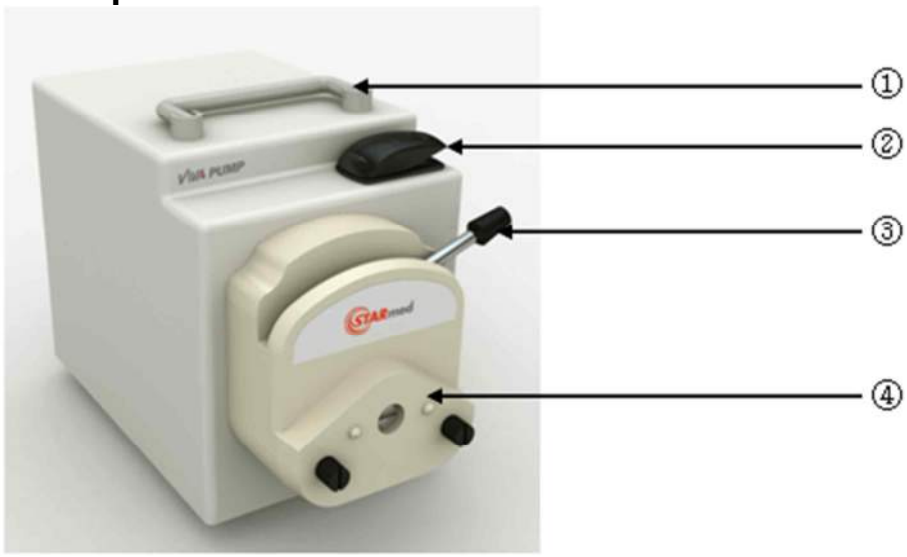
Specifications of radiofrequency lesion generator

Rated power	
Voltage:	110/220 VAC~
Voltage range:	100-240 VAC~
Maximum input voltage:	250 VAC~
Maximum input power:	450 VA
Maximum input current:	4A (100/120 VAC units), 2A (220/240 VAC units)
Fuse capacity:	T 5AL 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 to 95˚C
Resolution:	1˚C
Accuracy:	±5˚C
Operating environment	
Clean, dry area	
Temperature	15˚C to 40˚C
Humidity:	15-80% relative, non-condensing
Atmospheric Pressure:	800-1060 hPa

3. Peristaltic pump

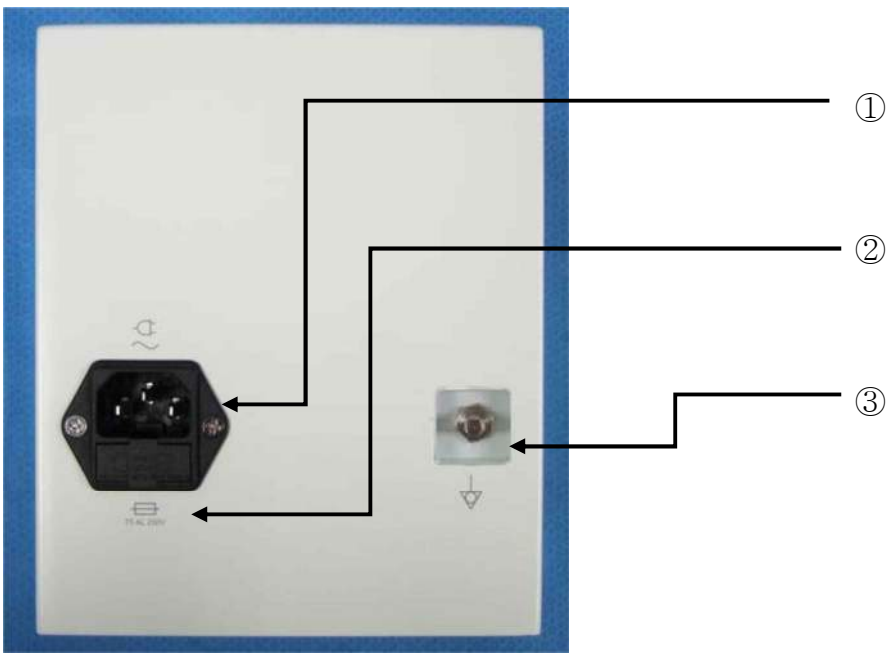
Caution
Use this peristaltic pump only after reading warning and caution messages and information on the usage first.
Use other accessories related to the peristaltic pump only after reading information on the usage, and warning and caution messages first.

Description



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



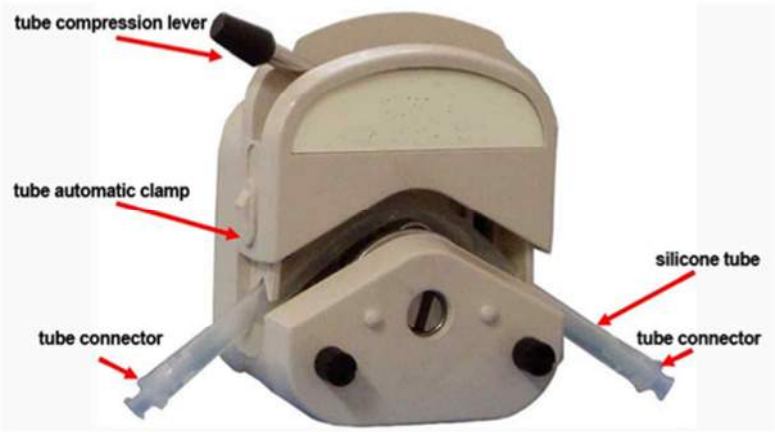
Description of the pump's rear part

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

Preparations

Mounting the pump tubing inside of the front part

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.



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

Explanation of symbols

Attention: Consult user's/Operator's guide

Equipotentiality terminal

Specifications of peristaltic pump

Rated power	
Input voltage	AC 100V-240V~
Frequency	50/60 Hz
Consumption power	80VA (max.)
Flow rate (when using while connecting to the electrode tubing set)	
Flow rate :	80-140 ml/min
Dimension	
Size (w x h x d)	193 * 160 * 135 mm
Weight	4Kg
Operating Environment	
Clean, dry area	
Temperature:	15˚C-40˚C
Humidity:	15-80% relative, non-condensing
Atmospheric Pressure:	800-1060 hPa

4. Others

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.

Device Classification

Classification as per EN 60601-1, 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:	IPX 0
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

Storage and management method after use

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

A) Turn off the power switch of the main frame'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 to 40℃.

D) Cleaning method: Use 70% isopropyl alcohol solution to wipe off the main frame. 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 to 40˚C
Humidity:	0% to 87%, including condensation

Waste equipment and management method

- Discard

Please call or Consult your local STARmed representative for supporting.

Cleaning and Disinfection

The RF lesion generator 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 or pump. Sterilization will destroy the unit's electronic components.

Maintenance and Service

The RF lesion generator and pump are not user serviceable, and both units should be returned to STARmed if any problems arise. Please call your local STARmed representative for support. To ensure accuracy of unit output and displays, the unit must be returned to STARmed every year for calibration.

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 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.

Matters to include

A. Product name: Radiofrequency lesion generator (ClassIIb by CE classification)
Brand name : VIVA combo RF Generator
Model name: VCS10
B. Manufacturer's business name: STARmed Co.,Ltd
Manufacturer's address: (Jungsan-dong, Daebang-Triplaon Business Tower), B-dong, 4F, 158, Haneulmaeul-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea
C. Purpose for the product use: Medical device that is used for the necrosis coagulation of the targeted tissue or for hemostasis by using radiofrequency current
D. Manufacture No. and date of manufacture: refer to the label
E. Weight:6 kg Packing unit: 1 set
F. Performance and use method: refer to the user's guide
G. Cautions during use: refer to the user's guide
H. Other matters to be included
(1) Rated power: 100-240VAC
(2) Frequency: 50/60 Hz
(3) Consumption power: 400
(4)Rated output: 0~200W(50Ω), 480 ㎑
(5) Format and degree of protection against electric shock: ClassI, BF type device
I. Attached part: product's exterior decor
J. This product is a medical device

Caution
Do not sterilize radiofrequency lesion generator or peristaltic pump. If do, it may a cause of damage of the devices.