EN/English

Overview

Please read the following information carefully before using this device. It provides important instructions regarding proper operation, potential risks, and potential damage to the product or individuals. In the event of any abnormal situation, follow the specified instructions to prevent harm to yourself or damage to the equipment. Failure to follow these instructions may result in compromised safety, performance, warranty, or maintenance, for which the manufacturer cannot be held liable. Please read the instructions for the Transducer and Ultrasonic Shears as well before using the device.
This document is designed to assist in using this device. It is not a reference for surgical techniques.

Standard Conventions Used: Caution, WARNING, and Note Statements

Please note the following statements, categorized as CAUTION, WARNING, or NOTE, which provide essential guidance for completing tasks safely and thoroughly. These statements can be found throughout the documentation and should be read before proceeding to the next step in a procedure.
WARNING: This statement highlights an operating or maintenance procedure, practice, or condition that, if not strictly followed, could lead to personal injury or loss of life.
CAUTION: This statement alerts the user to a potentially hazardous situation that, if not avoided, may result in minor or moderate injury to the user or patient, as well as damage to the equipment or other property. It may also serve as a warning against unsafe practices. This includes the necessary precautions for the safe and effective use of the Instrument and the care required to prevent damage resulting from proper or improper use.
NOTE: This statement indicates an operating practice or condition that is essential for executing a task efficiently.

Description

The ENER REACH Electrosurgical Instrument(herein referred as 'the device') is used in medical operating rooms for surgical procedures for cutting, coagulating human tissue, and ligating vessels. It features two separate slots: one for ultrasonic energy and the other for radio frequency waveform output.
In radio frequency mode, the generator delivers different energy schemas depending on the connected instrument/electrosurgery device. When an advanced bipolar instrument is connected, the generator delivers RF waveforms for sealing arterial and venous vessels, lymphatics, and tissue bundles up to 7 mm in diameter. When a basic bipolar instrument is connected, constant power energy is outputted for soft tissue cutting and coagulation.
In ultrasonic energy output mode, using the TRA6 transducer in combination with Disposable Ultrasonic Scalpels, including CH45PD, CH36PD, CH23PD, CH14PD, the device cuts soft tissues requiring bleeding control and minimal thermal damage, and seals vessels up to a maximum diameter of 5 mm. When connected with Disposable Ultrasonic Shears, including SRB14, SRB23, SRB36, SRB45, SRE14, SRE23, SRE36, and SRE45, the device cuts soft tissues requiring bleeding control and minimal thermal damage, and seals vessels up to a maximum diameter of 7 mm.

Intended Use

The device provides radiofrequency power to drive electrosurgical handpieces that are intended to seal vessels and cut, grasp, dissect tissues.

In addition, the generator provides ultrasonic power to drive ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

Indications

The device provides radiofrequency power to drive electrosurgical handpieces that are used during open surgeries or laparoscopic surgeries in general, pediatric, gynecologic, urologic, thoracic surgery to cut and seal vessels up to and including 7mm, and to cut, grasp, and dissect tissues.
In addition, the generator provides power to drive ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The ultrasonic surgical instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels for cutting and/or coagulating tissue in open surgeries or laparoscopic surgeries in general, pediatric, gynecologic, urologic, thoracic, and sealing and transection of lymphatic vessels.

Intended User

The device is intended for use by healthcare professionals for surgical applications.

Intended Use Environment

The device is intended to be used in a hospital.

Intended Patient Population

This device is suitable for patients aged 3 and older who require surgical procedures involving soft tissue incisions with bleeding control and minimal thermal injury.

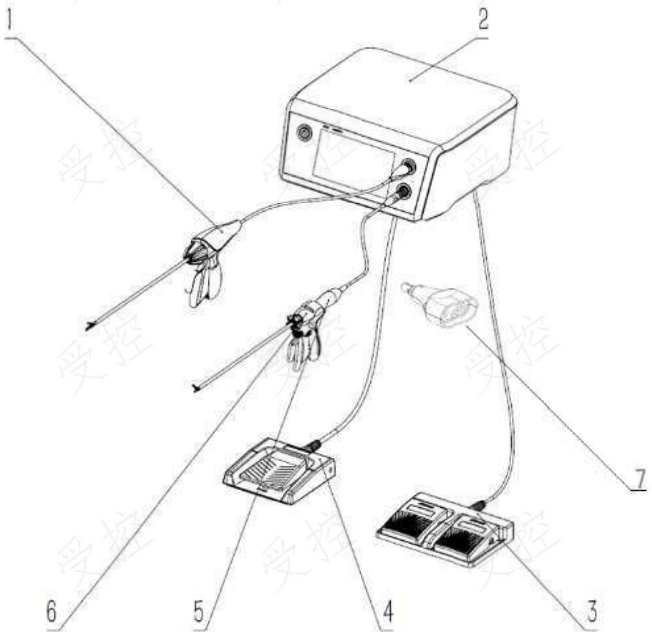
Clinical Benefit

The device can be used safely and effectively in ligation and division of vessels, tissue bundles, and lymphatics.

Contraindications

This device is contraindicated for bone incisions, contraceptive tubal occlusion, and coagulation procedures. It is also not intended for use in neurosurgery.

System Composition



[01] Electrosurgery handpiece	[02] OP9 Generator
[03] Ultrasonic footswitch	[04] Electrosurgical footswitch
[05] Transducer	[06] Ultrasonic Shears
[07] Electrosurgery Bipolar Converter	

[01] Electrosurgical Handpiece

The electrosurgical handpiece, connected to a generator, is operated by the surgeon during the procedure. It applies RF electrosurgical energy to tissue between its jaws to coagulate or seal. The instrument also includes a blade for tissue division. Model: OSA23, OSA37, OSA44. Refer to the instructions for detailed information. Note: The maximum operating voltage of The Osprey instrument is 250Vpk, which is compatible with the OP9 generator.

[02] OP9 Generator

The generator provides both electrosurgical energy and ultrasonic therapy energy through separate instrument connection ports. It consists of a chassis, shell, electronic board, LCD touch screen, power switch, and interfaces for accessory connection.
Model: OP9

[03] Ultrasonic Footswitch

Used to control the on/off output of ultrasonic energy with two switches ("MIN" and "MAX"). Model: OP-FSD

[04] Electrosurgical Footswitch

Used to control the on/off output of high-frequency energy with a single switch.
Model: OP-FSS

[05] Transducer

The transducer converts electrical energy from a compatible generator into mechanical motion for the instrument blades. It is a reusable instrument with a limited service life. The transducer is non-sterile and must be sterilized according to instructions before use. Refer to the TRA6 Transducer instructions for detailed information.
Model: TRA6.

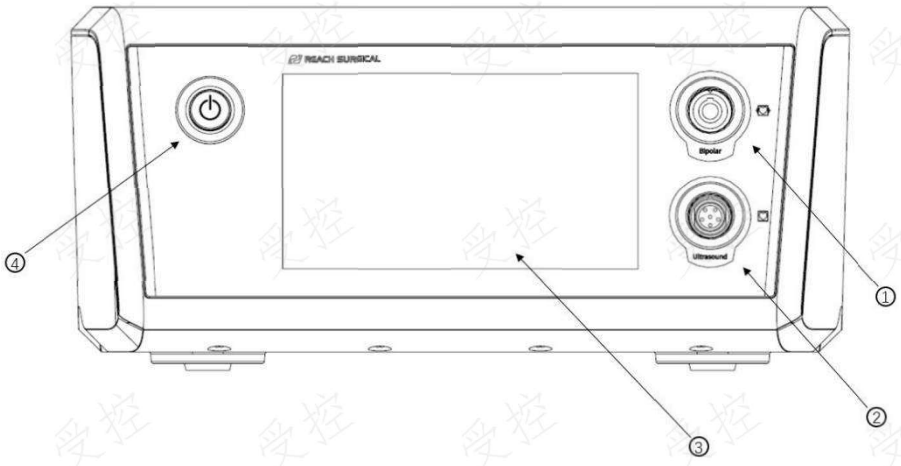
[06] Ultrasonic Shears

The Ultrasonic Shears use mechanical motion from the transducer and deliver ultrasonic energy for tissue cutting or coagulation. Caution should be taken as the mechanical vibration is not detectable and could unintentionally affect non-targeted areas. The Ultrasonic Shears are sterilized with ethylene oxide. If the shelf life is exceeded or the sterilization package is damaged, the Ultrasonic Shears should not be used and should be disposed of. Refer to the instructions of the Ultrasonic Shears for detailed information.
The following Ultrasonic Shears are compatible with the OP9 generator:
PD series: CH14PD, CH23PD, CH36PD, CH45PD
SRB series: SRB14, SRB23, SRB36, SRB45
SRE series: SRE14, SRE23, SRE36, SRE45

[07] Electrosurgery Bipolar Connector

Used to connect basic bipolar electrosurgical instruments to the generator for tissue coagulation.
Model: OP-BPC
Note: The rated maximum operating voltage of the basic bipolar electrosurgical instruments must be ⩾ 250Vpk, which is compatible with the OP9 generator. Please refer to the manual of the bipolar electrosurgical instruments

Generator Front Panel



[01] Electrosurgical socket

Used to connect advanced bipolar electrosurgical instruments or electrosurgery bipolar connector.

[02] Transducer socket

Connects the Transducer to the Generator.

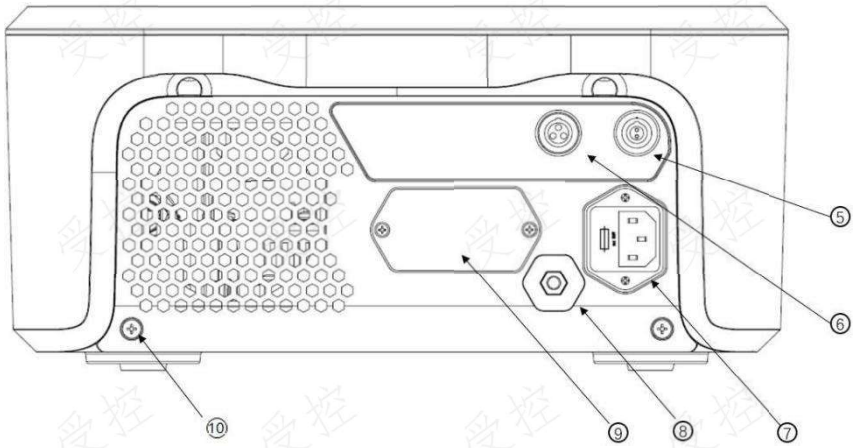
[03] LCD touch screen

Displays system information and serves as the interface for adjusting controls and settings.

[04] Power switch Button

Press to turn on the Generator; press and hold to power off.

Generator Back Panel



[05] Electrosurgical Footswitch Socket

Round socket for connecting the Electrosurgical Footswitch

[06] Footswitch of Ultrasound Surgical Equipment Socket

Round socket for connecting the Footswitch of Ultrasound Surgical Equipment.

[07] Power Socket

Connects the Power Cord to the Generator.

[08] Potential Equalization Port

If the power socket's grounding is uncertain, this port allows for connection to protected earth.

[09] Expansion Interface

Used for function expansion and maintenance.

[10] Mounting Hole

Instructions for use

Refer to the provided guidelines for the operating environment.

Unpacking

Please follow the instructions upon receiving the components below.

- Check for any visible transportation damages. If any damage is found, please contact Reach Surgical, Inc or the local agent for assistance.

Components included in the (For detailed technical specifications and product codes, refer to Chapter 'System Technical Conditions'):

Model	Description	Component
OP9	Generator	Generator, Power cord, Instructions
TRA6	Transducer	Transducer with cable
OP-FSD	Footswitch of Ultrasound Surgical Equipment	/
OP-FSS	Electrosurgical Footswitch	/
OP-BPC	Basic Bipolar Energy Connector	/

Safety Precautions

- During equipment inspection, keep the distal end of the instrument away from other apparatuses, surgical drapes, the patient, or any other objects to avoid injury.
- Implement necessary safety measures in the presence of vapors, following hospital procedures and regulations.

Ultrasonic Energy with PD Series Ultrasonic Shears

- Connect the transducer, foot switch, and PD series Ultrasonic Shear to the generator.
- After passing the transducer and Ultrasonic Shear test, adjust the power level (1-5) using the +/- icons on the LCD screen.
- Press the 'Min' button on the Ultrasonic Shear or Min pedal on the Foot switch to activate the ultrasonic energy at the preset power level.
- Press the 'Max' button on the Ultrasonic Shear or Min pedal on Foot switch to deliver the maximum power level of energy.
- Release the key or foot switch to stop energy output.

Ultrasonic Energy with SRB/SRE Series Ultrasonic Shears

- After passing the transducer and Ultrasonic Shear test, adjust the power level (1-5) using the +/- icons on the LCD screen.
- Press the Energy Button on the instrument or Min button on the foot pedal to activate the ultrasonic energy at the preset power level.
- Press the Energy Button with Advanced Hemostasis on the instrument to activate Advanced Hemostasis mode.
- Release the Button on the Ultrasonic Shears or the button on the Foot switch to stop energy delivery.

Electrosurgical Bipolar Energy with advanced bipolar instruments

- The LCD display shows the advanced bipolar icon and adjustable hand control icon.
- Pull the Lever on the instrument or press the footswitch pedal to activate the radio frequency.
- The generator will stop energy output when the closure is completed, indicated by the complete icon on the screen.
- If the ligation is incomplete, a warning tone will be played, and a warning icon will be displayed.

Electrosurgical Bipolar Energy with Bipolar Electrosurgical Instrument

- The LCD screen displays the power value, adjustable icons, and power level bars.
- Power settings range from 1-95 watts, with adjustable increments.
- Select the desired power output setting: Low (15 watts), Medium (30 watts), or High (60 watts).
- Press the button on the hand switch or footswitch pedal to activate the radio frequency.
- Release the button to deactivate the energy output.

Setting Recommendations

Effect Settings	Power Settings Range	Clinical application	Optimized device
Low	1-15 watts	Such as nerves/spine, hands and Facial surgery	· Devices with smaller surface areas · Microtip forceps (0.4 – 2.2 mm)
Mid	16-40 watts	Such as coagulation during head/neck, spine and anatomy	· Devices with medium surface area · Microtip forceps (1.0 – 2.2 mm) · Small flat-head laparoscopic forceps · Bipolar scissors
High	45-95 watts (5 watts increments)	Such as head/neck and plastic surgery (similar to medium effect, but with faster effect)	· Devices with large surface areas · Large flat-head laparoscopic forceps

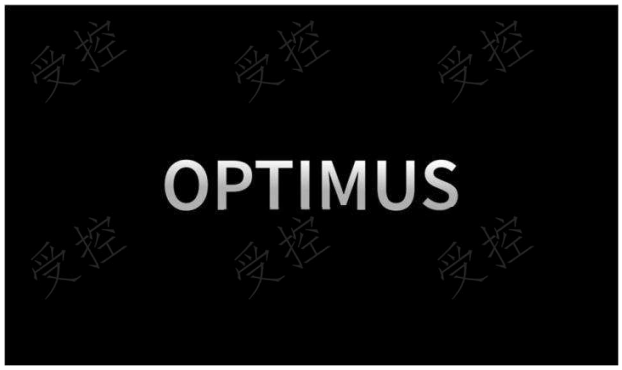
NOTE: This device is not compatible with neutral electrode.

NOTE: The Ultrasonic Shears and RF electric scalpel are patient contact applied parts

Using the generator

Turn on the device

- The system is ready for operation once it's been turned on. When the generator is connected to the mains supply and the standby switch light is on, the system is ready for use.
- After pressing the Standby Button, the following image will be displayed:



- If no Transducer or Shear is connected to the Generator, or if they are connected improperly, the following prompt will be indicated:

Using Ultrasonic instrument (Transducer and Ultrasonic Shear)

When transducer and Ultrasonic Shear are detected, the following image will be displayed.

NOTE: if the remaining use of the Transducer is less than 10, a warning message will be prompted in screen. User should pay attention to the number of remaining uses as the Transducer needs to be replaced when the number down to zero.

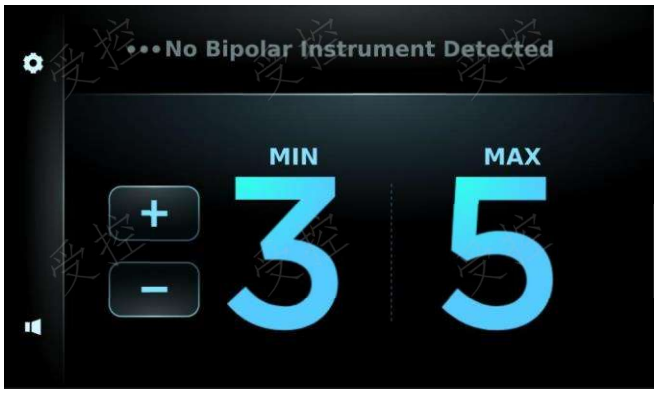
Next the following icon will be displayed, user will be asked to press any button on the Shear to start shear test with open jaws.

Press the any button, and system will start transducer & shear testing.

If the test fails, a test failed result with following icon will be shown in middle of screen.

When the transducer and Ultrasonic Shear test passes, the following image will be displayed:

The following working screen will be displayed when connecting Shears without Advanced Hemostasis function or single button shears.

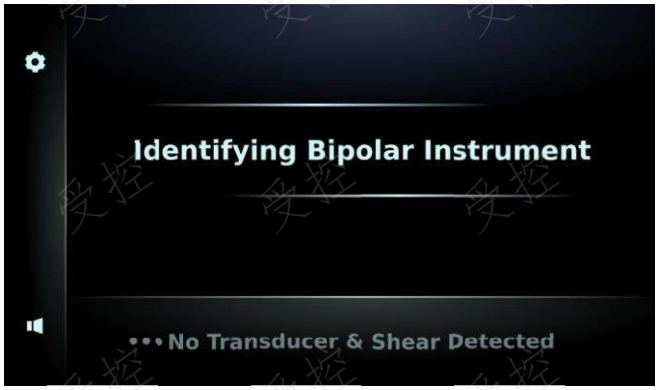


The following working screen will be displayed when connected new SRB or SRE Shears with Advanced Hemostasis.

Output mode will be highlighted it's activated.

Using Electrosurgical instrument

When an electrosurgical instrument is detected, the following image will be displayed.



When the electrosurgical instrument is ready for use, the following image will be displayed:

The following working screen will be displayed when connecting to advanced bipolar instrument.

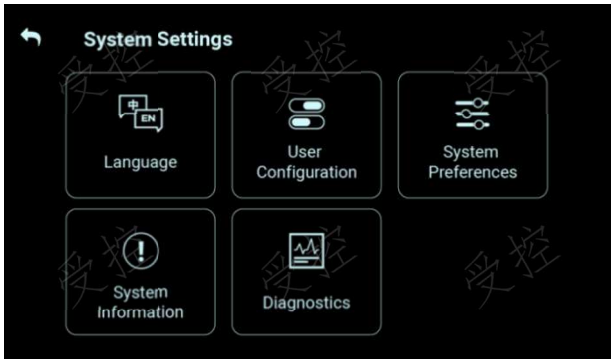
The following working screen will be displayed when connecting to basic bipolar instrument.

Using Electrosurgical instrument and Ultrasonic Shears

Please note that when the generator is connected to both a bipolar electrosurgical instrument and an Ultrasonic Shear, the system operates in a split-screen mode to display the current state. The device that is prioritized will be the first to activate the energy. This split-screen state is shown below:

System Settings

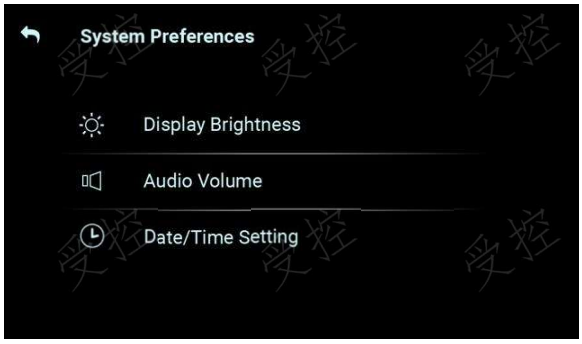
To access the system settings, click on the settings icon located in the upper left corner of the screen. The following system setting options are available:



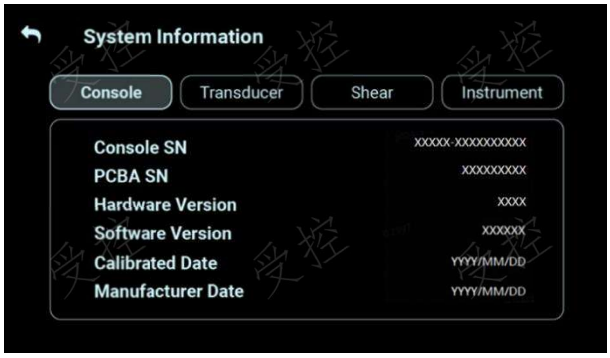
Language: Clicking on the Language item will display the language selection screen:

User Configuration: Clicking on the User Configuration item will display the user configuration screen:

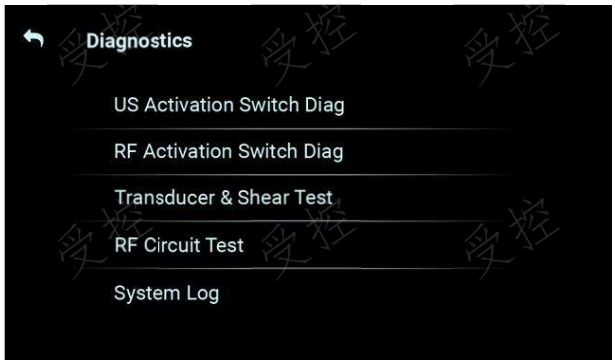
System Preferences: Clicking on the System Preferences item will display the system preferences screen:



System Info: Gently click on the System Info item to display the system information screen:



Diagnostics: Clicking on the Diagnostics item will display the diagnostics screen:



To exit the system settings and return to the system standby mode, press the 'Return' icon located in the top left corner of the screen.

Shutting down the system

Follow the steps below to safely shut down the system:

Press the Standby Button: Locate the Standby Button on the Generator and press it to initiate the shutdown process.

Disconnect Transducer and Ultrasonic Shear: Carefully disconnect the Transducer and the Ultrasonic Shear from the system. Refer to the operating instructions for proper handling of the Transducer and Ultrasonic Shear.

Unplug the power cable： Disconnect it from supply mains

Cleaning: Clean the Generator, Foot Switch, and Transducer in accordance with the specified procedures outlined in Chapter ‘Maintenance’.

Troubleshooting

The Generator incorporates various alert signals and error codes to aid in the identification and diagnosis of component faults. It is important to note that these signals and codes are designed to support clinical judgment and observation, rather than replace them.

Sound alert

Working Status	Sound Type	Possible cause and action
Self-check Status	Normal sound	/
	Abnormal sound	A hardware fault has been detected. Please contact the manufacturer for repair assistance.
Using Ultrasonic Instrument	Max Level sound	/
	Min Level sound	/
	Abnormal sound	The Ultrasonic Shear has come into contact with excessive tissue. Reduce the tissue contact with the Ultrasonic Shear. If a continuous sound persists, carefully remove any tissue that may be accumulating around the end of the Ultrasonic Shear. There is a fault detected with the Transducer and/or Ultrasonic Shear. Please refer to the manufacturer or contact support for further assistance.
	ADVANCED sound	/
	ITS sound	/
Activating Electrosurgical Instrument	Advanced bipolar warning tone	/
	Normal bipolar sound	/
	Abnormal sound	Unsuccessful Cutting: If the tissue contacted by the instrument does not meet cutting requirements, reduce the amount of tissue in contact with the instrument. If the fault tone persists, carefully clear any tissue that may be accumulating at the end of the instrument. Hardware Failure: This error indicates a potential short or failure in the Ultrasonic Shear's circuit or connector. In the event of any fault or error, it is recommended to consult the manufacturer or seek support for appropriate guidance and resolution.

Error Codes

The Energy Platform Generator is equipped with a comprehensive fault identification system consisting of alerts and system errors. When a fault is detected, the generator emits a warning tone, displays a warning signal on the control panel, and shows a corresponding fault code on the LCD screen. Follow the steps outlined below to address the issue:

Error Codes Table

Error code	Corresponding fault message
Warning	Please connect Ultrasonic Shear with Transducer correctly
Warning	Make sure jaws are open while testing
Warning	Ultrasonic Shear Error Detected
Warning	The remaining time of the transducer is zero
Warning	Please activate only one button at a time
Warning	Please reduce the force applied to the Ultrasonic Shear
Warning	Ultrasonic Shear button and footswitch cannot be closed simultaneously
Warning	Button stuck, please check and continue
Warning	Adjust jaws or clamp less tissue
Warning	Remove device from tissues
System Error	System Error
System Error	Self-check Failed

If an error appears on the screen during ultrasonic testing, perform the following actions:

- Ensure that the Transducer cable is fully inserted in the correct direction.
- Check if the Ultrasonic Shear has been tightened correctly or if any tissue has accumulated around the end of the Ultrasonic Shear. Adjust the Ultrasonic Shear's tightness and carefully remove any tissue accumulation around the Ultrasonic Shear casing. (If the test is initiated prior to the operation, ensure that the Ultrasonic Shear is pointing towards the air. If Ultrasonic Shears are being used, confirm that the clamping jaw is open and not in contact with any objects.)
- If the problem persists, consider replacing the Transducer or Ultrasonic Shear.
- Proceed to the equipment's working mode.

NOTE: The Transducer may not function properly if its temperature exceeds the specified limit. In such cases, use another Transducer immediately for recovery or follow the steps below to determine the cause of the error and explore optional recovery methods:

- Allow the Transducer to cool down at room temperature for a minimum of 45 minutes. This cooling method also applies if the Transducer becomes hot after prolonged operation at high power.
- If Transducer overheating is not evident and the problem remains unresolved, contact the manufacturer's maintenance representatives for assistance.
- Apart from fuses, there are no user-serviceable parts in the Generator. For any replacement or service requirements, please get in touch with service personnel who are trained and authorized by Reach Surgical, Inc. or your local representative.

Maintenance and upgrades of the Generator should be exclusively performed by service personnel trained and authorized by Reach Surgical.

Cybersecurity precautions should be considered to prevent potential threats. The following incidents pose cybersecurity risks:

- Unauthorized access to any non-related products for the device.

- Any unauthorized network communication with the device.
- Firmware or software upgrades that have not been authorized by Reach Surgical.

In the event of any of the above incidents, please contact the sales representative of Reach Surgical, Inc. or directly reach out to Reach Surgical, Inc. at Reachquality@reachsurgical.com.

Maintenance

Cleaning and disinfecting the generator and Basic Bipolar Energy Connector

Cleaning

Clean the Generator LCD screen and Basic bipolar connector in accordance with hospital procedures and regulations. Before cleaning, ensure that the main power supply of the Generator is disconnected and the Power Cord is removed from the output unit.

WARNING: Cleaning procedures must be followed carefully to avoid damaging the Generator, causing electric shock, or creating a fire hazard. Do not spill or splash liquids on or into the Generator, or immerse it in liquid.

Follow these steps for cleaning:

- Prepare a neutral pH detergent or neutral pH enzyme detergent as specified by the detergent manufacturer.
- Using a clean, soft cloth soaked with a small amount of cleaning solution, manually wipe all surfaces, including the Generator screen.
- Wipe all surfaces with a clean, soft cloth soaked in warm tap water.
- Finally, wipe all surfaces with a clean, soft cloth to ensure they are dry.

Disinfection

- If the generator becomes contaminated with blood or bodily fluids, it must be disinfected before reuse. The following chemical disinfectants have been validated for use on the generator: 70% isopropyl alcohol, 6% sodium hypochlorite, 10% hydrogen peroxide。
- Follow the manufacturer's recommendations for proper use, concentration, and contact time of the disinfectants.
- Ensure that disinfectors are configured and used according to the manufacturer's instructions.

Cleaning the Foot Switch

Clean the Foot Switch and cable after each use using the following procedure:

- Disconnect the Foot Switch from the Generator.
- Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer’s directions
- Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
- Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water
- Dry with a soft, clean cloth.

CAUTION: Keep the cable and Foot Switch securely connected during rinsing.

- Wipe all surfaces with a clean, soft cloth.

WARNING: Do not use an ultrasonic cleaning machine to clean the Foot Switch.

WARNING: Do not switch on the power supply of the Generator before connecting the AC power cable. Ensure all connections are dry before assembly.

Cleaning and disinfecting the transducer

Transducers are shipped non-sterile and require thorough cleaning and sterilization before each use.

Cleaning:

Thoroughly clean Transducer according to the following steps:

- Rinse the Transducer with the screw side up and clean with a soft bristle brush with purified water until there are no smudges on the surface;
- The Transducer is soaked in a pH neutral enzymatic detergent (main ingredients: protease, lipase, amylase, cellulase, pectinase and other biological enzymes, environmentally friendly surfactant, rust prevention factor and stabilizer) for a period of up to 10 minutes at an appropriate temperature 15℃ ~65℃. The ratio of detergent and purified water is 1:400.
- Rinse the Transducer with the screw side up with purified water for 2 minutes;
- Clean the Connecting Screw, Scalpel Mount Surface and Connector with an alcohol wipe.
- Soak the Transducer in 75% medical alcohol and hold and shake it for 30 times;
- Rinse the Transducer with the screw side up with purified water for 2 minutes.

Note: The use of ultrasonic cleaners is not recommended for the Transducer.

Drying:

Drying temperature: 50~70℃, drying time: 30min.

Transducer Sterilization:

Following the cleaning and drying steps above, the Transducer must be sterilized by one of the methods listed below.

Steam Sterilization (121℃)

- Sheath should be installed before sterilization. Transducer should be wrapped during sterilization. Put the Transducer into a high-temperature steam sterilization pot for sterilization, with a temperature of 121℃ and a duration of 30min.
- Drying temperature: 50~70℃, drying time: 30min.

Steam Sterilization (134℃)

- Sheath should be installed before sterilization. Transducer should be wrapped during sterilization. Put the Transducer into a high-temperature steam sterilization pot for sterilization, with a temperature of 134℃ and a duration of 10min.
- Drying temperature: 50~70℃, drying time:30min.

Safety and Functional Tests

Ensure the implementation of safety and functional tests for the Transducer, Generator, and Foot Switch in accordance with hospital procedures and regulations. For safety and function tests of other components used by multiple patients, refer to the operating instructions specific to each component.

Safety Test

Generator: Certified hospital technicians should perform a leakage current test.
Foot Switch: Inspect the pedal, cable connector, and cable for any cracks or damage. Replace any damaged components.
Other components: Check all other components as instructed in their respective operating instructions.

Functional Test

Ultrasound Mode

- Prepare the complete set of PD Ultrasonic Shear and connect the Transducer following the instructions provided in Chapter II - Installation and Operation of the Equipment.
- Verify if it is possible to enter the working state. Different Ultrasonic Shears may have different entry interfaces. Refer to Part 1, Section 3 of Chapter 2 for detailed instructions.
- Confirm the display of MIN power Level 3 and MAX power Level 5.
- Press the power increase and decrease buttons to ensure that the MIN power level can be adjusted from levels 1 to 5.
- Power on the generator and switch it to ultrasonic working mode. Verify the correct connection of the transducer and Ultrasonic Shear.
- With the jaw open, press the "MAX" button on the foot switch. The LCD screen should display the MAX power level "5," and an activation tone should sound.
- With the jaw open, press the "MIN" button on the foot switch. The LCD screen should display the MIN power level, and an activation tone should sound.

WARNING: Before activating the system, ensure that the jaw is kept away from tissues, other instruments, or any other objects to prevent injury to the user.

Bipolar Electrosurgical Mode

- Connect the advanced bipolar Electrosurgical instrument/basic bipolar instrument according to the instructions.
- Check if the system can enter the working interface. Basic bipolar mode should display the 30 power level icon, while advanced bipolar mode should display the "advanced bipolar" icon.
- Lightly touch the power increment and decrement keys under Basic bipolar mode to confirm that the power level can be adjusted between 1 and 95. Touch the Low, Medium, and High bars to switch directly between 15, 30, and 60.
- Power off the generator and wait for 5 seconds. Then, turn on the power supply of the generator and wait for 10 seconds. Check if the Basic bipolar mode displays the 30 power level interface, and the advanced bipolar mode displays the "advanced bipolar" interface. Verify if the generator is activated according to

the predetermined requirements.

- Connect the advanced and Basic bipolar Electrosurgical instruments and press the single foot switch. Check for flashing power level indications on the control panel and listen for an activation sound.

WARNING: Before activating the system, it is strictly prohibited to allow any contact of the Ultrasonic Shear with tissues, other instruments, or any other objects to prevent injury to the user.

Warnings and Precautions

System related

- Read the instructions prior to use and follow hospital guidelines for clinical practice for ultrasonic surgery, electrosurgery, gynecology, and laparoscopy.
- Minimally invasive devices may vary from manufacturer to manufacturer. If minimally invasive instruments and accessories from different manufacturers are used in a surgery at the same time, check the compatibility of instruments and accessories before the surgery and check whether the accessories inserted into the human body have a rough surface, sharp edge, or protrusion that may cause safety hazards.
- This device is intended for use by trained and licensed surgeons only. Do not use electrosurgical devices unless you have been properly trained in their use for the specific procedure that you will need to complete. Untrained use of this device can cause unintended serious injury to the patient, including bowel perforation and unconscious and irreparable tissue necrosis.
- Do not open the generator enclosure without permission to avoid possible shock hazards. Any repair and upgrade of the instrument shall be performed by a service person trained and authorized by Reach Surgical, Inc. Do not use this instrument for any purpose other than medical surgery.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to prevent shock and burn hazards to both the patient and medical personnel and damage to this device or other medical devices. Electrical insulation or grounding must not be compromised. Do not immerse electrosurgical devices in fluids unless the design requires it, and labeling states that they should be immersed.
- Safe and effective ultrasonic surgery and electrosurgery depend not only on the design of the equipment but also largely on many factors controlled by the operator. To improve safety and effectiveness, read, understand, and follow the instructions for use provided with the device.
- As with all energy sources (electrosurgical, laser, or ultrasound), consideration should be given to the carcinogenic and infectious risks that many tissue byproducts, such as smoke and aerosols, may present. Appropriate precautions such as safety glasses, filtration masks, and effective smoke evacuation equipment should be observed in both open and endoscopic procedures.
- After removing the device, check the tissue for hemostasis. If hemostasis is absent, appropriate methods should be used to achieve hemostasis.
- Products manufactured or distributed by companies not authorized by Reach Surgical, Inc. may not be compatible with the device. Use of such products may lead to unexpected results and may injure the user or patient.
- To reduce the risk of interference, the device and the shell be connected to an independent power circuit.
- The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Potential for sparking due to collision with other metallic devices. Sparks may ignite flammable gases, such as field gases.
- The must operate within the required ambient operating temperature range.
- Output socket voltage shall meet the requirements of the generator (Chapter ‘System technical conditions’). If the power supply is not connected correctly, it may damage the generator and cause

electric shock or fire hazards.

- Do not use extension cords to avoid fire hazards.
- Do not turn the activation tone to an inaudible level. Activation tones can be noticed by surgical team personnel while the generator is delivering energy.
- Smoke generated during electrosurgery has been shown to be potentially injurious to patients or surgical team personnel. Suggest adequate ventilation with a surgical smoke evacuator or other means.
- There are some components in the Ultrasonic Surgical Integrated Generator that are shipped non-sterile (e.g., Transducer). Sterilize the product as required before starting system installation. For cleaning and sterilization instructions, refer to each relevant instruction.
- To avoid injury to users or patients, the Ultrasonic Shear must avoid other devices, surgical drapes, patients, or other objects before pressing the test button and during system check. Safety measures in case of aerosol (according to hospital regulations) shall be implemented in the system inspection and test method.
- Do not apply too much pressure to the jaw to avoid inhibiting the delivery of ultrasonic energy.
- To avoid injury to the user, the blade must avoid contact with tissue, other devices, or other objects before activating the system.
- If liquid is sputtered or poured on or into the generator, or the generator is spilled or poured into the liquid, it may damage the generator and cause electric shock or fire hazards.
- Sparking and heating associated with vessel closure techniques can both serve as sources of ignition. Gauze and a sponge should remain moist. Keep electrosurgical electrodes away from combustible materials and oxygen-rich (O2) environments.
- When there is significant damage to the Transducer or if any parts show signs of damage after cleaning and disinfection maintenance, discard them. Damaged parts are clearly marked to avoid misuse prior to subsequent handling.
- Disposable waste and electronic waste shall be disposed according to hospital regulations and shall not be discarded at will to avoid environmental pollution.
- Avoid using the generator close to or stacked on other equipment. If adjacent or stacked use is necessary, monitor the generator and other equipment to ensure proper operation.
- The device does not contain any operator-serviceable parts. For service, contact your Reach Surgical sales representative or service personnel.
- Check all devices connected to the system and connections prior to use. Validate that the device performs as intended. Improper connection can lead to arcing, sparking, device malfunction, or unintended surgical results.
- To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth.
- Keep as far as possible between the generator and other electronic devices (e.g., monitors). Do not cross or tie electrical wires to electronic devices. The generator may cause interference with other electronic devices.
- Use the system with caution in the presence of internal or external pacemakers or other implanted Devices(IEDs). Interference produced by electrosurgical equipment can cause a pacemaker or other device to enter an unsafe mode or permanently damage the device. Consult the device manufacturer or responsible hospital department for further information when use is planned in patients with implanted

medical devices.

- Use caution if stacking instruments on top of the generator or placing the generator on top of electrical instruments. This is an unstable configuration and does not provide adequate cooling.
- If the generator fails, it may cause surgical interruption. A backup system shall be available.
- If required by local regulations, the generator should be connected to the hospital's equipotential connector using an equipotential cable.
- When the system and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrode shall be placed as far as possible from the instrument.
- In basic bipolar mode, choose the lowest possible output power for the desired effect.
- The failure of high-frequency surgical equipment may cause an unexpected increase in output power.
- The generator and basic bipolar electrosurgical connector may be invaded by water or particulate matter. In the process of use and cleaning, it is necessary to avoid the invasion of water or particulate matter.
- When the system is used in combination with an endoscope, it may increase the leakage current on the patient body. Pay attention during the procedure.
- A notice to the user and/or patient that any serious incident that has occurred in relation to the device sho uld be reported to Reach Surgical, Inc. through Reachquality@reachsurgical.com. and the competent aut hority of the Member State in which the user and/or patient is established.
- To avoid unknown risks ,do not use non-standard accessories to connect to generators.
- OP9 generator and ancillary devices should not be used when the physician believes that high-frequency bipolar or ultrasound surgery may be contrary to the best interests of the patient
- For contraindications when used with high-frequency bipolar devices or ultrasonic tool heads, please refer to the instructions for Use of each device (IFU).

Instrument related

During surgical procedures, it is important to be aware that the end portion of the instrument Ultrasonic Shear, Ultrasonic Shears pad, and shaft may experience elevated temperatures when ultrasound or bipolar electrocautery is applied to tissue for extended periods. To ensure safety, it is crucial to avoid any accidental contact between these instrument components and tissue, surgical drapes, surgical coats, or any unrelated areas throughout the procedure.

Furthermore, it is vital to exercise caution when positioning the bipolar instrument. Specifically, it should not be placed near or in contact with combustible materials such as gauze or surgical drapes. The bipolar instruments used in this context can generate heat during use, which could potentially lead to a fire hazard. When the bipolar electrosurgical generator is not in use, it should be properly stored in the protective sleeve or kept at a safe distance from the patient, surgical team members, and any combustible materials.

NOTE: Please refer to the respective Instructions for Use for additional warnings and precautions.

EMC Information

The product has passed the electromagnetic compatibility test, which meets the limitation requirements of IEC60601-1-2 standard for medical equipment. These restrictions provide reasonable protection against harmful interference in normal medical installations.

Product composition

Serial Number	Part Name	Model/Version No.	Remarks
1	Electrosurgical Instrument	OP9	/
2	Transducer of Ultrasound Surgical Equipment	TRA6	Compatible use
3	Ultrasonic Shear System for Single Use Ultrasonic Shear	Refer to Ultrasonic Shear Model in Chapter 2 List	Compatible use
4	Disposable ultrasonic high-frequency surgery unit Tissue Sealer	Refer to Ultrasonic Shear Model in Chapter 2 List	/
5	Ultrasonic footswitch	OP-FSD	/
6	Electrosurgical footswitch	OP-FSS	/
7	Electrosurgery Bipolar Connector	OP-BPC	/

Note：In addition to the accessories provided by our company, the use of other manufacturer's accessories may result in the degradation of the EMC performance of the ultrasonic high-frequency surgery integrated surgical system

Product cable

Serial Number	Cable Name	Length (m)	Shielded
1	Ultrasonic footswitch Cable	3	No
2	Electrosurgical footswitch Cable	3	No
3	Power cord	5	No
4	Osprey Bipolar Electrosurgical Cable	3	Yes
5	The cable of Transducer	2.9	Yes

EMC performance

This equipment may be subject to radio frequency interference caused by other medical equipment and radio

communications. To prevent such interference, this product has been tested according to IEC 60601-1-2 and meets its requirements. However, Reach Surgical, Inc. does not guarantee that there will be absolutely no interference in individual installation environments.
If it is found that the device is interfered (which can be determined by turning the device on and off), the user (or maintenance personnel approved by Reach Surgical, Inc.) should try to take one or more of the following measures to solve the interference problem:
Adjust the direction or position of the device that affects it.
Increase the distance between this device and the sending device.
Use other power sources (rather than the power used to affect the equipment) to power this equipment.
Consult the supplier or service representative for other suggestions.
The manufacturer is not responsible for any interference caused by the following situations: use other interconnecting cables other than the recommended cables; alter or modify this equipment without permission. Unauthorized changes or modifications may cause the equipment lose efficacy.
All types of electronic equipment may cause electromagnetic interference to other equipment through the air or other cables connected to it. Do not use devices that can emit RF signals, such as cellular phones, radio transceivers, or radio control products, near this device, as this may cause the performance of this device to fail to meet the specified specifications. When such devices are close to this device, turn off the power of these devices. The medical personnel in charge of this equipment should instruct technicians, patients and other personnel who may be close to this equipment to fully comply with the above requirements.
To fully achieve the specified EMC performance, the user should install the product correctly according to the steps described in the manual. If there are any EMC-related problems, please contact the maintenance personnel approved by Reach Surgical, Inc.
The Transducer (with cable) and Ultrasonic Shears are defined as the applied part of the whole system.

Precautions for product installation

The equipment can be used in a hospital environment but does not include radio frequency shielding rooms around active Radio frequency surgical equipment or where magnetic resonance impact equipment is placed, because the electromagnetic disturbance intensity in these locations is high.
Separation distance and impact of fixed radio communication equipment: magnetic field strength generated by fixed transmitters, such as base stations of wireless (cellular/cordless) telephones, land mobile radio receivers, amateur radio receivers, AM and FM radio broadcasts, and TV broadcasts Generators, etc., cannot be accurately measured theoretically. To assess the electromagnetic environment generated by fixed RF transmitters, measurement of the electromagnetic field should be considered. If the measured value of the magnetic field strength at the location of the device exceeds the corresponding radio frequency level specified in the "Anti-Interference Statement", the device should be inspected to ensure that it can operate normally. If abnormal operating conditions are found, additional measurements should be considered, such as reorienting or relocating the equipment, or using an anti-radio frequency room.
1）Use the Power Cord provided or designated by the Reach Surgical, Inc. Products equipped with a power plug should be plugged into a fixed power outlet with protective grounding. Do not use any type of adapter or connector to connect the power plug.
2）Keep this device away from other electronic devices as much as possible.
3）Follow the steps to connect the device.

General notes

(1) The specification of the cable.

The use of cables provided by the Reach Surgical, Inc will not damage the EMC performance of this product.

If unspecified cables are used, the EMC performance of this equipment may be significantly reduced.

(2) Precautions for unauthorized modifications

The user shall not modify this product, otherwise the EMC performance of this product may decrease.

The modification of the product includes the following changes:

a. Cable (length, material, and wiring, etc.).

b. Equipment installation/layout.

c. Equipment configuration/components.

d. Equipment protection parts (cover opening/closing and cover fixing parts).

(3) All protective covers should be closed when operating the equipment.

This product is expected to be used in the electromagnetic environment specified below, and the purchaser and user of this product should ensure that it is used in this electromagnetic environment.

Essential Performance

Ultrasonic Basic performance: None

High-frequency Basic performance:

1. For advanced high-frequency Radio energy output, the system shall ensure that the deviation of rated power output does not exceed 20% of the standard value

2. For basic high-frequency Radio energy output, the system shall ensure that the deviation of rated power output does not exceed 20% of the standard value

Guidance and MANUFACTURER'S declaration - ELECTROMAGNETIC EMISSIONS		
The device is intended for use in the electromagnetic environment specified as follows. The customer or the user of ENER REACH Optimus should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group1	ENER REACH Optimus 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.
RF emissions	Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals
Harmonic current IEC 61000-3-2	Class A	
Voltage changes/Voltage fluctuations/ flicker IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment Specified as follows. The customer or the user of the device 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	± 8 kV contact ± 2,4,8 ,15kV air	± 8 kV contact ± 2,4,8 ,15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, The relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line (s) ± 2 kV line (s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ultrasound surgical Equipment requires continued operation during power mains interruptions, it is recommended that the Ultrasound surgical Equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at level characteristic. Of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
The device aims at application under the electromagnetic environment specified as follows. Customer or user of the device should assure that it is used under such environment			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6 Radiated RF	3 Vrms 150 kHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 3 V/m	 3V 3V/m	Portable and mobile RF communications Equipment should be used no closer to any part of The device , including cables, than recommended separation distance calculated from the equation for frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V1}]\sqrt{P}$ $d = [\frac{3.5}{E1}]\sqrt{P}$ 80MHz to 800MHz $d = [\frac{7}{E1}]\sqrt{P}$ 800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter

IEC 61000-4-3	80 MHz to 2.7 GHz 80 % AM at 1 kHz		manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey.3 should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:  :NCLOSURE PORT of ME EQUIPMENT and ME SYSTEMS shall be tested as specified in Table 9 of IEC 60601-1-2 using the test methods specified in IEC 61000-4-3.

Separation distances recommended between portable and mobile RF communications equipment and the devices.

ENER REACH Optimus aims at application under an electromagnetic environment in which radiated RF disturbances are controlled. Customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The device as recommendation as follows., 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 $d = [\frac{3.5}{V1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E1}]\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.36999	0.36999	0.73681
1	1.17	1.17	2.33
10	3.69986	3.69986	7.36811
100	11.7	11.7	23.3

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Technical Conditions

Components required for system operation: Electrosurgical Instrument, Transducer, Ultrasonic footswitch, Electrosurgical footswitch, Ultrasonic Shear or Electrosurgery Handpieces Electrosurgery Bipolar Connector Bipolar Instrument.

Refer to the product description for this component.

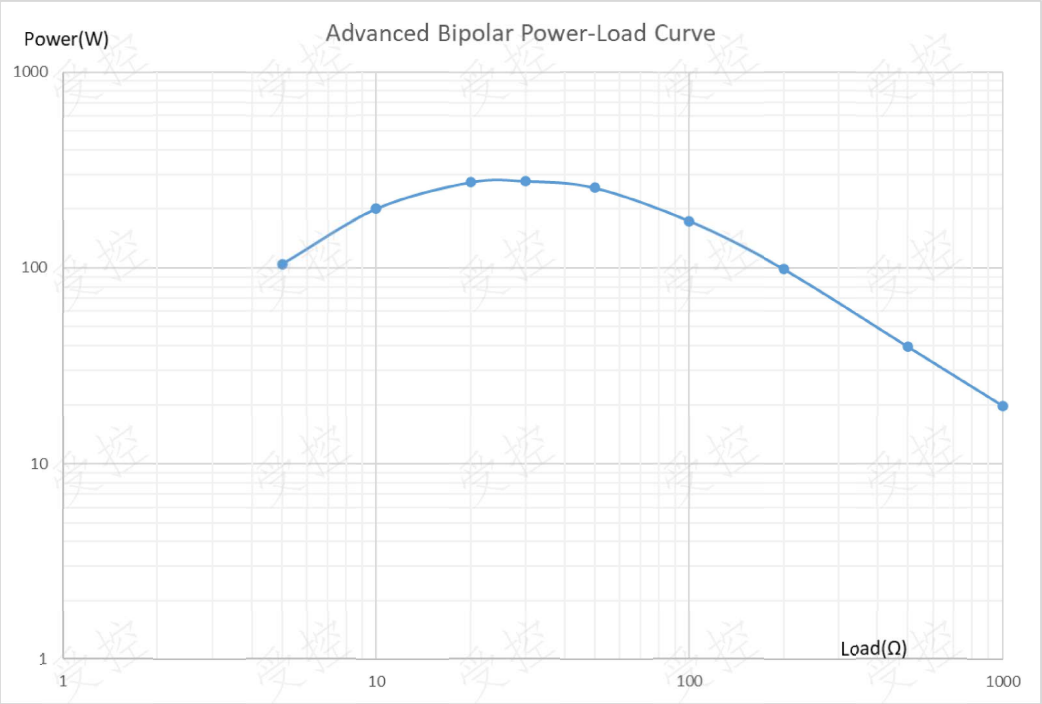
Degree of protection against electric shock	Ultrasound:  Type CF Applied Part; Bipolar Electrosurgical  Defibrillation-proof Type CF Applied Part
Degree of Protection against Electric Shock	Class I
Generator to harmful infusions	Normal equipment
Degree of Protection against Harmful Ingress of Water	Footswitch: IP68
Management Category	Class IIb
Ultrasound Mode Parameter Requirements:	
Input Power	Supply voltage: 100-240V
	Supply frequency: 50Hz/60Hz Input power: 400VA
Ultrasound Mode Parameter Requirements:	
Excitation frequency	54 kHz - 57 kHz
Primary tip vibration excursion	25 μm ~ 110 μm
Ultrasonic Shear tip main acoustic output surface Product:	1.53～2.75 mm2
Secondary Crosslink Acoustic at Ultrasonic Shears Tip Output Area:	19.32～35.88 mm2
Derived Output Sound at Ultrasonic Shear Tip at Reference Tip Primary Amplitude Power	< 30W
Type of system frequency control	Independent of load, the excitation frequency is automatically adjusted continuously.
Power reserve index	Not less than 2.5
Electrosurgical Parameters Requirements:	
Working frequency	400KHz ± 5%
Maximum output voltage	⩽ 250Vpk
Advanced Bipolar mode Maximum output current	⩽ 5.5Arms
Basic bipolar mode Maximum output current	⩽ 2.2Arms
Maximum output peak-to-peak voltage	⩽ 500Vpk

Peak Factor	1.6 ± 0.4
Rated Power	Radio frequency advanced bipolar: 270 W± 20% Radio frequency Basic bipolar: 95W± 20%
Rated load	Radio frequency advanced bipolar: 30Ω Radio frequency Basic bipolar: 200Ω

Operating Environment Conditions	Temperature: 10 ° C to 30 ° C	After generator is moved from a storage environment lower than 10°C or than 40°C to a running environment, stand the generator for one hour before starting it
	Relative humidity: 35%-75%	
	Atmospheric pressure range: 800 hPa to 1060 hPa	
Transportation and Storage Conditions	Temperature: -30 ° C to + 55 ° C (generator, foot switch, adapter) Temperature: -10 ° C to + 55 ° C (Ultrasonic Shear)	
	Humidity: ≤ 80%	
	Atmospheric pressure range: 800 hPa to 1060 hPa	
Date of manufacture	The manufacturing date can be determined by the serial number on the back panel of the generator.	
Power cord	Compliance with CCC certification requirements	
	Current rating: 10A	
Persistence Rate	Determined by transducer handpiece and Ultrasonic Shear used. For Persistence Rate information, refer to applicable Ultrasonic Shears and Transducer Handpiece Instructions or Chapter 7 – Warnings and Precautions.	
Fuse	¢5 * 20 T8AH250V	
Weight (without packaging)	Generator: nominal 8 kg	
Total Volume	OP9 generator: (length * width * height): 34 cm-34 cm-16 cm	
Disposition	Some internal components of generator, foot switch and foot switch cable contain lead. According to local Requirement and regulation for disposal. Dispose of batteries in accordance with appropriate waste disposal practices.	
AP/APG Classification	Not AP/APG equipment.	
Service life:	Service life: 7 years	
Software Release Version	V01.01	

Bipolar output waveform

Advanced bipolar output power-load curve

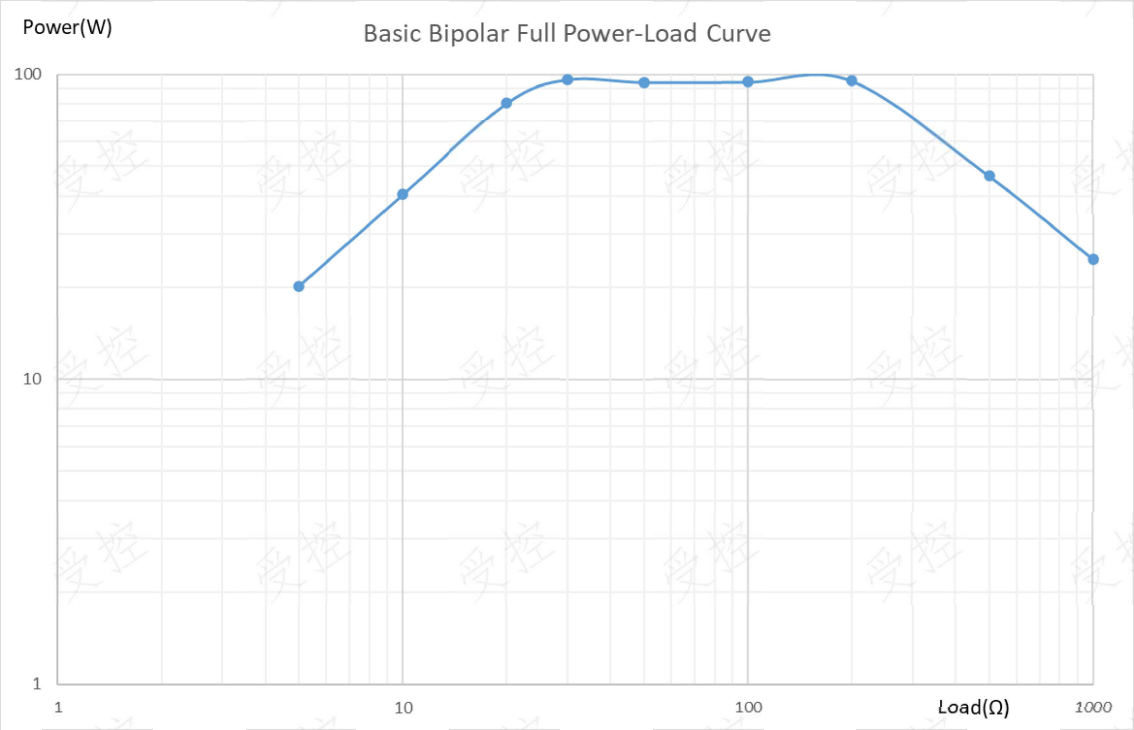


POWER CURVE LIMIT Max Output: 270[W]			
Load (Ω)	Lower Limit	Nominal	Upper Limit
5	83.6	104.5	125.4
10	159.84	199.8	239.76
20	216	270	324
30	216	270	324
50	204.64	255.8	306.96
100	138.72	173.4	208.08
200	78.88	98.6	118.32
500	31.6	39.5	47.4
1000	15.84	19.8	23.76

Nominal power curve of 270 watts output at rated load in accordance with the current/voltage limit of the power curve meter. The power curve represents the envelope that varies under operating condition.

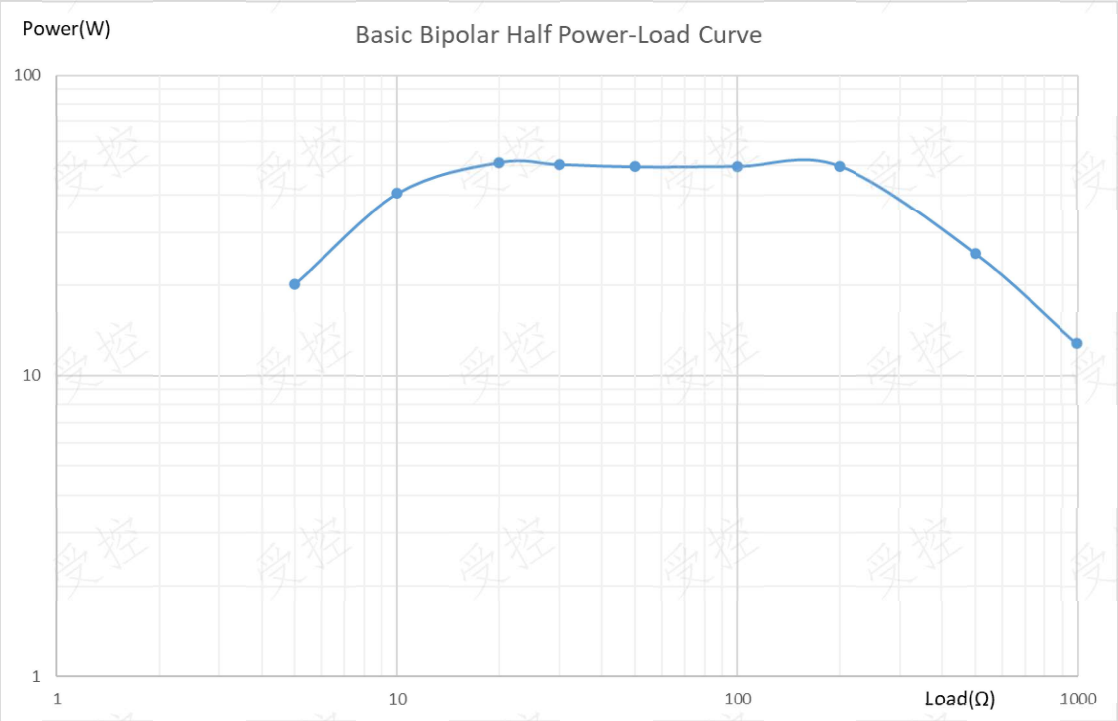
Note: Advanced bipolar output power-load curve was tested in engineering mode of generator.

Basic bipolar output full power-load curve



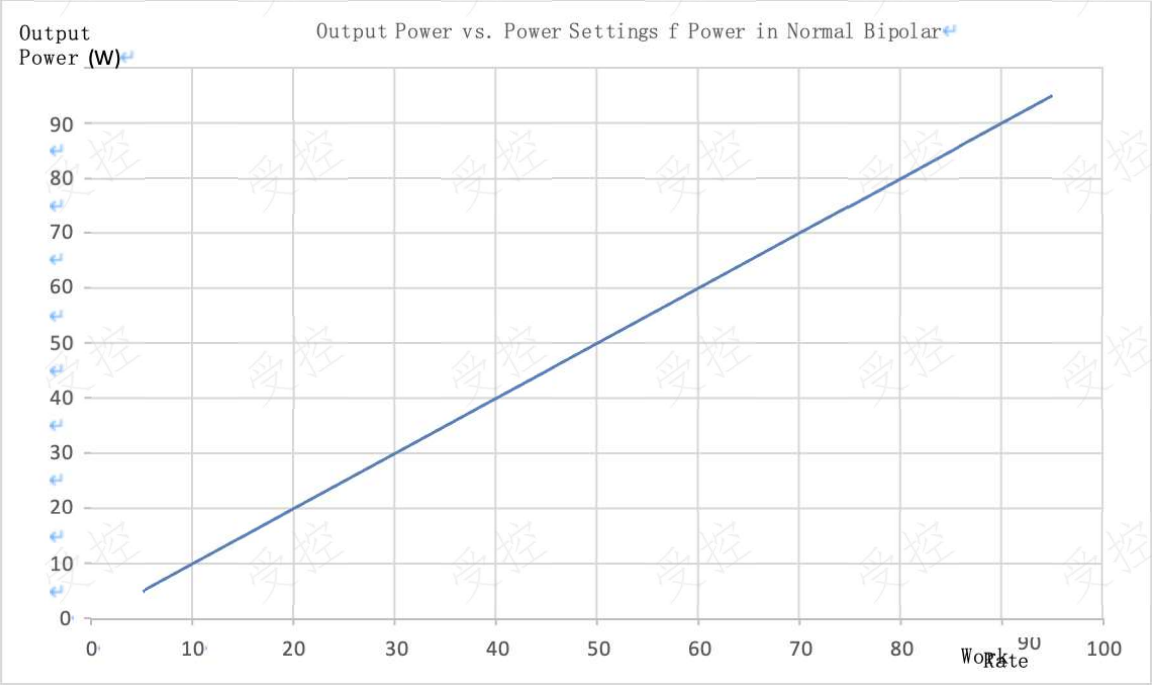
Full Power Curve Limit [W]: Max Power 95 Watts			
Load (Ω)	Lower Limit	Nominal	Upper Limit
5	16.16	20.2	24.24
10	32.32	40.4	48.48
20	64.48	80.6	96.72
30	76	95	114
50	75.52	94.4	113.28
100	75.68	94.6	113.52
200	76	95	114
500	37.12	46.4	55.68
1000	19.76	24.7	29.64

Basic bipolar output half power-load curve



Half Power Curve Limit [W]: Max Power 50 Watts			
Load (Ω)	Lower Limit	Nominal	Upper Limit
5	16.16	20.2	24.24
10	32.32	40.4	48.48
20	40	50	60
30	40	50	60
50	39.68	49.6	59.52
100	39.84	49.8	59.76
200	39.92	49.9	59.88
500	20.48	25.6	30.72
1000	10.24	12.8	15.36

Output Power vs. Power Settings for Power in Normal Bipolar



Output Power vs. Power Set Value for Normal Bipolar [W]; Load: 200Ω			
Set Power (W)	Output Power Lower Limit (W)	Nominal Power (W)	Upper Output Power Limit (W)
5	1	5	10
10	5	10	15
15	10	15	20
20	15	20	25
30	24	30	36
45	36	45	54
60	48	60	72
75	60	75	90
95	76	95	114

Service and Warranty

Reach Surgical, Inc. warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the warranty period specified below. Reach Surgical's obligation under this warranty is limited to repairing or replacing, at its option, any defective product or part that has been returned to Reach Surgical, Inc. or its authorized Distributor within the applicable warranty period and is found to be defective to Reach Surgical's satisfaction. This warranty does not apply to products or parts that have been:

- Adversely affected due to use with unauthorized devices manufactured or distributed by parties not authorized by Reach Surgical, Inc.
- Repaired or altered outside Reach Surgical's factory, if it affects the stability or reliability of the device as determined by Reach Surgical.
- Subjected to improper use, negligence, or accident.
- Used in a manner inconsistent with the design, use parameters, instructions, and guidelines for the product or with industry-accepted functional, operational, or environmental standards for similar products.

Warranty Periods

Basic Bipolar Energy Connector (OP-BPC): 1 year for components and labor.
Generator (OP9): 1 year for components and labor.
Foot Switch/Power cord: 1 year for components and labor.

This warranty is the exclusive remedy for the original purchaser and replaces all other warranties, express or implied, including warranties of merchantability and fitness for a particular purpose. Reach Surgical, Inc. shall not be liable for any special, incidental, or consequential damages, including damages resulting from loss of use, profits, business, or goodwill, except as expressly provided by applicable law.
Reach Surgical, Inc. does not authorize any person to assume any additional liability in connection with the sale or use of its products. There are no warranties that extend beyond the terms stated herein.
Reach Surgical, Inc. reserves the right to make changes to its products without incurring any obligation to retroactively apply those changes to previously sold or built products.