



For Benign Prostatic Hyperplasia (BPH)

Instructions for Use

AMS
Solutions for Life™

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Device Description

The patented TMx-3000™ Office 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™ Treatment Catheter (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.

Detailed Description

The TMx-3000™ System is designed to treat BPH using Transurethral Microwave Thermotherapy treatment. The TMx-3000™ System consists of three basic components:

1. A computerized monitoring and control subsystem
2. A 915-MHz microwave delivery subsystem
3. A proprietary, thermistor-based, thermometry subsystem

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.

Microwave Delivery Subsystem

The microwave subsystem includes a 23 watt 915 MHz microwave generator and the prostate Rx-200 Treatment Catheter, 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 Treatment Catheter 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 four heating lengths (2.0 cm, 2.5 cm, 3.5 cm, and 4.5 cm). The four antennae lengths provide heating targeted to the measured length of the urethra (between the verumontanum and bladder neck) of the patient being treated. The Rx-200 Treatment Catheter is a sterile single-use device.

Proprietary, Thermistor-based, Thermometry Subsystem

The 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 Treatment Catheter. 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 AMS, Inc.).

Treatment Overview

The TMx-3000™ thermotherapy treatment is applied transurethrally to the prostatic adenoma using the disposable Rx-200 Treatment Catheter. The microwave catheter 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 50.0°C to 52.5°C for 30 to 60 minutes. After the urethral Rx-200 Treatment Catheter, 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 catheter according to a temperature induction algorithm. The system is set to either a default urethral control temperature of 50.0°C and a treatment time of 40 minutes or a default urethral control temperature of 50.5°C and a treatment time of 30 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.

WARNING

Do not set the Desired Temperature above 50.0°C during ramp-up.

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-3000™ 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.

The Rx-200 Treatment Catheter 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.

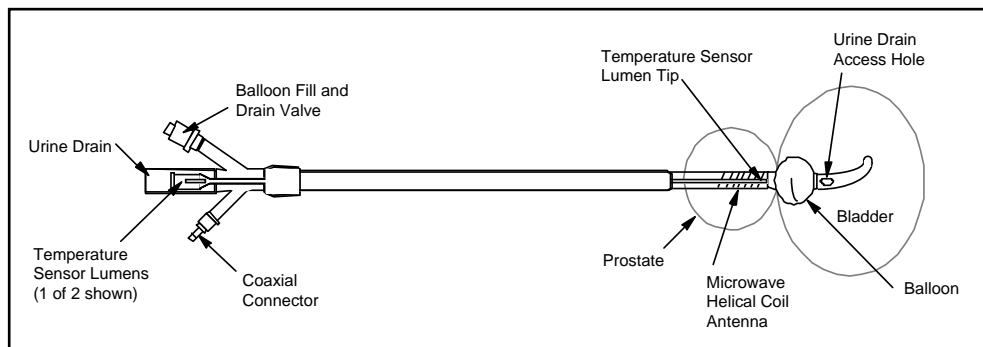


Figure 1-1. Rx-200 Treatment Catheter

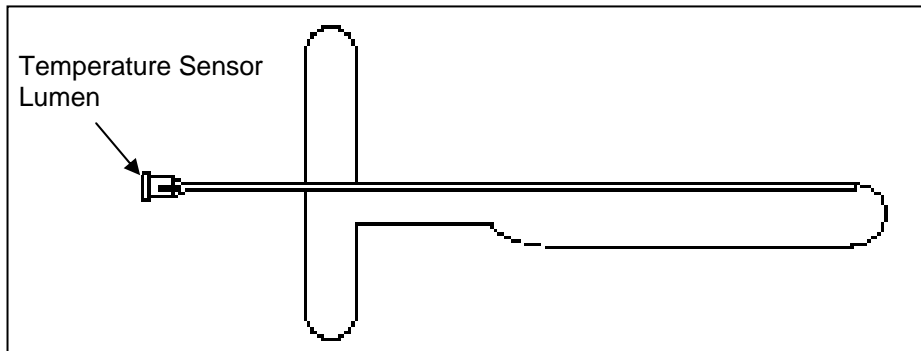


Figure 1-2. *Rectal Temperature Probe*

Indications for Use

The TMx-3000™ 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 25 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 <25mm and a total prostate volume <30 or >100 cc.
- 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-3000™ System.

WARNING

The TMx-3000™ System procedure has inherent risks of complications (refer to Adverse Events). The TMx-3000™ 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 Treatment Catheter could result in heating and severe injuries outside of the treatment area. If catheter 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-3000™ System.

Therapy Related-Before Treatment

- The safety and effectiveness of the AMS, Inc. TMx-3000™ System have not been established in patients with the following conditions:
 - Clinical or histological evidence of prostatic or bladder cancer.
 - 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 TMx-3000™ System must be prescribed and administered under the direct supervision of a qualified and trained physician, and only following appropriate urological evaluation of the patient.

- Select the proper Rx-200 Treatment Catheter based on the prostatic urethra length (bladder neck to verumontanum). The 2.0 cm coil length is for patients with a prostatic urethra length ≥ 2.5 but < 3.0 cm. 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.

- Patients with smaller prostates may experience some discomfort if the Shortened Protocol (8 min ramp, 30 minutes of treatment at 50.5°C) is used.

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

- Use the disposable Rx-200 Treatment Catheter prior to the “Use Before” date specified on the package.

- Care should be taken in handling all components of the TMx-3000™ 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-3000™ System. The control unit display must be monitored and controlled during the course of a therapy session to make sure that the Rx-200 Treatment Catheter and rectal temperatures are within prescribed treatment parameters. Failure to monitor and deliver the TMx-3000™ System procedure per recommendations by AMS, Inc. may pose safety risks and reduced clinical effectiveness.

- All components of the TMx-3000™ System (Rx-200 Treatment Catheter with temperature sensors and rectal probe with temperature sensor) must be used according to the instructions included in the TMx-3000™ 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 Treatment Catheter **must be used only with the TMx-3000™ Control System.**
- The disposable Rx-200 Treatment Catheter **must not, under any circumstances, be connected to the TMx-3000™ Control System before the treatment catheter 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 Treatment Catheter 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 catheter migration outside of the treatment area. **The patient's pain level, temperature fluctuations, urine drainage, and tension of drainage tube must be closely monitored.** Increased pain, a sudden drop in temperature $>2^{\circ}\text{C}$, 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 Treatment Catheter 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-3000™ 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 Treatment Catheter is intended for **one time use only. DO NOT** resterilize or reuse the Rx-200 Treatment Catheter, 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-3000™ System procedure are variable, the patients should be evaluated by their physician following treatment.
- Because the TMx-3000™ 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-3000™ System be monitored on annually to assess for prostatic changes.
- The safety and effectiveness of retreatment with the TMx-3000™ System has not been established.

Device Related – Microwave and AC Power

- Operate the TMx-3000™ 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, properly grounded power outlet.
- The TMx-3000™ Control System must be plugged into the appropriate voltage outlet.

Power Requirements:

Supply: 0/240 V [$\pm 10\%$] (8 A) Single phase 50 or 60 Hz or
110/120 V [$\pm 10\%$] (15 A) Single phase 50 or 60 Hz or
100 V [$\pm 10\%$] (15 A) Single phase 50 or 60 Hz

AC Connection: Hospital Grade Plug

- Do not use the equipment where there is danger of explosion.
- Exposure eyes to microwave energy may damage eyes.
- Failure to properly maintain the equipment may result in excessive exposure microwave energy for both patient and operator.
- The TMx-3000™ System requires potentially lethal current. Use extreme caution when performing maintenance of the TMx-3000™ System console.
- It is recommended that **all electronic medical devices be kept at a minimum distance of one meter from the TMx-3000™ System** when performing a thermotherapy procedure. However, a 1-meter separation of electronic medical devices from the TMx-

3000™ System does not guarantee that operation of other medical devices will not be impacted. Operation of all electronic medical equipment in proximity to the TMx-3000™ System must be closely monitored, as the functions of this equipment may be affected by the energy emitted during operation of the TMx-3000™ System.

- **Do not operate an electronic device or equipment emitting electromagnetic energy in proximity to the TMx-3000™ System during a thermotherapy procedure, as the electronic equipment may interfere with the operation of the TMx-3000™ System.**
- The ANSI/IEEE C95.1992 recommended stray field exposure level for partial body exposure, at 915 MHz, is 20 mW/cm², except for eyes and testes. Stray field testing on the Rx-200 Treatment Catheter has shown that the maximum stray field level observed at a 5 cm distance from the Rx-200 Treatment Catheter's coaxial cable is 5.2 mW/cm². The ANSI/IEEE recommended maximum stray field exposure level for whole body exposure, including the testes and eyes, is 3 mW/cm², as averaged for any 6-minute period. In order to comply with these ANSI/IEEE guidelines, AMS, Inc. recommends a **minimum distance of 10 cm be maintained between the Rx-200 coaxial cable and the operators during 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-3000™ 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, or patient deaths reported during the study.

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		
Hematuria	21	16.8%
Dysuria ¹	18	14.4%
Bladder spasm	17	13.6%
Urgency	8	6.4%
1-Month Visit		
Hematuria	11	9.1%
Dysuria ¹	8	6.6%
Bladder spasm	5	4.1%
Hemospermia	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-3000™ 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-3000™ 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).

Table 4: AUA Symptom Index

<i>Study</i>	<i>Pre-Treatment</i>	<i>Follow-up</i>	<i>p-value</i>	<i>p-value between groups at 3 months</i>
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-3000™ System treated patients experienced symptom improvement $\geq 25\%$ and 45.2% experienced improvement $\geq 50\%$. 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 $\geq 25\%$ and 22.6% experienced symptom improvement $\geq 50\%$. The mean improvement in AUA Symptom Score was 25.4%.

At 1-year post-treatment, 75.6% of the TMx-3000™ treated patients experienced symptom improvement $\geq 25\%$ and 52.1% experienced improvement $\geq 50\%$, 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-3000™ treated patients was noted comparing baseline to 3 and 12 months post-treatment.

Table 5: Peak Flow Rate (ml/s)

<i>Study</i>	<i>Pre-Treatment</i>	<i>Follow-up</i>	<i>p-value</i>	<i>p-value between groups at 3 months</i>
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-3000™ 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-3000™ 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-3000™ 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 side effects of thermotherapy treatments could possibly include the adverse events listed below; however, during the clinical study of the AMS, Inc. TMx-3000™ System, none of these adverse events were 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.

Instructions for Use

Initial Power-Up

Each time the AC Power ON/OFF Switch is turned to ON ('I' will show on the switch) a system self-test is initiated and Standard Protocol is selected by default. This self-test includes a check of the microwave (MW) module power output, temperature sensor

function, printer, the tone generator, and other system functions. Errors will be displayed on the touch screen monitor. Some errors will not allow a treatment to be initiated.

NOTE

Should a loss of power to the TMx-3000 console occur during a treatment, disconnect the Patient Cable from the RX-200 Catheter and call AMS Technical Service Operations for further instructions.

NOTE

The DESIRED TEMPERATURE and DESIRED TIME @ TEMPERATURE values can be changed during a treatment. The DESIRED TIME @ TEMPERATURE setting can be increased up to 60 minutes, but cannot be decreased past the actual displayed TIME @ TEMPERATURE.

Equipment Setup for Treatment

The TMx-3000™ System has been designed so that once the DESIRED TEMPERATURE and TREATMENT TIME @ TEMPERATURE have been set the required operator interface will be minimal. All system functions are automatically monitored, displayed, and printed by the TMx-3000™ Control Unit. The following is a treatment setup guide for the TMx-3000™ System and Rx-200 Treatment Catheter.

- Use an alcohol swab to clean the surface of the temperature sensors, attached cables, and mapping extensions.

Treatment Supplies

To perform a TMx-3000™ procedure the following equipment is required:

TMx-3000™ Control System	Sterile bowl
Rx-200 Treatment Catheter	Betadine
Rectal temperature fixture	Underpad
Disposable rectal catheter	Lubricating jelly
Condom / rubber glove	10 cc Lidocaine jelly
1-Foley catheter	2-10 cc luer syringe
Urine drainage bag	50 cc sterile water
2 pair sterile gloves	Leg band or tape
4x4" sterile gauze	Penile clamp
Urine drainage bag kit (for outpatient use)	1 pair non-sterile gloves

Pretreatment

- Prophylactic antibiotic regimen started one day prior to treatment. Insure that patient received pain medication and oral relaxant at least 45 minutes prior to Rx-200 Treatment Catheter insertion.
- Fleets enema (patient should self-administer approximately 2 to 3 hours prior to treatment).
- Rx-200 Treatment Catheter length determined from transrectal ultrasound.
- Turn on power to the TMx-3000™ Control System.
- Perform Temperature Sensor calibration procedure if necessary.

NOTE

If a Temperature Sensor cannot be calibrated to within the $\pm 0.2^{\circ}\text{C}$ tolerance, it may be defective. Contact AMS Technical Service Operations personnel.

- Select Utilities and select the desired treatment protocol.

NOTE: Each time the control unit power is cycled (on/off), the control unit will set the protocol to the Standard Protocol by default.

Table 1: Treatment Protocols

Protocol	Ramp Time	Treatment Time	Treatment Temperature
Standard (Default)	22 min	40 min	50.0°C
Shortened Ramp	10 min	40 min	50.0°C
Shortened	8 min	30 min	50.5°C

- Select print preferences in the Utilities and Live Treatment Print Format menus.
- Verify that there is sufficient printer paper available for the entire treatment.
- Enter the treatment catheter authorization code and patient identification data in the Treatment Data Entry. The catheter authorization code is located on the RX-200 package label, just above the bar code.
- Select correct heating length treatment catheter.

Treatment Setup – Non-sterile

- Insert Temperature **Sensor #3** into the disposable, blind end catheter supplied with the treatment catheter. Tighten the white Tuohy-Borst adapter on the blue mapping extension.
- Insert the blind end catheter through the hole in the handle of the rectal probe. Slide the catheter along the open channel to the tip of the rectal probe. Push firmly on the catheter tip to securely seat tip into the small retaining hole at the tip of the open channel on the rectal probe. Verify that catheter is securely seated in the end of the rectal probe.
- Cover the rectal probe with a condom. Stretch the condom over the shorter tab to secure the condom in place.
- Lubricate the condom with water based gel and insert the probe into the rectum so that the longer portion of the handle points upward toward the perineum.
- Place patient in a comfortable supine position for treatment setup. Provide torso elevation of less than 30° during treatment for patient comfort.

WARNING

To prevent excessive compression of the rectal probe into the prostatic tissues, the patient's torso should not be elevated more than 30° during treatment with the TMx-3000™ System.

Treatment Setup – Sterile Procedure

- Prep penis (using sterile procedure) for urethral catheterization.

WARNING

Infection could result if proper sterile field techniques are not utilized during installation of the treatment catheter and indwelling catheter.

- Gently instill 10cc Lidocaine jelly into the urethra, apply penile clamp and wait 10 minutes.
- Lubricate and insert the Rx-200 Treatment Catheter into the patient; orient the side temperature sensor lumens at 3 and 9 o'clock and the coude tip at the 12 o'clock positions.
- Place 5cc of sterile water into balloon after urinary drainage commences. If urine does not drain after balloon inflation, irrigate the bladder with normal saline to confirm free flow of urine. If catheter placement is still in question, verify the Rx-200 Treatment Catheter placement by ultrasound imaging.

WARNING

Filling the balloon beyond the 5cc capacity or contact with any abrasive materials including calcification or stones in the urethral track may cause the balloon to burst, which would allow the fluid from the balloon to flow into the bladder. To avoid the possibility of bladder infection if the balloon bursts, sterile water should always be used to fill the balloon.

WARNING

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

- Connect the urine drainage bag to the catheter.
- The sterile portion of the procedure is complete.

Treatment Setup – Non-sterile

- Position the Control System to the Patient and set the foot brake on the Control System.

CAUTION

Set the brake on at least two wheels at the base of the cart and the brake on the treatment bed before inserting the Temperature Sensors and connecting the Rx-200 Treatment Catheter to the MW Extension Cable.

NOTE

The administration of prophylactic oral antibiotics before and/or after catheterization and following treatment is recommended.

- Verify that urine is flowing through the urinary drainage lumen prior to heating to ensure that there is no obstruction in the catheter.
- Plug the Rx-200 Treatment Catheter connector in to the microwave cable connector.
- Place light traction on the Rx-200 Treatment Catheter to make sure that the balloon is seated against the bladder neck. Secure the drainage tube to the patient's leg to maintain light traction on the Rx-200 Treatment Catheter.
- Select Start Treatment on the Treatment Data Entry Screen.
- Insert temperature **Sensor #1** (red) into a side catheter track of the treatment catheter and position it at the midpoint of the coil. Secure the temperature sensor in position by tightening the Tuohy-Borst adapter.
- Insert temperature **Sensor #2** (yellow) into the second side catheter track of the treatment catheter until it stops at the tip of the sensor lumen. This will position the sensor at the distal end of the Rx-200 Treatment Catheter coil. Secure the temperature sensor in position by tightening the Tuohy-Borst adapter.

NOTE

Two thermistor type temperature probes will be used to monitor and control heating. Temperatures should be mapped throughout the heating pattern length. Each probe should be placed at the point of maximum temperature after mapping. The computer controls the power output based on the maximum temperature measured by either Sensor #1 or Sensor #2.

NOTE

If the displayed temperature of any Sensor is greater than 65°C, a temperature reading of 65.H will be displayed on the Sensor 2 LED and printed on the Treatment Data Record Sheet. (Refer to the *Maintenance* section for an explanation of the error codes.)

NOTE

If the displayed temperature of any Sensor is lower than 30°C, a temperature reading of 30.L will be displayed on the Sensor LED and printed on the Treatment Data Record Sheet.

WARNING

Some self heating of the Rx-200 Treatment Catheter coaxial cables can occur during treatment. The operator position the coaxial cable away from the patient. The operator should use caution when contacting the cables during treatment.

- Begin patient entertainment (e.g., video or music).

Treatment

- Verify the correct Treatment Protocol is displayed.
- Verify the DESIRED TEMPERATURE.

- Verify the DESIRED TIME @ TEMPERATURE.
- Select the START button to begin the treatment.

NOTE

If the Control Sensor's reading is below 30°C, an error code will be displayed and the warning message, "Warning, higher temperature expected," will be printed. A low body temperature reading usually indicates that the Control Sensors have not been inserted in the catheter tracks.

- When a temperature of 44°C has been achieved, perform a thermal map of Sensors #1, #2 and #3. The sensor displaying the lower temperature of the two sensors must be mapped first. Following thermal mapping, position the sensors at the maximum temperature point and secure the probes in place by retightening the connector.
- Perform thermal mapping of all three sensors again when the measured temperature is at 50°C.

NOTE

If the urethral surface temperature exceeds 2°C of the Desired Temperature, the microwave energy will be immediately turned off by the computer to decrease the temperature.

- Verify the Rx-200 Treatment Catheter and rectal probe placement, using visual, manual, or ultrasound verification techniques, every 15 minutes

PRECAUTION

It is possible that the balloon can unintentionally deflate during treatment, resulting in catheter 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.

PRECAUTION

If there is a sudden drop in temperature (>2°C) during treatment, positioning of the catheter should be verified as balloon may have ruptured, allowing the catheter to migrate.

- Complete the treatment as per protocol.

Thermal Mapping Procedure

1. Loosen the Tuohy-Borst connector and verify that the Temperature Sensor has been positioned at the distal end of the catheter track.
2. Allow the temperature of the thermistor at the tip of the Temperature Sensor to stabilize (approximately 5 seconds).
3. Pull the Temperature Sensor away from the catheter tip toward the proximal end of the catheter a distance of 0.5cm.
4. Repeat Steps 3 and 4 for each 0.5cm increment from the Temperature track tip to a distance 1cm beyond the end of the antennae coil.

5. Reposition the temperature sensor at the point of highest temperature measurement and retighten the Tuohy-Borst adapter.

NOTE

Each sensor should be placed at the point of maximum temperature after mapping. The computer controls the power output based on the maximum temperature measured by either sensor #1 or sensor #2.

End of Treatment

- When the desired TIME AT TEMPERATURE has been achieved, the system will automatically terminate the treatment and print the end of treatment statistics.
- Remove the three temperature sensors and Mapping Extensions from the Rx-200 Treatment Catheter and the Rectal Probe.
- Disconnect the Rx-200 Treatment Catheter from the microwave connector.

NOTE

If the operator removes the MW Extension Cable Adapter with the Rx-200, it must be replaced on the MW Extension Cable. **Do not discard the adapter.** To remove this adapter, hold the connector housings and pull the adapter from the catheter using a straight pulling action. To reattach this adapter to the MW Extension Cable, push the threaded connector end into the mating end of the MW Extension Cable and screw the two pieces together.

- Drain the 5cc of water from the balloon and remove the Rx-200 Treatment Catheter from the patient.

NOTE

Should the operator be unable to drain the balloon following the treatment, the catheter may be removed by overfilling the balloon with sterile water causing the balloon to rupture.

WARNING

Dispose of used Rx-200 Treatment Catheters and all other contaminated materials per appropriate standards and procedures for disposing of bio hazardous material.

- Remove rectal probe and discard the condom and the blind-end catheter.
- Prepare penis (using sterile procedure), install the indwelling urethral catheter, and attach the leg bag.
- Place the Power Switch in the OFF position at the rear of the TMx-3000™ System's Operator Console.
- Remove the treatment printout record and store with the patient's files.
- Swab the Temperature Sensors with alcohol. Place blind end catheters over the three temperature sensors to protect them, using the luer lock connections to secure the catheters in place.

- Clean the rectal probe fixture with soap and water, swab with alcohol, and store in a safe place.

Post Treatment Patient Instructions

Provide post treatment instructions to the patient. Following the treatment instruct the patient concerning the following:

- Foley Catheter care and duration (2–5 days).
- Voiding trial after catheter removal.
- Post-treatment antibiotic, NSAID, and antispasmodic.
- Adequate fluid intake and a balanced diet.
- Follow-up appointment date.
- Contact physician if fever >101.5°F, clogged catheter, excessive bleeding or discomfort.

NOTE

The administration of prophylactic oral antibiotics before and/or after catheterization and following treatment is recommended.

Sterilization

AMS does not guarantee the integrity, specifications, sterility, or operation of the Rx-200 Treatment Catheter if used for more than one patient treatment.

PRECAUTION

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

The Temperature Sensors used with the TMx-3000™ System are always placed inside closed-end catheters during the treatment and do not require sterilization and can be used with other patients. A Temperature Sensor that is not mishandled should be usable for several years. Temperature Sensors must be placed in closed-end catheters to avoid the need for sterilization.

Inventory Turns and Warranty Information

Before returning any RX-200 catheters, whether used or unused and sterile, customers must fill out the Return Goods Form located in the last page of the Patient Information Form. Follow all of the instructions on the form carefully and be sure that the catheters have been thoroughly cleaned before returning to AMS.

In all cases, obtaining credit or percentage of credit for a returned RX-200 catheter is subject to approval. For complete information regarding these policies, contact the AMS Customer Service Department.

This document is written for professional medical audiences.

AMS periodically updates product literature. If you have any questions regarding the currency of this information, please contact AMS.

AMS

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