TMx-2000 BPH Thermotherapy System

General Information And Instructions For Use

ThermMatrx, Inc.

TMx-2000™ BPH Thermotherapy System

The patented TherMatrx, Inc. TMx-2000™ BPH Thermotherapy System is a computer-controlled thermotherapy treatment device that delivers microwave energy to the prostate for the treatment of symptoms associated with Benign Prostatic Hyperplasia (BPH). The system is comprised of a mobile, stand-alone operator control console and the single use Rx-200 Applicator (transurethral antennae) that delivers microwave energy to the prostate. The system computer monitors all treatment parameters and automatically adjusts the microwave energy as needed to achieve and maintain thermotherapeutic temperatures for the selected duration of the treatment.

This manual contains essential information for operation of the TMx-2000™ BPH Thermotherapy System. A description of the equipment, function, setup and operation procedures, and heating patterns is also included in this manual. This information is intended to provide clinical guidance when using the TMx-2000™ System and the Rx-200 Applicator for BPH thermotherapy treatments.

This manual contains the following sections:

General Information
Provides a description of the TMx-2000™ System components, equipment specifications, indications for use, warnings, precautions, contraindications, and instructions for use.

Safety and Emergency Procedures
Provides safety warnings for the TMx-2000™ System.

Equipment Description and Function
Provides a description of the function and operation of the control panel switches and the Rx-200 Applicator.

Setup and Operation
Provides operating instructions and clinical guidance for use of the TMx-2000™ System and the Rx-200 Applicator.

Stray Field - EMC/I Testing Results, Heating Characteristics
Provides heating patterns and stray field data from homogeneous phantom testing of the Rx-200 Applicator at the recommended operating frequency.

Maintenance
Provides instructions for care of the TMx-2000™ System and Rx-200 Applicator and a listing of system error code messages and the method of correction.

General Information

CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained in the use of this device.

The clinician must operate the TMx-2000™ System in accordance with all of the instructions contained in this manual. This manual includes information applicable only to BPH treatments using the TMx-2000™ System and Rx-200 Applicator.

Instructions for Use

TMx-2000™ System Description

The patented TMx-2000™ System is designed to treat BPH using Transurethral Microwave Thermotherapy treatment. The TMx-2000™ System consists of three basic components: a 915-MHz microwave delivery subsystem; a proprietary, thermistor-based, thermometry subsystem; and a computerized monitoring and control subsystem. The computerized closed-loop feedback control system automatically monitors and controls the heating by adjusting the microwave power level based on urethral temperatures.

Indications For Use

The TMx-2000™ BPH Thermotherapy System is a non-surgical device for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH) in men who have a minimum prostatic urethra length of 30 mm and a total prostate volume between 30 and 100 cc.

Contraindications

- Patients with peripheral arterial disease with intermittent claudication or Leriches syndrome (i.e., claudication of the buttocks and perineum).
- Patients with severe urethral strictures, preventing easy catheterization.
- Patients with implanted defibrillators, pacemakers, or any other active implant.
- Patients with a penile or urinary sphincter implant.
- Patients with a metallic implant in the prostatic treatment area, pelvis, or hip.
- Patients with a minimum prostatic urethra length <30mm and a total prostate volume <30 or >100 cc.
- Patients with clinical or histological evidence of prostatic or bladder cancer.
- Patients who have undergone prior radiation therapy to the pelvic region.

Warnings

The following is a list of warnings for safe and effective operation of the TMx-2000™ System.

WARNING

The TMx-2000™ System procedure has inherent risks of complications (refer to Adverse Events). The TMx-2000™ System and components should not be used in any way other than the intended and indicated use and according to the instructions for use. Failure to do so could result in compromised patient safety and/or insufficient therapy.

WARNING

Failure to properly position the Rx-200 Applicator could result in heating and severe injuries outside of the treatment area. If applicator placement is in question, verify placement by ultrasound imaging after inflating the balloon. Inflation of the balloon with more than 5 cc of sterile water may position the catheter too high in the urinary channel, which may result in heating outside of the treatment area.

Precautions

The following is a list of precautions for safe and effective operation of the TMx-2000™ System.

Therapy Related - Before Treatment

- The safety and effectiveness of the TherMatrx, Inc. TMx-2000™ System have not been established in patients with the following conditions:
  - Interest in preserving future fertility
  - Coagulation disorders

- Renal impairment
- Neurological disorders which may affect bladder function
- Post void residual volume of > 200 mL
- Urinary retention requiring indwelling catheter
- Large median lobe of the prostate protruding into the bladder
- Active urinary tract infections
- Bacteriological evidence of bacterial prostatitis
- Bladder stones
- Previous pelvic surgery
- Previous rectal surgery (other than hemorrhoidectomy)
- Prostatic urethra lengths greater than 57 mm in length

- The use of the TherMatrx, Inc. TMx-2000™ System must be prescribed and administered under the direct supervision of a qualified and trained physician, after appropriate urological evaluation of the patient.

- Select the proper Rx-200 Applicator based on the prostatic urethra length (bladder neck to verumontanum). The 2.5 cm coil length is for patients with a prostatic urethra length of ≥3.0 but <4.0 cm. The 3.5 cm coil length is for patients with a prostatic urethra length of ≥4.0 but <5.0 cm. The 4.5 cm coil length is for patients with a prostatic urethra length of ≥5 cm.

- Do not use the disposable urethral Rx-200 Applicator if it appears damaged or if the package seal has been compromised.

- Use the disposable Rx-200 Applicator prior to the "Use Before" date specified on the package.

- Care should be taken in handling all components of the TMx-2000™ System procedure to avoid damage that may lead to subsequent failure of the component or procedure.

Therapy Related - Treatment

- Attention by a qualified physician is required during the use of the TMx-2000™ System. The control unit display must be monitored and controlled during the course of a therapy session to make sure that the Rx-200 Applicator and rectal temperatures are within prescribed treatment parameters. Failure to monitor and deliver the TMx-2000™ System procedure per recommendations by TherMatrx, Inc. may lead to decreased patient safety and/or reduced clinical effectiveness.

- All components of the TMx-2000™ System (Rx-200 Applicator with temperature sensors and rectal probe with temperature sensor) must be used according to the instructions included in the TMx-2000™ System Operator's Manual. Failure to do so may result in insufficient therapy or increased risk of injury or infection to the patient.

- The disposable Rx-200 Applicator must only be used with the TMx-2000™ Control System.

- The disposable Rx-200 Applicator must not, under any circumstances, be connected to the TMx-2000™ Control System before the applicator has been carefully passed into the patient's urethra.

- Following inflation of the balloon (maximum of 5 cc), the balloon must be positioned at the base of the bladder by gently pulling on the catheter. In order to maintain proper positioning of the radiating antenna within the prostate throughout the treatment, light tension must be maintained on the catheter by gently pulling on the urine drainage tube and securing the drainage tube, under tension, to the patient's leg.

- Risks of improper placement of the Rx-200 Applicator include procedure failure or heating damage of non-target tissues such as the bladder neck, external sphincter, or penile urethra.

- It is possible that the balloon can unintentionally deflate during treatment, resulting in applicator migration outside of the treatment area. Closely monitor patient's pain level, temperature fluctuations, urine drainage, and tension of drainage tube. Increased pain, a sudden drop in temperature >2°C, and decreased tension of drainage tube during treatment may be indications of catheter migration.

- Do not initiate treatment until the rectal probe is properly placed.

- The emission of microwaves must be off during placement and removal of the Rx-200 Applicator to avoid stray microwave radiation directed either towards the patient's or the operator's eyes or testes.

- The patient should be placed in a comfortable supine position during treatment. Elevating the patient's torso more than 30° may cause the rectal and prostatic tissues to be compressed, reducing the distance between the rectal tissues and the radiating antennae, which could result in higher rectal temperatures.

- BPH treatment using the TMx-2000™ System deposits 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 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.

- The disposable Rx-200 Applicator is intended for **one time use only. DO NOT** resterilize or reuse the Rx-200 Applicator, as this will likely result in compromised device performance and increased risk of injury or infection to a patient.

Therapy Related - Post-Treatment

- As patient responses to the TMx-2000™ System procedure are variable, the patient should be evaluated by their physician following treatment.
- Because the TMx-2000™ System procedure elevates intraprostatic tissue temperature, causing tissue damage that may result in acute urinary retention, it is advisable for the patient to be catheterized for 2 to 5 days following treatment (refer to Adverse Events, discussion of 2-5 Days Follow-up Events).
- Substantial changes in prostate specific antigen (PSA) level may be seen after transurethral microwave thermotherapy treatment. Physicians are cautioned to measure the serum PSA level before treatment for future comparisons. PSA levels should return to baseline by three months post-treatment and may be used again at that time as a diagnostic test.
- It is recommended that patients treated with the TMx-2000™ System be followed on an annual basis to assess for prostatic changes.
- The safety and effectiveness of retreatment with the TMx-2000™ System has not been established.

Device Related - Microwave and AC Power

- Operate the TMx-2000™ Control System and connected system components only in clinical environments where the 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 that has adequate grounding.
- The TMx-2000™ Control System must be plugged into the appropriate voltage outlet.

Power Requirements:

Supply:	220/240 V [±10%](8 A) Single phase 50 or 60 Hz or 110/120 V [±10%](15 A) Single phase 50 or 60 Hz or 100 V [±10%](15 A) Single phase 50 or 60 Hz
AC Connection:	Hospital Grade Plug

- Do not use the equipment in an explosive atmosphere.
- Exposing eyes to microwave energy may damage eyes.
- Failure to properly maintain the equipment may result in exposure of the patient and/or the operator to excessive microwave energy.

- The TMx-2000™ System uses voltages that are potentially lethal. Use extreme caution when performing maintenance of the TMx-2000™ System console.

- TherMatrx, Inc. recommends that all electronic medical devices be kept at a minimum distance of one meter from the TMx-2000™ System when performing a thermotherapy procedure. However, a 1-meter separation of electronic medical devices from the TMx-2000™ System does not guarantee that operation of other medical devices will not be impacted. The operations of all other electronic medical equipment used in proximity to the TMx-2000™ System must be closely monitored, as the functions of electronic equipment may be effected by the energy emitted during operation of the TMx-2000™ System.

- Do not operate an electronic device or equipment emitting electromagnetic energy in proximity to the TMx-2000™ System during a thermotherapy procedure, as the electronic equipment may interfere with the operation of the TMx-2000™ System.

- The ANSI/IEEE C95.1992 recommended stray field exposure level for partial body exposure, at 915 MHz, is 20 mW/cm^2, except for eyes and testes. Stray field testing on the Rx-200 Applicator has shown that the maximum stray field level observed at a 5 cm distance from the Rx-200 Applicator's coaxial cable is 5.2 mW/cm^2. The ANSI/IEEE recommended maximum stray field exposure level for whole body exposure, including the testes and eyes, is 3 mW/cm^2, as averaged for any 6-minute period. In order to comply with these ANSI/IEEE guidelines, TherMatrx, Inc. recommends that a minimum distance of 10 cm be maintained between the Rx-200 coaxial cable and the operators during a thermotherapy procedure.

Adverse Events

A total of 125 patients were treated with thermotherapy and evaluated for adverse events in the clinical investigation of the TMx-2000™ BPH Thermotherapy System. Sixty-six (66) (52.8%) patients reported adverse events during treatment and/or through 1-month post-treatment. All adverse events reported were minor and nearly all were transitory and self-resolving. There were no unanticipated adverse events, severe reactions to thermotherapy treatment, retreatments, or patient deaths reported during the study. There was no rectal damage, sphincter damage, decrease in sexual function (particularly with regard to erection and ejaculation), or urethral strictures noted during the follow-up.

The following table identifies the adverse events reported for this protocol. A description of these adverse events is provided following the table.

At Treatment	*Number*	*Rate*
Bladder Spasm	26	20.8%
Bleeding	19	15.2%
Burning Sensation after catheter insertion	1	0.8%

2-5 Day Visit	*Number*	*Rate*
Hematuria	21	16.8%
Dysuria[1]	18	14.4%
Bladder Spasm	17	13.6%
Urgency	8	6.4%

1-Month Visit	*Number*	*Rate*
Hematuria	11	9.1%
Dysuria[1]	8	6.6%
Bladder Spasm	5	4.1%
Hematospermia	1	0.8%

[1] *One patient reported dysuria at both the 2-5 day and 1-month visit, which persisted through the 12-month visit.*

At Treatment

Of the 125 patients, 38 (30.4%) reported 46 adverse events. Eight (8) of these patients reported more than one adverse event.

2-5 Days Follow-up Events

Of the 125 patients, 38 (30.4%) reported 64 adverse events. Seventeen (17) of these patients reported more than one adverse event.

All patients were discharged with a Foley catheter, which was left indwelling for 2-5 days. Twenty-three (23) of the 125 patients (18.4%) required re-catheterization due to continued voiding difficulty. Of these 23 patients, 14 patients required catheterization longer than 5 days. All patients were catheter free within 10 days post-treatment.

1-Month Follow-up Events

Of the 122 patients evaluated 1-month post-treatment, 22 (18.0%) reported 25 adverse events. Three (3) of these patients reported more than one adverse event.

The majority of these events resolved by the 3-month follow-up visit. One (1) of the 22 patients who reported an event at 1-month reported a new event at 3 months.

3-Month Follow-up Events

Of the 124 patients evaluated 3 months post-treatment, 2 (1.6%) reported 3 adverse events (two events of dysuria (1.6%) and one event of bladder spasm (0.8%)).

Adverse Events After 3 Months Post-Treatment

Of the patients who reported adverse events during treatment and at the 2-5 day, 1-month, and 3-month visits, only 3 patients reported adverse events not resolved by the 3-month visit. One patient reported bladder spasm that persisted through the 6 month visit and resolved prior to the 9-month visit. One patient reported dysuria that resolved by the 6-month visit. One patient reported bladder spasm that resolved by the 6-month visit and dysuria that persisted through the 12-month visit.

Two patients reported 2 new adverse events during the 9 and 12 month visits. The newly reported events included dysuria at 9 months (which persisted through 1-year) and hematospermia at 1-year (which resolved immediately).

Clinical Trial Summary

A prospective, multicenter, randomized, double blind, sham controlled clinical study was conducted to assess the safety and effectiveness of the TMx-2000™ BPH Thermotherapy System in the treatment of BPH. A total of 188 patients were treated in the study, 125 in the thermotherapy (TMx) group and 63 in the sham group. The sham group patients were only followed to the 3-month post-treatment visit. There were 124 TMx-2000™ treated patients and 62 sham patients available for evaluation at 3 months post-treatment and 119 TMx patients available for evaluation at 12 months post-treatment.

Analgesia/Sedation

Both the TMx group and the sham group received an oral analgesia and an oral sedative prior to treatment. All treatments were performed on an outpatient basis. No general or regional anesthesia was needed.

Clinical Effectiveness Data

Patients treated with thermotherapy had prostate volumes ranging from 30 to 99 cc and urethral lengths ranging from 3.0 to 5.7 cm. Of the active patients treated, the prostate volume ranges were: 36.3% between 30 and 39cc; 21.8% between 40 and 49cc; 16.1% between 50 and 59cc, 8.1% between 60 and 69cc, 8.9% between 70 and 79cc, and 8.9% between 80 and 99cc. Of the active patients treated, the prostatic urethral length ranges were: 57.6% between 3.0 and 3.9cm; 40.0% between 4.0 and 4.9cm; and 2.4% between 5.0 and 5.7cm. Although data for all prostate sizes are reported, there are little data regarding patients with prostate volumes greater than 80 cc and urethral lengths greater than 5.0 cm. Neither prostate size nor other clinically-relevant baseline characteristics were associated with increased treatment effectiveness.

The primary endpoint for effectiveness was improvement in the AUA Symptom Index (AUASI) at the 3-month follow-up visit. The results of this study show that the improvement in AUA Symptom Index was significant compared to sham. The AUASI is a symptom index scoring method that has been validated by the American Urological Association to assess BPH symptoms (Clinical Practice Guideline Number 8 Benign Prostatic Hyperplasia: Diagnosis and Treatment, U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, AHCPR Publication No. 94-0582, 1994).

AUA Symptom Index

Study	*Pre-Treatment*	*Follow-up*	*p-value*	*p-value between groups at 3 months*
TMx	22.5±5.0	12.4±6.6 (3 months) 11.9±7.1 (12 months)	<0.001 <0.001	
Sham	22.8±5.5	17.0±7.4 (3 months)	<0.001	<0.003

At 3 months post-treatment, 73.4% of the TMx-2000™ System treated patients experienced symptom improvement ≥ 25% and 45.2% experienced improvement ≥ 50%. The mean improvement in AUA Symptom Score was 44.8%. Improvement in AUA Symptom Index was maintained up to the 12 months follow-up visit demonstrating durability of the treatment. For the sham group, 51.6% of the sham patients experienced symptom improvement ≥ 25% and 22.6% experienced symptom improvement ≥ 50%. The mean improvement in AUA Symptom Score was 25.4%.

At 1-year post-treatment, 75.6% of the TMx-2000™ treated patients experienced symptom improvement ≥ 25% and 52.1% experienced improvement ≥ 50%, compared to baseline. The mean AUA Symptom Index decreased from 22.5±5.0 to 11.9±7.1, a 47.1% improvement. Results from 119 patients with paired data at baseline and 1-year showed a significant improvement in the AUA Symptom Index ($p<0.001$).

The secondary effectiveness endpoints were urine peak flow rate (PFR), Bother Index, Quality of Life Index, and Sexual Function Evaluation. As described in the following table, PFR did not significantly improve over sham at 3 months post-treatment. However, a significant improvement in the TMx-2000™ treated patients was noted comparing baseline to 3 and 12 months post-treatment.

Peak Flow Rate (ml/s)

Study	*Pre-Treatment*	*Follow-up*	*p-value*	*p-value between groups at 3 months*
TMx	8.6±1.9	11.4±5.4 (3 months) 13.6±8.4 (12 months)	<0.001 <0.001	
Sham	8.3±2.0	11.1±6.5 (3 months)	0.002	0.749

The mean peak flow rate for the TMx-2000™ treated patients increased from 8.6±1.9 cc/sec pre-treatment to 13.6±8.4 cc/sec at 1-year, an improvement of 58.1%. Results from 111 patients with paired data at baseline and 1-year showed a significant improvement in the peak flow rate ($p<0.001$).

Other Secondary Parameters

A significant improvement in Bother Index and Quality of Life were noted in the TMx-2000™ treated patients when comparing baseline to 3-months and 1-year post-treatment. Additionally, improvement in prostate mass was noted; however, the reduction is not believed to be clinically significant. No decrease in sexual function (ejaculation, problem assessment, overall satisfaction score, and total sexual score) was noted. (Bother Index and Quality of Life were assessed per Mebust, W. K., Bosch, R., Donovan, J. et al: Symptom evaluation, quality of life and sexuality. Proceedings of the 2nd International Consultation on Benign Prostatic Hyperplasia (BPH). Edited by A. T. K. Cockett S. Khoury Y. Aso *et al.* Channel Islands: Scientific Communication International, Ltd., chapter. 5, pp. 129-147, 1993. Sexual Function was assessed per Rosen, R. C., Riley, A., Wagner, G., Osterloh, I. H., Kirkpatrick, J. and Mishra, A.: The international index of erectile dysfunction (IIEF): a multidimensional scale for assessment of erectile dysfunction. Urology 49:822,1997.)

Information for Patients

Physicians should inform patients that an inherent risk of complications is associated with the TMx-2000™ procedure (refer to Adverse Events). Patients should be informed that they might experience:

- A feeling of warmth and discomfort in the prostate region
- Pain caused by catheter insertion and localized heating in the treated area
- A temporary increase in irritation of the urinary tract leading to more frequent urination, a sense of urgency, and dysuria
- Hematuria
- Hematospermia
- Urinary retention
- Bladder spasm during and after treatment

Patients should be informed that possible side effects of thermotherapy treatments could include the adverse events listed below. However, during the clinical study of the TherMatrx, Inc. TMx-2000™ System, these aderse events were **not** reported.

- Rectal damage/fistula
- Urinary infection
- Changes in ejaculation following treatment (retrograde, painful, or difficult ejaculation; loss of ejaculation; or decreased fluid volume)
- Burns within prostate from the heat treatments, which may lead to temporary bleeding or increased discomfort in the prostate area
- Urethral stricture from urinary scarring at a later date, leading to restriction of the urinary flow
- Temporary sterility (the therapy's effect on future fertility is unknown)

Patients should be informed that they will likely be catheterized for a 2-5 day period following the procedure.

System Specifications

Table 1-1 and 1-2 provide a listing of the system specifications for the TMx-2000™ BPH Thermotherapy System and the Rx-200 Applicator, respectively. Specific details concerning function of the equipment are found in the *Equipment Description and Function* section of this manual.

Product Description

The TherMatrx, Inc. TMx-2000™ System utilizes patented technology to deliver Transurethral Microwave Thermotherapy treatment to the prostate for the treatment of BPH. The heating process is controlled by the computer subsystem, which utilizes a closed-loop feedback control system to automatically monitor and control the heating by adjusting the power level based on urethral temperatures.

The TMx-2000™ System's microwave subsystem includes a 23 watt 915 MHz microwave generator and the prostate Rx-200 Applicator, which is comprised of a silicone urethral Foley urine drainage catheter, a radiating helical coil antenna, and two closed-tip urethane lumens bonded to the outside of the catheter. The Rx-200 Applicator is used for urine drainage, heating of the prostatic tissues, and positioning of the sensors that monitor the temperature of the prostatic tissues. In order to provide safe and effective heating of a wide range of prostate sizes, the microwave antenna comes in three heating lengths (2.5 cm, 3.5 cm, and 4.5 cm). The three antennae lengths

Table 1-1

TMx-2000 SYSTEM EQUIPMENT SPECIFICATIONS

AC POWER	100 ±10% or 120 ±10% or 220 ±10% VAC— 50 Hz to 60 Hz (1.5A at 120 volts)
CART SIZE	18 in. wide x 18 in. deep x 36 in. high (46cm x 46cm x 91cm)
COMPUTER	8031 Microprocessor, 12 MHz clock 32Kx8 EPROM (32Kx8 RAM)
CONSOLE SIZE	Enclosure: 18 in. wide x 18 in. deep x 7 in. high (46cm x 46cm x 18cm)
URETHRAL TEMPERATURE CONTROL SENSORS	Two thermistor type temperature sensors inserted into the side catheter tracks of the Rx-200 Applicator and connected to Ports #1 and #2 *(refer to Temperature Sensor for specifications)*
RECTAL TEMPERATURE MONITORING SENSOR	One thermistor type temperature sensor connected to Port #3 *(refer to Temperature Sensor for specifications)*
POWER REDUCTION BUTTON	Hand-held retractile cord mounted switch. (Reduces microwave treatment power by 3 Watts and maintains reduced power output level for 90 seconds)
EXTERNAL COMMUNICATION	9 pin D connector located on the rear of the control console for attachment of an external computer or printer
LEAKAGE	Protected by isolation transformer, less than 100 microamps, per UL544 Leakage through inserted devices will be less than 10 microamps DC.
PRINTER	40 Column Thermal Paper Tape — 112 mm wide
TREATMENT POWER	0 to 23 Watts maximum 915 MHz ±1 MHz *(434 MHz ±1 MHz - European)*
TEMPERATURE SENSOR	Special thermistor type sensor, precalibrated to an accuracy of ±0.2°C at 42°C Field calibration accuracy of ± 0.2°C between 37°C and 49°C, ±0.4° over the range from 30°C to 65°C

Table 1-2

Rx-200 TREATMENT APPLICATOR SPECIFICATIONS

DRAINAGE	Urine drainage flow rates greater than 20 ml/min.
FREQUENCY	915 MHz *(434 MHz - European)*
HEAT PATTERN DEPTH *(For homogeneous phantom)*	Typically 5mm from catheter wall
HEAT PATTERN LENGTH *(For homogeneous phantom)*	Heating length typically corresponds to the coil length - 4.5 cm for the 4.5 cm applicator, 3.5 cm for the 3.5 cm applicator and 2.5 cm for the 2.5 cm applicator. Heating starts 5mm from the inflated balloon.
LENGTH, Total	41cm (16.5 in)
INSERTION	Prelubricate urethra and applicator prior to insertion
BALLOON INFLATION	5 cc of sterile water
OPERATING TEMPERATURE	52.5°C maximum
POWER LEVEL	23 Watts maximum
REFLECTED POWER	Typically 10% or less
STERILIZATION	ETO gas
STERILIZATION TOLERANCE	120°C maximum

provide heating targeted to the measured length of the urethra (between the verumontanum and bladder neck) of the patient being treated. The Rx-200 Applicator is a sterile single-use device.

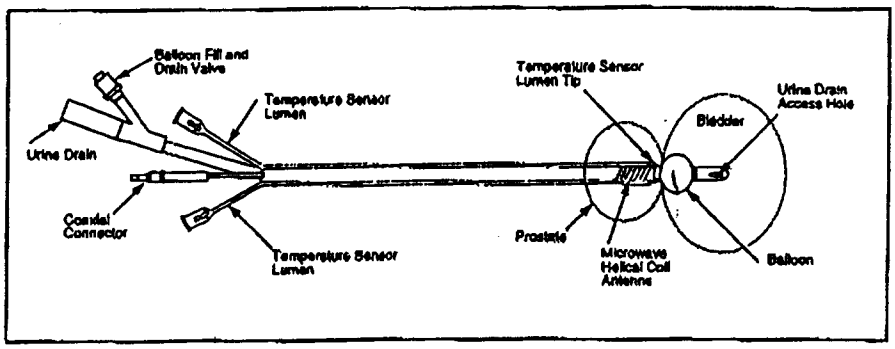

Figure 1-1. *Rx-200 Applicator Treatment Catheter*

The TMx-2000™ System's proprietary thermometry subsystem includes three, non-sterile, reusable, thermistor, temperature sensors and the associated electronics module. Two of the three sensors are inserted into the two closed-tip lumens of the disposable, sterile, Rx-200 Applicator. These sensors are used to continuously monitor the prostatic urethral temperatures along the length of the catheter and control the heating of the prostate. The third temperature sensor is inserted into a non-sterile, disposable, blind end, catheter that is attached along the anterior length of a reusable, non-sterile, silicone rubber, rectal probe and used to continuously monitor rectal temperatures. The temperature sensor measures the temperature of the anterior rectal wall directly adjacent to the prostate. The entire rectal probe fixture is covered with a condom (not supplied by TherMatrx, Inc.).

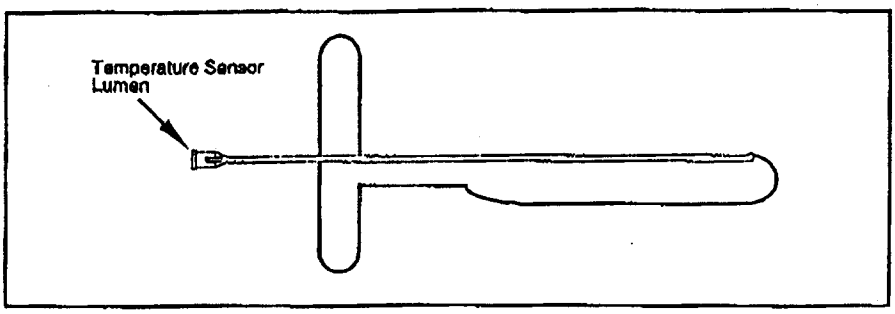

Figure 1-2. *Rectal Temperature Probe*

The TMx-2000™ BPH thermotherapy treatment is applied transurethrally to the prostatic adenoma using the disposable Rx-200 Applicator. The microwave applicator is a helical coil design antenna which is impedance matched to ensure efficient energy delivery (<10% reflected power). The antenna is positioned 5 mm below the balloon to ensure precise and consistent positioning within the targeted prostatic tissue. The inflated balloon, located at the distal end of the catheter, is seated in the bladder outlet and positions the radiating portion of the antennae within the prostatic urethra. Following inflation of the balloon, the balloon is positioned at the base of the bladder by gently pulling on the catheter. In order to maintain proper positioning of the radiating antennae within the prostate throughout the treatment, tension is maintained on the catheter by gently pulling on the urine drainage tube and securing the drainage tube, under tension, to the patient's leg.

The standard therapy regimen is delivery of a single treatment at a control temperature of 50°C to 52.5°C for 30 to 60 minutes. After the urethral Rx-200 Applicator, rectal probe and corresponding temperature sensors have been properly placed, treatment begins by the delivery of microwave power (maximum output of 23 Watts) to the urethral applicator according to a temperature induction algorithm. The system is set to a default urethral control temperature of 50.0°C and a treatment time of 40 minutes. This default temperature and time can be manually changed, but the maximum allowed urethral temperature is 52.5°C and the maximum allowed treatment time is 60 minutes. The maximum allowed rectal temperature of 42.5°C cannot be manually changed. The power output is automatically discontinued after the treatment time (at the operator-selected temperature) has elapsed.

During each patient's treatment, treatment parameters, including microwave energy output, urethral and rectal temperatures, and treatment time, are continuously monitored and controlled by the TMx-2000™ Control System. The power output level is controlled by the computer, based on pre-defined treatment parameters that have been shown to provide a safe and effective treatment. The application of microwave power is automatically discontinued if the urethral temperature rises 2°C above the operator selected treatment temperature or the rectal temperature rises above 42.5°C.

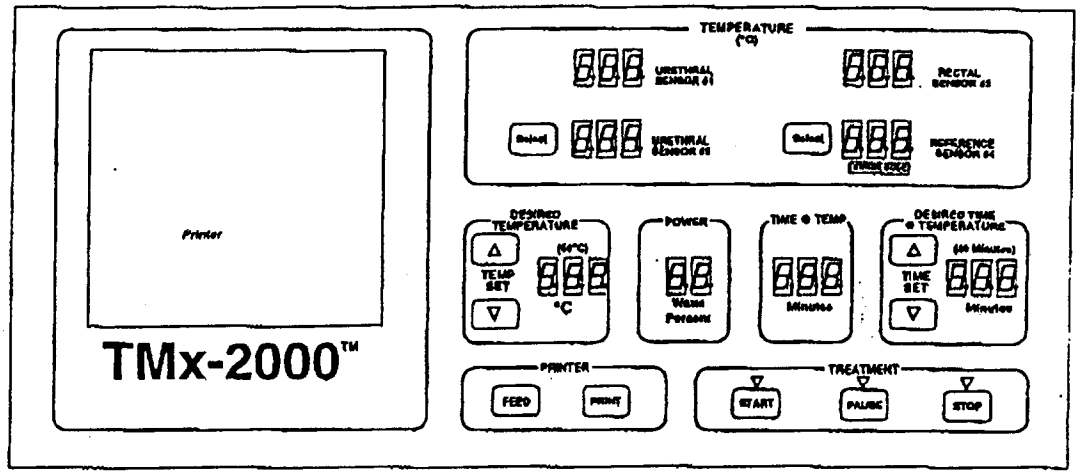

Figure 1-3. *TMx-2000™ System's Operator Console*

The Rx-200 Applicator is designed and manufactured to emit the microwave energy in a reproducible, cylindrically symmetrical pattern that targets the BPH tissues. The rationale behind the use of thermotherapy at temperatures of 50-52.5°C, without urethral cooling, is to target the heating to the BPH tissues immediately adjacent to the urethral lumen. The deposition of energy in the transition zone greatly reduces the chance of deleterious heating to adjacent structures, including the rectum, ejaculatory ducts, and urinary sphincter. Thus, side effects are minimized and necrosis of the BPH tissue in the transition zone is maximized.