Mara™

Mara™ Water Vapor Ablation System

GEN-16-050 Mara Console
DDK-16-050 Mara Water Vapor Probe Kit

Operator's Manual

Mara Console
(MODEL #GEN-16-050)

CooperSurgical®

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CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN TRAINED IN THE USE OF THE MARA WATER VAPOR ABLATION SYSTEM.

Read all instructions, cautions and warnings prior to use.

For comprehensive procedural instructions, warnings, precautions and potential adverse events for the combined use of the Mara Console and the Mara Water Vapor Probe, please refer to the Mara™ Water Vapor Ablation System *Instructions for Use* (packaged with the Mara Water Vapor Probe Kit).

Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury.

The Mara Water Vapor Probe and Mara Console must be used only in conjunction with each other. Both are to be used only by physicians who have reviewed and understand the Mara Water Vapor Ablation System labeling and training materials.

Contact CooperSurgical, Inc. with any questions about the information contained in the Instructions for Use or in the Mara Console Operator's Manual.

SECTION 1

INTRODUCTION TO MARA WATER VAPOR ABLATION SYSTEM

System Description

The Mara Water Vapor Ablation System consists of: (1) a reusable Mara Console with attached Cartridge and Cartridge Cable, and AC power cord; and (2) the single use Mara Water Vapor Probe Kit that includes a sterile Mara Water Vapor Probe with attached saline delivery conduit, syringe and saline supply line with spiked end.

Mara Console and Water Vapor Probe

The single use Mara Water Vapor Probe has been designed with SmartSeal™ technology to optimize device placement and to protect the cervix and vagina from thermal effects. The soft slender tip of the Water Vapor Probe is inserted transcervically into the uterine cavity. The Water Vapor Probe delivers water vapor to ablate the endometrial lining of the uterus. The water vapor is created within the Water Vapor Probe from saline, using energy provided by the Console.

The Mara Water Vapor Ablation System has been designed with the IntegrityPro™ safety feature which utilizes SmartSeal technology designed to ensure that the Water Vapor Probe tip is correctly placed in the uterine cavity and that there are no leaks from the uterine cavity or cervix through which water vapor could escape. The IntegrityPro safety feature is comprised of a Uterine Cavity Integrity Test and a Device Lumen Patency Test. Both tests are performed with normal saline (0.9% NaCl) after placement of the

Water Vapor Probe and prior to water vapor delivery. The Uterine Cavity Integrity Test is designed to assess for leaks in the uterus or in the cervical canal through which water vapor could escape. The Device Lumen Patency Test is performed directly following a successful Uterine Cavity Integrity Test. The Device Lumen Patency test is designed to confirm the Water Vapor Probe tip is positioned appropriately and that the Water Vapor Probe delivery lumen is not blocked by blood or tissue that could have impacted the saline flow rate and results of the Integrity Test. Water vapor delivery is initiated only after both tests pass consecutively.

Water vapor is delivered to the uterus for 140 seconds, with a treatment time of 120 seconds. The first 20 seconds of water vapor delivery serve to displace saline remaining in the uterus and device lines after the Device Lumen Patency Test. These 20 seconds are referred to as the "saline flush." Intrauterine water vapor pressure is regulated by the Mara Console, based on feedback from a pressure sensor near the distal tip of the Water Vapor Probe. The patient's uterus will be exposed to a temperature of 101°C (nominal) during water vapor delivery.

During treatment, SmartSeal provides automated real-time monitoring of sealing balloon pressure, uterine pressure and cervical temperature, with active management of uterine and cervical seals, designed to ensure that water vapor delivery is confined to the uterine cavity or terminated if a leak is detected.

The Console is designed to:

- Guide the physician through the procedure by use of a graphical user interface (GUI)
- Regulate the creation of water vapor in the Water Vapor Probe
- Test the Water Vapor Probe upon connection and preparation for use
- Perform an automated Uterine Cavity Integrity Test designed to assess for leaks from the uterine cavity before the Device Lumen Patency Test and delivery of water vapor can be initiated
- Perform an automated Device Lumen Patency Test designed to confirm the Water Vapor Probe tip is positioned appropriately and that the Water Vapor Probe delivery lumen is not blocked by blood or tissue that could have impacted the saline flow rate and results of the Integrity Test

- Utilize the same settings for delivery of water vapor to each patient, including time and intrauterine water vapor pressure
- Maintain a nominal intrauterine pressure during water vapor treatment
- Constantly monitor for potential alert conditions and automatically stop delivery of water vapor to the endometrial cavity accordingly.

The Console monitors the following:

- The elapsed water vapor delivery time
- Cervical temperature
- The intrauterine water vapor pressure
- Internal states and conditions including the triple balloon system through a variety of checks that are performed throughout the process that are designed for safety of the patient and user as well as proper performance

Indication for Use

The Mara Water Vapor Ablation System is indicated to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

Contraindications

The Mara Water Vapor Ablation System is contraindicated for use in:

- A patient who is pregnant or who wants to become pregnant in the future

  PREGNANCIES FOLLOWING ABLATION CAN BE DANGEROUS FOR BOTH MOTHER AND FETUS

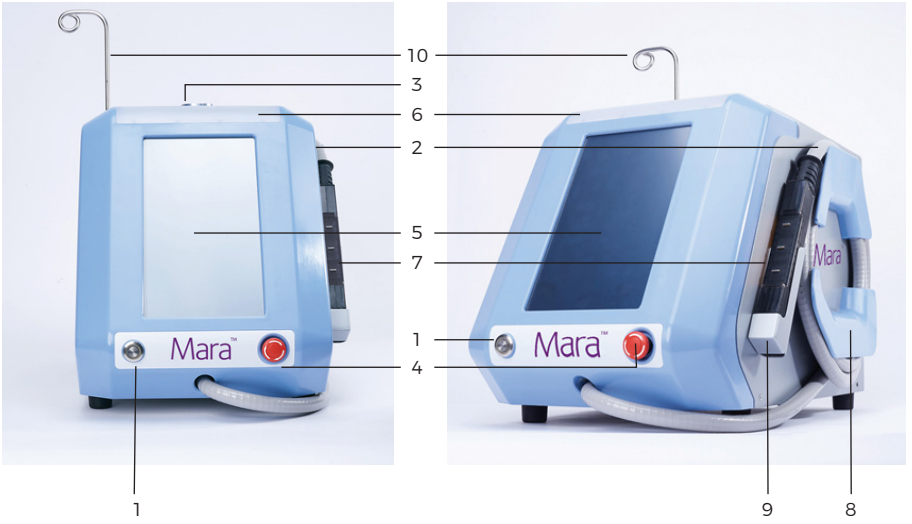
- A patient with known or suspected uterine cancer or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia
- A patient with endometrial hyperplasia as confirmed by histology
- A patient with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy, including hysteroscopic and/or laparoscopic myomectomy performed immediately prior to the Mara Water Vapor Ablation Treatment)
- A patient currently on medications that could thin the myometrial muscle, such as long-term steroid use (except for inhaler or nasal therapy for asthma)
- A patient with a uterine length < 6cm (external cervical ostium to internal fundus)
- A patient with a history of a prior completed endometrial ablation procedure and/or endometrial resection (including endometrial ablation/resection performed immediately prior to the Mara Water Vapor Ablation Treatment) regardless of the modality by which it was performed

  REPEAT ABLATION MAY RESULT IN SERIOUS PATIENT INJURY

- A patient with active genital or urinary tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis or cystitis) at the time of treatment
- A patient with bacteremia, sepsis or systemic infection
- A patient with an intrauterine device (IUD) currently in place
- A patient with active pelvic inflammatory disease or known or suspected hydrosalpinx based on history or ultrasound at screening
- A patient with undiagnosed vaginal bleeding

SECTION 2

CONTROLS, INDICATORS AND RECEPTACLES



1. Front Panel Power Button
2. Cartridge Cable
3. Syringe Port
4. Interrupt Button
5. Graphical User Interface (GUI) Display
6. Warning Light
7. Cartridge (see below for detailed view)
8. Cable Storage Location
9. Cradle
10. Saline Supply Hook

10. Saline Supply Hook
11. Power Cord Receptacle
12. Service Door (service only)
13. Circuit Breaker Reset Switch
14. Saline Supply Pole Release Lever
15. Equipotential Stud

Cartridge Detailed View

SECTION 3
PREPARING THE CONSOLE FOR USE

Carefully read and understand all instructions, cautions and warnings prior to use. Carefully read and understand the Instructions For Use, Mara Water Vapor Ablation System prior to use. Failure to follow any instructions or failure to heed any warnings or precautions could result in serious patient injury.

Clinical Use Checklist

Prior to use of the Mara Water Vapor Ablation System on a patient, the physician should complete the following checklist to better ensure a safe and effective use of the system. Note that this is not a comprehensive list, but an attempt to cover some of the key issues before a physician uses the Mara Water Vapor Ablation System.

The physician must:

- Along with ancillary personnel, thoroughly read and understand the Instructions For Use, Mara Console Operators Manual, Indications, Contraindications, Warnings, Technical Warnings and Precautions supplied with the Mara Water Vapor Ablation System
- Be able to maintain proper placement of the Water Vapor Probe and be able to maintain control of the Water Vapor Probe throughout the procedure
- Neither advance nor withdraw the Water Vapor Probe into or out of the uterine cavity once the Uterine Cavity Integrity Test and Device Lumen Patency Test have successfully completed and water vapor delivery is initiated, until prompted to remove the Water Vapor Probe from the patient
- Be aware of appropriate sequence of actions to stop water vapor delivery, resolve and/or continue treatment, in the event the Mara Water Vapor Ablation System stops water vapor delivery during treatment

General Warnings

Refer to the Mara Water Vapor Ablation System IFU for additional Warnings.

The Console is not packaged as sterile.

The Console may contain materials that are hazardous to the environment. Do not dispose. Contact CooperSurgical, Inc. for further information.

Equipment and Accessory Requirements

The following items are required when using the Mara Water Vapor Ablation System:

- One sterile, single-use Mara Water Vapor Probe Kit (includes a sterile Mara Water Vapor Probe with attached saline delivery conduit, syringe and saline supply line with spiked end)
- One Mara Console (with attached Cartridge and Cartridge Cable, and AC power cord)

For proper operation of the system, the following hospital supplies are also required:

- 1L bag of 0.9% normal saline. It is recommended that Normal Saline should be supplied at body temperature
- Patient fluid / waste collection container
- Uterine sound
- 10 inch tenaculum, straight-arm with ratchet
- Speculum

Quick Setup Instructions

If you are familiar with the Mara Console, you may prefer to follow these abbreviated instructions. Otherwise, use the detailed instructions that begin on the next page. All warnings and precautions from the detailed instructions need to be followed.

1. Attach the power cord from the Console's rear panel receptacle to a grounded wall receptacle
2. Press the Front Panel Power Button to turn on the Console. Verify that the initial Console self-test successfully completes and that there are no alerts displayed
3. Enter the device-specific password to continue
4. Firmly insert and rotate the Syringe clockwise to engage it in the Syringe Port in the top of the Console
5. Spike the saline bag with the Saline Supply line
6. Attach the Cartridge to the Water Vapor Probe Handle.
   Tip: Momentarily press the Cartridge Release Button at the base of the Water Vapor Probe to facilitate insertion
7. Follow the on-screen prompts to test the Water Vapor Probe

The system is ready for use. Follow the instructions in the Mara Water Vapor Ablation System Instructions for Use and on the Console display.

Proceed to Section 4 after the procedure.

Setup Instructions

- If the Console was transported or stored at temperatures outside the Transport and Storage ambient temperature range, allow at least one hour for the Console to reach room temperature before use. Refer to Appendix A for more information.
- If the Console was stored without use for longer than one year, the Console should be tested and calibrated before use.

Setting up the Mara Console for the first time:

1. Unbox the Console. Place the Console on a sturdy cart or table with a stable flat surface to the left or right side of the user. The front panel should be facing the user such that there is an unobstructed view of the touchscreen.
2. With the Console on a cart or table, ensure there are at least four to six inches of space from the sides and top of the Console to ensure proper airflow for cooling. It is normal for the outer surfaces of the Console to be warm when in use.

⚠ **Precaution:** The Console should not be stacked or used adjacent to other electrical equipment. Do not stack equipment to block the vents on the bottom or sides of the Console. If stacked or adjacent use is necessary, the Console should be observed to verify normal operation.

⚠ **Precaution:** Provide as much distance as possible between the Console and other electrical equipment to prevent interference. Portable and mobile RF communications equipment can affect the Console.

⚠ **Warning:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Mara Water Vapor Ablation System, including cables specified by CooperSurgical, Inc. Otherwise, degradation of the performance of this equipment could result.

3. Attach the power cord provided with the Console to the Console's rear panel receptacle.

⚠ **Precaution:** Console requires hospital grade power supply 110 to 120 V, 60 Hz with a minimum of 15 amp service. Hospital grade receptacles may be marked with a green dot, or wording such as “Hospital Grade” or “Hosp. Grade.” Consult your institution’s biomedical department if unsure.

⚠ **Warning:** The use of accessories, transducers and cables, other than those specified by CooperSurgical, Inc., may result in increased emissions or decreased immunity of the Console. Do not use accessories, transducers and cables other than those specified.

4. Insert the power cord to a grounded wall receptacle.

⚠ **Warning:** Connect the Console power cord to a properly grounded receptacle. Do not use power plug adapters. Do not use extension cords.

⚠ **Warning:** Ensure that the Console is connected to a reliable power source. Unreliable or inconsistent power may cause power loss to the Console resulting in an interruption of the procedure.

⚠ **Warning:** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠ **Precaution:** A temporary circuit overload can cause the internal circuit breaker to trip. If this were to occur, the power should be turned off, the Circuit Breaker reset switch should be pressed back in, and then the unit can be powered back on.

5. Verify that the red Interrupt Button on the front panel is not engaged (twist to disengage).

6. Press the Front Panel Power Button to turn on the Console, and verify the following:

   a. The blue light on the power button illuminates when the power is on

   b. The light above the display temporarily illuminates

   c. The display turns on and temporarily flashes a CooperSurgical, Inc. logo **(image 1)**

   d. An activation tone sounds indicating the speaker is functional

   e. The Console self-test (power on self-test) successfully completes (a status bar will show progression of the power on self-test)

Image 1

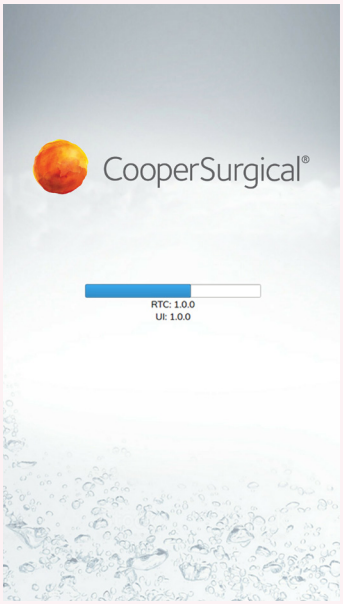
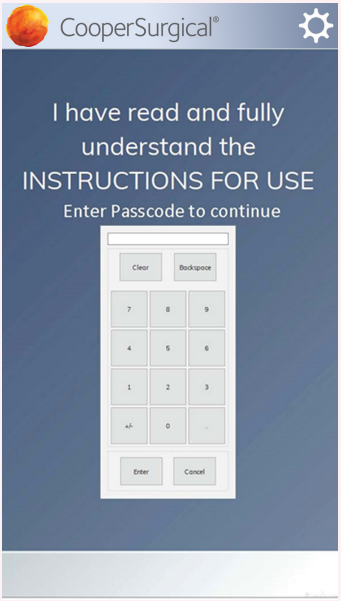


Image 2



Note: If the self-test is unsuccessful, an alarm tone will sound and an alert number will appear on the display. The Console will be disabled and will require the power to be turned OFF. Refer to the Troubleshooting Guide in Section 5 for more information about alert numbers.

f. The display transitions to the "IFU" screen at the completion of the power on self-test. Refer to #8 on the next page.

Note: The display allows adjustment of the speaker volume. Press the "gear" symbol and select volume, if desired.

Note: The Graphical User Interface Display will provide instructions and guidance to assist with performance of the procedure. It is also a touch screen to allow the user to respond to prompts and to control the procedure.

Note: There is a Warning Light above the display that will illuminate to indicate different status conditions, as follows:

- Orange (flashing) – Fault. Turn off the Console.
- Yellow (solid) – Alert (Alarm Condition). Follow instructions and continue the procedure.

- Orange (solid) – Alert (Information Signals). Clear the message and continue the procedure.
- Off (default)
- Green – Ready for Treatment
- Blue – Water Vapor Treatment

7. Enter the device-specific passcode to continue (image 2).

8. Prepare the Water Vapor Probe following standard aseptic procedures to maintain sterility of the Water Vapor Probe, while passing the Syringe with attached tubing out of the sterile field for connection to the Console.

⚠ **Warning**: Aseptic technique – Use aseptic technique in all patient-procedures.

9. Firmly insert and rotate the Syringe clockwise to engage it in the Syringe Port on the top of the Console **(images 3 and 4)**. Syringe will illuminate green to indicate proper insertion.

10. Spike the saline bag with the Saline Supply line. Ensure the pole for the Saline Bag is locked in the upright position, and hang the Saline Bag on the Saline Supply Hook **(image 5).**

Image 3

Image 4

Image 5

Image 6

Image 7

11. Firmly insert the Console's Cartridge to the Water Vapor Probe handle **(image 6). Tip**: Momentarily press the Cartridge Release Button at the base of the Water Vapor Probe handle to facilitate insertion.

    Note: Screen will automatically advance when Cartridge is connected properly.

12. Pull down on the Blue Tab at the base of the Water Vapor Probe Handle to pull the Sterile Sheath over the Cartridge Cable **(image 7)**.

13. Press green arrow on the Console display to begin the Water Vapor Probe Test and prepare it for use. The Console screen will indicate that the test is in progress and then will indicate that the test passed **(images 8 and 9)**.

If the Water Vapor Probe test is unsuccessful, the Console will indicate an alert code.

⚠ **Warning**: During the Water Vapor Probe test, the three balloons on the shaft of the Water Vapor Probe will inflate. Visually confirm the inflation of all three balloons. If one of the balloons does not inflate, do not proceed. Press the red Treatment Interrupt Button to disconnect and replace the Water Vapor Probe.

In addition to the balloon inflation test, the Console will test the intrauterine pressure sensor and the saline flow system.

⚠ **Warning**: During the Water Vapor Probe test, the tip cover, distal tip of the Vapor Probe and Water Vapor Probe Outflow Tube may become warm to the touch. Avoid prolonged contact with personnel or the patient.

Image 8

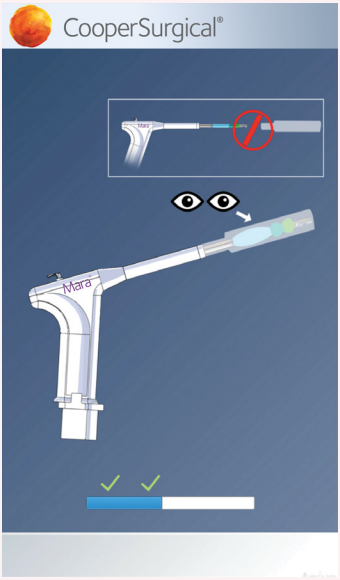


Image 9

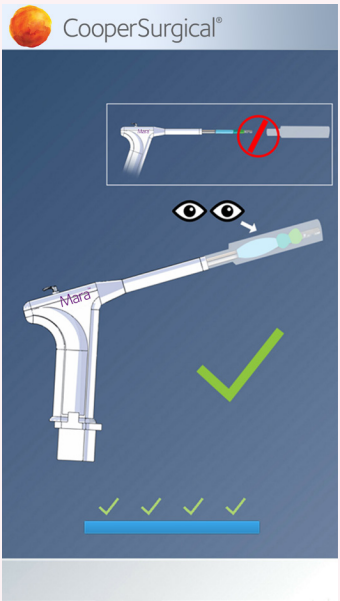
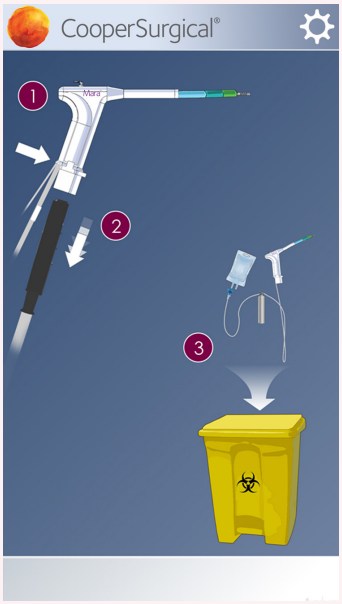


Image 10



SECTION 4

AFTER THE PROCEDURE

Powering Off and Storing the Console:

1. Disconnect the Water Vapor Probe handle from the Cartridge and disconnect the Syringe from the Syringe Port. Dispose per your institution's guidelines **(image 10)**.
2. Wrap the Cartridge Cable around the storage features on the side of the Console and insert the Cartridge into the Cradle **(image 10)**.
3. Unlock and lower the pole for the saline bag **(image 10)**.
4. Press the Front Panel Power Button on front of Console to turn the unit off.
5. Disconnect the power cord from the back of the Console. Store the power cord with the Console.

SECTION 5
TROUBLESHOOTING

The following is a list of common malfunctions, alarms and alert codes.

Note: As indicated with # in the table below, please follow these instructions when removal of the Water Vapor Probe is indicated: To remove the Water Vapor Probe, press the red Treatment Interrupt Button, twist to release, choose either "Clear" or "Quit," and then disconnect the Water Vapor Probe. If the issue persists with multiple Water Vapor Probes, turn off the Console and contact a CooperSurgical, Inc, representative.

Note: If an error(s) continuously occurs while a Water Vapor Probe is connected to the Console, turn off the Console's power and disconnect the Water Vapor Probe. Power on the Console and continue using a new Water Vapor Probe.

For service contact information, refer to back of Operator's Manual.

Malfunctions

Should the Console malfunction, return to CooperSurgical, Inc. for service. Do not attempt to repair or service if troubleshooting is ineffective.

Table 1: Troubleshooting

Situation	Possible Cause	Solution
Console does not respond when turned on	1. Disconnected power cord, faulty wall outlet or faulty power cord 2. Internal circuit breaker switch tripped 3. Internal component malfunction	1. Check power cord connections at wall outlet and Console. Connect power cord to a functional outlet. Replace power cord. 2. Press the rear panel Circuit Breaker Reset switch to reset 3. Contact your institution's biomedical department or contact a CooperSurgical, Inc. representative
Console is on, but does not complete Power On Self-Test	1. Software malfunction 2. Internal component malfunction	1. Turn Console OFF and then back ON 2. Turn off the unit, contact your institution's biomedical department or contact a CooperSurgical, Inc. representative
Console is on but does not deliver output	1. Water Vapor Probe defective or not ready 2. Interrupt Button on front panel is engaged 3. Internal component malfunction	1. Follow on-screen prompts for guidance. Check the Water Vapor Probe connections with the Cartridge. Replace Water Vapor Probe if necessary (refer to Table 3 for steps to disconnect and replace the Water Vapor Probe). 2. Twist the Interrupt Button to disengage 3. Turn off the unit. Contact your institution's biomedical department or contact a CooperSurgical, Inc. representative.

Situation	Possible Cause	Solution
Console does not advance to the next screen after inputting passcode	1. User entered wrong passcode 2. Console not recognizing correct passcode	1. Contact a CooperSurgical, Inc. representative for the correct passcode 2. Ensure the Interrupt Button is not engaged. Turn Console OFF, then back ON, and try again. If still unsuccessful, contact a CooperSurgical, Inc. representative – the Console may need to be serviced or replaced.
Display exhibits interference or is unreadable	1. Faulty power connections 2. Internal component malfunction	1. Check the power cord for damage. Check the power outlets for defective grounds. 2. Turn off the unit. Contact your institution's biomedical department or contact a CooperSurgical, Inc. representative.
Water Vapor Probe is in the patient and there is no power on the Console	Disconnected power cord, faulty wall outlet, faulty power cord, or interruption of facility power	Wait 10 seconds for water vapor to dissipate from the uterus. Disconnect the Cartridge from the Water Vapor Probe to deflate the Water Vapor Probe's balloons. After 5 seconds, remove the Water Vapor Probe from the patient. When facility power is restored, the Console will automatically start. Alerts may appear – if so, ensure the Water Vapor Probe is disconnected and then cycle power.
Water Vapor Probe is in the patient and a Fault condition requires turning the Console off	Malfunction	Wait 10 seconds for water vapor to dissipate from the uterus. Disconnect the Cartridge from the Water Vapor Probe to deflate the Water Vapor Probe's balloons. After 5 seconds, remove the Water Vapor Probe from the patient.

Situation	Possible Cause	Solution
Warning light is on (flashing orange or flashing orange/white) with either no instructions or the display is off	Malfunction	Turn off the Console. Contact your institution's biomedical department or contact a CooperSurgical, Inc. representative.
Display is off and the Warning light is off, but the Front Panel Power Button is illuminated	Malfunction	Turn off the Console. Contact your institution's biomedical department or contact a CooperSurgical, Inc. representative.
Cartridge is submerged in fluid	Use error	Remove the Cartridge from the fluid and shake excess fluids off. Repeat with the Cartridge inverted. Do not operate until Cartridge is fully dry
Water Vapor Probe internal balloon inflates outside of the uterus during Insertion	Touchscreen error	Do not insert with the internal balloon inflated. Press the back arrow to deflate the Internal balloon and start the insertion process again.

Alarms/Alert Codes

The Console provides alerts to inform the user of Alarm Conditions and additional Information Signals. Table 2 and Table 4 list all alerts. Alert Codes 101-199 are Information Signals, while Alert Codes 201-299 are Low Priority Alarms. For Alarm conditions, the system has determined that operator awareness or response may be required. Alarms will be accompanied by a double-beep tone and solid yellow light. Information signals will be accompanied by a single beep tone and solid orange light. The Alert system is not user adjustable, nor does it require user testing to function.

Note: The Alarm tones may stutter during certain alarm circumstances. This is normal for the Console and does not indicate a malfunction of the alarm hardware.

Table 2: Alert Codes 101-299

Alert Code/Name		Description/Action
101	**Cervical Temperature High**	The Console has detected a high reading on the Cervical thermocouple, indicating that the Water Vapor Probe may be defective. • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
102	**Cervical Temperature Sensor Failure**	The Console has detected that the Water Vapor Probe is defective (thermocouple issue) because the temperature reading is too low. • Depending upon the stage of the procedure, the Console may not allow the procedure to continue until the Water Vapor Probe is replaced • Ensure that the Water Vapor Probe is not touching other equipment • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
110	**Syringe Attached Too Early**	The Console has detected that the Syringe is attached before the appropriate step. • Please remove the Syringe to allow the Self-Test to proceed
116	**Pressure Sensor Not Zero**	The Console has detected an issue with initializing the Water Vapor Probe's Pressure Sensor. • Check that the Water Vapor Probe tip is not pressed against a surface • Check that the Protective Tip Cover is properly installed on the Water Vapor Probe. • Check that the Cartridge Cable is not impinged or pressed against any objects • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge

Alert Code/Name		Description/Action
117	**Pressure Sensor Calibration Issue**	The Console has detected that the Water Vapor Probe Pressure Sensor calibration is not within expected range. • Check that the Protective Tip Cover is properly installed on the Water Vapor Probe • Check the Cartridge connection to the Water Vapor Probe • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
118	**Saline Priming Issue**	The Console has detected that saline is not flowing as expected. • Check that the Vapor Probe tubing is connected to the saline source • Ensure that the tubing is not kinked or pinched
119	**Saline Priming Issue**	The Console has detected that saline is not flowing as expected. • Check that the Vapor Probe tubing is connected to the saline source • Ensure that the tubing is not kinked or pinched
120	**Saline Priming Issue**	The Console has detected a problem with the saline priming process. • Check that the Protective Tip Cover is properly installed on the Water Vapor Probe • Ensure that the tubing is not kinked or pinched • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge

Alert Code/Name		Description/Action
123	**Pressure Test Initialization Issue**	The Console has detected that the Water Vapor Probe Pressure Sensor calibration cannot be confirmed. • Check that the Protective Tip Cover is properly installed on the Water Vapor Probe • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
127	**Pressure Sensor Connection Issue (Optical)**	The Console has detected that the Water Vapor Probe is defective or not fully connected. • Check that the Cartridge is firmly inserted • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
128	**Pressure Sensor Connection Issue (Memory)**	The Console has detected that the Water Vapor Probe is defective or not fully connected. • Check that the Cartridge is firmly inserted • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
129	**Water Vapor Probe Disconnected (Pressure)**	The Console has detected the disconnection of the Water Vapor Probe pressure sensor. • Depending upon the stage of the procedure, the Console may not allow the procedure to continue until the Water Vapor Probe is replaced • Check that the Cartridge is firmly attached to the Water Vapor Probe • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge

Alert Code/Name		Description/Action
130	**Syringe Disconnected**	The Console has detected that the Syringe was unexpectedly released/disconnected. • Reinstall the syringe to resume treatment workflow • Depending upon the stage of the procedure, the Console may not allow the procedure to continue until the Water Vapor Probe is replaced
140	**External Balloon Inflation Too Slow**	The Console has detected a problem with balloon inflation (external). The balloon is taking too long to fill. • Ensure that the Cartridge Cable is not kinked or pinched • Ensure that the Cartridge is firmly connected to the Water Vapor Probe and is not leaking • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
141	**External Balloon Leak**	The Console has detected a problem with balloon inflation (external). • Ensure that the Cartridge Cable is not kinked or pinched • Check for balloon inflation during pre-procedure test • Ensure that the Cartridge is firmly connected to the Water Vapor Probe and is not leaking • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
142	**Middle Balloon Leak**	The Console has detected a problem with balloon inflation (middle). • Ensure that the Cartridge Cable is not kinked or pinched • Check for balloon inflation during pre-procedure test • Ensure that the Cartridge is firmly connected to the Water Vapor Probe and is not leaking • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge

Alert Code/Name		Description/Action
143	**Internal Balloon Leak**	The Console has detected a problem with balloon inflation (internal). • Ensure that the Cartridge Cable is not kinked or pinched • Check for balloon inflation during pre-procedure test • Ensure that the Cartridge is firmly connected to the Water Vapor Probe and is not leaking • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
144	**Air Reservoir Pump Overactive**	The Console has detected a problem with the balloon inflation system – the air reservoir pump is overactive. • Ensure that the Cartridge Cable of the Water Vapor Probe is not kinked or pinched • Ensure that the Cartridge is firmly connected to the Water Vapor Probe and is not leaking • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative
145	**External Balloon Not Deflating**	The Console has detected a problem with external balloon deflation. • Ensure that the Cartridge Cable of the Water Vapor Probe is not kinked, twisted or pinched • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge • Note: If the Water Vapor Probe is within the cervix, disconnect the Cartridge from the Water Vapor Probe Handle before removing the Water Vapor Probe from the patient • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative

Alert Code/Name		Description/Action
146	**Air Reservoir Pressure Low**	The Console has detected a problem with the balloon inflation system (low pressure issue). • Ensure that the Cartridge Cable of the Water Vapor Probe is not kinked or pinched • Ensure that the Cartridge is firmly connected to the Water Vapor Probe and is not leaking • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative
147	**Air Reservoir Pressure High**	The Console has detected a problem with the balloon inflation system (high pressure issue). • Ensure that the Cartridge Cable of the Water Vapor Probe is not kinked, twisted, or pinched • Ensure that the Cartridge is firmly connected to the Water Vapor Probe • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative
148	**Balloon Test Failure**	The Console has detected that the Water Vapor Probe has failed the balloon test. • Check that the Protective Tip Cover is attached to the Water Vapor Probe • Check the Cartridge connection to the Water Vapor Probe • Ensure that the Cartridge Cable of the Water Vapor Probe is not kinked, twisted or pinched • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge

Alert Code/Name		Description/Action
149	**Balloon Test Failure**	The Console has detected that the Water Vapor Probe has a failed balloon. • The Console may not allow the procedure to continue until the Water Vapor Probe is replaced • Check that the Protective Tip Cover is attached to the Water Vapor Probe • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
150	**Middle Balloon Not Deflating**	The Console has detected a problem with middle balloon deflation. • Ensure that the Cartridge Cable of the Water Vapor Probe is not kinked, twisted or pinched • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge • **Note**: If the Water Vapor Probe is within the cervix, disconnect the Cartridge from the Water Vapor Probe before removing the Water Vapor Probe from the patient • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative
151	**Internal Balloon Not Deflating**	The Console has detected a problem with internal balloon deflation. The internal balloon is not deflating. • Ensure that the Cartridge Cable of the Water Vapor Probe is not kinked, twisted or pinched • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge • **Note**: If the Water Vapor Probe is within the cervix, disconnect the Cartridge from the Water Vapor Probe before removing the Water Vapor Probe from the patient • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative

Alert Code/Name		Description/Action
152	**Middle Balloon Inflation Too Slow**	The Console has detected a problem with the middle balloon inflation. The middle balloon is taking too long to fill. • Ensure that the Cartridge Cable is not kinked, twisted or pinched • Ensure that the Cartridge is firmly connected to the Water Vapor Probe and not leaking • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
153	**Internal Balloon Inflation Too Slow**	The Console has detected a problem with the internal balloon inflation. The internal balloon is taking too long to fill. • Ensure that the Cartridge Cable is not kinked, twisted or pinched • Ensure that the Cartridge is firmly connected to the Water Vapor Probe • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
154	**Pressure Sensor Ambient Failure**	The Console has detected a problem with the intra-uterine Pressure Sensor in the Water Vapor Probe. The Pressure Sensor may be damaged. • Ensure that the Cartridge is firmly connected to the Water Vapor Probe • Press “Clear” and allow the Console to re-evaluate the Pressure Sensor system • If the Console was stored in a hot or cold area, allow the unit to stabilize to the room temperature environment • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge

Alert Code/Name		Description/Action
156	**Cartridge Leak Test Failure**	The Console has detected a pneumatic leak during the Cartridge leak test. • Inspect the Cartridge and Cartridge Cable for leaks during the next self-test • Check that the Cartridge Cable connection to the Console is not damaged • Ensure that the Cartridge Cable is not kinked, twisted or pinched • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative
158	**Pressure Sensor Diagnostic Failure**	The Console has detected a problem with the intra-uterine Pressure Sensor in the Water Vapor Probe. The Pressure Sensor may be damaged. • Ensure that the Cartridge is firmly connected to the Water Vapor Probe • Press “Clear” and allow the Console to re-evaluate the Pressure Sensor system • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
159	**Cartridge Under Temperature**	The Console has detected that the cartridge temperature is too low. • If the Console was stored in a cold area, allow the unit to stabilize to the room temperature environment • If this issue persists, contact a CooperSurgical, Inc. representative
160	**Cartridge Over Temperature**	The Console has detected that the cartridge temperature is too high. • Disconnect the Cartridge and allow it to cool down before proceeding • If the Console was stored in a hot area, allow the unit to stabilize to the room temperature environment • If this issue persists, contact a CooperSurgical, Inc. representative

Alert Code/Name		Description/Action
164	**Syringe Empty**	The Console has detected that the Syringe is empty. • The Console should automatically refill the syringe and allow the procedure to continue • Check that the syringe is installed correctly • Check that the IV bag is connected and that the tubing is not kinked • If this issue persists, contact a CooperSurgical, Inc. representative
165	**Pressure Sensor Calibration Not Complete (Thermal Factor Failure)**	The Console has detected a problem with the Pressure Sensor calibration. • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
166	**Pressure Sensor Calibration Outside of Expected Range (Thermal Factor Failure)**	The Console has detected a problem with the Pressure Sensor calibration. • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
168	**Flow Sensor Connection Issue**	The Console has detected that the Water Vapor Probe is defective or not fully connected. • Check that the Cartridge is firmly inserted • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
170	**RF Power Failure**	The Console has detected that the RF Power supply was not within acceptable range. • Retry operation or power-cycle Console • If the issue persists, consider replacing the Console. Contact a CooperSurgical, Inc. representative.

Alert Code/Name		Description/Action
171	**RF Power Failure**	The Console has detected that the RF Power supply has failed. • Retry operation or power-cycle Console • If the issue persists, consider replacing the Console. Contact a CooperSurgical, Inc. representative.
176	**Hypotube (Heating Coil) Heating Failure**	The Console has detected a Hypotube Heating failure. The heating element is not functioning properly. • Check the connection of the Water Vapor Probe to the Cartridge • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
179	**Heating Coil Impedance Error**	The Console has detected a Heating Coil Impedance Error. The heating element is not functioning or is not connected well. • Check the connection of the Water Vapor Probe to the Cartridge • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
180	**Hypotube Temperature Sensor Failure**	The Console has detected a Hypotube Temperature Sensor failure. The Water Vapor Probe is defective or not fully connected. • Check the connection of the Water Vapor Probe to the Cartridge • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
181	**Wire Temperature Sensor Failure**	The Console has detected a Wire Temperature Sensor failure. The Water Vapor Probe is defective or not fully connected. • Check the connection of the Water Vapor Probe to the Cartridge • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge

Alert Code/Name		Description/Action
184	**Cervical Temperature Sensor Failure**	The Console has detected a Cervical Temperature Sensor Failure. The Water Vapor Probe's temperature sensor has failed. • Check the connection of the Water Vapor Probe to the Cartridge • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
185	**Temperature Sensor Connection Issue**	The Console has detected multiple Temperature Sensor failures. The Water Vapor Probe is defective or not fully connected. • Check the connection of the Water Vapor Probe to the Cartridge • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
186	**Vapor Probe Memory Error**	The Console has detected a Water Vapor Probe Memory Error. The Water Vapor Probe's memory has failed. • Check the connection of the Water Vapor Probe to the Cartridge • Check the connection of the Cartridge Cable to the Console • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
187	**Probe Not Supported**	The Console has detected that the Water Vapor Probe is not supported by this Console or has a memory failure. • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge

Alert Code/Name		Description/Action
188	**Vapor Probe Reuse Not Allowed**	The Console has detected that the Water Vapor Probe is being re-used. Reuse of the Water Vapor Probe is not allowed. • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
189	**Vapor Probe Temperature Sensor Failure**	The Console has detected multiple Temperature Sensor failures. The Water Vapor Probe is defective or not fully connected. • Clear error message(s). • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
190	**Pressure Sensor Communication Alert**	The Console has detected that the intrauterine pressure sensor is not being measured correctly. • Upon clearing the alert, the Console will try to restore functionality • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge
191	**Water Vapor Probe Attached to Cartridge**	The Console has detected that the Water Vapor Probe is attached to the Cartridge before the appropriate step. • Disconnect the Water Vapor Probe from the Cartridge to allow the Self-Test to proceed
197	**Water Vapor Probe Disconnected**	The Console has detected the disconnection of the Water Vapor Probe. • Clear error message(s) • If the issue persists, refer to Table 3 for instructions to disconnect and reconnect/replace the Water Vapor Probe from the Cartridge • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative

Alert Code/Name		Description/Action
199	**Interrupt Button Engaged**	The Console has detected that the Interrupt Button is Engaged. • Release the Interrupt button by rotating it clockwise to release the Interrupt button and proceed - Press Quit to end the procedure and/or replace the Water Vapor Probe - Press Clear to resume
201	**Cervical Temperature High**	The Console has detected a cervical temperature higher than expected. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear” and prepare to remove the Water Vapor Probe from the patient
202	**Cervical Temperature Sensor Failure**	The Console has detected that the Water Vapor Probe temperature sensor is defective. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear” and prepare to remove the Water Vapor Probe from the patient
205	**Intrauterine Pressure Does Not Rise**	The Console has detected that the intrauterine pressure is not responding correctly or the pressure is not rising. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear” and prepare to remove the Water Vapor Probe from the patient
206	**Intrauterine Pressure Too High**	The Console has detected that the intrauterine pressure is too high. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear” and prepare to remove the Water Vapor Probe from the patient
207	**Sudden Loss of Intrauterine Pressure**	The Console has detected that the intrauterine pressure is not responding correctly and/or a sudden pressure drop could indicate a leak in the uterus or Water Vapor Probe. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear” and prepare to remove the Water Vapor Probe from the patient

Alert Code/Name		Description/Action
208	**Intrauterine Pressure Too Low**	The Console has detected that the intrauterine pressure is not responding correctly and the pressure is too low. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear” and prepare to remove the Water Vapor Probe from the patient
211	**IU Pressure High After Treatment**	The Console has detected that the intrauterine pressure has remained high after the treatment. • Ensure that the conduits of the Water Vapor Probe are not kinked or pinched, and specifically ensure the Water Vapor Probe’s outflow line is not blocked or has its end submerged in liquid • Consider the potential for the uterus to be pressurized with vapor due to a Console malfunction. Disconnect the Cartridge to prevent the possibility of additional vapor delivery. • Press “Clear” to continue. Use caution when removing the Water Vapor Probe from the patient to reduce any risk of possible excess vapor from the distal end of the Water Vapor Probe.
219	**Intrauterine Pressure Very Low**	The Console has detected a very low intrauterine pressure. The Water Vapor Probe positioning may have been compromised. Water Vapor delivery has stopped and treatment has ended. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear”, wait 10 seconds, and then remove the Water Vapor Probe from the patient.
229	**Vapor Probe Disconnected**	The Cartridge has become detached from the Water Vapor Probe. • Water vapor delivery has terminated early and treatment has ended. Press “Clear”, wait 10 seconds, and then remove the Water Vapor Probe from the patient.
230	**Syringe Disconnected**	The Console has detected that the syringe was disconnected and unexpectedly released from the Console. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear”, wait 10 seconds, and then remove the Water Vapor Probe from the patient.

Alert Code/Name		Description/Action
242	**Middle Balloon Failure**	The Console has detected a leak in the middle balloon. • Water vapor delivery has terminated early and treatment has ended. Press “Clear,” wait 10 seconds, and then remove the Water Vapor Probe from the patient.
243	**Internal Balloon Failure**	The Console has detected a leak in the internal balloon. • Water vapor delivery has terminated early and treatment has ended. Press “Clear”, wait 10 seconds, and then remove the Water Vapor Probe from the patient.
251	**Internal Balloon Not Deflating**	The Console has detected a problem with internal balloon deflation. • If the Water Vapor Probe is within the cervix, disconnect the Cartridge from the Water Vapor Probe before removing the Water Vapor Probe from the patient • If the issue persists, turn off the Console and contact a CooperSurgical, Inc. representative
261	**Treatment Incomplete (during Flush)**	The patient did not receive a full treatment. Water Vapor delivery was automatically stopped during the flush. The procedure may be re-started from the beginning after replacing the Water Vapor Probe.
262	**Treatment Incomplete (after Flush)**	The patient did not receive a full treatment. Vapor delivery was automatically stopped during water vapor treatment. A second vapor treatment in the same operative setting must not be attempted for this patient. A repeat ablation with the Mara Water Vapor Ablation System has not been studied and the effects are unknown.
264	**Syringe is Empty**	The Console has detected that the syringe is empty. • Water vapor delivery has terminated early and treatment has ended. Press “Clear” and prepare to remove the Water Vapor Probe from the patient.
271	**RF Power Failure**	The Console has detected that the RF Power has failed. • Water vapor delivery has terminated early and treatment has ended. Press “Clear,” wait 10 seconds and remove the Water Vapor Probe from the patient

Alert Code/Name		Description/Action
280	**Hypotube Temperature Sensor Failure**	The Console has detected that the intrauterine pressure is not responding correctly and the pressure is too low. • Water vapor delivery has stopped and treatment has terminated early. Press “Clear” and prepare to remove the Water Vapor Probe from the patient
281	**Wire Temperature Sensor Failure**	The Console has detected that the Wire Temperature Sensor has a Failure. • Water vapor delivery has terminated early and treatment has ended. Press “Clear,” wait 10 seconds and remove the Water Vapor Probe from the patient.
284	**Cervical Temperature Sensor Failure**	The Console has detected a Cervical Temperature Sensor Failure. • Water vapor delivery has terminated early and treatment has ended. Press “Clear,” wait 10 seconds and remove the Water Vapor Probe from the patient.
289	**Vapor Probe Temperature Sensor Failure**	The Console has detected multiple Temperature Sensor failures. • Water vapor delivery has terminated early and treatment has ended. Press “Clear,” wait 10 seconds and remove the Water Vapor Probe from the patient.
290	**Pressure Sensor Communication Alert**	The Console has detected that the intrauterine pressure measurement function is not operational. • Water vapor delivery has terminated early and treatment has ended. Press “Clear,” wait 10 seconds and remove the Water Vapor Probe from the patient. • If the issue persists, replace the Console
298	**Treatment Interrupted (Flush)**	The Console has detected that the Interrupt button has been activated while Flushing. • Twist the Interrupt button on the front of the Console to Release the button
299	**Treatment Interrupted (After Flush)**	The Console has detected that the Interrupt button has been activated during treatment. • Twist the Interrupt button on the front of the Console to Release the button

Table 3 lists the steps for disconnecting or reconnecting the Water Vapor Probe from the Cartridge or replacing the Water Vapor Probe if an issue persists at various stages of the procedure.

Note: If instructed to disconnect or reconnect the Water Vapor Probe from the Cartridge or replace the Water Vapor Probe, be sure to wait 10 seconds before taking the necessary action.

Table 3: Disconnecting and Reconnecting/Replacing the Water Vapor Probe

Scenario	Action
Any Step Prior to Water Vapor Probe Test	1. Disconnect Water Vapor Probe from Cartridge 2. Clear error message(s) 3. Reconnect Water Vapor Probe to Cartridge 4. If issue persists, replace the Water Vapor Probe
Any Step After Saline is Delivered During Water Vapor Probe Test	1. Press Red Interrupt button, twist to release button 2. Choose “Quit” on screen 3. Disconnect Water Vapor Probe from Cartridge 4. Turn Console off 5. Turn Console on 6. Obtain new Water Vapor Probe 7. Follow on-screen instructions
Any Step After Water Vapor Probe Insertion Into the Uterus	1. Press Red Interrupt button, twist to release button 2. Choose “Quit” on screen 3. Remove Water Vapor Probe from the patient 4. Disconnect Water Vapor Probe from Cartridge 5. Turn Console off 6. Turn Console on 7. Obtain new Water Vapor Probe 8. Follow on-screen instructions

Table 4 lists Alert Codes releated to when the system setects an internal tchnical issue, preventing the continuation of use. These are also accompanied by a tone and a orange light.

Table 4: Alert Codes 501-699

Alert Code/Name		Description/Action
5XX	**Any Alert Code Beginning with 5**	The Console has detected a hardware fault. • Turn off the Console and contact a CooperSurgical, Inc. representative
6XX	**Any Alert Code Beginning with 6**	The Console has detected a hardware fault. • Turn off the Console and contact a CooperSurgical, Inc. representative

All Alerts are recorded by the Console in an internal log accessible by CooperSurgical, Inc. authorized personnel. This log is saved even with a loss of power.

SECTION 6
MAINTENANCE AND REPAIR

Routine Maintenance

Service or maintenance of the Console should not be performed while in use. Routine maintenance of the Console is not required.

Power Cord Inspection – Check the power cord prior to each use for exposed wires, cracks, frayed edges or a damaged connector. Replace any damaged power cords.

Fuses – There are no fuses to be replaced. The Console is equipped with an Internal circuit breaker that re-sets when the rear panel Circuit Breaker power switch is cycled.

The Console is equipped with a data monitoring function. With the use of a computer, a trained CooperSurgical, Inc. representative can monitor the Console and its function. This data monitoring function may be used to assess proper function of the Console and/or to assist in the event of a malfunction. Users should not attempt to access the inside of the Console or open the Service Door.

The Console is not provided with networking capabilities.

Returning the Console for Service

Before returning the Console, contact your CooperSurgical, Inc. representative for assistance. If you are instructed to send the Console back to CooperSurgical, Inc., you will be issued a Return Material Authorization (RMA) Number.

Cleaning the Console and Cartridge

WARNING: Always turn off and unplug the Console before cleaning.

Follow the procedures approved by your institution or use a validated infection control procedure.

- Thoroughly wipe all surfaces of the Console, Cartridge and power cord with a mild cleaning solution (listed below) and a damp cloth.

Do not clean the Console or Cartridge with abrasive compounds, solvents, or other materials that could scratch the panels or damage the Console. Use common hospital cleaning solutions, such as:

- 70% Alcohol
- 3% Hydrogen Peroxide Solution
- 10% Bleach Solution

Do not allow cleaning fluids to enter the Console or Cartridge. Cartridge must be fully dry before use with Water Vapor Probe.

Do not attempt to sterilize the Console or Cartridge.

APPENDIX A: TECHNICAL DESCRIPTION

Input Rating

110-240V ~50/60HZ 9A

Operating Parameters

Ambient Temperature Range	10º to 35º C (50º to 95ºF)
Relative Humidity	30% to 75%, noncondensing
Atmospheric Pressure	700 to 1060 hPa
Warm-up Time	If the Console was transported or stored at temperatures outside the Transport and Storage ambient temperature range, allow at least one hour for the Console to reach room temperature before use.

Transport and Storage

Ambient Temperature Range	2º to 60º C (36º to 140ºF)
Relative Humidity	25% to 85%, condensing
Atmospheric Pressure	500 to 1060 hPa
Duration of Storage	If the Console was stored for longer than one year, the Console should be tested and calibrated before use.

Duty Cycle

Continuous with Intermittent operation (3 min on / 7 min off) during water vapor delivery.

Audio Volume

40-75 dBa

Audible tone volume is adjustable on the first screen. However, audible tones for Alarms are not adjustable.

⚠ **Warning:** Auditory alarm signal sound pressure levels that are less than ambient levels can impede Operator recognition of alarm Conditions.

Power Cord

Use CooperSurgical, Inc. provided power cords with the Console:

- Length, 8'

Technical Compliance Information

IEC 60601-1 Classifications:

- Type of protection against electric shock: Class I Equipment
- Degree of protection against electric shock: Type B Applied Parts
- Degree of protection against the ingress of water or particles:
  - Console IP21
  - Cartridge IPX0
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The Console needs special precautions regarding EMC (Electromagnetic Compatibility) and needs to be installed and put into service according to the EMC information provided in this Operator's Manual. The Console is intended to be used in a professional healthcare facility environment.

The testing results documented below are for the entire Vapor System which includes the Console (GEN-16-050) and the Water Vapor Probe (DDK-16-050).

Table A1

Guidance and Manufacturer's Declaration (Electromagnetic Emissions)		
The Mara™ Water Vapor Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Mara™ Water Vapor Ablation System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment-Guidance**
Conducted and Radiated RF Emissions CISPR 11	Group 1, Class A	The Mara™ Water Vapor Ablation System 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.
Harmonic Distortion IEC 61000-3-2	Class A	
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	

The Mara™ Water Vapor Ablation System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

⚠ **Warning:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

Table A2

Guidance and Manufacturer's Declaration (Electromagnetic Immunity)

The Mara™ Water Vapor Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Mara™ Water Vapor Ablation System 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, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV 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 Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% 110 or 230 VAC (>95% dip in 110 or 230 VAC) for 0.5 cycle <5% 110 or 230 VAC (>95% dip in 110 or 120 VAC) for 1 cycle 70% 110 or 230 VAC (30% dip in 110 or 230 VAC) for 0.5 sec <5% 110 or 230 VAC (>95% dip in 110 or 230 VAC) for 5 sec	<5% 110 or 230 VAC (>95% dip in 110 or 230 VAC) for 0.5 cycle <5% 110 or 230 VAC (>95% dip in 110 or 230 VAC) for 1 cycle 70% 110 or 230 VAC (30% dip in 110 or 230 VAC) for 0.5 sec <5% 110 or 230 VAC (>95% dip in 110 or 230 VAC) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the GEA-SYS-16-0500 requires continued operation during power mains interruptions, it is recommended that the GEA-SYS-16-0500 be powered from an uninterruptible power supply or a battery.
(60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration (Electromagnetic Immunity)

The Mara™ Water Vapor Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Mara™ Water Vapor Ablation System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Proximity Fields from RF Wireless Communications IEC 61000-4-3	385 MHz at 27 V/m, Pulse 18 Hz 450 MHz at 28 V/m, FM ± 5kHz, Deviation 1 kHz sine 710 MHz at 9 V/m, Pulse 217 Hz 745 MHz at 9 V/m, Pulse 217 Hz 780 MHz at 9 V/m, Pulse 217 Hz 810 MHz at 28 V/mPulse 18Hz 870 MHz at 28 V/m, Pulse 18 Hz 930 MHz at 28 V/m, Pulse 18 Hz 1720 MHz at 28 V/m, Pulse 217Hz 1845 MHz at 28 V/m, Pulse 217 Hz 1970 MHz at 28 V/m, Pulse 217 Hz 2450 MHz at 28 V/m, Pulse 217 Hz 5240 MHz at 9 V/m, Pulse 217 Hz 5500 MHz at 9 V/m, Pulse 217 Hz 5785 MHz at 9 V/m, Pulse 217 Hz	385 MHz at 27 V/m, Pulse 18 Hz 450 MHz at 28 V/m, FM ± 5kHz,Deviation 1 kHz sine 710 MHz at 9 V/m, Pulse 217 Hz 745 MHz at 9 V/m, Pulse 217 Hz 780 MHz at 9 V/m, Pulse 217 Hz 810 MHz at 28 V/mPulse 18Hz 870 MHz at 28 V/m, Pulse 18 Hz 930 MHz at 28 V/m, Pulse 18 Hz 1720 MHz at 28 V/m, Pulse 217Hz 1845 MHz at 28 V/m, Pulse 217 Hz 1970 MHz at 28 V/m, Pulse 217 Hz 2450 MHz at 28 V/m, Pulse 217 Hz 5240 MHz at 9 V/m, Pulse 217 Hz 5500 MHz at 9 V/m, Pulse 217 Hz 5785 MHz at 9 V/m, Pulse 217 Hz	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the GEA-SYS-16-0500 than 30 cm (12 inches), including cables.

Table A3

Guidance and Manufacturer's Declaration (Electromagnetic Immunity)			
The Mara™ Water Vapor Ablation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Mara™ Water Vapor Ablation System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 80 MHz to 2.7 GHz 3 V/m	3 Vrms 150 kHz to 80 MHz 80 MHz to 2.7 GHz 3 V/m	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the GEA-SYS-16-0500, including cables. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:. 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Mara™ Water Vapor Ablation System is used exceeds the applicable RF compliance level above, the Mara™ Water Vapor Ablation System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Mara™ Water Vapor Ablation System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

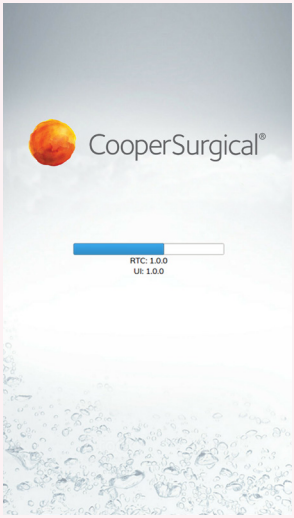
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by Absorption and reflection from structures, objects and people.

For the Mara Water Vapor Ablation System, Essential Performance is listed as:

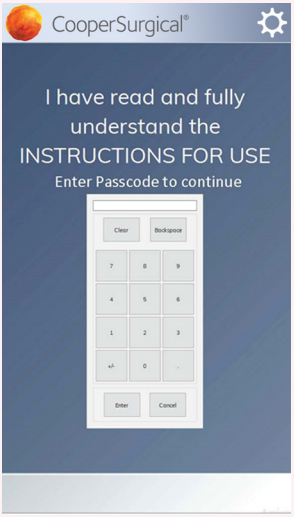
- The System shall deliver water vapor to the uterus at a pressure of 20-52 mmHg, or prevent treatment, or discontinue treatment.
- The System shall detect a sealed uterus when the Water Vapor Probe is placed, or prevent treatment.

APPENDIX B: DISPLAY SCREENS

Screen 03



Screen 04

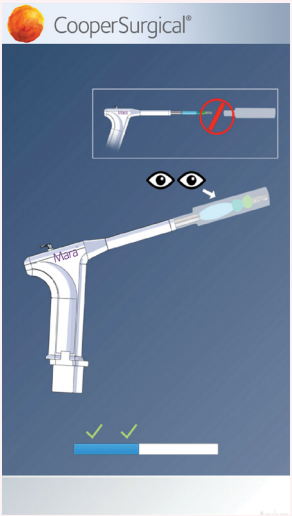


Screen 05

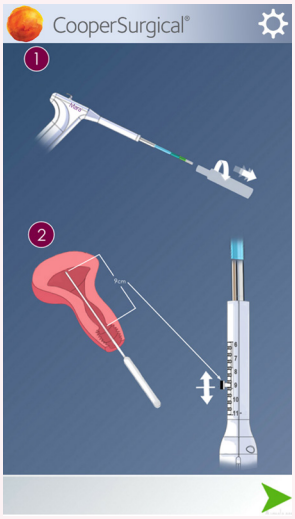
Screen 06

Screen 07

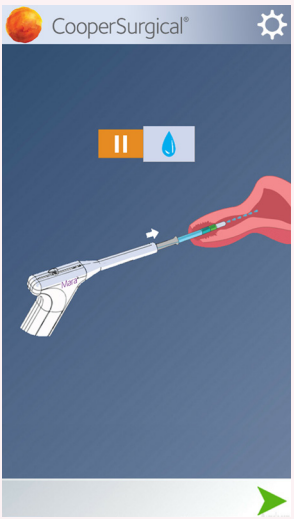
Screen 08



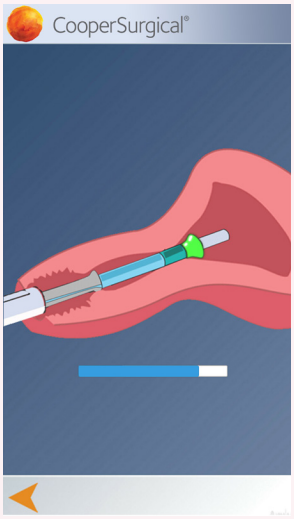
Screen 09



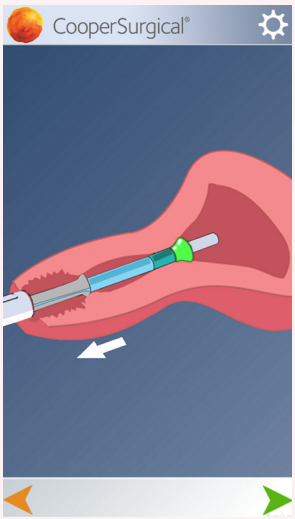
Screen 10



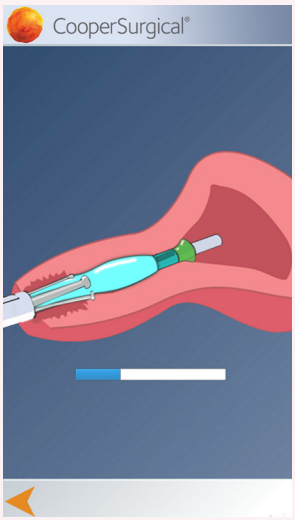
Screen 11



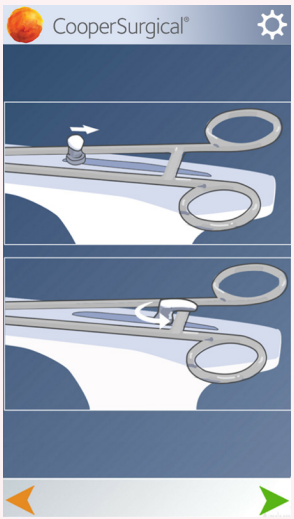
Screen 12



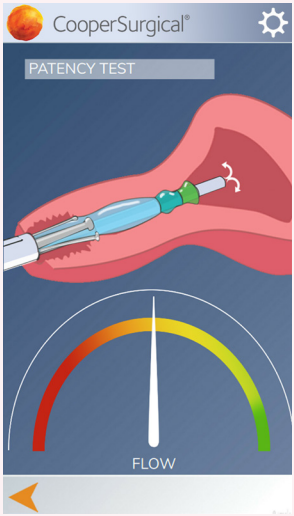
Screen 13



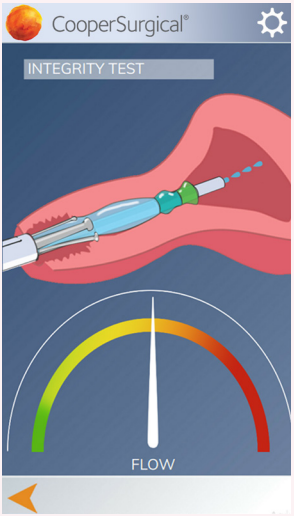
Screen 14



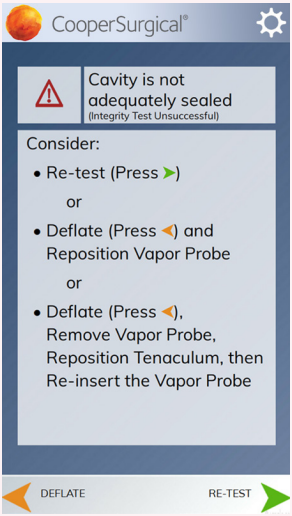
Screen 15 (Integrity)



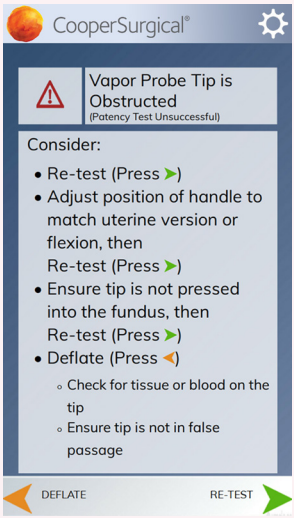
Screen 15 (Patency)



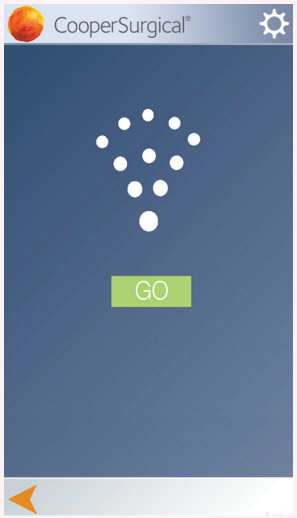
Screen 16 (Integrity)



Screen 16 (Patency)

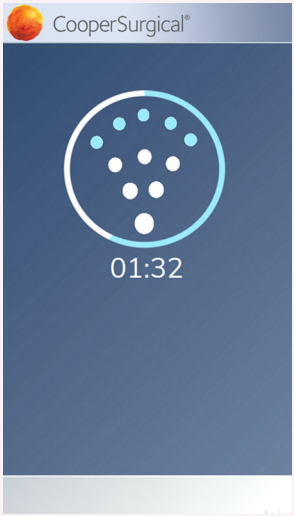


Screen 18

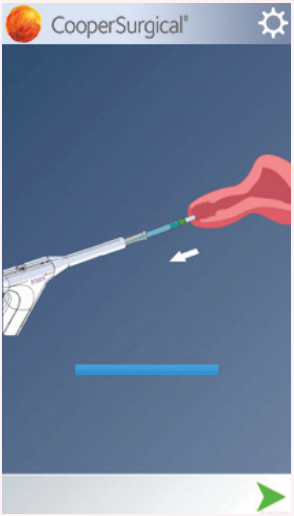


Screen 19 (Flush)

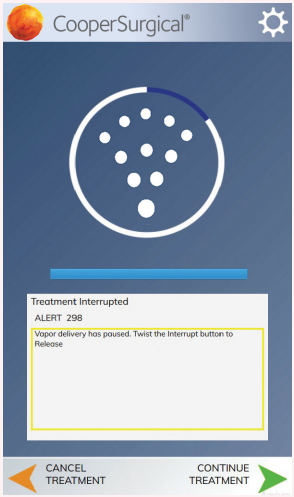
Screen 19 (Treatment)



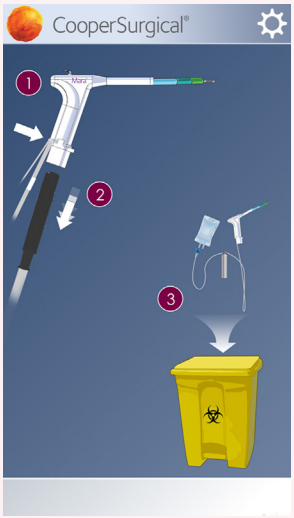
Screen 20



Screen 21



Screen 22



Screen 25

APPENDIX C: SYMBOL DEFINITIONS ON LABELING


Caution


Refer to Instruction Manual/Booklet

Lot Number

Catalog Number

Serial Number


Do Not Reuse

Sterilized by ETO

Non-Sterile


Use by Date


Date of Manufacture


Manufacturer


Power On/Off


Alternating Current


Shock Protection Type B


Protective Earth Terminal


Temperature Limit


Humidity Limitation


Atmospheric Pressure Limitation


Consult Instructions for Use


Do Not Use if Package is Damaged


Keep Away from Sunlight


Keep Dry


Do Not Dispose


Outflow Conduit Warning

IP21 Protects persons against access to hazardous parts with fingers; protection against vertically falling water drops

CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611
USA

Phone: (800) 243-2974
Fax: (800) 262-0105

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