



**THERMASPEC™**  
**OPERATING**  
**MANUAL**



REVISION B04

**GROUNDBREAKING TECHNOLOGY**  
*Within Your Reach*

This manual is the property of **MEDISPEC LTD.** and may not be transferred or reproduced in any form without the written permission of the company. This manual is produced under the copyright laws of USA.

Treatment procedures and clinical practices specified in this manual should be considered as recommendations only and must be determined and implemented by the physicians supervising the treatment.

This manual may be amended by the company without prior notice at any time.

**Warning:** Product liability claims, warranties as well as guarantees made by Medispec with respect to the product are voided, if it is not used, serviced or maintained in accordance with the instructions in this manual.

## LABELS AND SYMBOLS

	Manufacturer
	Manufacturing Date
	This label indicates that the user must refer to the Warnings Section
	Type B applied part classification
	Equipotential Terminal
	Consult Instructions for Use
	Electrical and Electronic Equipment. Do NOT dispose of in the Municipal Waste Stream
	Non-Ionizing Radiation
	Mass of mobile Medical Electrical (ME) equipment (per IEC60601-1)
	CE Marking indicates that the device is in compliance with applicable EU regulations for medical devices.

**Table of Contents**

1 INTRODUCTION ..... 6

1.1 Indications for Use ..... 6

1.2 Contraindications ..... 6

1.3 Warnings ..... 6

1.4 Precautions ..... 7

1.5 Adverse Effects ..... 7

1.6 SAFETY CONSIDERATIONS..... 8

2 SYSTEM DESCRIPTION ..... 9

2.1 Main Unit ..... 10

2.2 Applicator Assembly ..... 12

2.2.1 Applicator..... 12

2.2.2 Catheter ..... 13

3 SOFTWARE ..... 15

3.1.1 The Main Menu..... 15

3.1.2 The Treatment Option (F2) ..... 16

3.1.3 3.3.3 Follow-up Option (F3) ..... 23

3.1.4 Database Option (F4) ..... 24

3.1.5 Utilities Option (F5)..... 28

3.1.6 Exit Without Shutdown Option (F6) ..... 30

4 SYSTEM SETUP AND OPERATION ..... 31

4.1 Room Preparation..... 31

4.2 System Power-up ..... 31

4.3 Deciding where to locate the applicator ..... 31

4.4 Applicator Insertion Technique ..... 31

4.5 Applicator insertion ..... 32

4.6 Treatment Procedure..... 32

4.7 Shut-Down Procedure..... 34

5 MAINTENANCE..... 35

5.1 Schedule ..... 35

5.2 Operator Calibrations ..... 35

6 TROUBLESHOOTING..... 36

7 TECHNICAL SPECIFICATIONS ..... 37

**Table of Figures**

Figure 2-1: Thermaspec™ device ..... 9

Figure 2-2: Thermaspec™ applicator and Catheter ..... 10

Figure 2-3 Front Panel..... 11

Figure 2-4: Storage Compartment and rear Panel ..... 11

Figure 2-5: Side view ..... 12

Figure 2-6: Applicator and the maximal heating point..... 12

Figure 2-7: Applicator plug and fitting ..... 13

Figure 2-8: The Catheter ..... 14

Figure 3-1: Main Menu ..... 16

Figure 3-2: Patient List Window..... 17

Figure 3-3: Empty Edit Patient Window ..... 18

Figure 3-4: Edit Patient Window ..... 18

Figure 3-5: Patient History Window ..... 19

Figure 3-6: Pre-Treatment Window..... 20

Figure 3-7: Treatment Window ..... 21

Figure 3-8: Post-Treatment Window ..... 22

Figure 3-9: Follow-Up Window ..... 23

Figure 3-10: The Database Menu..... 24

Figure 3-11: The Database Follow-Up List ..... 25

Figure 3-12: The Database Statistics Menu ..... 26

Figure 3-13: The Age Distribution Report ..... 27

Figure 3-14: The Patient Recurrence Report ..... 27

Figure 3-15: Utilities Menu ..... 28

Figure 3-16: Change Hospital Name window ..... 29

Figure 3-17: Follow-Up Form ..... 29

Figure 3-18: Restore File Confirmation Window ..... 30

Figure 4-1: Indicators for applicator positioning inside the catheter..... 31

Figure 4-2: Applicator Catheter Orientation..... 32

Figure 4-3: Applicator insertion to the catheter..... 32

Figure 4-4: Applicator fitting fixed to the catheter..... 32

Figure 4-5: Balloon Placement..... 33

Figure 4-5: The Treatment Screen ..... 34

Figure 4-6: Heating Diagram ..... 34

Note: Images are subjected to change without notice

## **1 INTRODUCTION**

THERMASPEC™ is a device designed to deliver RF energy for the treatment / symptomatic relief of Benign Prostatic Hyperplasia (BPH). It utilizes an integrated temperature control for automated temperature regulation and allows the user to control and monitor the energy delivered.

### **1.1 Indications for Use**

The Thermaspec™ is a transurethral integrated, minimally invasive device for the thermotherapy treatment of symptomatic Benign Prostatic Hyperplasia (BPH). It is designed to treat BPH in men with prostate size of 20 to 70 grams, and prostatic urethra length of 12 to 55 mm.

### **1.2 Contraindications**

The Thermaspec™ is contraindicated under the following circumstances:

1. Suspected or confirmed malignancy of the prostate;
2. Previous history of Transurethral Prostatectomy;
3. When there has been previous rectal, or radical pelvic surgery (not including Hemorrhoidectomy ;
4. Where there are large metallic implants in the treated area. Electromagnetic radiation from the thermotherapy applicators may excessively, and even preferentially, heat such implants;
5. Previous prostatic or pelvic irradiation;
6. Neurogenic bladder;
7. U.T.I (recent);
8. Untreated balanitis or Urethritis;
9. Anti-coagulant therapy;
10. Urethral stricture/bladder neck contracture;
11. Bladder calculi;
12. Bladder tumor;
13. Urination problems stemming from causes other than BPH (i.e. chronic prostatitis);
14. Intravesical median lobe;
15. Post void residual volume > 250cc;

### **1.3 Warnings**

1. The physician should seriously consider thermotherapy treatment if the patient is interested in future fertility. Changes in ejaculation have been reported after microwave therapy, and the therapy's effect on ability to produce sperm is unknown.
2. The physician should seriously consider thermotherapy treatment if the patient has an implanted defibrillator, pacemaker or any other active (electronic) implant. The microwave energy of this treatment can harm electronic devices.
3. If a patient has compromised renal function or upper tract obstructive disease it is recommended that the patient be discharged with an indwelling catheter according to the physician's best judgment.
4. This device may cause and may be sensitive to electromagnetic interference. Do not operate in the vicinity of electro surgery, diathermy, or nuclear magnetic resonance imaging equipment.

5. A single high dose of microwave radiation to the testes, or testicular heating for a prolonged period of time, may result in temporary or permanent sterility<sup>1</sup>.

## 1.4 Precautions



The device should be used only by qualified and trained personnel under supervision of the physician trained and/or experienced in the use of this device as outlined in an appropriate training program.

1. The sale, distribution and use of the Thermaspec™ BPH System are restricted to its prescribed use.
2. The discretion of the attending physician should be used in the treatment of all patients.
3. Thermotherapy treatment presents a potential safety hazard in patients whose pain response is reduced due to disease or previous surgery.
4. It is important to adhere to recommended procedure for applicator placement and the selection of the control probe to minimize the probability of excessive temperature on normal tissue or of insufficient temperature in the treated area.
5. Strictly adhere to sterilized measures during the placement of the applicators to avoid localized infections.
6. In order to reduce the likelihood of surface burns and blistering from the subsequent delivery of therapeutic heat the operator must adhere to recommended applicator placement.
7. Elevated temperatures can possibly affect the pharmacological activity of some drugs, with unpredictable results. Altered vascular perfusion may dramatically affect the local tissue effects of systemic or infused drugs.
8. The applicator and overall system is designed so that under normal conditions no stray electromagnetic field is present in the patient or the operator.
9. The output power must be switched off during the applicator positioning process.
10. The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
11. **Maintenance:** For continuous and safe operation, regular maintenance and inspection by Medispec authorized technicians is required. For the maintenance procedures and schedule refer to the Maintenance chapter of this manual and to the Service Manual.

## 1.5 Adverse Effects

The list below includes a variety of potential adverse events related to Thermotherapy. However, it should be noted that those actually observed with the Thermaspec™ BPH System are limited to the direct effects from heating the tissue.

- Burning/blisters;
- Fistula;
- Urethral injury or trauma
- Bladder neck contracture
- Pain and discomfort;
- Urinary tract infection
- Urinary retention
- Bladder spasms

---

<sup>1</sup> Murca, G.J., et al. 1976. A Study of Microwave Radiation of the Rat Testes. In Biological Effects of Electromagnetic Waves. Washington, DC pp. 484-494.

- Urinary incontinence
- Patient sterility
- Prostatitis

## 1.6 SAFETY CONSIDERATIONS

**Microwave Output** The system provides a single SMB female connector for microwave output at an impedance of 50 ohms.

High energy microwave fields are potential hazard to occupants of the treatment room. The Thermaspec™ is designed to prevent accidental microwave leakage. Proper and careful operation of the equipment, however, is required to reduce the possibility of hazardous microwave leakage.

The Applicator aperture should never be pointed at anyone's eye while the power is ON.

Proper cabling on all microwave components (generator and applicator) should be verified before turning ON the generator.

**Electrical Shock** 115 or 230 VAC power is used for the primary power of the equipment. Equipment covers should never be removed with the primary power connected to the equipment.

Peripheral equipment (e.g. printer) must only be connected in accordance with the relevant requirements and standards.

**Secure applicator** Verify the applicator is secured to avoid its dislocation due to patient movement.



**Warning:** This unit must not be operated without attaching the proper applicator or auxiliary load to the output port prior to use.



**Warning:** Any modifications made to the equipment without explicit approval from Medispec Ltd. voids warranty and service contract obligations and pose a potential safety threat to both operators and patients.

## 2 **SYSTEM DESCRIPTION**

The Thermaspec™ system consists of the following main parts:

1. Main Unit with:
  - Personal Computer
  - Microwave generator
  - Designated software for operation and control of the energy delivered by the device
  - Swivel casters with brakes
2. Multi use applicator containing antenna with two thermal sensors (thermocouples)
3. A designated single use Foley catheter

The applicator is inserted into the catheter and together they form the applicator assembly.



Figure 2-1: Thermaspec™ device



Figure 2-2: Thermaspec™ applicator and Cathether

## 2.1 Main Unit

The main unit contains the following components:

- Power Control Switch with 3 positions:
  - Low: 20 Watt
  - High: 40 Watt
  - OFF
- Keyboard
- Mouse
- Power Entry Module and On/Off Switch
- Equipotential Terminal
- Applicator cable to which the applicator is connected during treatment
- USB ports for mouse and keyboard
- Storage compartment for consumables and accessories



**Caution:** Do not connect or install any external equipment or software to the system unless authorized by Medispec.



Figure 2-3 Front Panel

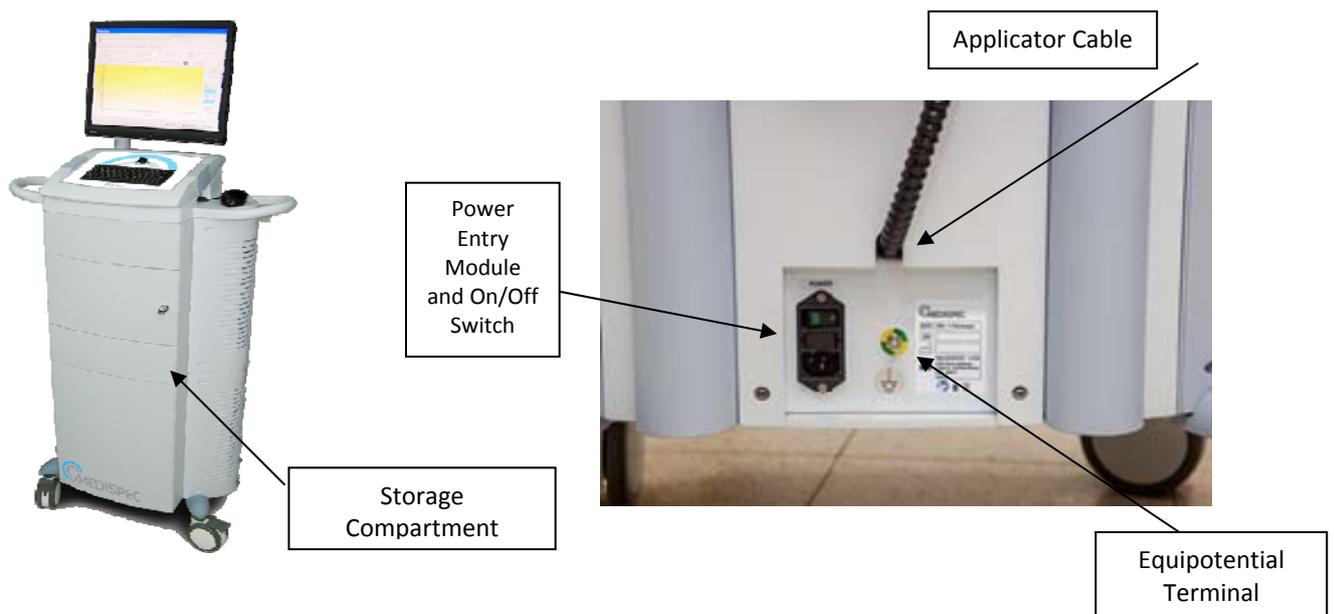


Figure 2-4: Storage Compartment and rear Panel



Figure 2-5: Side view

## 2.2 Applicator Assembly

The Applicator Assembly is comprised of a multi-use applicator which is inserted in a disposable single use catheter.

### 2.2.1 Applicator

The Applicator is designed especially for the Thermaspec™ BPH System. The applicator has a Maximum Heating Point (MHP) located between 2cm and 2.5cm from its tip, providing a heating zone of 2.7 cm in each direction enabling safe treatment of prostates of various lengths. The MHP is marked by black line on the applicator. An additional mark mirrors the MHP to assist while inserting the applicator through the catheter.

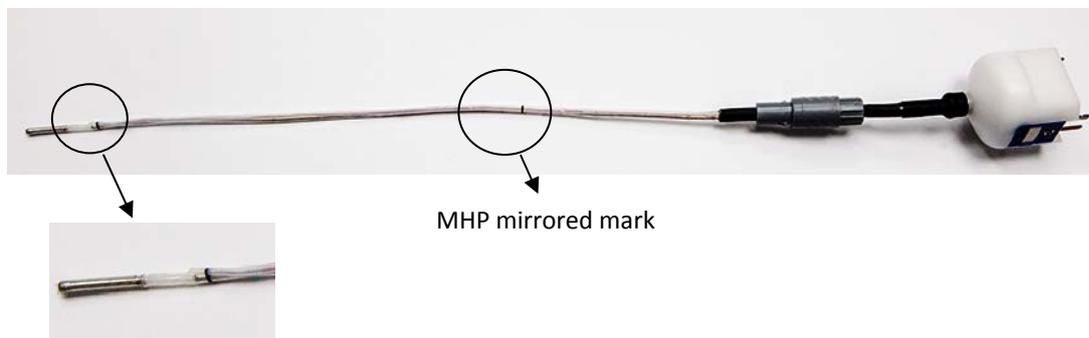


Figure 2-6: Applicator and the maximal heating point

The applicator has 2 channels of temperature reading located 5mm and 15 mm from the maximal heating point.

In its other end the applicator has a fitting to fix it permanently to the catheter during treatment and a plug to connect it to the applicator cable which is a part of the main unit (Figure 2-7).

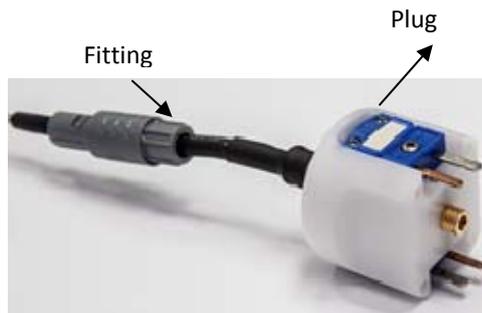


Figure 2-7: Applicator plug and fitting



**Warning:** The Applicator should only be used in conjunction with the "Foley" Catheter specially designed for use with the Thermaspec™ BPH System and is available through Medispec Ltd.

### 2.2.2 Catheter

The Catheter structure defines the placement of the Applicator with the thermal sensors, while inserted into the prostate. The Catheter is a custom made for the Thermaspec™ BPH System to optimize its operation. It is a 3-way 18Fr "Foley" type, with a 20cc bladder balloon and comes in a sterile pack. To avoid the risk of infection the Catheter should be disposed after each treatment.

The central Catheter channel is designed to hold the Applicator. The other channels are used for inflating the balloon and urination.

On the catheter, 2 sets of 3 black lines are marked. The front set (next to the tip) designates the heating zone and the middle line designates the maximal heating point (Figure 2-8) to be located in the middle of the patient's prostate (Figure 2-9). The rear set of 3 lines is a mirror of the front set and is visible to the operator during treatment. It is used for verifying the M.H.P location.

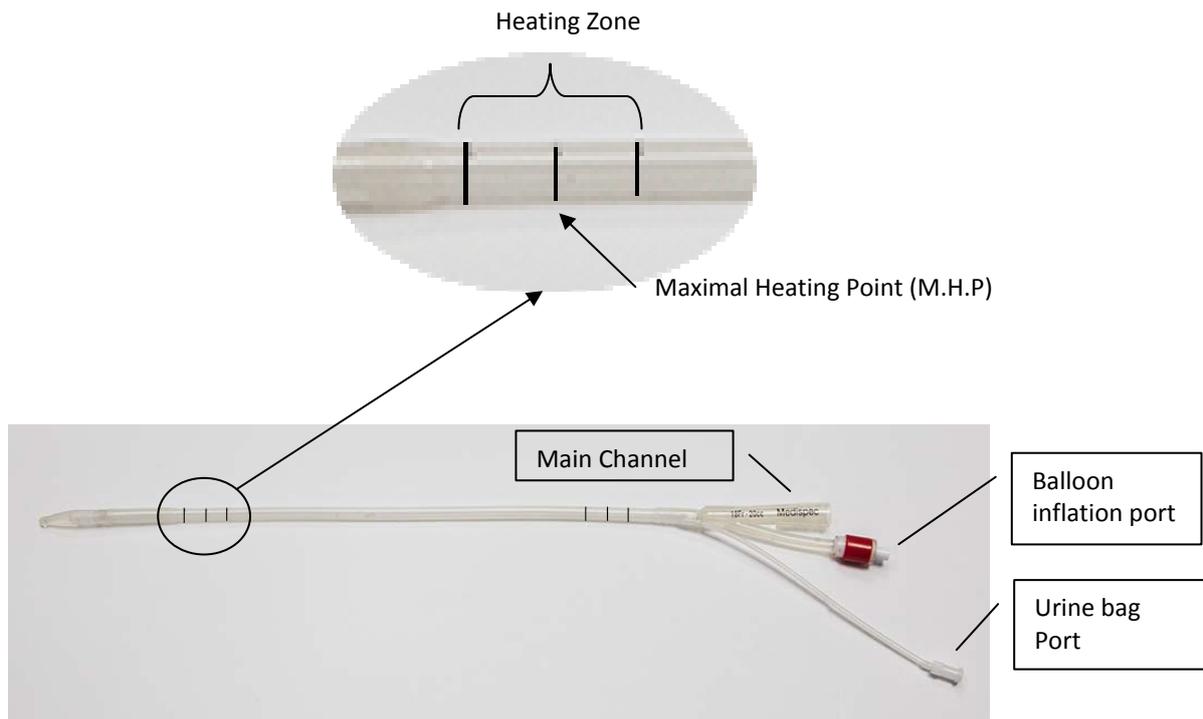


Figure 2-8: The Catheter

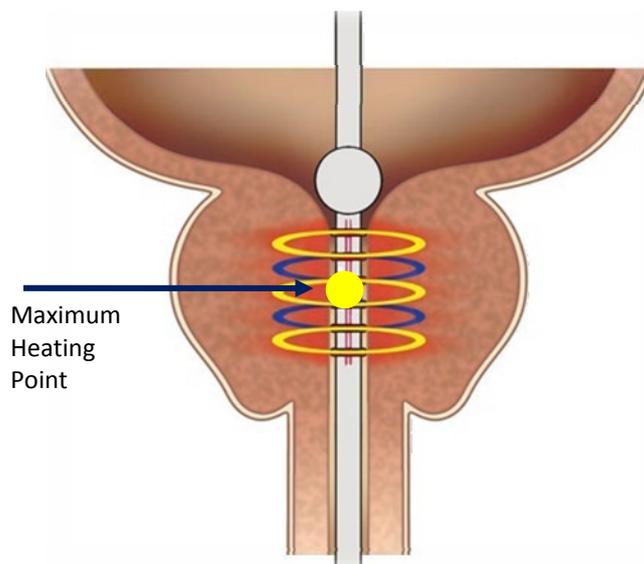


Figure 2-9: Applicator placement relative to the prostate

### 3 SOFTWARE



**Caution:** Installation or operation of any software program that gets access to external communication, as well as making physical connection to any communication line is forbidden in this equipment.

The software menu is structured as follows:

**Main Menu**

- **F2 – Treatment**
- **F3 – Follow Up**
- **F4 – Database**
  - F2 – Patient List
  - F3 – Patient Records
  - F4 – Future Follow-Up List
  - F5 – Statistics
    - F2 – Age Distribution
    - F3 – Patient Recurrence
- **F5 – Utilities**
  - F2 – Change Hospital Name
  - F3 – Follow-Up Form (empty)
  - F4 – Restore Database Index Files
  - F5 – Technician
    - F2 – Maintenance
    - F3 – Change Password
    - F4 – Enable Windows Shortcuts (enabling multitasking)
- **F6 – Exit Without Shutdown**

#### 3.1.1 The Main Menu

This is the first screen that appears after booting-up the System. From within this screen, the user can access the major software segments using the following buttons and keyboard shortcuts:

<b>Help (F1)</b>	Open Help window
<b>Exit</b>	Exit the program, shutdown computer
<b>Alt A – About</b>	View general information about the software
<b>Alt D - Date/Time</b>	Set the computer clock
<b>Alt N - Notebook</b>	Edit the Thermaspec™ notebook
<b>Alt X - Shutdown</b>	Close the system
<b>F2</b>	Treatment
<b>F3</b>	Follow Up
<b>F4</b>	Database
<b>F5</b>	Utilities
<b>F6</b>	Exit Without Shutdown

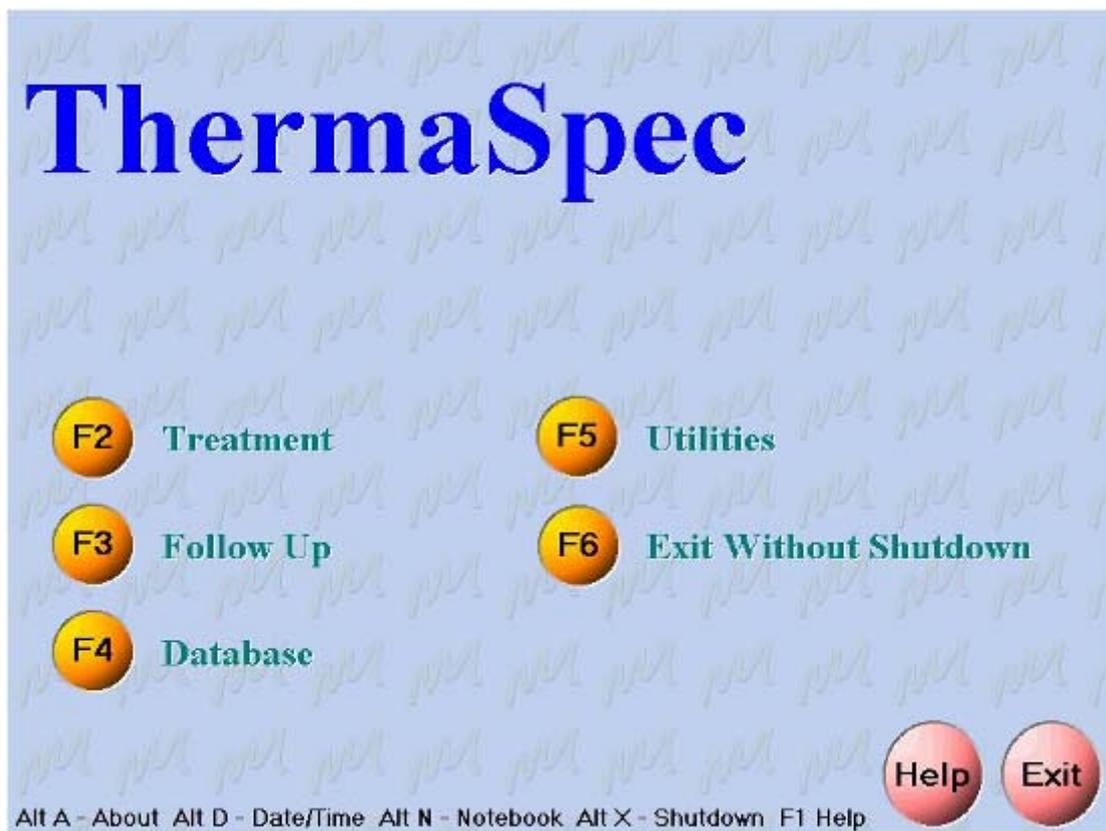


Figure 3-1: Main Menu

### 3.1.2 The Treatment Option (F2)

The first Treatment window is the **Patient List**. From this window, a new patient may be entered into the database, or an existing patient could be selected for ongoing treatment. The user can also edit patient information and/or access his history records.

The following buttons and keyboard shortcuts can be accessed in the Treatment window:

<b>Add Patient</b>	Add a new patient to the database
<b>Edit Patient</b>	Edit patient information, for the patient who's marked in the list
<b>Select Patient</b>	Select the patient, who's marked in the list, and continue
<b>History</b>	View history for the marked patient in the list

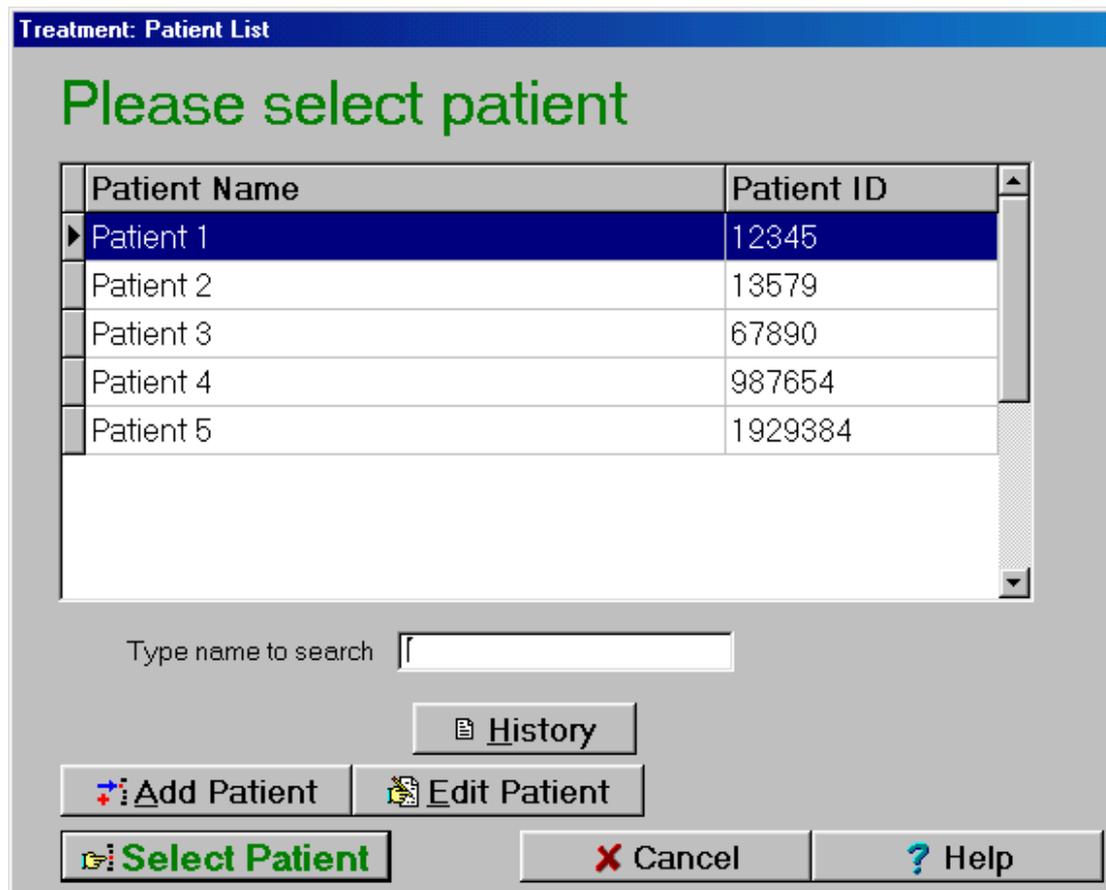


Figure 3-2: Patient List Window

### Add Patient

When 'Add Patient' is pressed, the new patient window appears. To add a new patient, enter a numeric ID for the new patient and press **Continue**.

This window contains the following Buttons and Keyboard Shortcuts:

<b>Continue</b>	Add the new patient ID to the database (after typing the ID)
<b>Cancel</b>	Cancel previous action. Don't add a new patient to the database
<b>Help (F1)</b>	Open Help window

Next, if **Continue** is selected, an empty 'Edit Patient' window appears, including the ID number only. The following functions are accessible in this screen:

<b>ID</b>	Patient's ID. The ID cannot be changed once entered into the 'new patient' window
<b>Last Name</b>	Patient's surname
<b>Name</b>	Patient's given name
<b>Birth Year</b>	Patient's year of birth (legal values are from 1900 up to the last year) and calculated <b>Age</b>

Buttons and keyboard shortcuts include:

<b>Continue</b>	Accept the changes you made, and return to Patient List window
<b>Cancel</b>	Cancel the changes you made, and return to Patient List window

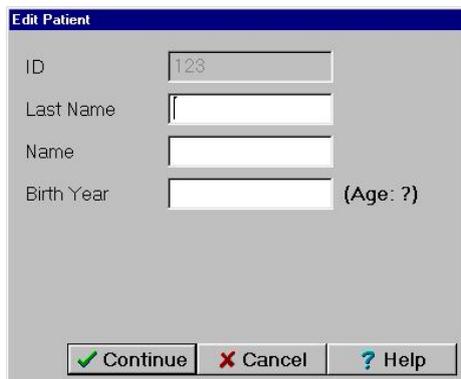


Figure 3-3: Empty Edit Patient Window

### Edit Patient

When 'Edit Patient' is pressed, information of the patient selected from the Patient List appears. Patients' information can be edited in this window. Fields, Buttons and Keyboard Shortcuts are the same as in the 'Add Patient' section.

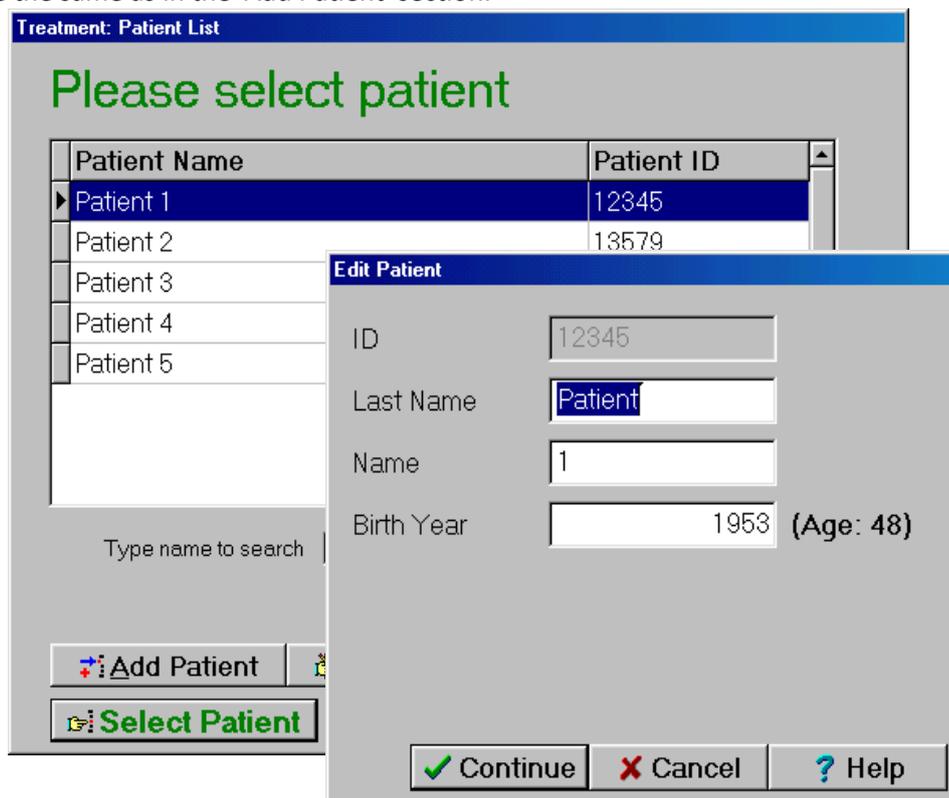


Figure 3-4: Edit Patient Window

**History**

When 'Patient History' is pressed, patient information (ID, Name and Age) of the patient selected from the Patient list appears. At the bottom of the screen, free text of the patients' history can be typed or edited. The 'Patient Records' window can be accessed from this screen.

This window contains the following Buttons and Keyboard Shortcuts:

**View Patient Records** - Open the Patient Records window

<b>Print</b>	Print the Patient History information
Exit	Exit the Patient History window
Help (F1)	Open Help window

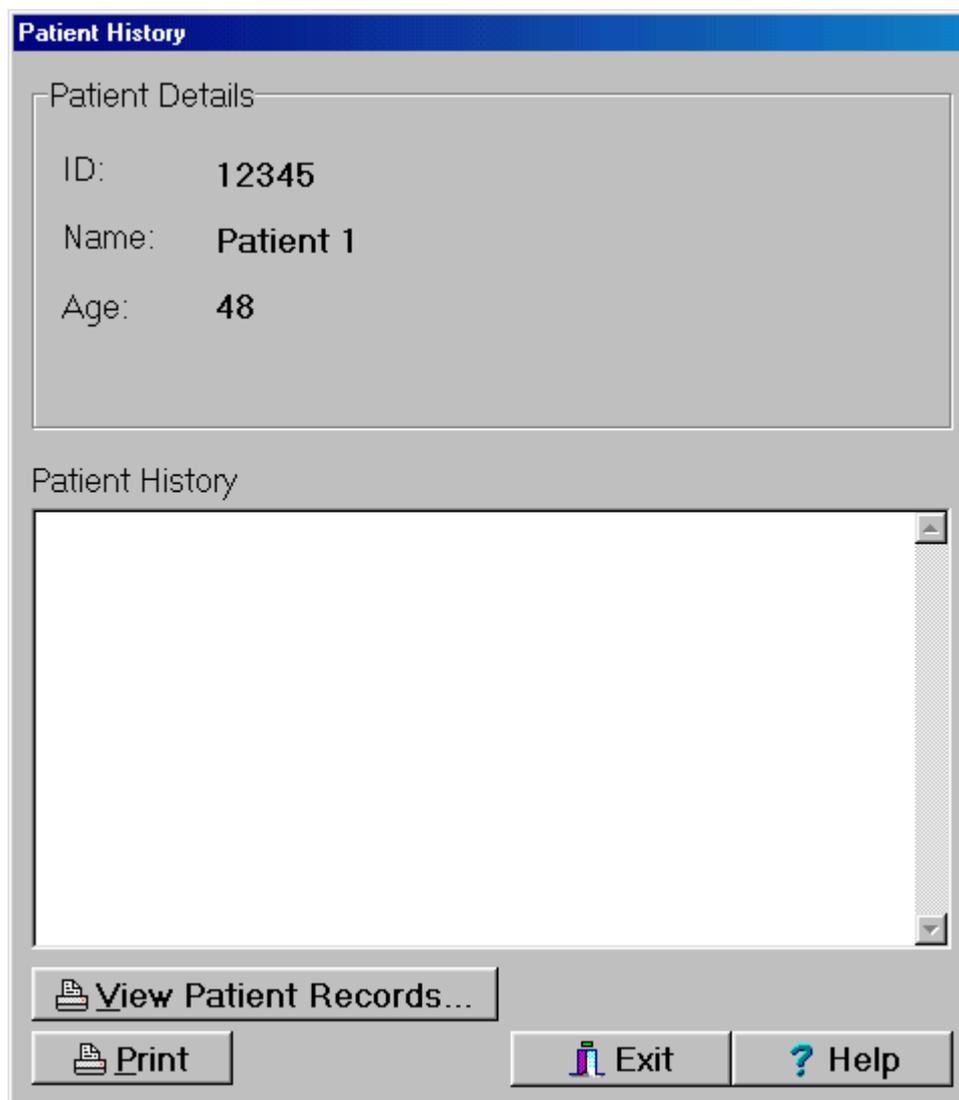


Figure 3-5: Patient History Window

### Select Patient

When 'Select Patient' is pressed, patient information (ID, Name and Age) of the patient selected from the Patient List appears. Alternatively, when you double click on the patient name, the same window opens. In this window, the user can select (one at a time) any of the following tab options:

#### 1. Pre-Treatment Tab

Enter all pre-treatment medical parameters in the appropriate fields. Pressing the **Save** button allows the system to store the information and immediately opens the 'Treatment' tab. Pressing the **Cancel** button, at any time, cancels the current session and switches back to the Main Menu.

Figure 3-6: Pre-Treatment Window

#### 2. Treatment Tab

First, make sure to set the control panel switch to *LOW* or *HIGH* power. Select the desired temperature, and then press the **Start** button to begin the treatment.

The Applicator tip temperature vs. time is displayed in a large area of the 'Treatment' window; looks similar to a chart recorder. In the same window, other treatment status information is displayed. The following display fields and indicators are shown:

<b>Treatment</b>	Elapsed time from treatment onset
<b>Start Time</b>	Treatment onset or starting hour
<b>Forward</b>	The amount of RF power being delivered
<b>Reflected</b>	The amount of RF power reflected
<b>Status</b>	Shows RED when transmitting RF power
<b>T1</b>	The temperature read by thermal sensor 1
<b>T2</b>	The temperature read by thermal sensor 2

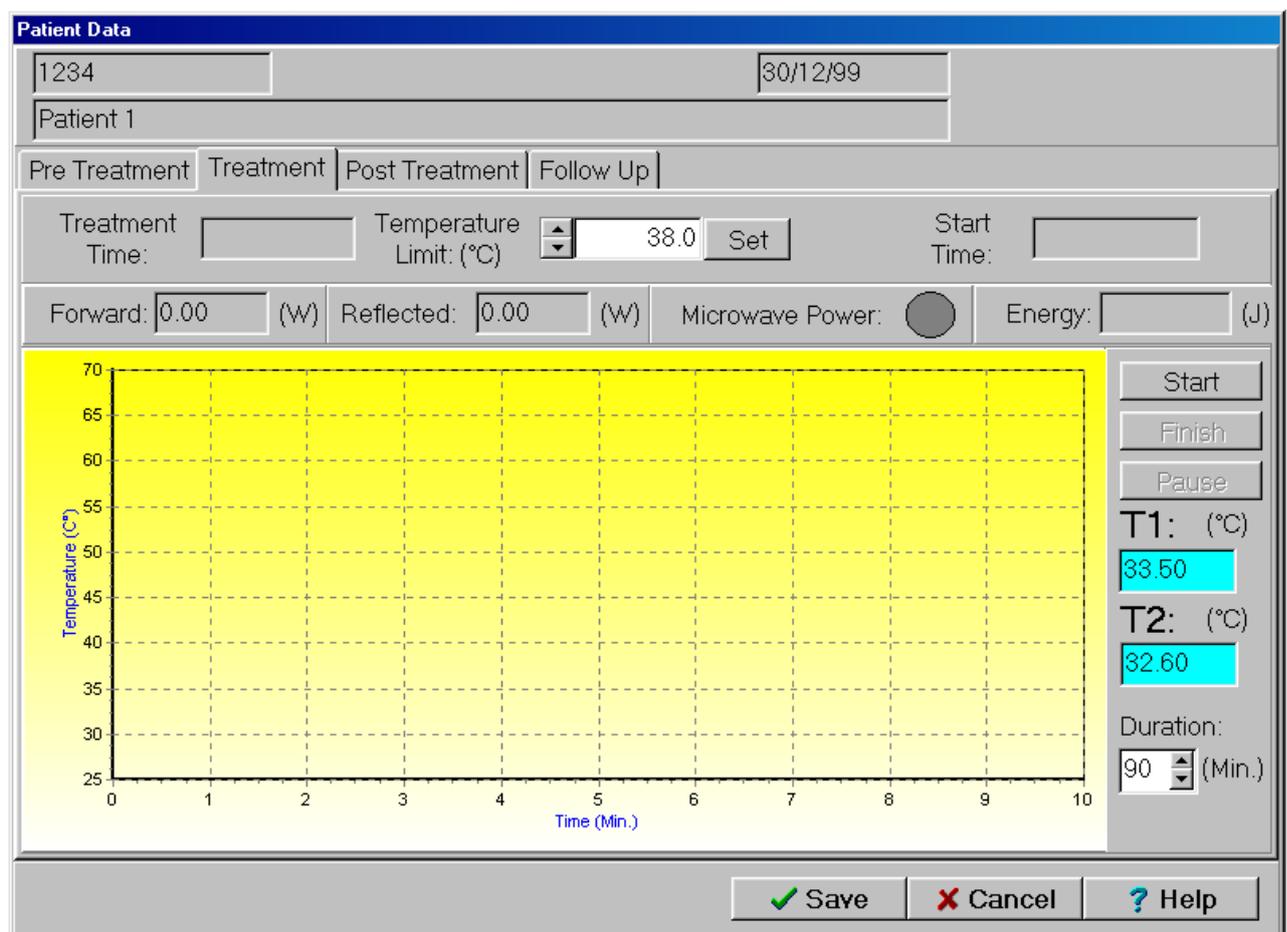


Figure 3-7: Treatment Window

The Treatment procedure can be stopped, at any time, by pressing the **Finish** button, or can be paused by pressing the **Pause** button. To resume treatment, from **Pause**, press **Continue**. To exit out of the Treatment window, press the **Finish** button, then the **Save** button to save the session's information and continue to the Post-Treatment Tab. If the **Cancel** button is pressed, the system will go back to the Main Menu without saving the current information.

### 3. Post-Treatment Tab

All post-treatment parameters and information should be entered in this window. The following information should be entered:

<b>Catheter</b>	Select N/A (not available), YES, or NO
<b>Follow-up</b>	Select N/A, YES, or NO
<b>Days</b>	Number of Follow-up days
<b>Systolic</b>	Blood pressure value
<b>Diastolic</b>	Blood pressure value
<b>Pulse</b>	Pulse Rate value
<b>Treatment</b>	Overall treatment time (displayed)
<b>Maximum</b>	Maximum value
<b>Pain</b>	Select N/A, YES, or NO
<b>Hematuria</b>	Hematuria value

The screenshot shows a software window titled "Patient Data" with a close button (X) in the top right corner. The patient ID is "12345" and the name is "Patient 1". There are four tabs: "Pre Treatment", "Treatment", "Post Treatment", and "Follow Up", with "Follow Up" being the active tab. The form contains the following fields:

- Catheter:** A dropdown menu with a blue background.
- Followup:** A dropdown menu.
- Days:** A text input field.
- Blood Pressure:** A group box containing:
  - Systolic:** A text input field with the value "1".
  - Diastolic:** A text input field.
- Pulse:** A text input field.
- Treatment:** A text input field with the value "00:00".
- Maximum:** A text input field.
- Pain:** A dropdown menu.
- Hematuria:** A text input field.
- Remarks:** A large text area for notes.

At the bottom right, there are three buttons: "Save" (with a green checkmark icon), "Cancel" (with a red X icon), and "Help" (with a blue question mark icon).

Figure 3-8: Post-Treatment Window

**NOTE:** Pressing the **Save** button or the **Cancel** button will return the present window to the Main Menu.

4. Follow-Up Tab

All follow-up medical parameters should be entered in the appropriate fields. When pressing the **Save** button, the system stores the information in the database and immediately returns to the Main Menu. If the **Cancel** button is pressed, before saving, the current session is canceled and returns to the Main Menu.

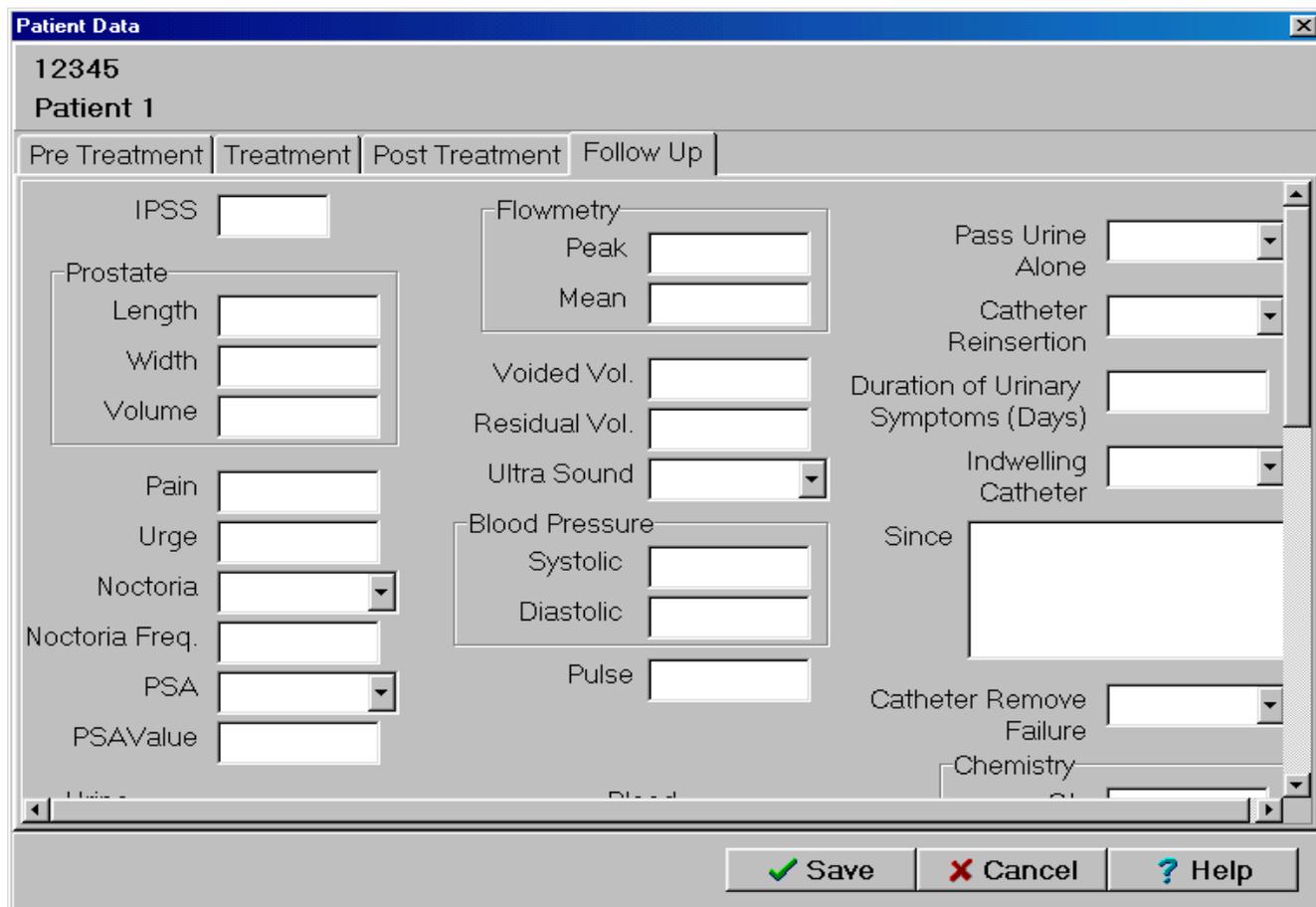


Figure 3-9: Follow-Up Window

### 3.1.3 3.3.3 Follow-up Option (F3)

By selecting the Follow-Up option, the user can perform most of the **Treatment (F2)** activities using similar windows. The **'Pre-Treatment'**, **'Treatment'**, and **'Post-Treatment'** tabs, however, can not be accessed in this window.

### 3.1.4 Database Option (F4)

From the Database Option menu, the user can view and directly edit the database records. After selecting the Database option, four sub menus appear:

- F2** – Patient List
- F3** – Patient Record
- F4** – Future Follow Up List
- F5** - Statistics

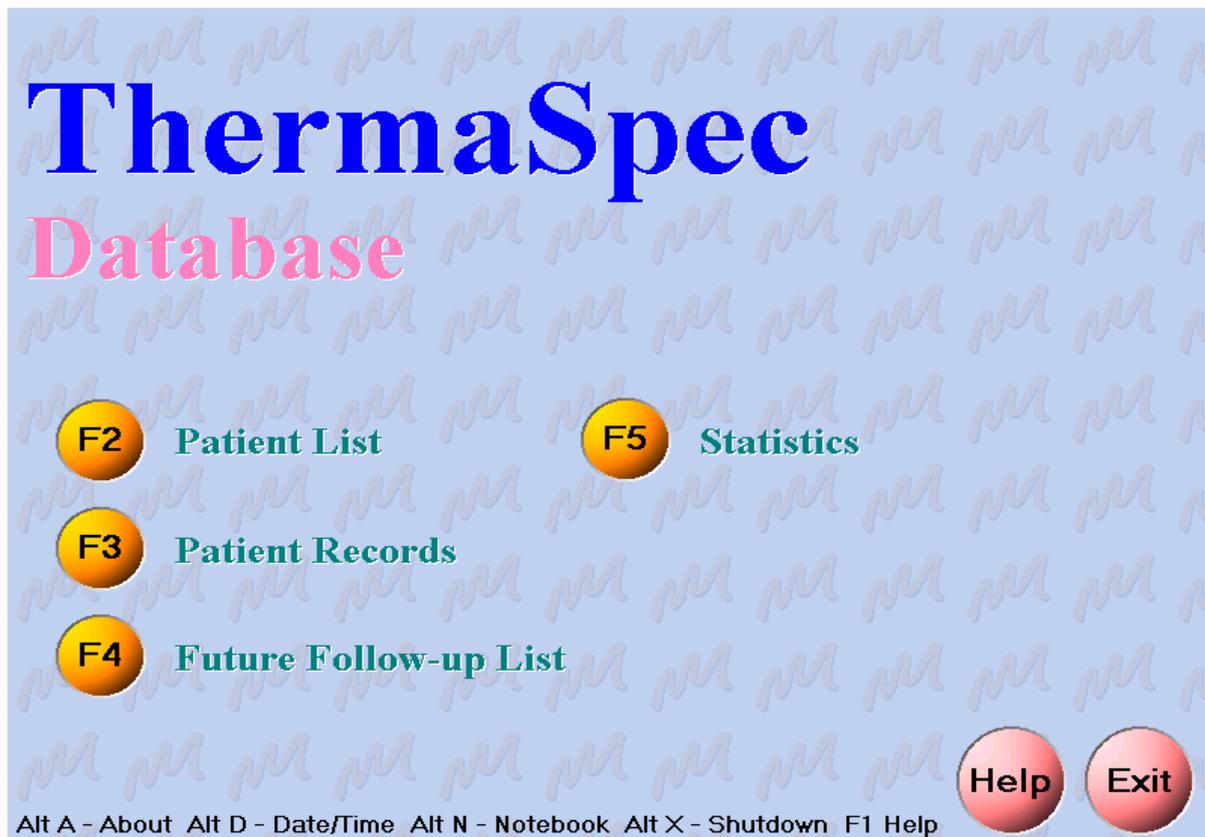


Figure 3-10: The Database Menu

#### Patient List (F2)

A detailed Patient List window appears when **F2** or **Patient List** is selected. The functionality of this window is similar to the **Treatment** option window, but there are different keys. Selecting a patient for a treatment session is not allowed from this list.

The following buttons and keyboard shortcuts are used in this window:

<b>Print Patients List</b>	Print the entire list
<b>History</b>	View patient history for the selected patient in the list
<b>Print Patient Record</b>	Print the selected patient's records

<b>Add Patient</b>	Add a new patient to the database
<b>Edit Patient</b>	Edit patient information for the selected patient
<b>Delete Patient</b>	Delete patient (selected patient) and their records from the database
<b>Exit</b>	Return to the Database Menu
<b>Help (F1)</b>	Open Help window

### Patient Records (F3)

When F3 Patient Records is selected a standard **Patient List** window appears (Fig. 7). All '**Patient List**' features described under the '**Treatment**' section are also available in this window with the exception of the **Select Patient** option. By pressing **Select Patient**, the **Patient Data** window appears and includes the two following tabs:

**Pre-Treatment Tab** - Same as Fig.11 with printing capabilities

**Post-Treatment Tab** - Same as Fig.13 with printing capabilities

### Future Follow-Up List (F4)

The **Future Follow-up List** window allows the user to view or print the follow-up list, and sort the list using three filter options:

1. Show All
2. Show Future
3. Select a date range

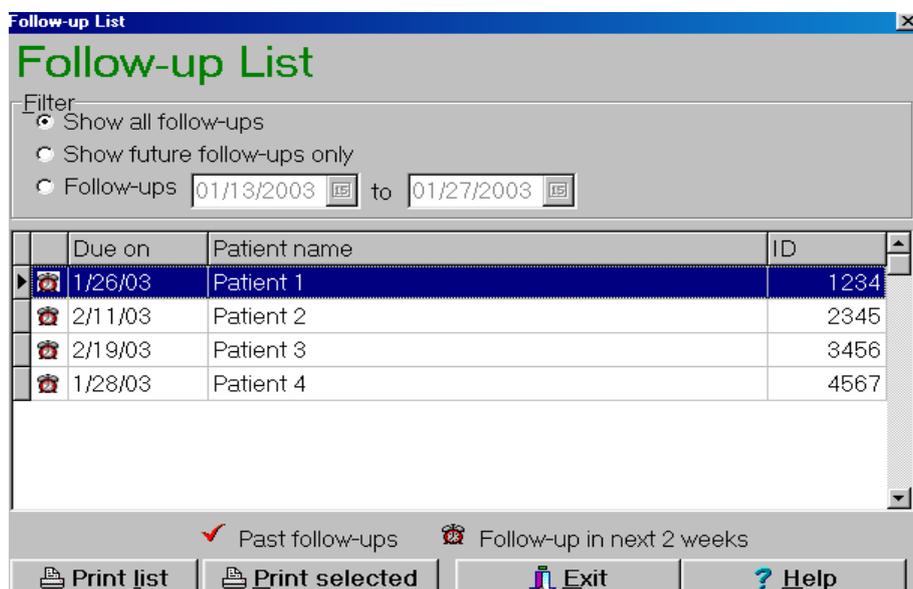


Figure 3-11: The Database Follow-Up List

### Statistics (F5)

When 'Statistics' is selected a new menu appears: the Database Statistics sub-menu including the following two functions:

**F2** – Age Distribution

**F3** – Patient Recurrence

**F2** generates an Age Distribution report. This report is built as an *Age vs. Patient Percentage* table (See Fig. 17). **F3** provides a report on the number of treatments done on a single patient. This report is built as a *No. of Treatments vs. Percentage of Patients* table (See Fig. 18). Both report windows have printing capabilities.

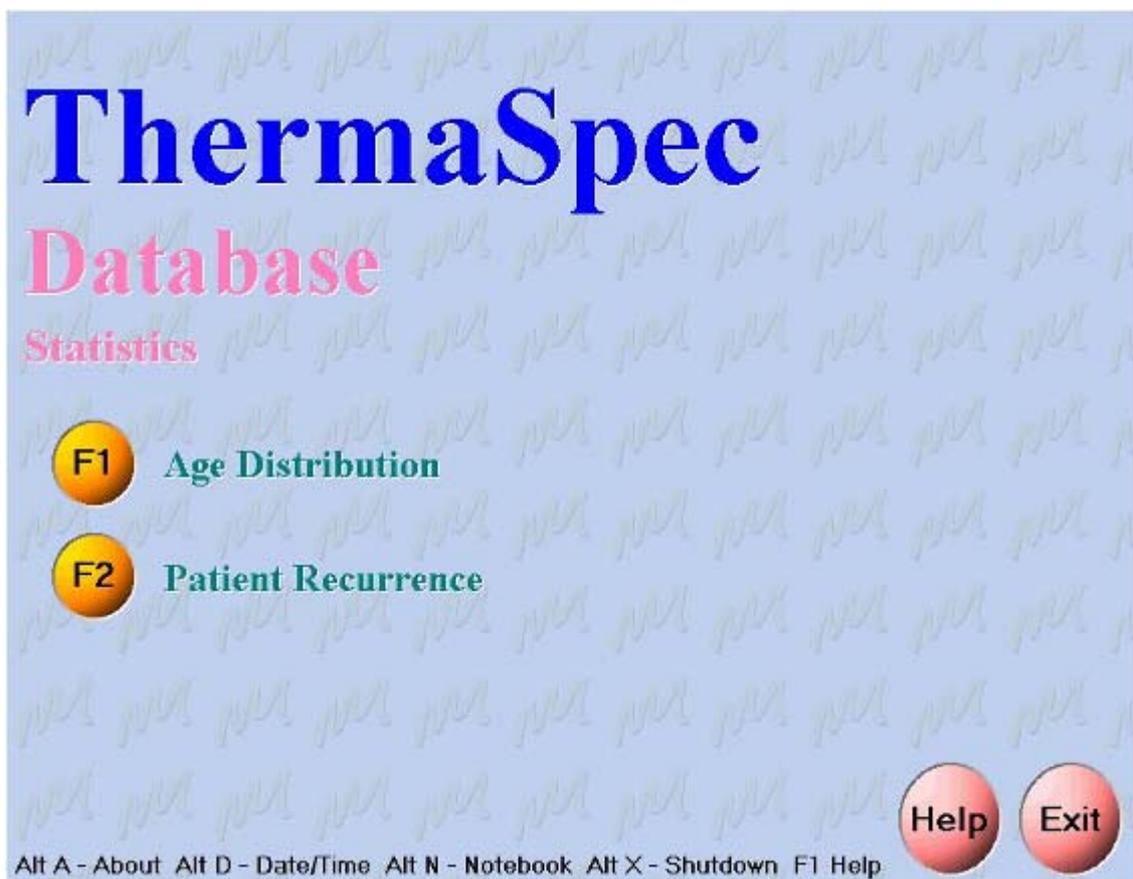


Figure 3-12: The Database Statistics Menu

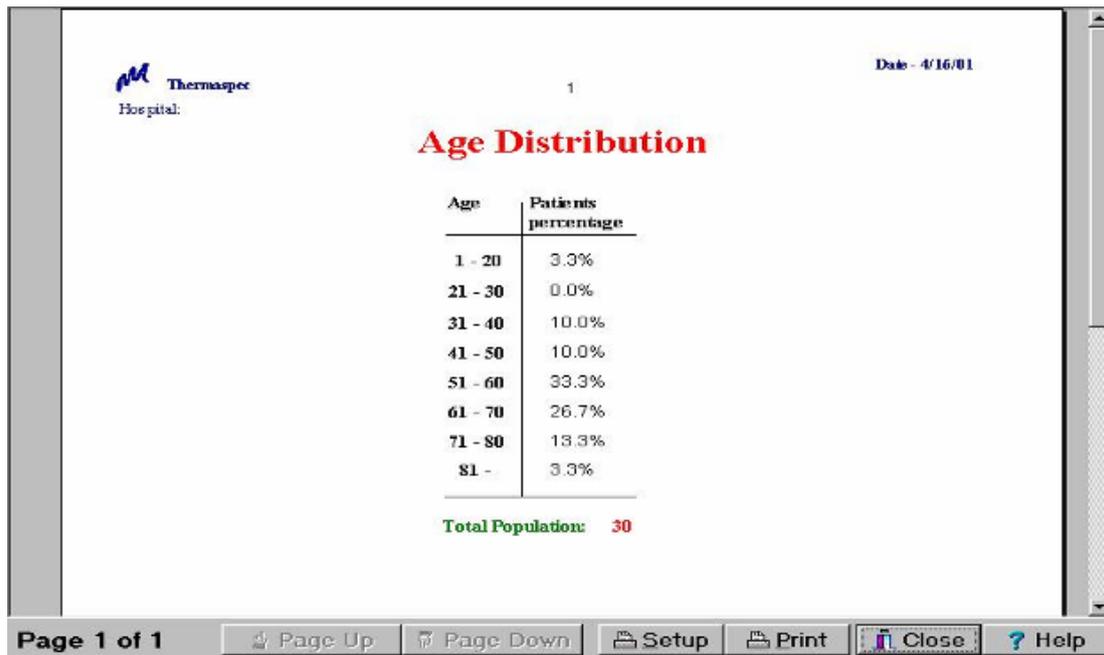


Figure 3-13: The Age Distribution Report

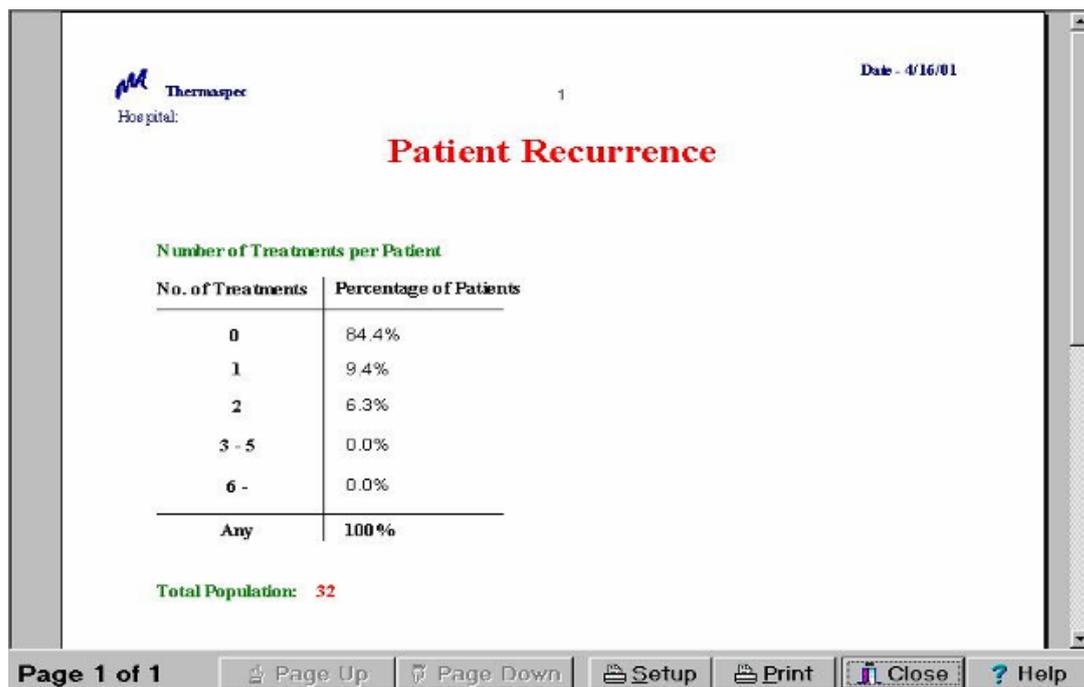


Figure 3-14: The Patient Recurrence Report

### 3.1.5 Utilities Option (F5)

From this menu, the user can change hospital name, print an empty follow-up form, and restore database files. The fourth function is for the technician for service purposes only. The following functions are accessible through this menu:

- F2** - Hospital Name
- F3** – Follow-Up Form
- F4** – Restore Database Index Files
- F5** – Technician

**NOTE:** Do not press the Technician button. Only authorized technicians are allowed to change system's settings.

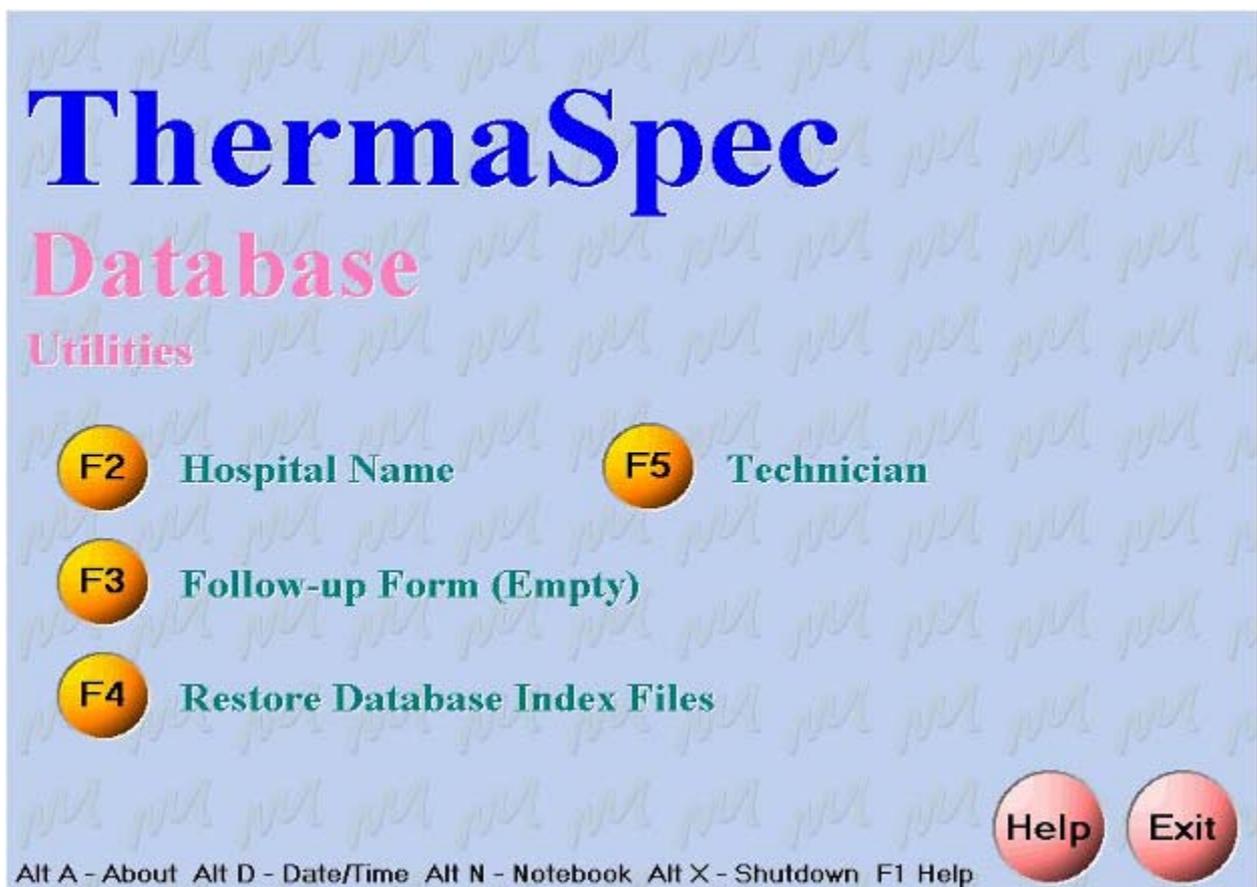


Figure 3-15: Utilities Menu

#### Hospital Name (F2)

The hospital name can be changed in this window.



Figure 3-16: Change Hospital Name window

### Follow-Up Form

When this function is selected, a new and empty form will appear on the screen. This form can not be edited only printed.

Figure 3-17: Follow-Up Form

### Restore Database Index Files (F4)

When this function is selected it allows the user to request confirmation to perform restoration actions. This function defrags database files.



Figure 3-18: Restore File Confirmation Window

### 3.1.6 Exit Without Shutdown Option (F6)

This last menu option enables the user to terminate the Thermaspec™ program without shutting down the computer. This option allows the user to switch into the PC operating system and run other Windows programs.

	<p><b>Warning:</b> Any modifications made to the equipment without explicit approval from Medispec Ltd voids warranty and service contract obligations and pose a potential safety threat to both operators and patients.</p>
---	---

## 4 SYSTEM SETUP AND OPERATION

### 4.1 Room Preparation

In addition to the Thermaspec™ system, the treatment room should include a standard treatment table.

### 4.2 System Power-up

1. Connect the Thermaspec™ to the main outlet.
2. Turn ON the power switch.
3. Wait until the treatment screen appears.
4. Verify that the temperature shown in the data display reflects the room temperature correctly.

### 4.3 Deciding where to locate the applicator

Correct positioning of the applicator in the catheter is an important factor affecting the treatment safety and success. It prevents thermal injury to the external sphincter and allows the most effective prostatic heating.

The image and the table below explain the relation between the indicators marked on the catheter and the M.H.P indication on the applicator:

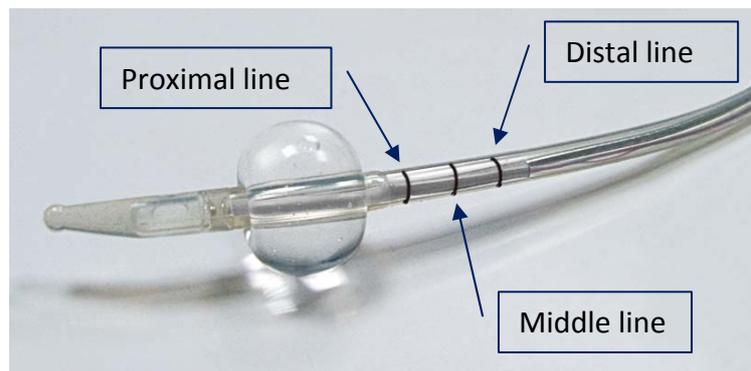


Figure 4-1: Indicators for applicator positioning inside the catheter  
(balloon is shown inflated only for the illustration)

Prostate Length (cm)	M.H.P Positioning
Prostate < 4	Proximal line
4 < Prostate < 6	Middle line
Prostate > 6	Distal line

### 4.4 Applicator Insertion Technique

The 18 Fr catheters and the applicator do not have a complete circular cross section. Therefore it is important to insert the applicator into the catheter in the correct orientation. To insert the applicator use the following illustration:

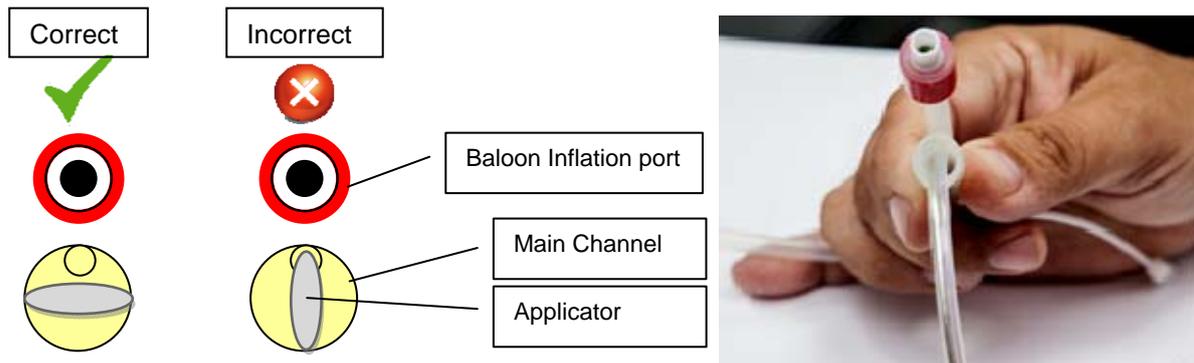


Figure 4-2: Applicator Catheter Orientation

#### 4.5 Applicator insertion

1. Insert the applicator into the main channel of the catheter according to figure 4-2.
2. Gently guide it until the M.H.P reaches the line corresponding the patients' prostate size (see paragraph 4.3).
3. Slide the fitting and fix it to the catheter's main channel (Figure 4-4).
4. Lock the fitting by turning it clockwise.



**Important:** Prepare the catheter as close as possible to the beginning of the treatment and ensure its sterility throughout the preparation process.



Figure 4-3: Applicator insertion to the catheter



Figure 4-4: Applicator fitting fixed to the catheter

#### 4.6 Treatment Procedure

1. Connect the applicator to the applicator cable
2. Prepare a 20cc syringe filled with sterile or distilled water

3. Insert the applicator assembly (applicator inside catheter) through the urethra and into the bladder.
4. Pay attention and minimize as possible the applicator bending. This will keep its service life longer.
5. Inflate the catheter balloon using the syringe prepared before.
6. Gently pull back the applicator assembly until the balloon fits snugly in the opening of the bladder. The Applicator's final adjusted position should be maintained throughout the treatment. This can be achieved by fixing the Catheter with a Band-Aid.
7. On the Treatment screen, adjust the desired treatment temperature
8. On the front panel, turn the energy switch to the appropriate level; LOW or HIGH
9. Press the **Start** button to start the treatment



**Warning:** Only use the recommended amount of distilled or sterile water. Improper water will affect the microwave heating characteristics and present a risk of contamination should the balloon burst.

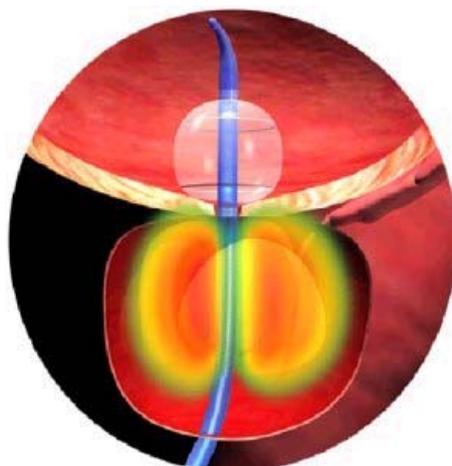


Figure 4-5: Balloon Placement



**Caution:** Make certain that during the insertion procedure, the position of the Thermal sensor and the Applicator remain unaffected.

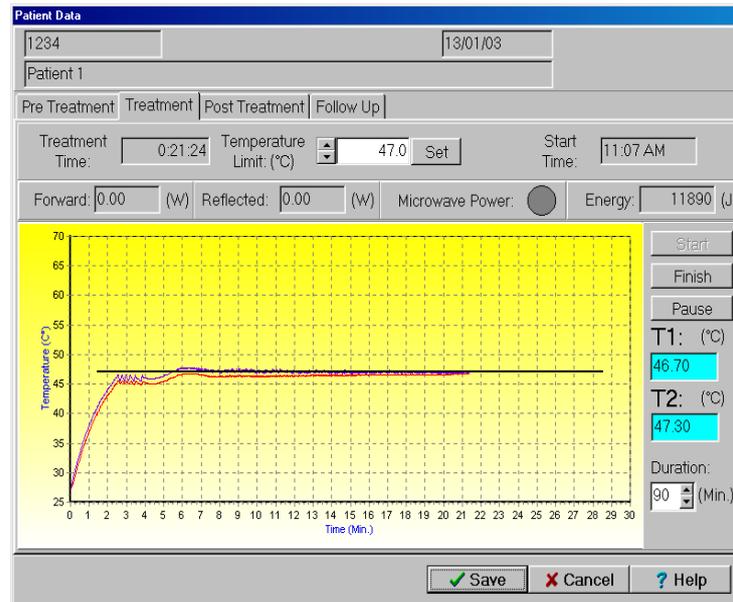


Figure 4-5: The Treatment Screen

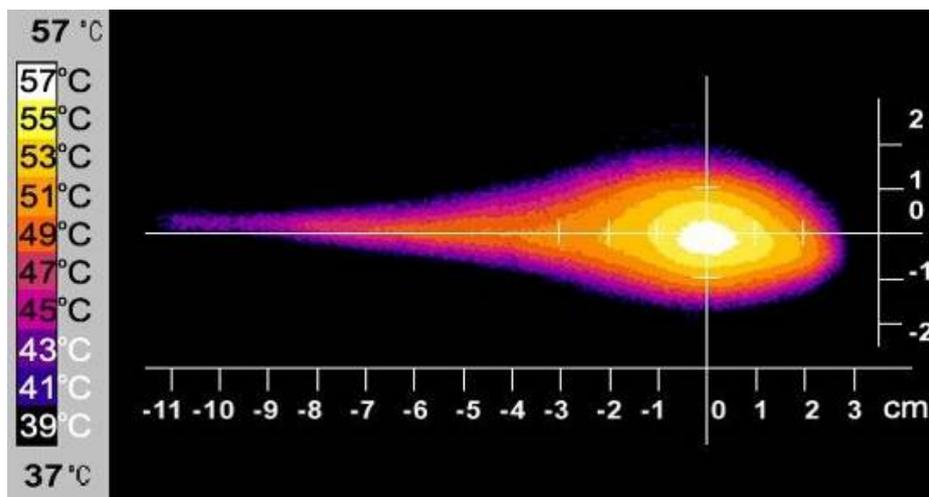


Figure 4-6: Heating Diagram

#### 4.7 Shut-Down Procedure

1. Press **Finish** switch.
2. Save treatment information.
3. Remove the applicator assembly and dispose of the Catheter.
4. Do not leave the catheter inside the patient's body after the treatment. In case there is a clinical need for an indwelling catheter use a designated catheter for this purpose.
5. **Exit** the program
6. Turn **OFF** the Thermaspec.

## 5 MAINTENANCE

### 5.1 Schedule

Preventative maintenance should be scheduled on regular basis the maintenance intervals which are listed below are intended to be used as a guide for maintenance scheduling.

#### Routine and Preventive maintenance

<b>A – ROUTINE MAINTENANCE</b> <i>Under the supervision of the Hospital</i>	<b>Period</b>	<b>Part number</b>
▪ Replace the Catheter	Each Treatment	▪ MW-3-E090
▪ Clean the Thermaspec Body	Monthly	

<b>B – PREVENTIVE MAINTENANCE:</b> <i>Under supervision of an authorized technician</i>	<b>Period</b>	<b>Part number</b>
• Check the Power Output	▪ 12 Months	▪ Wattmeter
• General inspection of Applicators and Cables	▪ 6 Months	
• Electrical Safety Test - Ground bond test - Check the Leakage current	▪ 6 Months	▪ Safety Test Analyzer

### 5.2 Operator Calibrations

The thermometry system should be checked for functionality before each session by checking that the display shows body temperature. If any or all of the probes are out of calibration, either replace the probe or refer to the service manual for complete procedures to calibrate the thermometer modules. Module calibration should be performed on a 12 month cycle or as required.

## 6 TROUBLESHOOTING

<b>FAILURE</b>	<b>CHECK</b>	<b>REPAIR ACTION</b>
1. Software is not booting up	<ul style="list-style-type: none"> <li>– Mains connection (failure)</li> <li>– Monitor connection (failure)</li> <li>– Non-system diskette left in drive</li> </ul>	<ul style="list-style-type: none"> <li>– Check cable, fuses, and outlet</li> <li>– Check electric and data cables</li> <li>– Remove diskette from drive and re-start</li> </ul>
2. After START, temperature remains low	<ul style="list-style-type: none"> <li>– Applicator connection (failure)</li> <li>– HIGH/LOW switch remains OFF</li> <li>– Microwave generator (failure)</li> </ul>	<ul style="list-style-type: none"> <li>– Check applicator connections</li> <li>– Switch to HIGH or LOW</li> <li>– Call for service</li> </ul>
3. Temperature readings are unstable	<ul style="list-style-type: none"> <li>– Thermal sensors mounted improperly</li> </ul>	<ul style="list-style-type: none"> <li>– Check thermal sensor installation</li> </ul>
4. Unusual reading deviation between the two temperature channels	<ul style="list-style-type: none"> <li>– Thermal sensor (failure)</li> </ul>	<ul style="list-style-type: none"> <li>– Check thermal sensor installation</li> </ul>
5. Temperature is increasing above the limit value	<ul style="list-style-type: none"> <li>– Temperature controller (failure)</li> </ul>	<ul style="list-style-type: none"> <li>– Call for service</li> </ul>
6. Mouse pointer freezes	<ul style="list-style-type: none"> <li>– Mouse connection (failure)</li> <li>– Mouse (failure)</li> </ul>	<ul style="list-style-type: none"> <li>– Check mouse connection</li> <li>– Replace mouse</li> </ul>
7. Keyboard error	<ul style="list-style-type: none"> <li>– Keyboard connection (failure)</li> <li>– Keyboard (failure)</li> </ul>	<ul style="list-style-type: none"> <li>– Check Keyboard connection</li> <li>– Replace Keyboard</li> </ul>

## 7 TECHNICAL SPECIFICATIONS

<b>Dimensions (basic cabinet)</b>	
Height	1185 mm (1072 mm for the mobile version)
Width	411 mm (459 mm for the mobile version)
Length	775 mm
Weight	85 kg
<b>Computer and software</b>	
Hard disk	250 GB SSD
Display	19" LCD monitor –1280 X 1024 pixels
<b>Microwave Unit</b>	
Output Power	Low: 20±2 Watt High: 40±3 Watt
Frequency	915 MHz
Output Impedance	50 ohms
Overload Protection	60 sec
Power Display	Directed and reflected power, by software
<b>Temperature Control</b>	
Sensors	2 type "T" Thermocouples (TC)
Range	25°C - 65°C
Selection	Software Selector 1°C
Display	Digital, by software – TC1 and TC2 Graphic, by software – TC1 and TC2
Treatment Time	Adjustable, by software – up to 90 minutes with elapsed time display
<b>Applicator Set</b>	
Catheter Type	Customized Foley catheter
Extension Cable	2.6 m
<b>Electrical Supply</b>	
Voltage (Volts AC)	230 V/3.15A or 115V/5A ± 10%
Line Frequency (Hz)	60/50
<b>Compliance with Standards</b>	
IEC 60601-1-2:2001	
IEC 60601-1:1988 +A1:1991 +A2:1995	
EN60601-1:1990 + A1:1993 +A2:1995 +A13:1996	
<b>Electrical classification</b>	
Electrical shock degree of protection	 Type B Applied Part
Electrical safety	Class I
<b>Environmental Conditions for Transport and Storage</b>	
Ambient temperature range, C°: 0 – 45	
Relative humidity range: 30% – 95%	
Atmospheric pressure range, hPa: 700 - 1060	

## **PRODUCT CONTACT INFORMATION**

If an adverse event occurs, such as a malfunctioning of the device, a mistake in using the device, or an injury relating to the use of the device, report the occurrence immediately. Alert the physician of any patient health issues that occur while using the Thermaspec™. For troubleshooting assistance, complaints or additional questions, contact the Service Department:

Medispec Ltd.

203 Perry Parkway, Suite 6

Gaithersburg, MD 20877

Tel: 301-944-1575

Toll Free: 1-888-663-3477

Fax: 301-972-6098

Email:

USA: [servicedept@medispec.com](mailto:servicedept@medispec.com)

Rest of world: [service-int@medispec.com](mailto:service-int@medispec.com)

Site: [www.medispec.com](http://www.medispec.com)