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® Targis® System.

You must establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

The Targis System is intended for use only by qualified medical personnel. Federal law in the United States restricts this device for sale, distribution, use by or on the order of physicians. 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 Targis System in *Section 5.3, Description of symbols*.

Safety Symbol	Definition
 **Note**	A note indicates important information that helps you operate the Targis Control Unit or use the disposable devices.
 **Caution**	A caution contains instructions that must be followed to avoid the Control Unit or disposable devices from malfunctioning or from damage. 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 Targis System User Manual.

1.3 User manual overview

This manual combines technical reference material as well as information on how to use the Targis System.

Notes:

- For information regarding the contents of this manual, please call Urologix Customer Service at 1-888-229-0772.
- Read this manual before operating equipment, and keep the manual in the holder on the Control Unit for reference.

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

Section 2: Treatment Session Setup describes how to prepare the patient, prepare the Control Unit, install the Targis Coolant Bag, and insert the MDS (treatment catheter) and the RTU (rectal unit).

Section 3: Treatment Instructions provides instruction on how to use the Control Unit from logging into the Control Unit to beginning and ending a Targis 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 Control Unit. Finally, this section discusses how to maintain the equipment, though some maintenance requires a Urologix trained service representative.

Section 5: Appendix 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 Targis Patient Comfort Kit, and a glossary of terms used in Targis System literature.

1.4 Precautions

Only those physicians who have been thoroughly trained on the operation of the Targis System and the Targis procedure should deliver the Targis procedure.

The Targis procedure must not be initiated without assurance that the treatment 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 treatment catheter may lead to procedure failures or heating damage of nontarget tissues such as the bladder neck, external sphincter, or penile urethra.**

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 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 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 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 instruction 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 his own expense.

The Urologix Targis System emits a small amount of electromagnetic energy during a procedure. 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-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 can not be predicted due to age and quality of maintenance. The performance of each piece of equipment operated near the Targis System, during a procedure, must be evaluated for degradation.

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 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/cm^2, as averaged for any 6 minute period. The maximum radiated field, at full power, from the Targis Control Unit patient cable and treatment catheter, at 5 centimers, 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 catheter

during the procedure.

Operate the Control Unit and connected devices only in clinical environments where the electrical installation 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 Control Unit must be plugged into the appropriate voltage outlet.

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

1.5 Introduction to the Targis System

The Targis System 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 treatment catheter. This catheter also minimizes patient discomfort and risk to the urethra by circulating cooling fluid. In addition, the treatment catheter protects the rectal wall from damage: The system targets microwave power at the prostate while continuously monitoring rectal wall temperature readings throughout treatment. However, if during a treatment, urethra or rectal temperatures exceed protocol parameters, the system will adjust microwave power to protect the urethra or rectal wall from overheating.

1.6 Targis System equipment overview

The Targis System includes the Targis CoolWave™ Control Unit, Model 5000A, the Targis Procedure Kit (comprised of a treatment catheter, a rectal unit, and a Coolant Bag), and accessories. For this user manual, the representative treatment catheter is the Targis Cooled ThermoCath® treatment catheter.

1.6.1 Control Unit

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

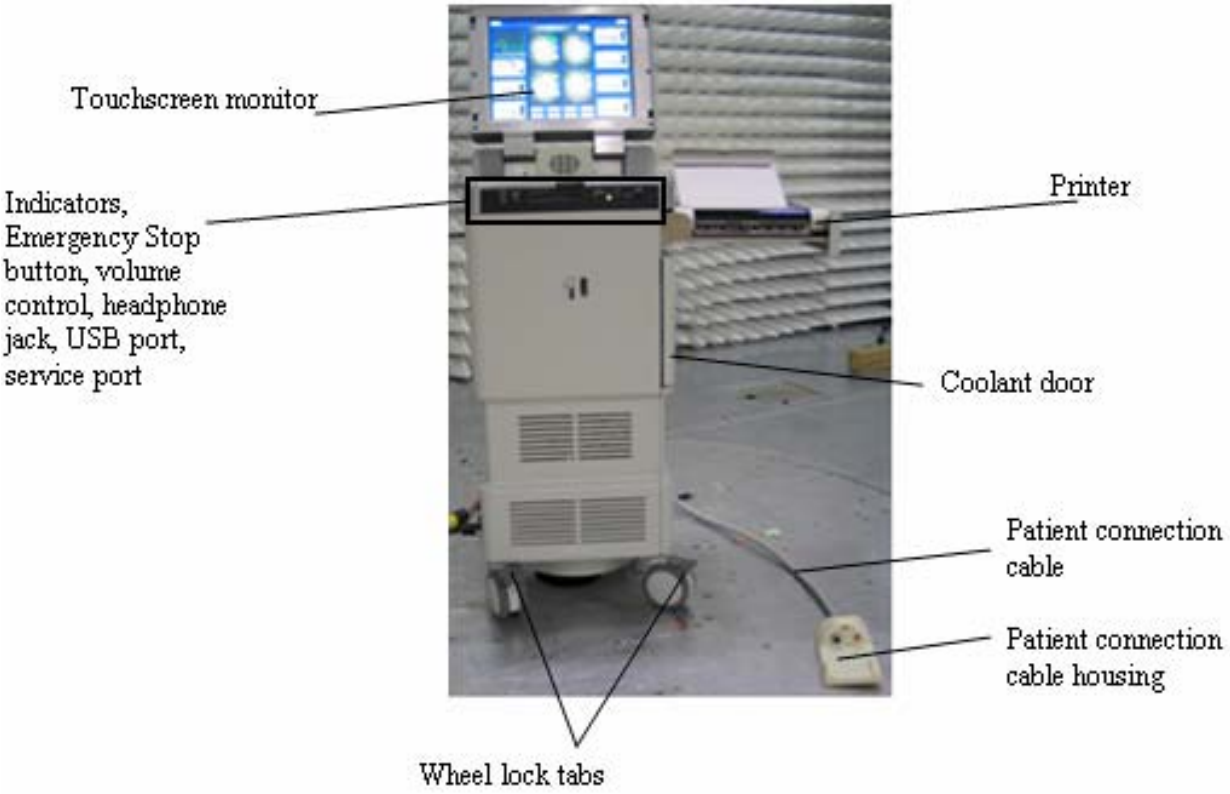


Figure 1. Control Unit

The 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
- Emergency Stop button
- Other: Volume control, headphone jack, USB port, and service port

Patient connection cable and patient connection cable housing

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

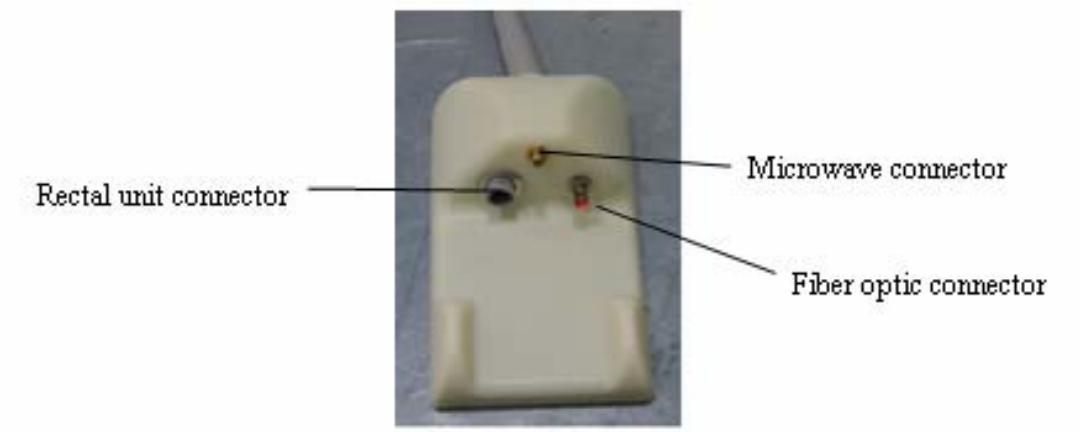


Figure 2. Patient connection cable housing

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

Touchscreen monitor

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

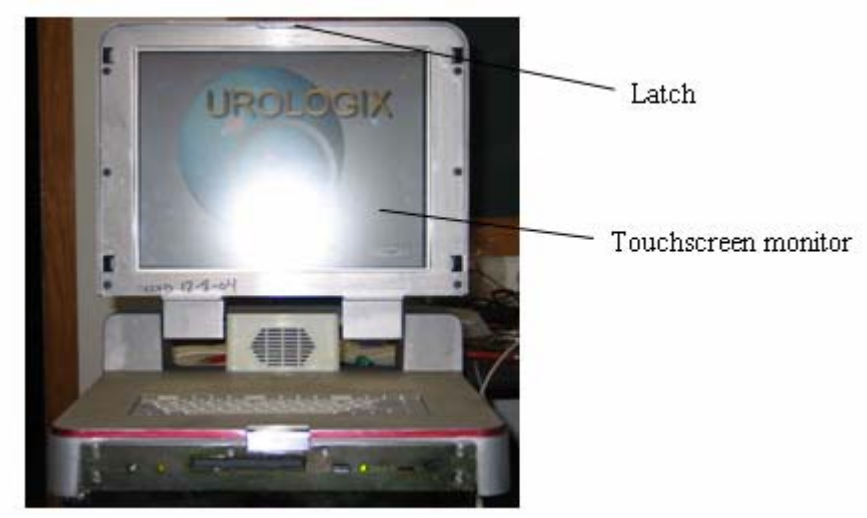


Figure 3. Touchscreen monitor

Keyboard

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

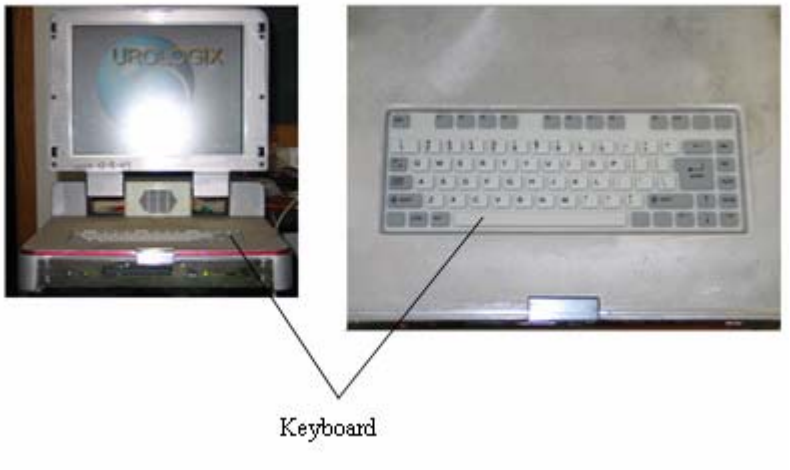


Figure 4. Keyboard

Printer

Caution: The 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).

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

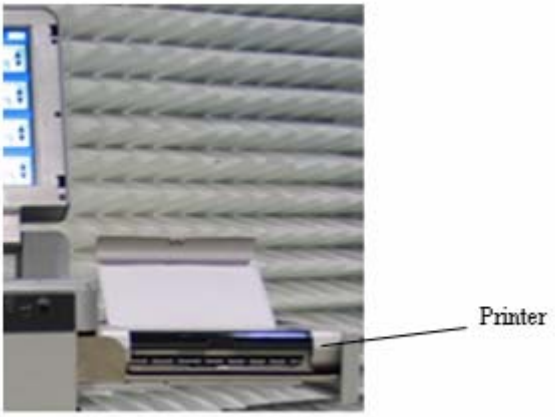


Figure 5. Printer

ON/OFF power switch

Instruction Manual: Read the Targis System User Manual before turning ON and operating the system.

Turn the Control Unit ON or OFF with this power switch (Figure 6).

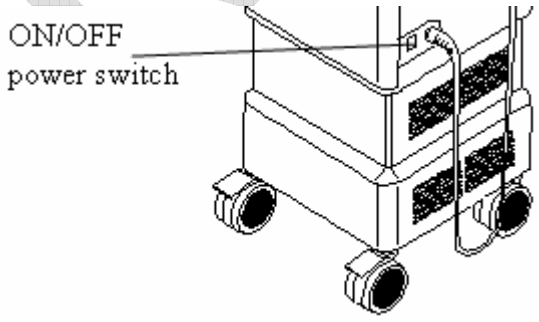


Figure 6. ON/OFF power switch

Lockable wheels

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

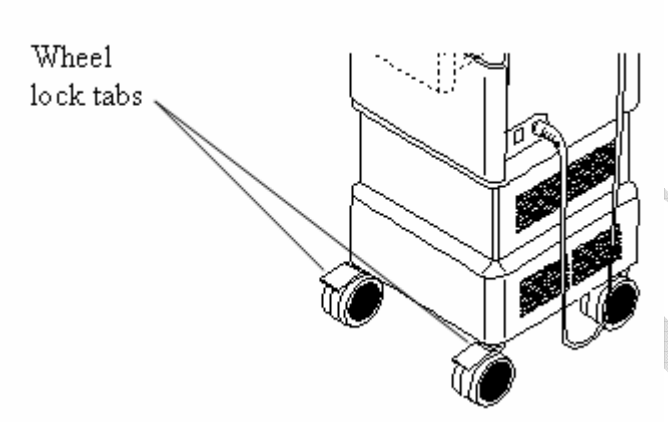


Figure 7. Wheel lock tabs

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 8).

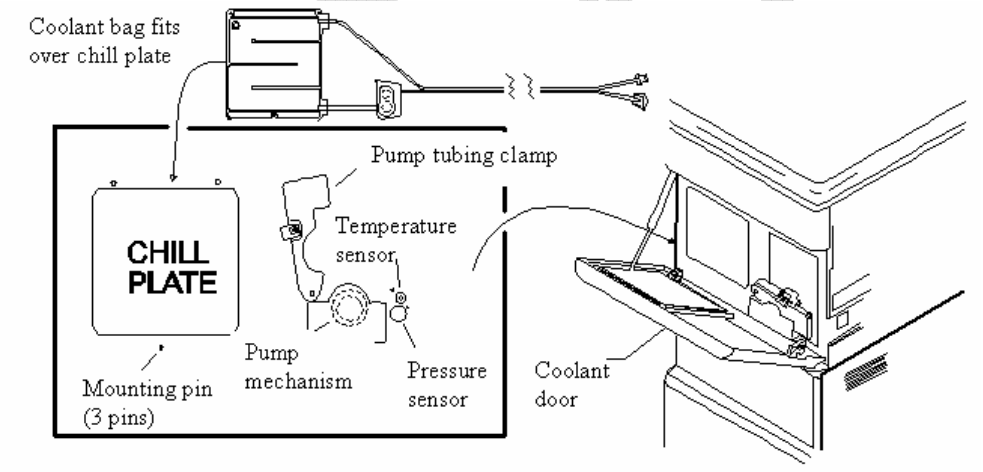


Figure 8. Coolant system features

Chill plate: The chill plate, located behind the coolant door (Figure 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 Control Unit, monitor the coolant temperature and the coolant pressure (Figure 8).

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

Coolant bag: The coolant bag serves as the reservoir for the coolant.

Main power indicator and microwave power indicator

The main power indicator (Figure 9), located in front of the keyboard, is a green LED that illuminates when the Control Unit is ON. The microwave power indicator (Figure 9), also located in front of the keyboard, is an amber LED that illuminates when the Control Unit delivers microwave power to the prostate.

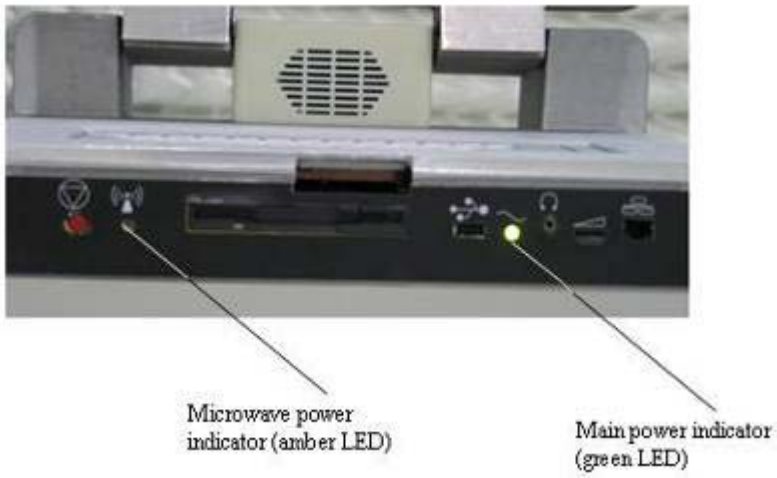


Figure 9. Power indicators

Emergency Stop button

If there is an emergency, press the red **Emergency Stop** button (Figure 10), located to the left of the amber LED, to immediately turn the microwave power OFF.

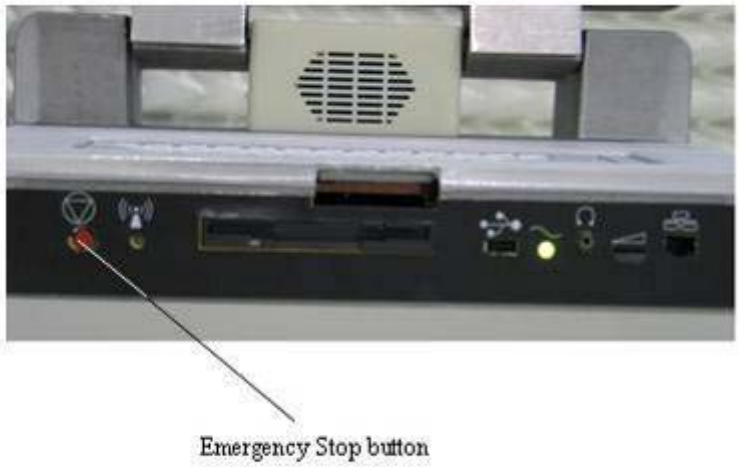


Figure 10. Emergency Stop button

Other: Volume control, headphone jack, USB port, and service port

The Control Unit includes a volume control, a headphone jack, a USB (Universal Serial Bus) port, and a service port (Figure 11). The USB port can accommodate a USB flash drive.

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

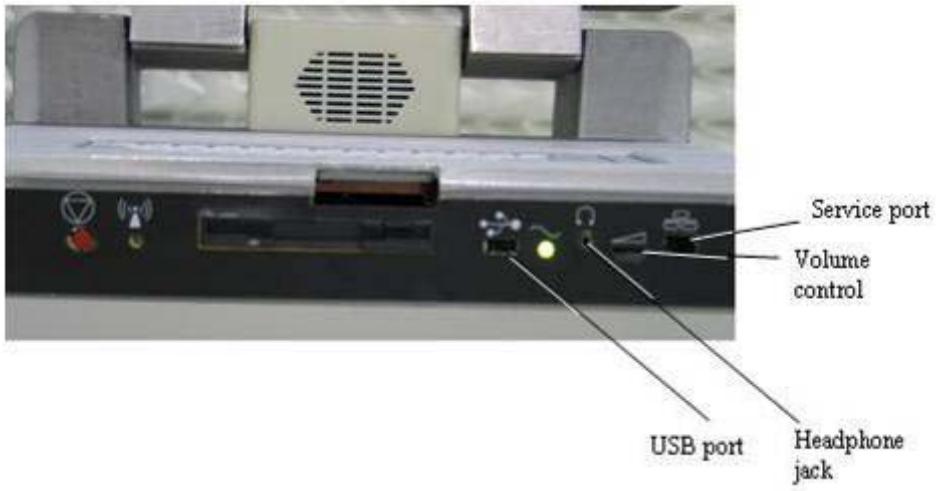


Figure 11. Volume control, headphone jack, USB port, and service port

1.6.2 Treatment catheter

The single-use treatment catheter includes a fiber optic temperature sensor to measure urethral temperature, a microwave antenna and cable, coolant 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 12). The microwave antenna and temperature sensor are connected to the Control Unit via the patient connection cable housing and patient connection cable. To ensure that the treatment catheter is positioned properly within the urethra, the location balloon is inflated to hold the catheter in place during treatment.

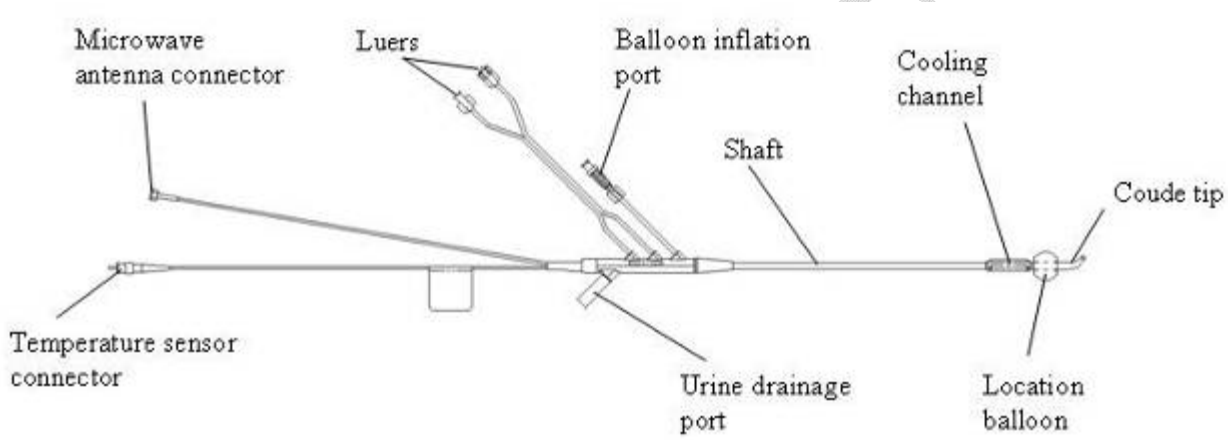


Figure 12. Treatment catheter

The treatment catheter is used for:

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

1.6.3 Rectal unit

The Targis System requires the use of either the single-use standard Targis RTU or the Targis RTU Plus® with reusable handle and single-use balloon. The standard RTU and RTU Plus (Figure 13 and Figure 14) both consist of an inflatable balloon with 5 temperature sensors. These sensors monitor rectal temperature along the anterior rectal wall and sends this information to the 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.

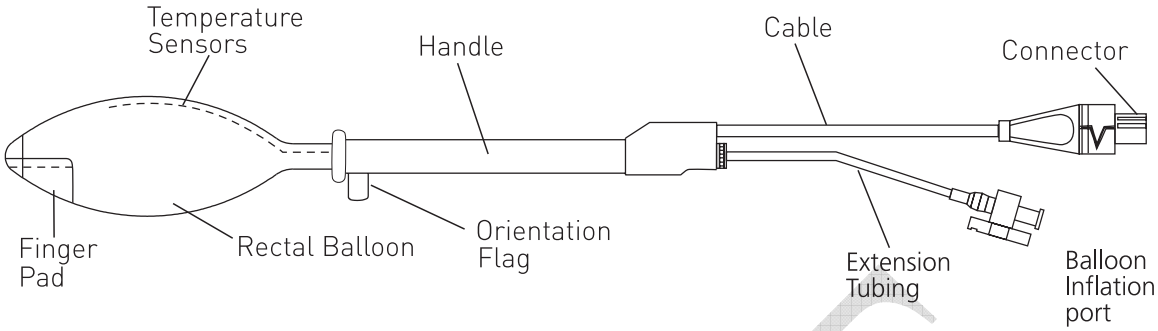


Figure 13. Single-use standard RTU

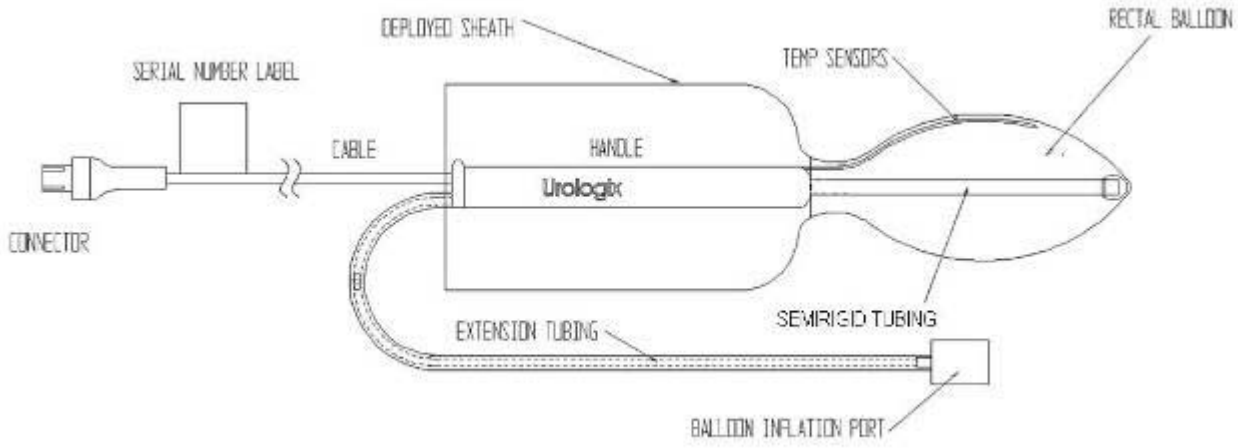


Figure 14. Assembled RTU Plus (with the reusable handle and single use balloon)

1.6.4 Coolant Bag

The single-use Coolant Bag includes a coolant bag, inlet and outlet tubing, connectors, and a sensor module (Figure 15). The sensor module allows the 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.

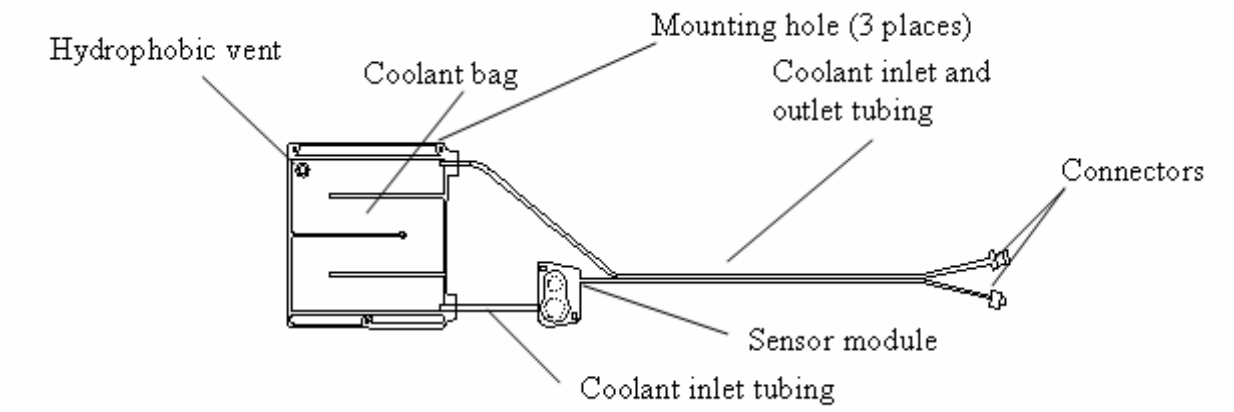


Figure 15. Coolant Bag

The function of the coolant bag is to provide a reservoir for the coolant that circulates through the treatment 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 treatment 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 Targis System.

1.7.1 Equipment provided by Urologix

Urologix provides the following equipment.

Quantity	Equipment/Material
1	Control Unit
1	Targis System User Manual
1	Targis Procedure Kit containing: • 1 treatment catheter • 1 rectal unit (standard RTU or RTU Plus) • 1 Coolant Bag
1	Patient cable holder
1	Patient Comfort Kit (2 knee cushions and an MDS Holder)
1	Targis Transport Kit, optional (trolley and electrical safety tester)

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 (Urojet or lidocaine jelly)
50 cc	Local bladder anesthetic of choice (eg, 50 cc of 1% or 2% lidocaine without epinephrine)
As needed	Water soluble lubricating gel (eg, K-Y® Jelly)
1	60 cc luer-lok syringe
1	60 cc catheter-tip syringe (ie, Toomey™ syringe)
2	10 cc luer-lok 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

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

- 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
- Treatment 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 Control Unit and its connected devices only in clinical environments where the electrical installation is in accordance with the international standard, DIN VDE 0107; and the national standard, ANSI/NFPA 70-1993. (Refer to section 517 of the National Electric Code®.)

The equipment must be connected to a fully tested, hospital-grade power outlet with adequate grounding.

Power requirements

Control Unit, Model 5000E (Europe): 220/240 V [+/- 10%] (8 A) Single phase 50 or 60 Hz
Control Unit, Model 5000A (US): 110/120 V [+/- 10%] (15 A) Single phase 50 or 60 Hz
Control Unit, Model 5000J (Japan): 100 V [+/- 10%] (15 A) Single phase 50 or 60 Hz

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

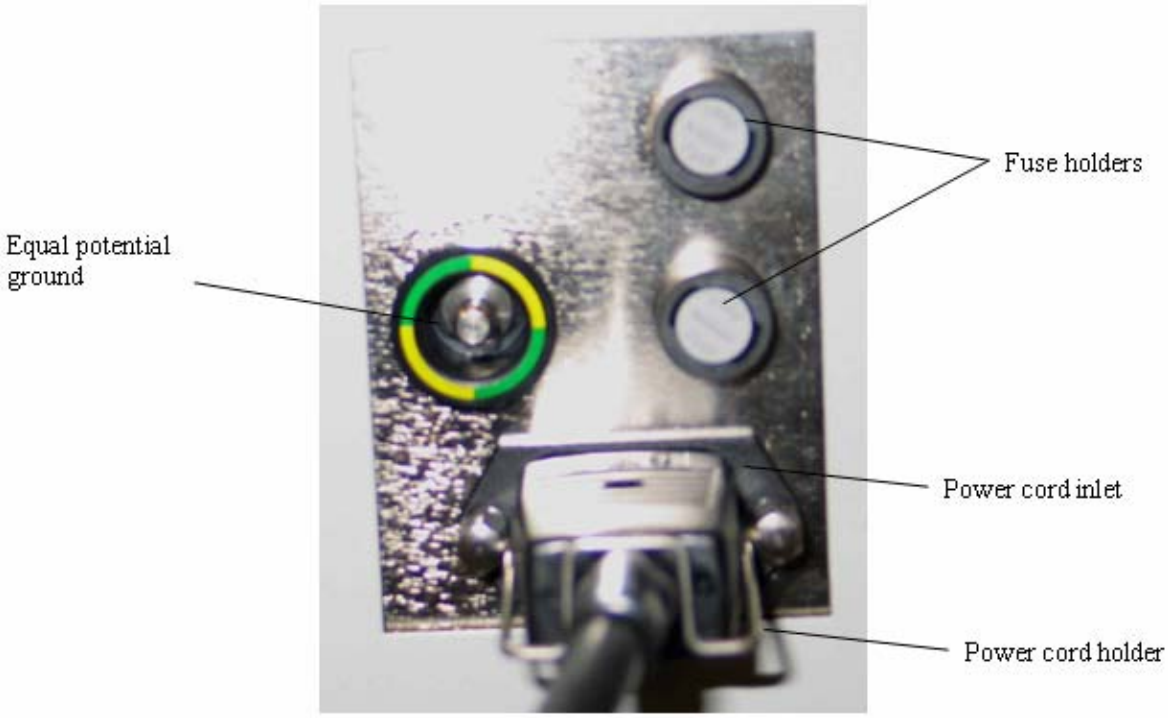


Figure 16. Control Unit rear cover

Control Unit power cords

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

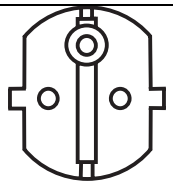
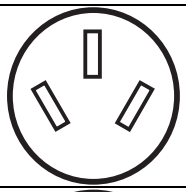
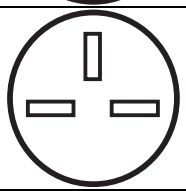
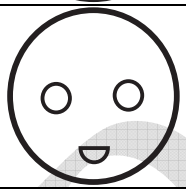
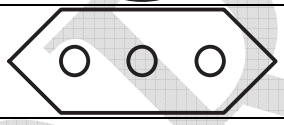
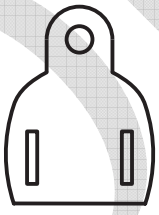
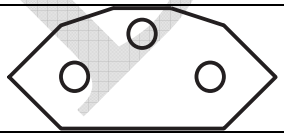
End View	Power Cord Catalog Number
	Catalog Number: AC1011 France Austria Germany Norway Belgium Sweden Netherlands Finland
	Catalog Number: AC1012 Australia New Zealand
	Catalog Number: AC1013 United Kingdom Ireland
	Catalog Number: AC1014 Denmark
	Catalog Number: AC1015 Italy
	Catalog Number: AC1016 Japan
	Catalog Number: AC1017 Canada United States Mexico
	Catalog Number: AC1018 Switzerland

Figure 17. Control Unit power cords

Equipment connections

The Control Unit must not be connected to any device other than the treatment catheter, rectal unit, or Coolant Bag. In addition, the treatment catheter, rectal unit, and Coolant Bag must not be connected to any other device or outlet.

Equipment testing

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

1.8.2 Use environment

Cautions:

- Do not stack any objects on top of Control Unit, treatment catheter, rectal unit, or Coolant Bag.
- Do not place the 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 Control Unit for operation.
- Do not turn ON the Control Unit with the touchscreen monitor lid closed. The touchscreen will turn OFF, and the lid may become warm to the touch.
- Operate the Control Unit on a level surface.
- Operate the 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 Control Unit; doing so risks receiving an electric shock.

- Refer all Control Unit servicing to qualified Urologix personnel.

Warning: This equipment is not intended for use in areas where there is a danger of explosion.

- Do not use the Control Unit in the presence of flammable substances.

Caution: The Targis System 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 and determine the applicability of regulatory limitations prior to use.

Perform the following Control Unit safety checks at least 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.