(Jungsan-dong, Daebang-Triplaon Business Tower), B-dong, 4F&12F, 158, Haneulmaeul-ro,
IlsanDong-gu, Goyang-si,Gyeonggi-do, Korea, 10355

User's Guide

VIVA RF Electrode

(ST-UM-24E(US)(Rev.2)

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 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 RF Electrode

Part No. 15-15V05-30X, 15-20V05-30X, 17-15V05-30X, 17-20V05-30X,
18-07V05-30X, 18-10V05-30X,
15-15V05-30X_V2, 15-20V05-30X_V2, 17-15V05-30X_V2, 17-20V05-30X_V2,
18-07V05-30X_V2, 18-08V05-30X_V2, 18-10V05-30X_V2

Effective date: 2020.12

Notices

Manufactured for:

STARmed Co., Ltd.
(Jungsan-dong, Daebang-Triplaon Business Tower), B-dong, 4F&12F, 158, Haneulmaeul-ro,
Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea, 10355
TEL: +82(506)-816-3546
FAX: +82(506)-816-4546

Internet address

www.STARmed4U.com

Product Warranty

STARmed warrants sufficient care for the design and manufacture of this device. We cannot warrant any content that is not described in this manual.
STARmed's device under this warranty is limited to repair and replacement, and STARmed Co., Ltd. is not responsible for any economic expenditures caused by unexpected issues, significant loss or damage. STARmed Co., Ltd. is not transferring responsibility and duty related to this device to other parties, and will not take any responsibility regarding reuse, and usage of re-sterilized or expired products.

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

Table of Contents

1. Introduction

The active electrodes are a sterile, single-use, hand-held electrosurgical instrument designed for use with RF lesion Generator. Cooling of the electrode is provided by chilled water which is pumped through the inflow tubing, the electrode and out through the outflow tubing. This is an enclosed system within the electrode and the water is not to be in contact with the patient.

The electrode for this electrosurgical unit is used by connecting with RF lesion generator from STARmed Co., Ltd. which is designed to coagulate tissues. Tissues can be coagulated with the supply of radiofrequency energy from electrosurgical unit, which is connected for monitoring resistance of continuous tissues and temperature.

The exposure length of VIVA RF Electrode is adjustable with 5mm units(6steps) by a button found on the handle.

There are two types of electrodes, one is with a marker and the other is without a marker. The one with a marker can be easily located via X-ray imaging.

The VIVA RF Electrode is MONOPOLAR. Therefore, the grounding pad should be used with the generator to prevent burns/injury to the patient.

1.1. VIVA RF Electrode

- Rated Voltage: 100-240 V~, 50/60 Hz
- Compatible Generator: VIVA combo RF System
- Limitation on Generator Output and Duration of Activation: 0 – 200 watts max output @ 50 ohm / 30minutes max.
- Recommended ablation time per lesion size:

Gauge	Tip Exposure Length (mm)	Watt	Time	Width (Cm)	Depth (Cm)	Volume (mL)
15	5	40	3	1.00	0.93	0.49
	15	130	8	2.50	2.50	8.27
	20	160	10	2.90	3.10	13.63
	25	190	12	3.40	3.50	22.42
	30	200	12	3.80	4.25	31.27
17	5	30	3	0.89	0.82	0.34
	15	120	6	2.00	2.30	4.33
	20	150	8	2.43	3.00	9.34
	25	180	10	2.85	3.50	15.14
	30	200	12	3.20	4.10	23.34
18	5	12	2	0.66	0.73	0.2

Gauge	Tip Exposure Length (mm)	Watt	Time	Width (Cm)	Depth (Cm)	Volume (mL)
	15	110	6	1.8	2.1	3.36
	20	135	8	2.3	2.98	8.42
	25	165	10	2.7	3.48	13.26
	30	175	12	3.01	3.9	18.98

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.

1.2. Grounding Pad

- Dimension: 187(H) x 145(W) (mm)
- Conductive Area: 160 cm^2
- Compatible Generator: VIVA combo RF System
- Limitation on Generator Output and Duration of Activation: 0 – 200 watts max output @ 50 ohm / 30minutes max.
- Appropriate patient population: Adult

2. Guide for use

- Users should read all of the following information and also the provided user's guide to the corresponding components such as generator and neutral electrodes.
- VIVA RF Electrode is designed to be used in conjunction with RF lesion generator from STARmed Co., Ltd. If the guidelines are not properly followed, damages from electricity or heat can be caused and the equipment may malfunction.

3. Intended Use

- VIVA RF Electrode is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.

4. WARRANTY

- STARmed Co., Ltd. warrants sufficient care for the design and manufacture of this device.

We cannot warrant any content that is not described in this manual.

- STARmed's device under this warranty is limited to repair and replacement, and STARmed Co., Ltd. is not responsible for any economic expenditures caused by unexpected issues, significant loss or damage. STARmed Co., Ltd. is not transferring responsibility and duty related to this device to other parties, and will not take any responsibility regarding reuse, and usage of re-sterilized or expired products.

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 (N_2O) 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.
- INSPECT instruments and cables for damage prior to each use. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.
- Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation
- Before using this product, check whether there is any damage to the packaging.
- The expiration date is 3 years from the sterilization date. Use of the products after the expiration date is prohibited.
- This device is disposable and reuse is prohibited.
- This device is designed to be used by a qualified and trained Medical Doctor.
- This device is designed to be used in conjunction with VIVA combo RF generator. Do not use in conjunction with other manufacturer's generator.
- This device should be stored in a cool place without sunlight and humidity.
- Do not touch the exposed tip of electrode while power supply is on.
- Do not touch the shaft of electrode with fingers or other tools (insulator and components of metallic response)
- Do not touch hand piece/ electrode cable with metallic materials. Patient or operator might get shocks, fire accident or injury.
- Do not use near conductive materials such as part of metallic bed or spring mattress.
- Like all other electrosurgical units, do not use in the presence of flammable anesthetics, nitrous oxide, oxygen or any other flammable substances. It might be a cause of fire in the electrosurgical unit.

- Do not activate electrode while it is in touch with metallic substance or tools because it might cause unexpected injury to patient.
- Do not touch metals or tools with the electrode while the power supply is on. It might cause unexpected injury to patients and also damage the electrode or other devices.
- When use the electrode, do not hold the tip of the electrode by tongs (ex. Kelly), do not pass the electrode through a hole of other devices, and do not scratch the surface on the electrode's tip by sharp things. These actions might destroy the insulation of the electrode and damage the end of the electrode. It might be a cause of unexpected injury to patient or user
- 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.
- 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 grounding pad 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 grounding pad or poor contact in its connections.
- If the provided grounding pad is not used, the alarm for CQM indicating the loss of safe contact between the neutral electrode and the patient will not be activated.

Grounding Pad

- 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 Grounding pads that is provided by the STARmed and that satisfies the applicable standards 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 coagulation 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 coagulation.
  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.

5. Adverse Effect

- Burning by overheating of surgical unit.
- Dangers from inexperienced operator's use.
- Side effects or cross infection from reuse.
- Weakness of liver functions.
- Delayed bleeding in the operated body parts.
- Recurrence of cancer.
- Symptoms after RFA treatment include

(abdominal) pain, fever, nausea, headache, right shoulder joint pain and chest discomfort might occur.

6. EMC Information

Phenomenon	Basic EMC standard or test method	Port tested	Test level/requirement
Mains terminal disturbance voltage	CISPR11:2015	AC Mains	Group2, Class A
Radiated disturbance	CISPR11:2015	Enclosure	Group2, Class A
Harmonic Current Emission	IEC 61000-3-2:2014	AC Mains	Class A
Voltage change, Voltage fluctuations and Flicker Emission	IEC 61000-3-3:2013	AC Mains	Pst: 1 Plt: 0.65 Tmax:0.5 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	IEC 61000-4-2:2008	Enclosure	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3:2006 A1:2007+A2:2010	Enclosure	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3:2006 A1:2007+A2:2010	Enclosure	Table 9 in IEC 60601-1-2: 2014

Electrical Fast Transient/Burst Immunity	IEC 61000-4-4:2012	AC Mains	± 2 kV, 100 kHz repetition frequency
Surge Immunity	IEC 61000-4-5:2014	AC Mains	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to Conducted Disturbances Induced by RF fields	IEC 61000-4-6:2013	AC Mains	3 V 0.15-80 MHz
		Sip/Sop Patient Connected	6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	IEC 61000-4-8:2009	Enclosure	30 A/m 50 Hz & 60 Hz
Voltage dips	IEC 61000-4-11: 2004	AC Mains	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
			0 % UT; 1 cycle and 70 % UT; 25/30 Cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11: 2004	AC Mains	0 % UT; 250/300 cycle

7. Before using

7.1. Preparation of coolant

The temperature of the coolant should be maintained at almost 0℃ by keeping the IV bag in the refrigerator for 4 hours or one day before the procedure, and it is used just before performing the procedure.

7.2. Grounding pads

Caution

- Re-using grounding pad is prohibited.

- After removing the transparent plastic protection films, attach the apse lines of grounding pads on the thighs widthwise.
- Be careful not to form air bubbles between grounding pads and skin while attaching. If it is necessary, remove hair at the site, clean and dry the area.
- Attach the grounding pads at the same distance from treated area.
- Make sure the lines connected to grounding pads and electric surgical unit are not twisted.

- Recommended attachment sites of the grounding pads are as follows-Body parts with clear blood vessels and muscle, convex surface of thigh.
- Check that the alarm does not activates on the generator, when the grounding pad connect to patient. If the alarm activate, the connection is NOT stable.
- The areas to be avoided for correct attachment of grounding pads are as below.

Caution
- Fire injury, inflammation, fatty areas, protrusion with bones, ECG electrode and electric line, metal implanted part, areas where liquid can be collected, pacemaker.

7.3. Tubing set-up

- Connect electrode, input/output tubes and pump tubing.
- Open the cover of pump head upwards, place pump tube(rubber tube) in the middle of roller, and place the tube precisely at the groove of pump head. Then, secure the tube in the pump by closing the cover.
- Straighten the tube by stretching both sides.
- Hang coolant on the I.V. pole and puncture the bag with the spike. The roller clamp should be temporarily closed until the beginning of the procedure.

8. During use

1. Connect the RF lesion generator and electrode and check the connection status.

Caution
- Before inserting the electrode into lesion, check if exposed length of the electrode and other specifications are identical with specifications on labels.

2. Check the location of lesion to be treated using diagnostic imaging devices such as US and CT, and place the electrode in the lesion.

How to perform multiple ablations on a single lesion
- Use an image guide such as CT and US to check the tip of the electrode and relocate it to the place where multiple ablations are needed. Conduct tract ablation before taking out the electrode for the relocation of the electrode or multiple ablations if needed.

3. Once the electrode is placed in the lesion, check that the coolant is flowing out from the electrode's output tube by operating the pump connected with the input tube. Turn on RF lesion generator by pressing the output switch.

Caution
- The generator’s output voltage does NOT exceed the rated accessory voltage.

4. Adjust the length of the exposure tip with the button by either pulling or pushing.

Caution

- After adjusting the length of the expose tip, check whether the button is fixed by checking the status of button and the insulation before use.

5. Once the procedure is completed, turn off the power switch of the RF lesion generator and separate electrode and parts from the generator.

How the user knows when an ablation is complete

- Through the image guide of the MRI and CT, check the necrosis area to see if it is coagulated 5-10mm larger than the initial target lesion.

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.*

9. After using

1. Grounding pad

- When the procedure is finished, turn off the power switch on the RF lesion generator and separate connectors of the grounding pads.
- Slowly remove the grounding pads in order to prevent injury on the skin surface.
- Do not remove the grounding pads by pulling the electric lines.

2. Upon completion of the procedure, turn off the power switch of RF lesion generator and Separate electrode, parts and etc.

3. Dispose of the electrode according to the waste materials disposal procedure.

10. Storage

- Keep at room temperature

Caution.

- This device is intended to be sold, used by order of doctor according to the related medical device laws.

11. Action for product damage

Caution.

- If any damage on product is visually noticed, do not use to prevent any injury to patient.

12. Expiration date

- 3 years from sterilization

13. How to Order

- To order a VIVA RF Electrode indicated in the below, please contact to STARmed Co., Ltd. The contact information is indicated the end of this user manual.

Part number	Electrode Length (mm)	Tip Exposure Length (mm)	Gauge
15-15V05-30X	150	5/10/15/20/25/30	15
15-20V05-30X	200	5/10/15/20/25/30	
15-15V05-30X_V2	150	5/10/15/20/25/30	
15-20V05-30X_V2	200	5/10/15/20/25/30	
17-15V05-30X	150	5/10/15/20/25/30	17
17-20V05-30X	200	5/10/15/20/25/30	
17-15V05-30X_V2	150	5/10/15/20/25/30	
17-20V05-30X_V2	200	5/10/15/20/25/30	
18-07V05-30X	70	5/10/15/20/25/30	18
18-10V05-30X	100	5/10/15/20/25/30	
18-07V05-30X_V2	70	5/10/15/20/25/30	
18-08V05-30X_V2	80	5/10/15/20/25/30	
18-10V05-30X_V2	100	5/10/15/20/25/30	

14. Symbol


Consult instructions for use


Manufacturer

Catalogue number

Sterilized using ethylene oxide


Caution


Use-by date

Batch code


Do not re-use


Date of manufacture

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

15. Reuse Precaution Statement

- The contents of this product have been sterilized with E.O. gas. If sterilized package is damaged, do not use it and call STARmed Co., Ltd.
- This product can be used only one time. Reuse, re-treatment or re-sterilization is not allowed.
- If the electrode is reuse, re-treated or re-sterilizated, it might cause defects in the structural functions of electrode and damage of RF lesion generator which might lead to injury, disease or death to patient. Reuse, re-treatment or re-sterilization can bring dangers such as device contamination, and infections among patients or from other diseases.
- Contamination of this device might be a cause of patients' injury, disease or death.

16. Descriptions

- Product name : Electrode for electrosurgical unit
- Model name : VIVA RF Electrode
- Model number : Refer to the product label
- Lot number. : Refer to the product label
- Date of manufacture : Corresponding year and date
- Number of items : 1 set
- Sterilization method : E.O. gas
- Expiration date : 3 years from sterilization
- Method of use : Refer to the manual
- Purpose of use : Refer to the manual
- Cautions in use : Refer to the manual
- Method of storage : Store at room temperature
- Name of manufacturing Co.: STARmed Co., Ltd.

※ This product is a disposable medical device and reuse is not allowed.

STARmed Co., Ltd.

Address : (Jungsan-dong, Daebang-Triplaon Business Tower), B-dong, 4F&12F, 158, Haneulmaeul-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea, 10355

T E L : +82 506 816-3546

F A X : +82 506 816-4546

http://www.starmed4u.com

E-mail : Inquiry@STARmed4u.com

Date of issue: 2020.12