EverPace™

Instruction for Use

OptimAblate™ Irrigation Pump

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Statement

This manual is exclusively used as installation, operation, and repair and maintenance instruction for the Irrigation Pump. All diagnosis should be provided by physician authorized to use this system combining his or her medical expertise and is at the physician's own risk. Shanghai MicroPort EP MedTech Co., Ltd. assumes no legal liability for any diagnosis or appropriate therapeutic measures.

Please follow close to instructions in the manual where important information has been noted.

CE 2797

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Foreword

This manual describes use of all parts and attachments of OptimAblate™ Irrigation Pump in detail and provides specification of OptimAblate™ Irrigation Pump, contents of the pump controller and display window as well as operation sequence of the pump. For user's convenience, other important information has also been contained in this document.

1 Equipment Description

① The OptimAblate™ Irrigation Pump is a kind of peristaltic pump designed to deliver perfusate when used in conjunction with the tubing set. The pump has double flow velocity function, which enables it to switch between high flow and low flow. Both flow velocities can be adjusted by user.

② Front panel includes a color LCD to display flow rate, alarm information and system state.

③ The pump head is protected by a transparent door where the operator can see the entire tubing set during pump operation.

④ It's designed with due-bubble detectors to enhance safety, which can prevent air admission effectively. If bubble exists in pipeline, alarm will be raised.

⑤ The pump provides both-way communication, and can be connected to external equipment.

⑥ The pump has built-in security functions, including self-test upon starting up and stopping work when alarms raised (including acoustic and visual alarm) for various kinds of failures.

⑦ The OptimAblate™ Irrigation Pump and its attachments described in this manual are applicable to hospital environment.

2 Instructions before Use

The OptimAblate™ Irrigation Pump is a kind of peristaltic pump, specially used to deliver perfusate into patient's body through the irrigated ablation catheter. OptimAblate™ Irrigation Pump can only be used with the tubing set (refer to section 5.3).

2.1 Open package of the pump

Take the pump and power supply cable out of shipping case. Check the pump. In case of any damage due to transportation, please contact the closest sales person and customer service representative of MicroPort products.

2.2 Cable connection

The pump is operated with AC power of 100-230V and 50/60Hz. It must be connected to a medical grade three-wire receptacle properly grounded. Battery power supply is not available and the pump cannot be used as portable equipment.

2.3 Notice

Please read the instructions for use before operation.

3 Safety Information

3.1 Indications

OptimAblate™ Irrigation Pump is a peristaltic pump which is intended for use in conjunction with the tubing set and irrigation devices to provide irrigation solution.

3.2 Warnings

① OptimAblate™ Irrigation Pump can only be used with the tubing set. In case of being used with other tubing types, OptimAblate™ Irrigation Pump may work abnormally or cause improper Irrigation.

② Medical personnel of hospital should make sure correct perfusate is used. Check flow rate visually by monitoring the instillation velocity in drip chamber. Medical personnel of the hospital should inspect and monitor the flow rate to prevent insufficient supply of perfusate, and need to check the flow rate accuracy regularly during pump using.

③ OptimAblate™ Irrigation Pump is designed to be capable of stopping ingress of perfusate when failure has happened. Irrigation can be continued only when all alarms have been dealt with. Interruption of communication with external devices will not stop perfusate ingress, but may switch high flow rate to low value.

④ Medical personnel of the hospital should monitor total saline transfused into patient to avoid excessive transfusion of perfusate.

⑤ Medical personnel of the hospital should check if OptimAblate™ Irrigation Pump works normally, whether the used perfusate is compatible with the Irrigation device. Only perfusate can be used with both OptimAblate™ Irrigation Pump and tubing set are specially designed. If they're used with incompatible liquid or delivery device, the pump may fail to maintain the specified flow rate. In application process, monitor the tubing set for visible air bubbles, when bubble's observed, OptimAblate™ Irrigation Pump should be stopped immediately.

⑥ Medical personnel of the hospital should monitor the line pressure and stop Irrigation once abnormity occurs in line pressure to avoid insufficient Irrigation.

⑦ OptimAblate™ Irrigation Pump should be placed away from or stacked with other devices when used. If it's really required to be used as this, remember to check if OptimAblate™ Irrigation Pump operates normally under such situation.

⑧ Do not put any other objects on the pump when it's mounted on IV pole.

⑨ Intentional misuse of OptimAblate™ Irrigation Pump may cause serious injury to the operator and patient.

⑩ Flushing of catheter is not allowed when catheter is remained inside patient.

⑪ Be extremely careful for disposing used tubing set.

⑫ The tubing set does not contains DEHP (phthalate).

⑬ The equipment can only be used by trained operator or doctor.

⑭ Warnings: In order to avoid shock hazard, the equipment must be connected with power supply under the situation of protective grounding.

⑮ The operator shall face the pump during usage to timely observe its status, and disconnect the power cord under emergency.

⑯ The irrigation pump will conduct self-test at starting-up, and the Alarm light will flicker and ring out for once at self-test. If the Alarm light is abnormal, or the loudspeaker doesn't ring out, there is something wrong with the alarming system, and you should stop using the pump and sending it to designated after-sales service network or contact with the after-sales service personnel for repairing.

⑰ In order to avoid Irrigation of unexpected dosage into human body for instant release of pipeline after being blocked, the leather pipe shall be taken off from the catheter, and the pressure shall be released from the pipeline and the pipeline shall be cleaned to ensure that it is free from bubbles. Then it is connected to the catheter.

3.3 Considerations

① Please operate as per instructions of system setting to achieve optimal using effect.

② In order to guarantee the precision of flow rate, the interval for changing of Irrigation pipelines shall be no more than 6 hours.

③ The OptimAblate™ Irrigation Pump should not be used with other transfusion systems, including gravity-flow intravenous Irrigation system.

④ To avoid biological contamination and make sure of normal operation, never reuse or re-disinfect the tubing set which is intended for single use.

⑤ The OptimAblate™ Irrigation Pump is applicable to the irrigation catheter. The irrigation flow rate shall be monitored constantly to avoid the damage for insufficient irrigation flow rate. It isn't enough to indicate flow rate simply by Irrigation Pump, as the flow rate it indicates is worked out through calculating the motor speed of Irrigation Pump. If the Irrigation Pump can't work as per the flow rate set by the user, the alarms will raise. However, as the situation under which the motor is still running normally while no liquid outflows may happen, the drip speed in the drip chamber needs to be tested repeatedly for approximation to set flow rate. The liquid in the drip chamber shall fill in half or three fourths of the container to ensure that no bubble enters the dropper and to provide visibility of drip speed. The staff of hospital shall determine and monitor the flow rate to avoid insufficient flow rate. The staff of hospital is responsible for monitoring the total volume of liquid transfused into body of patient to avoid the excess volume of liquid transfusion. Please refer to direction for use of catheter for recommended flow rate.

⑥ The used tubing set, residual liquid and waste should be disposed in accordance with conventions of medical institutions on potential pollutants.

⑦ To prevent explosion hazard, never use the OptimAblate™ Irrigation Pump in environments with flammable anesthetic.

⑧ To prevent electric shock and fire hazard, keep OptimAblate™ Irrigation Pump from excessive wet.

⑨ Surface of OptimAblate™ Irrigation Pump should be cleaned with non-flammable cleanser; lint-free flannel/mat dipped in soap water is recommended.

⑩ The equipment has been tested to be in accordance with restricted conditions for medical device specified in IEC 60601-1-2, which conditions are designed to provide reasonable protection against harmful interference during installation of general medical devices.

A. High-energy RF interference (RFI) and electromagnetic radiation (EMR) from outside may lead to false alarm or malfunction of electrical unit like OptimAblate™ Irrigation Pump. What's more, such electrical units as OptimAblate™ Irrigation Pump may also cause ECG monitoring system which is not under optimal condition to generate false signals. Although the OptimAblate™ Irrigation Pump described in this manual is designed with capability to prevent such interference, safe running inspection should be conducted on it before it's used with RF electric surgical device, electromagnetic navigation system and ECG monitoring system on patient. In case of any disturbance, please reconfirm position of OptimAblate™ Irrigation Pump.

B. Failing to install and use it may cause harmful interference over other devices near it. The pump has been tested to meet restricted conditions of medical device, but we cannot promise certain installation won't produce any disturbance. In case harmful interference really occurs to other devices (to determine by turning on and off the pump system), user can eliminate it in one or more ways listed below:

a) Change direction or position of the receiving device.

b) Expand distance between devices.

c) Connect the pump system to socket in other circuits, which is different from that used by other devices.

d) Consult manufacturer for help.

⑪ The OptimAblate™ Irrigation Pump does not contain any parts with user-performed maintenance.

⑫ The OptimAblate™ Irrigation Pump should be calibrated by manufacturer; any setting modification may lead to abnormal running of the equipment and shall void warranty.

⑬ Although such moving parts as transparen0t door, IV pole clamp and rotating head of OptimAblate™ Irrigation Pump are designed to make sure of safe operation, caution is required during application.

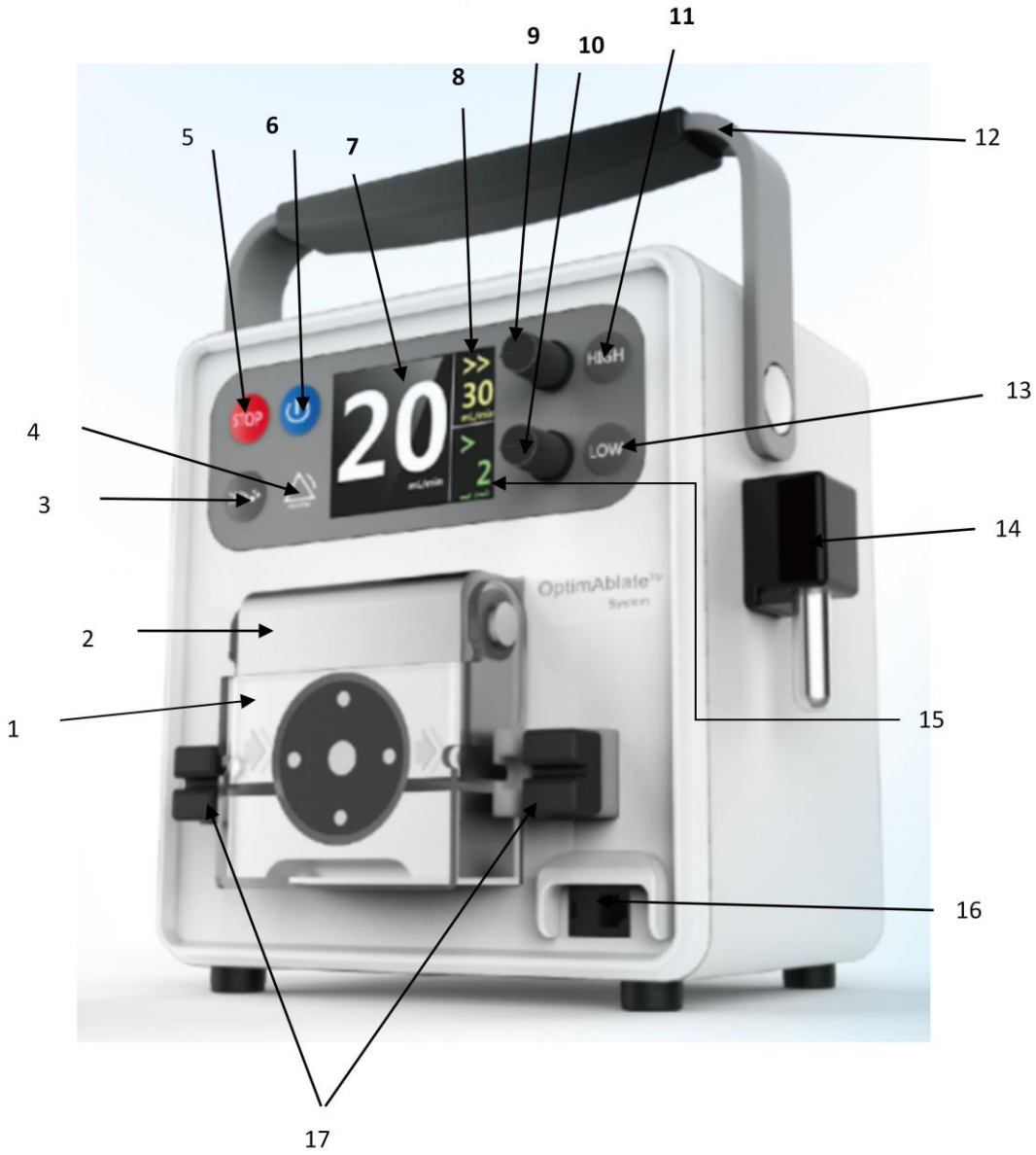
⑭ The Irrigation catheter used with OptimAblate™ Irrigation Pump should have a rated pressure of at least 115 psi (7.82 atm, 0.79MPa).

⑮ During surgery, when the RF device is to discharge, please pay attention to whether the Irrigation Pump has begun to infuse in large flow. If the Irrigation Pump hasn't been started up, please start it before the RF device discharges, or make the RF device stop discharging and check the Irrigation Pump.

⑯ After the equipment is turned off, the prevalue of pressure alarm of equipment won't be changed.

4 Pump Setup

4.1 Irrigation pump front



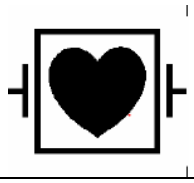
No.	Description
1	Pump door
2	Pump head
3	Flushing button
4	Alarm light
5	Stop button
6	Power button
7	Real-time flow rate

8	High flow rate
9	High flow-rate knob
10	Low flow-rate knob
11	High flow-rate button
12	Handle
13	Low flow-rate button
14	Installation beam
15	Low flow rate
16	Pressure sensor interface
17	Bubble sensor

4.2 Irrigation Pump rear

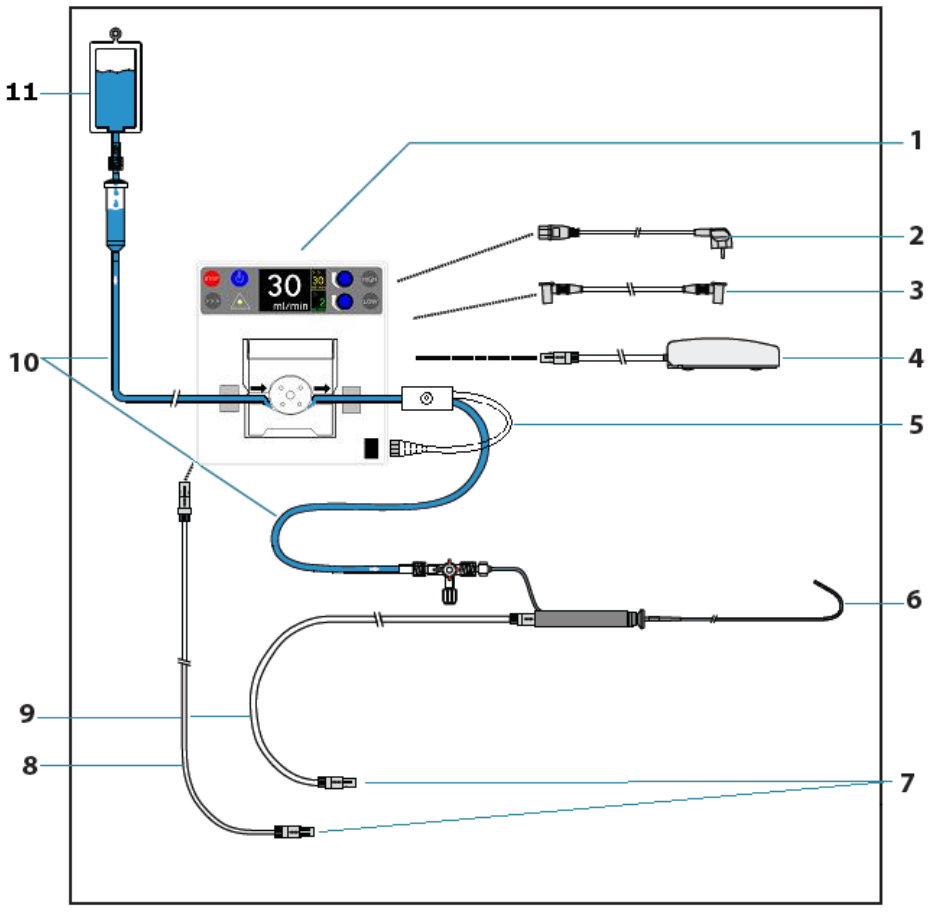
No.	Description
18	Equipment label
19	Fuse cover
20	Power socket
21	Power rating label
22	Ground pole and its label
23	Reserved interface, no function temporarily
24	Label of foot pedal
25	Foot pedal interface
26	Reserved interface, no function temporarily
27	Communication interface of RF device

Label:

Mark of defibrillation-prevention of CF type		The equipment is mark of defibrillation-prevention of CF type
Equipotential identification		Beside equipotential terminal of Irrigation Pump
protective earth identification		Beside protective earth terminal of switching power supply
Authorized representative		The identification is “Authorized representative in EU market”
Manufacturer		Representing the identification of Irrigation Pump manufacturer
Caution		Please read the specification before using the Irrigation Pump
Upward		Correct placement direction of packing case during transportation

Fragile		The goods are fragile, and please handle with care during transportation
Keep dry		Please keep dry during transportation
Protection class		The protection class of the equipment is IP52
Separate collection of electronic and electrical equipment		The equipment and accessories shall abide by requirements of separate collection of electronic and electrical equipment at end of life

4.3 Connection diagram of OptimAblate™ Irrigation Pump



No.	Description
1	OptimAblate™ Irrigation Pump
2	Power supply cable
3	Grounding cable
4	Foot pedal
5	Pressure sensor
6	Catheter
7	Interface of RF device
8	Communication cable of RF device
9	Catheter cable
10	Tubing set
11	Saline bag

4.4 Power connection


OptimAblate™ Irrigation Pump can adapt itself to the supply voltage of 100-230V～ and supply frequency of 50/60Hz. To avoid electric shock, connect the pump to a three-hole receptacle. Use the power supply cable supplied by manufacturer of local distributor.

4.5 Fuse


Fuse shall be mounted under cover as shown in diagram. Please use the fuse supplied by manufacturer.

4.6 Connection of circular plug

Circular plugs of communication cable and foot pedal cable are distinguished from color, making the plugs easier to be connected appropriate ports on back of OptimAblate™ Irrigation Pump. To insert the circular plug to socket, target arrow on the plug toward groove on the socket, insert plug tightly until ticking sound is heard. If plugging fails, check if the plug color matches with socket and whether the pin number is correct. Hold casing of the plug to pull it out directly.

4.7 Ground pole


To avoid the possible potential difference between the pump and other devices, OptimAblate™ Irrigation Pump must be connected to grounding cable (IEC / EN 60601 - 1). Connect one terminal of the yellow-green grounding cable to ground pole on back of OptimAblate™ Irrigation Pump, and connect the other terminal to ground wire in center of the room. Connect all concerning devices to the same grounding cable

(electrocardiograph, Columbus 3D EP Navigation system, RF device, etc.) to prevent radiation (noise) disturbing ECG signals.

4.8 Connection of foot pedal

See the connection of circular plug in section 4.6.

4.9 Connected to RF device

Turn on RF device and OptimAblate™ Irrigation Pump. Connect one terminal of the communication cable to communication interface on back of RF device, and the other terminal shall be connected to communication interface on back of OptimAblate™ Irrigation Pump. For more information, refer to the connection with RF device in section 6.5.

5 Installation of OptimAblate™ Irrigation Pump

5.1 Unpacking and general inspection

① Check appearance of all shipping containers for sign of damage. If yes, contact with the freight corporation at once.

② Tack parts out of the shipping case and package, check all components and make sure there's no damage during loading and transportation. In case of any questions, please contact local sale representative or customer representative of MicroPort provided on cover of the manual.

③ The following items are required for use contained in shipping case:

- OptimAblate™ Irrigation Pump
- Operation manual for OptimAblate™ Irrigation Pump
- Power supply cable in plastic bag
- IV pole mounting clamp (C-clamp)
- Foot pedal
- Communication cable with RF device
- Spare fuse

④ Items below are necessary for use and can be supplied additionally:

- Tubing set

⑤ Take power supply cable out from the plastic bag and insert it to AC socket on back of OptimAblate™ Irrigation Pump.

5.2 Attaching the Irrigation Pump to the IV pole

① The Irrigation Pump can be mounted on a standard IV pole or horizontal mounted crossbar using a removable C-clamp.

② Firmly fasten the C-clamp onto the IV pole or mounting rail near the patient.

③ Slide the pump mounting bracket into the C-clamp.

④ Connect any optional equipment needed.

Notes：

- Use a six-legged hospital grade IV pole capable of supporting the weight of the Irrigation Pump.
- Hang the 1 liter bag of perfusate on the side opposite the Irrigation Pump (on the hook of the IV pole) at a height of no more than 7 feet (2.1 m) above the ground.

- Attach the C-clamp to the IV pole no more than 5 feet (1.5 m) above the ground.

5.3 Connect tubing set to the pump

Notes:

- Only tubing set can be used. To avoid contamination, the tubing set should be taken out of package following standard hospital safety specification and must be inspected for integrity. Warning: Using other tubing sets may fail to guarantee basic performance.
- The tubing set is sterilized and only for single use.
- Incorrect installation is possible to cause pipeline damage.
- Use new pipeline for any individual operation.

① Connect the Irrigation Pump to overhead contact power and turn on the power switch of Irrigation Pump.

② Open the pump door. Attention: open the pump door completely, if not, the pipeline may fail to be installed.

③ Install the pipeline between chassis and pump head, making sure the pipeline direction consists with that indicated on pump head and the pipeline is locked in the stainless steel grooves on two sides inside the pump head, and stuck close to inboard baffle.

④ Lock pipeline gently into the bubble detector on two sides inside the pump head.

⑤ Close the pump door carefully to avoid get hands nipped, by when, the pipeline should be completely seized in pump head with no free flowing of liquid.

⑥ Insert the pressure sensor into an appropriate sensor socket if the pipeline with pressure sensor is used.

⑦ The equipment should be flushed by pressing the flushing key before use, so as to drain bubbles and prevent bubble flowing into the patient's body. If not flushed, the Irrigation Pump cannot start irrigation.

⑧ Pierce the needle of pipeline into saline bag, which is hanged on drip rack, and the height between saline bag and Irrigation Pump is 0.8m-1m.

5.4 Bring into use

Warning: Do not perform flushing when catheter is inserted in patient's body.

Flushing is allowed only when the following events are completed:

- OptimAblate™ Irrigation Pump is not in error state (alarms must be cleared).
- OptimAblate™ Irrigation Pump has stopped running.
- Pump door is closed.
- Hold down the flushing button for less than 2min.

① Take the catheter out of package following standard hospital specification and check catheter for integrity.

② Prepare catheter in accordance with its instructions for use.

③ Connect the catheter to plug end of the tubing set.

④ Open the three-way valve at the end of tubing set.

⑤ Pressure sensor plug

⑥ Guide pin of tubing set

⑦ Hold down the flushing button to start flushing with flow rate of 100ml/min generating regular beep sound. If flushing time exceeds 120s, OptimAblate™ Irrigation Pump will raise alarm and indicate the flushing button being stuck.

⑧ Inspect flowing situation of perfusate in pipeline visually. Ensure there's no leakage from or bubble in the tubing set or catheter when delivering perfusate with catheter.

⑨ Check visually the flowing rate of tubing set and the situation of irrigation in pipeline during irrigation.

⑩ Verify the perfusate has appropriate and available temperature before being delivered.

11 Press the low flow-rate key to start liquid flow at default value of 2ml/min.

12 Check the blocking alarm (if applicable)

13 Close the three-way valve to stop flowing so as to check if the blocking alarm works normally:

- Pump head stops running.
- Alarm sound is given out repeatedly.
- Indication of pipeline blocking is displayed.
- Alarm light flashes red.
- Halt indicator flashes red.
- Open the three-way valve and press stop button.
- If blocking alarm cannot be detected, install the tubing set again, and then repeat steps in 5.3.

14 Press the low flow-rate button to start liquid flowing at the preset or default value of 2ml/min.

15 OptimAblate™ Irrigation Pump is completely prepared and ready for use.

6 Instructions for Use

6.1 Startup & Shutdown

Connect the OptimAblate™ Irrigation Pump to network power source via standard soft power supply cable. Press the power button to start OptimAblate™ Irrigation Pump, when the power indicator lights up and logo of the ablation system appears on screen for 3s. Both the alarm light and bubble detection indicating light flash red and give out short sound.

Press down the Stand-by key for 3s, when OptimAblate™ Irrigation Pump closes. OptimAblate™ Irrigation Pump can be disconnected from the network power by unplugging the standard soft power supply cable.

If RF device is on OptimAblate™ Irrigation Pump is connected to it, the pump will be on automatically; if RF device is off when OptimAblate™ Irrigation Pump is connected to it, the pump shall be on as RF device is turned on; when RF device has been connected to OptimAblate™ Irrigation Pump correctly, if RF is turned off, OptimAblate™ Irrigation Pump will be off automatically.

When OptimAblate™ Irrigation Pump is connected to RF device which is on, in case of no alarm, OptimAblate™ Irrigation Pump will be switched into dormant state by pressing Stand-by key, when an alert of dormant state is displayed in center of the screen.

6.2 Irrigation

6.2.1 Start irrigation

The OptimAblate™ Irrigation Pump provides two flow-rate settings: low flow-rate irrigation and high flow-rate irrigation. The actual flow rate is displayed on screen in real time and can be switched between the low grade and high grade by corresponding keys on the panel.

- When button of low flow-rate irrigation is pressed, the pump would start irrigation at the preset low flow rate and give out alert sound, the default low flow rate being 2ml/min.

- When the button of high flow-rate irrigation is pressed, the pump will start irrigation at the preset high flow rate and give out alert sound simultaneously. During high flow-rate irrigation, the rotary button of high flow rate flashes to indicate the mode of high flow-rate irrigation at default value of 17ml/min.

6.2.2 Stop irrigation

Irrigation can be stopped by pressing STOP button or the Stand-by key (for less than 3s), when an alert sound would be given out. When OptimAblate™ Irrigation Pump stops operation, the actual flow rate is displayed as 0.

6.2.3 Flushing

Air in the pipeline and catheter can be drained out by pressing the “Flushing” button for long, at the flushing rate of 100ml/min. Continue real-time bubble detection during flushing, when there’s bubble detected, the pump would beep and the screen shall indicate bubbles.

Note: The “Flushing” button shall be pressed for no more than 25s.

6.3 Flow rate setting

The flow rate can be set when OptimAblate™ Irrigation Pump is in alarm-free state. The set value is displayed on LCD in real time and always takes effect. The high and low flow rates would return to default value when OptimAblate™ Irrigation Pump is turned on again after being turned off first.

- Adjustment of high flow rate button (up) can change the high flow rate setting, with step of 1ml/min and set range being 6-60ml/min.
- Adjustment of low flow rate button (down) can change the low flow rate setting, with step of 1ml/min and the set range being 1-5ml/min.

6.4 Foot pedal

When connected to a foot pedal, the OptimAblate™ Irrigation Pump can be started for irrigation by treading the foot pedal. Icon of foot pedal is displayed on bottom of the screen. If OptimAblate™ Irrigation Pump is in stop or low flow-rate irrigation state, treading down the pedal can start high flow-rate irrigation when the pump beeps. Treading down the pedal continuously will hold the pump in high flow-rate running. Release foot pedal, the pump would return to previous state and shall beep as alert.

Note:

If high flow-rate irrigation is started by treading foot pedal, pressing the low flow-rate button will fail to switch the pump into low flow-rate irrigation. Similarly, when high flow-rate irrigation is started by pressing the high flow-rate button, treading or releasing foot pedal also shall fail to switch the pump into low flow-rate irrigation.

6.5 Connected to RF device

Insert one terminal of the communication cable supplied by manufacturer into the blue communication socket on back of OptimAblate™ Irrigation Pump, and insert the other terminal into specialized interface for OptimAblate™ Irrigation Pump on the MicroPort RF device, after which, the OptimAblate™ Irrigation will be under control of RF device.

When all OptimAblate™ Irrigation Pump has been turned on and checked to be able to work normally, RF device icon will appear on the OptimAblate™ Irrigation Pump screen and the RF device shall alert OptimAblate™ Irrigation Pump has been connected and then start low flow-rate irrigation as per set value of 2ml/min, which is KOR.

In case OptimAblate™ Irrigation Pump is off state, it shall be on automatically and has RF device icon displayed on

screen, when RF device alerts the OptimAblate™ Irrigation Pump has been connected.

When RF device is connected to OptimAblate™ Irrigation Pump normally, the high and low rate irrigation can be changed in RF device where log flow-rate irrigation, stop and flushing can also be controlled. When operation run on OptimAblate™ Irrigation Pump is in different state from that of RF device, RF device will give notice. Alarm given from OptimAblate™ Irrigation Pump will also occur to RF device.

When RF device starts discharge, OptimAblate™ Irrigation Pump starts high flow-rate irrigation at once; when RF device stops discharge, OptimAblate™ Irrigation Pump continues irrigation for as long as the preset irrigation extension time.

6.6 Power on self-test

OptimAblate™ Irrigation Pump will begin self-test after being started and would beep as alert, with a progress bar displayed on screen. When self-test is completed, the pump beeps again. If self-test fails, the pump beeps continuously with corresponding faults shown on screen.

Power-on self-tests include:

- If buttons get stuck
- If horns and indicating lights work normally
- If the foot pedal works normally
- If bubble detector is connected normally
- Encoder self-test
- Motor self-test
- Hardware self-test

When replacing the pipeline after the end of a surgery, the user is suggested to restart the Irrigation Pump and begin to use it after the self-test has passed.

If power on self-test fails, do not use the equipment, restart at once; if failure lingers, please contact the manufacturer or local agent.

6.7 Pressure detection

MicroPort provides two kinds of pipeline with or without pressure sensor, which depends on material and specification of the pipeline. If pipeline with pressure sensor is used, remember to get the pressure sensor connected.

When the pressure sensor is being connected, the pump will detect pipeline pressure and display pressure value on LCD in real time. If the actual pressure exceeds limit, the pump shall give out blocking alarm; when pressure sensor is not connected, pipeline pressure wont' be detected and there's no blocking alarm generated, the equipment can run normally.

Warning:

- Excessively high pressure may cause rapid aging of pipeline and reduce irrigation accuracy.

- Pay attention to the pipeline pressure displayed on screen, if the value is significantly higher, check the pipeline for smoothness.

6.8 System setup

Turn off OptimAblate™ Irrigation Pump, press the button of low flow-rate irrigation for long and then press the power key, when OptimAblate™ Irrigation Pump will start up and display the system setup interface. Pressing the key button would shut down directly.

The system setup page includes such items as sound, screen luminance, language, blocking level, RF detection, set time, and service. Press the high flow-rate irrigation button after selecting service to enter service list which includes: export data, burn serial number, exit and battery.

Items can be selected by turning the high flow-rate setting button, and the selected item can be modified by adjusting the low flow-rate setting button.

① Three sound grades, the sound pressure of the first grade is 60dBA, the sound pressure of the third grade is 80dBA, with default value being the first. Notice: when the environmental sound is too loud, proper volume shall be selected to prevent the operator from failing in hearing the alarm.

② Three grades of screen luminance, arranged from low to high, with default value being the second grade.

③ Two language types, including Chinese and English, the latter being default.

④ Three grades of blocking warning, including 1:0.30-0.40MPa; 2:0.40-0.50 MPa; 3:0.50-0.60 MPa. Default value 0.50Mpa-0.60Mpa. When connecting the pressure leather pipe in normal use, the lower right corner of LCD will indicate the real-time pressure value and blocking warning grade. When selecting the first grade, the left side appears yellow; when selecting the second grade, the middle part appears yellow; when selecting the third grade, the right side appears yellow. After the blocking warning is generated, the maximum perfusion is 1 ml. Note: do not set the alarm limit to the limit value.

⑤ When the blocking warning has happened, the blocking threshold value is set as 1, and the transfusion speed is 17ml/min, the triggering time of warning is 45s, and the bolus volume is 12g; when the blocking threshold value is set as 3, and the transfusion speed is 17ml/min, the triggering time of warning is 55s, and the bolus volume is 17g. Notice: don't set the warning limit as limit value; you shall confirm whether the blocking warning grade is applicable or not before each surgery, in order to avoid failure in activating the warning.

⑥ RF detection has a total of 25 files, detection current in order from 0.1A to 2.5A, the default is 1 file.

⑦ Set time: It's available to set the current system time which is to record alarm generation time in report.

⑧ Service: This option is used by after-sales service personnel.

7 Symbol Description

Symbol	Description
	Quantity
	Follow operating instructions
	Upper and lower temperature limits (storage and transport conditions)
	Keep dry
	All patient connections of the device are defibrillation-proof type CF applied parts
	Alarms
	Flow direction
	Potential equalization port
	Foot pedal receptacle
	Fuse
	AC Current
	Manufacturer
	Manufacturing date
	Serial Number
	Caution
	Follow operating instructions
	CE marking with the number of the notified body
	Separate collection for electrical and electronic equipment
IP52	Instruments with dust and splash protection

8 Warning and Alarm

The OptimAblate™ Irrigation Pump shall give out warning or alarm sound according to severity in case of any situation possible to cause risks during operation, when appropriate indication will appear on screen. If alarm occurs during irrigation, OptimAblate™ Irrigation Pump will stop work in 3s; if fault only occurs to RF device communication, the OptimAblate™ Irrigation Pump will switch into low flow-rate irrigation. Pressing stop button can suspend alarming which may reoccur after 2 minutes if fault has not been cleared.

Note:

In case of multi-alarm, the screen shall give only one warning, and the alarm with high priority classified according to severity should be displayed. The priority is classified from high to low: system error>abnormal flow rate>disconnection of pressure sensor>button stuck>RF device communication abnormal>RF device communication disconnected>bubble>foot pedal> door being open> blocking of pipeline.

8.1 Warning

Warning	Audio	Alarm light	Cause	Solution
Pump door is open.	2kHz±20%, duration: 25ms	Dark	Pump door is opened when pump head is not rotating.	Close pump door.
Battery power is low	2kHz±20%, duration: 25ms	Dark	Capacity of button battery for alarm logging is too low.	Contact the local agent for battery replacement.
Communication is disconnected	2kHz±20%, duration: 25ms	Dark	MicroPort RF device is not connected.	Connect to MicroPort RF device.
Icon of foot pedal	2kHz±20%, duration: 25ms	Dark	The foot pedal is not connected.	Connect foot pedal
Air bubbles	2kHz±20%, duration: 25ms	Dark	Air bubbles are detected during flushing or when the pump head stops working.	Drain air bubbles through flushing.

Note: When flushing, the bubble warning will be disabled, and the screen only indicates that there are bubbles.

8.2 Alarm

All the following alarms are technical with high priority.

After alarm raised, the alarm light, sound and (or) indication will generate in 500ms.

Video	Audio	Alarm light	Cause	Solution
Air bubbles	910Hz±20%	Flash red	Air bubbles are detected during high flow-rate or low flow-rate irrigation.	Press the stop button, and then press the flushing button for long.
System error	910Hz±20%	Flash red	System error or hardware failures are detected during self-test or application, when error codes will appear on the screen. For specific faults, see Appendix I.	Restart OptimAblate™ Irrigation Pump.
Abnormal flow rate	910Hz±20%	Flash red	Flow rate is more than or lower than 1⁄3 of set value or the motor reverses;	After shutdown by pressing stop button, restart the irrigation after the self-test has passed. If the self-test fails, please contact the manufacturer and agent;
Pipeline blockage	910Hz±20%	Flash red	Head end of catheter is blocked, causing irrigation failure.	Clear the blockage and press stop button.
Pump door being open	910Hz±20%	Flash red	The pump door is opened or not well closed during irrigation or flushing.	Press the stop button and close pump door appropriately.
Button stuck	910Hz±20%	Flash red	The high flow-rate irrigation button, low flow-rate irrigation button, flushing button or stop button may fail to bounce back after being pressed, according to warning on the screen.	Press the stop button or power button, then release the stuck button.

Pressure sensor is disconnected	910Hz±20%	Flash red	The pressure sensor is not properly connected.	Plug the pressure sensor.
Communication of RF device is abnormal	910Hz±20%	Flash red	RF device is connected to OptimAblate™ Irrigation Pump but fails to communicate to it properly.	Disconnect and perform connection again, or replace the communication cable.
Communication of RF device is disconnected	910Hz±20%	Flash red	The communication cable is disconnected when the RF device and OptimAblate™ Irrigation Pump are running normally as one system.	Perform reconnection or replace the communication cable.

Note:

In case fault lingers after the above measures, pull out the soft power supply cable immediately and contact the manufacturer or local agent.

9 Equipment Care, Maintenance and Disposition

Daily care and maintenance is not necessary for OptimAblate™ Irrigation Pump. In case the pump fails to run after being plugged into an appropriate AC socket with the power switch to “On” position, check fuse. If failure reoccurs after inspection, please contact MicroPort for maintenance.

Clean the OptimAblate™ Irrigation Pump and get it repackaged, send it to any maintenance centre authorized by MicroPort for maintenance. If the pump is beyond warranty period, the maintenance centre would provide a reasonable disposition or maintenance cost after receiving and examining the product.

There’re no parts that can be maintained by user in OptimAblate™ Irrigation Pump. Disassembling and repairing the equipment by unapproved personnel will cause danger and void the warranty.

Note:

Do not take panel apart from the OptimAblate™ Irrigation Pump, since personal injury or pump damage may be caused.

9.1 Fuse replacement

Turn off OptimAblate™ Irrigation Pump and unplug the power supply cable. Dismount the fuse cover at the “AC power inlet module” on the pump back, take down the fuse holder and replace the fuse blown out. The replacing fuse must conform to specifications and types defined in “Technical Parameters” of chapter 10. Place the fuse holder with replaced fuse to its original position, making sure the arrow on fuse holder aligns with the arrow direction on inner side of the fuse cover. Put down the fuse cover and plug power supply cable to the OptimAblate™ Irrigation Pump.

9.2 Clearing

Turn off power or pull out plug of the pump before clearing.

Wipe the pump head with wet lint-free cloth after each use.

If clearing is necessary, user may clear external surface of the pump with wet cloth dipped in gentle cleanser.

Notes:

- Never immerse the pump or any other parts into any liquid.
- Avoid using corrosive cleanser or abrasive cleaner.
- Do not clean or disinfect the flammable material.
- Ensure the pump never touches high pressure steam or ethylene oxide disinfector.

External surface of the pump can be cleaned with wet cloth dipped in warm soap solution or one chemical agent of the following or any other like cleanser:

- Gentle dishes washing agent
- Isopropanol (70% solution)

- Bleaching liquid (10% solution)
- Window-cleaning solution (containing isopropanol and ammonia)
- Hydrogen peroxide (3% solution)

9.3 Safety

Apart from operation and maintenance according to the instructions, preventative measures must be taken appropriately for OptimAblate™ Irrigation Pump, including stable placement of the pup, protection against damp and contamination, avoid contacting flammable and explosive materials, as well as making sure the cable equipment and accessories arrangement will not influence personnel passage.

The original package of pump is required for long-distance transportation. If there's no original package, please contact the manufacturer or local agent for replacement.

9.4 Disposition

Electronic wastes not disposed properly may lead to environmental and health risks. Please abide by local laws and regulations concerning e-waste disposition. In order for appropriate disposition, you may send the discarded OptimAblate™ Irrigation Pump to local agent for disposition. When lower power is displayed for OptimAblate™ Irrigation Pump, contact the manufacturer for replacement under guidance of professionals or by after-sales personnel.

9.5 Calibration/adjustment

There're no parts that can be maintained by user in OptimAblate™ Irrigation Pump. The pump has been calibrated by manufacturer before delivery, and any calibration by unauthorized personnel may lead to abnormal running or damage of the pump. The flow rate accuracy of pump is suggested to be examined by the manufacturer every year, in case of any accuracy questions, maintenance can only be performed by after-sales personnel receiving specific training.

9.6 Storage

Pull out the AC plug before long-time storage of the pump. Make sure the pump door has been closed if it's not used. Store the pump in environment recommended in section 10.1 "Storage and transportation conditions".

10 Technical Parameters

Product model:

EPE-IGP-1A

Network power supply

Supply voltage: 100-230V～

Supply frequency: 50-60 Hz

Maximum power consumption: 35VA

Operation mode:

Continuous running

Flow-rate accuracy:

-5% - +15%

Bubbles detection:

Visible detection of air bubbles ≥2ul

Adjustment range of irrigation (step of 1ml/min):

Low flow-rate irrigation: 1 ml/min - 5 ml/min

High flow-rate irrigation: 6 ml/min - 60ml/min

Flushing: 100 ml/min (fixed flow rate)

Maximum irrigation pressure:

115psi

Sound pressure of alarm tone:

60-85dBA

Fuse:

T2AH, 250V

Others:

Safety classification: Type I, CF defibrillation-prevention equipment

Weight: 5kg

Size: 220mm (length) ×235mm (height) ×160 (depth)

IP protection grade: IP52

10.1 Storage and transportation conditions

- Temperature: -20℃- +55℃
- Relative humidity: 10% - 90%, non-condensation
- Atmospheric pressure: 50-106 Kpa (0.49 atm – 1.05 atm)

10.2 Working conditions

- Temperature: 10℃- 40℃
- Relative humidity: 10% - 90%, non-condensation
- Atmospheric pressure: 70-106 Kpa (0.69 atm – 1.05 atm)

10.3 Safety inspection

Note:

To ensure safety performance of the product, repair and safety inspection can only be performed by the manufacturer, the engineer or service centre approved by the manufacturer. According to IEC / EN 60601 – 1 and its sub-standard as well as IEC /EN 62353, at least one safety check is required every year after repair.

10.4 Maintenance

Self-test of OptimAblate™ Irrigation Pump is required before every use, and maintenance is not allowed during the pump application (connected to patient). Specific inspection items are as below:

- Both the high flow-rate and low flow-rate knobs are not released, adjustment of the knob can modify values on the screen properly.
- There's no damage or loosening of the socket.
- There's no damage or loosening of the equal-potential port.
- There's no damage of the power cable.
- There's no damage of the foot pedal.

Perform the above and following verifications once a year:

- The equipment is transported with complete label and legible text.
- The foot pedal can work normally.
- Accurate flow rate. See the diagram below for specific measurement method.

If necessary, sign a service contact; please contact the customer support.

10.5 Repair

Except fuse, the user is not allowed to dismount and maintain other parts of OptimAblate™ Irrigation Pump. (Exception: The product fuse can be replaced according to section 4.5 and section 9.1.)Maintenance or modification of any pump and accessories must be performed by manufacturer or the service engineer and service center approved by manufacturer.

11 Authorization

11.1 Transportation damage

User should inspect the OptimAblate™ Irrigation Pump at once for any damage after receipt. In case of any pump and accessories damage, please contact the local agent. Compensation is only provided after being verified by local agent or the logistics company. For your convenience, an “Error Report” form will be attached with the equipment, you can record any damage in it.

11.2 Guarantee

Guarantee period of OptimAblate™ Irrigation Pump supplied by MicroPort is one year from purchase. The guarantee does not cover power cable, communication cable, pipeline and other connection cables. Maintenance can only be performed by the manufacturer or after-sales service center approved by manufacturer, otherwise, guarantee is invalid. The guarantee period will not be extended for any reason.

11.3 Disclaimer

For application of the OptimAblate™ Irrigation Pump not in accordance with the following items, we’ll not be responsible for consequent damages and loss:

- Only accessories provided by MicroPort are used and operate the equipment according to the instruction.
- Electric installations in the equipment application environment conform to the instruction and other concerning requirements.
- Except fuse replacement, any other maintenance should be performed by the manufacturer or after-sales service center approved by the manufacturer.

12 EMC Information

The EMISSIONS characteristics of this equipment make it suitable for use in hospitals (CISPR 11 class A).
Electromagnetic compatibility information and technical instructions require special precautions on electromagnetic compatibility (EMC), and must be installed and used according to the EMC information provided in this user manual. The OptimAblate™ Irrigation Pump maintain basic safety and essential performance in regards to EMC

⚠ Warning: In order to complete its expected function, it must cooperate with the host of RF generator to transmit electromagnetic energy. Nearby electronic equipment may be affected. Users should pay attention to the operation of other electronic equipment nearby. If abnormal operation is found, measures should be taken immediately to remove the equipment or add shielding. Portable and mobile radio frequency communication equipment will affect the operation of. RF communications equipment be used no closer than 30 cm (12 inches) to any part of the OptimAblate™ Irrigation Pump, including cables specified by the manufacturer.

⚠ Warning: In addition to converters and cables approved by the manufacturer as replacement parts for internal components, the use of accessories, converters and cables that are not specified may result in increased radiation or reduced anti-interference capability.

⚠ Warning: It should not be used close to or stacked with other equipment. If it must be used close to or stacked with other equipment, it should be observed and verified that it can operate normally under the configuration.

<table>
<tr><td colspan="3">Electromagnetic radiation</td></tr>
<tr><td colspan="3">OptimAblate™ Irrigation Pump is intended for use in the electromagnetic environment specified below. The customer of the user of OptimAblate™ Irrigation Pump should assure that it is used in such and environment.</td></tr>
<tr><td>Radiation test</td><td>Compliance</td><td>Electromagnetic environment guidance</td></tr>
<tr><td>Radiated emission</td><td>CISPR 11 Group 1 Class A</td><td rowspan="2">The OptimAblate™ Irrigation Pump uses 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.</td></tr>
<tr><td>Conducted emission</td><td>CISPR 11 Group 1 Class A</td></tr>
<tr><td>Radiated emission</td><td>CISPR 11 Group 1 Class A</td><td rowspan="3">The OptimAblate™ Irrigation Pump is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Voltage fluctuation / Scintillation emission
IEC 61000-3-3</td><td>Not applicable</td></tr>
<tr><td>Harmonic radiation
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td colspan="3">Electromagnetic anti-interference</td></tr>
<tr><td colspan="3">The OptimAblate™ Irrigation Pump is intended for use in the electromagnetic environment specified below. The customer or the user of OptimAblate™ Irrigation Pump should assure that it is used in such an environment.</td></tr>
</table>

Anti-interference test	**Test level**	**Working level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact discharge ± 15 kV air discharge	±8kV contact discharge ± 15 kV air discharge
EFT IEC 61000-4-4	±1kv 100kHz repetition frequency	±1kv 100kHz repetition frequency
Surge IEC 61000-4-5	Line-to-ground：±2kv	Line-to-ground：±2kv
Voltage dips IEC 61000-4-11	0% U_T; 0.5 cycle： At 0°，45°，90°，135°，180°，225°，270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycle： Single phase： at 0°	0% U_T; 0.5 cycle： At 0°，45°，90°，135°，180°，225°，270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycle： Single phase： at 0°
Voltage Interruptions IEC 61000-4-11	0% U_T; 250/300 cycle	0% U_T; 250/300 cycle
Power frequency(50 Hz) Magnetic field IEC 61000-4-8	30A/m	30A/m

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic anti-interference

The OptimAblate™ Irrigation Pump is intended for use in the electromagnetic environment specified below. The customer or the user of OptimAblate™ Irrigation Pump should assure that it is used in such an environment.

Anti-interference Test	**Test Level**	**Compliance Level**	**Electromagnetic environment Guidance**
Conductive RF IEC 61000-4-6	0.15MHz-80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the OptimAblate™ Irrigation Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
	In ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz	6V	
Radiation RF IEC 61000-4-3	80-2.7GHz	3 V/m	

Test specification for ENCLOSURE PORT IMMINITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

13 Production Date and Expiration Date

The production date of the Irrigation Pump is detailed on the product label, and the recommended service life is 10 years.

14 Appendix I: Error Code

Error code	Type
ERR 1	Master CPU RAM abnormality
ERR 2	Master CPU abnormality
ERR 3	Master CPU ROM abnormality
ERR 4	There being keys pressed down
ERR 5	Foot pedal being trodden down
ERR 6	Master-slave communication abnormality
ERR 7	EEPROM abnormality
ERR 8	Flash abnormality
ERR 9	Pressure sensor abnormality
ERR 10	RF device communication abnormality
ERR 11	Slave CPU ROM abnormality
ERR 12	Slave CPU RAM abnormality
ERR 13	Slave CPU abnormality
ERR 14	Failure of bubble sensor on the left
ERR 15	Failure of bubble sensor on the right
ERR 16	Failure of power supply of slave CPU motor
ERR 17	Motor abnormality

Manufacturer:

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