EverPace™

OptimAblate ™

Cardiac RF Generator

Instruction for Use (IFU)

（Please read this manual carefully before use and pay attention to all kinds of warning）

Shanghai MicroPort EP MedTech Co., Ltd.

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Statement

This IFU is only for installation, operation, and maintenance instructions of the RF generator. All diagnosis will be made by the authorized doctor that can use this system, based on his medical professional knowledge, and the doctor is responsible for the diagnosis. Shanghai MicroPort EP MedTech Co., Ltd., will bear no legal responsibility for any diagnosis conclusion and the corresponding treatment measures.

Please strictly comply with the instructions in this IFU which covers important information.

CE 0123

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1 Introduction

1.1 Objective and purpose

OptimAblate cardiac RF generator is the special device for cardiac ablation. The equipment transmit RF energy by connection special catheter and neutral electrode. Then RF energy transfer to the heart and organization lose function which block undesired ecg signal transduction pathway, achieve the goal of treatment of arrhythmia.

This IFU is intended to describe the operation function of the OptimAblate cardiac RF generator (hereinafter referred to as RF generator). Please read this IFU in whole and use it as a reference guide to obtain the knowledge about the operation of the system.

This IFU is intended to be used by professionals in the catheter laboratory and to be used by workers who perform maintenance and troubleshooting for this device.

1.2 Schematic illustration and names

All of the schematic illustrations in this IFU are only provided as examples. They may not reflect the data monitor settings displayed on your monitor.

In this IFU, all names used in the examples and schematic illustrations are imaginary. The use of any real name is coincident.

1.3 Brief introduction of the product

The maximum RF energy this product can output is up to 100 W, it can support power, temperature and irrigation modes, it is compatible with a variety of catheters, and it can provide real-time impedance and temperature detection and a variety of protection and alarm modes, all these functions together can provide safe and effective, as well as stable and reliable products for clinical doctors.

The device provides a simple and intuitive interface and a friendly operation interface, which can select parameters and set up through touch screen. When the device is used with an irrigation pump, relevant settings of the irrigation pump that can be controlled through the interface of the RF generator can be achieved. In the event of failure, prompts will be displayed on the two devices at the same time, and the safety of the device is improved significantly.

2 Functional Principle

2.1 Functional principle of radiofrequency Ablation

The cardiac radiofrequency ablation refers to the damage of the electrical function (cardiac conduction) of the myocardial tissue with the use of radiofrequency energy.

The term "Radiofrequency (RF)" refers to the non-modulated sine wave in the range of 300 KHZ to 500 KHZ. During ablation, the radiofrequency electric current flows through the biological tissues, and physiological saline provides the electrical conductivity. The tissue conductivity can be expressed as tissue impedance. Low impedance indicates the high conductivity, while high impedance indicates low conductivity.

When radiofrequency current flows through the biological tissue, high temperature will be produced, the higher the current, the higher the temperature. Ablation time is associated with the output power, the smaller the power, the longer the ablation time.

Too high power will lead to overheating, or cause gas due to evaporation of the moisture. Tissue overheating could cause carbonization, which will impair the normal activity of myocardial tissue, and result in catheter blocking due to catheter thrombosis or tissue adhesion, etc. Water vapor can cause air embolism in the body. Therefore, it is recommend not to use too high power for ablation.

The cell tissue will experience change when there is a current flowing through it (the soluble protein in the tissue will change into a solid state). When the current is small, ablation is slow and cells will experience water loss. If the power is too high, although the ablation is quick, the cell moisture also evaporates quickly, water vapor from evaporation will result in pressure which can destroy the cell wall. If the power is extremely high, we can even feel the bubble burst, such as hear a sound or feel vibrations on the handle. Under extreme cases, it will result in the crack of the normal tissue or perforation. Selection of appropriate power output and complete contacting can effectively reduce such phenomena.

The RF generator used in cardiac ablation utilizes the unipolar discharge mode, the RF generator is connected to the body through two cables, one of the cables is connected into the body to the tissue site to be acted on, known as "procedural electrode. The other cable is connected to the skin surface electrode, known as the “neutral electrode”. The two electrodes constitute the radiofrequency current circuit, the human body is part of the radiofrequency circuit, both the procedural electrode and neutral electrode are current pathways. As the electrode area is smaller, the field strength surrounding it is stronger, and thus it will produce obvious heat effect the local tissue, making the tissue being dry or necrosis due to coagulation. The neutral electrode will not produce heating effects on the local tissue does due to larger area.

2.2 Power control mode

As mentioned in the above section, the higher the power, the faster the ablation. Under the power control mode, the RF generator can perform ablation constantly at the power of the user sets, even if the temperature is very high. Users should understand the situation of pathological changes of different sites in the case of high current, and the current intensity is associated with the output power of the RF generator and contacting of the catheter electrode. Users can only assess the effect of the output power when the intracardiac signal at the ablation sites decreases.

2.3 Temperature control mode

Temperature refers to the temperature detected by the temperature sensor of the catheter. For non-irrigation catheter, catheter temperature is an indicator of the temperature of site connecting with the catheter electrode. Under the temperature control mode, the output power of RF generator is limited to not producing temperature higher than the value the user sets, as a result, the risk of tissue charring, adhesion and air embolism are greatly reduced. The main influence factors for tissue pathological changes include ablation temperature and duration.

Note: the temperature the RF generator indicates is the temperature of catheter electrode, rather than the tissue temperature, therefore, too high temperature of the myocardial tissue is still possible. So the temperature control can only act as one of the measures to prevent overheating, but can not absolutely guarantee no occurrence of overheating.

In addition, the difference between the measured temperature and the actual temperature is also associated with the catheter used. When a non-irrigation catheter is used, the temperature error is related to the size of the catheter electrode, the larger the electrode, the greater the error, and the tissue temperature is certainly greater than the measured temperature. If an irrigation catheter is used, then the temperature error may not be absolutely related tissue temperature, and the measured temperature can only serves as a reference at this time.

3 Important Information

3.1 Description of the system

The radiofrequency ablation surgery system is composed of two subsystems:

- The RF generator
- A catheter with temperature sensor, both of which with a catheter connection cable connected to the RF generator.

The RF generator is intended to be used with the commercially available disposable neutral electrode for external use. The catheter transfer RF energy in unipolar mode between the tip electrode and DIP electrode. Please refer to the attached IFU for detailed information of the catheter.

This system utilizes the Arm processor for control, and the RF generator can produce a continuous 460kHz Sine frequency output. Its front panel uses the touch screen for displaying the power output, tissue impedance, and the tissue temperature and ablation duration. RF generator measure the root mean square (RMS) of voltage, RMS of current, and take the average value of the product of voltage and current to measure the power output, and this value represents the effective heat transferred to the tissue by the large electrode of the (tip catheter electrode or other ablation electrode).

When a catheter with a temperature sensor is used, the user can choose the required temperature, if the measured temperature under the temperature control mode is greater than the set value, then the power output of the RF generator will be reduced automatically; if the temperature is greater than setting of cut off temperature, then the power output will be shut down automatically.

The RF generator have built-in security mechanisms, including when the measured impedance is lower than 20 ohms or the default impedance values, or greater than 500 ohms or the default impedance values, the RF power will be shut down automatically.

The RF generator can work through the two control modes: power control and temperature control.

The power control function can choose the amount of power the catheter transfer and duration and the temperature window shows the temperature data. If the measured temperature is greater than the set temperature, the equipment will notify the user that the measured temperature exceeds the upper limit by warning tone.

Under temperature control mode, the power output of the RF generator will be automatically adjusted according to the value the user set, to achieve and maintain the set temperature, and the risk of charring, tissue adhesion or thrombus is reduced greatly.

Under any kind of control mode, the maximum power of the catheter delivered must be chosen. If the power selected under the temperature control mode is not enough, the tissue will not reach the required temperature.

Note: under some conditions, the measured temperature may not prevent the tissue from overheating. The temperature measured value is a reference value, rather than an absolute value

3.2 Applicable conditions

The OptimAblate™ radiofrequency generator and all accessories together with the compatible catheter for radiofrequency are used for ablation process of conventional intracardiac radiofrequency.

Read the IFU and follow the instructions before using the system in clinical application. Please also refer to the instruction to use treatment of catheter fittings and compatible.

3.3 Safety information

Safe and effective use of the radiofrequency energy is largely dependent on the operator's control. Correct training of the personnel in operating room is irreplaceable. Read the IFU carefully before use, and understand the requirements and operation in accordance with the instructions are very important.

The terms "danger", "warning" and "caution" in this IFU are for indicating the hazards and their severity or level. Please be familiar with the definition and meaning of these terms.

The term "hazard" is defined as the source of potential damage to the human body.

The term “danger” refers to the upcoming hazard, if the hazard can not be avoided, it will result in death or serious personal injury or product/property damage.

Warning indicates potential hazards or unsafe practice, if the warning contents can not be avoided, it could result in death or serious personal injury or product/property damage.

Caution refers to potential hazards or unsafe practice, if the caution contents can not be avoided, it could result in death or serious personal injury or product/property damage.

3.3.1 Warning

1. Please do not operate the OptimAblate™ system before read this IFU carefully.

2. Those who have not received proper training can not use the ablation system. This book and the devices introduced are only use by qualified professional staffs during specific procedure.

3. During catheter ablation procedure, X-ray is often used, and thus produces large amounts of radiation. According to the intensity and duration of X-ray, serious radiation damage may be resulted in and harms may be caused to the patients or staff. Also, long time exposure to X-ray can cause unknown risks. Therefore, radiation protection must be ready before catheter ablation. The operator must carefully consider whether to use X-ray before performing catheter ablation procedure for pregnant women and minors.

4. Stimulation and ablation simultaneously may cause ventricular fibrillation, so unless the stimulator special permits, it is strictly prohibited.

5. Be sure to verify whether the voice and light alert of the RF generator is normal before use.

6. To completely shut down the device, please turn off the power switch behind the RF generator. Please place the device at the place easy access to the back button, so that when a failure occurs, it will be able to pull out the power cord as soon as possible.

7. After open the RF generator, please use the device at the end of the successful self-checking of the RF generator. If the device is connected to other devices (such as Columbus three-dimensional cardiac electrophysiology mapping system, the OptimAblate irrigation pump, etc.), please confirm whether the device is also ready.

8. Only the catheter can withstand the maximum voltage of mentioned in this IFU can be used. User shall avoid HF output settings where MAXIMUM OUTPUT VOLTAGE may exceed RATED ACCESSORY VOLTAGE

9. Only the accessories provided or approved by the manufacturer can be used, and the unauthorized accessories may damage the equipment. Forbid disassemble or change the device at will. Regularly check whether the accessory is damaged. If sterile accessories are used, please make sure that the accessory is stored in a sterile environment.

10. Please place the RF generator on a safe plane not for easy sliding, such as on the device cart of the Columbus three-dimensional cardiac electrophysiology mapping system. If placed on other planes, please make sure that plane is fixed. Please don't place the RF generator on other devices, and also do not place any device on the RF generator. Please make sure that there is enough space around the RF generator for heat dissipation.

11. When installing a neutral electrode, please try to close to the operation area and to ensure reliable contact with the human body. There should be not too much grease or hair on the contacting surface.

12. Please make sure that the patient will not touch the grounding site during the process of ablation (such as the metal panel of the instrument cart). Therefore, insulation measures must be done for the work station. Electrostatic discharge (ESD) will lead to a high current in the tube tip and injury the patient, so don't touch the end of the catheter or pins at the end of the socket of the catheter cable after the catheter inserted into the body .

13. To avoid contact between each part of the human body. You can use dry gauze for avoidance .

14. When the RF generator and multichannel recorder are connected to the patient at the same time, all electrodes without protection resistance or electrodes with low pass filters should be as far as possible away from the catheter electrode. Needle electrode shall not be used for multichannel recorder.

15. Don't make the cable contact with the patients or contact with each other. Keep the electrode not used temporarily as far as possible from patients.

16. In order to avoid carbonization or blood clots, please carefully select the output power.

17. When an irrigation catheter is used, please pay attention to risk may be caused by hypoirrigation. The medical personnel can roughly estimate the flow rate from the water droplets of the titrator. The medical staff should also control the total quantity of the irrigation in case of too much irrigation. Please refer to the recommended flow rate for use of catheter in the IFU.

18. If surgical site is chest or head, it is prohibited to use flammable or oxidizing anesthetic, unless it can be completely cleaned out or relevant safety equipment are used. If detergents and disinfectants, or other flammable solvents are used, please start ablation after evaporation of these agents. Flammable substances on the back and the cavity of the patients are more likely to trigger risks, please wipe them clean before starting the RF generator. You also must be careful to use other flammable items such as cotton and gauze, these items is likely to be lit by an electric spark.

19. If a pacemaker installed in the patient, then the operator must be careful during ablation, as the RF energy is likely to interfere with the ablation or even damage the pacemaker. If there are questions, please contact the manufacturer of equipment.

20. The RF generator may produce electromagnetic interference if it is too close to the equipment. Similarly, other equipment is also likely to interfere with the normal work of the RF generator.

21.The socket of the catheter is prohibited to contact with high pressure parts (such as a power socket) or metal objects. Patients are likely to be electric shocked, severe cases may even lead to death.

22. In order to avoid damage to cable for connection, do not wind the cable around the RF generator or other equipment. During the process of use, the winding of cable will produce inductive electromotive force, which will influence the accuracy of detection, thus leading to misdiagnosis.

23. This equipment can produce large amounts of radiation and release high frequency energy, despite the EMC protection measures were taken, if operate the device not in accordance with this IFU, it is likely to lead to radiation leakage and damage. Similarly, mobile communications equipment may also affect our equipment.

24. If system errors often occur, please stop using and looking for maintenance.

25. In order to avoid damage to the RF generator and accessory, please use the cleaning method recommended in this IFU.

26. To avoid risk of electric shock, please ensure that the socket to meet requirements in section 7.1 of this document.

27. The RF generator can only be disassembled by authorized professionals by the manufacturer, after the case is opened, there may be dangerous voltage or high temperature, the person touching it will cause injuries. If the case is opened by unauthorized personnel, the manufacturer will not assume any damage or loss. Users are not allowed to disassemble the RF generator for maintenance or modification.

28. If there is liquid permeates into the device, please stop using immediately and contact the manufacturer for maintenance.

29. Once system error occurs, please immediately pull out the power cord.

30. All of monitoring devices and stimulating electrodes and probe are RF current conductors. These electrodes and probe should be placed as far as possible away from the area of ablation and neutral electrode can effectively reduce the risk of burning the patients.

31. In order to avoid unnecessary damage to patients, don't start discharge before the catheter reaching the ablation area.

32. In order to minimize disturbance to the multichannel recorder, don't make the cable of the catheter contact with the patient and other cables. Make surface electrode as far as possible away from patients so as to collect the best ECG signals.

33. To prevent fluid affect the performance of the system, ensure that the catheter and cable of socket are in dry condition.

34. In order to ensure the system to work properly, please check the accessory that are reusable, and do not use a damaged cable.

35 The ablation data the RF generator saved can not be used for clinical diagnosis, and can only used for archiving and research purposes.

36 Recommendation to use monitoring systems incorporating the RF generator current-limiting devices

37 Apparent low output or failure of the RF generator to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power

38 Neuromuscular stimulation which can occur especially with modes which produce electrical arcs between the ACTIVE ELECTRODE and tissue.

39 Position the connection cables of the ablation electrodes in such a way that they do not touch either the patient or other cables. Keep active electrodes that are temporarily not in use at a safe distance from the patient.

40 Shock hazard: Connect power cable of RF generator to the appropriate grounding terminal. Do not use plug converter.

41 Shock hazard: Do not connect moist accessory to the RF generator.

42 Shock hazard: To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

3.3.2 Warning (Safety and connection of the system)

The OptimAblate™ RF generator can be connected to many equipment and accessories, and it constitute a system with the equipment and accessories mentioned below.

1. There is current passing through among the RF generator, the ECG signals and the stimulator. Only CF type of equipment and accessories can be connected with the device.

2. All the equipment and its accessories connected to the RF generator must meet the requirements of the MDD/MPG for class 1 devices, and they shall be monitored and certificated.

3. Installation or use of the system must follow the requirements of IEC/EN 60601-1-1

4. All system components shall be used in accordance with the specification or standard operation procedure and with label attached.

5. If you need more information about the related components, please contact the suppliers of components.

6. If there are other devices connected to the device, all these equipment shall conform to the requirements of IEC/EN60601-1 and the corresponding special standard, as well as the requirements of IEC/EN60601-1-2. Please note: the ECG signal creates an electrical connection between the equipment and the patient. Incorrect use will endanger the safety of the patients. To ensure that in any case, the leakage current will not exceed the limit.

7. Considering the leakage current of the RF generator may be affected by other system components, the maximum acceptable values have explicitly been specified in IEC/EN 60601-2-2. The base cable drift of surface signal indicates that there are unknown high frequency leakage current passing through the surface electrodes. The temperature variation of surface electrodes will causes Dc voltage rise and then causes base cable drift, therefore, check the status of all parts of the whole system in order to avoid the unknown high frequency leakage current. Electrocardiogram machine, however, does not apply, and excessively high surface electrode impedance is the irrefutable fact. Please confirm whether ECG device is suitable for the situation. Burn marks at the skin of the surface electrode can be one of the symbols of unknown leakage current.

8. A lot of electrocardiogram machine can be directly connected to the stimulator. But before starting discharge, ensure the stimulator has been isolated or disconnected. The connection of the RF generator and stimulator is in

parallel, if stimulator is not isolated, the patient interface unit and isolation is very dangerous, the RF energy is likely to enter the stimulator and hurt the patient.

9. Only the classified medical devices can be connected to the RF generator. If the PC system does not meet the requirements of IEC/EN 60601-1 / UL 60601-1 and corresponding special standards, then the distance of PC from the patient should be at least 1.83 m, and must meet all requirements of IEC 950 / UL 60950-1. All the medical equipment electrically connected to the RF generator must meet the requirements of IEC/EN 60601-1-1.

10. Failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power

3.3.3 Warning (ablation process)

1. Vascular perforation is the inherent risk in procedure, the operator must be careful when catheter migrates.

2. When perform ablation on left atrial wall, please take care to avoid damage to the esophagus.

3. Avoid high temperature. High temperature could lead to formation of blood clots, carbonization of tissue and other damages.

4. The temperature displayed on the RF generator is not the tissue temperature, but the temperature of the electrode, both of the temperatures are not completely equal, especially when the irrigation pump is used for cooling. And tissue temperature could be far higher than the value, and could lead to a bubble due to liquid evaporation. So as far as possible lower output power should be used, and with reference to the IFU of the catheter used.

5. Avoid impedance mutation to reduce the charring in the process of ablation, as charring can reduce radiofrequency power and embolism.

6. Ensure that the radiofrequency electrode does not contact with other catheters or metal materials such as pacemaker cables. This could lead to the radiofrequency energy transmitted to other parts of the body.

7. Don't set an extreme limit that can not reach. When the limit is exceeded, the alarm will be triggered. But if the threshold setting is unrealistic, then it cannot be reached, the alarm will be difficult to or even not issued.

9. When the catheter is improper operation, it is likely to trigger the alarm for abnormal connection of the cable or poor adherence of the neutral electrode.

10. Continuous attention shall be paid to the impedance value in the process of ablation, if it is found that the impedance experience sudden change, please stop the ablation, remove the catheter and use a sterile cloth to wipe deposits on the surface of the electrode.

11. If any abnormality is found for radiofrequency energy, touch screen operation, knob, foot switch, etc in the process of ablation, please immediately stop discharging by pressing the STOP button on the front panel of the RF generator, loosen the pedal or press the power button. If it is unable to stop discharging by the above manners, please pull out the power cord directly.

12. If it is unable to communicate with irrigation pump normally, please disconnect the communication cable, and manually control the operation of the irrigation pump.

3.3.4 Safety of the device

The safety statement described in this chapter refers to the conditions that, under most cases, are applicable to all

aspects of the product.

Sequence of the safety statement does not mean that the order of importance.

3.4 Compatible external devices

1. OptimAblate irrigation pump

2. Columbus three-dimensional mapping system

4 Accessories

4.1 Configuration of accessories

The RF generator is with the following accessories:

1. Power cord

2. Foot switch

3. Clip-on earthing cable:

4. ECG cable:

5. Catheter ablation cable:

6. Neutral electrode cable

4.2 Applied parts

The RF generator is equipped with the following applied parts:

1. Catheter connecting socket, which is used to connect to the EP ablation catheter cable

2. Neutral electrode plate socket, which is used to connect the disposable neutral electrode plate stern cable

3. ECG interface, which is used to connect the ECG signal

The above applied parts can only be connected to external accessories specified by Shanghai MicroPort EP MedTech Co., Ltd., and please inform Shanghai MicroPort EP MedTech Co., Ltd. if damaged during use.

4.3 List of standard configuration

Name	quantity
Cardiac RF Ablation Generator	1
ECG Communication Cable	1
Foot pedal	1
Grounding Cable	1
Power supply	1
A set of Fuse	6

Cable for indifferent-Electrode Patch	1
Instruction for Use	1
Cable for ablation Catheter	1

5 Installation

The OptimAblate ™ cardiac RF generator is a RF energy generator which specially designed for cardiac radiofrequency ablation procedure, the RF generator can be used with multiple devices, and satisfy the requirements of safety, accuracy and practical standards.

The RF generator is used by a simple user interface, and the various operations are performed through clicking the screen with fingers (even with gloves) or with a pen.

The RF generator is controlled by two ways to ensure safety. A main processor is used to response user events, and another processor is used to directly to control the RF circuit. A memory is included in the RF generator and the settings and data set by the use is still available when powered off.

5.1 Installation environment

The OptimAblate ™ RF generator can be used in rooms meeting the requirements of only in accord with Clause 16, Annex A.4, IEC/EN, the RF generator shall be placed on a safe and smooth plane (such as the Columbus instrument cart) . If the device is placed on other plane, please ensure that the surface is smooth stable. The RF generator cooling opening is at the bottom, and it must ensure that the thermovent not jammed.

Do not place RF generator on other device, also not place any device on the RF generator, and please make sure that there is enough space around the RF generator for heat dissipation.

Do not place RF generator on other equipment, also do not place the other devices on the RF generator, and ensure the RF generator around there is enough space for heat dissipation.

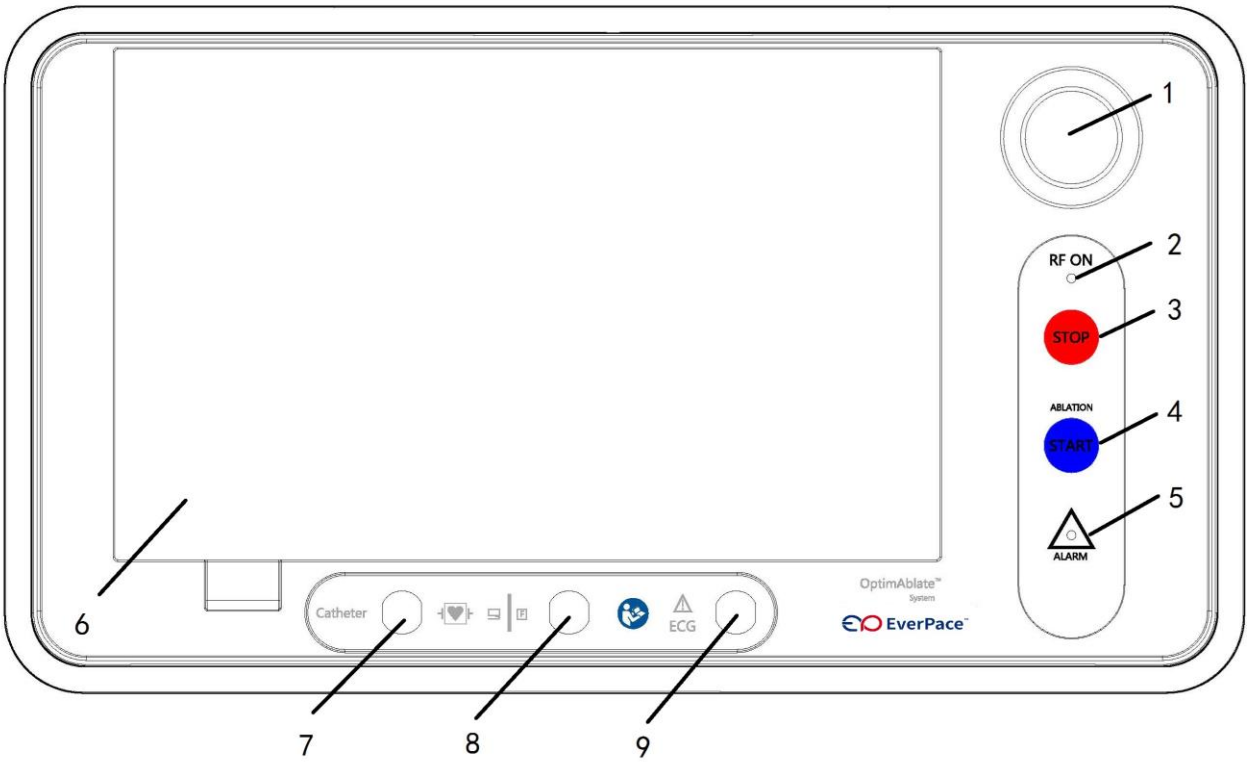
5.2 Installation personnel

System and its components shall be installed by Shanghai MicroPort EP MedTech Co., Ltd. The package containing the system components shall be opened by the personnel from Shanghai MicroPort EP MedTech Co., Ltd.

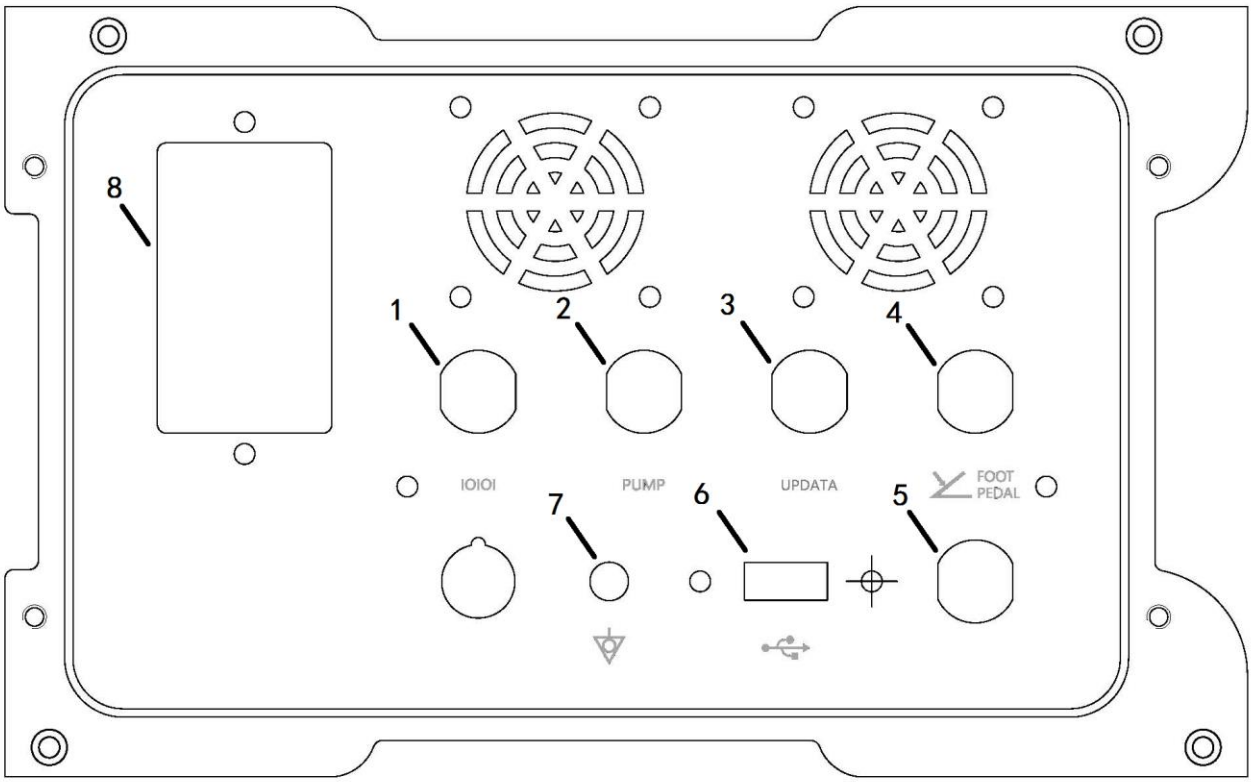
5.3 Testing and training

The OptimAblate ™ RF generator is a medical product. In some countries and regions, the device can not be used until the RF generator pass the testing and complete the training of related personnel due to the requirements of local regulations.

5.4 Controls on the Front and Back of the Generator



1、Data Entry Knob	6、Touch screen
2、RF On indicator	7、receptacle for ablation catheter cable
3、Stop button	8、Receptacles for indifferent electrode cables
4、Ablation Start button	9、Receptacle for ECG cable
5、Alarm indicator	



1、MP3D – Receptacle for Columbus 3D EP Navigation System cable	5、empty port（for future use）
2、Pump – Receptacle for OptimAblate ™ Irrigation Pump cable	6、USB port
3、Serial data port	7、Potential equalization port
4、Foot Pedal	8、Mains socket （with fuse and power switch）

5.4.1 Power supply wiring

 In order to reduce the loss caused by electric shock, the power cable for connection shall meet the requirements of technical parameters of the power socket, and do not use power cords from other companies.

5.4.2 Fuse

 The fuse can be changed by user is located above the power interface, and only the fuse provided with the built-in fuse.

5.4.3 Potential equalization port

 During the use process, in order to avoid the electric potential difference as compared with the reference voltage of other devices connected to the RF generator, and the RF generator must be grounded. One end of the yellow-green grounding cable shall be connected to the earthing rod behind the RF generator, and the other end is

connected to the indoor location of the operation room. In order to avoid electromagnetic interference of the ECG signal, and same earthing rod shall be used for all devices.

5.4.4 Circular plug connection

The color of the circular plug for all the cables used in the device shall be same as the color of the corresponding socket. Make the slot plug face upward, insert the slot into the socket along the direction of the arrow, and it is well plugged when a sound is heard; when it has to be pulled out, pull it out by holding the outer casing of the plug.

5.4.5 Connecting cable, catheter

Only the catheter with a temperature sensor and the original connection cables can be used, For recommended catheters, please use a catheter that could satisfy the requirement of CE, if necessary, please contact Customer Support. Confirmed that Rated accessory VOLTAGE should over than the output VOLTAGE of generator. When connecting the catheter, use a sterile cable to connect to one end of the high catheter, and connect the other end to the RF generator. If the RF generator is connected to the Columbus ™ 3 D mapping system, then connect the end of the cable originally connected at one end of the RF generator to the corresponding position of the patient interface unit (PIU).

5.4.6 Neutral electrode connection

The neutral electrode located at the bottom of the front panel interface doesn't support the separation of neutral electrode.

5.4.7 USB interface

The USB interface at the back of the RF generator only supports mass storage devices, thus please do not connect other devices.

5.4.8 Connecting the irrigation pump

Use the communication cable provided with the OptimAblate™ irrigation pump to position both the 10 cores at the top right corner and behind the RF generator in the socket.

5.4.9 Turnover the front panel of the RF generator

The touch screen of RF generator installed at the reversible bottom plate, and can turn over the touch screen from the slot at the left bottom of the touch screen, and fixed at any angle in the range of 0-90°, so as for convenient view of the screen display during the procedure.

5.4.10 Horn

The horn is located behind the touch screen, and the volume could be increased when the screen is open.

6 Operation of the RF Generator

6.1 Start-up and shutdown of the system

Open the power switch at the top of the power socket behind the RF generator, and the RF generator will start.

When the RF generator is opened, The alarm lamp lights up in red; The RF ON indicator lights up in blue, and the RF ON sound will be issued.

The system enters into the self-checking state, the Logo will be displayed on the screen of the RF generator, and the software version will be displayed at the lower right corner.

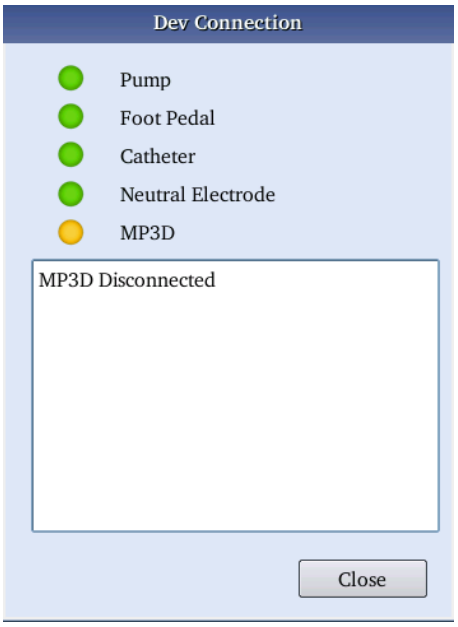
After self-inspection, If the self-inspection succeeds, it will directly enter the ablation interface; Otherwise, an error code will be displayed on chapter 14.

Cut-off power switch, the RF generator will turn off.

6.2 Interface

The RF generator has the following interfaces: connection, editing, presetting, ablation, post and system setting interfaces.

6.2.1 Connection interface



When click the "connect" button, the system will enter the connection interface, and the interface will:

- display all devices can be connected to the RF generator

- display the currently connected and normal work devices, with different colors representing different status, green: normal connection; Red: abnormal connection; Yellow: unusual connection, but it maybe no effect to the ablation, the RF generator can be used normally.

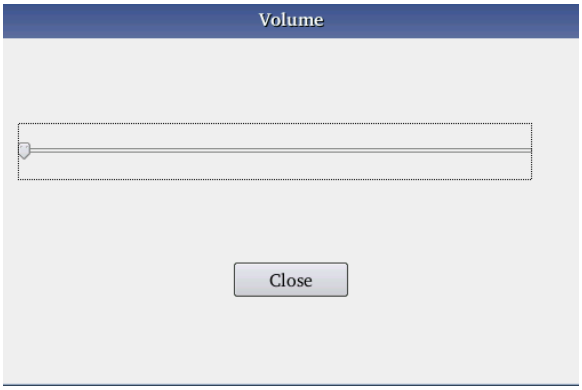
6.2.2 System setting interface

Click the "system setting", the system will enter the system setup interface. The information displayed on the

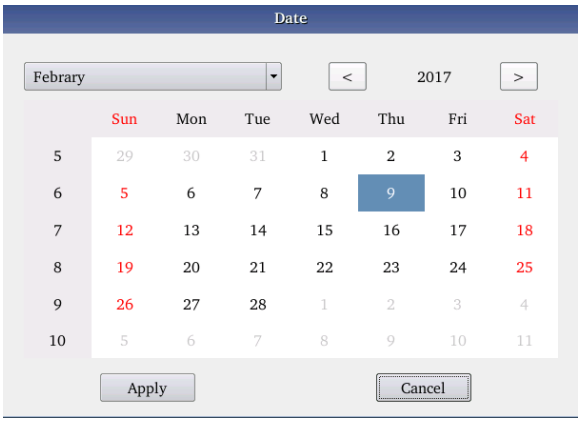
system setting interface include:

- When press the brightness button, the screen brightness can be manually adjusted, but the screen is always visible

- When press the sound button, the sound output can be changed. But the alarm sound setting will not affect the neutral electrode



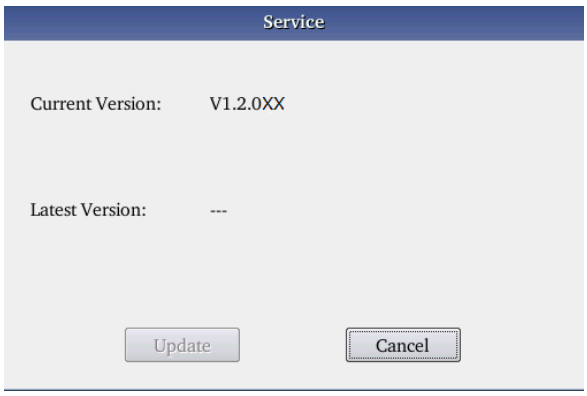
- When press the date button, the date setting can be changed



- When press the time button, the time setting can be changed

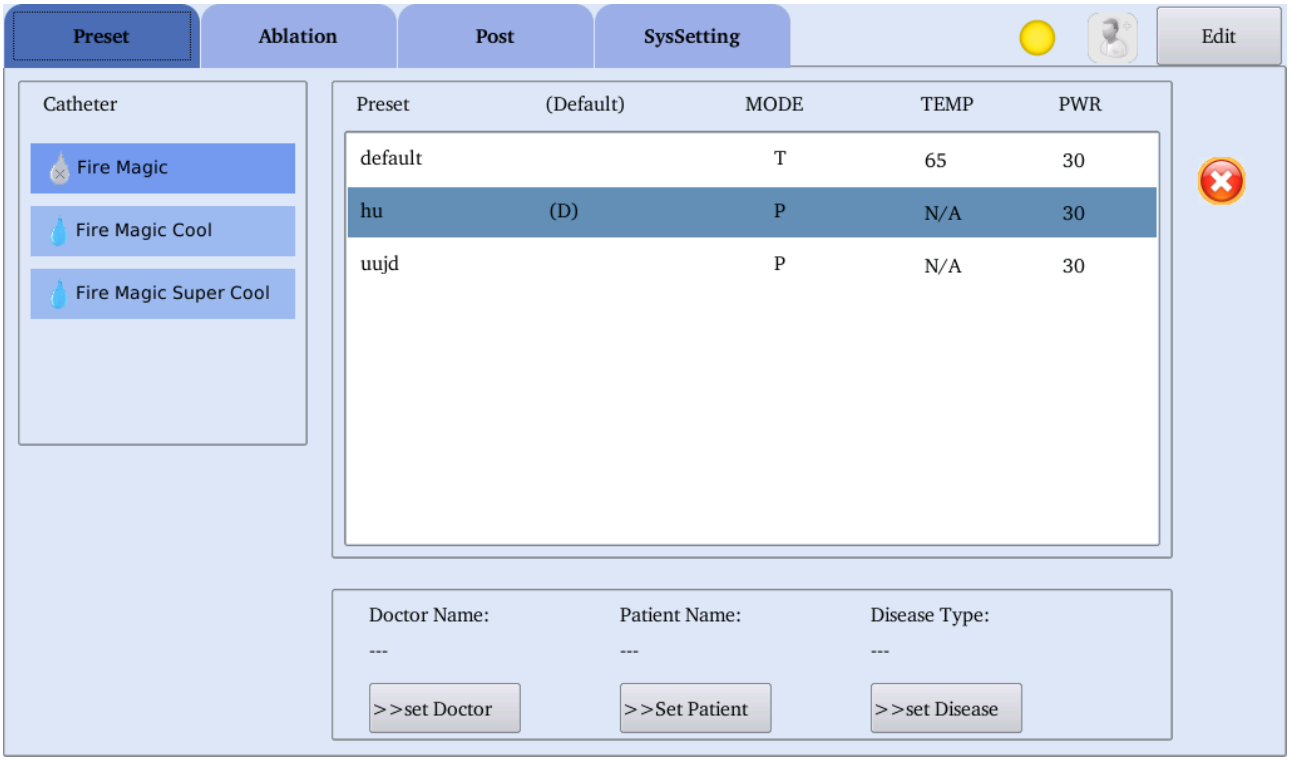
- Language setting can be changed between with Chinese and English.

- Service button: only for the use by technical personnel



- About button: Show the information of the generator

6.2.3 Default interface



Press the "preset default" button to enter the connection interface of the system, and the interface:

You can select, edit, and delete default templates

The RF generator provides the standard template for each catheter type, and it is always first item displayed in the list and cannot be deleted.

You can create templates for different doctors. Choose the doctor name in the doctor list and display the template.You can review all the template list in the corresponding list for selected catheter types, and you can also only review corresponding template by the doctor selected and tube type selected.

When having selected a catheter type, the corresponding template will be automatically selected, you can also specify other displayed default template as the new default value for this type of catheter. The currently selected

default template will be highlighted. The main interface "preset default" page button will display the names of the selected default templates.

The second and third kinds of catheter is infusion catheter, when you choose the catheter, the RF generator could connect with OptimAblate™ irrigation pump linkage in real time.

When the default template is changed, the names of the "preset default " displayed by the "default setting" page button will be marked with *

The temporary change will continue to be effective until a different template is selected, or when the system is shutdown. Once a different template is selected, the temporary changes made to the previous template will be lost.

All setting changes made on the "default" page are temporary changes.

When a template is selected, after the settings changed, click the "save as", enter the names of the doctor and the template, a new template can be created and saved.

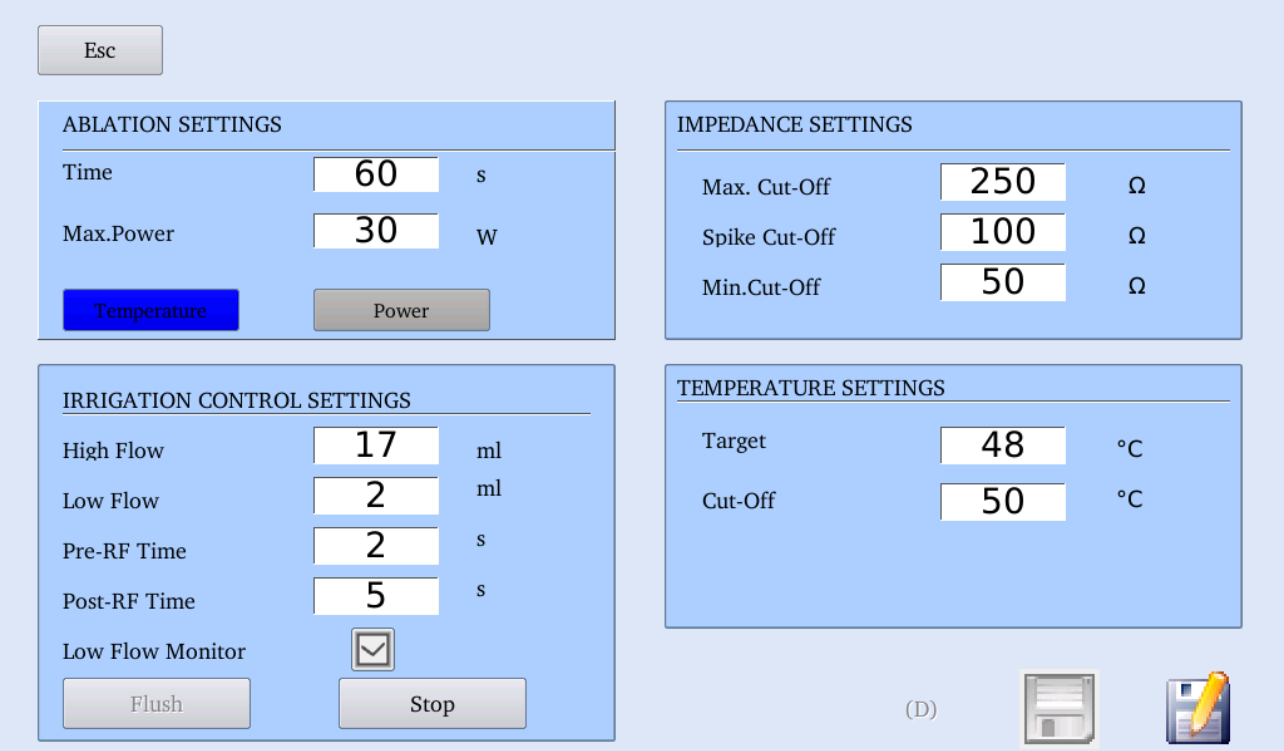
If the doctor names entered into the new template does not appear on the list, then the doctor name will automatically be added to the list of the doctors, but the doctor name newly created can not be all.

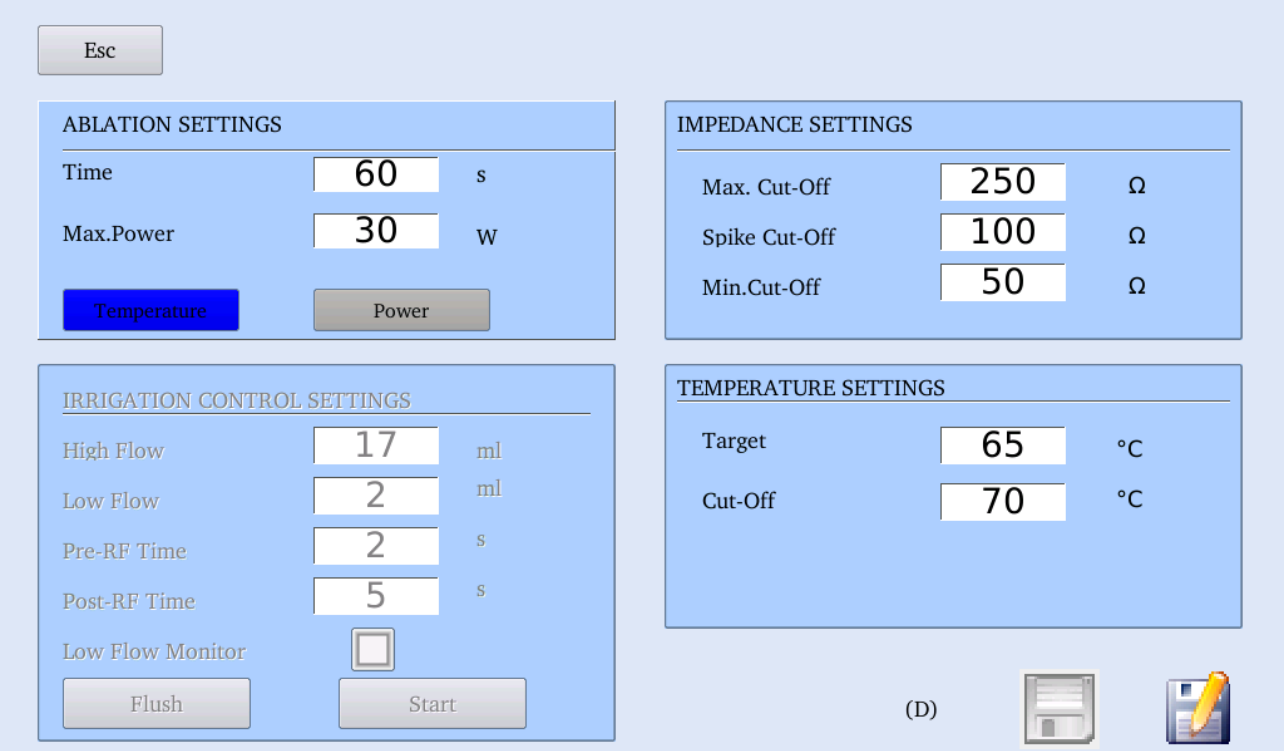
The new template applies only to the selected catheter type created

When a catheter is selected, the system will automatically call the default template. A (D) mark will be after the name of the template.

Select a template, and press the "delete", and then press "ok", the template can be deleted. The default template comes with the system cannot be deleted. When default template is deled, System template will be selected as default template .When all the templates under a doctor are deleted, the doctor will be automatically deleted from the list of doctors.

6.2.4 Edit Interface





Under the default interface or ablation interface, click the edit button on the navigation bar to enter the edit interface

On the ablation setting bar, select "temperature" or "power", the control mode can be changed.

Click any displayed value, use the knob to change the value, and press "save", the values on the template will be changed. Click "save as" to create a new template, and in which the values will be saved; Press "back", the settings page will be exited, and the changed value will be temporarily saved.

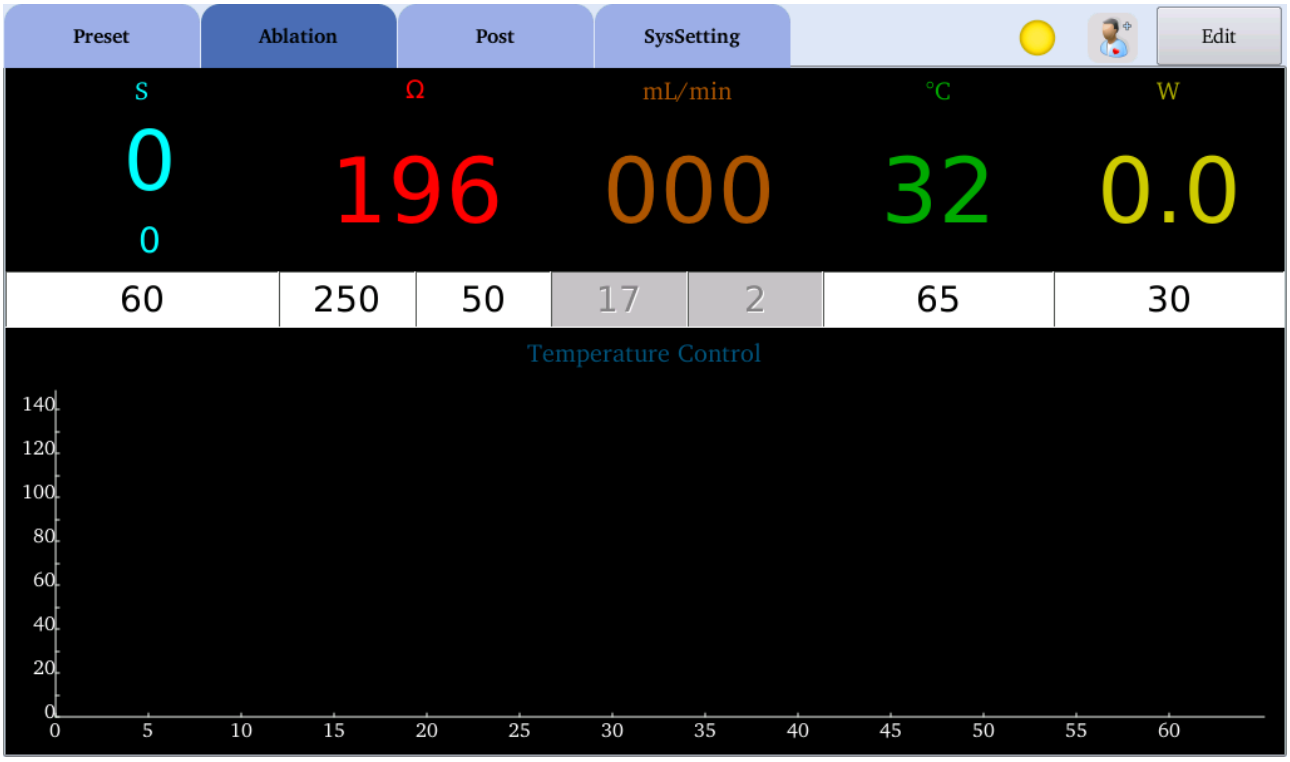
The setting items on each block setting bar depend on the catheter type or the ablation control mode.

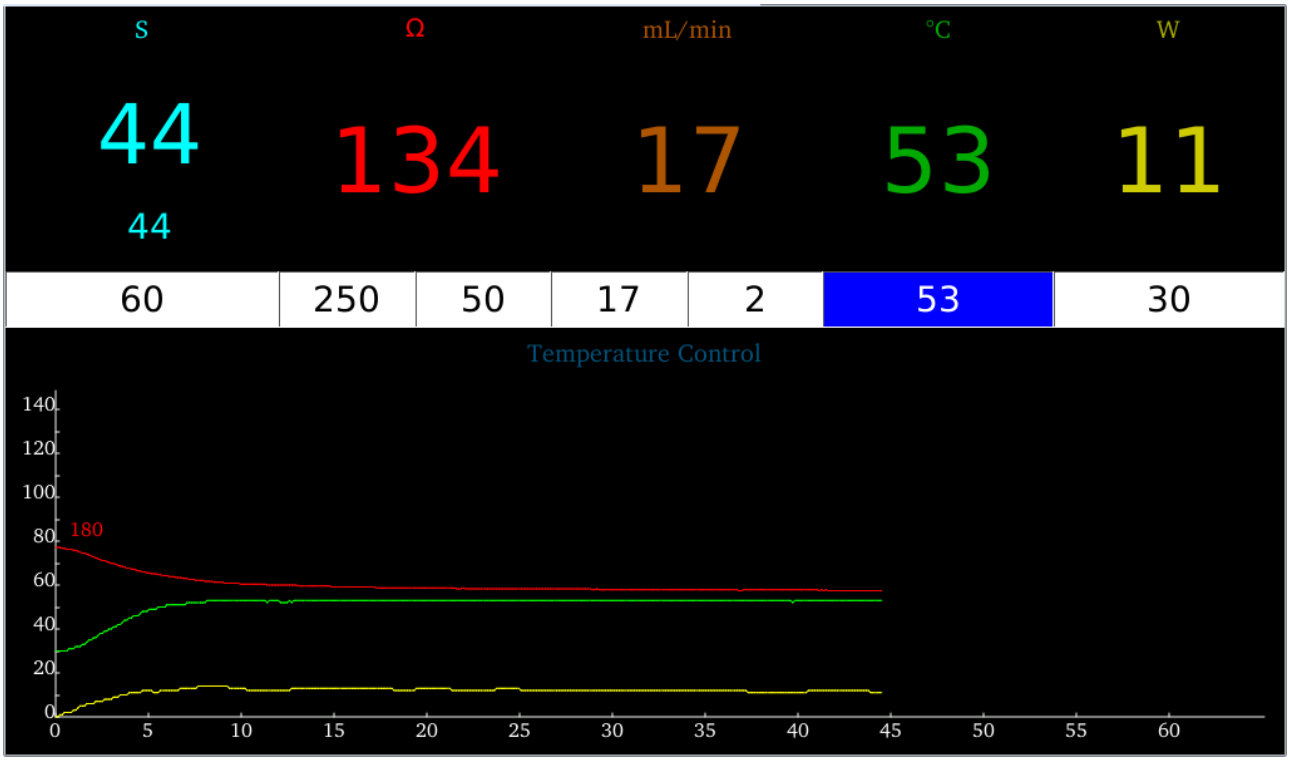
The default values on the template can not be changed. If the values on the default template are changed, Save button is invalid,please press "save as", then a new template can be created to save the changes.

Model	Item	Description	Setting value
Ablation	Time	Restrict the discharge time of single ablation, when time reaches the set value, ablation will automatically stop	0--900 The default value is 60
	Maximum power	Only effective under the temperature control mode and it is the upper limit of temperature control algorithm. The temperature control algorithm will automatically control the power output without exceeding the maximum power values. The set values for different types of catheters are different.	0--100 The default value is 30
	Power	Only effective under the power control mode, and it is the output power value maintained during the process of ablation of the RF generator. The set values for different types of catheters are different.	0--100 The default value is 30
	Increase time	Only effective under power control mode, and it the time the power of the RF generator increase from 0 W up to set "power" value	2--9 The default value is 2
Irrigation	Monitor low flow rate	When this option is selected, warning will be issued by the system for the following condition: When the catheter has entered into the body of the patient and the irrigation pump has not begun to work	The default value is “No”
	High flow rate	Irrigation flow rate setting in the process of ablation, before RF and after RF	6--60 The default value is 17
	Low flow rate	The irrigation flow rate setting before RF and after RF	1--5 The default value is 2
	Pre-irrigation	The time from press the "Start" to RF energy output. During this time period, the irrigation pump will irrigate with high flow rate, without RF energy output, but with "irrigation" indicator, and there is RF power output after the irrigation time	1--10 The default value is 2
	Sustain irrigation	After the radiofrequency energy output stopped,	1--10

		the time during which still at a high flow rate of irrigation time. When the time is reached, the irrigation will be automatically switched to low flow rate	The default value is 5
	Flush button	Press "flush" to expel the air, and the button will display "stop" if the button is pressed down	/
	Start button	Press the "start" and the irrigation pump will operate at low flow rate, and the button will display "stop" if the button is pressed down	/
Impedance	Minimum impedance	When the measured impedance value between the ablation electrode and the neutral electrode plates is greater than the "maximum cutting" resistance, the RF power output will be cut off automatically	50--500 The default value is 250
	Peak cut off	In any period between half a second, if the impedance change degree is greater than the set value, the RF power output will be cut off automatically	20-500 The default value is 100
	Minimum impedance	When the measured impedance value between the ablation electrode and the neutral electrode plates is less than the "minimum cutting resistance, the RF power output will be cut off automatically	20--200/Minimum impedance-20
Temperature	Target	Only effective under temperature control mode, and it is the temperature value the ablation electrode can reach. The RF generator will output the energy of the set "maximum power" to try to make temperature reach the "target" set temperature	Refer to section 7.1
	Warning	Only effective under power control mode, when the temperature of the ablation electrode reaches the set value, the RF generator will issue a warning. The energy output of the RF radiofrequency will continue	
	Cut off	When the temperature of the ablation electrode reaches the set value, the energy output of the RF radiofrequency will stop automatically	

6.2.5 Ablation interface





When the screen shows the ablation interface and floating window did not open , the ablation start and stop can be controlled through the ablation start and stop buttons or through the foot switch..

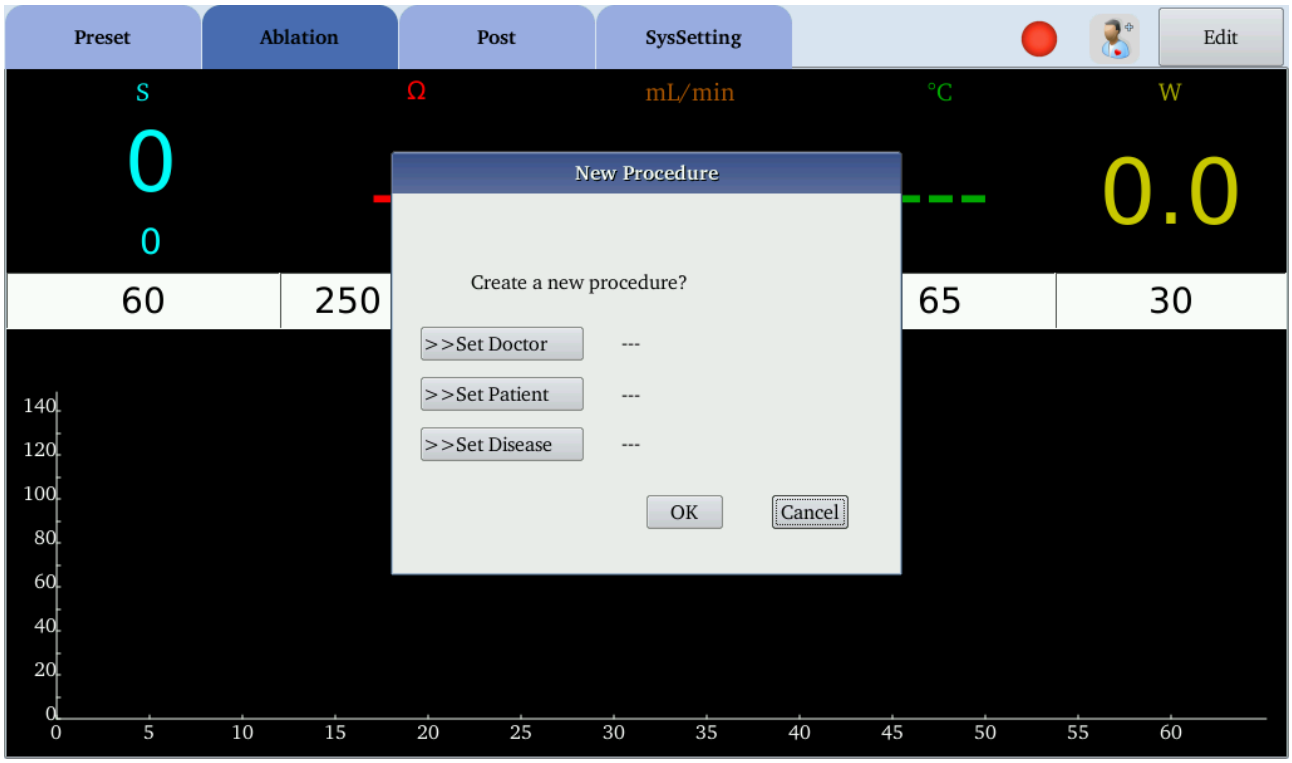
The ablation interface displays ablation information by different colors, the common settings can changed, and the displayed information include:

- Measured impedance
- Setting impedance (maximum and minimum values)
- Set time
- Ablation duration
- Set flow rate(large and small flow rate)
- Real-time flow rate
- Set temperature (temperature control mode)
- Measured temperature
- Maximum power/set power (temperature control mode/power mode)
- Measured power

When the ablation interface is displayed on the navigation bar, you can press the "edit" button on the navigation bar to change advanced settings.

When ablation stops, the ablation summary information will be displayed on the screen.

On the "ablation" interface, press the "new procedure " on the navigation bar, then click "ok", select a template, and a new procedure can started.



When a new procedure is started, all the previously accumulated data will be cleared, and all the new data will be

recorded in the new procedure. The information summary page will summarize all activities in the procedure.

Press the "ablation" page button to enter the ablation page, press the "Start" button on the panel, or continue to trample the foot switch. When ablation starts, the RF ON light located on the RF generator will be lit up, and the "ablation sound" will be issued; If you select an irrigation catheter and irrigation pump connection is normal, the irrigation pump will start the large flow irrigation.

Press the "Stop" button on the panel, or loosen the pedal switch, output of RF energy will stop, the ON light located ON the RF generator is put out, and the alert sound will stop; If the irrigation pump is connected and irrigation pump is irrigating with high flow rate, then the irrigation pump will switch to irrigation with a small flow rate.

During ablation process, the navigation bar disappear; After the ablation, the navigation bar will appear again.

If the ablation conditions are not right, the ablation will automatically stop.

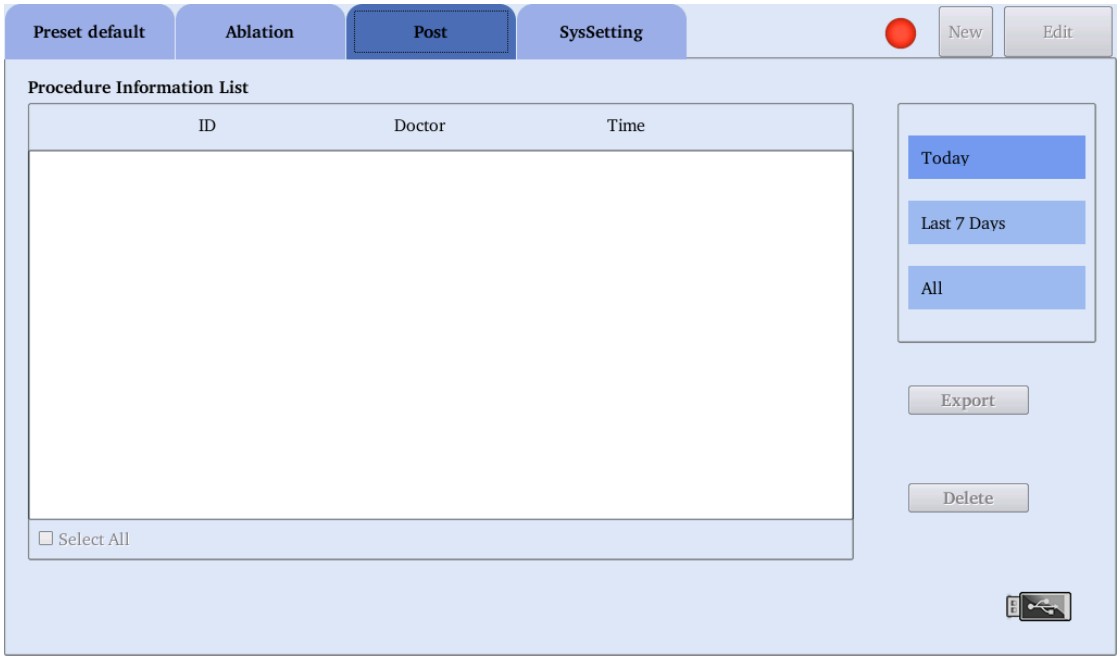
Stop ablation, and the ablation summary information will be displayed. Under the ablation information summary page, the reason why the ablation stop will be displayed.

When entering to the ablation page for the first time, the displayed parameter values depend on the selected template. Press the displayed various parameters, adjust the rotation button to change the value of the parameters.

When the power mode or temperature is selected, the "power" or "temperature" will be displayed in the middle of the screen.

On the ablation page, before and in the process of the ablation, the time and power output value can be changed. Under the temperature control mode, the temperature setting can be changed. For irrigation catheter, the flow rate can be changed. Change of these settings will work immediately, and there is no need to confirm. All these changes are temporary changes, the name of template shown on the “default setting” button will be marked with "*", to indicate that the template has been amended temporarily, but has not been saved. These settings will continue to be effective until a different template is selected or the system is shutdown.

6.2.6 Information summary interface



Press the "Post" button to display the post interface, and you can review the summary information of the whole procedure. When a new procedure is started, an information summary will be started.

You can select and review previous procedure data in the list, and the list will show the doctor's name, ID, and time. Check the procedure and click delete to delete the data.

Insert the USB storage device on the back of the RF generator and check the procedure needs to be exported on the list, press "export" to complete the data export, and a progress indication is given during the export process. The format of the exported data is PDF, it could review in the PC.

6.3 Warning and alarm

6.3.1 Warning and alarm

Serial No.	Type	Reason	Status	Handling
1	Alarm	Disconnect of the neutral electrode	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Restore the neutral electrode connection
2	Alarm	Catheter temperature greater than the cutting off value	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Stop discharge, waiting for cooling
3	Alarm	Impedance greater than the maximum value	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Increase the maximum impedance, and check the contacting of the neutral electrode, replace the catheter
4	Alarm	Impedance less than the minimum value	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Reduce the minimum impedance, replace the catheter
5	Alarm	Block of the irrigation pump	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Clean clots in the catheter tip or replacement of the catheter, check whether the three-way valve is opened
6	Alarm	Bubbles occurs in the catheter	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Expel the air bubbles, to eliminate the bubble alarm of the irrigation pump

7	Alarm	The door of the irrigation pump is opened during irrigation	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Close the door of the pump, to eliminate door alarm of the irrigation pump
8	Alarm	Fault of the irrigation pump	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Replace the irrigation pump
9	Alarm	Abnormal connection of the irrigation pump	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Restore the connection
10	Alarm	The catheter not connected	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Connect the catheter
11	Alarm	Foot pedal not connected	the alarm indicator blinks in red the ablation stops an alarm sound will be issued ablation information summary	Connect the foot pedal
12	Alarm	Impedance spike cut-off	the alarm indicator blinks in red the ablation stops ablation information summary the ablation alert sound stops	If the problem persists, change the catheter
13	Alarm	Insufficient irrigation	the alarm indicator blinks in red the ablation stops ablation information summary the ablation alert sound stops	Restart ablation
14	Alarm	Output power too high	the alarm indicator blinks in red the ablation stops ablation information summary the ablation alert sound stops	Stop using generator, contact Customer Support
15	warning	Catheter temperature warning (power mode)	a warning sound will be issued	Reduce output power, increase the infusion(if use the infusion catheter)
16	warning	No low flow	a warning sound will be issued	Start low flow, take out the catheter
17	The ablation stops	Catheter temperature change	ablation information summary the ablation alert sound stops	If the problem persists, change the catheter

6.3.2 Alarm and touch specification

When the alarm events occur, the production of related sound, light and alert information may be delayed no more than 500 ms, and the alarm state can be eliminated by pressing the STOP button.

All the alarm events will be recorded and stored in RF generator, including the time, the alarm threshold, and the alarm state parameters of the alarm.

If powered off, the alarm event log data will be kept intact for 30 days.

6.3.3 Voice and light alert

	The ablation stops	Alarm	Warning	Discharge	Irrigation
Explanation	Alert sound	Alarm sound	Alert sound	Alert sound	Alert sound
Pulse form	ti	ti-ti-ti-ti-ti…ti-ti-ti-ti-ti	ti	ti-	ti-
Frequency	600Hz	900Hz	600Hz	1200Hz	600Hz
Interval of pulse groups	None	4.2s	1s	Sustained	Sustained
Validity of the pulse	125 to 250ms	75 to 200ms	125 to 250ms	Sustained	Sustained
Repeat	No	Until manually stopped	Sustained	Sustained	Sustained
Alarm indicator	Closed	Lit up, red 1.4Hz-2.8Hz 20%-60% duty cycle	Closed	Closed	Closed

7 Technical Parameters

7.1 Technical parameters

- Type：EPE-CRF-1A
- Impedance measurement range: 0-600Ω ± Max {5%, 3 Ω}, with resolution of 1 Ω
- Setting range: Min20-200Ω , with default value of 50 Ω；Max50-500Ω, with default value of 250 Ω；
- temperature Settings:
  - No irrigation pump: target temperature: 43-90 ℃, with default value of 65 ℃ and resolution of 1 ℃; Cutting off temperature: 48-95 ℃, with default value of 70 ℃ and resolution of 1 ℃
  - Connection of irrigation pump: targettemperature: 38-53 ℃, with default value of 48 ℃ and resolution of 1 ℃; Cutting off temperature: 40 to 55 ℃, with default value of 50 ℃ and resolution of 1 ℃
- Initial discharge temperature ： above 25 ℃
- Measuring range: 10 ℃ to 60 ℃±2 ℃, 61 ℃ to 100 ℃±3 ℃
- Ablation time: 0-900 seconds
- RF frequency: 460 kHz
- RF power: 0-100W / 100 Ω, default value: 30 W, step value: 1W

- Power measuring range: 0-100 W±Max{10%, 2W} / (75-150Ω)
- RF maximum output voltage: 250 V_p
- Mode: power model, temperature model
- Communication interface: RS232, USB
- Supply voltage: 115 V / 230 V
- Power frequency: 50/60 Hz
- Input Power: 280 VA
- Fuse: T3.15 AH for 230 V, T6.3AH for 115V
- Max intensity of the sound: > 65 dB(A)

7.2 Storage and transportation conditions

Ambient temperature: - 20 ° to + 55 ° C

Relative humidity: 10% to 90% (non - condensing)

Atmosphere: 50 to 106 Kpa(0.49 atm – 1.05atm)

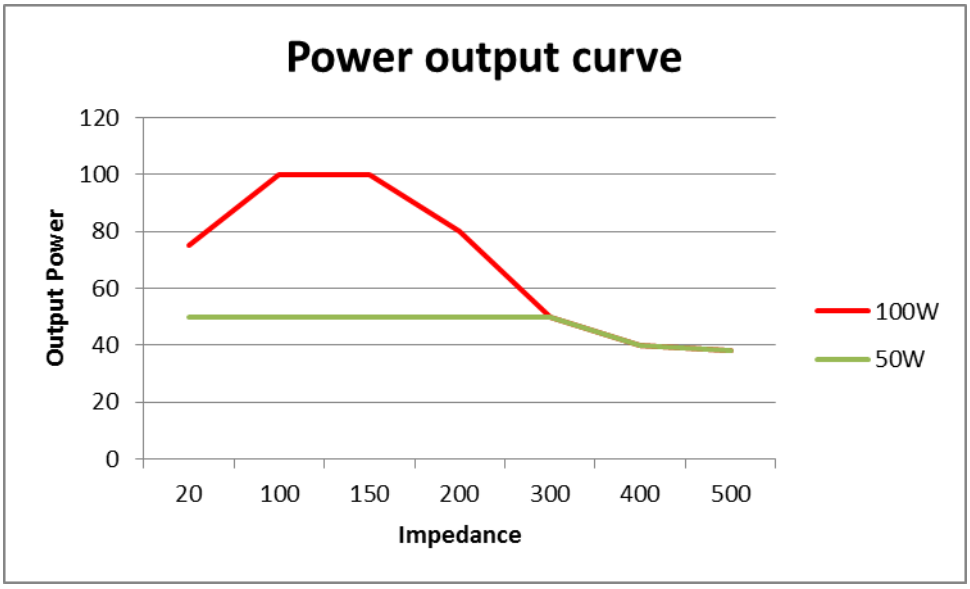
7.3 Running environment

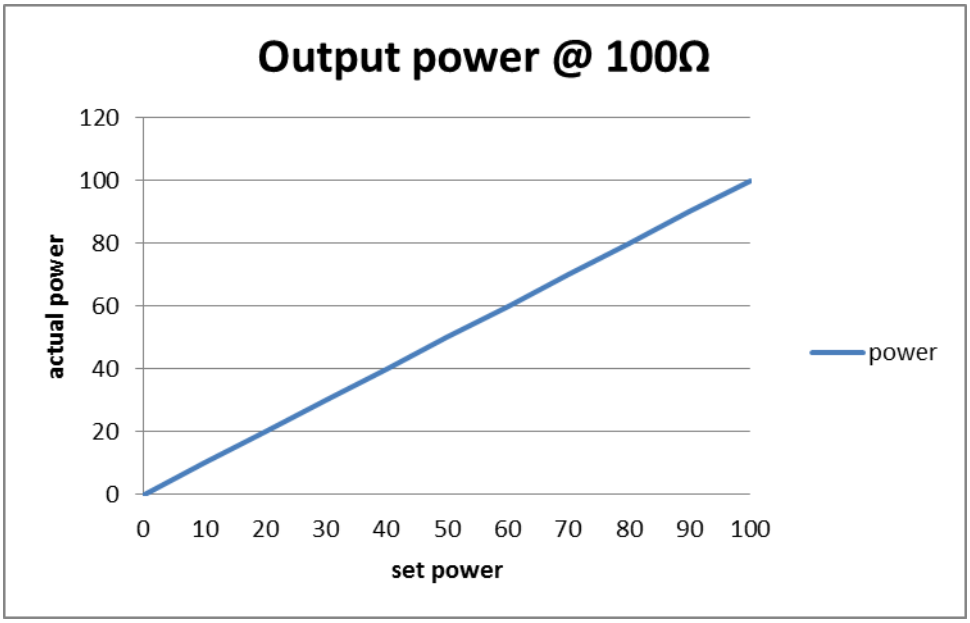
Ambient temperature: 10° to 40℃

Relative humidity: 10% to 85% (non-condensing)

Atmosphere: 70 to 106 Kpa(0.69atm -1.05atm)

7.4 Power output





7.5 Service life

The Service life of the product is five years, but Shanghai MicroPort EP MedTech Co., Ltd. will take no responsibility for shortening of shelf life as a result of environment worsening or improper use.

User should contact the Shanghai MicroPort EP MedTech Co., Ltd. or agent at the end of product life to deal with the product.

8 Safety Classification and Standards

8.1 Classification of the RF generator

In accordance with the requirements of IEC 60601-1 medical electrical equipment, the cardiac RF generator is classified into Class I devices, with CF level application components.

[1] Electric shock proof type: Class I device.

[2] Electric shock proof level: CF type applied parts.

[3] Whether with the function to prevent fibrillation: Yes.

[4] Waterproof and dustproof level: host: IP21; Foot switch: IPX8.

[5] Flammable anesthetic gas protection: not AP classes or APG equipment.

[6] Duty points: continuous operation with intermittent loading. Duty cycle:0-100W 900s on/300s off

[7]. Signal input and output parts: signal input and output part.

8.2 EMC information

The data in the following table shows that the Irrigation pipe conforms to requirements in IEC60601-1-2:2007;

Guidance and manufacturer's declaration – electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The RF Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the RF Generator should assure that they are used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The RF Generator use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The RF Generator is suitable for use in all establishments other than 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 –
For all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The RF Generator is intended for use in the electromagnetic environment specified below. The customer or the user of RF Generator should assure that it is used in such an environment.			
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 floor 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	±2kV 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 interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RF Generator requires continued operation during power mains interruptions, it is recommended that the RF Generator be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The RF Generator is intended for use in the electromagnetic environment specified below. The customer or the user of RF Generator should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V_{rms}
150 kHz to 80 MHz</td><td>3V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the RF Generator including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 metres (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:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, 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.</td></tr>
<tr><td colspan="4">[a] 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 RF Generator is used exceeds the applicable RF compliance level above, the RF Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RF Generator.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the RF Generator			
The RF Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RF Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RF Generator as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1167	0.1167	0.2333
0.1	0.3689	0.3689	0.7379
1	1.1667	1.1667	2.3333
10	3.6893	3.6893	7.3786
100	11.6667	11.6667	23.3333
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			

The medical electrical equipment should be taken with special preventative measures for EMC and shall be provided with precautions about EMC during installation and application in the user manual.

The portable and handheld RF communication device may influence the pump equipment.

Note: Addition of attachments or parts or modification of the medical device or system will lead to reduction of EMI performance. Replacing internal components of the Irrigation pump may cause radiation increase or EMI performance reduction.

Note: The RF Generator may be put neighboring the RF device for using together, but the RF Generator cannot be placed close to other devices failing to past EMC test for using together; if inevitable, check the RF Generator at intervals to ensure normal operation.

Note: The RF Generator may be influenced by other devices, although these devices conform to requirements specified by International Special Committee on Radio Interference.

To avoid measurement errors, the items below must be followed:

• The RF Generator must be used with the special leather pipe supplied by the manufacturer;

• The RF Generator must be connected to an independent earth point via earth lead;

• All devices connected to the RF Generator in patient environment should use one network power supply;

• All devices connected the RF Generator in patient environment must be connected one earth point via special earth leads for the devices respectively.

9 Troubleshooting

9.1 Primary inspection items

The following items are the most common reasons for system failure:

➢ Ensure the ablation catheter cable, neutral electrode plate have been properly connected.

➢ Ensure the wall socket charged. Check the power supply of the sockets and grounding sockets using a cable analyzer.

➢ Ensure that the power supply of the RF generator has been turned on.

9.2 Visual inspection

A thorough visual inspection of the devices can save time. The factors such as cable disconnection, foreign debris on the circuit boards, lack of hardware, loose of the components, these factors seem to be with no correlation but hard to track, and often lead to device failure.

9.3 Inspection list

Area	Looking for the following problems
Ablation cable or neutral electrode joint	□ Wear and tear or other damage □ Bent inserting needles or pins □ loosen inserting needles in the plug
Fuse	□ Type, rating, and burn out, and replace according to the need
Interface cable	□ Too tensioned or wear □ Loose connection □ Incorrect location of the strain relief
Installation hardware	□ Loose or missing screws or other hardware
Grounding cable/ routing	□ Loose connection of cables or grounding bus bar □ Wrong routing

	□ Cable squeezed or in the position of easy to damage
Power supply	□ Wrong routing, especially the AC socket □ Circuit is not the dedicated system □ Power supply problems lead to electrostatic discharge, reset and noise

The customer support department of Shanghai MicroPort EP MedTech Co., Ltd. will provide you with the help information not involved in this chapter, and you can contact them by telephone.

10 Maintenance

10.1 Equipment maintenance

The RF generator does not require regular maintenance, if the RF generator does not respond when insert in the plug connecting with AC power and the switches are turned, check the fuse first; If it still not works, please inform Shanghai MicroPort EP MedTech Co., Ltd.. The RF generator does not provide maintenance parts for users, equipment should be maintenance by qualified personnel，open and repair by persons without acknowledgment can cause danger and disable the warranty rights.

Warning: do not remove the lid of the RF generator. Removal of the lid may cause harm to person and/or RF generator.

10.2 Fuse replacement

1) Disconnect the main power supply cord of the RF generator

2) Host fuse:

Replace with a fuse of the same type and rating, and please refer to the label on the rear panel. Pull the fuse box out from the power supply module, and you can use a screwdriver for help. Insert a new fuse into the fuse box, and then insert the fuse box to the power supply module.

3) If it is due to the problem of the RF generator itself, please contact with Shanghai MicroPort EP MedTech Co., Ltd. to understand how send the RF generator back to Shanghai MicroPort EP MedTech Co., Ltd. for maintenance

11 Cleaning and Maintenance of the Device

11.1 Environment protection of the RF generator

Although the RF generator can work in various environments, but there are still some preventive measures must follow.

- Please pay attention to avoid extremely high or low temperature and humidity, as the device is not waterproof.
- Protect the RF generator from the damage of spillage or other debris. During procedure or maintenance of the RF generator, no eating, drinking and smoking are allowed near the generator.

11.2 Cleaning of the RF generator

Use neutral detergent and wet cloth to wipe the instrument enclosure, front panel and the power cord. It is strictly prohibited to sterilize devices in the system. No liquid is allowed getting into the host. You can clean the device by dipping conventional medical equipment cleaning agents, such as ammonia, 10% to 10% of bleaching water, isopropyl alcohol, glutaraldehyde (Cidex), mildly clean soap with soft cloth. Spraying or dumping any detergents or acetone solution onto the device is strictly prohibited.

When clean the foot pedal, wipe the foot pedal and the surface of the connecting cable with detergent and wet cloth. No liquid is allowed to getting inside. Be careful not to wet electrical connections of the connector head. Do not use caustic cleaner. Do not sterilize the foot pedal. You can disinfect the foot pedal with a soft cloth by

dipping alcohol solution usually used in hospital.

Note: do not directly spray liquid onto the device.

Warning: to avoid ignition of cleaning agents, please use non-flammable cleaning agents or disinfection equipment. If you must use flammable cleaning agents, then you should use the device after the material completely evaporated. If liquid getting inside accidently, please clean the liquid before connecting the power supply.

11.3 Inspection and maintenance of the RF generator

The RF generator requires little maintenance. However, in order to prolong the service life of the generator, Shanghai MicroPort EP MedTech Co., Ltd. still recommend to perform the following maintenance plan for the RF generator, so as to maintain the equipment running safely and efficiently:

Maintenance	Maintenance operation
Once per day	Check the enclosure for cracks or other damage. If the handle is damaged (can't locked or rotated). Check all wires and cables with or without abrasion or other damage. Check all the plugs, cables and connectors with or without bent inserting needles or pins. Check whether all the cables and connectors are firmly fixed in place. Check whether the foot pedal can ensure the normal

	operation.
Once per week	Wipe the surface with a clean soft cloth dipped with isopropyl alcohol, to clean the external cable (such as ECG and ducts input) and "catheter input module". Don't put the external cables and "catheter input module" in isopropyl alcohol or any kind of liquid. Check whether the foot pedal cables, connecting head broken, damaged, or cannot be inserted into the foot pedal connector of the generator, or whether the foot pedal is damaged, depress and release the foot pedal to check whether the foot pedal can normally boot the RF energy output Check whether there are any liquid or other tainted liquid on the foot pedal
Once per month	Check all the peripheral joint of cables, and clean them with alcohol and cotton swabs when necessary. Remove all dirt and debris on the cable connector. Check whether the indicator light damaged
Once per year	Check the sum of leakage current. The overall leakage current of the system shall be not greater than 50 muA. After the power supply cable disconnected, verify whether the resistance between the grounding terminal of the AC

entrance on the amplifier and any bare metal surface is less than 0.1 ohms to check grounding connection.

Note: the annual maintenance of RF generator can only be performed by certified technicians.

11.4 Grounding performance

This test is intended to verify the connectivity (less than 0.1 Ω resistance) between all bare metal surface (there is potential of applying voltage) and the grounding inserting needle on the AC power cord of the main communication cable. If the metal surface is treated with anodize or paint, scrape a small part at the never visible region to allow contact between the probe and the metal.

1. Use a digital multidevice to check all the metal surface of the device. Adjust any resistance from the test cable.

2. If the measured results are clearly beyond the required range, then check whether the power cord or internal connection of the device is disconnected.

12 Warranty

12.1 Warranty of the device

Shanghai MicroPort EP MedTech Co., Ltd. ensure that, the RF generator or foot pedal, within twelve (12) months from the date delivery from the company or from the distributor or within fifteen (15) months from the date delivery from the company to distributor (whichever is short), will have no material and production defects and other problems under normal use, otherwise, they are warranted. We only accept products with intact original packaging for warranty.

When requiring warranty, you should provide the original purchase invoice to confirm the purchase date.

The testing and repair period of the RF generator is about two weeks, and plus the shipping time.

No maintenance parts are provided for this product of the company. Don't repair the device by yourself, and don't open the RF generator or the enclosure of the foot pedal. If this product is abused, misused, altered, or tampered, then the warranty is invalid.

12.2 Damage during transportation

The distributor or user is responsible for loss and damage in the process of shipping. Shanghai MicroPort EP MedTech Co., Ltd. will review and examine the product received. If the product meet the requirements of the limited warranty terms or other related contracts, Shanghai MicroPort EP MedTech Co., Ltd. will replace or repair

any defective product for free (decided by Shanghai MicroPort EP MedTech Co., Ltd.); Then the product will sent back to the customer (postage in advance by the user).

The distributor or user is responsible for loss and damage in the process of back shipping. The company will provide the distributor a written report to list the repaired items.

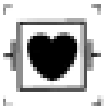
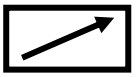
If Shanghai MicroPort EP MedTech Co., Ltd. believes that there is no defects need to be repaired, or beyond the warranty period or other relevant contract guarantee, then the product will be sent back to the customer. The customer will pay for the back shipping. The distributor or user is responsible for loss and damage in the process of back shipping.

12.3 Disclaimer

The catheter products produced by Shanghai MicroPort EP MedTech Co., Ltd. (hereinafter referred to as "MicroPort EP") are designed to be disposable devices, shall not be reused. For those products and radiofrequency ablation catheter device not used according to the allowed methods, MicroPort EP will take no responsibility. Hereby, MicroPort EP states that, except the contents listed on the label, including the use location, instructions and information, etc., other promises, either clearly mentioned or implied, are guaranteed, including whether this product is suitable for in a certain application and certain use and their quality guarantee. MicroPort EP will take no responsibility for direct, indirect, special, occasional, and any other damage due to use of this product by the customer. In any case, MicroPort EP will take no

responsibility greater than the purchase prices paid by customers for defective products. In addition, if the stability and reliability of the product is affected due to maintenance or modification by personnel not form MicroPort EP (completely determined by MicroPort EP), or misused, or used not according to the instructions/guidance, then MicroPort EP will take no responsibility for any loss due to use and purchasing this product if these conditions occur, and the warranty is invalid. This limited warranty, excludes and replaces any other clearly mentioned or implied warranty and MicroPort EP's duty responsibility. MicroPort EP will not assume nor any authorize any personnel responsible for making any other commitments for the products. If the defects of the product lead to dangers beyond the general sense during sale or use, but if constrained by relevant law code, MicroPort EP will not be exempted from rigorous civil liability due to the above statement.

13 Annotation of Symbol

Physiological warning		HF ISOLATED PATIENT CIRCUIT	
Must read the IFU		CF type Applied parts	
Usb port		Serial port	
Foot pedal		Remote control	
Power supply off		Power On	
Functional grounding		“ALARM” Indicator	
Neutral electrode interface		Authorized representative	
Manufacturer		Separate collection of electronic and electrical	

14 Error Code

Err 1	Impedance self test fail
Err 2	RAM self test fail
Err 3	Start button adhesion
Err 4	Foot Switch adhesion

【MANUFACTURER】

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