CoolWave®

Targis® System

CoolWave® Control Unit

User Manual

UROLOGIX®

Part #250023-001 Rev L

Patient Safety Summary

This patient safety summary is an overview of the key patient safety information provided in the CoolWave Control Unit User Manual. Please refer to the user manual to obtain all safety information pertaining to the use and operation of the CoolWave Control Unit.

- The treating physician should be present at all times during treatment.
- Perform an enema 1 to 2 hours before treatment or per physician instructions. An enema is mandatory.
- It is critical that, throughout the patient's treatment, the treating physician verify the correct position of the microwave catheter and the rectal unit. Patient safety is at risk if the following simple and straightforward safety check procedures are not correctly observed.

SAFETY CHECKS

1. Throughout the duration of the treatment, verify that the position mark on the catheter remains at a fixed distance from the penile meatus.
2. It is strongly recommended that at least every 5 - 10 minutes of the treatment, the correct position of the location balloon and the rectal unit is checked.
3. Always immediately check microwave catheter and rectal unit placement if the patient complains of any abnormal or sudden increase in pain. Pause the treatment if the patient complains of serious pain.
4. Observe the treatment parameters for sudden changes in readings, especially decreases in temperatures that might indicate a sensor has moved from its previous position.

WARNINGS

- The Cooled ThermoTherapy™ treatment must not be initiated without assurance that the microwave catheter is properly positioned in the patient. **The correct positioning of the catheter must always be checked by ultrasound imaging prior to commencing treatment. Improper placement or orientation of the microwave catheter may lead to treatment failures or heating damage of nontarget tissues such as the bladder neck, external sphincter, or penile urethra.**
- Do not underinflate or overinflate the microwave catheter balloon. Underinflation can cause the microwave antenna to be misplaced in the prostate, affecting the external sphincter or penile urethra. Overinflation may result in balloon malfunction and possible improper positioning of the microwave antenna.
- The rectal unit must be positioned and inflated properly to ensure correct temperature sensing.

Table of Contents

1 Systems Description

1.1 Notice

The information contained in this manual is subject to change. This manual does not necessarily address all safety concerns associated with the Urologix CoolWave Control Unit.

The CoolWave Control Unit is intended for use only by qualified medical personnel. Federal (USA) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program.

Medical equipment, however sophisticated, should never be a substitute for the human care, attention, and critical judgment that only trained healthcare professionals can provide.

1.2 Safety symbols and definitions

The following safety symbols are used throughout this manual. Familiarize yourself with each symbol and its meaning before using this equipment. You can find additional symbols associated with the CoolWave Control Unit in *Section 5.4, Description of symbols*.

SAFETY SYMBOL	DEFINITION
 **Note**	A note indicates important information that helps you operate the CoolWave Control Unit or use the disposable devices.
 **Caution**	A caution contains instructions that must be followed to avoid a possible malfunction of or damage to the equipment or its connected devices. Do not proceed beyond a caution sign until the indicated conditions are fully understood and met.
 **Warning**	A warning contains important information about possible danger to you or the patient. Do not proceed beyond a warning sign until the indicated conditions are fully understood and met.
 **Instruction Manual**	The instruction manual symbol is displayed on the product when it is necessary for you to refer to the CoolWave Control Unit User Manual (this document).

Table 1-1. Safety Symbols and Definitions

1.3 User Manual Overview

This manual combines technical reference material as well as information on how to use the CoolWave Control Unit.

Notes:

- For information regarding the contents of this manual, please call Urologix Customer Service at 1-888-229-0772.
- Read this manual before operating the CoolWave Control Unit.

Section 1: System Description provides an overview of the CoolWave Control Unit equipment. This section also provides important notes about using the CoolWave Control Unit including information on installation, use environment, equipment connections, equipment testing, and safety instructions.

Section 2: Treatment Session Setup describes how to prepare the patient, prepare the CoolWave Control Unit, install the coolant bag, and insert the microwave catheter and the RTU (rectal unit).

Section 3: Treatment Instructions provides instruction on how to use the CoolWave Control Unit from logging into the CoolWave Control Unit to beginning and ending a Cooled ThermoTherapy treatment. You will also find information on how to change system settings, handle system errors, and work in demonstration mode.

Section 4: Equipment Maintenance presents information on post-treatment cleaning procedures and storage instructions. You will also find information on how to move and ship the CoolWave Control Unit. Finally, this section discusses how to maintain the equipment, though some maintenance requires a Urologix trained service representative.

Section 5: Appendix A includes a troubleshooting guide, a flowchart of the treatment screens, a description of the symbols used in the manual and on the labels, an overview of the Patient Comfort Kit, and a glossary of terms used in CoolWave Control Unit literature.

Section 6: Appendix B includes a Course Description, Analgesia Guidelines, Frequently Asked Questions and Sample Practice Forms.

Section 7: Index

1.4 Precautions

Only those physicians who have been thoroughly trained on the operation of the CoolWave Control Unit and the Cooled ThermoTherapy treatment should deliver the treatment.

The Cooled ThermoTherapy Treatment must not be initiated without assurance that the microwave catheter is properly positioned in the patient. **The correct positioning of the microwave catheter must always be checked by ultrasound imaging prior to commencing treatment. Improper placement or orientation of the microwave catheter may lead to treatment failures or heating damage of non-target tissues such as the bladder neck, external sphincter, or penile urethra.**

All components of the CoolWave Control Unit must be used in a manner consistent with the instructions set forth in their respective instructions for use insert and the CoolWave Control Unit User Manual (this document). Failure to do so may result in insufficient treatment or increased risk of injury or infection to the patient.

Note: Use of the CoolWave Control Unit results in the deposition of microwave energy in the patient's prostate and in adjacent regions of the body. Some animal studies in the literature suggest that there may be as yet unknown health effects from exposure to microwave radiation, including an increased incidence of tumors. Although it is not possible to extrapolate these studies to humans, they suggest that unnecessary microwave radiation exposure should be avoided.

At least 20 cm of ventilation clearance must be provided around the base of the CoolWave Control Unit.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the Federal Communication Commission (FCC) Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the CoolWave Control Unit User Manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at the users' own expense.

The Urologix CoolWave Control Unit emits a small amount of electromagnetic energy during a treatment. Urologix recommends that all electronic medical devices be kept at a minimum distance of 1.0 meter from the CoolWave Control Unit when performing a treatment. However, a 1-meter separation of electronic medical equipment from the CoolWave Control Unit does not guarantee that operation of other devices will not be impacted. The effect of this electromagnetic energy on all equipment cannot be predicted due to age and quality of maintenance. The performance of each piece of equipment operated near the CoolWave Control Unit, during a treatment, must be evaluated for degradation. For more detailed EMC requirements, refer to *Section 5.7 Electromagnetic Compatibility (EMC) Tables* in the Appendix.

Since microwave energy can travel through walls, ceilings, and floors to affect other devices, it is important to understand that the 1-meter safety distance applies not only to the treatment room, but also to all adjacent rooms in the building, including the rooms above and below the treatment room. Do not operate the CoolWave Control Unit near equipment that emits electromagnetic energy, unless the effect on the CoolWave Control Unit has been evaluated and no degradation of performance was found. The national standard ANSI/IEEE C95.1 - 1999 Edition (Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields) recommends a maximum stray field exposure level for whole body exposure of 3 mW/cm^2, as averaged for any 6 minute period. The maximum radiated field, at full power, from the CoolWave Control Unit patient cable and microwave catheter, at 5 centimeters, is 2.1 mW/cm^2. Urologix recommends that the operator maintain a minimum distance of 5 centimeters from the patient cable and exposed portions of the microwave catheter during the treatment.

Operate the CoolWave Control Unit and connected devices only when connected to a fully tested, hospital grade power outlet with adequate grounding.

The CoolWave Control Unit must be plugged into the appropriate voltage outlet.

The electrical equipment inside the CoolWave Control Unit uses voltages capable of causing serious injury or death from electric shock. To avoid this hazard, never open the housing of the CoolWave Control Unit.

1.5 Introduction to the CoolWave Control Unit

The CoolWave Control Unit treats Benign Prostatic Hyperplasia (BPH) by applying microwave power to the prostate. This microwave power, when applied to the prostate, heats the diseased tissue via a microwave catheter. This microwave catheter also minimizes patient discomfort and risk to the urethra by circulating cooling fluid. In addition, rectal wall damage is prevented by continuously monitoring rectal wall temperature readings throughout the treatment. If during a treatment, urethra or rectal temperatures exceed protocol (treatment) parameters, the system will adjust microwave power to protect the urethra or rectal wall from overheating.

1.6 Targis System: CoolWave Control Unit equipment overview

The Targis System is comprised of a CoolWave Control Unit model 5000 series, a Procedure Kit (comprised of a microwave catheter, a rectal thermosensing unit, and a coolant bag), and accessories. For this user manual, the representative microwave catheter is the CTC Advance® Microwave Catheter

1.6.1 CoolWave Control Unit

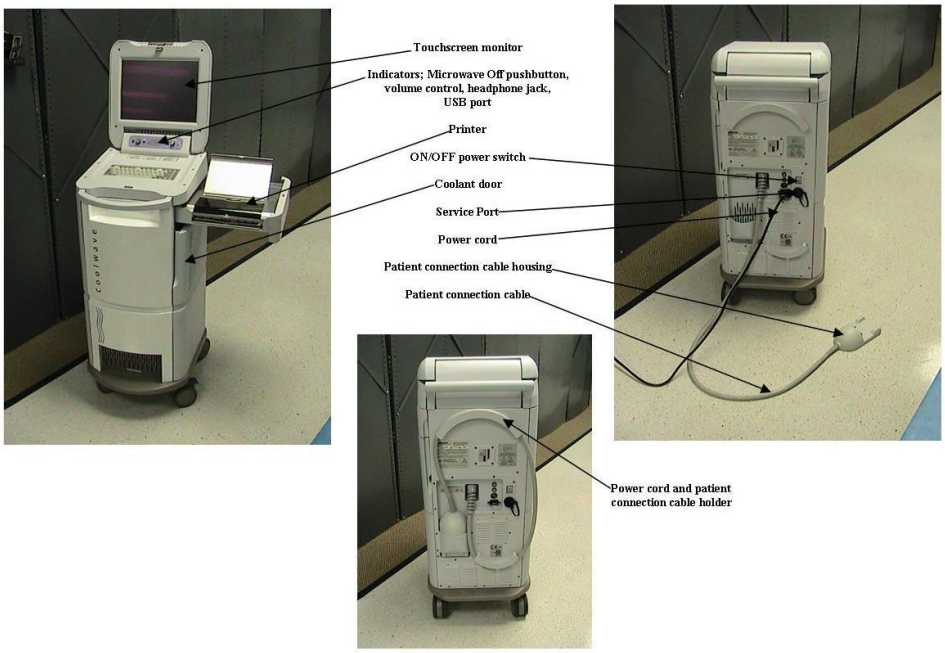


Figure 1-1. CoolWave Control Unit

The CoolWave Control Unit (Figure 1-1) supplies microwave energy and coolant to the microwave catheter and collects temperature data from the microwave catheter and the rectal unit.
The CoolWave Control Unit also provides a way of entering patient data, controlling treatment parameters (e.g., ramp rate, coolant temperature, and treatment time), and monitoring rectal and urethra temperatures. The CoolWave Control Unit includes these features:

- Patient connection cable and patient connection cable housing
- Touchscreen monitor
- Keyboard
- Printer
- ON/OFF power switch
- Lockable wheels
- Coolant system
- Main power indicator and microwave power indicator
- Microwave Off pushbutton
- Other: Volume control, headphone jack, USB ports

Note: The service port is reserved for use by Urologix service personnel only.

Patient Connection Cable and Patient Connection Cable Housing

Data from the microwave catheter and the rectal unit enters the CoolWave Control Unit via the patient connection cable and patient connection cable housing (Figure 1-2).

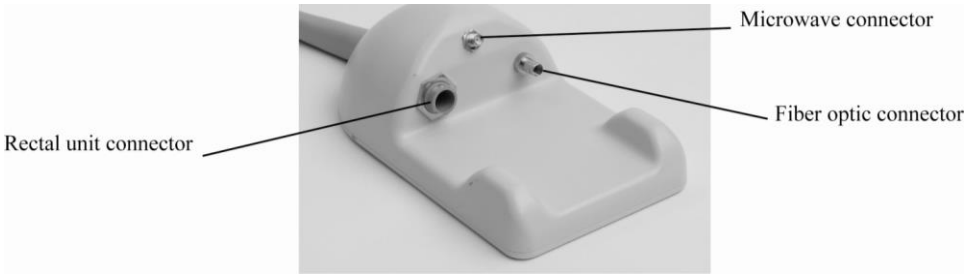


Figure 1-2. Patient Connection Cable Housing

The patient connection cable housing contains connectors for the rectal unit, fiber optic connector, and microwave antenna connector. When not in use, place the patient connection cable and housing in the cable holder located on the back of the CoolWave Control Unit.

Touchscreen monitor

View a treatment using the touchscreen monitor (Figure 1-3) and, when necessary, adjust treatment parameters. The monitor can be tilted for improved viewing. To open the monitor, operate the latch and lift.

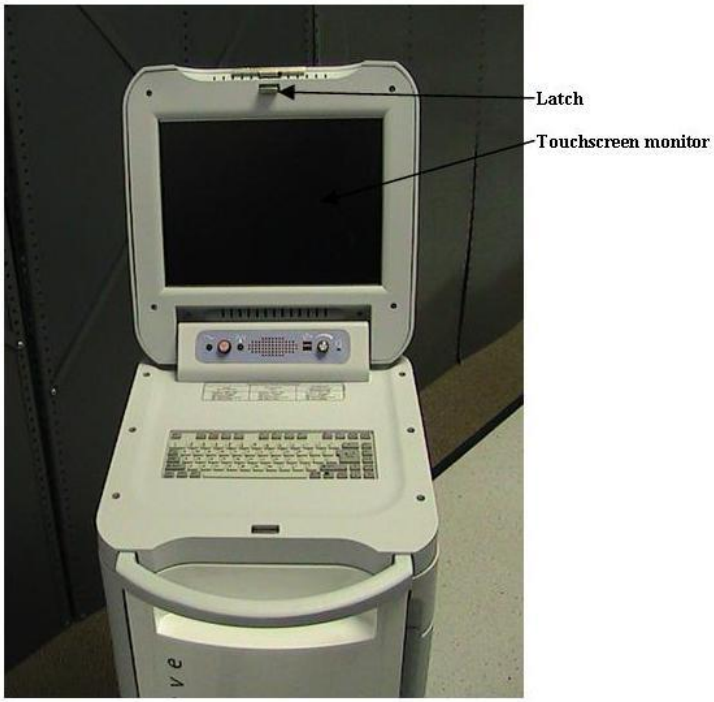


Figure 1-3. Touchscreen monitor

Note: Keep the touchscreen clean, since debris (water droplets or lidocaine jelly) can affect its ability to register a touch.

Keyboard

Enter patient data using the keyboard (Figure 1-4). The keys are sealed to prevent damage from spillage onto the keyboard. To access the keyboard, lift the touchscreen monitor into an upright position.

Figure 1-4. Keyboard

Printer

Print data from any treatment using the Canon® color inkjet printer (Figure 1-5). The printer drawer pulls out and holds the printer.

Caution: The CoolWave Control Unit can tip over if you press down on the open printer drawer with too much weight. Do not press down on the open drawer with more than 20 kg (44 lbs).

Figure 1-5. Printer

ON/OFF power switch

Instruction Manual: Read the CoolWave Control Unit User Manual (this document) before turning ON and operating the system.

Turn the CoolWave Control Unit ON or OFF with this power switch (Figure 1-6) located on the back of the CoolWave Control Unit. When not in use, place the power cord in the cable holder located on the back of the CoolWave Control Unit.

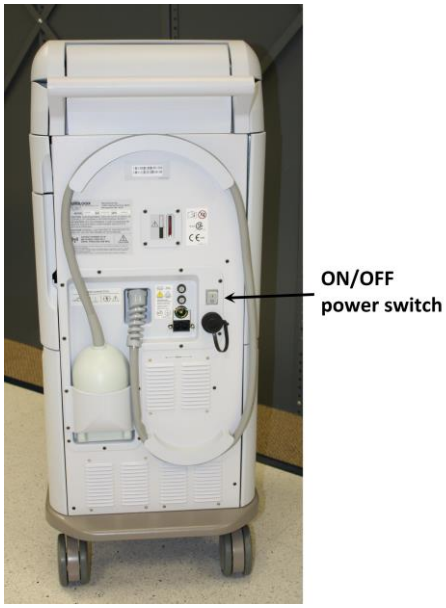


Figure 1-6. ON/OFF power switch

Lockable wheels

Keep the CoolWave Control Unit from moving by locking the front wheels (Figure 1-7).

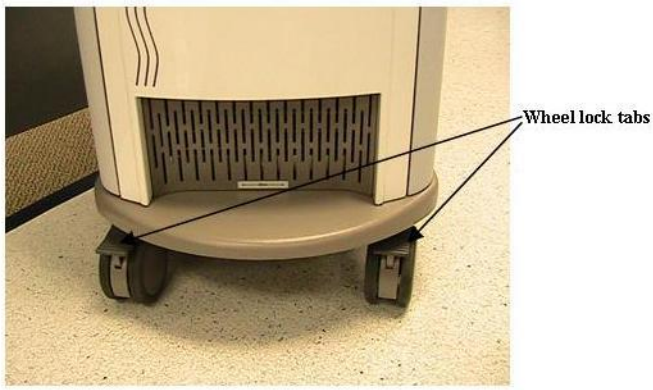


Figure 1-7. Wheel lock tabs

To lock the wheels, use your foot to press down on the wheel lock tabs. To unlock the wheels, press on the back part of the wheel lock tabs.

Coolant System

The Coolant System consists of a chill plate, temperature and pressure sensors, a peristaltic pump mechanism, and a coolant bag (Figure 1-8).

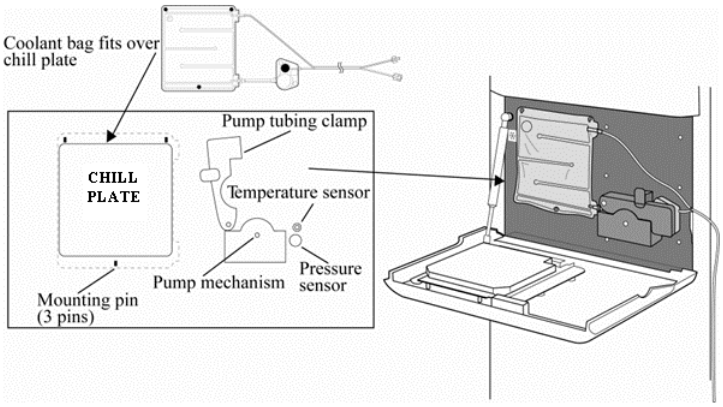


Figure 1-8. Coolant System features

Chill plate: The chill plate, located behind the coolant door (Figure 1-8), is equipped with mounting pins to hold the coolant bag securely against the chill plate surface.

Temperature and pressure sensors: These sensors, located on the CoolWave Control Unit, monitor the coolant temperature and the coolant pressure (Figure 1-8).

Peristaltic pump mechanism: The peristaltic pump mechanism (Figure 1-8) circulates the coolant.

Coolant bag: The coolant bag (Figure 1-8) serves as the reservoir for the coolant.

Main power indicator and microwave power indicator

The main power indicator (Figure 1-9), located under the touchscreen monitor, is a green LED that illuminates when the CoolWave Control Unit is ON. The microwave power indicator (Figure 1-9), also located under the monitor, is an amber LED that illuminates when the CoolWave Control Unit delivers microwave power to the prostate.

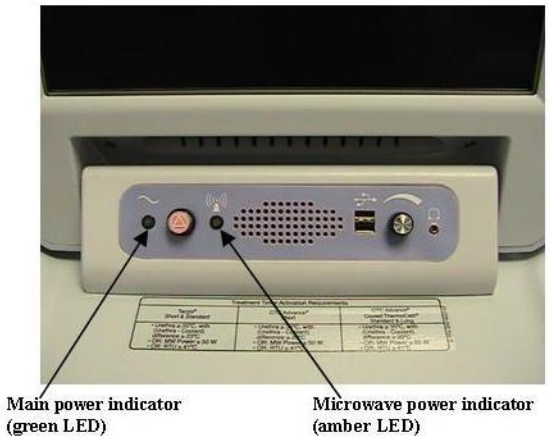


Figure 1-9. Power indicators

Microwave Off pushbutton

If there is an emergency, press the red **Microwave Off** pushbutton (Figure 1-10), located under the touchscreen monitor and right of the green LED, to immediately turn the microwave power OFF.

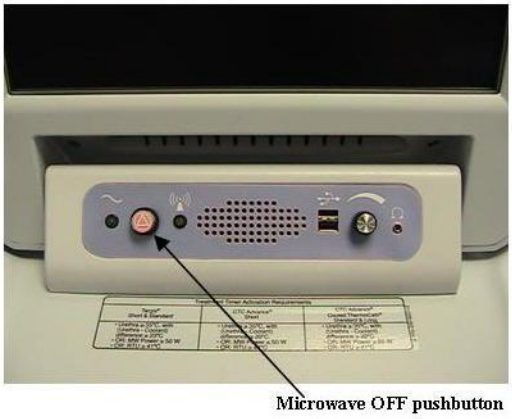


Figure 1-10. Microwave Off pushbutton

Other: Volume control, headphone jack, USB ports

The CoolWave Control Unit includes a volume control, a headphone jack, and two USB (Universal Serial Bus) ports (Figure 1-11), all located under the touchscreen monitor. Either of the USB ports can accommodate a single USB flash drive, and/or a wired USB mouse.

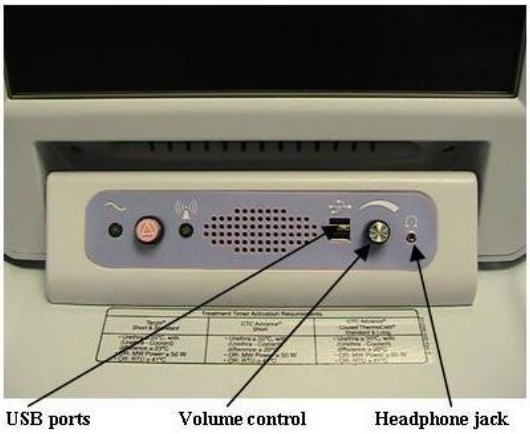


Figure 1-11. Volume Control, Headphone jack, USB Ports

1.6.2 Microwave Catheter

The single-use microwave catheter includes a fiber optic temperature sensor to measure urethra temperature, a microwave antenna and cable, cooling channels and connectors, a urine drainage port that connects to a standard urine drainage bag, and a location balloon to position the catheter at the bladder neck (Figure 1-12). The microwave antenna and temperature sensor are connected to the CoolWave Control Unit via the patient connection cable housing and patient connection cable. To ensure that the microwave catheter is positioned properly within the urethra, the location balloon is inflated to hold the catheter in place during treatment.

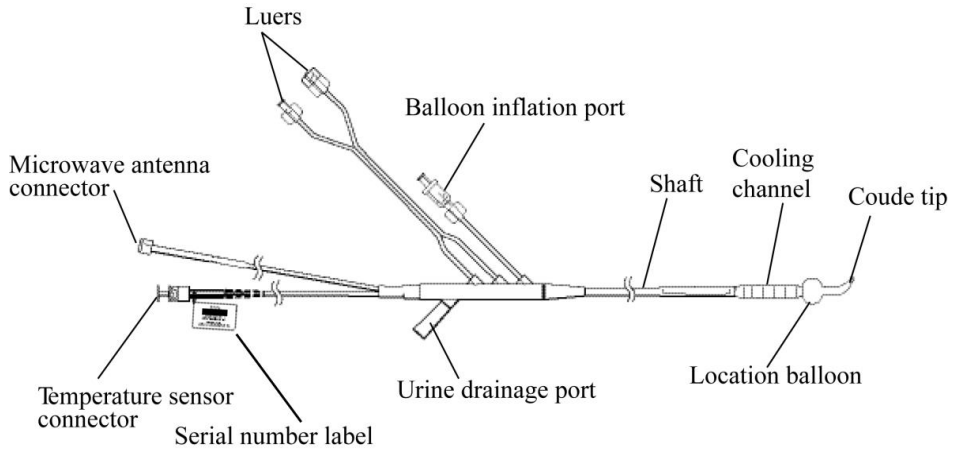


Figure 1-12. Microwave Catheter

The microwave catheter is used for:

- Delivering microwave energy to the targeted prostatic tissue.
- Monitoring the urethra temperature.
- Cooling the urethra during treatment.
- Draining urine during treatment.

1.6.3 Rectal Thermosensing Unit (RTU)

The CoolWave Control Unit requires the use of either the single-use standard RTU or the RTU Plus with reusable handle and single-use balloon. The standard RTU and RTU Plus (Figure 1-13 and Figure 1-14) both consist of an inflatable balloon with 5 temperature sensors. These sensors monitor rectal temperature along the anterior rectal wall and send this information to the CoolWave Control Unit during a treatment. After inserting one of the rectal units into the rectum, inflating the rectal balloon with air holds the thermosensors in place against the anterior rectal wall nearest the prostate.

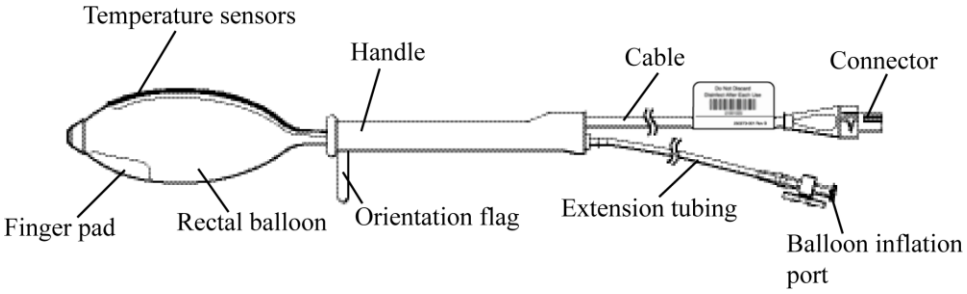


Figure 1-13. Single-use standard RTU

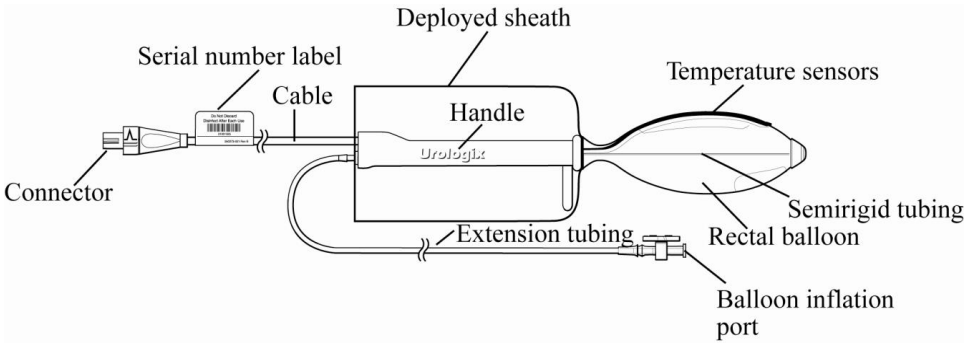


Figure 1-14. Assembled RTU Plus (with the reusable handle and single use balloon)

1.6.4 Coolant Bag

The single-use coolant bag includes a coolant bag, inlet and outlet tubing, connectors, and a sensor module (Figure 1-15). The sensor module allows the CoolWave Control Unit to monitor coolant temperature and pressure in order to maintain coolant temperatures within acceptable limits and to ensure that the coolant circulates properly. The coolant bag also includes 2 small holes on the top and 1 hole on the bottom for mounting the bag on the chill plate and a hydrophobic vent to release air (but not coolant) from inside the bag.

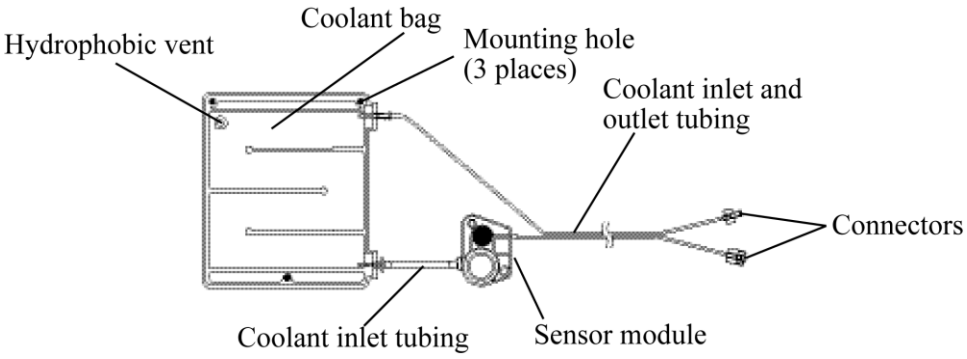


Figure 1-15. Coolant Bag

The function of the coolant bag is to provide a reservoir for the coolant that circulates through the microwave catheter during a treatment. The coolant circulates through the coolant bag via the peristaltic pump mechanism. The coolant inlet tubing runs across the pump mechanism, which pushes the coolant through the inlet tubing, the sensor module, the coolant bag, and the outlet tubing. Coolant continuously circulates through the microwave catheter, connected to the coolant outlet tubing, and returns to the coolant bag via the coolant inlet tubing. The coolant bag resides against the chill plate, which chills the circulating coolant.

1.7 Required equipment

The following equipment, **including an ultrasound system**, is needed to successfully treat patients with the CoolWave Control Unit.

1.7.1 Equipment provided by Urologix

Urologix provides the following equipment.

QUANTITY	EQUIPMENT/MATERIAL
1	CoolWave Control Unit
1	CoolWave Control Unit User Manual (this document)
1	Kit containing a CTC Advance Microwave Catheter • 1 microwave catheter • 1 Rectal Thermosensing Unit (standard RTU or RTU Plus) • 1 coolant bag
1	Patient Comfort Kit (2 knee cushions and a microwave catheter holder)
1	Transport Kit, optional (trolley and electrical safety tester)

Table 1-2. Urologix provided equipment

1.7.2 Equipment provided by the Clinic

The clinic typically provides the following equipment.

QUANTITY	EQUIPMENT/MATERIAL
1	Foley catheter, 16-18 French
1	Straight catheter, 14-16 French
1	Urine drainage bag
As needed	Sterile gloves
As needed	Anesthetic lubricating jelly (e.g., Urojet or lidocaine jelly)
50 cc	Local bladder anesthetic of choice (e.g., 50 cc of 1% or 2% lidocaine without epinephrine)
As needed	Water soluble lubricating gel (e.g., K-Y Jelly)
1	60 cc luer-lock syringe
1	60 cc catheter-tip syringe (e.g., Toomey™ syringe)
2	10 cc luer-lock syringe
200 cc	Sterile water for coolant bag and catheter balloons
1	Ultrasound system
1	Catheter plug
As needed	Permanent marker or tape
As needed	Nonsterile gloves
1	Penile clamp
1	Specimen cup
1	Urinal or graduate
As needed	Ice or ice pack

Table 1-3. Clinic provided equipment

1.8 CoolWave Control Unit Installation and Use Environment

1.8.1 Installation

Warning: DO NOT USE components that have evidence of a compromised package or damage.

Before unpacking the CoolWave Control Unit, inspect the shipping crate for signs of damage. Remove the CoolWave Control Unit from the shipping crate, and retain the shipping crate to return the CoolWave Control Unit for service, if needed. Then, prior to using the CoolWave Control Unit, visually inspect the following components for damage:

- CoolWave Control Unit for obvious damage
- Pump latch and coolant door to see that they are operating correctly
- Patient connection cable, patient connection cable housing, and connectors for kinks, cuts, dirt, contamination, or obvious damage
- Microwave catheter for kinks, cuts, or obvious damage
- Rectal unit for kinks, cuts, or obvious damage
- Coolant Bag for kinks, cuts, or obvious damage

Operate the CoolWave Control Unit and its connected devices only in clinical environments where it can be connected to a fully tested, hospital-grade power outlet with adequate grounding.

Power requirements

CoolWave Control Unit, Model 5000E (Europe):	220/240 V [+/- 10%] (4.25 A) Single phase 50 or 60 Hz
CoolWave Control Unit, Model 5000A (US):	110/120 V [+/- 10%] (8.5 A) Single phase 50 or 60 Hz

If required, an equal potential ground cable should be connected to the CoolWave Control Unit (Figure 1-16) and the appropriate ground.

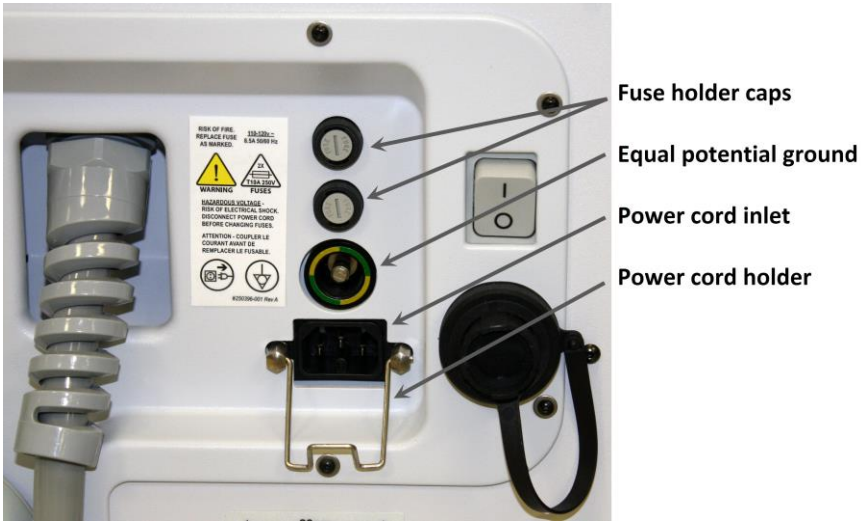


Figure 1-16. CoolWave Control Unit Rear

CoolWave Control Unit Power Cords

Urologix provides the following power cords for use with the CoolWave Control Unit.

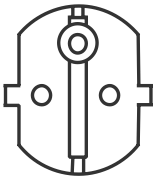
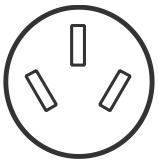
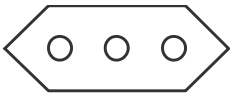
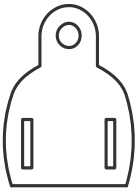
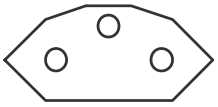
END VIEW	POWER CORD CATALOG NUMBER
	Catalog Number: AC1011 France Austria Germany Norway Belgium Sweden Netherlands Finland
	Catalog Number: AC1012 Australia New Zealand
	Catalog Number: AC1013 United Kingdom Ireland
	Catalog Number: AC1014 Denmark
	Catalog Number: AC1015 Italy
	Catalog Number: AC1017 Canada United States Mexico
	Catalog Number: AC1018 Switzerland

Table 1-4. CoolWave Control Unit Power Cords

Equipment connections

The CoolWave Control Unit must not be connected to any device other than the microwave catheter, rectal unit, or coolant bag. In addition, the microwave catheter, rectal unit, and coolant bag must not be connected to any other device or outlet.

Equipment testing

Turn the CoolWave Control Unit ON, and verify that the Login screen display appears. Do not use the CoolWave Control Unit if there are any irregular sounds or vibrations present.

Prior to beginning a Cooled ThermoTherapy treatment, verify that all components of the Procedure Kit (microwave catheter, RTU, and coolant bag) have arrived in a sealed condition.

1.8.2 Use Environment

Cautions:

- Do not stack any objects on top of CoolWave Control Unit, microwave catheter, RTU, or coolant bag.
- Do not place the CoolWave Control Unit near any electronic device or other equipment emitting electromagnetic waves. The interference may compromise the operation of the equipment.
- Provide ventilation space of at least 20-cm clearance around the base of the CoolWave Control Unit for operation.
- Do not turn ON the CoolWave Control Unit with the touchscreen monitor lid closed. The touchscreen will turn OFF, and the lid may become warm to the touch.
- Operate the CoolWave Control Unit on a level surface.
- Operate the CoolWave Control Unit under these operating conditions:
  An ambient temperature range of +10°C to +30°C,
  A relative humidity range of 30% to 75%,
  An atmospheric pressure range of 700 hPa to 1,060 hPa

1.9 Safety instructions

Warning: Do not open the housing of the CoolWave Control Unit. Doing so risks receiving an electric shock. Refer all CoolWave Control Unit servicing to qualified Urologix personnel.

Warning: Do not modify this equipment without authorization of the manufacturer.

Warning: This equipment is not intended for use in areas where there is a danger of explosion. Do not use the CoolWave Control Unit in the presence of flammable substances.

Caution: The CoolWave Control Unit must be operated by trained and authorized personnel. You should read and understand the instructions in this manual before operating the system.

This manual does not claim to address all of the safety concerns associated with the use of this equipment. You must establish appropriate safety and health practices prior to use.

Perform the following CoolWave Control Unit safety checks at least once every 12 months:

- Cables and connectors for damage
- Equipment for physical damage
- Safety labels are readable

Maintain a written record of these safety checks, and service any equipment that does not meet these standards.

2 Treatment Session Setup

2.1 General safety precautions

The CoolWave Control Unit is a medical device equipped with the ability to emit microwave radiation. Therefore, observe the following general safety precautions:

- The CoolWave Control Unit must only be installed and serviced by qualified service personnel.
- The CoolWave Control Unit may not be used for any purpose other than those for which it is designed and approved, and then only in accordance with this manual.
- The CoolWave Control Unit may be used only by authorized and properly trained personnel and the treating physician must be present throughout the duration of the Cooled ThermoTherapy treatment. The CoolWave Control Unit display must be monitored and controlled during the course of a treatment session to make sure that the urethral and rectal temperatures are within prescribed treatment parameters.
- The CoolWave Control Unit must never be left unattended when the machine is switched ON.

The CoolWave Control Unit is exclusively for use by physicians who have been trained.

The treating physician should be present at all times during treatment.

2.2 Treatment session setup overview

The treatment session requires several preparation steps. Some of these steps may be done concurrently.

- Preparing the patient for treatment.
- Positioning and preparing the CoolWave Control Unit.
- Installing the coolant bag.
- Inserting the microwave catheter.
- Inserting the single-use standard RTU, or inserting the RTU Plus with reusable handle and single-use balloon.
- Connecting the microwave catheter and RTU to the CoolWave Control Unit.

2.3 Preparing the Patient for Treatment

Ensure the patient has received adequate information about the treatment and post-treatment expectations and has provided informed consent.

Perform an enema 1 to 2 hours before treatment or per physician instructions.
An enema is mandatory.
Administer pre-treatment medications such as local anesthetics, antibiotics, non-steroidal anti-inflammatory agents, analgesics, or anti-anxiety medications (generally given 1 hour prior to the start of microwave power delivery). It is important that the patient not be over sedated. This may compromise his ability to communicate pain.

Note: Medications, such as anti-inflammatory agents, may be given to the patient at the discretion of the physician based on the patient's physical and mental well-being.

2.4 Positioning and preparing the CoolWave Control Unit

Position the CoolWave Control Unit on a level surface and close enough to the patient so that the patient connection cable connects easily to the microwave catheter and the RTU. Do not position the CoolWave system so that it is difficult to remove the electrical cord separable plug.

Lock the front wheels of the CoolWave Control Unit to prevent it from accidentally moving. To lock the wheels, use your foot to press down on the wheel lock tabs. To unlock the wheels, press on the back part of the wheel lock tabs.

Plug the CoolWave Control Unit electrical cord to a wall outlet. The connection requires a fully tested, hospital-grade power outlet with adequate grounding, and the power supply must meet the following specifications:

POWER REQUIREMENTS	
Control Unit, Model 5000E (Europe):	220/240 V [+/- 10%] (4.25 A) Single phase 50 or 60 Hz
Control Unit, Model 5000A (US):	110/120 V [+/- 10%] (8.5 A) Single phase 50 or 60 Hz

Warning: Do not move the CoolWave Control Unit while the electrical cord is connected to a power source.

Turn ON the CoolWave Control Unit and login to the system. Refer to *Section 3.2, CoolWave Control Unit setup***,** for further information.

Note: Turn ON the CoolWave Control Unit at least 5 minutes before treatment begins to allow the system to warm up.

Enter patient and clinical information on the Patient Information screen. Refer to *Section 3.3.1, Patient Information screen*, for further information.

Note: For first-time users, it may be helpful to read *Section 3.1, System Navigation and Screen Overview*, prior to entering patient and clinical information on the Patient Information screen.

2.5 Installing the Coolant Bag

Instruction Manual: Read the CoolWave Control Unit User Manual (this document) before installing the coolant bag.

Open the package containing the coolant bag, and remove the coolant bag.

Fill the coolant bag with 100 cc (± 5 cc) of sterile water by injecting the water into the female luer fitting of the coolant bag with a syringe (Figure 2-1).

Cautions: Use only sterile water in the coolant bag. Do not fill the coolant bag with saline solution. Saline solution has electrical properties that can interfere with microwave energy from the microwave catheter during treatment. Do not allow the coolant bag connectors to fall on the floor during installation.

Note: To prevent water from leaking out of the coolant bag once it has been filled; temporarily connect the coolant bag connectors together.

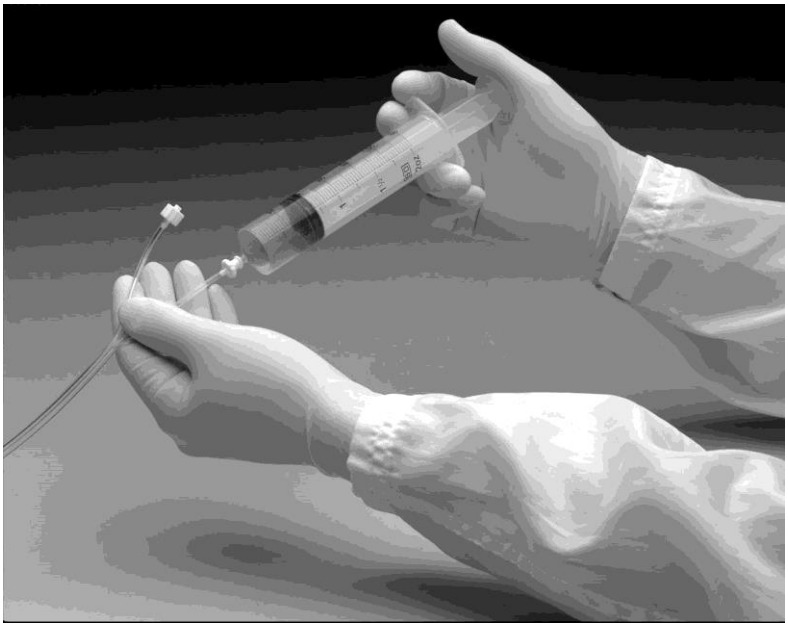


Figure 2-1. Filling the Coolant Bag

Open the coolant door on the right side of the CoolWave Control Unit by pulling the top of the door forward. Position the coolant bag over the chill plate by aligning the top two mounting holes of the coolant bag with the top two mounting pins on the chill plate. Gently position the coolant bag onto the pins (Figure 2-2).

Figure 2-2. Positioning the Coolant Bag onto the Top Mounting Pins

Position the bottom mounting hole of the coolant bag over the lower mounting pin below the chill plate to complete the process of installing the coolant bag (Figure 2-3).

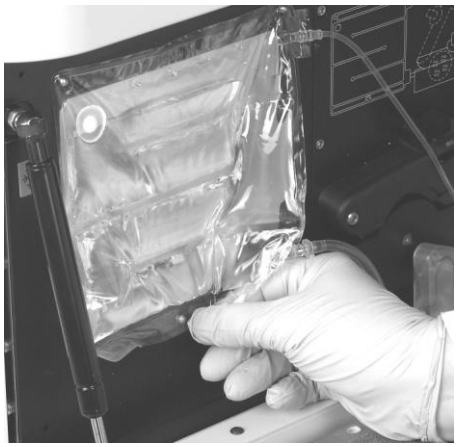


Figure 2-3. Positioning the Coolant Bag onto the Lower Mounting Pin

Route the coolant inlet tubing through the pump mechanism by pulling out the locking lever, located on the upper pump tubing clamp, and lifting the tubing clamp up (Figure 2-4).

Lay the coolant inlet tubing across the center of the pump mechanism. When the coolant bag is mounted correctly on the chill plate, the inlet tubing and sensor module are aligned with the pump mechanism (Figure 2-4).

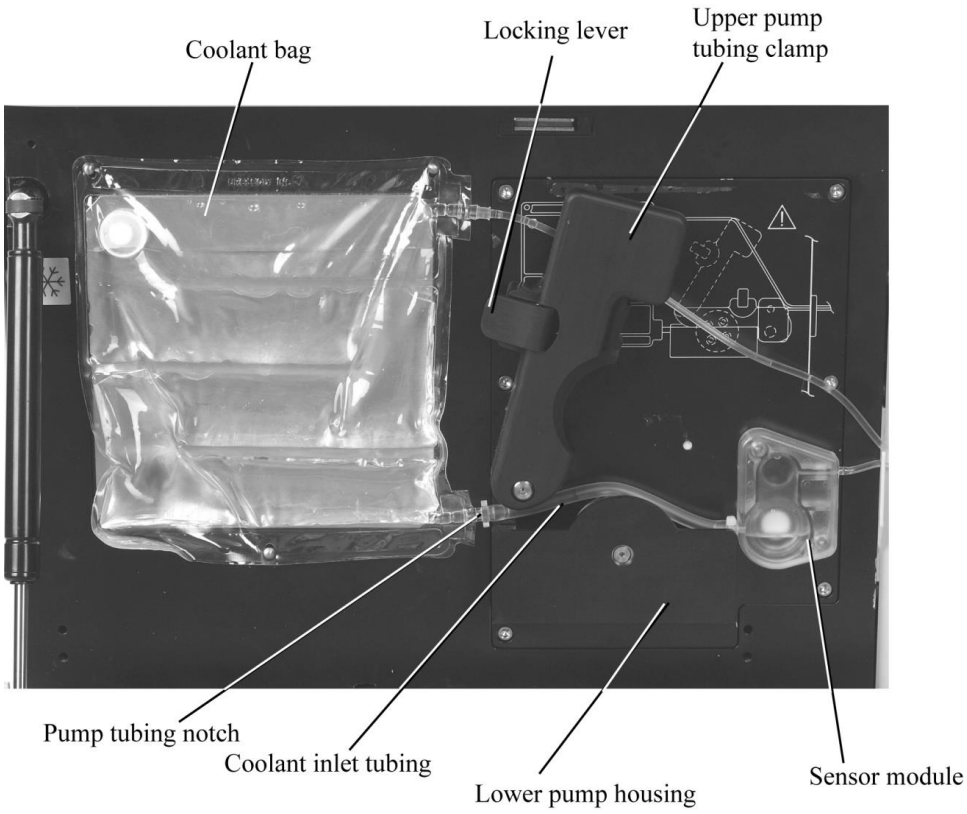


Figure 2-4. Coolant System with Pump Mechanism Open

Place the coolant inlet tubing under the upper pump tubing clamp and across the rotor of the pump mechanism (Figure 2-4).

Note: Ensure that the coolant inlet tubing is not twisted.

Align the sensor module with the locating pins to the right of the pump mechanism (Figure 2-5).

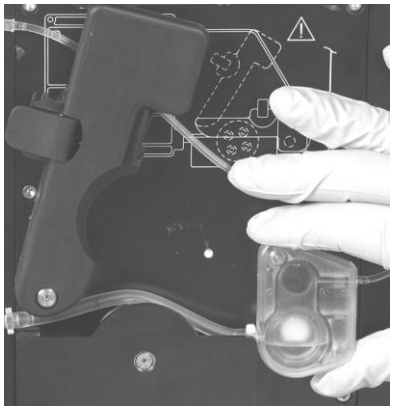


Figure 2-5. Positioning the Sensor Module

Ensure the coolant inlet tubing is properly seated in the notch of the lower pump housing. Then, firmly push down on the upper pump tubing clamp until it snaps into position (Figure 2-6).

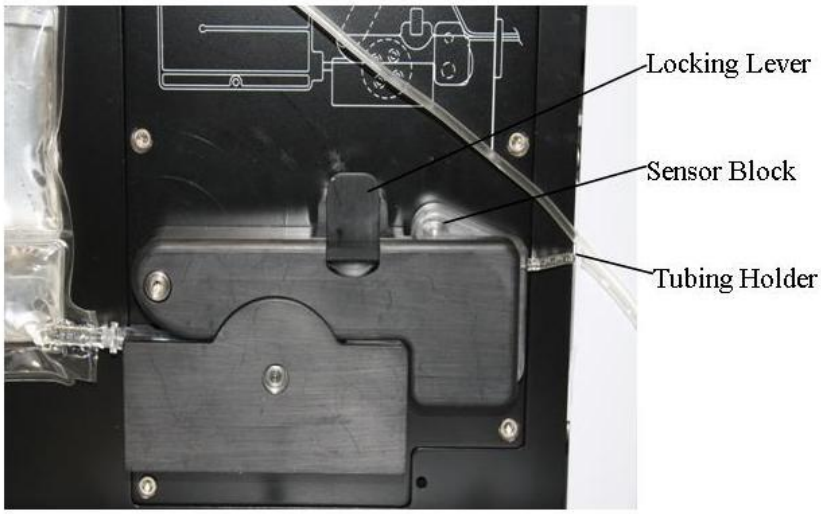


Figure 2-6. Coolant System with Pump Closed

Insert the coolant inlet and outlet tubing into the tubing holder. This will prevent the tubing from being pinched by the coolant door. Close the coolant door completely.

Note: The coolant delivered to the microwave catheter may not be at the desired temperature if the coolant door is not completely closed. In addition, a closed coolant door prevents damage to the coolant bag.

2.6 Inserting the Microwave Catheter

Drain the patient's bladder using only water-soluble lubricant in the process.
Instill an anesthetic mixture of choice into the bladder.
Insert a water-based anesthetic lubricant mixture of choice into the urethra, and clamp the penis to contain the lubricant mixture within the urethra for 20-30 minutes.

Warning: Do not overinflate the microwave catheter balloon. Overinflation may result in balloon malfunction and possible improper positioning of the microwave antenna. Underinflation can cause the antenna to be misplaced in the prostate, affecting the external sphincter.

Warning: Selection and use of the appropriate catheter model is required to assure patient safety. Verify that the correct catheter has been inserted in the patient using the catheter identifiers provided in Table 2-1. Microwave Catheter Identification.

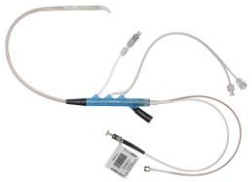
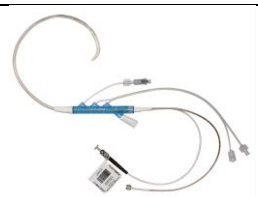
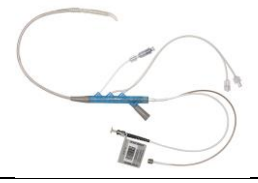
Microwave Catheter	**Prostatic Urethral Length**	**Catheter Color Scheme**	**Catheter Picture**	**Serial Number Tag Color**	**Serial Number Prefix**
CTC Advance - Short	2.5 to 3.5 cm	Blue Handle Black Accents		Black	TH
CTC Advance - Standard	3.0 to 5.0 cm	Blue Handle White Accents		White	TC
CTC Advance - Long	≥ 4.5 cm	Blue Handle Grey Accents		Grey	TF

Table 2-1. Microwave Catheter Identification

Note: The serial number label is attached to the cable of the microwave catheter near the connection to the patient cable.

Caution: The microwave antenna on the distal end of the microwave catheter may break if you bend it. Do not grab the microwave catheter or squeeze it in the area of the antenna or the shaft. The optical fiber located in the flexible shaft may be broken if it is clamped.

Open the package containing the microwave catheter (Figure 2-7). Test the location balloon by filling it with 10 cc of sterile water and examining it for leaks.

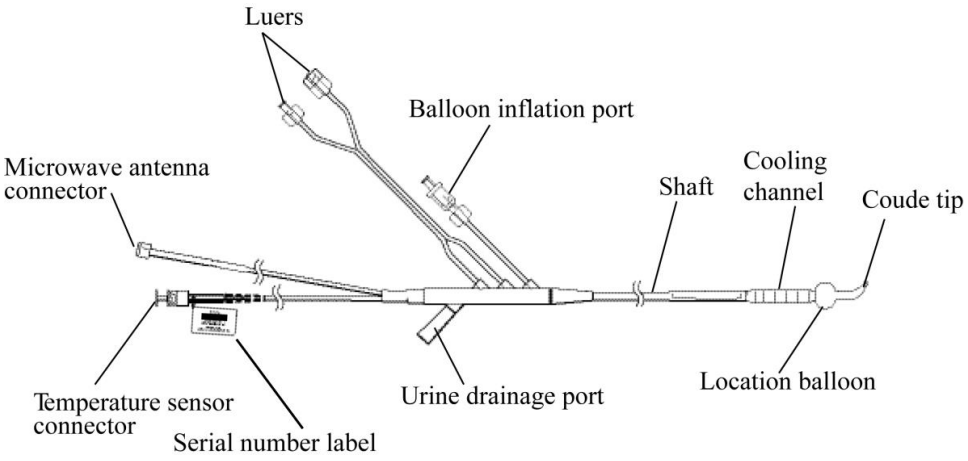


Figure 2-7. CTC Advance Microwave Catheter

Note: For this user manual, the representative microwave catheter is the CTC Advance Microwave Catheter.

Lubricate the microwave catheter with a water-based lubricant or local anesthetic.
Insert the microwave catheter into the patient's urethra until the location balloon is completely in the bladder. Align the microwave catheter so that the urine drainage port is pointed toward the patient's posterior and the coolant tubing is in an anterior orientation.

Warning: Avoid excessive force when pulling back on the microwave catheter to seat the balloon at the bladder neck. Excessive force could injure the patient or damage the catheter.

Inflate the location balloon with 10 cc of sterile water. Pull back on the microwave catheter until mild resistance is felt.

Flush the urine drainage lumen with 4-5 cc of sterile water. Insert a catheter plug (to retain bladder anesthetic, if used), or attach a urine drainage bag.

Note: Failure to flush the urine drainage lumen may cause system calibration errors.

Position the microwave catheter properly by pulling on it until the balloon is seated in the bladder neck, locating the microwave antenna within the preprostatic urethra (Figure 2-8). **Verify microwave catheter position with the ultrasound probe.**

Warning: Proper position of the location balloon is essential to patient safety.

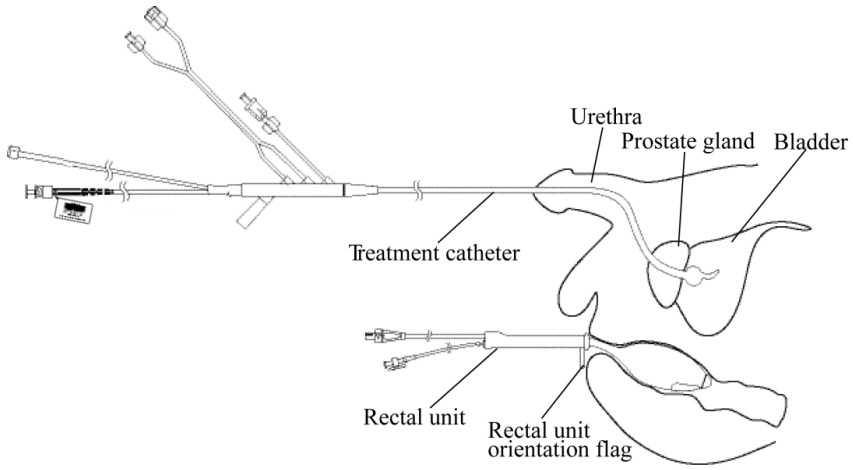


Figure 2-8. Inserted Microwave Catheter and Standard RTU

If the microwave catheter position is not acceptable, it may have to be rotated or reinserted. Push the catheter through the urethra until the tip and the location balloon is completely in the bladder. Rotate the microwave catheter, and then pull back until you feel mild resistance (Figure 2-8). Verify the microwave catheter position with ultrasound prior to proceeding with rectal unit insertion.

2.7 Inserting the Single-Use Standard RTU

Verify the patient has received an enema.
Open the package, and remove the rectal unit (Figure 2-9).

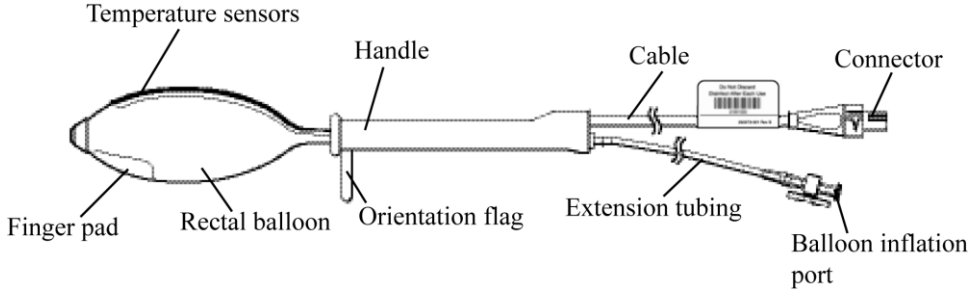


Figure 2-9. Standard RTU

Deflate the rectal balloon completely by attaching a 60 cc syringe to the inflation port and withdrawing air. The balloon should be deflated with the temperature sensors midline.

Lubricate the rectal balloon with a water-based lubricant (e.g. K-Y Jelly), and insert the balloon into the rectum with the index finger. Inserting the balloon can be done with the patient on his side or supine with knees bent. The temperature sensors must be oriented toward the prostate. The orientation flag must be pointing toward the patient's posterior.

Warning: The rectal unit must be positioned properly to ensure correct temperature sensing.

Inflate the rectal balloon by injecting 120 cc of air into the inflation port, located on the proximal end of the rectal unit. Adjust air volume for patient comfort to no less than 80 cc. Close the valve on the inflation port.
Re verify proper positioning of the rectal unit by observing that the orientation flag, located on the balloon, is facing away from the prostate and toward the patient's posterior.

Warning: A minimum of 80 cc of air in the standard RTU rectal balloon is required to maintain contact between the temperature sensors and the rectal wall.

Warning: This visual reference should be made every 5 to 10 minutes throughout the treatment to verify the proper position of the rectal unit. Failure to properly orient the rectal unit during treatment can result in patient injury (e.g. fistula or scrotal burn).

2.8 Inserting the RTU Plus Reusable Handle and Single-Use Balloon

Verify the patient has received an enema.
Open the package for the RTU Plus Reusable Handle, or obtain a disinfected RTU Plus Handle from a previous treatment (Figure 2-10). The RTU Plus Handle with the temperature sensors should not be used in more than 30 treatments.

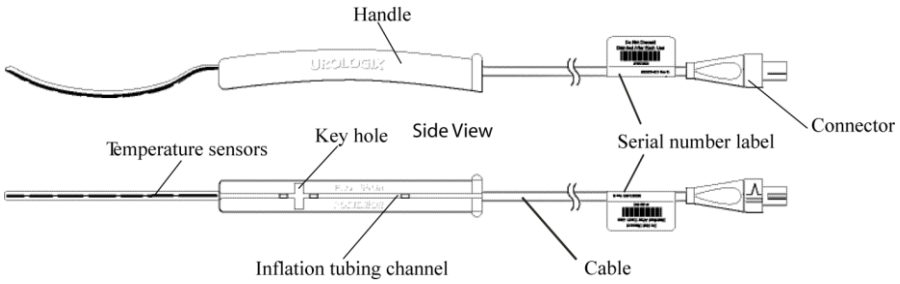


Figure 2-10. RTU Plus Reusable Handle

Open the package for a RTU Plus Disposable Balloon (Figure 2-11).

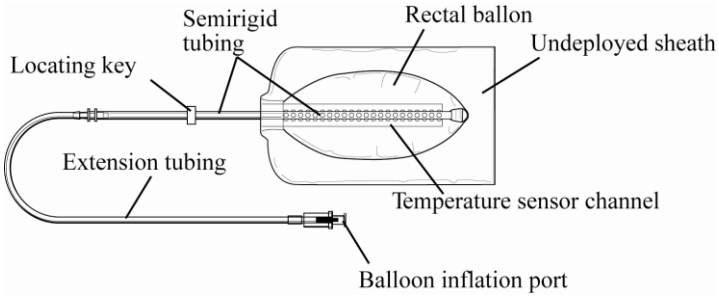


Figure 2-11. RTU Plus Disposable Balloon

Insert the temperature sensor strip into the sensor channel of the disposable balloon, as shown in Figure 2-12. Orient the sensors toward the outside of the balloon, and do not bend the temperature

strip significantly. The temperature sensor strip should extend to the distal end of the channel, and the temperature sensor channel should be aligned with the top side of the handle.

Figure 2-12. Inserting the Temperature Sensor Strip

Seat the balloon inflation tubing in the inflation tubing channel located in the base of the rectal unit handle. The locating key should snap into place within the handle key hole; if not, reorient/reassemble the device. The proper positioning of the temperature sensor strip in the disposable balloon is assured by the locating key/handle interaction (Figure 2-13).

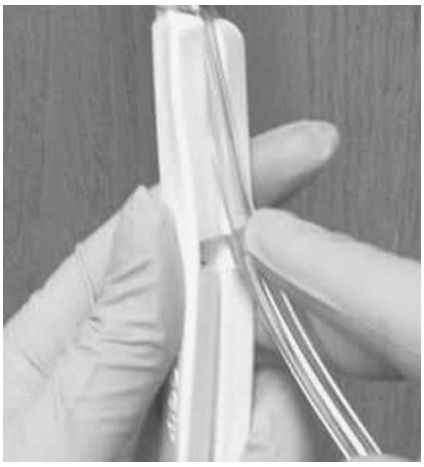


Figure 2-13. Proper Positioning of the Temperature Sensor Strip

Slide the protective sheath down from the balloon, and pull it over the handle as shown in Figure 2-14.

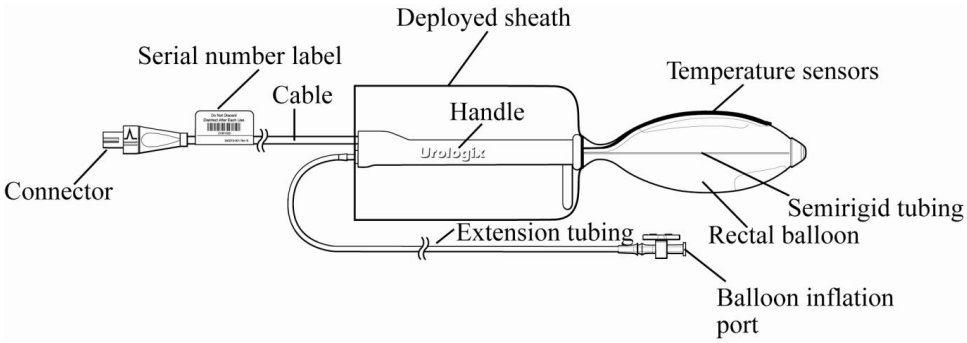


Figure 2-14. Assembled RTU Plus with Deployed Sheath

Attach a syringe to the inflation port, and inflate the balloon with approximately 90 cc of air to verify that no leaks are present. Remove all air to ensure that the balloon is completely deflated. Then, remove the syringe before proceeding to step 8.
Lubricate the balloon area with a water-based lubricant (e.g. K-Y® Jelly).

Warning: The rectal unit must be positioned properly to ensure correct temperature sensing.

Insert the balloon slowly into the rectum using the semirigid tubing to guide placement. This can be done by initially grasping the sensor/support tubing in the middle of the balloon area and slowly introducing the balloon into the rectum. Then, move the guiding hand back to the handle. Slowly advance the balloon while grasping the handle until the entire balloon is inserted. Inserting the balloon can be done with the patient on his side or supine with knees bent.

Note: The rectal temperature sensors must be oriented toward the prostate: The RTU Plus Reusable Handle is labeled anterior and posterior to help with placement.

Verify rectal unit orientation by confirming that the inflation tubing channel in the rectal unit handle (Figure 2-10) is facing towards the patient's posterior. Therefore, with the patient supine, the handle base would be against the treatment table surface with the Urologix logo visible on both sides of the handle. This orientation ensures that the temperature sensors of the RTU Plus are pointed towards the patient's anterior rectal wall nearest the prostate.

Warning: This visual reference should be made every 5 to 10 minutes throughout the treatment to verify the proper position of the rectal unit. Failure to properly orient the rectal unit during treatment can result in patient injury (e.g. fistula or scrotal burn).

Warning: A minimum of 70 cc of air in the RTU Plus rectal balloon is required to maintain contact between the temperature sensors and the rectal wall.

Inflate the rectal balloon by injecting 90 cc of air into the inflation port, located on the proximal end of the rectal unit. Adjust the air volume for patient comfort to 70 cc. Remove the syringe. The physician must confirm the proper positioning of the rectal unit prior to proceeding.

Note: When using an RTU Plus Reusable Handle, the Protocol screen will display the number of times the handle has been used and the number of remaining uses. The RTU Plus Reusable Handle should not be used in excess of 30 times.

2.9 Connecting the Microwave Catheter and Rectal Unit to the CoolWave Control Unit

Warning: Excessive elevation of the patient torso may put additional pressure on the rectal unit, resulting in increased patient discomfort and higher rectal temperatures.

If the rectal unit was placed in the rectum while the patient was on his side, reposition the patient supine, with head and shoulders at no greater than a 20º angle. This position relieves pressure on the rectal unit and increases patient comfort.

Pull gently on the microwave catheter to reseat the location balloon at the bladder neck in case it moved during rectal unit insertion. If ultrasound was not used to verify microwave catheter position prior to rectal unit insertion, use ultrasound at this point to verify proper microwave catheter position.

Position the rectal unit cable underneath the microwave catheter holder. Secure the microwave catheter into the microwave catheter holder, with the cooling lines in the anterior position, once the microwave catheter position is acceptable. If desired, position the patient's legs on the knee cushions that come with the Patient Comfort Kit. Refer to *Section 5.5, Patient Comfort Kit*, to view the accessories in the kit.

Make a mark, with a permanent marker or tape, on the microwave catheter at the meatus. Use this mark as a visual reference to confirm proper microwave catheter position.

Warning: This visual reference on the Microwave catheter and RTU should be checked every 5-10 minutes throughout the treatment to verify proper position.

Secure the microwave catheter fiber optic and microwave connectors to the patient connection cable housing (Figure 2-15).

Note: Rotate the Microwave Antenna Connector nut 4 full turns with your fingers until snug to ensure a proper connection.

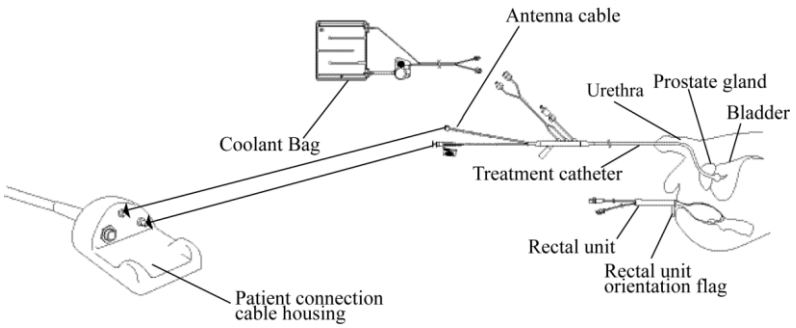


Figure 2-15. Connected Microwave Catheter and Rectal Unit

Connect the male luer fitting of the microwave catheter coolant tubing to the female luer fitting of the coolant bag tubing. Then, flush the female luer fitting of the microwave catheter coolant tubing with 4-5 cc of sterile water, and connect the microwave catheter to the coolant bag. This will preinflate the microwave catheter cooling channel.

Note: Place the Patient Connection Cable Housing unit on a non-metal surface. This will ensure the RFID field is not weakened.

Warning: Do not touch the antenna cable or the catheter handle while microwave power is ON. Touching the cable or the handle while microwave power is ON can cause burns as the CTC Advance antenna cable may reach up to 69.7 ºC at room temperature. To prevent burns during treatment, isolate the antenna cable and the catheter handle away from the patient's legs.

To reduce the risk of burns, isolate the antenna cable (Figure 2-15) and the catheter handle away from the patient's legs:

- Using the microwave catheter holder from the Patient Comfort Kit to secure the microwave catheter/antenna cable/handle location (Figure 2-16),
- If the microwave catheter holder is not available, place the antenna cable and handle between the patient's legs—not over the legs—and use a towel to isolate the legs and keep them from moving.
- Then, verify that the cable and handle are sufficiently isolated from the patient prior to beginning treatment

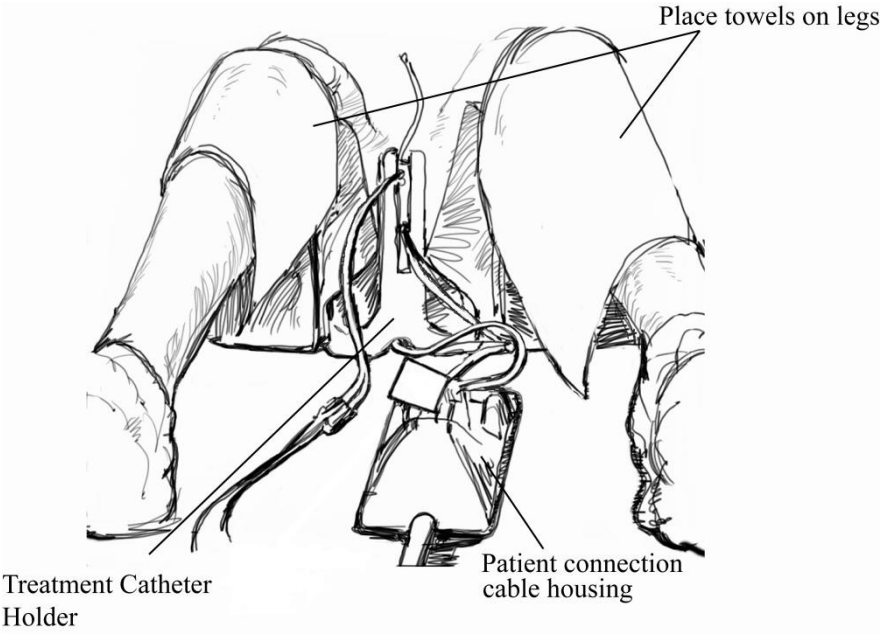


Figure 2-16. Isolate the Antenna Cable and Catheter Handle Using the Microwave Catheter Holder

Connect the rectal unit connector to the patient connection cable housing (Figure 2-17).

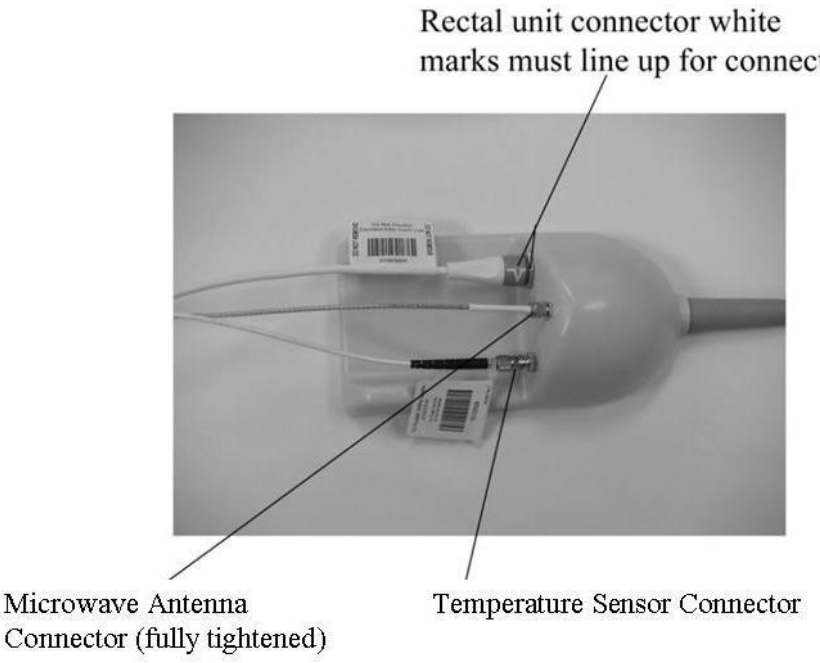


Figure 2-17. Patient Connection Cable Housing

If not already completed, attach a urine drainage bag to the urine drainage port of the microwave catheter.

Proceed to *Section 3, Treatment Instructions*, for information on how to perform a Cooled ThermoTherapy Treatment.

3 Treatment Instructions

3.1 System Navigation and Screen Overview

This section provides the information needed to navigate the CoolWave Control Unit as well as an overview of the screens, including demonstration mode. Please read this section prior to using the CoolWave Control Unit for the first time.

3.1.1 System Navigation

The CoolWave Control Unit includes a touchscreen monitor. This touchscreen monitor makes it easy to move around in the CoolWave Control Unit. Simply use your finger to gently press on the buttons on the screen. You will hear a “tick” sound when you press a button. You may also notice that a “pressed” button looks flat on the screen while a “nonpressed” button looks more 3-dimensional (Figure 3-1).

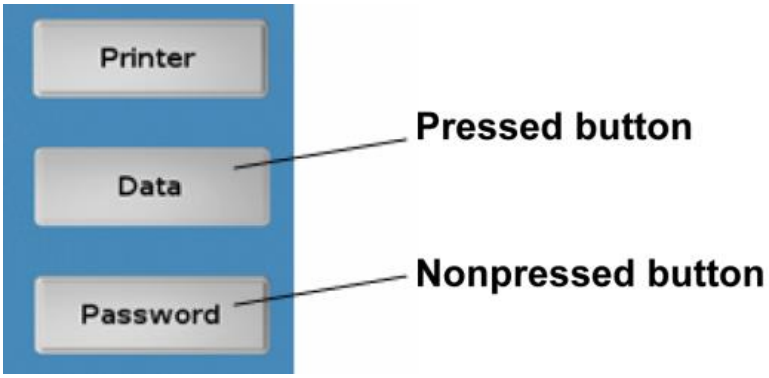


Figure 3-1. Pressed and Nonpressed Buttons

Some screens require entering information into a data field (Figure 3-2). Touch the screen in the desired data field, and when the cursor appears in that data field, use the keyboard to enter the requested information.

Note: You only need to touch the data field once with your finger to activate the operation of that field.

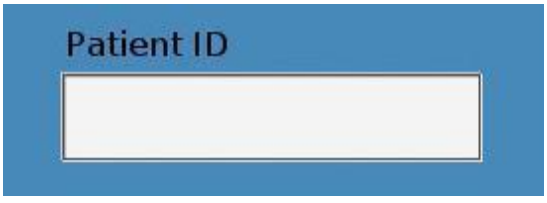
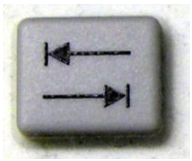


Figure 3-2. Data Field

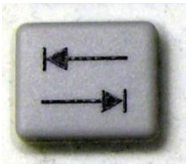
When you are done entering information, touch the screen in the desired data field or use the TAB key (or the TAB and SHIFT keys) to move from one data field to the next data field.



TAB KEY

Press the TAB key to move the cursor ahead to the next data field.

SHIFT KEY



TAB KEY

Press and hold the SHIFT key while pressing the TAB key to move the cursor back to the previous data field.

In addition, you will encounter dialog boxes as you use the CoolWave Control Unit. A dialog box provides additional information or instruction (Figure 3-3). When a dialog box appears on the screen, read the information or follow the instructions before continuing with the Cooled ThermoTherapy Treatment.

Figure 3-3. Example of a CoolWave Control Unit Dialog Box

Demonstration mode

If you are training on the CoolWave Control Unit, you will be in demonstration mode. Demonstration mode simulates a Cooled ThermoTherapy Treatment and allows you to work with the CoolWave Control Unit as though you were performing a treatment on a patient. Follow the instructions in *Section 3, Treatment Instructions,* and look for additional information regarding demonstration mode under the heading **Demonstration mode**.

3.1.2 Screen Overview

The following information appears on all of the CoolWave Control Unit screens, except for the Login screen: date, time, screen name, user name, and software version. Each screen, except for the Login screen, also contains access to the CoolWave Control Unit help feature, which contains the CoolWave Control Unit User Manual. In addition, on the treatment screens, you will find a Notes button. This button provides access to the notes feature where you can enter patient or treatment information (Figure 3-4).

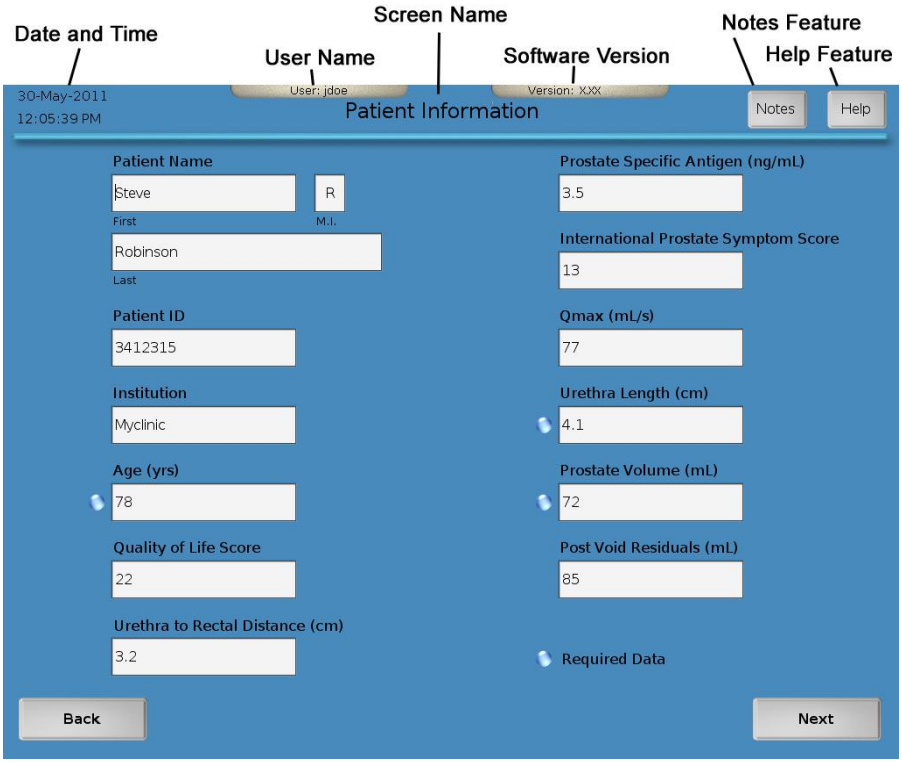


Figure 3-4. Screen Overview

Demonstration mode

A yellow bar at the top of the screen, with the text “Demonstration Mode,” signals that you are in demonstration mode (Figure 3-5.).

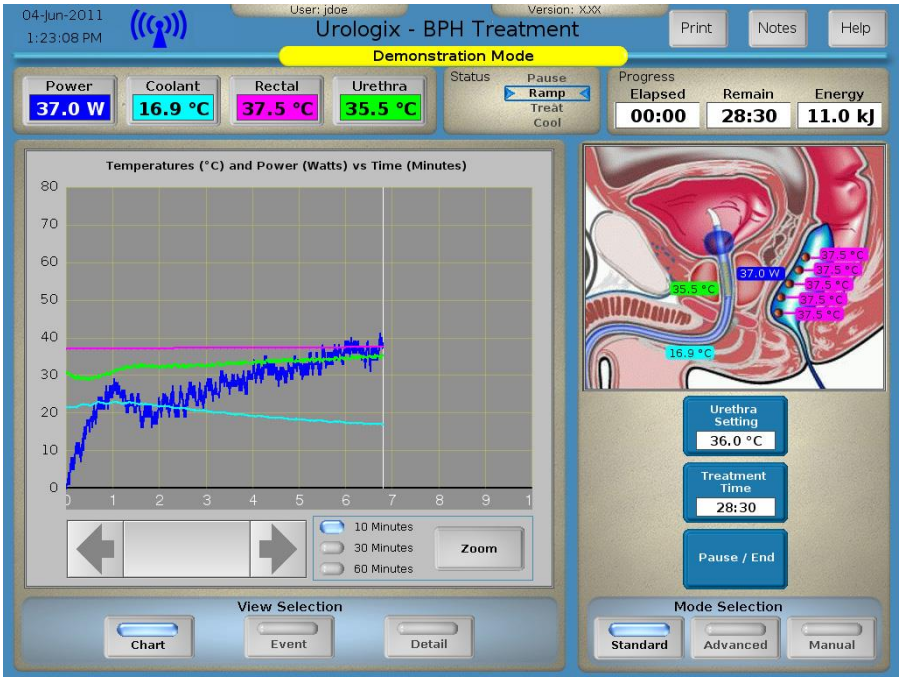


Figure 3-5. Example of a Treatment Screen in Demonstration Mode

3.1.2.1 Help

Note: If you receive an error message on the System Calibration screen, the System Error screen, or while on the Urologix - BPH Treatment screen, press the **Help** button to view information about the displayed error message.

1. Press the **Help** button. The Help window (Figure 3-6) appears containing the appropriate help information based on your location in the CoolWave Control Unit System software.

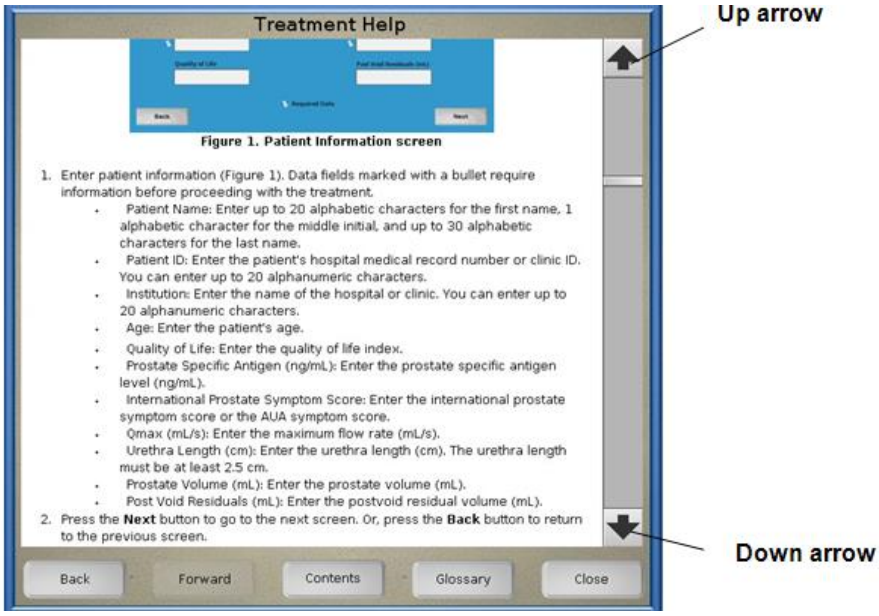


Figure 3-6. Help Window

2. Press the up and down arrows to scroll through the Help window. Or, press the **Back**, **Forward**, **Contents**, **Glossary**, or **Close** buttons to move through the help feature.
   - Press the **Back** button: Move back through the help topics viewed recently.
   - Press the **Forward** button: Move forward through the help topics viewed recently.
   - Press the **Contents** button: View the CoolWave Control Unit User Manual table of contents.
   - Press the **Glossary** button: View the CoolWave Control Unit User Manual index glossary.
   - Press the **Close** button: Close the Help window.

3.1.2.2 Notes

1. Press the **Notes** button. The Notes dialog box appears (Figure 3-7).

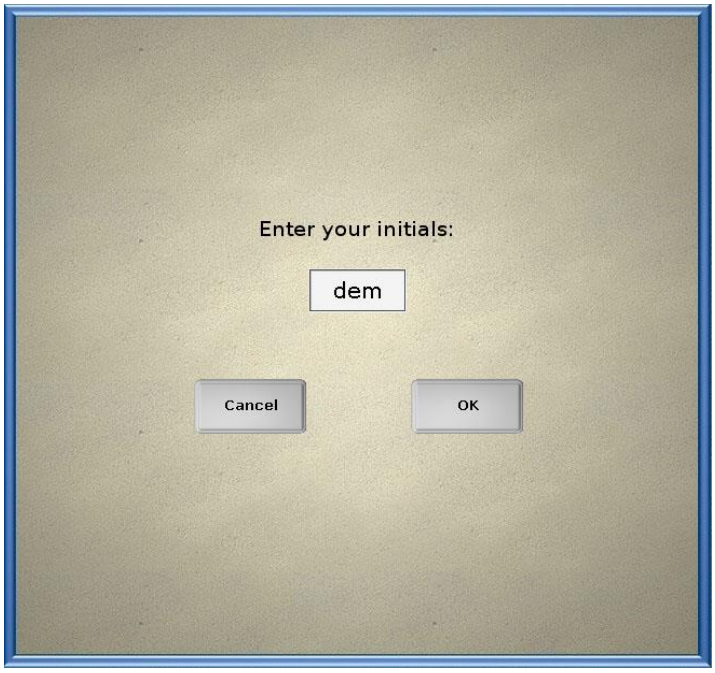


Figure 3-7. Notes Dialog Box

2. Enter your initials in the data field. You can use from 1 to 3 alphanumeric characters.
3. Press the **OK** button, and proceed to step 4. Or, press the **Cancel** button to exit the notes feature.
4. Enter patient treatment information in the Notes Entry window (Figure 3-8). Each time you access the notes feature throughout a treatment, you will see a date and time stamp, the elapsed time, and your initials. The elapsed time indicates the time since system calibration started, when you are on the System Calibration screen. Or, when on the Urologix - BPH Treatment screen, the elapsed time indicates the time since the treatment started. If you have not started system calibration or a treatment, then the elapsed time will be 00:00.

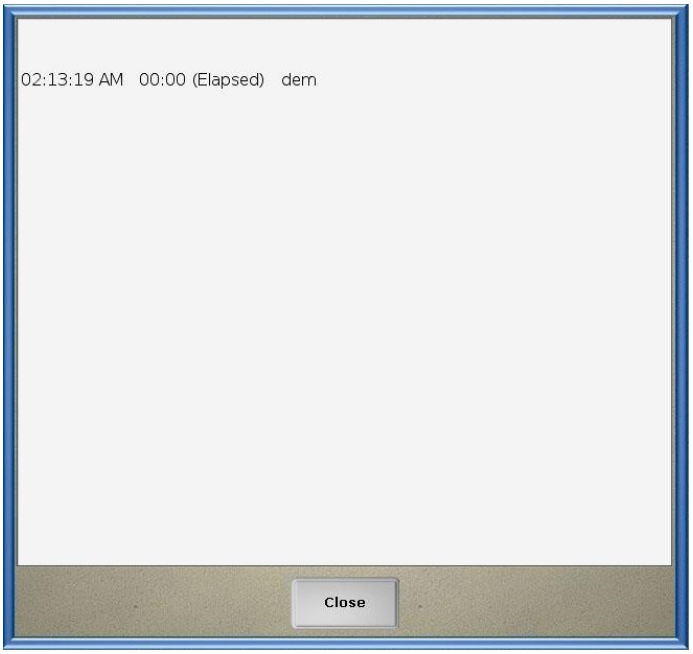


Figure 3-8. Notes Entry Window

5. Press the **Close** button when finished.

3.2 CoolWave Control Unit setup

Warning: Do not move the CoolWave Control Unit while the electrical cord is connected to a power source.

Note: Turn ON the Control Unit at least 5 minutes before the treatment begins to allow the system to warm up.

3.2.1 Turn ON the Control Unit

Press the ON/OFF power switch (located on the back of the unit, see Figure 1-6. ON/OFF power switch) to the "I" position. The CoolWave Control Unit turns ON and proceeds with its startup routine. The Login screen appears.

3.2.2 Login screen

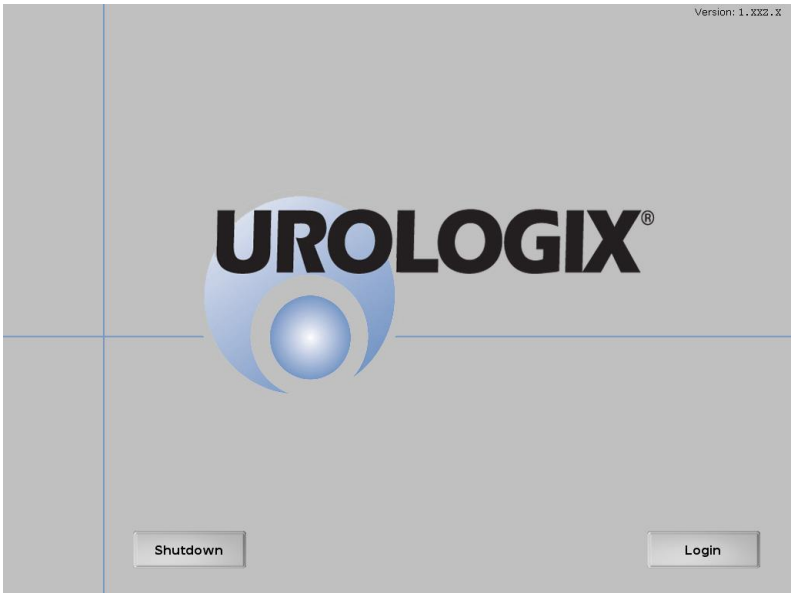


Figure 3-9. Login Screen

Note: You can turn OFF the CoolWave Control Unit at this point during system startup without losing any stored data by pressing the Shutdown button.

Note: Entering an invalid password returns you to the Login screen.

1. Press the **Login** button (Figure 3-9). The User Login window appears (Figure 3-10).

Figure 3-10. User Login Window

2. Determine if you are a new user or a current user. If you are a new user, proceed to step 3. If you are a current user, proceed to step 10.
3. Press the **New User** button. The Create New User window appears (Figure 3-11).

4. Enter your full name in the Full Name data field.

Figure 3-11. Create New User Window

5. Enter a user name in the User Name data field. Your user name, which is case sensitive, may contain from 3 to 20 alphanumeric characters.
6. Enter a password in the Password data field. Your password, which is case sensitive, may contain from 3 to 20 alphanumeric characters.
7. Re-enter your password in the Password Confirm data field.
8. Press the **OK** button to return to the Login screen. Your user name and password are saved. Proceed to step 9. Or, press the **Cancel** button to exit without creating a new user name and password.
9. Press the **Login** button (Figure 3-9). The User Login window appears (Figure 3-12).

Figure 3-12. User Login Window

10. Enter your user name, which is case sensitive, in the User Name data field.

11. Enter your password, which is case sensitive, in the Password data field.
12. Press the **OK** button to go to the Main Menu screen. Or, press the **Cancel** button to return to the Login screen.

Demonstration mode

To enter demonstration mode, type the following word as the user name and the password: Demo. The capitalization of the letter "D" in Demo is required.

3.2.3 Main Menu Screen

After logging into the CoolWave Control Unit, your user name and the software version appears at the top of the Main Menu screen (Figure 3-13).

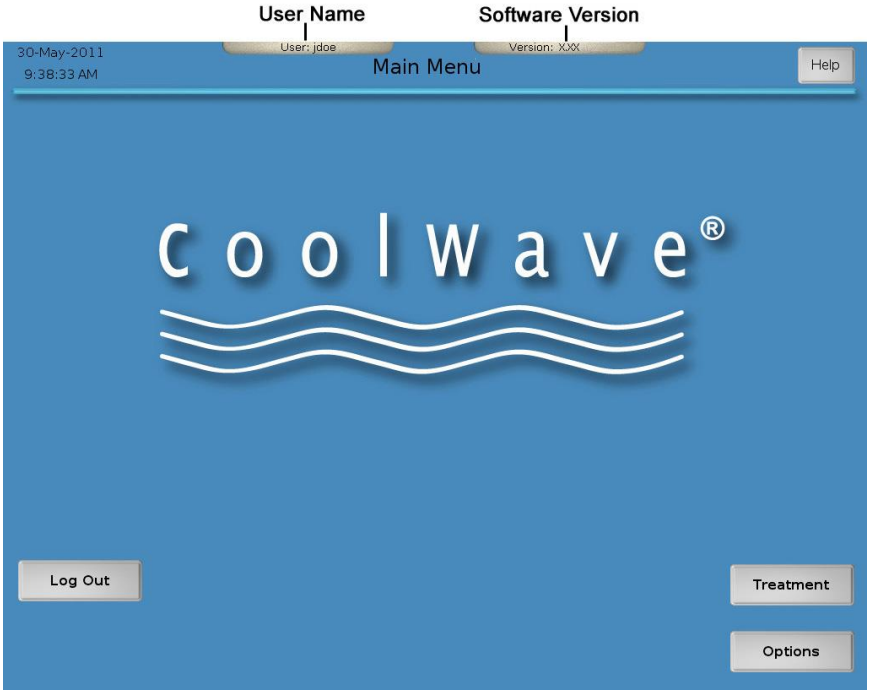


Figure 3-13. Main Menu Screen

Note: Turning OFF the Control Unit at this point during system startup will cause a loss of stored data. If necessary to shut down at this point, press Log Out and then Shutdown.

1. Press the **Treatment** button to proceed with a treatment. Refer to *Section 3.3, Cooled ThermoTherapy Treatment*, for further information.
2. Press the **Options** button to view CoolWave Control Unit system options. Refer to *Section 3.5, Control Unit options*, for further information.
3. Press the **Log Out** button to return to the Login screen. Refer to *Section 3.2.2, Login screen*, for further information.

3.3 Cooled ThermoTherapy Treatment

This section of the user manual steps you through a Cooled ThermoTherapy Treatment for Benign Prostatic Hyperplasia (BPH) using the CoolWave Control Unit. As you proceed through the various treatment screens described in this section, beginning with the Patient Information screen, you will be entering data and selecting treatment protocols. You may also be modifying the following treatment parameters:

- Treatment time: The treatment time reflects the length of time for a Cooled ThermoTherapy Treatment. The default treatment time is 28 minutes and 30 seconds.
- Coolant setting: The coolant setting reflects the set point (target) temperature at which the coolant flows through the microwave catheter. The default coolant setting temperature for the CTC Advance Microwave Catheter is 15°C.

The coolant temperature will ramp to its coolant setting temperature during a treatment.

- Urethra setting: The urethra setting reflects the set point (target) temperature of the microwave catheter. The default urethra setting temperatures for the CTC Advance Microwave Catheter are 40°C.
- Ramp rate: The ramp rate reflects the speed at which the microwave catheter and coolant temperatures change from their current values to their set point (target) values.

Then, once you reach the System Calibration screen, the calibration process begins. After the calibration process completes, the CoolWave Control Unit enters the automatic treatment mode. To learn more about the automatic treatment mode, and the manual treatment mode, please refer to *Section 3.7, Treatment modes*, for further information. Otherwise, proceed to *Section 3.3.1, Patient Information screen*, to begin the Cooled ThermoTherapy treatment.

SAFETY CHECKS DURING TREATMENT

IMPORTANT

It is critical that, throughout the patient's treatment, the treating physician verify the correct position of the microwave catheter and the RTU. Patient safety is at risk if the following simple and straightforward procedures are not correctly observed.

1. **Throughout the duration of the treatment, verify that the position mark on the catheter remains at a fixed distance from the penile meatus.**
2. **It is strongly recommended that at least every 5-10 minutes of the treatment, the correct position of the location balloon in the bladder be checked by transabdominal ultrasound. Document the action by placing the ultrasound in the permanent patient record.**
3. **Check the correct positioning of the rectal unit at least every 5 to 10 minutes to ensure the rectal unit has not moved.**
4. **Always immediately check microwave catheter and rectal unit placement if the patient complains of any abnormal or sudden increase in pain. Pause the treatment if the patient complains of serious pain.**
5. **Observe the treatment parameters for sudden changes in readings, especially decreases in temperatures that might indicate a sensor has moved from its previous position.**

Table 3-1. Safety Checks During Treatment

3.3.1 Patient Information screen

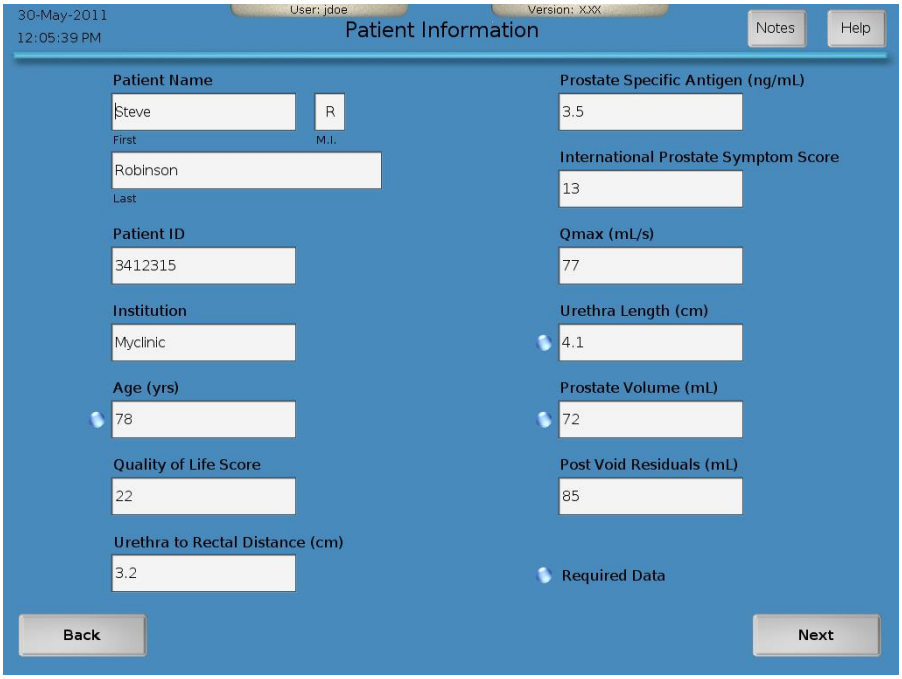


Figure 3-14. Patient Information Screen

1. Enter patient information (Figure 3-14). Data fields marked with a bullet require information before proceeding with the treatment.
   - Patient Name: Enter up to 20 alphabetic characters for the first name, 1 alphabetic character for the middle initial, and up to 30 alphabetic characters for the last name.
   - Patient ID: Enter the patient's hospital medical record number or clinic ID. You can enter up to 20 alphanumeric characters.
   - Institution: Enter the name of the hospital or clinic. You can enter up to 20 alphanumeric characters.
   - Age (yrs): Enter the patient's age in years. *This is a required field.*
   - Quality of Life Score: Enter the quality of life index.
   - Urethra to Rectal Distance (cm): Enter the distance from the patient's urethra to the rectal wall in cm, as measured by ultrasound.
   - Prostate Specific Antigen (ng/mL): Enter the prostate specific antigen level (ng/mL).
   - International Prostate Symptom Score: Enter the international prostate symptom score or the AUA symptom score.
   - Qmax (mL/s): Enter the maximum flow rate (mL/s).
   - Urethra Length (cm): Enter the prostatic urethra length (PUL) in cm, as measured from the bladder neck to verumontanum by ultrasound. The prostatic urethra length must be at least 2.5 cm. *This is a required field.*
   - Prostate Volume (mL): Enter the prostate volume (mL). *This is a required field.*
   - Post Void Residuals (mL): Enter the postvoid residual volume (mL).

2. Press the **Next** button to go to the next screen. Or, press the **Back** button to return to the previous screen.

Note: If any Patient Information entry is invalid, a dialog box will display (Figure 3-15), and the text that is invalid is highlighted in yellow.

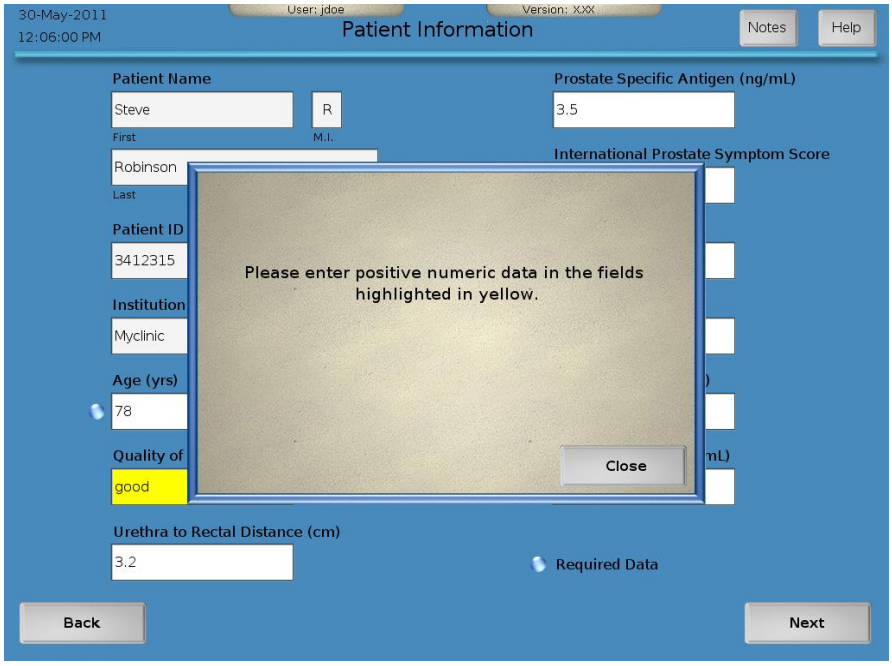


Figure 3-15. Patient Data Error Screen

Demonstration mode

Enter “dummy” text on the Patient Information screen. Be sure to include information in the data fields marked with a bullet.

3.3.2 Protocol screen

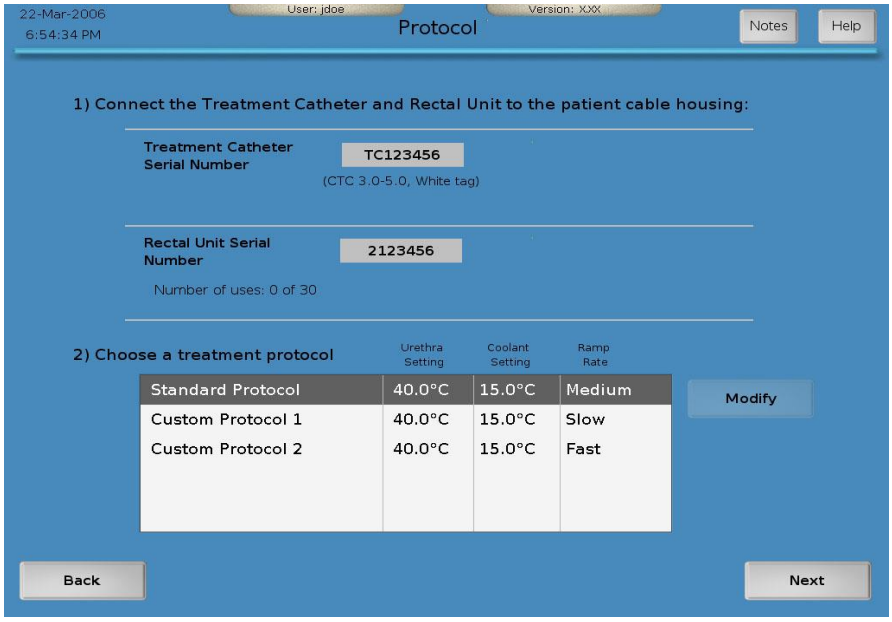


Figure 3-16. Example of a Protocol screen

Note: The RTU Plus Reusable Handle should not be used in excess of 30 times. The control unit will display the number of times the RTU Plus Reusable Handle has been used on the Protocol screen (Figure 3-16).

If the size of microwave catheter and the urethra length do not meet our requirements, a dialog box will display (Figure 3-17). The user will not be able to proceed through Treatment Protocol until the PUL and catheter are compatible.

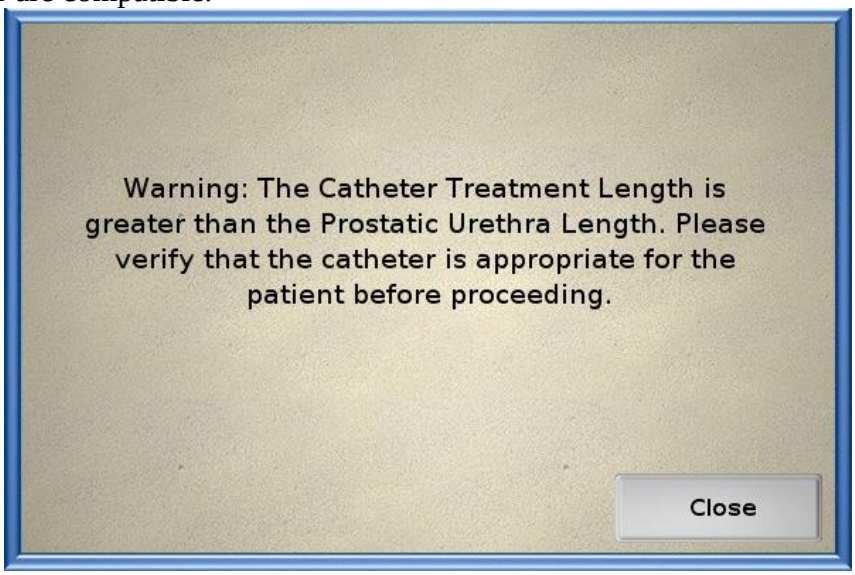


Figure 3-17. Warning Screen for Catheter Size Error

1. Connect the microwave catheter and the rectal unit to the Patient Connection Cable Housing if you have not done so already (refer to *Section 2.9, Connecting the Microwave Catheter and Rectal Unit to the CoolWave Control Unit***)**.

2. Verify that the CoolWave Control Unit automatically inserted the microwave catheter and rectal unit serial numbers in the appropriate data fields in step 1 on the Protocol screen (Figure 3-16).
   a) If both serial numbers appear in the data fields, proceed to step 3.
   b) If both serial numbers appear in the data fields, but the microwave catheter serial number indicates that a used catheter is connected to the system, a caution symbol appears. To use a new microwave catheter, refer to *Section 2.6, Inserting the Microwave Catheter*, for further information. Once a new microwave catheter is in place, the CoolWave Control Unit automatically reads the new serial number. Proceed to step 3.
   c) If both serial numbers appear in the data fields, but the rectal unit serial number indicates that the rectal unit has exceeded its maximum number of uses, a caution symbol appears. To use a new rectal unit, refer to *Section 2.7, Inserting the Single-Use Standard RTU*, or *Section 2.8 , Inserting the RTU Plus Reusable Handle and Single-Use Balloon*, for further information. Once a new rectal unit is in place, the CoolWave Control Unit automatically reads the new serial number. Proceed to step 3.

d) If one or both serial numbers do not appear in the data fields, then the treatment protocol list appears blank. Readjust the connectors, tags, and serial number labels (Figure 3-18) until the serial number(s) appear in the data field(s). Proceed to step 3.

Note: Placing the patient cable housing on a metal surface can reduce the RFID tag reading range of the antenna within the patient cable housing. Placing a folded disposable bed pad between the patient cable housing and the metal surface may resolve the issue.

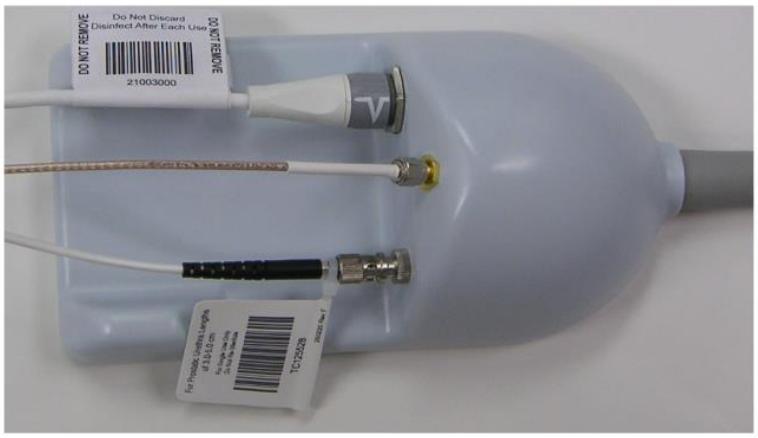


Figure 3-18. Readjust connectors, tags, and serial number labels

Warning: Selection and use of the appropriate catheter model is required to ensure patient safety. Verify that the correct catheter has been read by the Control Unit using the instructions provided in step 3.

3. Verify that the correct microwave catheter was read by the CoolWave Control Unit. The microwave catheter serial number and the description provided on the Protocol CoolWave screen must match the microwave catheter selected and inserted in the patient. The catheter can be verified using the information provided in Table 3-2.

Note: The serial number label is attached to the cable of the microwave catheter near the connection to the patient cable (Figure 3-18).

Note: The control unit will display a warning indicator if the microwave catheter is expired (Figure 3-19).

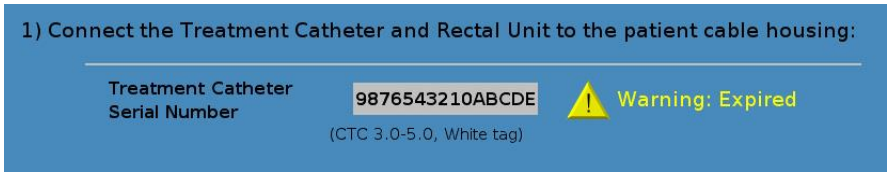


Figure 3-19. Expired Catheter Warning screen

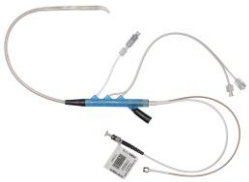
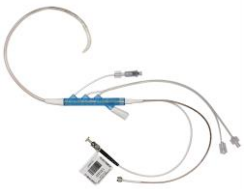
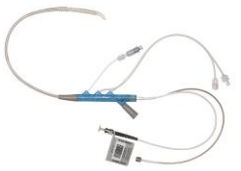
Microwave Catheter	**Prostatic Urethral Length**	**Catheter Color Scheme**	**Catheter Picture**	**Serial Number Tag Color**	**Serial Number Prefix**
CTC Advance - Short	2.5 to 3.5 cm	Blue Handle Black Accents		Black	TH
CTC Advance - Standard	3.0 to 5.0 cm	Blue Handle White Accents		White	TC
CTC Advance - Long	≥ 4.5 cm	Blue Handle Grey Accents		Grey	TF

Table 3-2. Microwave Catheter Identification

4. Select the desired treatment protocol, in step 2 on the Protocol screen, for your patient, and then press the treatment protocol name (Figure 3-16). Protocols can vary depending on the microwave catheter in use and user preference. The description next to each protocol defines first the urethra temperature, second the coolant temperature, and third the ramp rate; all treatment times default to 28 minutes and 30 seconds, though that time can be modified from the standard mode or advanced mode CoolWave Control Panel on the Urologix - BPH Treatment screen. In addition, a custom protocol is user defined and can be modified. To modify a custom protocol, proceed to step 5. Otherwise, proceed to step 8 to continue with the treatment.
5. Select a custom protocol, if you have not done so already, by pressing on the treatment protocol name. Then, press the **Modify** button (Figure 3-20).

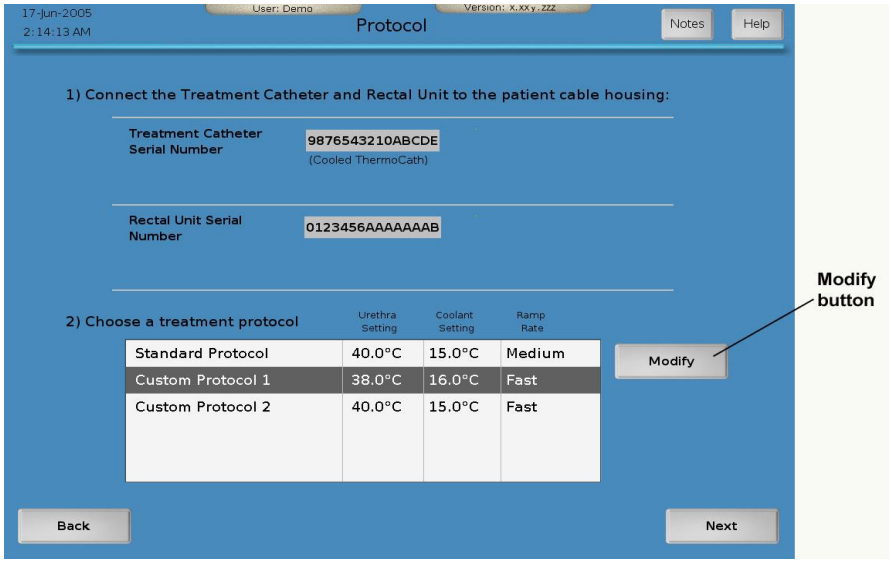


Figure 3-20. Example of Protocol screen - modify

6. Adjust the urethra setting, coolant setting, and ramp rate (Figure 3-21), as desired:

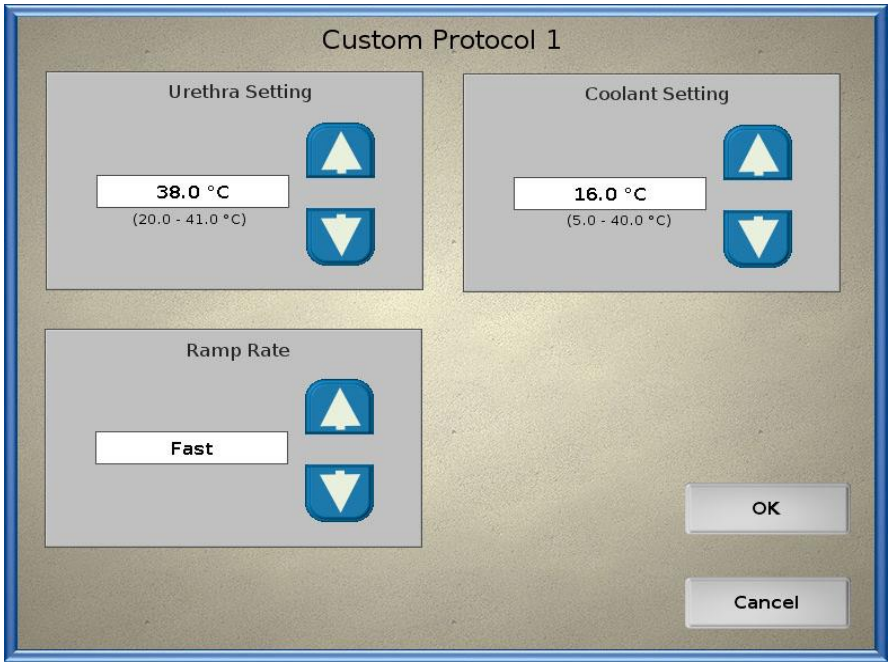


Figure 3-21. Example of treatment protocol - modify

Note: The treatment timer runs when the following conditions occur:

CTC Advance Short	CTC Advance Standard & Long
• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **50W** • OR: RTU >= **41°C**	• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **65W** • OR: RTU >= **41°C**

Table 3-3 Treatment Timer algorithms

a) Urethra setting: Press the up and down arrows to adjust the urethra setting temperature in 0.5°C increments. The default urethra setting temperature for the CTC Advance Microwave Catheter is 40°C.

b) Coolant setting: Press the up and down arrows to adjust the coolant setting temperature in 0.5°C increments. The default coolant setting temperature for the CTC Advance Microwave Catheter is 15°C.

The coolant temperature will ramp to its coolant setting temperature during a treatment.

c) Ramp rate: Press the up and down arrows to select the ramp rate: slow / medium / fast, (approximately 12 / 8 / 4 minutes, respectively)

7. Press the **OK** button to save the new treatment parameter(s). Or, press the **Cancel** button to return to the original treatment parameters for that protocol.
8. Press the **Next** button to go to the next screen. Or, press the **Back** button to return to the previous screen.

Demonstration mode

The CoolWave Control Unit will automatically fill in the microwave catheter serial number and rectal unit serial number data fields with simulated information. Start with step 4 above.

3.3.3 Treatment Checklist screen

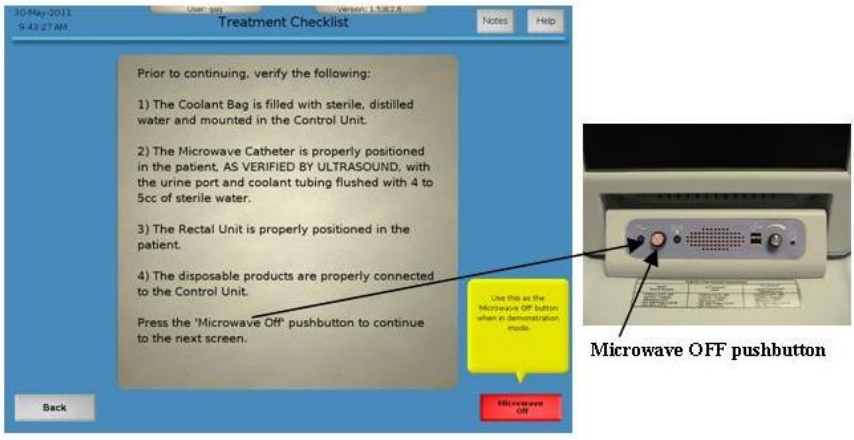


Figure 3-22. Treatment Checklist screen and Microwave Off pushbutton

1. Read the Treatment Checklist screen for information about the treatment (Figure 3-22). Prior to continuing this treatment, verify that all of these steps are complete.
2. Follow the instructions on the Treatment Checklist screen to go to the next screen. Or, press the **Back** button to return to the previous screen.

Note: When you press the **Microwave Off** pushbutton on the CoolWave Control Unit, the system will confirm that the **Microwave Off** pushbutton functions properly.

Demonstration mode

When in demonstration mode, you will not press the **Microwave Off** pushbutton. Instead, press the **Microwave Off** button on the Treatment Checklist screen (Figure 3-23).

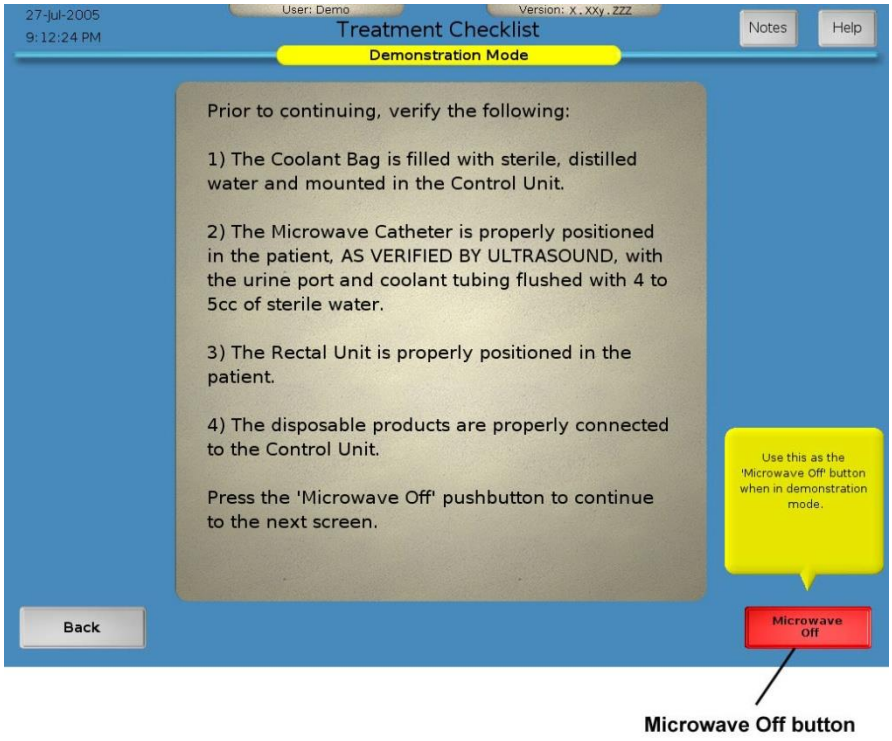


Figure 3-23. Treatment Checklist screen - Demonstration mode

3.3.4 System Calibration screen

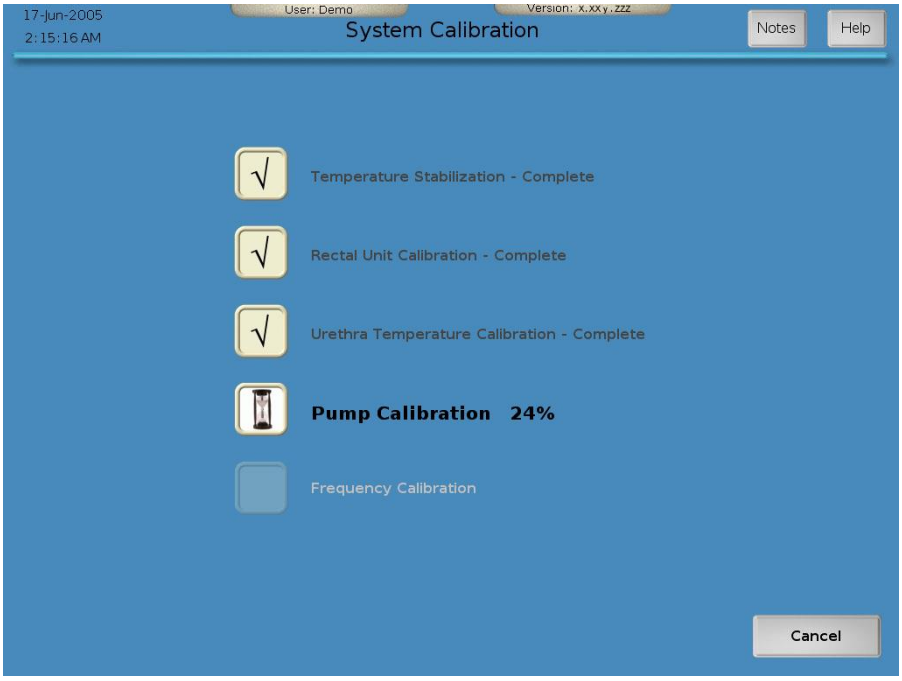


Figure 3-24. System Calibration screen

1. Wait while the Control Unit proceeds through a calibration process (can take up to 7 minutes) (Figure 3-24):
   - Temperature stabilization
   - Rectal unit calibration
   - Urethra temperature calibration
   - Pump calibration
   - Frequency calibration

   As each item in the list completes calibration, a checkmark appears in the box next to that item.
   a) Calibration completes successfully: Proceed to *Section 3.3.5, Urologix - BPH Treatment screen*, if the Control Unit completes the calibration process and automatically goes to the Urologix - BPH Treatment screen.
   b) Calibration does not complete successfully: An error message appears on the System Calibration screen. Proceed to step 2.
   c) Calibration needs to stop due to user needs: Press the **Cancel** button to stop the calibration process. An error message appears on the System Calibration screen. Proceed to step 2.
2. Read the System Calibration screen (Figure 3-25), and use the error message to resolve the problem. In addition, use one of the actions listed on the System Calibration screen to help you determine what to do next.

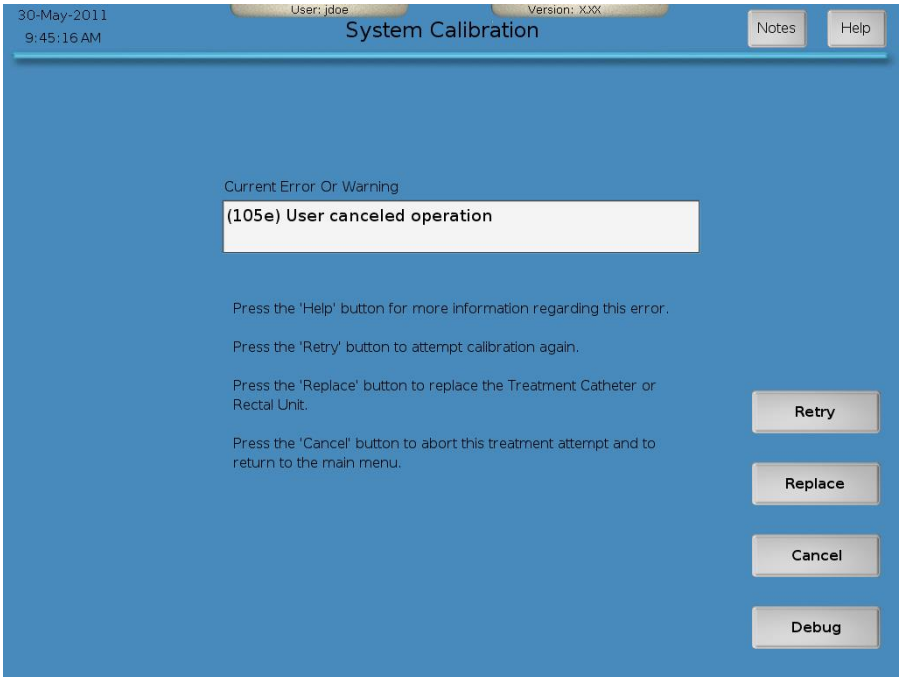


Figure 3-25. System Calibration Screen - Error Message

Notes:

- If a calibration error message appears, refer to *Section 5.1, Troubleshooting guide*, for further information.
- Before replacing a microwave catheter or rectal unit, contact Urologix Customer Service at 1-888-229-0772.

a) Press the **Help** button: Learn more about the error message and the appropriate response.
b) Press the **Retry** button: Attempt the calibration process again.
c) Press the **Replace** button: Replace the microwave catheter or the rectal unit, as needed. Refer to *Section 2.6, Inserting the Microwave , Section 2.7, Inserting the Single-Use Standard RTU*, or *Section 2.8, Inserting the RTU Plus Reusable Handle and Single-Use Balloon*, for further information. The CoolWave Control Unit returns you to the Protocol screen. Refer to *Section 3.3.2, Protocol screen*, for further information.
d) Press the **Cancel** button: Exit this treatment, and return to the Main Menu screen.
e) Press the **Debug** button: Display a panel of information to help in troubleshooting. See *Section 5.1, Troubleshooting guide*, for further information. At this point, contact Urologix Customer Service (1-888-229-0772) to help you resolve any remaining errors.

3.3.5 Urologix - BPH Treatment screen

The Urologix - BPH Treatment screen allows you to monitor patient progress during the treatment. If you need to make any adjustments to the treatment parameters, make those adjustments from this screen. Otherwise, treatment proceeds automatically based on the selected treatment protocol. If a caution or error occurs during treatment, a caution icon or error icon appears in the blue bar at the top of the screen (Figure 3-26). If there is an emergency, press the red **Microwave Off** pushbutton (Figure 3-27), located under the touchscreen monitor and right of the green LED, to immediately turn the microwave power OFF.

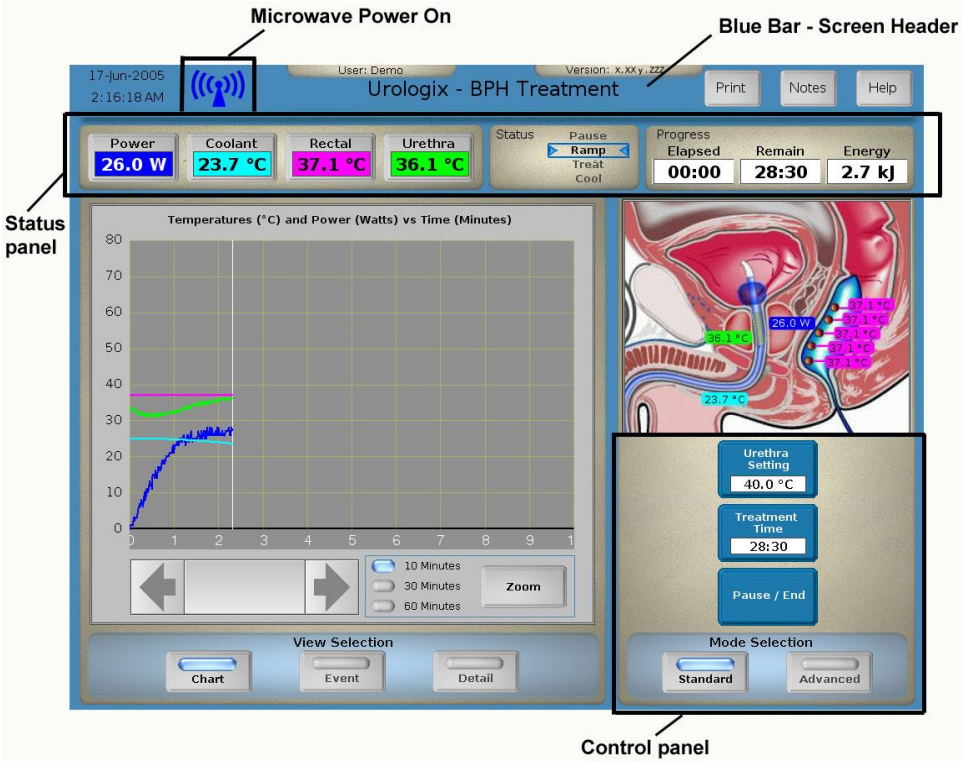


Figure 3-26. Urologix - BPH Treatment screen

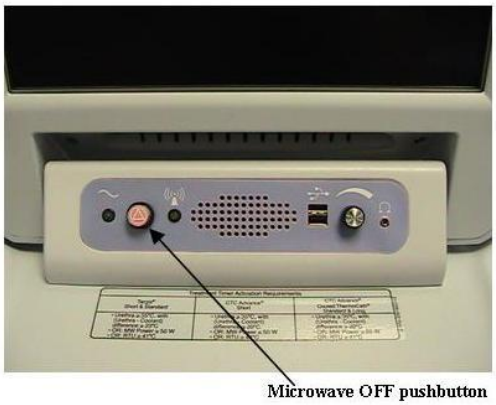


Figure 3-27. Microwave Off Pushbutton

1. View treatment data in the Status Panel at the top of the Urologix - BPH Treatment screen (Figure 3-26).
   - Power: Displays microwave power in watts, measured at the patient connection cable. When power is ≥1 W, an animated microwave power ON graphic appears and the amber LED, located to the right of the red **Microwave Off** pushbutton, lights.
   - Coolant: Displays coolant temperature in °C as measured by the Coolant Bag sensor. If the coolant pump is turned OFF, this reading will gradually approach room temperature.
   - Rectal: Displays the warmest of the 5 rectal temperatures in °C.
   - Urethra: Displays the urethra temperature in °C.
   - Status: Highlights status as pause (treatment OFF), ramp (system preparing for treatment), treat (treatment ON), or cool (cooldown ON).
   - Progress: Displays treatment time (minutes:seconds) elapsed, treatment time (minutes:seconds) remaining, and energy (kilojoules). Treatment time elapsed, also referred to as the treatment timer, is defined by the following algorithms:

CTC Advance Short	CTC Advance Standard & Long
• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **50W** • OR: RTU >= **41°C**	• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **65W** • OR: RTU >= **41°C**

Table 3-4. Treatment Timer algorithms

Treatment time remaining is calculated by subtracting the current elapsed treatment time from the treatment time setting. You can tell, from the time remaining, when the CoolWave Control Unit will enter cooldown.

2. View treatment details at the left side of the Urologix - BPH treatment screen.
   a) Press the **Chart** button: View the microwave power, coolant temperature, rectal temperature, and urethra temperature for this treatment in a scrolling strip chart format (Figure 3-28). The colors of each trace on the chart correspond to the color of the item in the Status Panel: The white vertical line indicates the current values and the end of the chart. Press the left and right arrows to scroll left and right through the chart. The **Zoom** button allows you to view this information in a 10 minute view, a 30 minute view, or a 60 minute view.

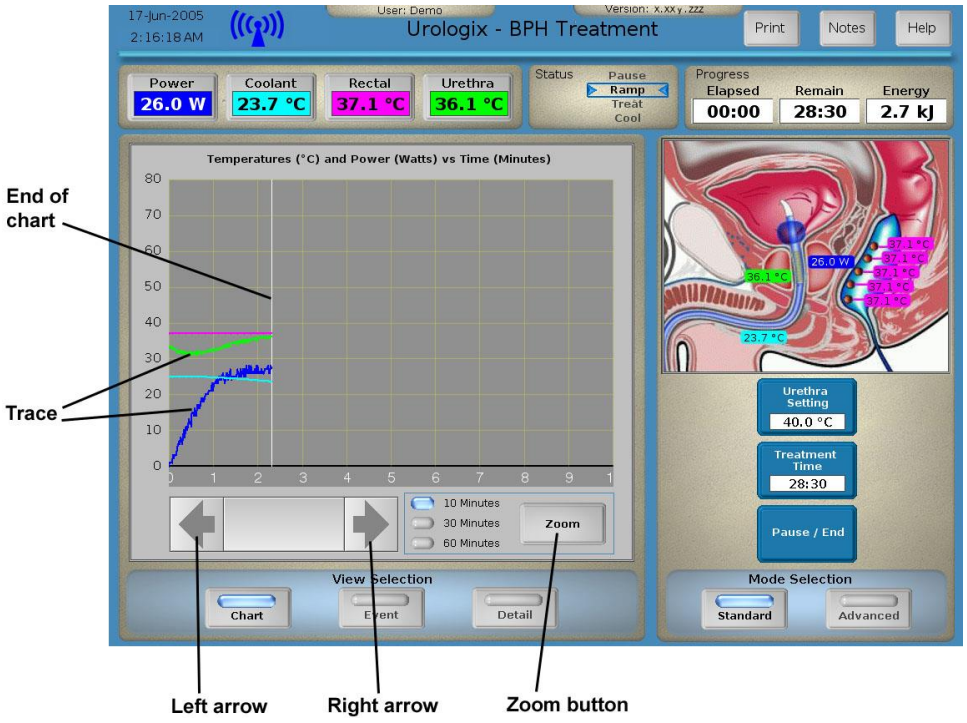


Figure 3-28. Chart pane

b) Press the **Event** button: View the treatment event log: events, errors, and warnings (Figure 3-29). Press the up and down arrows to scroll through the log. You can also view the current error or warning (listed in priority order, errors first) in the Current Error or Warning window. To reset current errors and warnings, press the **Reset** button. If the system does not return to the treatment and an error remains, refer to *Section 5.1, Troubleshooting guide*, for further information. For additional information about system errors, refer to *Section 3.6, System errors*.

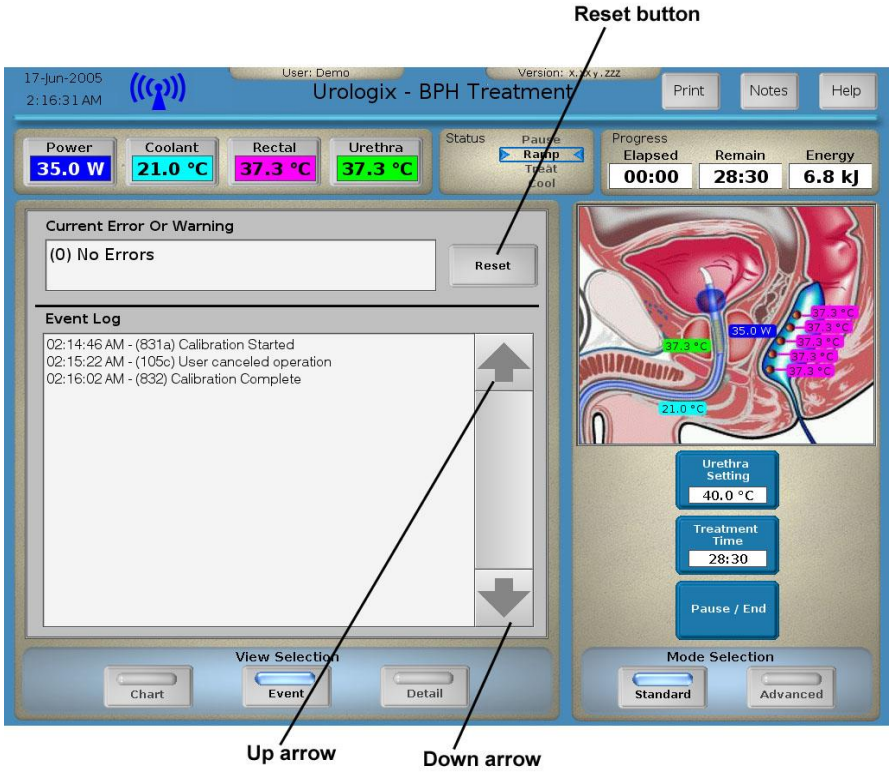


Figure 3-29. Event pane

c) Press the **Detail** button: View a detailed overview of the microwave power, coolant temperature, rectal temperature, and urethra temperature for this treatment (Figure 3-30). This overview also highlights current warnings and errors: An active error is marked with a red light. To reset warnings and errors, press the **Reset** button. For additional information about system errors, refer to *Section 3.6, System errors*.

Note: The Detail button provides a detailed overview of the CoolWave Control Unit and its settings. A typical treatment does not require access to this overview. However, you may need to view this information if an error occurs and does not resolve. At this point, contact Urologix Customer Service (1-888-229-0772) to help you resolve any remaining errors.

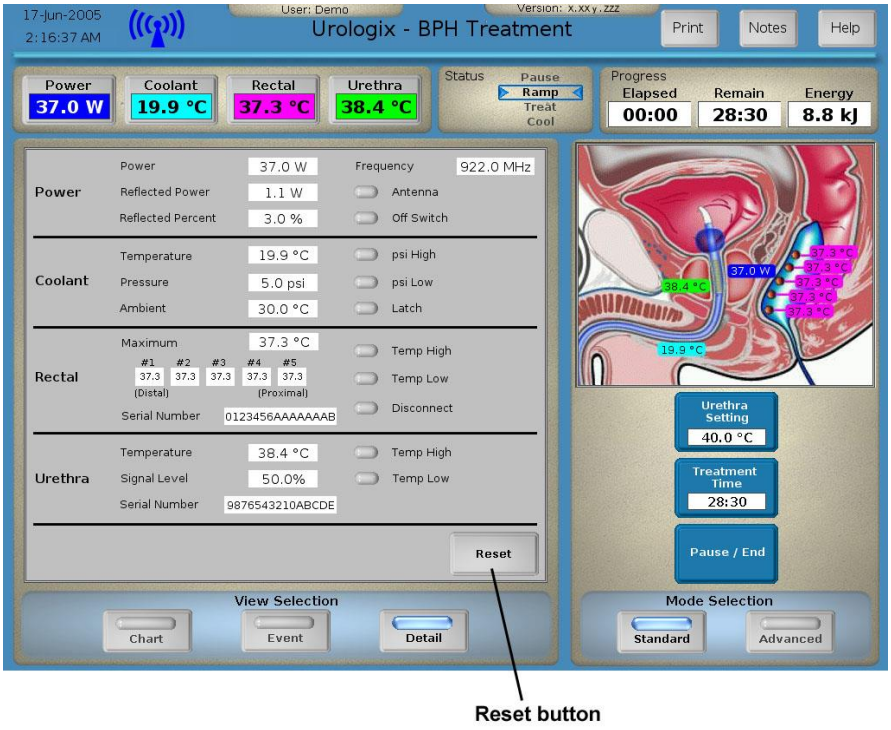


Figure 3-30. Detail pane

Power section

Power	The current measured microwave power
Reflected Power	The amount of power reflected from the antenna
Reflected Percent	The reflected power measured in percent
Frequency	The current operating frequency
Antenna	The antenna efficiency error indicator
Off Switch	The microwave off button indicator

Coolant section

Temperature	The temperature read by the coolant sensor
Pressure	The pressure read by the pressure sensor
Ambient	The temperature inside the control unit
psi High	The high pressure error indicator
Psi Low	The low pressure error indicator
Latch	The pump latch error indicator

Rectal section

Maximum	The highest reading of the five rectal sensors
#1 through #5	The individual rectal sensor readings
Serial Number	The serial number read from the RFID tag. Note: this field is blank if the RFID tag is not currently being read
Temp High	The high temperature error indicator
Temp Low	The low temperature error indicator
Disconnect	The rectal sensor disconnect error indicator

Urethra section

Temperature	The temperature read by the urethra sensor
Signal Level	A measure of the urethral sensor's optical loss. Higher readings may indicate a dirty or damaged fiber-optic connector
Serial Number	The serial number read from the RFID tag. Note: this field is blank if the RFID tag is not currently being read
Temp High	The high temperature error indicator
Temp Low	The low temperature error indicator

3. View treatment data in a diagram format at the right side of the Urologix - BPH Treatment screen (Figure 3-31).

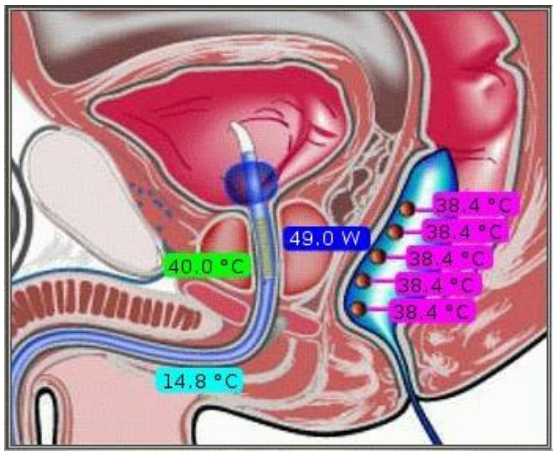


Figure 3-31. Treatment diagram

4. Press the **Print** button, located in the upper right corner of the Urologix - BPH Treatment screen. Then, select one of the following print options: Print Treatment Report, Print Event Log, and Clear Print Queue (Figure 3-32). Or, press the **Close** button to return to the Urologix - BPH Treatment screen.

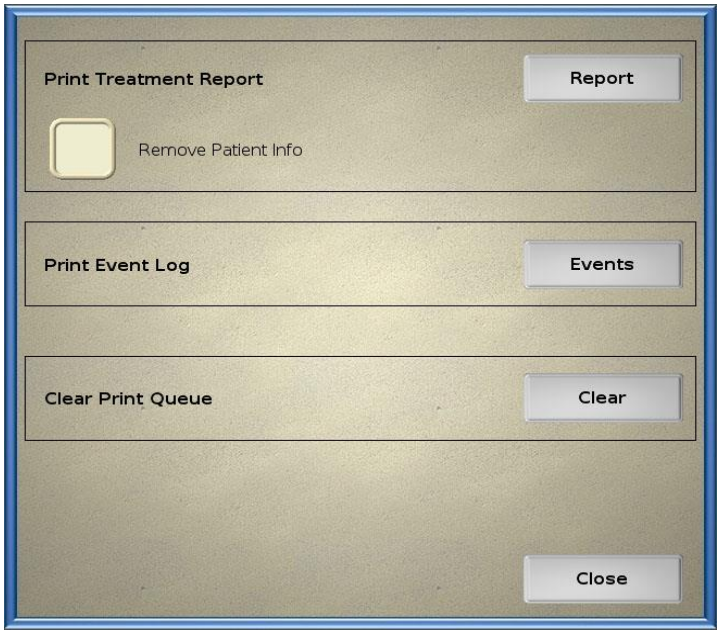


Figure 3-32. Print window

Note: Refer to *Section 4.3, Maintaining the printer* (Figure 4-3), for a printer overview.

a) Print Treatment Report: Press the **Remove Patient Info** button (optional) to remove a patient's name from a treatment report. A check mark appears in the button. Turn the printer ON, load paper, if needed, into the printer, and press the **Report** button. (However, if you pressed the **Report** button and paper was not in the printer, the printer flashes 1 long green and 2 short orange lights. Insert paper into the printer, and press the Resume/Cancel button on the printer.) The CoolWave Control Unit automatically returns to the Urologix - BPH Treatment screen while the treatment report prints. The report includes the following information:
   - Patient data
   - Treatment protocol data
   - Treatment data
   - Treatment chart
   - Event log
   - Case notes

b) Print Event Log: Turn the printer ON, load paper, if needed, into the printer, and press the **Events** button to print the event log. (However, if you pressed the **Events** button and paper was not in the printer, the printer flashes 1 long green and 2 short orange lights. Insert paper into the printer, and press the Resume/Cancel button on the printer.) The CoolWave Control Unit automatically returns to the Urologix - BPH Treatment screen while the event log prints.

c) Clear Print Queue: Press the **Clear** button to clear the print queue. The CoolWave Control Unit automatically returns to the Urologix - BPH Treatment screen while the print queue clears.

5. Select one of the following options to view and adjust treatment parameters:
   a) Press the **Standard** button on the Control Panel: View the controls for the urethra temperature and the treatment time. Refer to *Section 3.3.5.1, Using standard mode*, for further information.
   b) Press the **Advanced** button on the Control Panel: View the controls for the urethra temperature, treatment time, coolant temperature, and ramp rate. Refer to *Section 3.3.5.2, Using advanced mode*, for further information.
   c) Press the **Manual** button on the Control Panel: View the controls for microwave power, coolant pump ON/OFF, coolant temperature, and ramp rate. Refer to *Section 3.3.5.3, Using manual mode*, for further information.

   Note: If you do not have access to the manual treatment mode, you will not see this option on the Control Panel.

6. Press the **Pause/End** button on the Control Panel to pause a treatment or end a treatment early (before the treatment time expires). Refer to *Section 3.3.5.4, Pausing a treatment or ending a treatment early*, for further information.
7. Continue with the treatment until the treatment time ends and the Treatment Cooldown window (Figure 3-33) appears: Treatment is now complete. Refer to *Section 3.3.5.5, Ending a treatment*, for further information.

Figure 3-33. Treatment Cooldown window

3.3.5.1 Using standard mode

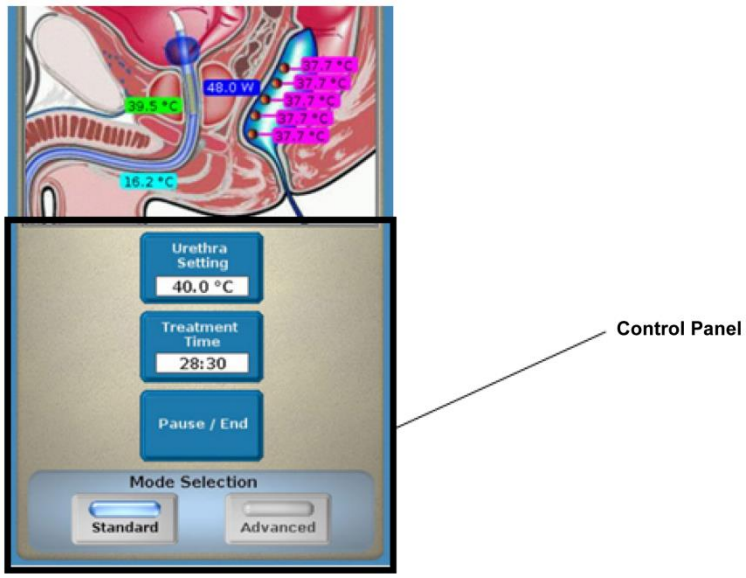


Figure 3-34. Standard mode

Adjust the urethra setting and treatment time from the Control Panel (Figure 3-34), if desired:

Note: The treatment timer runs when the following conditions occur:

CTC Advance Short	CTC Advance Standard & Long
• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **50W** • OR: RTU >= **41°C**	• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **65W** • OR: RTU >= **41°C**

Table 3-5 Treatment Timer algorithms

- Press the **Urethra Setting** button: Press the up and down arrows to adjust the urethra setting temperature in 0.5°C increments. The default urethra setting temperature for the CTC Advance Microwave Catheter is 40°C. Press the **Close** button when done.
- Press the **Treatment Time** button: Press the up and down arrows to adjust the treatment time in 30 second increments (Figure 3-35). Press the **Close** button when done.

Note: In automatic treatment mode , the treatment time is limited to 28 minutes and 30 seconds for the CTC Advance Microwave Catheter.

Figure 3-35. Example of a Treatment Parameter Control Panel

3.3.5.2 Using advanced mode

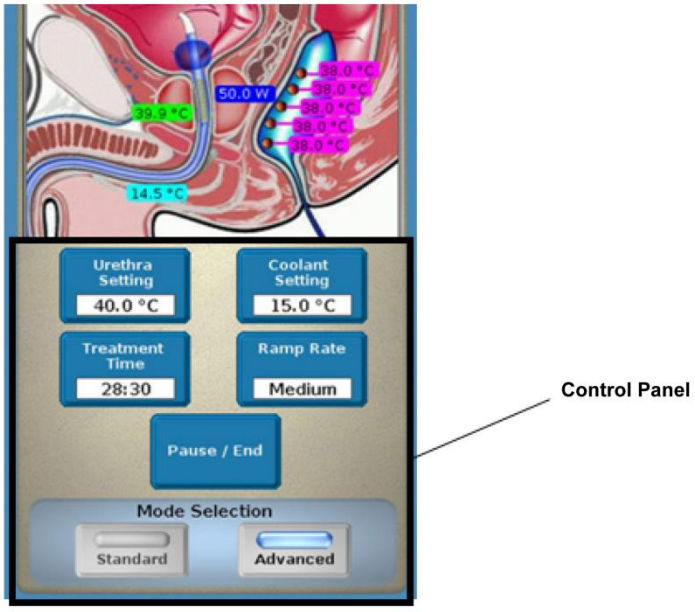


Figure 3-36. Advanced mode

Adjust the urethra setting, treatment time, coolant setting, and ramp rate from the Control Panel (Figure 3-36), if desired:

Note: The treatment timer runs when the following conditions occur:

CTC Advance Short	CTC Advance Standard & Long
• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **50W** • OR: RTU >= **41°C**	• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **65W** • OR: RTU >= **41°C**

Table 3-6 Treatment Timer algorithms

- Press the **Urethra Setting** button: Press the up and down arrows to adjust the urethra setting temperature in 0.5°C increments. The default urethra setting temperature for the CTC Advance Microwave Catheter is 40°C. Press the **Close** button when done.
- Press the **Treatment Time** button: Press the up and down arrows to adjust the treatment time in 30 second increments (Figure 3-37). Press the **Close** button when done.

Note: In automatic treatment mode , the treatment time is limited to 28 minutes and 30 seconds for the CTC Advance Microwave Catheter.

- Press the **Coolant Setting** button: Press the up and down arrows to adjust the coolant setting temperature in 0.5°C increments. The default coolant setting temperature for the CTC Advance Microwave Catheter is 15°C.

  The coolant temperature will ramp to its coolant setting temperature during a treatment. Press the **Close** button when done.

- Press the **Ramp Rate** button: Press the up and down arrows to select the ramp rate: slow, medium, fast. Press the **Close** button when done.

Figure 3-37. Example of a treatment parameter control panel

3.3.5.3 Using manual mode

When the manual treatment mode is active, the interval timer will appear on the Status Panel. This timer indicates the amount of time elapsed since you last adjusted microwave power and can be used to help you in timing a manual treatment. Refer to *Section 3.7.2, Manual treatment mode*, for further information on using the manual treatment mode.

Note: If you do not have access to the manual treatment mode, you will not see this option on the Control Panel.

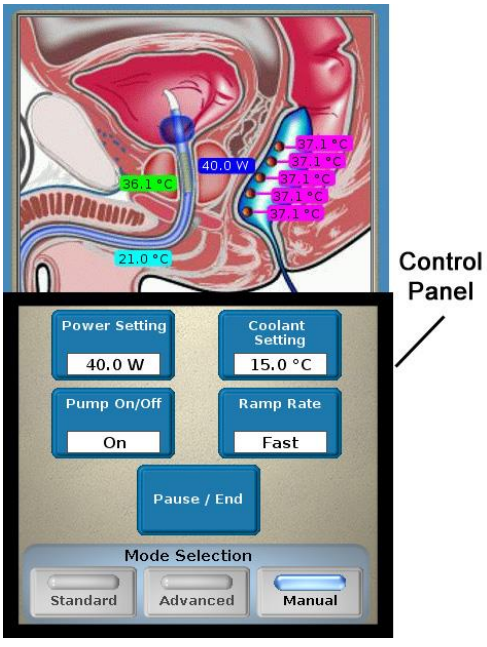


Figure 3-38. Manual mode

1. Select “Yes” or “No” when the Enter Manual Mode dialog box appears. Proceed to step 2 if entering the manual treatment mode (selecting “No” returns you to the Urologix - BPH Treatment screen).

2. Adjust the power setting, pump ON/OFF, coolant setting, and ramp rate from the Control Panel (Figure 3-38), if desired:
   a) Press the **Power Setting** button: Press the up and down arrows to adjust the microwave power setting (from 0.0 W to 60.0 W for a CTC Advance Short Microwave Catheter, and from 0.0 W to 75.0 W for a CTC Advance Standard or Long Microwave Catheters) in 1 W increments (Figure 3-39). Press the **Close** button when done.
   b) Press the **Pump On/Off** button: Press the up and down arrows to turn the coolant pump ON or OFF. In addition, if microwave power was ON when turning the pump OFF, microwave power will automatically turn OFF as well. Press the **Close** button when done.
   c) Press the **Coolant Setting** button: Press the up and down arrows to adjust the coolant setting temperature in 0.5°C increments. The default coolant setting temperature for the CTC Advance Microwave Catheter is 15°C.

      The coolant temperature will ramp to its coolant setting temperature during a treatment. Press the **Close** button when done.

   d) Press the **Ramp Rate** button: Press the up and down arrows to select the ramp rate: slow, medium, fast. Press the **Close** button when done.

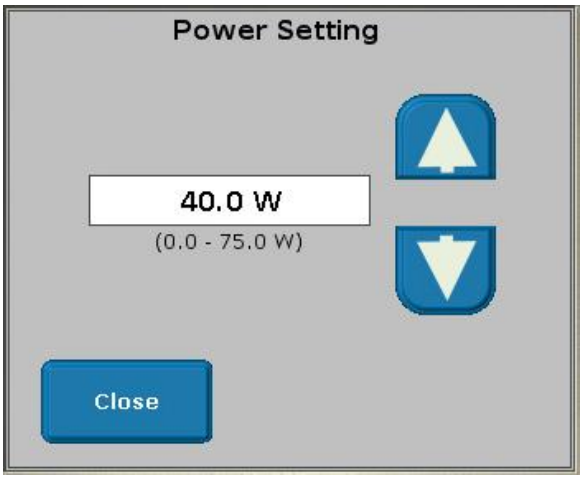


Figure 3-39. Example of a treatment parameter control panel

3. Exit manual treatment mode by pressing the **Standard** button or the **Advanced** button from the Control Panel. The Control Unit will return to the automatic treatment mode.

3.3.5.4 Pausing a treatment or ending a treatment early

1. Press the **Pause/End** button from the Control Panel to pause the treatment and turn OFF microwave power.
2. Press the **Resume** button to resume treatment (Figure 3-40). To end treatment and go to cooldown, proceed to step 3.

Figure 3-40. Resume Treatment dialog box

3. Press the **Go To Cooldown** button (Figure 3-40). The cooldown 5-minute timer appears (Figure 3-41). This timer shows the time remaining until the end of cooldown, which also indicates how much time has passed since the microwave power was turned OFF (with the coolant pump still running).

Figure 3-41. Treatment Cooldown window

4. Select one of the following options in cooldown: remain in cooldown for the full 5 minutes, 10 minutes, 15 minutes, resume the treatment, or end the cooldown.
Begin the cooldown at 5 minutes. You may add additional cooldown time by pressing one of the grey buttons. You can exit at any time, but it is recommended to pump coolant for at least 5 minutes.

Notes:

- It is recommended that the cooldown phase last 5 minutes prior to exiting the treatment.
- Once you exit cooldown, the treatment is done and cannot be resumed.

a) Remain in cooldown: Cooldown ends after 5 minutes, and the Treatment Cooldown - End window appears (Figure 3-41). If you need to resume treatment, proceed to step 4b. Or, you can exit the treatment. Press the **Exit** button. A dialog box appears to confirm that you want to exit, and therefore end, this treatment.
b) Resume the treatment: Press the **Resume Treatment** button (Figure 3-41) and then the **Resume** button (Figure 3-40) to resume the treatment.
c) End the cooldown: Press the **Cooldown End** button to end the cooldown (Figure 3-41). A dialog box appears to confirm that you want to end the cooldown, and therefore end, this treatment.

3.3.5.5 Ending a treatment

1. Monitor the cooldown 5-minute timer (Figure 3-33). This timer shows the time remaining until the end of cooldown, which also indicates how much time has passed since the microwave power was turned OFF (with the coolant pump still running).
2. Select one of the following options in cooldown: remain in cooldown for the full 5 minutes, 10 minutes or 15 minutes reset the 5-minute cooldown timer, or end the cooldown.

Notes:

- It is recommended that the cooldown phase last 5 minutes prior to exiting the treatment.
- Once you exit cooldown, the treatment is done and cannot be resumed.

a) Remain in cooldown: Cooldown ends after 5 minutes, and the Treatment Cooldown - End window appears (Figure 3-41). If you need to reset the 5-minute cooldown timer, proceed to step 2b. Or, you can return to the Urologix - BPH Treatment screen (Status Panel - status at pause). Press the **Resume Treatment** button (Figure 3-41). Finally, you can exit the treatment. Press the Exit button (Figure 3-41). A dialog box appears to confirm that you want to exit and therefore end this treatment.

b) Reset the timer: Press the **Resume Treatment** button (Figure 3-41) and then the **Resume** button (Figure 3-40) to reset the 5-minute cooldown timer.

c) End the cooldown: Press the **Cooldown End** button to end the cooldown (Figure 3-41). A dialog box appears to confirm that you want to end the cooldown and therefore end this treatment.

3.4 Post-treatment

This section includes the steps to follow after completing a treatment: what to do with the CoolWave Control Unit and associated devices and instructions for the patient post-treatment.

3.4.1 CoolWave Control Unit

Caution: Verify that the disposable components are removed intact.

1. Disconnect the coolant bag from the microwave catheter. To prevent water from draining out of the coolant bag and onto the floor, connect the coolant bag connectors to each other.
2. Disconnect the microwave catheter from the CoolWave Control Unit.
3. Remove all water from the microwave catheter location balloon, and withdraw the catheter from the patient.
4. Disconnect the rectal unit from the patient connection cable.
5. Remove all air from the rectal unit, and withdraw the device from the patient. If desired, pull the sheath of the RTU Plus up over the balloon to contain contaminants.
6. Remove the coolant bag from the CoolWave Control Unit.
7. Dispose of the single-use microwave catheter, single-use rectal unit or component, and the coolant bag in accordance with Universal Precautions for Contamination. Refer to *Section 4.1.1, Cleaning the RTU Plus Reusable Handle Post-Treatment*, for instruction on cleaning and disinfecting the RTU Plus Reusable Handle.

8. Print the treatment report or copy it to a Universal Serial Bus (USB) flash drive. Refer to *Section 3.5.3, Data View/Print/Copy screen*, for further information. Or, if you do not wish to print the treatment report or copy it to a USB flash drive, and no more treatments are scheduled for the day, turn the Control Unit OFF by pressing the ON/OFF power switch, located on the back of the unit ("0"). Hang the patient connection cable on the cable holder located on the back of the Control Unit. Cover the connectors at the end of the patient connection cable.
9. Follow these instructions if there are no other treatments in the near future: Disconnect the CoolWave Control Unit electrical cord from the wall outlet. Roll the CoolWave Control Unit to a storage location.

3.4.2 Patient Post-treatment Instructions

Due to edema from the thermal damage caused during treatment, the patient's prostate may swell and obstruct the urethra for a short period of time. For patient comfort, the physician may recommend the following treatment:

1. Instruct the patient in how to self-perform Clean Intermittent Catheterization, as needed, at home. If the patient fails a voiding trial after treatment, the physician may place a Foley catheter in the urethra before discharging the patient. The catheter may be removed within 24 to 60 hours or as the physician directs.
2. Instruct the patient, at discharge, to take prophylactic oral antibiotics for 3 days.
3. Provide the patient with sedatives, pain relievers, or anti-inflammatory medication as necessary.

3.5 Control Unit options

The Options Menu screen lists the following CoolWave Control Unit options: users, printer, data, password, and system (Figure 3-42). These options allow you to access printer utilities, copy a treatment file to a USB flash drive, print a treatment report, modify a password, or adjust system settings. And if you have administrative privileges, you will also have access to user settings. If you do not have administrative privileges, you will not see the **Users** button on the Options Menu screen.

Demonstration mode

When in demonstration mode, you will not have access to user settings. Therefore, you will not see the **Users** button on the Options Menu screen.

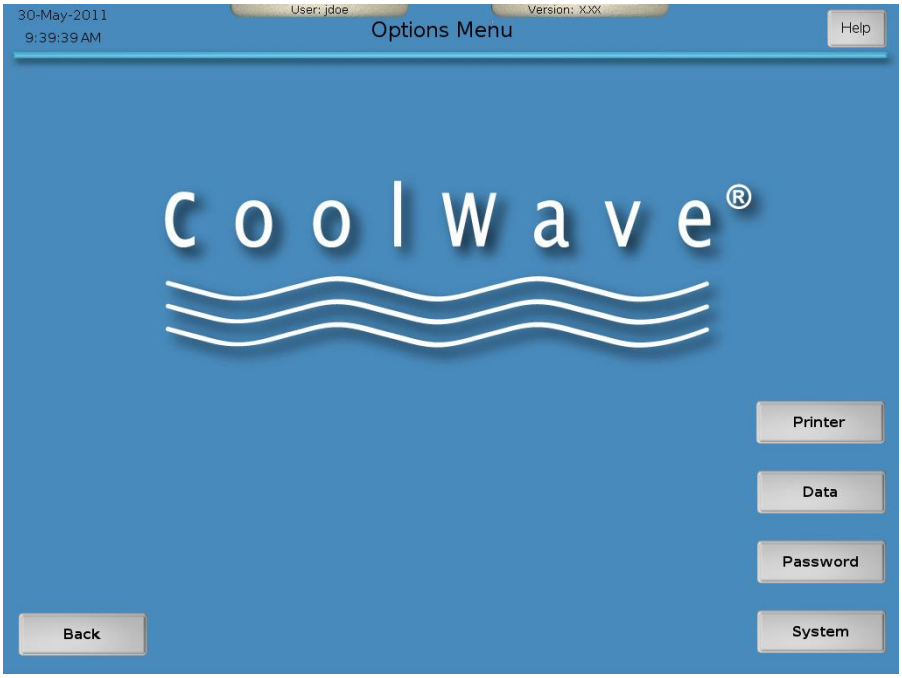


Figure 3-42. Options Menu screen

1. Press the **Users** button to view the User Settings screen. Refer to *Section 3.5.1, User Settings screen*, for further information.
2. Press the **Printer** button to view the Printer Utilities screen. Refer to *Section 3.5.2, Printer Utilities screen*, for further information.
3. Press the **Data** button to view the Data View/Print/Copy screen. Refer to *Section 3.5.3, Data View/Print/Copy screen*, for further information.
4. Press the **Password** button to view the Password Setup window. Refer to *Section 3.5.4, Password Setup window*, for further information.
5. Press the **System** button to view System Settings screen. Refer to *Section 3.5.5, System Settings screen*, for further information.
6. Press the **Back** button to return to the Main Menu screen. Refer to *Section 3.2.3, Main Menu Screen*, for further information.

3.5.1 User Settings screen

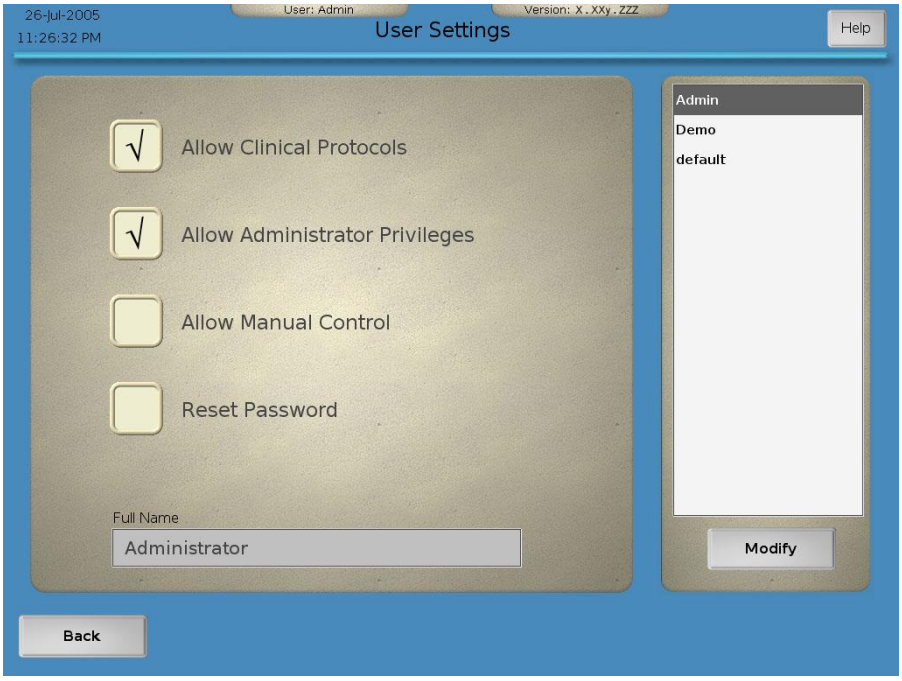


Figure 3-43. User Settings screen

1. Select a user from the menu on the right side of the screen, and press on the user name (Figure 3-43). That person's name appears in the Full Name data field on the bottom of the screen.
2. Press the **Modify** button.

   Note: The **Modify** button toggles between the **Modify** button and the **Apply** button.
3. Select the user setting(s) you want to change: Allow Clinical Protocols, Allow Administrator Privileges, Allow Manual Control, or Reset Password. Then, press the associated button.
   a) Press the **Allow Clinical Protocols** button: Provide or remove access to the clinical protocols for the selected user. If the button has a checkmark, remove access by pressing on the button. If the button does not have a checkmark, provide access by pressing on the button. Proceed to step 4.

      Note: Clinical protocols are not available unless provided by Urologix for a Urologix-sponsored clinical study.

   b) Press the **Allow Administrator Privileges** button: Provide or remove administrator access (allows access to User Settings screen and all CoolWave Control Unit data files) for the selected user; there is at least 1 site administrator per hospital or clinic. If the button has a checkmark, remove access by pressing on the button. If the button does not have a checkmark, provide access by pressing on the button. Proceed to step 4.
   c) Press the **Allow Manual Control** button: Provide or remove access to the manual treatment mode for the selected user. If the button has a checkmark, remove access by pressing on the button. If the button does not have a checkmark, provide access by pressing on the button. Proceed to step 4.

d) Press the **Reset Password** button: Activate or deactivate the password reset function for the selected user. If the button does not have a checkmark, reset the user's password to "password" by pressing on this button. If the button does have a checkmark, the password reset function is already active. Proceed to step 4.

4. Press the **Apply** button.
5. Press the **Back** button to return to the Options Menu screen.

3.5.2 Printer Utilities screen

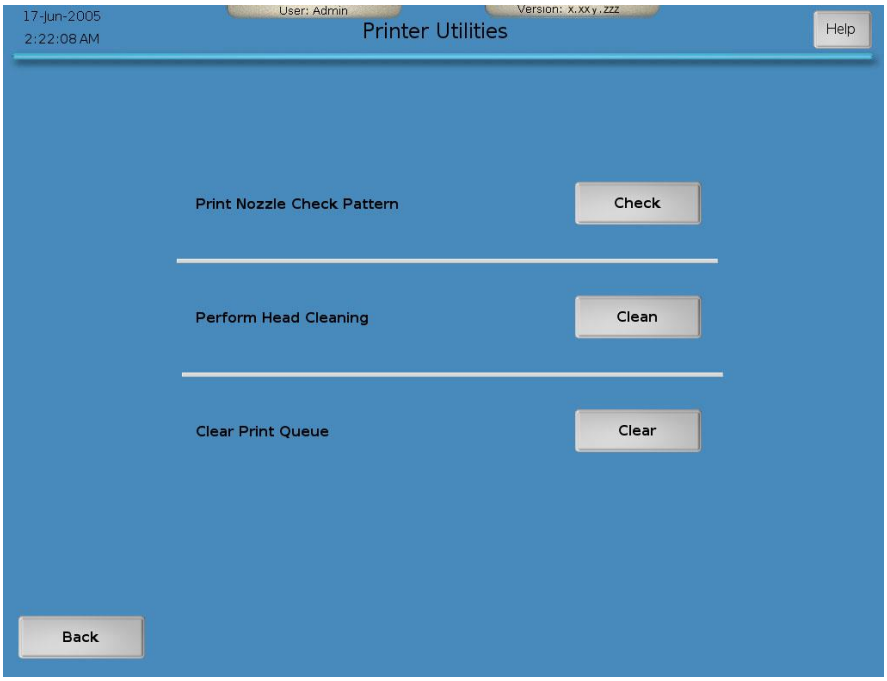


Figure 3-44. Printer Utilities screen

Note: Refer to *Section 4.3, Maintaining the printer*, Figure 4-3, for a printer overview.

1. Select one of the following printer utilities: Print Nozzle Check Pattern, Perform Head Cleaning, or Clear Print Queue (Figure 3-44).
   a) Print Nozzle Check Pattern: Determine if the ink is ejecting properly from the print head nozzles. A fuzzy printout means the print head needs cleaning. Turn the printer ON, load paper into the printer, and press the **Check** button. (However, if you pressed the **Check** button and paper was not in the printer, the printer flashes 1 long green and 2 short orange lights. Insert paper into the printer, and press the Resume/Cancel button on the printer.) The printer prints a nozzle check pattern.

   Note: You can also print the nozzle check pattern from the printer. Refer to *Section 4.3.3, Printing the nozzle check pattern*, for further information.

   b) Perform Head Cleaning: A fuzzy printout means the print head needs cleaning. Clean the print head. Press the **Clean** button. The printer cleans the print head.

Notes:

- Print and inspect the nozzle check pattern before cleaning the print head: A print head cleaning uses up ink and should be performed only when needed.
- You can also clean the print head from the printer. Refer to *Section 4.3.4, Cleaning the Print Head*, for further information.

c) Clear Print Queue: Clear all print jobs from the printer memory. Press the **Clear** button. The printer clears the print queue.

2. Press the **Back** button to return to the Options Menu screen.

3.5.3 Data View/Print/Copy screen

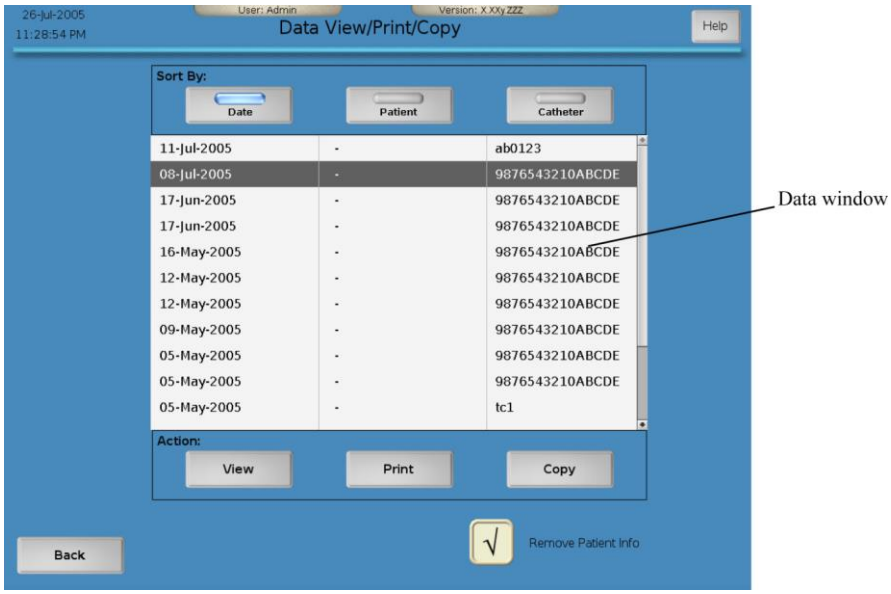


Figure 3-45. Data View/Print/Copy screen

1. Press the **Date**, **Patient**, or **Catheter** button to sort treatments by date (recent date first), by patient (alphabetical by last name - letter A first), or by microwave catheter serial number (lowest number first) (Figure 3-45). Unless you have administrative privileges, you can only access those treatment files you created: You cannot access treatment files created by other users.
2. Select a treatment in the Data window by pressing on the date, patient, or microwave catheter serial number. Then, press the **Remove Patient Info** button (optional) before choosing an action (view, print, or copy) to remove a patient's name from the treatment report: A check mark appears in the button.
    a) View: Press the **View** button to view a treatment report that includes patient data, treatment protocol data, treatment data, a treatment chart, the event log, and case notes. Use the arrows to scroll through the summary. Press the **Close** button to return to the Data View/Print/Copy screen.

b) Print: Turn the printer ON, load paper into the printer, and then press the **Print** button. (However, if you pressed the **Print** button and paper was not in the printer, the printer flashes 1 long green and 2 short orange lights. Insert paper into the printer, and press the Resume/Cancel button on the printer. Press the **Print** button again.) The printer prints the treatment report.

c) Copy: Insert a USB flash drive into the USB port. Press the **Copy** button to copy a treatment report to the drive. (However, if you pressed the **Copy** button before inserting the flash drive into the USB port, a dialog box appears instructing you to insert the drive. Insert the drive, close the dialog box, and press the **Copy** button again.) A dialog box appears to confirm that copying is in progress.

Note: The output file is encrypted with the password "ez4u2p". To view the file contents, you can use the free 7-zip utility from www.7-zip.org. The encryption method is also compatible with the WinZip utility.

3. Press the **Back** button to return to the Options Menu screen.

3.5.4 Password Setup window

Figure 3-46. Password Setup window

1. Enter the following information in the Password Setup window: Current Password, New Password, and New Password Confirm (Figure 3-46). Your password, which is case sensitive, may contain from 3 to 20 alphanumeric characters.
2. Press the **OK** button to complete password setup. Or, press the **Cancel** button to leave the Password Setup window without changing the password.

3.5.5 System Settings screen

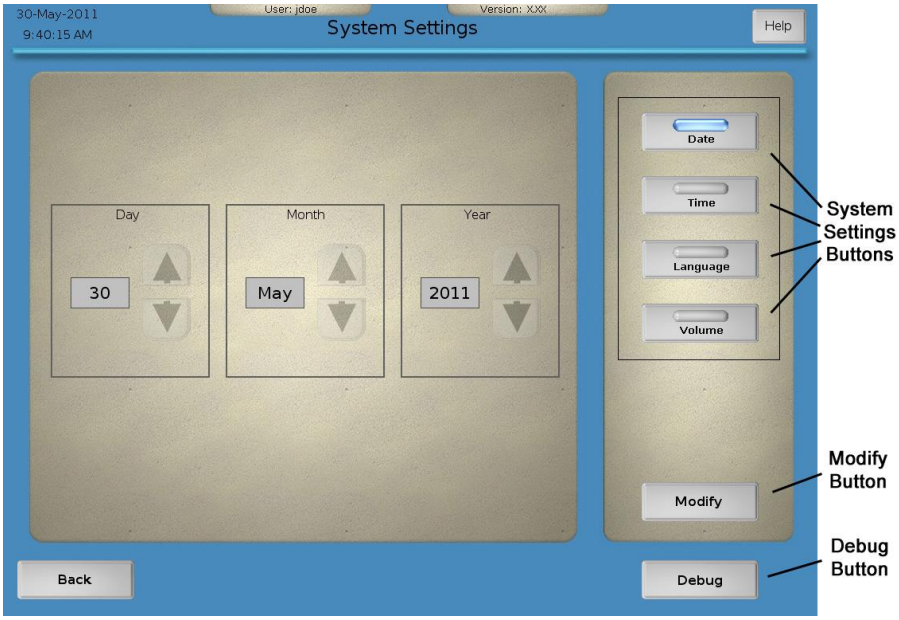


Figure 3-47. Example of a System Settings screen

1. Select the system setting to change: **Date**, **Time**, **Language**, or **Volume**. Then, press the associated button (Figure 3-47).
2. Press the **Modify** button (Figure 3-47). Refer to one of the following instructions based on the selected system setting.

   Note: The **Modify** button toggles between the **Modify** button and the **Apply** button.

   a) Date: Change the day, month, and year by pressing on the up and down arrows (Figure 3-48). Proceed to step 3.

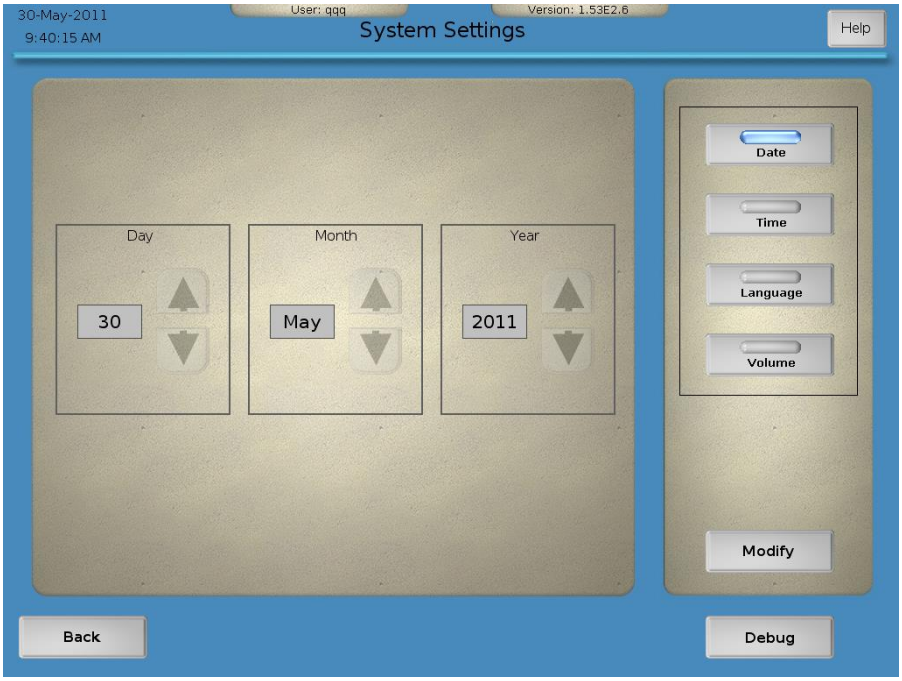


Figure 3-48. System Settings screen—date

b) Time: Change the hours, minutes, and AM/PM by pressing on the up and down arrows (Figure 3-49). Proceed to step 3.

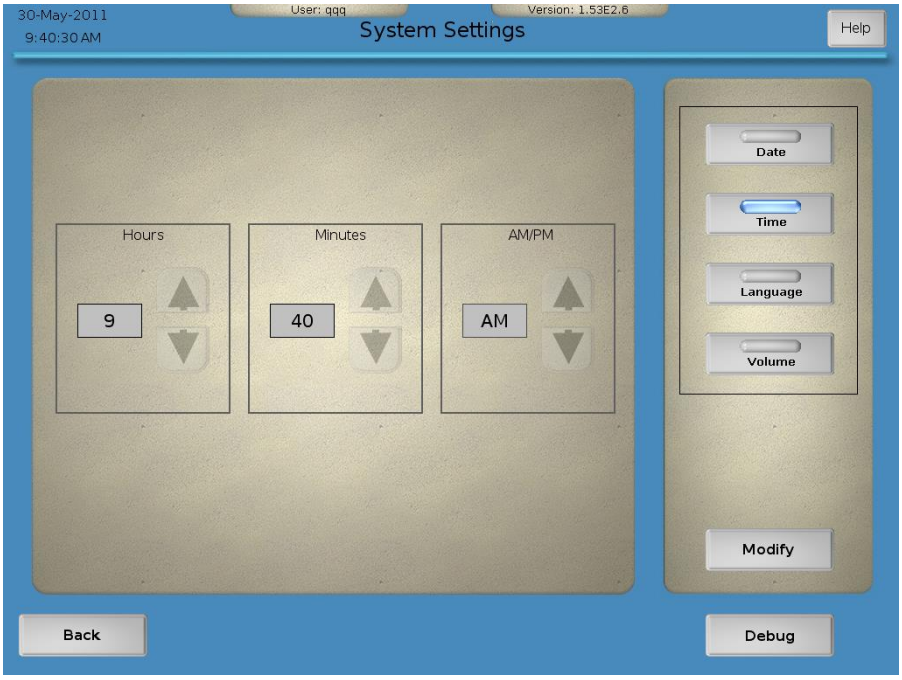


Figure 3-49. System Settings screen—time

c) Language: Change the language by pressing on the desired language (Figure 3-50). Proceed to step 3.

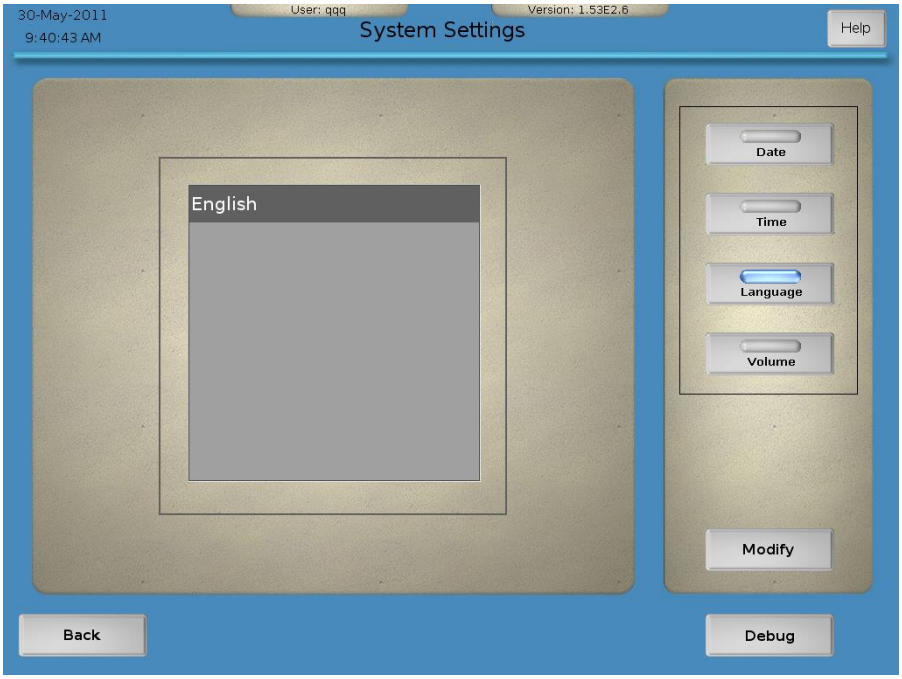


Figure 3-50. System Settings screen—language

d) Volume: Change the speaker volume by pressing on the bar and sliding it left (softer) or right (louder) (Figure 3-51). Proceed to step 3.

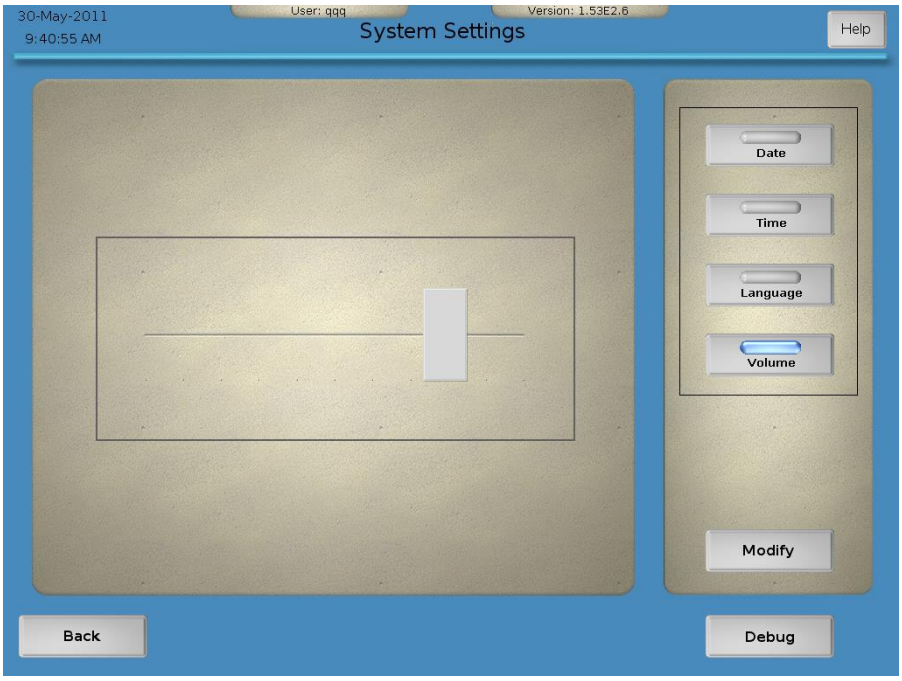


Figure 3-51. System Settings screen—volume

3. Press the **Apply** button to save the new system setting(s) (Figure 3-52).

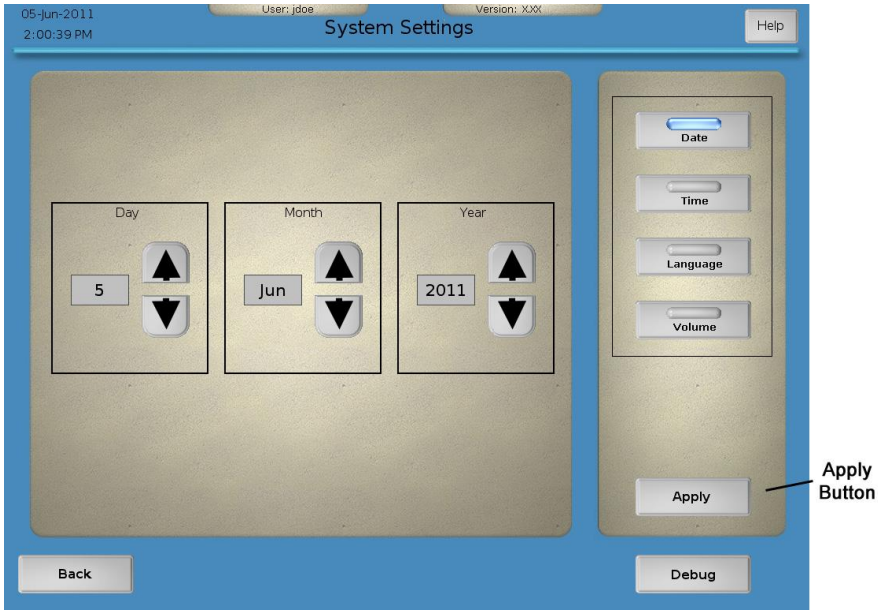


Figure 3-52. Example of a System Settings screen—apply

4. Press the **Debug** button to display the Debug Panel. This panel provides a method to display current measurements of the control unit and disposable components (Figure 3-53).

   The Debug Panel also highlights current errors: An active error is marked with a red light. To reset warnings and errors, press the **Reset** button. To close the Debug Panel, press the **Close** button.

   For additional information about system errors, refer to *Section 3.6, System Errors*. You may need to view this information if an error occurs and does not resolve. At this point, contact Urologix Customer Service (1-888-229-0772) to help you resolve any remaining errors.

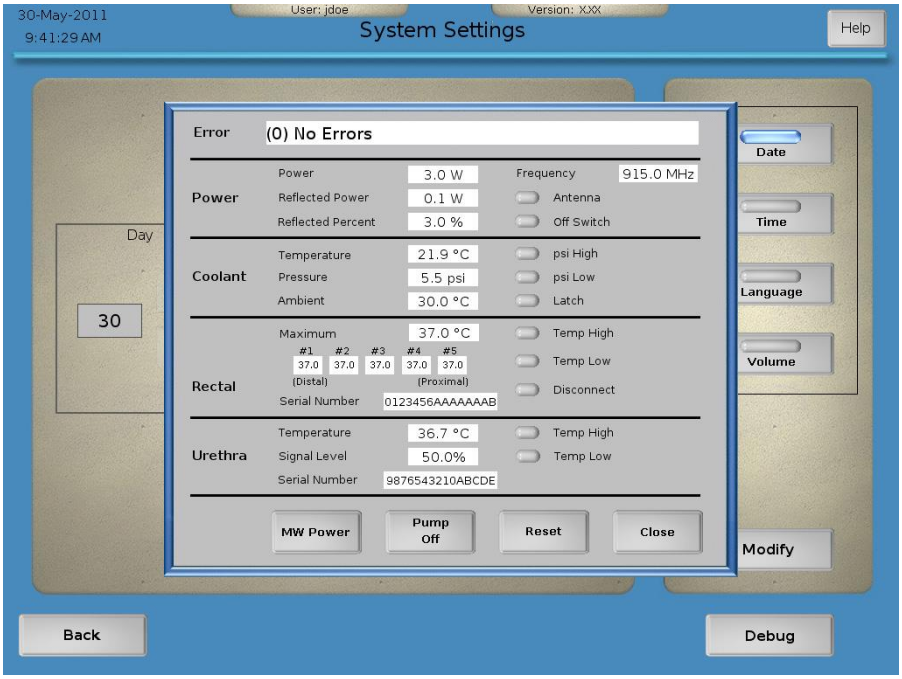


Figure 3-53. Example of a Debug screen

5. Press the **Back** button to return to the Options Menu screen.

3.6 System errors

This section contains information on system errors: general halt errors, calibration errors, and treatment errors. Error messages can appear on the System Error screen, the System Calibration screen, the Event pane, and the Detail pane.

Note: If you receive an error message on the System Calibration screen, the System Error screen, or while on the Urologix - BPH Treatment screen, pressing the **Help** button provides you with information about the displayed error message.

3.6.1 General halt errors

If the CoolWave Control Unit discovers a significant hardware problem, you will hear a single beep and an error message will appear on the System Error screen (Figure 3-54), in the Detail pane, or in the Event pane. You cannot continue using the CoolWave Control Unit: The **Reset** button (Event and Detail panes and System Error screen) and the **Resume Treatment** button (Cooldown pane) will appear grayed out. Review the following conditions and actions:

- Microwave power will turn OFF if there is a treatment in progress.
- The error message will be saved to the event log.
- The keyboard will no longer function.
- Run the CoolWave Control Unit for 5 minutes to cool the patient's urethra before removing the microwave catheter, if applicable.

- Contact Urologix Customer Service at 1-888-229-0772 for assistance.

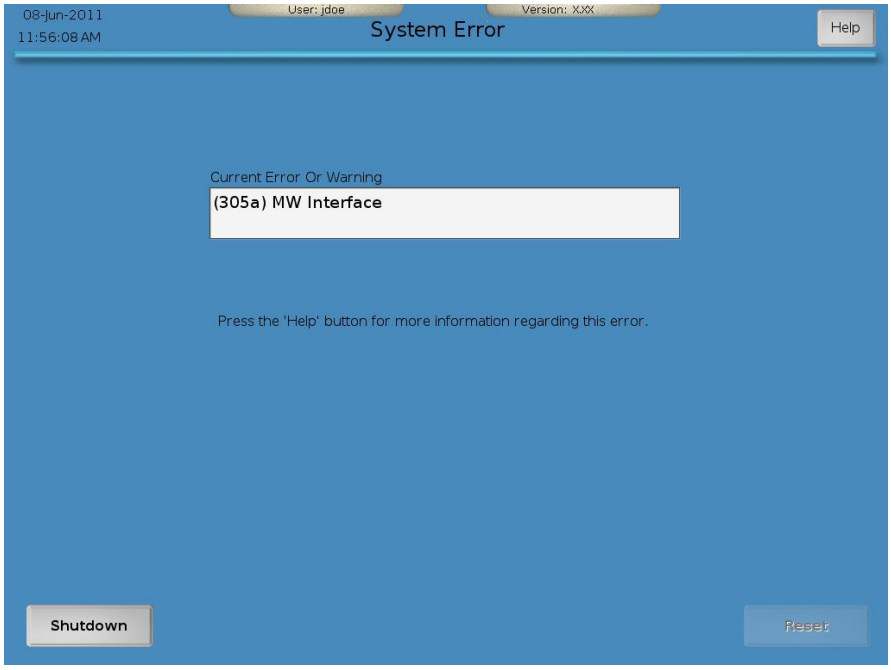


Figure 3-54. Example of a System Error screen - error message

3.6.2 Calibration errors

If an error occurs during the Control Unit calibration process, you will hear a single beep and an error message will appear on the System Error screen or the System Calibration screen. Review the following conditions:

- Microwave power will turn OFF if there is a calibration in progress.
- The error message will be saved to the event log.

First, determine if the error message is on the System Error screen (Figure 3-54) or the System Calibration screen (Figure 3-55). Error messages on the System Error screen indicate a system or patient critical error. You cannot continue using the CoolWave Control Unit: The **Reset** button will appear grayed out. Contact Urologix Customer Service at 1-888-229-0772 for assistance.

However, if the error message appears on the System Calibration screen, you will need to correct the problem. In most cases, an error message appears because the CoolWave Control Unit failed to read or detect the microwave catheter temperature sensor, the rectal unit temperature sensors, the microwave catheter antenna connection, or the coolant bag pressure during the calibration process.

Normally, to correct the problem, you can readjust the appropriate connector to the device. Then, press the **Retry** button to restart the calibration process. Ultimately, you should use the error message to resolve any error condition. You can also refer to the actions listed on the System Calibration screen to help you determine what to do next.

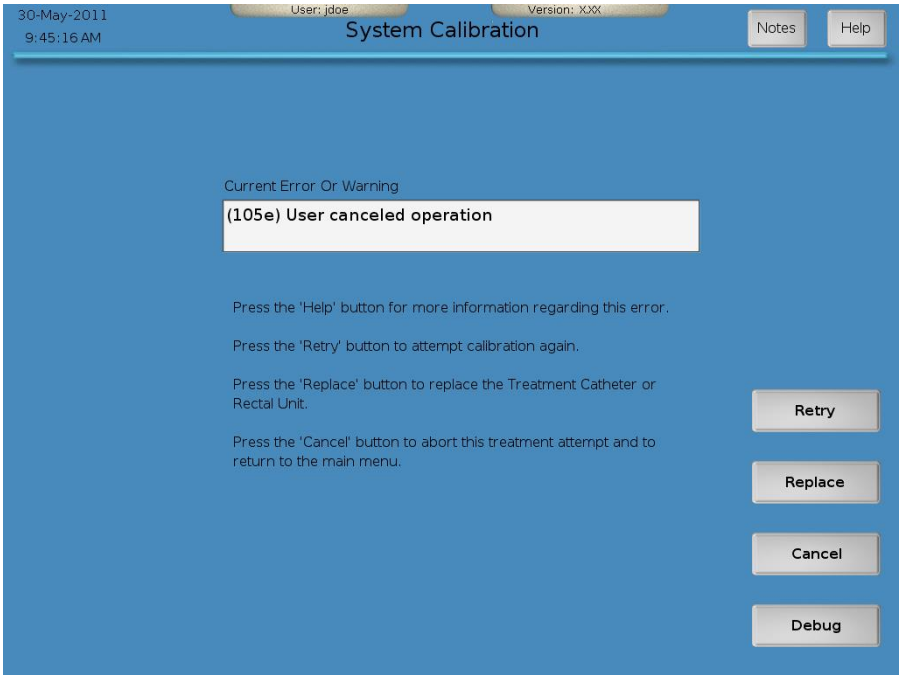


Figure 3-55. Example of a System Calibration screen - error message

Notes:

- If a calibration error message appears, refer to *Section 5.1, Troubleshooting guide*, for further information.
- Before replacing a microwave catheter or rectal unit, contact Urologix Customer Service at 1-888-229-0772.

- Press the **Help** button: Learn more about the error message and the appropriate response.
- Press the **Retry** button: Proceed with CoolWave Control Unit calibration. Refer to *Section 3.3.5, Urologix - BPH Treatment screen*, for further information.
- Press the **Replace** button: Replace the microwave catheter or the rectal unit, as needed. Refer to *Section 2.6, Inserting the Microwave* , *Section 2.7, Inserting the Single-Use Standard RTU,* or *Section 2.8, Inserting the RTU Plus Reusable Handle and Single-Use Balloon*, for further information. The CoolWave Control Unit returns you to the Protocol screen. Refer to *Section 3.3.2, Protocol screen*, for further information.
- Press the **Cancel** button: Exit this treatment, and return to the Main Menu screen. Refer to *Section 3.2.3, Main Menu Screen*, for further information.
- Press the **Debug** button: Display the Debug panel, which can be used to determine which system component is reporting an error condition. Refer to *Section 5.1, Troubleshooting guide*, for further information. At this point, contact Urologix Customer Service (1-888-229-0772) to help you resolve any remaining errors.

3.6.3 Treatment errors

If an error occurs during the treatment, you will hear a single beep and an error message will appear on the System Error screen, in the Event pane, or in the Detail pane. Some errors will not allow you to continue using the CoolWave Control Unit: The **Reset** button (Event and Detail panes and System Error screen) and the **Resume Treatment** button (Cooldown pane) will appear grayed out. However, some errors can be corrected: You will notice that the **Reset** button is not grayed out. Use the error message in the Event pane to correct the error. Then, press the **Reset** button to resume treatment. Review the following conditions and actions:

- Microwave power will turn OFF if there is a treatment in progress.
- The error message will be saved to the event log.
- The keyboard will no longer function (applies to errors on the System Error screen only).
- Run the CoolWave Control Unit for 5 minutes to cool the patient's urethra before removing the microwave catheter, if applicable.
- Contact Urologix Customer Service at 1-888-229-0772 for assistance.

Note: If one of these messages appears, refer to *Section 5.1, Troubleshooting guide*, for further information.

3.7 Treatment modes

After completing the calibration process, the CoolWave Control Unit will enter the automatic treatment mode. The other treatment mode, available from the Urologix - BPH Treatment screen, is the manual treatment mode. This section provides background information on both of these treatment modes. However, for specific information on using the CoolWave Control Unit, begin with *Section 3.3, Cooled ThermoTherapy Treatment.*

3.7.1 Automatic treatment mode

In automatic treatment mode, the CoolWave Control Unit automatically ramps the urethra and coolant temperatures to their settings based on the selected ramp rate. In addition, a CoolWave Control Unit operating in automatic treatment mode will adjust the coolant temperature to respond to rectal and urethra temperatures and will discontinue microwave power when the treatment timer has elapsed, therefore automatically beginning cooldown. The automatic treatment mode consists of 3 parts: ramp, treatment, and cooldown.

Note: If an error occurs during automatic treatment mode, the CoolWave Control Unit will turn OFF microwave power.

3.7.1.1 Ramp

- Monitor the patient for discomfort, and adjust the ramp rate, if necessary, from the advanced mode on the Control Panel.
- Adjust the microwave catheter and coolant setting temperatures as desired. However, Urologix recommends using the default microwave catheter and default coolant setting temperatures.

3.7.1.2 Treatment

The treatment timer counts up the amount of time elapsed when the criteria defined in Table 3-4, *Section 3.3.5, Urologix - BPH Treatment screen*, are met. If the rectal unit temperature is nearing 41°C, the CoolWave Control Unit automatically increases the temperature of the coolant (but not the displayed setting temperature) to compensate.

Adjust the treatment time to select when the automatic treatment mode automatically stops microwave power.

Note: The treatment timer runs when the following conditions occur:

CTC Advance Short	CTC Advance Standard & Long
• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **50W** • OR: RTU >= **41°C**	• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **65W** • OR: RTU >= **41°C**

Table 3-7 Treatment Timer algorithms

Monitor the patient for discomfort, and adjust the following settings, if necessary:

- Decrease the urethra setting temperature from the standard mode or the advanced mode on the Control Panel.
- Increase the coolant setting temperature from the advanced mode on the Control Panel.

Read all error messages and respond accordingly. If possible, clear the error message by pressing the **Reset** button. After the message clears, the Control Unit resumes the treatment in the automatic treatment mode.

After the treatment time expires, cooldown will automatically start, and the Treatment Cooldown window will appear.

3.7.1.3 Cooldown

The cooldown 5-minute timer shows the time remaining until the end of cooldown, which also indicates how much time has passed since the microwave power was turned OFF (with the coolant pump still running).When the 5-minute cooldown period ends, the coolant pump will continue running with the cooldown timer at 00:00. Coolant will continue circulating until you end the treatment.

- Resume the treatment, remain in cooldown, or end the cooldown (exit treatment), if desired, from the Treatment Cooldown window.
- Remain in cooldown, reset the 5-minute cooldown timer, or end the cooldown (exit treatment) when the Treatment Cooldown - End window appears.

3.7.2 Manual treatment mode

In manual treatment mode, you can adjust the microwave power, the coolant pump status (ON vs. OFF), the coolant setting, and the ramp rate; the physician defines the treatment time. And in manual treatment mode, the CoolWave Control Unit will continue to deliver microwave power until the physician ends the treatment. The manual treatment mode consists of 3 parts: ramp, treatment, and cooldown.

Notes:

- If you do not have access to the manual treatment mode, you will not see this option on the Control Panel.
- When the automatic treatment mode is turned ON from the manual treatment mode, the CoolWave Control Unit will ensure that the treatment time is increased to have at least 2 minutes of treatment remaining, unless doing so exceeds the treatment time setting temperature. The CoolWave Control Unit will also return to the previous urethra setting temperature.

3.7.2.1 Ramp

1. Verify that the coolant temperature is at the default setting, and wait until the measured coolant temperature has reached ≤ the default setting +4°C before applying microwave power.
2. Use the **Power Setting** button to apply 20 W of microwave power. Wait 2 minutes. Use the interval timer as a guide for timing additional power adjustments.
3. Continue to increase microwave power by 5 W, at 2 minute intervals, until:
   - The microwave catheter ≥ 35°C (the treatment timer will begin automatically, since the conditions for it to run should have been met), or
   - The rectal unit reaches 40°C, or

- The patient is experiencing discomfort.

4. Increase microwave power by 1 W per minute, once 1 of the 3 conditions in step 3 are met, until:
   - The microwave catheter reaches 40°C +/-1°C, or
   - The rectal unit ≥ 41.5°C, or
   - Microwave power reaches 60 W for a CTC Advance Short Microwave Catheter or 75 W for CTC Advance Standard & Long Microwave Catheters
   - The patient is experiencing discomfort.

3.7.2.2 Treatment

Throughout the treatment, carefully monitor the patient's comfort level and the microwave catheter and rectal unit temperatures.

Note: The treatment timer runs when the following conditions occur:

CTC Advance Short	CTC Advance Standard & Long
• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **50W** • OR: RTU >= **41°C**	• Urethra >= **35°C**, with (Urethra - Coolant) difference >= **23°C** • OR: MW Power >= **65W** • OR: RTU >= **41°C**

Table 3-8 Treatment Timer algorithms

Maintain the optimum microwave catheter temperature of 40°C +/-1°C.

Monitor the patient for discomfort, and adjust the following settings, if necessary:

- Decrease the urethra setting temperature by decreasing the microwave power from the manual mode on the Control Panel.
- Increase the coolant setting temperature from the manual mode on the Control Panel.

Decrease microwave power, if the rectal unit exceeds 42°C, in 1 W per minute increments until the rectal unit is 41.5°C. If the rectal unit temperature does not respond as quickly as needed, decrease power by 3 W increments. When the rectal unit temperature begins to decrease, try to increase microwave power to achieve and maintain the microwave catheter at 40°C +/-1°C while maintaining rectal temperatures at or below 42°C.

After at least 28 minutes and 30 seconds of treatment, end the treatment by pressing the **Pause/End** button from the Control Panel and go to cooldown. The Treatment Cooldown window will appear.

3.7.2.3 Cooldown

The cooldown 5-minute timer shows the time remaining until the end of cooldown, which also indicates how much time has passed since the microwave power was turned OFF (with the coolant pump still running).You can add additional cooldown to by pressing the 10 minute or 15 minute button on the Cooldown window. When the cooldown period ends, the coolant pump will continue running with the cooldown timer at 00:00. Coolant will continue circulating until you end the treatment.

- Resume the treatment, remain in cooldown, or end the cooldown (exit treatment), if desired, from the Treatment Cooldown window.
- Remain in cooldown, press the 5-minute 10-minute or 15-minute button, or end the cooldown (exit treatment) when the Treatment Cooldown - End window appears. It is recommended to remain in cooldown for at least 5 minutes.

4 Equipment Maintenance

4.1 Cleaning the equipment

4.1.1 Cleaning the RTU Plus Reusable Handle Post-Treatment

The following process will be used to clean and disinfect the RTU Plus Reusable Handle (containing the temperature sensors) for subsequent use. The RTU (rectal unit) handle should not be used more than 30 times.

1. Remove and discard the disposable rectal balloon if not already discarded.
2. Tie a glove over the rectal unit cable connector to prevent it from being splashed or soaked.
3. Rinse the rectal unit handle with warm running tap water until all visible gross debris is removed. Avoid any water contact with the connector. Gently shake to remove excess water and to avoid splashing or casting of solution.
4. Place the rectal unit handle in a bath with water and enzymatic detergent (e.g., ENZOL®) mixture diluted according to the manufacturer's instructions for 2 minutes. **Do not soak or immerse the connector**. After soaking 2 minutes, clean the crevices with a soft bristle brush. Pay special attention to the temperature sensor "flex circuit" bend points, sensor/handle junction, and inflation tubing channel to avoid damage and to ensure adequate cleaning.
5. Rinse the rectal unit handle for 2 minutes using warm tap water. Gently shake to remove excess water and to avoid splashing or casting of solution.
6. Inspect the rectal unit handle under standard lighting to verify that all soil was removed. If not, repeat above steps.
7. Rinse the rectal unit handle with deionized water to remove any excess residues left by the tap water. Gently shake to remove excess water and to avoid splashing or casting of solution.
8. Soak the rectal unit handle (again, do not soak or immerse the connector) in a 3.4% glutaraldehyde solution according to the manufacturer's instructions.
9. After soaking, rinse devices per manufacturer's instructions.
10. Gently dry the rectal unit handle. Store in dry, ambient conditions between 59°F -95°F (15°C -35°C) until the next use. Always avoid bending the temperature sensor strip significantly.

4.1.2 Cleaning the Control Unit

There are no special clean-up operations required after a Cooled ThermoTherapy Treatment for the CoolWave Control Unit. The CoolWave Control Unit exterior should be cleaned periodically following these instructions:

- Clean the exterior surface of the CoolWave Control Unit with a soft, lint-free cloth dampened with warm water and a diluted detergent, 10% dilution of bleach, or a diluted, nonabrasive, nonstaining standard hospital disinfectant. Use a lint-free cloth dampened with warm water to rinse the surface of the unit.
- Do NOT use isopropyl alcohol (IPA) to wipe the exterior CoolWave Control Unit housing. Using cleaning solvents such as IPA could result in damage to the CoolWave Control Unit.

4.1.3 Cleaning the touchscreen

The touchscreen should be cleaned periodically following these instructions:

- Clean the touchscreen with a soft, lint-free cloth dampened with a solution of 50% IPA and 50% warm water. Or, use 100% IPA instead of the IPA and water solution.
- Do NOT spray the cleaning solution directly on the screen. The solution may seep inside the display or stain the bezel.

4.2 Maintaining the CoolWave Control Unit

If a product failure occurs, the defective device must be returned to Urologix for evaluation and reimbursement.

4.2.1 Daily Maintenance

Before using the CoolWave Control Unit, you should visually inspect system components for damage. Refer to *Section 1.8.1, Installation*, for a list of the system components requiring inspection.

- Wipe the exterior surface of the CoolWave Control Unit with a 10% solution of bleach or mild detergent. Wipe the exterior surface of the unit with water to rinse.
- Keep the touchscreen clean. If the screen needs cleaning, refer to *Section 4.1.3, Cleaning the touchscreen*, for further information.
- Check the printer paper. If the printer needs a paper refill, refer to *Section 4.3.1, Refilling the printer with paper*, for further information.
- Check all cables and power connections. Be certain that all cables are firmly attached and routed away from normal traffic paths.
- Check the sight gauge on the rear of the CoolWave Control Unit to ensure that the internal coolant level is within the white open section of the correct level indicator (Figure 4-1).

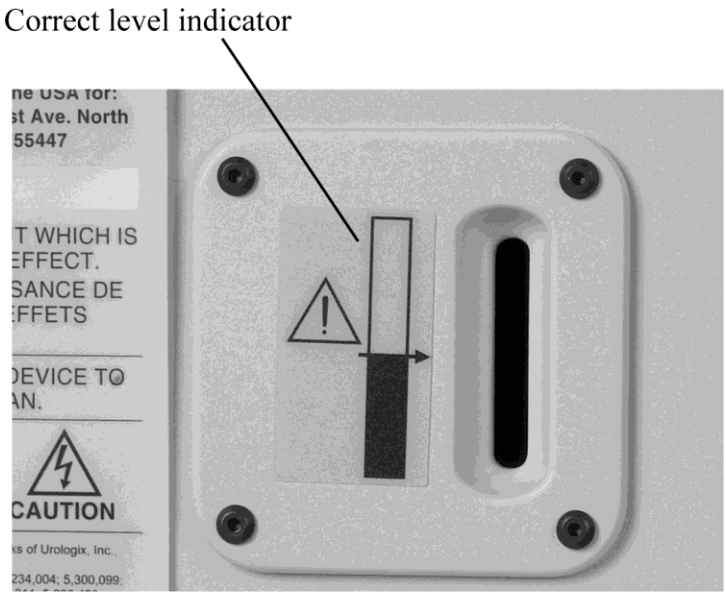


Figure 4-1. Internal coolant level indicator

4.2.2 Periodic maintenance

Equipment service and yearly preventive maintenance must be performed by a Urologix trained and authorized service representative. Contact Urologix Customer Service (1-888-229-0772) if more than 12 months have passed since the last preventive maintenance. Refer to Additional **Terms and Conditions, Exhibit A**, packaged with the CoolWave Control Unit, for equipment warranty information. Please note: An extended service agreement is available through Urologix. Contact your Urologix sales representative for further information. Equipment is to be serviced only by Urologix Authorized Service Personnel. Any other type of service or maintenance arrangement will void all warranties and claims.

4.2.3 Replacing the fuses

1. Use a flat screwdriver to remove the fuse holder caps (Figure 4-2).

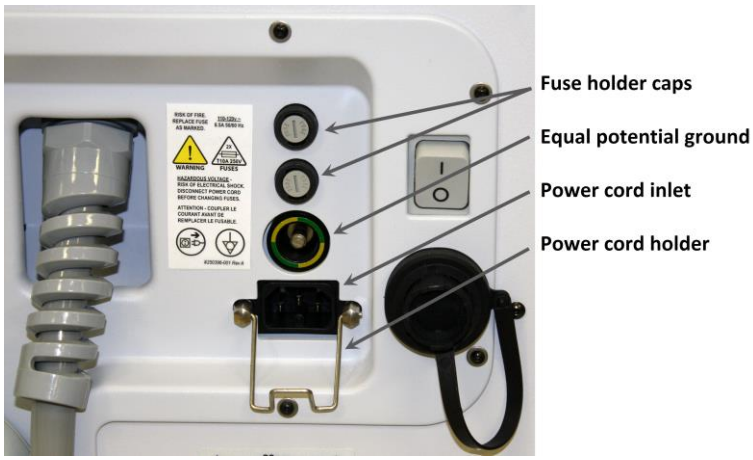


Figure 4-2. Control Unit rear cover

2. Replace the defective fuses with the appropriate Urologix fuses listed below.

CONTROL UNIT MODEL	FUSE CATALOG NUMBER	FUSE TYPE/RATING
Model 5000A	AC1008	1 1/4" x 1/4" / 10 A
Model 5000E	AC1009	5 mm x 20 mm / 5 A

Table 4-1. Fuse overview

Warning: Only replace CoolWave Control Unit fuses with Urologix supplied components.

3. Replace the fuse holder caps.

4.2.4 Cleaning Cooling System Vent

1. By hand carefully remove the upper front control unit cover by grasping and carefully pulling the cover straight back.
2. Next remove the lower front control unit panel in the manner exposing the cooling system vent at the lower portion of the control unit.
3. Using a vacuum carefully remove any dust and lint from the front of the cooling system vent.
4. The cooling system vent should be cleaned or inspected periodically to ensure the cooling vent is not blocked and to ensure the control unit has proper airflow to the control unit cooling unit (Figure 4-2).

5. Replace the control unit upper and lower front covers in reverse order installing the bottom cover then the top by pushing them back into place onto the control unit frame.

Warning: Never remove control unit panels or perform cleaning or maintenance while the control unit is "ON" or plug into a wall outlet.

4.3 Maintaining the printer

Printer maintenance consists of refilling the printer with paper, replacing an ink tank, printing the nozzle check pattern, and cleaning the print head. Refer to the instructions below as well as the technical manual that comes with your Canon color inkjet printer.

Note: To prevent the inkjet printer head from drying out:

- Before turning off the CoolWave's AC power switch, make sure to turn off the power switch on the printer and wait until the green power lamp has stopped blinking and remains unlit. This indicates that the printer has finished stowing the printer head in its sealed storage location.
- Print a nozzle check pattern once per month to flush fresh ink through the printer head.

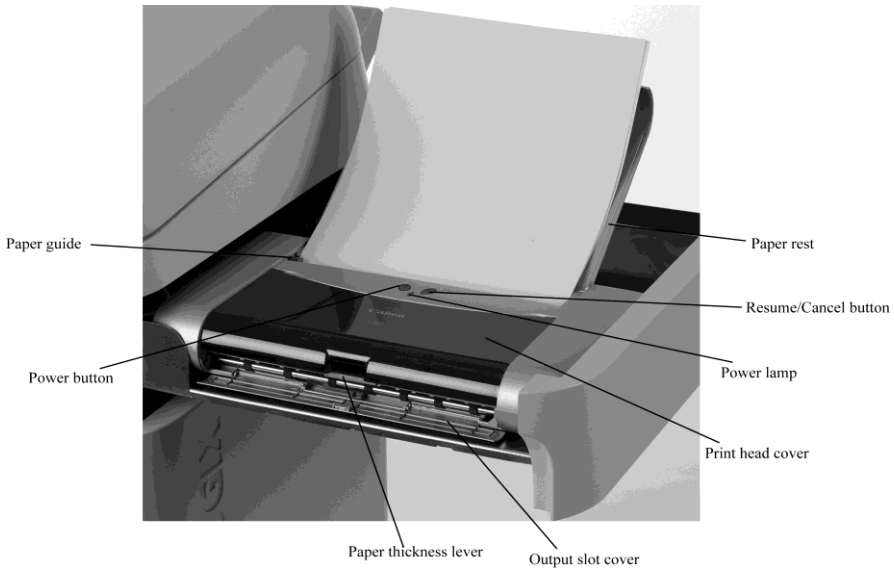


Figure 4-3. Printer overview

4.3.1 Refilling the printer with paper

Notes:

- Do not load more than 10 sheets of paper in the output slot cover.
- Avoid touching a printed sheet until the ink dries.

1. Make sure the paper is flat and not curled at the edges.
2. Open the paper rest and output slot cover (Figure 4-3).
3. Slide the paper thickness lever (Figure 4-3) to the right position.
4. Insert the paper into the sheet feeder while aligning it against the right side of the feeder.
5. Position the paper guide (Figure 4-3) against the left side of the paper.

4.3.2 Replacing an Ink Tank

Notes:

- Replace an empty ink tank immediately. Printing with an empty ink tank may cause problems with the printer.
- Check the model number on the new ink tank to make sure you are using the correct one.
- Be careful not to stain your clothing or other items while replacing an ink tank.
- Dispose of an empty ink tank according to local laws and regulations regarding disposal of consumables.
- Use an ink tank within the first 6 months after it is installed.
- Do not remove an ink tank, leave it out in the open, and then place that ink tank back into the printer. The ink in the ink tank will have dried out and may cause the printer to malfunction.

1. Open the paper rest, and press the Power button (Figure 4-3). The power lamp, next to the Power button, will be green when the printer is ready (Figure 4-3).

2. Open the print head cover (Figure 4-3).
3. Push the tab on the old ink tank, and remove the tank.
4. Remove the new ink tank from its package, and remove the orange protective cap.

Notes:

- Do not replace the orange protective cap after removing it from the new ink tank.
- Do not touch the open ink port after removing the orange protective cap.

5. Insert the new ink tank, with it slightly slanted, into the ink tank slot (Figure 4-4).

Figure 4-4. Insert the new ink tank

6. Push down on the PUSH symbol on the ink tank until it clicks into place.
7. Close the print head cover. The print head will move to the right.

4.3.3 Printing the nozzle check pattern

Note: You can also print the nozzle check pattern from the Printer Utilities screen. Refer to *Section 3.5.2, Printer Utilities screen*, for further information.

1. Open the paper rest, and press the Power button (Figure 4-3). The power lamp, next to the Power button, will be green when the printer is ready (Figure 4-3).
2. Load paper into the printer.
3. Press and hold the Resume/Cancel button (Figure 4-3) on the printer. When the power lamp flashes twice, the printer prints the nozzle check pattern.
4. Inspect the nozzle check pattern printout. Missing lines in the chart mean the print head for the black ink cartridge needs cleaning. White stripes in the bar graph mean the print head for the color ink cartridge needs cleaning. Refer to *Section 4.3.4,Cleaning the Print Head*, for further information.

Note: If the nozzle check pattern does not print properly, and the ink level is low, replace the ink tank. Refer to *Section 4.3.2, Replacing an Ink Tank*, for further information.

4.3.4 Cleaning the Print Head

Notes:

- Print and inspect the nozzle check pattern before cleaning the print head: A print head cleaning uses up ink and should be performed only when needed.
- You can also clean the print head from the Printer Utilities screen. Refer to *Section 3.5.2, Printer Utilities screen*, for further information.

1. Open the paper rest, and press the Power button (Figure 4-3). The power lamp, next to the Power button, will be green when the printer is ready (Figure 4-3).
2. Press and hold the Resume/Cancel button (Figure 4-3) on the printer. When the power lamp flashes once, the printer cleans the print head.

4.3.5 Printer Replacement

Notes:

- Printer replacement maybe necessary if an issue arises that cannot be addressed by the routine maintenance described above in *Sections 4.3.1 - 4.3.4.*
- Contact the Urologix field service department to obtain the appropriate Canon color inkjet replacement printer.

1. With the control unit main power off and the control unit unplugged open the printer access drawer (Figure 4-3).
2. Remove the printer by carefully separating the printer from the Velcro coins that are attached to the printer and printer drawer.
3. Carefully disconnect the printer power connector and serial connector at the printer.
4. Install the replacement printer by attaching the appropriate Velcro coins and connecting the power and serial cable connections and installing the printer in place onto the printer drawer.
5. If not already installed, install the new printer ink cartridges. (refer to *Section 4.3.2*)

Notes:

- If the user is uncomfortable performing the printer replacement or any other printer maintenance tasks described it is highly recommended that the Urologix field service department is contacted to provide guided assistance.

4.4 Moving the CoolWave Control Unit

When moving the CoolWave Control Unit, grip the handle at the top of the unit. This handle is designed to allow one person to push or pull the unit with little effort.

The wheels of the unit pivot to assist you when turning the unit in a new direction. The front wheels have an individual lock you can use when the unit is stationary. To lock the wheels, use your foot to press down on the wheel lock tabs. To unlock the wheels, press on the back part of the wheel lock tab.

Several safeguards or cautions apply when moving the CoolWave Control Unit.

Protect the patient connection cable when moving the CoolWave Control Unit. Although a cable holder is provided on the rear of the CoolWave Control Unit for the patient connection cable, the cable is still susceptible to damage. Do not pull on or stress the cable.

- Always handle the touchscreen with care.
- Maintain the CoolWave Control Unit in an upright position when it is in use or being stored.
- Avoid tipping the unit. Since the CoolWave Control Unit is heavy; it will be damaged if it were to tip over. In addition, personal injury could result.
- Do not lift or elevate the CoolWave Control Unit.

4.5 Storing the CoolWave Control Unit

For short and long-term storage, handle the CoolWave Control Unit as you would other sensitive medical equipment: Store the CoolWave Control Unit in a low-moisture equipment storage area where it may be kept long-term. Keep the surfaces and components of the CoolWave Control Unit free of dust by covering the unit with plastic.

4.6 Shipping the CoolWave Control Unit

In the event that it becomes necessary to ship the CoolWave Control Unit, contact Urologix Customer Service at 1-888-229-0772. For repeated transportation of the CoolWave Control Unit, Urologix offers a Transport Kit, which is the only FDA-approved method for transporting the CoolWave Control Unit.

4.7 CoolWave Control Unit specifications

CoolWave Control Unit Models:	5000E (Europe) 5000A (US)
Power Requirements:	5000E: 220/240 V [+/- 10%] (4.25 A) Single phase 50 or 60 Hz 5000A: 110/120 V [+/- 10%] (8.5 A) Single phase 50 or 60 Hz
Microwave Output:	Power: 0 W-75 W output from the microwave antenna connector on the patient cable, continuous duty Frequency: 902 MHz to 928 MHz
Coolant Circulation System:	Chill Element: Thermoelectric Capacity: 100 W element Configuration: Disposable Coolant Bag Bag Dimensions: Approximately 15.2 cm x 17.8 cm Bag Capacity: Approximately 100 mL Pump: Peristaltic pump
User Interface:	Display: Color liquid crystal display or LCD Input: Touchscreen Keyboard: Silicone rubber keyboard
Operating Conditions:	Temperature: +10°C to +30°C Humidity: 30% to 75% relative humidity Atmospheric Pressure: 700 hPa to 1,060 hPa
Shipping / Storage Conditions:	Temperature: -20°C to 70°C Humidity: 10% to 95% relative humidity Atmospheric Pressure: 700 hPa to 1,060 hPa
Class/Type:	IEC 60601-1 Class I, Type BF with defibrillation protection
Measurements Range and Accuracy:	Rectal Sensor: Range 1°C-50°C, Accuracy 1°C from 35°C to 45°C and 2°C outside this range Urethra Sensor: Range 27°C-47°C, Accuracy ±1°C Coolant Temperature: Range -25°C-75°C, Accuracy ±3°C Microwave Power: Range 0 W-75 W, Accuracy ±10%
FCC Registration	#0012913901
Physical Characteristics	Size: 18” wide X 24” deep X 42” high Weight: less than 300 lbs.

Table 4-2. CoolWave Control Unit specifications

5 Appendix A

5.1 Troubleshooting guide

Each system error has a unique number, and may be followed by a single letter suffix that indicates where the error occurred. For example, 000x is a system error where "000" is the system error number, and the "x" is the single letter suffix. See the following table for the letter suffix definitions:

X	WHERE THE SYSTEM ERROR OCCURRED
blank	during treatment
a	calibration—temperature stabilization
b	calibration—rectal sensor
c	calibration—fiber optic sensor
d	calibration— coolant pump
e	calibration—frequency sweep
p	prior to treatment

Below is a list of system errors (in numerical order), possible causes, and the actions to take to resolve the error (s). If you still cannot resolve an error after using this troubleshooting guide, please contact Urologix Customer Service at 1-888-229-0772.

ERROR #1 - RECTAL TEMP. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. Loose connector.	Reattach connector.
2. Temperature in rectum has exceeded 42.5°C.	Allow rectal temperature to drop below 42°C.
3. Enema not performed within 2 hours of treatment.	Remove rectal unit and perform enema.
4. Air may not have been removed from the original volume (cc's) in the rectal unit.	Remove air per Section 2.7 or 2.8.
5. Rectal unit may not be inserted properly.	Check that the rectal unit is properly positioned.
6. Patient improperly positioned.	Reposition patient with head and shoulders elevated no higher than a 20° angle.
7. Microwave catheter may not be positioned properly.	Check that the microwave catheter is properly positioned.
8. Rectal unit may be defective.	Replace rectal unit.

ERROR #2 - RECTAL TEMP. LOW

POSSIBLE CAUSES	ACTION STEPS
1. Loose connector.	Reattach connector.
2. Rectal unit temperature below 31°C.	Check that the rectal unit is inserted properly.
3. Rectal unit expelled or not properly inflated.	Reinsert the rectal unit, or inflate the rectal unit.
4. Rectal unit may not be inserted properly.	Check that the rectal unit is properly positioned.
5. Rectal unit may be defective.	Replace the rectal unit.

ERROR #3 - COOLANT PRESS. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. Pressure too high in tubing.	Check that the pump tubing clamp is properly fastened, and that the tubing is not kinked.
2. Coolant bag may be defective.	Disconnect coolant luers from the microwave catheter, temporarily connect coolant luers to each other, and then restart treatment. If error repeats, replace coolant bag. Otherwise, check the microwave catheter.
3. Microwave catheter may be defective.	Disconnect coolant luers from microwave catheter and flush microwave catheter coolant luers with sterile water. Reconnect coolant bag luers to microwave catheter and restart treatment. If error repeats, replace microwave catheter.

ERROR #4 - COOLANT PRESS. LOW

POSSIBLE CAUSES	ACTION STEPS
1. Pressure is too low in the tubing.	Check water level in the coolant bag. Check that pump tubing clamp is properly fastened.
2. Coolant tubing between coolant bag and sensor module may be twisted.	Verify tubing is not twisted.
3. Coolant bag may be defective.	Replace the coolant bag.
4. Microwave catheter may be defective.	Replace the microwave catheter.

ERROR #5 - URETHRA TEMP. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. Loose microwave catheter fiber connector.	Reattach fiber connector. Clean both ends of connection with alcohol wipe or swab.
2. Temperature in urethra > 44.5°C	Allow microwave catheter temperature to drop ≤ 41°C.
3. Microwave catheter may be defective.	Replace the microwave catheter.

ERROR #6 - URETHRA TEMP. LOW

POSSIBLE CAUSES	ACTION STEPS
1. Loose microwave catheter fiber connectors.	Reattach fiber connector. Clean both ends of connection with alcohol wipe or swab.
2. Microwave catheter may be defective.	Replace the microwave catheter.

ERROR #7 - CATHETER EFFICIENCY LOW

POSSIBLE CAUSES	ACTION STEPS
1. Cable may not be connected properly.	Rotate the Microwave Antenna Connector nut 4 full turns with your fingers until snug to ensure a proper connection.
2. Urine drainage line not purged.	Purge urine drainage line.
3. Microwave catheter may not be inserted properly.	Check that the microwave catheter is inserted properly.
4. Defective microwave catheter.	Replace the microwave catheter, and recalibrate.

ERROR #8 - CONTROL UNIT TEMP. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. CoolWave Control Unit vents blocked.	Remove any item blocking vents.
2. Treatment room too warm.	Observe CoolWave Control Unit operating temperature requirements.

ERROR #9 - CONTROL UNIT TEMP. LOW

POSSIBLE CAUSES	ACTION STEPS
1. CoolWave Control Unit stored in a cold environment prior to treatment.	Observe CoolWave Control Unit operating temperature requirements, and wait until the system has reached room temperature before beginning treatment.

ERROR #10 - MW FLANGE TEMP. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. CoolWave Control Unit vents blocked.	Remove any item blocking vents.
2. Treatment room too warm.	Observe CoolWave Control Unit operating temperature requirements.

ERROR #11 - COOLANT TEMP. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. Coolant door open.	Close coolant door.
2. Coolant temperature > 40°C.	Reduce coolant set point to the proper temperature, and wait for coolant to drop below 40°C.
3. Coolant Bag may be defective.	Replace the Coolant Bag.

ERROR #12 - COOLANT TEMP. LOW

POSSIBLE CAUSES	ACTION STEPS
1. Coolant door open.	Close coolant door.
2. Coolant bag may be defective.	Replace the coolant bag.

ERROR #13 - RECTAL TEMP. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. Loose connector.	Reattach connector.
2. Temperature in rectum has exceeded 42.5°C.	Allow rectal temperature to drop below 42°C.
3. Enema not performed within 2 hours of treatment.	Remove the rectal unit, and perform enema.
4. Air may not have been removed from the original volume (cc's) in the rectal unit.	Remove air per Section 2.7 or 2.8.

5. Rectal unit may not be inserted properly.	Check that the rectal unit is properly positioned.
6. Patient improperly positioned.	Reposition patient with head and shoulders elevated no higher than a 20° angle.
7. Microwave catheter may not be positioned properly.	Check that the microwave catheter is properly positioned.
8. Rectal unit may be defective.	Replace the rectal unit.

ERROR #14 - RECTAL TEMP. LOW

POSSIBLE CAUSES	ACTION STEPS
1. Loose connector.	Reattach connector.
Rectal unit temperature below 15°C.	Check that the rectal unit is inserted properly.
2. Rectal unit expelled or not properly inflated.	Reinsert the rectal unit, or inflate the rectal unit.
3. Rectal unit may not be inserted properly.	Check that the rectal unit is properly positioned.
4. Rectal unit may be defective.	Replace the rectal unit.

ERROR #15 - COOLANT PRESS. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. Pressure too high in tubing.	Check that pump tubing clamp is properly fastened, and that the tubing is not kinked.
2. Coolant bag may be defective.	Disconnect coolant luers from microwave catheter, temporarily connect the coolant luers to each other, and then restart treatment. If error repeats, replace coolant bag. Otherwise, check the microwave catheter.
3. Microwave catheter may be defective.	Disconnect coolant luers from the microwave catheter and flush microwave catheter coolant luers with sterile water. Reconnect coolant bag luers to the microwave catheter, and restart treatment. If error repeats, replace the microwave catheter.

ERROR #16 - COOLANT PRESS. LOW

POSSIBLE CAUSES	ACTION STEPS
1. Pressure is too low in the tubing.	Check water level in the coolant bag. Check that the pump tubing clamp is properly fastened.
2. Coolant tubing between coolant bag and sensor module may be twisted.	Verify tubing is not twisted.
3. Coolant bag may be defective.	Replace the coolant bag.
4. Microwave catheter may be defective.	Replace the microwave catheter.

ERROR #17 - URETHRA TEMP. HIGH

POSSIBLE CAUSES	ACTION STEPS
1. Loose microwave catheter fiber connector.	Reattach fiber connector. Clean both ends of connection with alcohol wipe or swab.
2. Temperature in urethra > 44.5°C.	Allow microwave catheter temperature to drop ≤ 41°C.
3. Microwave catheter may be defective.	Replace the microwave catheter.

ERROR #18 - URETHRA TEMP. LOW

POSSIBLE CAUSES	ACTION STEPS
1. Loose microwave catheter fiber connectors.	Reattach connector.
2. Microwave catheter may be defective.	Replace the microwave catheter.

ERROR #19 - CATHETER EFFICIENCY LOW

POSSIBLE CAUSES	ACTION STEPS
1. Cable may not be connected properly.	Reattach connector. Rotate the Microwave Antenna Connector nut 4 full turns with your fingers until snug to ensure a proper connection.
2. Microwave catheter may not be inserted properly.	Check that the microwave catheter is inserted properly.
3. Urine drainage line not purged.	Purge urine drainage line.
4. Defective microwave catheter.	Replace the microwave catheter, and recalibrate.

ERROR #20 - PUMP LATCH OPEN

POSSIBLE CAUSES	ACTION STEPS
1. Coolant pump clamp latch is open.	Close the latch.
2. Lift lever has failed.	Open and close lift lever, and listen for 2 clicks.

ERROR #21 - USER PRESSED "MICROWAVE OFF"

POSSIBLE CAUSES	ACTION STEPS
1. User accidentally pressed the Microwave Off pushbutton.	Press the **Resume** button or the **Reset** button to continue.
2. Patient was experiencing pain.	Resume treatment after the pain level has reduced.
3. Microwave indicator was illuminated when it should not have been.	Call Urologix Customer Service.

ERROR #22 - RECTAL UNIT DISCONNECTED

POSSIBLE CAUSES	ACTION STEPS
1. Rectal unit has become disconnected.	Reattach the rectal unit to the patient connection cable housing.

ERROR #23 - URETHRA SIGNAL WEAK

POSSIBLE CAUSES	ACTION STEPS
1. Loose microwave catheter fiber connectors.	Reattach connector.
2. Microwave catheter may be defective.	Replace the microwave catheter.
3. Patient cable may be defective.	Call Urologix Customer Service.

ERROR #50 - MAXIMUM TREATMENT TIME EXCEEDED

POSSIBLE CAUSES	ACTION STEPS
1. Treatment timer has exceeded 60 minutes.	Press the **Pause/End** button to begin cooldown.

ERROR #51 - MAXIMUM MWG TIME EXCEEDED

POSSIBLE CAUSES	ACTION STEPS
1. 100 minutes have elapsed since completing calibration.	Press the **Pause/End** button to begin cooldown.

ERROR #52 - WARNING: URETHRA TEMP. >41°C

POSSIBLE CAUSES	ACTION STEPS
1. Urethra temperature is too high.	Reduce microwave power to maintain urethra temperature below 41°C.

ERROR #54 - WARNING: RECTAL TEMP. > 42°C

POSSIBLE CAUSES	ACTION STEPS
1. Rectal temperature is too high.	Reduce microwave power to lower the rectal temperature to less than 42°C.

ERROR #59 - WARNING: CRUISE UNAVAILABLE

POSSIBLE CAUSES	ACTION STEPS
1. An error condition is active.	Resolve any indicated errors before turning on Automatic treatment mode.

ERROR #99 - URETHRA TEMP PROBE ERROR

POSSIBLE CAUSES	ACTION STEPS
1. Loose microwave catheter fiber connectors.	Reattach connector.
2. Microwave catheter may be defective.	Replace the microwave catheter.

ERROR #100 - RECTAL UNIT CAL. FAILURE

POSSIBLE CAUSES	ACTION STEPS
1. All 5 rectal sensors are not within required temperature range.	Allow time for temperatures to stabilize, and press the **Retry** button. If unsuccessful, replace the rectal unit.

2. Rectal unit not properly inserted or inflated.	Ensure that the rectal unit is inserted and inflated properly. Then, press the **Retry** button.
3. Defective rectal unit.	Replace the rectal unit.

ERROR #101 - URETHRA TEMP CAL FAIL

POSSIBLE CAUSES	ACTION STEPS
1. Fiber optic connector may be improperly connected.	Disconnect and reconnect microwave catheter fiber optic connector to patient connection cable housing.
2. Fiber optic connector may be dirty.	Disconnect fiber optic connector, inspect for foreign material, and clean with isopropyl alcohol and swab.
3. Microwave catheter may not be properly inserted.	Ensure that the microwave catheter is properly inserted in patient.
4. Microwave catheter may be defective.	Replace the microwave catheter.
5. Patient cable may be defective.	Call Urologix Customer Service.

ERROR #103 - MW CALIBRATION FAILURE

POSSIBLE CAUSES	ACTION STEPS
1. Antenna connector may be improperly connected.	Reattach the connector, being careful not to cross-thread it. Rotate the Microwave Antenna Connector nut 4 full turns with your fingers until snug to ensure a proper connection.
2. The urine drainage lumen may contain air.	Purge the urine drainage lumen with fluid.
3. Microwave catheter may be defective.	Replace the microwave catheter.

ERROR #105 - USER CANCELED OPERATION

POSSIBLE CAUSES	ACTION STEPS
1. Calibration stopped by user.	Address reason for stopping calibration, and resume calibration sequence.

ERROR #198 - INVALID CATHETER TYPE DETECTED

POSSIBLE CAUSES	ACTION STEPS
1. Microwave catheter type in RFID does not match.	Replace the microwave catheter.

ERROR #199 - URETHRA TEMP. CROSS-CHECK.

POSSIBLE CAUSES	ACTION STEPS
1. Internal voltage fluctuation relating to fiber optic sensor.	Press the **Retry** button if available.

ERROR #300 - CONTROL UNIT TEMP. TOO HIGH

POSSIBLE CAUSES	ACTION STEPS
1. CoolWave Control Unit vents are blocked on the sides or back of the machine.	Remove any item that may be blocking the vents.
2. CoolWave Control Unit internal temperature > 60°C.	Allow the CoolWave Control Unit to continue pumping coolant through the catheter. Call Urologix Customer Service.

ERROR #317 - LOW VOLTAGE STARTUP

POSSIBLE CAUSES	ACTION STEPS
1. Low voltage at start-up.	Verify that an extension cord is not being used, and check the circuit breaker for sufficient current capability.
2. Hardware failsafe switch in wrong position.	Call Urologix Customer Service.

ERROR #422 - INVALID RECTAL RFID

POSSIBLE CAUSES	ACTION STEPS
1. The rectal unit RFID tag is being read, but it contains invalid data.	Replace the rectal unit with one that contains a valid RFID tag.

ERROR #423 - DIFFERENT RECTAL RFID

POSSIBLE CAUSES	ACTION STEPS
1. The rectal unit RFID tag is different from the one displayed on the Protocol Screen.	Reattach the original rectal unit and select the **Retry** button, or select the **Replace** button to return to the Protocol Screen using the currently attached rectal unit.

ERROR #424 - INVALID TAG

POSSIBLE CAUSES	ACTION STEPS
1. An RFID tag is being read, but it contains invalid data.	Remove the connectors from both disposable devices, and replace them individually. Observe the rectal unit and microwave catheter serial number fields to determine which RFID tag is invalid.

ERROR #425 - DIFFERENT CATHETER RFID

POSSIBLE CAUSES	ACTION STEPS
1. The catheter RFID tag is different from the one displayed on the Protocol Screen.	Reattach the original microwave catheter and select the **Retry** button, or select the **Replace** button to return to the Protocol Screen using the currently attached catheter.

ERROR #426 - MULTIPLE CATHETER RFIDS

POSSIBLE CAUSES	ACTION STEPS
1. More than 1 microwave catheter near the patient connection cable housing.	Remove the extra microwave catheters from the area around the patient cable.

ERROR #427 - MULTIPLE RECTAL RFIDS

POSSIBLE CAUSES	ACTION STEPS
1. More than 1 rectal unit near the patient connection cable housing.	Remove the extra rectal units from the area around the patient cable.

ERROR #428 - NO CATHETER RFID SENSED

POSSIBLE CAUSES	ACTION STEPS
1. The microwave catheter RFID tag has been removed from the patient connection cable housing area.	Replace the same microwave catheter so that the CoolWave Control Unit can access the RFID tag.
2. The microwave catheter RFID tag is not in range.	Adjust the orientation of the tag label on the microwave catheter so that it can be read.

ERROR #429 - NO RECTAL RFID SENSED

POSSIBLE CAUSES	ACTION STEPS
1. The rectal unit RFID tag has been removed from the patient connection cable housing area.	Replace the same rectal unit so that the CoolWave Control Unit can access the RFID tag.
2. The rectal unit tag is not in range.	Adjust the orientation of the tag label on the rectal unit so that it can be read.

ERROR #431 - MANY RFIDS SENSED

POSSIBLE CAUSES	ACTION STEPS
1. More than 4 RFID tags are near the patient connection cable housing.	Remove other microwave catheters and rectal units from the patient connection cable housing area.

CONTROL UNIT DOES NOT RECOGNIZE SERIAL NUMBER

POSSIBLE CAUSES	ACTION STEPS
1. RFID Tag not in Antenna Field Connection cable housing	Verify that serial tag is adjacent to connector and rotated such that it touches the flat portion of the Patient Cable Connector
2. RFID field being affected by surrounding metallic surfaces	If Patient cable Connector is setting on a metallic surface, raise it off the surface by setting it on a nonmetallic spacer such as a towel.

ERROR# AND ERROR NAME - DETECTED BY SOFTWARE

309	Synthesizer Unlocked	466	Msg Queue Open Error
311	File Open Error	467	Msg Queue Not Open
312	Urethra Temp Comm Fail	468	Msg Queue Already Open
313	MW Comm. Failure	469	Msg Queue Create Error
314	Parameter Error	470	Process Internal Error
315	Watchdog Timeout	471	Process Start Error
316	Disk Free Error	472	Condvar Wait Error
322	File CRC Failure	473	Error Reading Safety Data
375	MW Software (Low)	501	Coolant Regulation Aborted
376	MW Software (High)	502	Urethra Regulation Aborted
377	MW Software (Mid)	510	Data Write Error
378	MW Software Reverse	511	Data Read Error
379	MW Software Forward	512	Mutex Set Error
398	Memory Free Error	513	Mutex Clear Error
399	Urethra Temp Setup Error	514	Write Error
418	Urethra Temp. Failure	515	Read Error
430	RFID Comm. Failure	516	Seek Error
432	RFID Update failure - RTU	517	Language File Open Error
433	RFID Update failure - Catheter	518	Language Internal Error
442	File Missing	519	Language String Overflow
443	Msg Queue Filling Warning	520	Language Array Overflow
444	Memory Free Warning	521	Language Array Underflow
445	Disk Free Warning	522	Language Mgr Not Open
451	Software Watchdog Test Failure	523	Language Mgr Init Error
452	Msg Queue Overflow	524	Data Manager Not Open
453	Process Status Error	525	Data Manager Initialization
456	Resource Mgr Read Error	526	File Length Error
457	Mutex Unlock Error	527	File Size Error
458	Mutex Lock Error	529	Device Not Open
459	Mutex Init Error	530	Device Already Open
460	Timer Multiple Ticks Missed	531	Device Open Error
461	Data Corruption Error	532	Process Spawn Error
462	Msg Queue Receive	533	Scan Data Error
463	Msg Queue Send Error	534	Ini File Range Error
464	Msg Queue Destroy Error	535	Ini File Label Error
465	Msg Queue Open Error	536	Ini Section Error

POSSIBLE CAUSES	ACTION STEPS
1. Detected in the software.	Allow coolant system to run for 5 minutes on the System Error screen. Reboot the CoolWave Control Unit by pressing the shutdown button, and turning it OFF after the "okay to shutdown message" is displayed. Wait until the fans stop, and then turn the unit ON again. If the error occurred during treatment, use the Treatment Restart feature (see section 5.2) to continue the treatment. Note: The error may repeat again. Call Urologix Customer Service to report the error.

ERROR# AND ERROR NAME - HARDWARE FAILURES

301	Coolant Hotside Low	319	HWFS Disconnected
302	Coolant Coldside Low	320	MW Supply
303	Hardware Failsafe Malfunction	321	Quad Power Supply Error
304	HW Sensor Address Error	387	Coolant Coldside High
305	MW Interface	388	Coolant Hotside High
306	Internal Sensor	389	Control Unit Temp. Too Low
307	MW Hardware	449	HW Control Register Error
308	Rectal Sensor Interface		

POSSIBLE CAUSES	ACTION STEPS
1. Nonresolvable hardware failure.	Will probably need a field service visit to resolve the problem. Allow coolant system to run for 5 minutes on the System Error screen and call Urologix Customer Service. Note: If the coolant pump is not running, manually irrigate.

5.2 Treatment Restart

The purpose of the treatment restart function is to allow the user to continue a previously running treatment without having to swap the catheter should the control unit need to be restarted. The "Treatment Restart – Available" screen (Figure 5-1) will automatically appear if the control unit is restarted within 30 minutes of a shutdown.

Figure 5-1. Treatment Restart - Available

Verify the information the screen is correct:

- Shutdown Time: indicates when the control unit stopped working.
- User Name: the user that had been logged in at the time of shutdown.
- Treatment Catheter SN: the serial number on the RFID tag of the catheter that was connected at the time of shutdown.
- Treatment Time: the amount of time the patient has received treatment at the time of shutdown.
- Elapsed Time: the total amount of time after calibration completed at the time of shutdown. This includes the initial ramp, treatment, and cooldown phases of treatment.
- Total Energy: the amount of microwave energy applied during the treatment at the time of shutdown.

If the above information is not correct or you wish to discontinue treatment, press the Exit button, confirm your selection by hitting Exit again, to advance to the Welcome (login) screen.

If the above information is correct, press the Cool button to begin the 5 minute cooldown and prepare to recalibrate with the current catheter and RFID tags. The control unit will begin pumping coolant at 37° C for a minimum of 5 minutes before the Calibrate button becomes active (Figure 5-2).

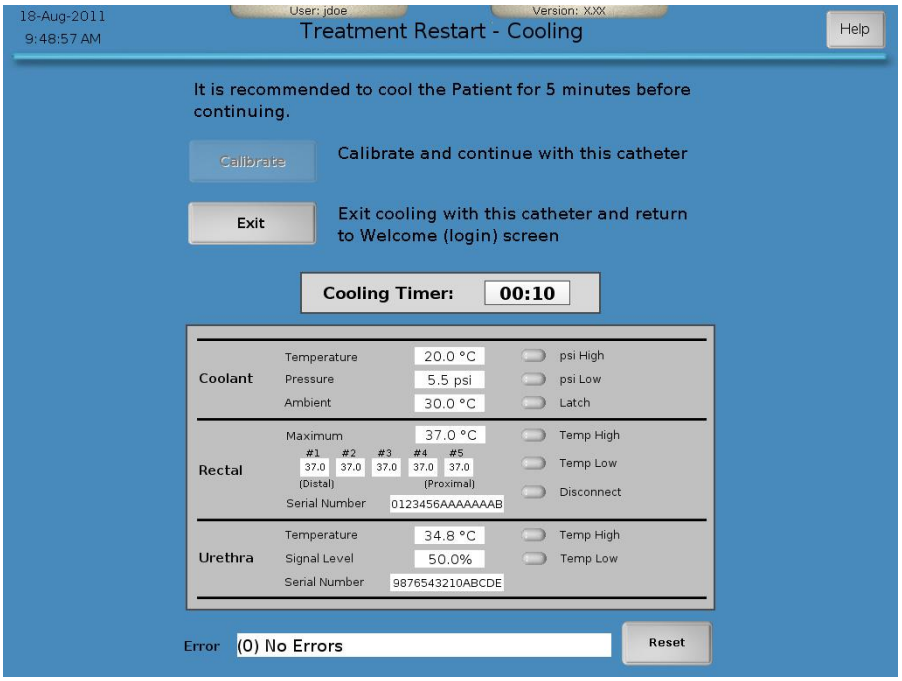


Figure 5-2. Treatment Restart - Cooling

This screen (Figure 5-2) will display the current values for the coolant, rectal, and urethra sensors as well as current warnings and errors. Any active error will be marked with a red light. To reset warnings and errors, press the Reset button. For additional information about system errors, refer to *Section 3.6, System Errors*.

Note: You may need to review this information if an error occurs and does not resolve. At this point, contact Urologix Customer Service (1-888-229-0772) to help you resolve any remaining errors.

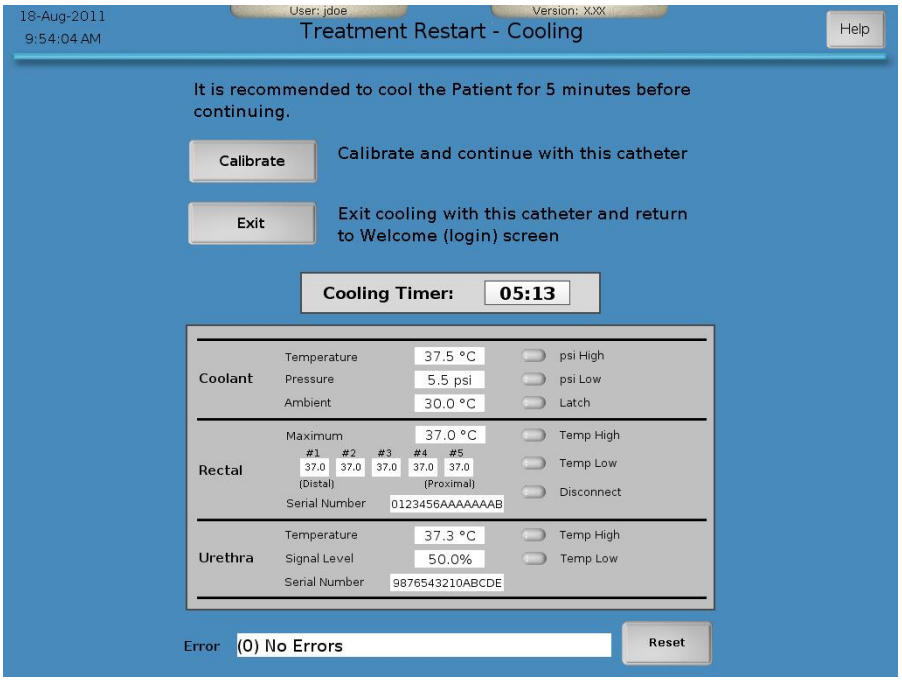


Figure 5-3. Treatment Restart - Cooling [Calibrate]

After the Cooling Timer has reached 5 minutes, press Calibrate button to continue to the Treatment Checklist screen and begin calibration.

Note: The same catheter RFID tag must be connected.

In the event of a catheter RFID tag error, the following message will appear (Figure 5-4):

Figure 5-4. RFID Tag Error

Upon completion of Calibration, the Treatment screen will appear. Resume previous treatment until the desired treatment time is achieved.

5.3 Treatment screen flowchart

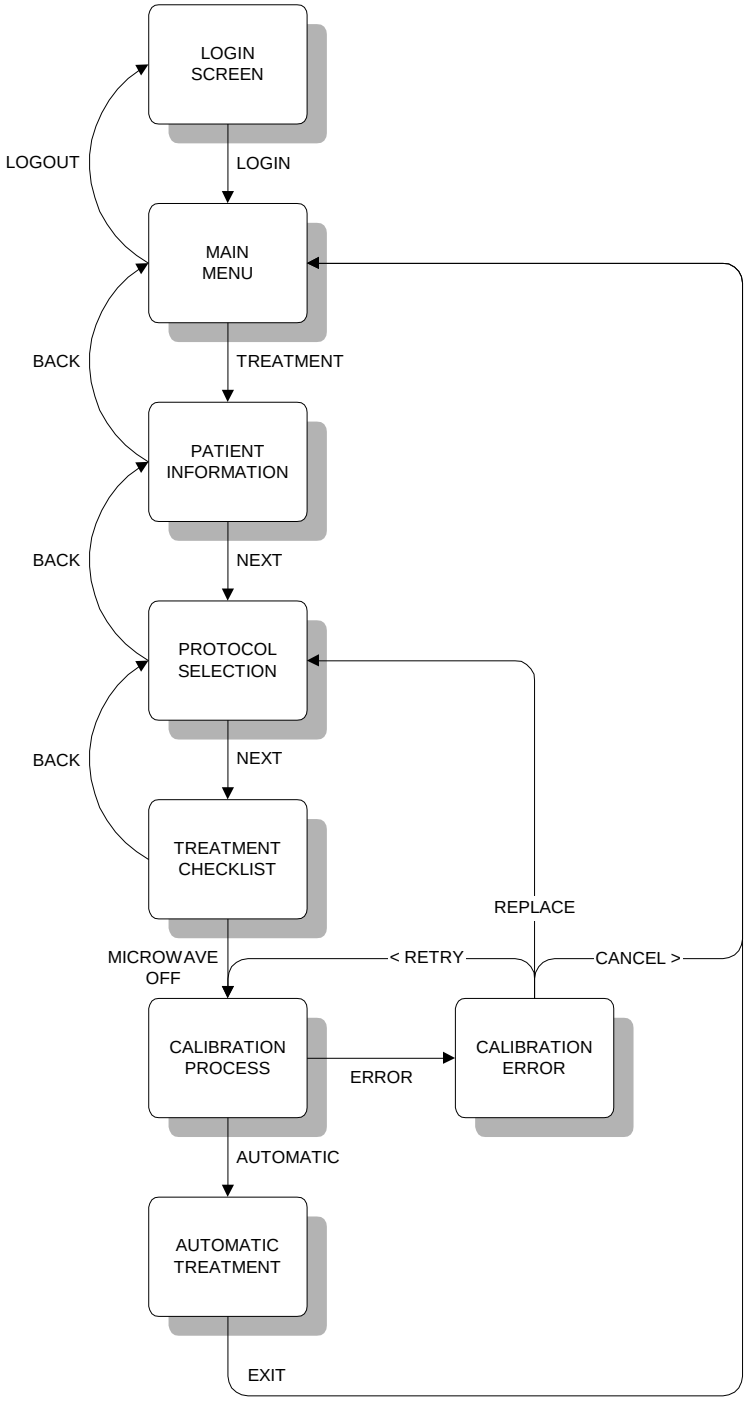
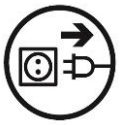
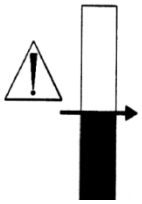
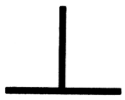
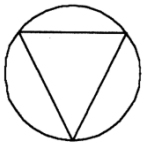
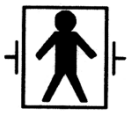


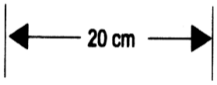
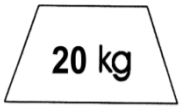
Figure 5-5. Treatment screen flowchart

5.4 Description of symbols

There are a number of symbols associated with the Targis System CoolWave Control Unit, Microwave Catheter, RTU and Coolant Bag. Some of these symbols appear in Section 1 of this manual. Other symbols Urologix adopted from the international community to assist you in understanding Urologix labeling.

SYMBOL	DESCRIPTION
	Alternating current
	Catalog Number
	Batch Code / Lot Number
	Serial Number
	Do not re-use
	Equal potential ground
	Remove cord before servicing
	Fuse type and value
	Internal reservoir level

SYMBOL	DESCRIPTION
	Nonionizing radiation (microwave power)
	Operate on a level surface
	Do Not Tip Over
RTU	Rectal unit
	Consult Instructions for Use
	Caution
	Stop microwave energy
	Type BF equipment with defibrillation protection
STERILE EO	Sterilized Using Ethylene Oxide
	Use By Date
	Temperature Limitation

SYMBOL	DESCRIPTION
	Do Not Resterilize
	Recyclable Package
	Keep objects 20 cm from vents
	Do not place heavy objects on drawer
	Caution cold surface
	Do Not Use if Package is Damaged
℞ ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program
	Note
	Caution
	Warning
	Date of Manufacture

SYMBOL	DESCRIPTION
	Manufacturer
	Authorized Representative in the European Community
	CSA Certification Mark
	CE Mark

Table 5-1. Description of symbols

5.5 Patient Comfort Kit

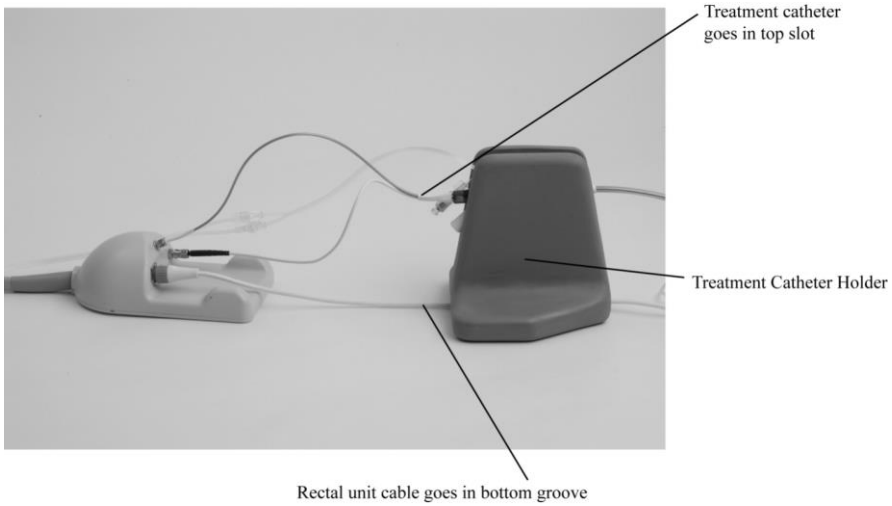


Figure 5-6. Microwave catheter Holder

Figure 5-7. Knee cushions

5.6 Glossary

Advanced mode
Select advanced mode from the Control Panel on the Urologix - BPH Treatment screen to adjust treatment parameters (urethra setting, treatment time, coolant setting, and ramp rate) during a Cooled ThermoTherapy Treatment in automatic treatment mode.

Analgesia
The reduction of pain stimulus without the corresponding loss of consciousness.

Analgesic
A medication that reduces or eliminates pain. In BPH patients, depending on the clinician's diagnosis, there are several agents that might be considered for the reduction of pain.

Antibiotic
A substance that is used to destroy or inhibit the growth of microorganisms.

Anti-inflammatory
A medication that is used to reduce inflammation, which is often characterized by localized heat, redness, swelling, and pain in the tissues.

Automatic treatment mode
The CoolWave Control Unit begins a Cooled ThermoTherapy Treatment, based on the selected treatment protocol, and continues with that treatment until the end of cooldown, without the need for adjusting any treatment parameters.

Benign Prostatic Hyperplasia (BPH)
A nonmalignant but abnormal increase in the tissue of the prostate gland that sometimes results in constriction of the urethra.

BPH
The acronym for Benign Prostatic Hyperplasia.

Cable holder
Located on the back of the CoolWave Control Unit, the cable holder provides a place to store the power cord and the patient connection cable and housing.

Calibration process
A diagnostic test that the CoolWave Control Unit runs to determine whether its components are functioning properly: (1) Rectal unit and temperature sensors are operating within 2 degrees of each other; (2) Urethra temperature sensor is operational; (3) Pressure in the microwave cooling system is normal; and (4) Antenna is operational, as verified by a frequency sweep.

Catheterization
The placement of the microwave catheter or urine drainage catheter into the urethra.

Chill plate
One of the components of the CoolWave Control Unit coolant system that removes heat from the coolant bag.

Computer subsystem
The CoolWave Control Unit contains a computer that allows the clinician to input patient identification data, control the treatment, and collect treatment data.

Control Panel
The area of the Urologix - BPH Treatment screen that allows you to adjust urethra temperature, treatment time, coolant temperature, and ramp rate. You can also pause or end a treatment.

Coolant Bag
The coolant bag is comprised of 3 main subassemblies: coolant bag (coolant reservoir), sensor module, and tubing with connectors. The coolant bag is a container that fits against the chill plate. It is filled with sterile, distilled water (coolant) that circulates through the microwave catheter during treatment to preserve urethral tissue.

Coolant door
The large panel on the right side of the CoolWave Control Unit behind which is located the coolant bag, chill plate, temperature sensor, pressure sensor, and peristaltic pump mechanism.

Coolant pump
See peristaltic pump mechanism.

Coolant set point
The temperature at which the cooling system is set to regulate the temperature of the water circulating through the microwave catheter. The actual water temperature may be different from this value during the time that the system chills or warms the water. Once the water reaches the coolant set point value, the coolant temperature is maintained within a small tolerance of this value.

Coolant system
The coolant system consists of a chill plate, temperature and pressure sensors, a peristaltic pump mechanism, and a coolant bag.

Coolant temperature
The actual measured temperature of the water circulating through the microwave catheter. This temperature is measured at the sensor block just before the water leaves the Control Unit.

Cooldown
The time in a treatment when the microwave power is OFF, the coolant pump is running, and the cooldown 5-minute timer appears.

Cooled ThermoTherapy Treatment
A medical treatment that uses microwave energy to destroy the prostatic tissue that constricts the urethra while preserving urethral function and tissue.

Cooling channel
The tiny passageways, adjacent to the antenna within the microwave catheter, that transport chilled, sterile water throughout the catheter to maintain a urethral temperature.

Cooling lumen
See cooling channel.

CTC Advance Microwave Catheter
A type of microwave catheter.

Data field
An area on the touchscreen where you can enter information.

Demonstration mode
Demonstration mode simulates a Cooled ThermoTherapy Treatment and allows you to work with the CoolWave System as though you were performing a treatment on a patient.

Dialog box
A dialog box appears on the touchscreen and provides additional information or instruction during a treatment.

Ejaculation
The discharge of semen through the penis during sexual excitement.

Exclusion criteria
A list of conditions that may bar a prospective patient from participating in a BPH clinical trial.

Frequency sweep
An internal diagnostic test the CoolWave Control Unit performs to determine the functional status of the microwave antenna once it is placed inside the patient.

Gross hematuria
A profuse quantity of blood in the urine.

Help feature
Provides information on error messages and topics within the CoolWave System.

Hospital or clinic ID
The patient’s medical record number.

Impotence
The inability to achieve an erection.

Incontinence
The inability to control urination.

Interval timer
The mechanism in the CoolWave Control Unit that displays the time at which the last power adjustment occurred.

Location balloon
The inflatable portion of the microwave catheter found near the tip that locates the microwave antenna within the bladder/bladder neck.

Manual mode
Though the CoolWave Control Unit begins a treatment, based on the selected treatment protocol, you can manually adjust the microwave power and coolant pump (ON vs. OFF) during the treatment.

Messages
Directions or reports that assist the clinician in monitoring a Cooled ThermoTherapy treatment.

Microwave antenna
The component within the microwave catheter that generates heat energy to destroy prostate tissue.

Microwave Off pushbutton
The red button, located under the touchscreen on the CoolWave Control Unit, that allows you to discontinue the delivery of microwave power immediately.

Microwave catheter
A disposable, catheter-based device (which is delivered sterile) that is inserted into the urethra. It includes a fiber optic temperature sensor to measure urethral temperature, a microwave antenna and cable, cooling channels and connectors, a urine drainage port that connects to a standard urine drainage bag, and a location balloon to position the catheter at the bladder neck.

Microwave catheter balloon
See location balloon.

Microwave Catheter Holder
The Microwave Catheter Holder is designed to hold the microwave catheter in position during treatment.

Microwave catheter serial number
The serial number of the microwave catheter used in a treatment and required for the patient's data file.

MW
An abbreviation for microwave.

Neurogenic bladder
Dysfunctional urinary bladder caused by a lesion of the nervous system.

Notes feature
A place to enter a patient's treatment information during a treatment.

Obstructive bladder neck syndrome
An impairment of the outlet area of the bladder caused by prostate tissue constricting the urethra.

Orientation flag
The vertical guide on the rectal unit, approximately 1" in height that serves the clinician in correctly positioning the rectal balloon.

Patient Comfort Kit
A CoolWave Control Unit accessory which includes 2 knee cushions and Microwave Catheter Holder. It provides comfort for the patient and holds the catheter in position for the duration of treatment.

Patient connection cable
An extension cable that connects the patient connection cable housing to the CoolWave Control Unit.

Patient connection cable housing
The patient connection cable housing contains connectors for the rectal unit, fiber optic connector, and microwave connector.

Perineum
An anatomical landmark between the scrotum and the anus.

Peristaltic pump mechanism
The small, wheel-like motorized drive behind the coolant door of the CoolWave Control Unit that uses peristaltic action to propel coolant through the coolant inlet tubing to the microwave catheter and beyond. Also referred to as the coolant pump.

Power set point
Represents the actual microwave power output exactly equal to the power setting within the accuracy limits of the CoolWave Control Unit.

Preprostatic urethra
The proximal portion of the prostatic urethra. It runs through the prostate beginning just distal to the bladder neck and ending just proximal to the verumontanum.

Pressure sensor
The small metal disk that fits against the diaphragm of the sensor module on the lower right front side of the CoolWave Control Unit. Its function is to detect changes in pressure within the tubing of the microwave catheter and signal potential coolant leaks.

Procedure Kit
The Procedure Kit contains 1 disposable microwave catheter, 1 disposable rectal unit, and 1 coolant bag.

Prostate gland
A partly muscular, partly glandular organ that surrounds the neck of the bladder and the urethra. It secretes an alkaline viscose fluid that provides maintenance and activation of sperm at ejaculation.

Prostatic median lobe
The middle rounded mass of 3 rounded masses of tissue that develop adjacent to the urethra in the hyperplastic prostate.

Prostatism
Disease of the prostate gland.

Pump mechanism
See peristaltic pump mechanism.

Pump tubing clamp
The fastening arm just above the peristaltic pump mechanism that locks the coolant inlet tubing in place as it is routed out of the Control Unit console to the microwave catheter.

Rectal temperature
The temperature reported by the warmest of the 5 sensors in the rectal unit.

Rectal thermosensing unit (RTU)
A device with temperature sensors that monitors the patient's rectal temperatures when the device is positioned correctly within the rectum along the rectal prostatic wall. It is connected to the patient connection cable, via the patient connection cable housing, of the CoolWave Control Unit.

Rectal unit serial number
The serial number of a rectal unit.

Rectum
The terminal portion of the intestine (continuation of the sigmoid colon) that ends in the anus.

Retrograde ejaculation
Sometimes called "dry climax," this event refers to the discharge of semen backwards into the bladder. The condition may result from surgery that cuts the muscle that blocks the entrance to the bladder.

RFID
An acronym for radio frequency identification.

RTU
A single-use rectal unit, and an acronym for what was previously referred to as the Rectal Thermal Unit.

RTU Plus
The rectal unit with a reusable handle and single-use balloon.

Standard mode
Select standard mode from the Control Panel on the Urologix - BPH Treatment screen to adjust treatment parameters (urethra setting and treatment time) during a Cooled ThermoTherapy treatment in automatic treatment mode.

Startup routine
The CoolWave Control Unit internal checking procedure, which runs each time the system is turned ON.

Status Panel
Treatment data at the top of the Urologix - BPH Treatment screen: microwave power, coolant temperature, rectal temperature, urethra temperature, treatment status, and treatment progress.

Targis Microwave catheter
A type of microwave catheter.

Temperature sensor
A device within the microwave catheter that monitors the urethral temperature of the patient; or a device within the rectal unit that monitors the rectal temperature of the patient.

Testes
The male reproductive glands that reside in the scrotum and produce spermatozoa. Interstitial cells in the testes secrete a hormone, an androgen, that aids the growth and development of the prostate gland.

Touchscreen monitor
The 15" diagonal color display with a touch sensitive glass covering. A gloved or ungloved finger can activate the touchscreen: a pen or stylus will not.

Transport Kit
The only FDA-approved method, other than the original shipping crate, for transporting a CoolWave Control Unit. It includes a trolley and electrical safety tester.

Transrectal ultrasound (TRUS)
Procedure where a clinician inserts a probe into the rectum to obtain an image of the prostate. This image appears on the display to assist the clinician in placing a biopsy needle.

Transurethral incision (TUIP)
A surgical procedure that widens the urethra by making small cuts in the prostate and the bladder neck where the bladder and urethra join.

Transurethral resection (TURP)
A surgical procedure that involves the removal of tissue from the interior of the prostate with an instrument called a resectoscope.

Treatment parameters
CoolWave Control Unit values, such as the microwave catheter and the rectal temperatures, that the clinician monitors during treatment.

Treatment protocol
The step-by-step plan the clinician follows when treating the patient’s prostate condition. Or, the set of treatment parameters clinicians choose to treat a patient’s prostate condition.

Treatment session
A treatment session begins when the patient enters the clinic and ends when the treatment is over and he is discharged.

Treatment timer
The mechanism in the CoolWave Control Unit that advances increments of seconds and minutes at therapeutic temperature.

TRUS
An acronym for transrectal ultrasound.

TUIP
An acronym for transurethral incision of the prostate.

TURP
An acronym for the transurethral resection of the prostate.

Universal Precautions Guidelines
A standard set of safeguards that apply to patients undergoing treatment. For example, the CoolWave Control Unit should not be moved while the electrical cord is connected to a power source.

Urethra set point
The urethra temperature the Control Unit maintains during a treatment. The system increases or decreases microwave power until it reaches the urethra set point.

Urethra temperature
The temperature at the tip of the microwave catheter in the center of the treatment region.

Urinary tract
The pathway in the urogenital system that urine travels as it is eliminated from the body. It consists of the renal tubules and pelvis of the kidney, the ureter, the bladder, and the urethra.

Urination
Discharge of liquid waste from the body.

USB flash drive
A Universal Serial Bus (USB) flash drive is a portable storage device that plugs into a computer USB port.

Verumontanum
An elevation in the floor of the prostate gland where it joins the urethra and the entrance of the seminal ducts.

5.7 Electromagnetic Compatibility (EMC) Tables

Guidance and manufacturer's declaration - Electromagnetic Emissions		
The Targis System with CoolWave Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Targis System with CoolWave Control Unit should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 2	The Targis System with CoolWave Control Unit must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CSPR 11	Class A	The Targis System with CoolWave Control Unit is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic proposes, provided that the following warning is heeded: **Warning:** This equipment is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the Targis System with CoolWave Control Unit or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 5-2 Electromagnetic Emissions

Guidance and manufacturer's declaration - Electromagnetic Immunity			
The Targis System with CoolWave Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Targis System with CoolWave Control Unit should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If 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 and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle <40% U_T (>60% dip in U_T) for 5 cycles <70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle <40% U_T (>60% dip in U_T) for 5 cycles <70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Targis System with CoolWave Control Unit requires continued operation during power mains interruptions, it is recommended that the Targis System with CoolWave Control Unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is an A.C. mains voltage prior to application of the test level			

Table 5-3 Electromagnetic Immunity

<table>
<tr><td colspan="4">Guidance and manufacturer’s declaration - Electromagnetic Immunity</td></tr>
<tr><td colspan="4">The Targis System with CoolWave Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Targis System with CoolWave Control Unit should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 Test Level</td><td>Compliance Level</td><td>Electromagnetic Environment - Guidance</td></tr>
<tr><td colspan="4">Portable and mobile RF communications equipment should be used no closer to any part of the Targis System with CoolWave Control Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td></tr>
<tr><td></td><td></td><td></td><td>Recommended separation distance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3V</td><td>$d = 1.2\sqrt{P}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80MHz to 2.5 GHz</td><td>3V/m</td><td>$d = 1.2\sqrt{P}$ 80MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800MHz to 2.5GHz</td></tr>
<tr><td colspan="4">Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strength from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range.**

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">Note 1. At 80 MHz and 800 MHz, the higher frequency range applies
Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">* 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, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Targis System with CoolWave Control Unit is used exceeds the applicable RF compliance level above, the Targis System with CoolWave Control Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Targis System with CoolWave Control Unit.</td></tr>
<tr><td colspan="4">** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m</td></tr>
</table>

Table 5-4 Electromagnetic Immunity (continued)

Recommended separation distance between portable and mobile RF communications equipment and the Targis System with CoolWave Control Unit			
The Targis System with CoolWave Control Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Targis System with CoolWave Control Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Targis System with CoolWave Control Unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 5-5 Recommended Separation Distances

6 Appendix B

6.1 Training Course

Course Description

Cooled ThermoTherapy, or transurethral microwave thermotherapy (TUMT) is a non-surgical treatment for benign prostatic hyperplasia (BPH). Urologists require specific training in the safe and effective use of the Targis System: CoolWave Control Unit, for treating patients with BPH. Training relevant to the urologists' nurses and assistants is available and recommended.

Required Training

- Receive and review the *Targis System: CoolWave Control Unit User Manual* and *Instructions for Use* for the CoolWave Control Unit and components.
- Understand the information presented in the training session that covers the key elements of the Cooled ThermoTherapy treatment including indications, contraindications, warnings and precautions; patient selection and assessment; pre and post-treatment parameters; inherent risks of treatment; system components and protocols; and safety precautions.
- Perform and/or observe a minimum of 2 patient treatments, proctored by a Urologix Clinical Specialist, Certified Master Trainer, or Certified Trainer.
- Complete a post-test, achieve a minimum score of 90% and sign a Training Confirmation form confirming that all required instructional materials have been read, and instruction and understanding of the key elements of Cooled ThermoTherapy have been achieved.

Program Objectives

Upon completion of the program, participants will be able to:

1. Describe the mechanism of microwave thermotherapy.
2. List the indications, contraindications, warnings and precautions, and inherent risk of complications (as stated in the Adverse Events and Complications sections in the *Instructions for Use*).
3. Describe patient selection, pre and post-treatment patient preparation and comfort management, including analgesia options.
4. Describe the system components and treatment protocols for the Targis System.
5. Describe the safety precautions.

Faculty

A Clinical Specialist and/or Certified Master Trainer or Certified Trainer.

Instruction Materials

Targis System: CoolWave User Manual, *Instructions for Use*, and post-test.

Training Methods

Didactic session: Includes instruction on the principles of microwave thermotherapy, patient selection and management, office medication protocol, description of Targis System components and treatment protocols for the CoolWave Control Unit.

Perform or observe a minimum of 2 patient treatments, proctored by a Urologix Clinical Specialist, Certified Master Trainer or Certified Trainer.

Evaluation Methods

Written post-test with a minimum score of 90% and signed Training Confirmation form.

Certificate of Training

A Certificate of Training is issued to urologists and staff members who satisfactorily complete all of the aforementioned training requirements.

6.2 Cooled ThermoTherapy Overview

Cooled ThermoTherapy – Overview

- Heat is the result of energy whose biologic effects depend on the intensity, duration, and means of application. The majority of minimally invasive, non-surgical modalities that have emerged during the last decade apply thermal energy to the prostate by either the rectal or urethral route, using a variety of heat applicators, such as laser devices, high-intensity focused ultrasound (HIFU), or transurethral radiofrequency. Currently, a drawback of these options is the necessity for general anesthesia or a higher level of analgesia.

- The use of microwave as a heat source has been investigated extensively. Pioneer microwave research efforts in the early 1980s were focused on the use of hyperthermia by applying microwave heat rectally or urethrally. It became apparent that hyperthermia target temperatures of less than 45ºC were not effective, and higher temperatures were required. This led to the development of microwave thermotherapy that was designed to apply microwave energy deep within the lateral prostatic lobes, and to simultaneously cool the urethral mucosa.

- Cooled ThermoTherapy, or transurethral microwave thermotherapy (TUMT), is a non-surgical, minimally invasive treatment for benign prostatic hyperplasia (BPH). The goal of the Cooled ThermoTherapy treatment is to improve patient symptoms and voiding function by thermoablation of the adenomous prostatic tissue while maintaining lower temperatures in non-target tissue.

- A Cooled ThermoTherapy treatment treats BPH by applying microwave energy to the prostate via its transurethral Microwave Catheter that precisely heats diseased areas while simultaneously cooling and protecting the pain-sensitive urethral tissue. This method of circulating cooling fluid through the Microwave Catheter minimizes patient discomfort and risk of thermal damage to the urethra. The cooling of the urethra provides an analgesic effect during treatment while maintaining the urethral temperature at less than 45ºC. This effect allows the treatment to be performed on an ambulatory basis without the need for general anesthesia.

- Continuous energy delivery allows for a durable and consistent treatment for many men with symptomatic and/or obstructive BPH. The preservation of urethral integrity is a unique feature of Cooled ThermoTherapy that defines it as a minimally invasive treatment and limits morbidity.

Principles of Operation

- Cooled ThermoTherapy is a process that delivers microwave energy to the prostatic adenoma and minimizes the effect on surrounding structures. It combines the principles of:
  - Microwave radiative (inductive) heating delivered through the urethra
  - Water conductive cooling

- The biologic effects of applying thermal energy to the prostate depend on the intensity, duration, and means of application. The goal of Cooled ThermoTherapy is to heat tissue within the prostate to therapeutic levels (≥50ºC within the adenomous tissue) during a single treatment (28.5 minutes to one hour), while preserving the external urinary sphincter and surrounding healthy tissues with continuous cooling.

Biophysics of Cooled ThermoTherapy

- Microwaves comprise the 300 – 3000 MHz range of the electromagnetic spectrum. The entire spectrum of electromagnetic waves (e.g., X-rays, visible light, infrared) can interact with living matter, but the mechanisms of interactions are not the same on the entire frequency range. The interaction with microwaves results in the heating of biological tissue.

- As microwaves propagate through biological tissue, they transfer energy to heat by the electromagnetic field oscillation of free charges of electrons and ions and by the polarization of small molecules, primarily water.

- The resulting molecular kinetic energy raises the temperature of the tissue and causes heating. The frequency of the microwave energy and the type of tissue targeted affect the depth of penetration. A frequency of 915 MHz is used in the CoolWave Control Unit. The water in treated tissues reduces the penetration of microwaves. Therefore, the penetration of microwaves is greater in low water content tissue (adipose) than in high water content tissue (muscle). Cooling of tissue surrounding the treatment zone during microwave thermotherapy can protect normal tissue[1].

- Tissue temperatures achieved in a microwave field depend on the energy delivered and thermal conduction and thermal convection (e.g., tissue perfusion). Cell necrosis only occurs when the cell temperatures exceed their thermal cytotoxic threshold. The thermal cytotoxic threshold depends on thermal history (i.e., time and temperature).

[1] Bernardo NO, Smith AD. Transurethral microwave thermotherapy of the prostate for BPH. C Urol.1999;1-6.

Application of Energy to the Prostate

- The thermal cytotoxic threshold for prostatic adenomatous tissue is believed to be about 50ºC maintained for approximately 30 minutes[2]. As temperature increases above this level, the required time decreases. No irreversible thermal mediated injury can be demonstrated histologically in areas of the prostate where temperatures are below this threshold.

- Not all cells are affected within the treated area. The thermal cytotoxic threshold varies with cell type. While capillaries are thrombosed, larger vessels can be preserved due to the blood flow cooling the vessel wall. Consequently, a full necrotic process does not necessarily occur.

- In most cases, no prostatic urethral damage occurs because conductive cooling preserves the urethral mucosa. The urethral cooling allows higher temperatures to be achieved, and also minimizes discomfort during treatment. Refer to the Instructions for Use for more information.

[2] Bischof, J et al. Heat sensitivity of human prostatic tissue: Implications for thermal therapy. J Urol. 2003; 169:287

6.3 Cooled ThermoTherapy Treatment

Patient Selection

Proper patient selection and education, including setting realistic expectations for the treatment and its outcomes, are essential for successful Cooled ThermoTherapy, or transurethral microwave thermotherapy (TUMT), treatment in the office setting.

Patient Assessment

Pretreatment patient assessment may include:

- International Prostate Symptom Score (IPSS) also known as American Urological Association Symptom Score.
- Quality of Life (QOL) score.
- Medical history, including medications.
- Physical exam, including digital rectal exam (DRE).
- Urinalysis.
- Blood analysis, specifically PSA, BUN, creatinine and glucose (consider INR if patient is anticoagulated).
- Uroflowmetry.
- Post-void residual (PVR).
- Cystoscopy (to rule out enlarged obstructing median lobe protruding into the bladder and to measure prostatic urethral length).
- Transrectal ultrasound to assess prostate volume.
- Appropriate evaluation to identify conditions that can mimic LUTS secondary to Benign Prostatic Hyperplasia (BPH) such as UTI, Parkinson's Disease, bladder or prostate cancer.

Urologists must establish, to their satisfaction, that:

- Prostate lengths are measured accurately from the verumontanum to the bladder neck.
- The patient has BPH (symptom score, uroflowmetry, quality of life).
- Treatment is clinically indicated.
- No active infection is present.
- The median lobe is not protruding into the bladder (a "ball-valve" median lobe).

Only physicians who have been thoroughly trained on the operation of the Targis System: CoolWave Control Unit and the Cooled ThermoTherapy treatment should deliver the Cooled ThermoTherapy treatment. Attention by a qualified physician is required during the use of the Targis System. The Control Unit display must be monitored and controlled during the course of the treatment to make sure that the urethral and rectal temperatures are within prescribed treatment parameters.

Indications for Cooled ThermoTherapy

The Targis System: CoolWave Control Unit, is a non-surgical device intended to relieve symptoms and obstruction associated with BPH and is intended for men with prostatic urethra lengths of ≥ 2.5 cm. There are several Microwave Catheter options:

Microwave Catheter	Prostatic Urethra Length	Time of Treatment
CTC Advance Microwave Catheter 2.5-3.5 cm	2.5-3.5	28.5 minutes
CTC Advance Microwave Catheter 3.0-5.0 cm	3.0-5.0	28.5 minutes
CTC Advance Microwave Catheter 4.5+ cm	4.5+	28.5 minutes

Contraindications for Cooled ThermoTherapy

- Patients with a prostatic urethra length of < 2.5 cm as measured from the bladder neck to the verumontanum as indicated in the table above for the specific Microwave Catheter.
- Patients with urinary sphincter or any implant (metallic or non-metallic) which is within 1.5 inches (38 mm) of the prostatic urethra.
- Patients with urethral stricture (unable to pass 22F urethroscope).
- Patients with peripheral arterial disease with intermittent claudication or Leriches Syndrome (e.g. claudication of the buttocks or perineum).
- Patients who have undergone pelvic radiation therapy.
- Patients with implanted active devices, including pacemakers or defibrillators, within 2.6 inches (6.5 cm) of the prostatic urethra.

Warnings for Cooled ThermoTherapy

- The Cooled ThermoTherapy treatment has inherent risks of complications (refer to Adverse Events and Complications). The Targis System and components should not be used in any way other than the intended and indicated use and according to the *Instructions for Use*.

Precautions for Cooled ThermoTherapy

- Only physicians who have been thoroughly trained on the operation of the CoolWave Control Unit and the Cooled ThermoTherapy treatment should deliver the Cooled ThermoTherapy treatment.

- Selection and Use of the appropriate catheter model is required to ensure patient safety.

- The Cooled ThermoTherapy treatment must not be initiated without assurance that the Microwave Catheter is properly positioned in the patient.

- **The correct positioning of the Microwave Catheter must always be checked by ultrasound imaging prior to commencing treatment. Improper placement or orientation of the Microwave Catheter may lead to treatment failures or heating damage of non-target tissues such as the bladder neck, external sphincter or penile urethra.**

- The Cooled ThermoTherapy treatment must not be initiated until an enema has been given and the Rectal Thermosensing Unit (RTU) is properly placed into the patient's rectum and inflated.

- It is important that the patient not be over sedated. Over sedation may compromise his ability to communicate pain.

- The safety and effectiveness of the Cooled ThermoTherapy treatment has not been established in patients with the following conditions:
  - Patients with clinical or histological evidence of prostatic cancer or bladder cancer.
  - Interest in preservation of future fertility.
  - Post-void residual (PVR) >350mL.
  - Previous pelvic surgery.
  - Previous rectal surgery (other than hemorrhoidectomy).
  - Obstructing median lobe enlarged out of proportion to the rest of the prostate
  - and protruding significantly into the bladder, sometimes referred to as a "ball valve" median lobe.
  - Active urinary tract infection.
  - Gross hematuria not due to BPH.
  - Prior prostatic surgery (excluding balloon dilatation).
  - Coexisting illness or specified obstructive symptoms found to be caused by any of the following conditions:

Neurologic bladder disorders	Bladder stones
Prostate volume greater than 100 cc	Evidence of bacterial prostatitis
Bladder neck contracture	Renal impairment
Urinary sphincter abnormalities	Coagulation disorders

- For patients with active implanted devices located greater than 2.6 inches (6.5 cm) from the prostatic urethra, it is recommended that non-cardiac devices be turned OFF during the treatment with the Targis System, if possible (e.g., active implanted devices used in the treatment of pain or incontinence), to lessen the likelihood of adverse interaction caused by electromagnetic interference. If possible, active implanted devices that must remain ON should be programmed to the bipolar configuration. Implanted cardioverter defibrillators should be set to monitor only mode during therapy. Regardless of whether active implanted devices > 2.6 inches (6.5 cm) from the prostatic urethra can be turned OFF, the patient should be monitored during the Cooled ThermoTherapy treatment for possible interactions. In the unlikely event of an active implanted device programming change, the device should be interrogated following the treatment with the Targis System.

- All components of the Targis System must be used in a manner consistent with the instructions set forth in their respective *Instructions for Use* insert and the Targis System: CoolWave Control Unit *User Manual*. Failure to do so may result in insufficient treatment or increased risk of injury or infection to the patient.

- Use of the Targis System results in the deposition of microwave energy within the patient's prostate and in adjacent regions of the body. Some animal studies in the literature suggest that there may be as yet unknown health effects from exposure to microwave radiation, including an increased incidence of tumors. Although it is not possible to extrapolate these studies to humans, they suggest that unnecessary microwave radiation exposure should be avoided.

- At least 20 cm of ventilation clearance must be provided around the base of the CoolWave Control Unit.

- The Targis System emits a small amount of electromagnetic energy during a treatment. Urologix recommends that all electronic medical devices be kept at a minimum distance of 1.0 meter from the Targis System when performing a treatment. However, a 1.0 meter separation of electronic medical equipment from the Targis System does not guarantee that operation of other devices will not be impacted. The effect of this electromagnetic energy on all equipment cannot be predicted due to age and quality of maintenance. The performance of each piece of equipment operated near the Targis System, during a treatment, must be evaluated for degradation.

- Since microwave energy can travel though walls, ceilings and floors to affect other devices, it is important to understand that the 1 meter safety distance applies not only to the treatment room, but also to all adjacent rooms in the building, including the rooms above and below the treatment room.

- Do not operate the Targis System near equipment that emits electromagnetic energy, unless the effect on the Targis System has been evaluated and no degradation of performance was found.

- The national standard ANSI/IEEE C95.1 - 1999 Edition (Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields) recommends a maximum stray field exposure level for whole body exposure of 3 mW/cm2, as averaged for any six minute period. The maximum radiated field, at full power, from the CoolWave Control Unit patient cable and Microwave Catheter, at five centimeters, is 2.1 mW/cm2. Urologix recommends that the operator maintain a minimum distance to five centimeters, from the patient cable and exposed portions of the Microwave Catheter during the treatment.

- Operate the CoolWave Control Unit and connected devices only in clinical environments where the electrical insulation is in accordance with international standard DIN VDE 0107; and the national standard, ANSI/NFPA 70. The equipment must be connected to a fully tested, hospital grade power outlet with adequate grounding.

- The CoolWave Control Unit must be plugged into the appropriate voltage outlet.

- The electrical equipment inside the Targis System uses voltages which are capable of causing serious injury or death from electric shock. To avoid this hazard, operators must never open the housing of the CoolWave Control Unit.

Power Requirements

Supply:	*European Version: 220/240V [+/- 10%] (8 A) Single phase 50 or 60 Hz* *US Version: 110/120V [+/- 10%] (15 A) Single phase 50 or 60 Hz*
Connections:	*Hospital Grade plug*

While the above summarizes the use of Targis System, please refer to specific product labeling, the Targis System: CoolWave Control Unit *User Manual* and *Instructions for Use*. For product performance related questions, please contact Urologix at 800.475.1403.

6.4 CoolWave System Software

Review *Section 3* - *Treatment Instructions* of this User Manual with the Physician.

6.5 Performing a Cooled ThermoTherapy Treatment

Implementation Guidelines

Facility

- Adequate space should be available for patient preparation and post-treatment recovery.
- The treatment room should have adequate floor space to accommodate the
- following:
  - CoolWave Control Unit
  - Treatment table
  - Ultrasound unit
  - Working space for staff
- Other treatment room requirements include:
  - A standard 110-volt electrical supply for the CoolWave Control Unit (European Version: 220/240V [+/- 10%] (8 A) Single phase 50 or 60 Hz)
  - Air conditioning to maintain ambient room temperature between 59º F (15º C) and 95°F (35°C) Room ventilation system should provide 8 – 10 air changes per hour for natural odor removal.
  - 20 cm clearance around the base of the CoolWave Control Unit.
- Please refer to the Section 2 of this User Manual for additional information.

Required Supplies and Equipment

Ultrasound Equipment with Transrectal or Transabdominal Probe

Recommended Supplies and Equipment

Standard Urological Supplies

- Straight catheter, 14-16 French
- Foley catheter, 16-18 French
- Anesthetic lubricating jelly (Urojet, Anestecon or lidocaine jelly)
- Local bladder anesthetic of choice (e.g., 50 cc of 1% or 2% lidocaine without epinephrine)
- Water-soluble lubricating gel (e.g., KY)
- 200 cc sterile water for Coolant Bag and Microwave Catheter balloons
- 60 cc catheter-tip syringe (e.g., Toomey syringe)
- 60 cc luer-lok syringe
- 10 cc luer-lok syringe x2
- Catheter plug
- Urine drainage bag
- Permanent marker or tape
- Sterile gloves
- Non-sterile gloves
- Penile clamp
- Specimen cup
- Urinal or graduate
- Ice or ice pack

Targis System

- CoolWave Control Unit
- Patient Comfort Kit including: Microwave Catheter Holder and Knee Cushions
- Procedure Kit including:
  - Sterile Microwave Catheter and
  - Rectal Thermosensing Unit (RTU)
  - Coolant Bag

Pretreatment and Treatment Preparation

The Facility Environment

A comfortable and restful atmosphere helps to minimize patient stress and anxiety during the treatment and promotes a positive clinical outcome.

Prior to the patient's arrival:

- Set up the ultrasound system
- Assemble and set up the treatment field with all necessary equipment, medications and supplies (Please refer to the Targis System: CoolWave Control Unit *User Manual* or *Instructions for Use* for proper system assembly)
- Prepare patient discharge supplies (e.g., medications, Foley Catheter with instructions)
- Provide a restful atmosphere with a quiet room, comfortable treatment bed (use the Knee Cushions), dimmed lighting if possible, and a minimal number of medical personnel

During the treatment:

- Offer the patient diversions such as conversation, music, TV or video.

Pretreatment Patient Instructions

The following guidelines are suggested for the day before and the day of treatment.

- Avoid alcohol, coffee and other caffeinated beverages 48 hours prior to the treatment.
- The night before treatment, eat a light meal.
- The day of treatment, eat a light breakfast such as toast, juice or milk.
- Continue taking all routine prescription medications.
- Administer a self-enema such as a Fleet enema 1-2 hours prior to the treatment. **An enema cleanses the rectum and is essential for accurate rectal temperature measurement during the treatment.**
- Plan to arrive about 60 minutes before the treatment. This will allow enough time to prepare for the treatment, including pretreatment medication, as needed, to help relax.
- Arrange for transportation home after the treatment; patient should not drive himself home.

Prior to the treatment, and as instructed by the treating urologist, facility staff should:

- Ensure that an enema has been administered (recommended 1 to 2 hours prior to the treatment), and that the patient had results.
- Give the patient pre-medication such as relaxants, analgesics, antibiotics, and anti-inflammatories.
- Explain the treatment by reviewing the patient information in the Instructions for Use with the patient.

- Instruct patient to disrobe.
- Administer routine skin preparation of the meatal area (e.g., Betadine prep).
- Catheterize the patient; drain the bladder and instill urethral and bladder local anesthetic.
- Assist patient into a supine position with a maximum head / shoulder elevation of 20º.
- Follow the treating urologist's recommendations for monitoring.

Managing Patient Expectations – Keys to Success

An appropriately trained staff member directly involved in patient care should be with the patient throughout the treatment. **Only physicians who have been thoroughly trained on the operation of the CoolWave Control Unit and the Cooled ThermoTherapy treatment should deliver the Cooled ThermoTherapy treatment. Attention by a qualified physician is required during the use of the Targis System.**

A patient who is informed of all aspects of the treatment should respond more favorably and with less anxiety when provided with these facts:

- Clear pre- and post-treatment instructions.
- Description of the Cooled ThermoTherapy (transurethral microwave thermotherapy) treatment (the mechanics of the process).
- Explanation of what to expect during the treatment (e.g., pressure in the bladder and penis; heat sensation; need to urinate; bladder spasm).
- The length of the treatment (28.5 or 60 minutes).
- The risks associated with the treatment (e.g., common side effects, secondary reactions, medications and methods):
  - Physicians should inform patients of an inherent risk of complications associated with the Cooled ThermoTherapy treatment (refer to Adverse Events and Complications in the Instructions for Use).
  - Physicians should inform patients that a loss of ejaculation may occur as a result of the Cooled ThermoTherapy treatment, which should be considered by men who may wish to have further offspring.
  - Physicians should inform patients that the volume of ejaculate may be decreased in some men who undergo the Cooled ThermoTherapy treatment. Temporary acute urinary retention, temporary incontinence, minimal bleeding, pain on urination and intercourse and urinary tract infection may be associated with the Cooled ThermoTherapy treatment.
  - The patient should be informed that a small risk of urethral stricture may result from the treatment, requiring further intervention (refer to Adverse Events and Complications in the Instructions for Use).
  - Patients may likely be catheterized for a 2 to 5-day (median 3-day) period or longer, following the Cooled ThermoTherapy treatment.
  - Patients may be prescribed anti-inflammatory and antibiotic medications for a period following the treatment.
  - Patients should be informed that they may experience discomfort during the treatment that may require the use of analgesics or sedatives to deliver an effective treatment.

Analgesia Guidelines

Anesthesia is **NOT** required for patients undergoing a Cooled ThermoTherapy treatment. *It is important that the patient not be over-sedated.* This may compromise his ability to communicate pain or other experiences.

Pretreatment Medications

- Many urologists choose to treat patients with a non-steroidal anti-inflammatory drug for 2-5 days and to start the patient on antibiotic one day pretreatment and continuing post-treatment as required.
- If a patient is not on alpha blockers prior to treatment many physicians will start him on alpha blockers approximately one week prior to treatment, continuing post-treatment for 6-8 weeks.

Treatment Medications

- It is suggested that topical lidocaine jelly and/or a bladder cocktail be instilled into the urethra, and allowed to dwell for 20-30 minutes before the Microwave Catheter is inserted.
- Additional medication may be required for a comfortable Cooled ThermoTherapy treatment. It appears that the treatment is best tolerated by patients who have been given an NSAID and/or an oral anxiolytic or analgesic, **ONE HOUR PRIOR TO BEGINNING THE TREATMENT**, or as the specific drug label requires for maximum effect during treatment.
- An anticholinergic or antispasmodic may also be given to relieve bladder spasms, and additional analgesics may be administered if warranted by the patient's individual tolerance.

Post-Treatment Medications

- A short course of an oral NSAID is beneficial in many cases, unless contraindicated. Other options may include a 5-day minimum cycle of antibiotics and/or alpha blockers for 6-8 weeks.

Note: All medication decisions are the prerogative of the treating urologist.

Post-Treatment Care

- The patient may experience several days of prostatic discomfort and increased irritative symptoms following the Cooled ThermoTherapy treatment. Overall, post- treatment side effects vary in duration and intensity. At pre- and post-treatment, it is important to explain to the patient that there is a possibility his symptoms may transiently worsen after treatment, and that it may take up to several weeks before noticing significant improvement. A Foley catheter for 2-5 days (or longer for some patients) may be used following the treatment to reduce the incidence of urinary retention and the associated pain and discomfort resulting from the treatment.
- The patient may also experience a few side effects from the treatment, and may notice some (or none) of the following:
  - Soreness in the lower abdomen
  - Urgency to urinate even after the catheter is removed
  - Frequent urination
  - Bladder spasms
  - Small amounts of blood in the urine
  - Aching and/or discomfort in the prostate area
- Failure to void upon Microwave Catheter removal does not mean treatment failure.
- Prior to discharge home, the patient and urologist should discuss patient expectations, and the patient should be given 1) instructions to maintain an adequate fluid intake; 2) prescriptions for an NSAID, an antibiotic, and antispasmodic; 3) Foley catheter care instructions; 4) a follow-up appointment; and 5) instructions similar to the following:

  The patient should be told to contact the physician if he:
  - *Develops a high fever, with temperature above 101.5ºF.*
  - *Notices a painful, swollen and/or inflamed testicle(s) or scrotum.*
  - *Is unable to void spontaneously or the indwelling catheter is not draining urine and is blocked.*
  - *Has difficulty moving his bowels.*
  - *Has excessive urinary bleeding or bleeding from the penis.*
  - *Has continuous bladder spasms.*

For a complete description of System Components, refer to *Section* 1 - *System Description.*

6.6 Frequently Asked Patient Questions

What is a prostate gland?

The prostate gland, located just below the bladder, is about the size and shape of a walnut. Its primary function is to produce semen, the fluid that carries sperm. The prostate surrounds the urethra—the tube that carries urine from the bladder.

What is BPH?

BPH is Benign Prostatic Hyperplasia, also known as enlarged prostate. It is a non-cancerous condition in which the prostate cells increase in number as a normal part of aging.

What are the symptoms of enlarged prostate?

The symptoms of enlarged prostate are:

- Frequent and urgent need to urinate both day and night
- Difficulty starting urination
- Weak urine flow
- Urine flow that stops and starts
- Feeling of being unable to completely empty your bladder
- Urinary incontinence
- Interference with sexual activity
- Urinary tract infections

How does Cooled ThermoTherapy work?

The treatment uses a Microwave Catheter that your doctor inserts into your urethra. This Microwave Catheter contains an antenna that delivers heat to the enlarged prostate tissue and destroys it. At the same time, cool water circulates through the Microwave Catheter to protect the surrounding tissues from the heat generated by the microwave energy.

How do I know if the treatment is right for me?

If your physician has diagnosed you with BPH or an enlarged prostate, you may qualify for the Cooled ThermoTherapy treatment. Your physician will complete an exam to determine if the treatment is right for you.

As a patient, why should I choose Cooled ThermoTherapy?

It is a convenient, simple, safe and effective treatment. Cooled ThermoTherapy is a non-surgical office procedure that requires only one visit for a full treatment. This durable and proven therapy is often a better alternative to a lifetime of drug therapy and is less invasive than surgery.

Where is the treatment performed?

The treatment may be performed in your physician's office or in the outpatient treatment room of a hospital.

Are there any pre-existing conditions that would exclude me from this treatment?

Yes, as with any treatment it is not for everyone. There is a small list of contraindications that could exclude you from treatment. However, the person best able to assess this is your urologist.

What should I expect Pre/During /Post-treatment?

After completion of your initial visit (work-up) if the doctor decides you are a candidate for Cooled ThermoTherapy, the doctor will go over and give you a complete list of instructions.

Am I awake during the treatment?

Yes. The treatment does not require anesthesia, so you can watch television, read, or listen to music during the treatment.

Will I have any pain during the treatment?

Some patients experience discomfort during the treatment. The clinic staff will try to make the treatment as comfortable as possible for you. Your physician may decide to give you medication at the start of the treatment. You will also be positioned on the treatment table to make you feel relaxed and comfortable.

How long does the treatment take?

The treatment takes between 28.5 and 60 minutes, excluding time of arrival, preparation time and departure from the office.

Will I need someone to drive me home?

Yes, you will.

How long will it take for me to recover and return to normal activity?

You will be able to go home shortly after the treatment. You may have a urinary drainage catheter for 2-5 days post-treatment which should not preclude you from returning to normal activities. Most patients do not require bed rest after treatment; however, recovery time to return to your normal activities varies from patient to patient. You should notice results within 6 – 12 weeks.

Will I have pain after the treatment?

You may be uncomfortable for several days after treatment. You may feel sore in your lower abdomen and it may be uncomfortable to sit down. Some blood may be discharged from your penis, which is normal. It is important to take the medications your doctor prescribes after the treatment.

Will I need a urinary catheter after the treatment?

The tissue surrounding the urethra will be irritated and swollen after the treatment, so you may go home with a urinary catheter in place. The catheter will drain urine from your bladder while the swelling and inflammation recede. The catheter may be in place for 2 –5 days after the treatment. Your physician or nurse will provide you with instructions for catheter care.

What are the risks or side effects?

There are few risks or side effects associated with the Cooled ThermoTherapy treatment. Possible Cooled ThermoTherapy side effects include: blood in urine, clots in urine, painful or difficult urination, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm. Many patients experience post-treatment catheterization for an average of 2-5 days. The outcome of the treatment depends on your overall health as well as other factors. Your physician or nurse will discuss all of your concerns before you receive the treatment.

How many patients have been treated with Cooled ThermoTherapy?

More than 275,000[1] patients have been successfully treated.

How much does the treatment cost and will my insurance cover it?

Your doctor's office staff will contact your insurance company to determine benefits.

Is Cooled ThermoTherapy cost effective?

Yes, Cooled ThermoTherapy is a cost effective therapy. It avoids the higher costs and risks of surgery and the expense and burden of chronic medication therapy.

Is Medicare Reimbursement available for Cooled ThermoTherapy?

Yes, Medicare reimburses for the Cooled ThermoTherapy Treatments. Most private insurance carriers also cover the treatment.

Who do I call with questions?

Call your urologist or a designated nurse and/or assistant.

Who will do the treatment?

Your physician will insert the Microwave Catheter into your urethra and will be in attendance during the treatment. A nurse or clinician may also assist.

What will I do if I have problems after the treatment?

Your physician or nurse will discuss with you what to expect after the treatment. If you think you have a problem after the treatment, contact your physician as soon as possible. You may also be instructed to go to your local emergency room for treatment.

Does Cooled ThermoTherapy make drugs and surgery obsolete?

No, drugs and surgery are still options. Your physician will make a recommendation based on your specific needs.

Will I have to miss work?

You may have a urinary drainage catheter for 2-5 days post-treatment which should not preclude you from returning to work. Most patients do not require bed rest after treatment; however, recovery time to return to your normal activities varies from patient to patient. The majority of men return to work in less than one week.

How soon can I have sex?

Once you return home and the urinary drainage catheter has been removed (if needed), you can resume intercourse as soon as you are comfortable.

How significant and long lasting is the improvement in my symptoms?

Cooled ThermoTherapy produces durable improvements in symptoms, quality of life and flow rates to at least 5 years after treatment[3].

[1]Data on file at Urologix, Inc.

[3]Mynderse LA, Roehrborn CG, et al. Results of a 5-Year Multicenter Trial of a New Generation Cooled High Energy Transurethral Microwave Thermal Therapy Catheter for BPH. Journal of Urology. Vol. 185, 1804-1811, May 2011

6.7 Example Patient Documents

These patient documents on the following pages are provided as examples to assist physicians and their staff on possible content for the purpose of aiding in their office processes and treatments. This is not intended to constitute medical advice or is it meant to be exhaustive in acquiring patient information upon which to make medical decisions. Rather, it is a list of possible forms, questions and information that physicians and office staff may use in managing patients throughout the treatment. A physician must exercise his/her own best judgment in gathering patient history, consent, patient instructions, treatment protocol and/or any follow up and discharge instructions.

Cooled ThermoTherapy Patient Screening Form

Patient Name: _____ Telephone: _____

Address: _____

City: _____ State: _____ Zip: _____

Insurance: _____

Referring Physician Name: _____

PRE-SCREENING QUESTIONS TO DETERMINE ELIGIBILITY (Questions 1 – 6 must be NO):

	Yes	No	Don't Know
Patients with a prostatic urethra < 2.5 cm in length as measured from the bladder neck to the verumontanum.			
Patients with urinary sphincter or any implant (metallic or non-metallic) which is within 1.5" (38 mm) of the prostatic urethra.			
Patients with urethral stricture (unable to pass 22 F urethroscope).			
Patients with peripheral arterial disease with intermittent claudication or Leriches Syndrome (i.e. claudication of the buttocks or perineum).			
Patients who have undergone pelvic radiation therapy.			
Patients with implanted active devices, including pacemakers or defibrillators, within 2.6" (6.5 cm) of the prostatic urethra.			

If the patient answers "No" to the patient pre-screening questions, schedule a screening visit:
Your appointment is scheduled for:

Date: _____

Time: _____

Location: _____

Physician: _____

At this visit we will:

- Answer additional questions you may have about the Cooled ThermoTherapy treatment
- Review and sign a patient consent form (optional per hospital and / or office policy)
- Obtain medical history information
- Perform tests to determine your current medical condition

Please come to the appointment with a full bladder, medical records that pertain to any condition you are now being treated for and a list of medications and the dosage that you are taking.

Cooled ThermoTherapy is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical treatments may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the treatment that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.[1] For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.urologix.com or call us at 1.800.475.1403.

[1]Data taken from the CTC Advance Instructions for Use, 250348.

Informed Consent Form for Cooled ThermoTherapy™ Treatment

Description of Treatment: Cooled ThermoTherapy, or transurethral microwave thermotherapy (TUMT), is a non-surgical treatment for benign enlargement of the prostate gland (also known as benign prostatic hyperplasia, or BPH). The treatment is delivered through a medical device that uses microwave energy to heat the diseased prostate gland areas in conjunction with a circulating cooling system that cools and protects the urethral tissue. During this treatment, a catheter-like probe will be inserted into my urethra after application of an anesthetic jelly. This probe contains the microwave generating applicator and the cooling system used to treat my prostate gland. In addition, a temperature-sensitive probe will be inserted into my rectum to monitor the temperature during the treatment. The treatment time will be approximately 30 minutes to one hour. Pain medications may be given before, during, and / or after treatment.

Anticipated Benefit: I understand that the anticipated benefit of having a Cooled ThermoTherapy treatment is to relieve my bladder outflow obstruction and associated symptoms.

Risks / Possible Complications: I understand that the risks of this treatment to be: decreased sexual function and/or impotence, temporary or permanent loss of ejaculation (a consideration for men who may wish to have further offspring), post treatment urinary retention which will require catheterization, temporary or permanent incontinence, urethral stricture. I understand that I may have temporary: pain and inflammation in the reproductive tract, post treatment urethral discharge, bleeding from the urethra/penis, urinary tract infection, rectal discomfort. I may likely have to wear a catheter for a 2 to 5 day (median 3 day) period following the treatment.

Alternative to Treatment: I understand there are alternative methods for the treatment of benign prostatic hyperplasia (BPH). These include: 1) a procedure known as transurethral resection of the prostate (TURP), which involves surgical removal of part of the prostate; 2) laser and vaporization therapy; 3) transurethral needle ablation of the prostate (TUNA), using radio frequency waves; 4) drug therapy with specific medications; and 5) insertion of a urethral stent. These therapies may or may not be considered advantageous alternatives based on my particular condition. They may have risks and / or complications that are greater or lesser in nature than the Urologix Cooled ThermoTherapy treatment. My physician has discussed the alternatives with me and answered any questions I have about these alternative treatments.

Consent for Treatment: My physician has discussed with me the contraindications and precautions, along with the above information, concerning this treatment. I certify by my signature below that I have read (or have had read to me) and understand this Informed Consent form. Any questions that I asked have been answered in a language that I understand. I voluntarily consent to this treatment.

_____ _____
Signature of Patient Date

_____
Printed Name of Patient

_____ _____
Signature of Physician Date

_____ _____
Signature of Witness Date

Cooled ThermoTherapy is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical treatments may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the treatment that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.[1] For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.urologix.com or call us at 1.800.475.1403.

[1]Data taken from the CTC Advance® Instructions for Use, 250348.

Patient Instructions for a Cooled ThermoTherapy™ Treatment

1. Your treatment is scheduled for: _____

2. Please arrive promptly by: _____

   at the following address _____

   _____

   _____

3. The following guidelines are suggested for the day before and the day after treatment.

   - Reduce fluid intake the day before treatment, but do not stop drinking fluids altogether.
   - Avoid alcohol, coffee and other caffeinated beverages 48 hours prior to the treatment.
   - The night before treatment, eat a light meal.
   - The day of treatment, eat a light breakfast such as toast, juice or milk.
   - Continue taking all routine prescription medications.
   - Administer a self-enema such as a Fleets enema 1 – 3 hours prior to the treatment. An enema cleanses the lower bowel to aid in rectal temperature measurement and helps to maximize comfort during the treatment.
   - Plan to arrive about 60 minutes before the treatment or as instructed by the office. This will allow enough time to prepare for the treatment, including pre-treatment medication, as needed, to help relax.
   - Arrange for transportation home after the treatment.
   - Allow approximately 2 – 3 hours for completion of the treatment.
   - If you have questions or for any reason you will be unable to make this appointment, please call:

_____ _____

Clinician / Physician's Name Clinician / Physician's Phone Number

Cooled ThermoTherapy is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical treatments may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the treatment that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.[1] For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.urologix.com or call us at 1.800.475.1403.

[1]Data taken from the CTC Advance® Instructions for Use, 250348.

Patient Instructions for Medication Management

It is important that you follow your doctor's medication instructions as closely as possible. This is necessary for your health and speedy recovery. Your physician has ordered the following medication:

Name of medication: _____

This medication is used for: _____

Take it at the following times: _____

Dose: _____

Take the medication until: _____

The medication is known to have the following side effects: _____

_____

_____

If you have ANY questions after you return home, please do not hesitate to call.

Your physician / clinician is: _____

Phone number: _____

After normal business hours call: _____

Cooled ThermoTherapy™ is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical treatments may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the treatment that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.[1] For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.urologix.com or call us at 1.800.475.1403.

[1]Data taken from the CTC Advance® Instructions for Use, 250348.

Cooled ThermoTherapy™ Treatment Flow Sheet

Name: _____ Date: _____ Physician: _____

PRE-TREATMENT CHECKLIST

Allergies: _____ Consent Signed: _____ Enema: _____
Routine Medications: _____
Cysto: _____IPSS: _____QMax: _____PSA: _____ Prostate Size: _____PUL: _____
Pre-Treatment Vital Signs: B/P _____ P _____ Temp _____ Loc: _____

Pre-Medication	Time

Pre-Medication	Time

INTRA TREATMENT

Time In: _____Time Out: _____ Treatment Start: _____ Treatment End: _____

Time	B/P	P	R	O2 Sat

Medications	Time

Catheter S/N _____

RTU Lot # _____

Treatment Time _____

POST TREATMENT

Post Therapy Catheter: _____ LOC: _____ Discharge Vital Signs: _____
Catheter Removal: _____ Return Appointment: _____
Discharge Medications: _____
Discharge Instructions Given by: _____
Nurse Signature: _____ MD Signature: _____

Cooled ThermoTherapy is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical treatments may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the treatment that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.[1] For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.urologix.com or call us at 1.800.475.1403.

[1]Data taken from the CTC Advance® Instructions for Use, 250348.

Discharge Instructions Following Cooled Thermotherapy™ Treatment

GENERAL EXPECTATIONS

Some men may experience discomfort after the treatment. On occasion, some bloody discharge may be apparent from the penis. You may have soreness in the lower abdomen, and it may be uncomfortable to sit. You may experience the need to urinate more frequently and with greater urgency. These are all normal reactions to the treatment. It is important to take care of yourself the next couple of days to facilitate a speedy recovery. The following are some suggestions:

1. Have someone drive you home after the treatment.
2. Drink plenty of water.
3. Do not engage in strenuous activity until the catheter is removed.*
4. You may take a shower. Avoid a bath until your catheter has been removed.
5. Take your medication as prescribed.

MEDICATIONS

Take the following medications as directed:

_____ _____

_____ _____

_____ _____

- When taking pain medications, you may experience dizziness or drowsiness. Do not drink alcohol or drive when you are taking these medications.
- If you are given an antibiotic to prevent urinary tract infection, it is important to finish all medications as directed.

*See instructions for Care of Catheter.

COMPLICATIONS

You should contact your physician, _____ at _____
if you experience any of the following:

1. Temperature above 101.5° (taken by mouth).
2. Excessive urinary bleeding or bleeding from the penis.
3. Continuous bladder spasms.
4. Painful, swollen and/or inflated testicle(s) or scrotum.
5. Unable to void spontaneously or the indwelling catheter is not draining urine or is blocked.
6. Difficulty moving bowels.

Always call your physician before going to the emergency room. If your doctor suggests that you go to the emergency room or other facility for catheterization for inability to urinate, be sure to tell the facility personnel to use a Coudé (pronounced coo-day) tipped catheter. If you cannot reach your physician and need immediate attention, go to the hospital emergency room for treatment.

Date: _____ Time: _____

Location: _____

Cooled ThermoTherapy is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical treatments may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the treatment that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.[1] For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.urologix.com or call us at 1.800.475.1403.

[1]Data taken from the CTC Advance® Instructions for Use, 250348.

Cooled Thermotherapy™
Patient Instructions for Care of Catheter

Some swelling of the urinary tract tissue is normal following Cooled ThermoTherapy treatment. The swelling may cause some difficulty in urination. To prevent this problem, a urinary drainage catheter may be inserted prior to your return home. The catheter will drain the urine from your bladder while your urinary tract heals. The following information will help you manage the care of the catheter during recovery period.

1. A catheter is a urinary drainage tube that allows the drainage of urine from the bladder. The tube has a small balloon on one end that is inflated with sterile water. This balloon keeps the catheter in and prevents the tube from sliding out of the bladder.
2. The catheter will remain in place for _____ days.
3. It is important to clean the catheter (the area of the tube where it enters your penis) daily.
   - First, wash your hands before caring for your catheter.
   - Use a clean wash cloth and soap to clean the catheter and the penis.
   - You may wish to use a special cleaning liquid, such as Betadine soap that can be purchased at your local pharmacy.
   - Always clean by wiping away from the tip of the penis.
   - Apply an antibiotic ointment to the tip of the penis after cleaning. Antibiotic ointment can be purchased at your local drug store.
4. The catheter has a drainage bag attached to it. It is important to ensure that the drainage bag is below the level of the bladder to prevent urine from going back up the tube and contaminating the bladder. This reduces the possibility of urinary tract infection.
5. It is important to avoid any tension on the catheter. Tension on the catheter can cause discomfort to tender tissues or dislodge the catheter from the bladder.
6. You may take a daily shower. However, avoid a bath until the catheter has been removed.
7. Observe the catheter for any signs of infection. Note and report any signs of swelling, inflammation, colored discharge or elevated temperatures to your physician.

If you have **ANY** questions after your return home, please do not hesitate to call.

Your physician / clinician is: _____

Phone number: _____

After normal business hours call: _____

Cooled ThermoTherapy is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical treatments may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the treatment that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.[1] For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.urologix.com or call us at 1.800.475.1403.

[1]Data taken from the CTC® Advance Instructions for Use, 250348.

Cooled ThermoTherapy™ Treatment Note

Patient: _____

Date of Service: _____

Pre-Treatment Diagnosis: BPH with obstructive symptoms

Treatment: Cooled ThermoTherapy

Urethra length was: _____CM

Physician: _____

The patient has been advised of the risks of and benefits of this treatment and an informed consent has been obtained from the patient.

Treatment: The patient was given appropriate pre-treatment medication as described in the chart notes. The patient was on the procedure table in the supine position. The Microwave Catheter was then introduced into the bladder and the retention balloon was filled with 10 ml of sterile water. The Rectal Thermosensing Unit (RTU) was introduced into the rectum with the sensor strip in the anterior position and the retention balloon was filled with 70cc of air. Proper catheter balloon orientation was confirmed via ultrasound. A catheter holder was used to maintain the microwave catheter and RTU in the proper position and these units were connected to the Targis/CoolWave Control Unit. After the calibration process was satisfactorily completed, the treatment started when the treatment parameters were met and was completed after_____ minutes. After a 5 minute cool-down period the microwave catheter and the RTU were removed and a _____fr. Foley catheter was inserted into the patient's bladder and retained. A drainage bag was attached. Complete instructions on catheter care and follow up appointments were given to the patient. Please see the chart notes for detail.

_____ _____

Physician's signature Date

Cooled ThermoTherapy is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical treatments may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the treatment that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.[1] For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.urologix.com or call us at 1.800.475.1403.

[1]Data taken from the CTC Advance® Instructions for Use, 250348.

6.8 Urologix Return Material Instructions

Urologix is committed to providing you with the best support and service for your Cooled ThermoTherapy system. In order to ensure the greatest accuracy in tracking product performance, we urge you to contact Field Service at any time (before, during or after treatment) for assistance with any questions or issues that you may encounter. **Please call 1-888-229-0772 and request to speak to Field Service**. You may also request to speak to Urologix Customer Service at this telephone number to report a product issue or complaint, obtain your RMA (Returned Material Authorization) number, or to ask questions pertaining to a specific RMA or the RMA process.

Contents of Return Material Kit:

- 1 RMA Kit Box with shipping label
- 1 Biohazard bag with absorbent pad for un-sterile product

Requirements for RMA Number Issuance:

- If you receive an error code during the treatment, please take a moment to document the error code number and message as this will assist us in determining cause of error.
- Please have detailed information of the pre-testing, treatment and the errors that have occurred during the treatment. Any and all information will be helpful.
- Keep all tags and boxes of product to assist in obtaining product information (e.g. serial and lot number, catheter size and type).
- Call Urologix Customer Service at **1-888-229-0772** to report the product issue or complaint.

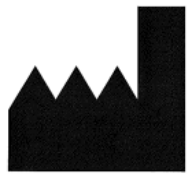
Please follow the steps below for Return Materials:

Please ship defective product within 3 days of reporting the incident. If you are unable to do so, please communicate this with Customer Service at the time of your initial phone call. Follow these steps for returning product:

1. Place the defective product in the middle liner of the biohazard bag. (NOTE: The outer two pockets are for paperwork only.)
2. Remove the adhesive strip and securely seal the bag.
3. Place the sealed bag in the RMA Kit box.
4. Seal the box for secure shipment.
5. A UPS return shipping label should already be affixed to the outside of the box. If a label has not been provided, one will be sent to you.
6. The box can be shipped with your daily UPS pick-up, dropped off at a UPS store, or UPS can be called to schedule a pick-up.

7 Index

Urologix, Inc.
14405 Twenty First Avenue North
Minneapolis, MN 55447-4640
(763) 475-1400 Phone
(800) 475-1403 Toll-free
(763) 475-1443 Fax
(888) 229-0772 Toll-free 24-hour customer service
www.urologix.com



Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands

CE 0086

CoolWave User Manual - Part #250023-001 Rev L, July-2015