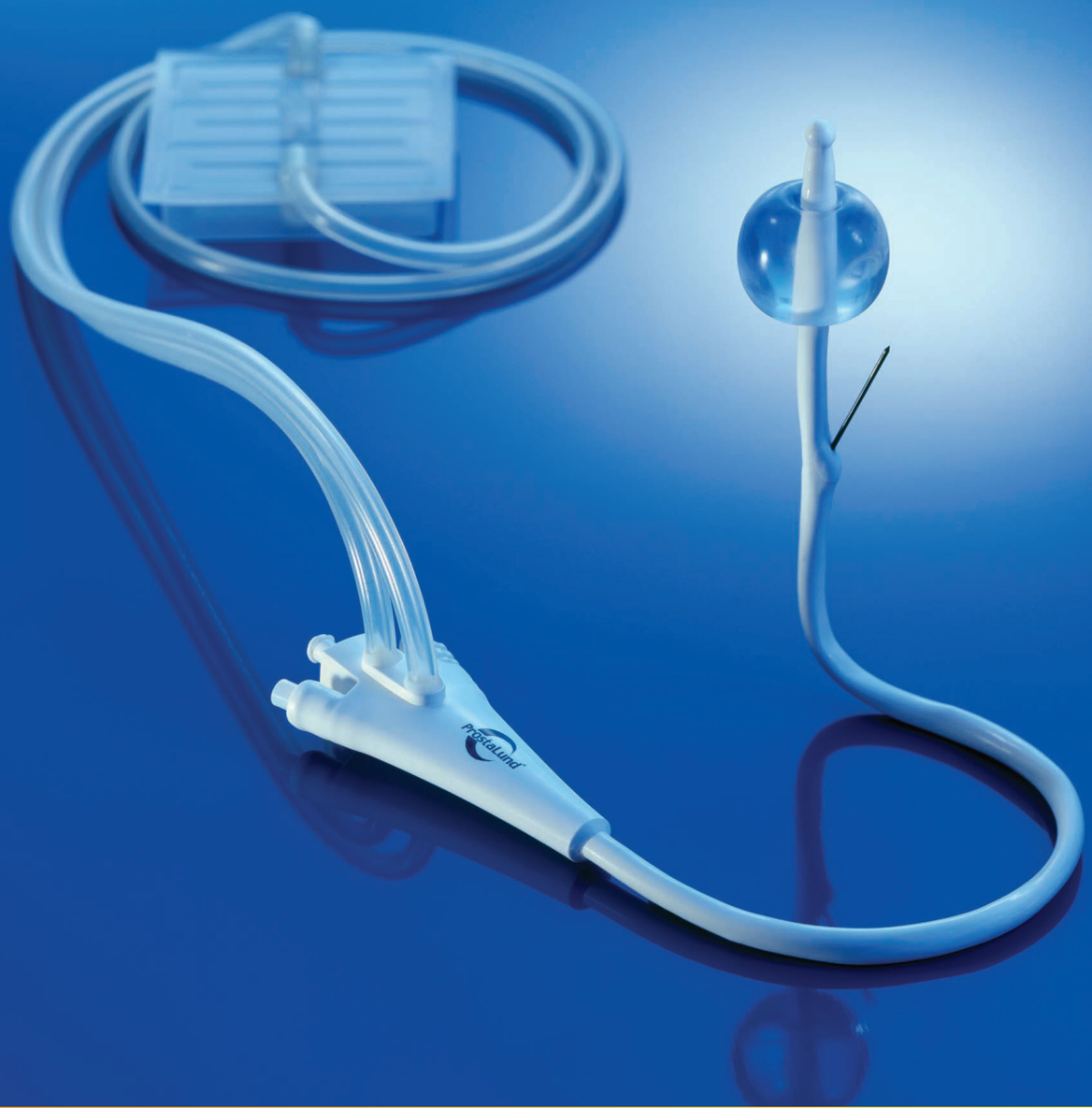
Instruction for use

CoreTherm® System



CoreTherm System
Specific text about CoreTherm® System.

CoreTherm SE System
Specific text about CoreTherm® SE System.

CoreTherm
EVIDENCE-BASED TREATMENT FOR BPH

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CORETHERM / SE SYSTEM

PREFACE

This manual contains information for both the CoreTherm System and the CoreTherm / SE System. If the information is applicable for both systems, it will be indicated with CoreTherm / SE System. If the information is specific for one of the systems, it will be indicated with CoreTherm System and CoreTherm SE System respectively as shown below.

CoreTherm System

Specific text about CoreTherm System.

CoreTherm SE System

Specific text about CoreTherm SE System.

Before using your CoreTherm / SE System, please read this manual in its entirety. The information here is crucial to the proper operation and maintenance of the equipment.

This manual is intended for trained medical personnel. It contains complete, step-by-step instructions on how to set up and use the CoreTherm / SE System for the treatment of benign prostatic hyperplasia (BPH) using microwave technology.

Operators of the CoreTherm / SE System must be familiar with the use of the Microsoft® Windows graphical user interface. CoreTherm Treatment has formerly been named ProstaLund Feedback Treatment (PLFT). This abbreviation may still occur in this manual.

Restrictions

The sale, distribution, and use of the CoreTherm / SE System is restricted to prescription use. The CoreTherm / SE System must only be used by qualified operators upon the prescription and under the supervision of a physician who is experienced in clinical thermotherapy treatment of the prostate. The CoreTherm / SE system is intended for use in a professional health care facility. Only original components and accessories should be used with the CoreTherm / SE System to ensure that the electromagnetic compatibility (EMC) emission and immunity of the equipment is within the accepted limits. See *chapter 35* for further information and warnings regarding electromagnetic phenomena.

Electrical Safety

Electrical Safety is handled in chapter 36 of this manual contains important information about electrical safety. You must always read this information before using the CoreTherm / SE System and follow the instructions.

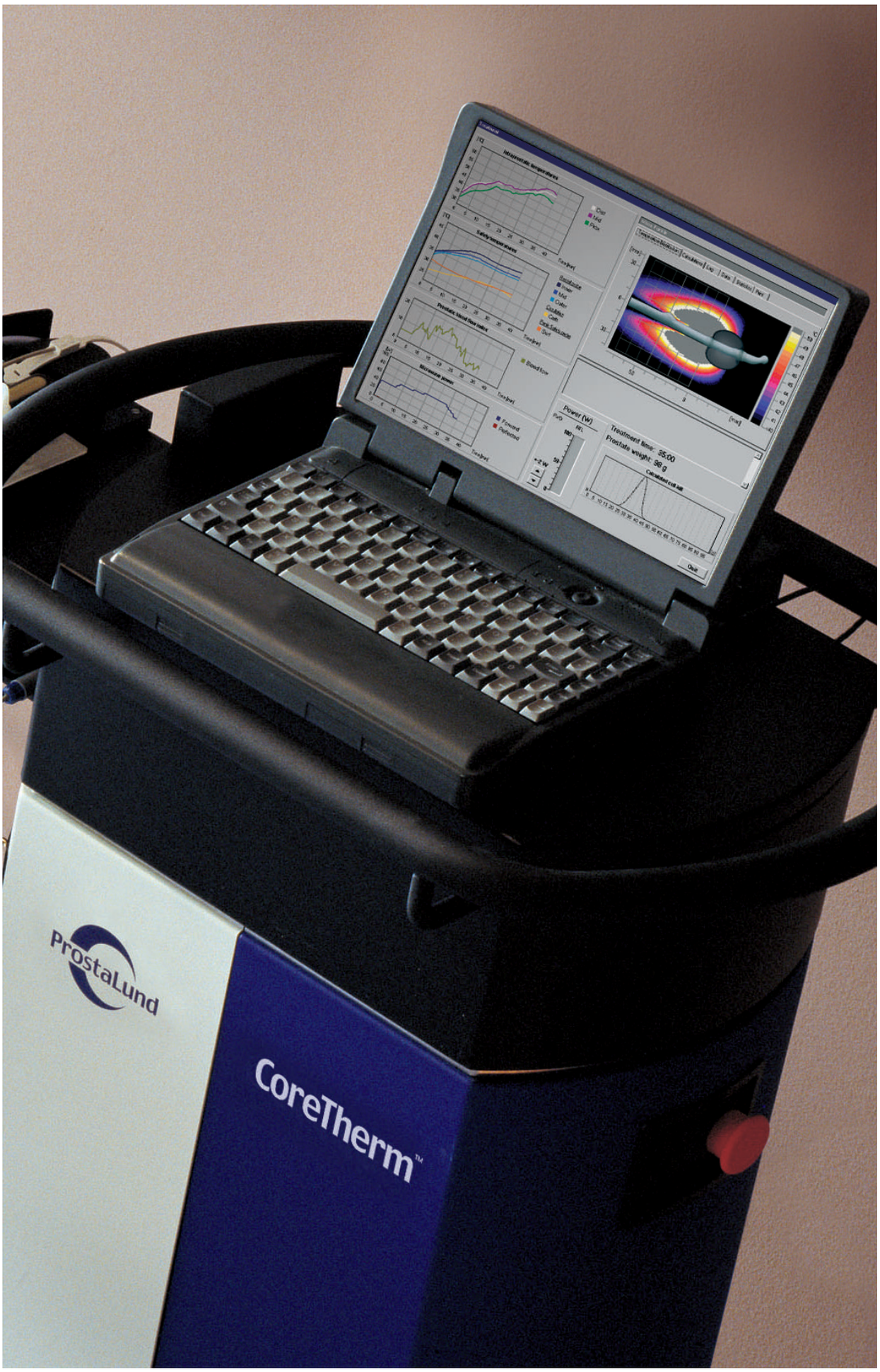
Definitions

Temperatures are reported in Centigrade (°C) Microwave power is reported in Watt (W). Antenna radiation pattern is given in specific absorption rate, SAR (W/kg). Microwave energy is reported as Kilojoule (kJ)

Cell kill is reported in grams of calculated dead tissue (g) or in percentage (%) of prostate weight.

Prostate size is reported in mm and in grams (g) Dimensions are given in millimeters (mm)

Last updated 03-2023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CoreTherm™

CONTENTS

1. DEVICE DESCRIPTION

1.1 Microwave Thermotherapy

The purpose of microwave thermotherapy is to use heat to coagulate and, with a certain degree of latency, remove tissue from the prostate in patients with symptomatic benign prostatic hyperplasia (BPH). The overall objective is to bring about a reduction in the tissue of the prostate nearest to the urethra and thereby reduce symptoms and increase the urinary stream. Thermotherapy aims at treating the tissue using temperatures between 50°C to 70°C.

Microwaves are electromagnetic radiation with an oscillating electric and magnetic field. Microwave thermotherapy uses a special transurethral catheter, with an antenna that radiates microwaves. Heat is produced when the microwaves are absorbed into the tissue, and is mainly the result of two processes:

- electric dipoles (e.g. water molecules), oscillating in the field
- electric carriers (e.g. ions), moving back and forth in the field.

The intraprostatic temperature during microwave treatment of BPH depends on three factors:

- heat generation through microwave absorption in the tissue - this is specific to the antenna in use
- heat diffusion due to heat conduction in the tissue - this depends on the composition of the tissue
- loss of heat due to blood flow - this depends on the intraprostatic blood flow.

1.2 CoreTherm Treatment

CoreTherm Treatment represents a way to use microwave thermotherapy by monitoring the actual intraprostatic temperature during treatment. The temperature is measured with a specially designed intraprostatic temperature probe. The probe contains four temperature sensors and protrudes in a 30° angle into the prostate tissue. The temperature probe, and the microwave antenna, is carried by a transurethral catheter during the treatment session.

During CoreTherm Treatment the intraprostatic temperature is measured and monitored at a computer screen. By using this feedback information, the medical operator can adjust the level of microwave power to achieve the required intraprostatic temperature (50°C to 70°C). Tissue necrosis and intraprostatic blood flow are also calculated and monitored as a further guide to the operator. The amount of tissue necrosis due to heat can be assessed by knowing the intraprostatic temperature and the period that the tissue is exposed to a certain temperature[1].

The treatment strategy is to reach the therapeutic temperature, above 50 °C for as many minutes that is required to kill 20 % of the tissue in the gland. By using the information about temperatures, calculated intraprostatic blood flow and tissue necrosis, the operator can adjust the microwave power to reduce the risk of over-treatment or under-treatment. Furthermore, by measuring the intraprostatic temperature at several places from the bladder neck down to the apex, the operator is provided with an early warning of excessively high temperatures. Thus, the risk of injury to the external sphincter is minimized. The prevalence of all complications, except for the repeated surgery, are substantially lower for the CoreTherm treatment compared to TURP.

2. INTENDED PURPOSE OF CORETHERM / SE SYSTEM

2.1 Intended use

The CoreTherm / SE system with accessories is intended for treatment of benign prostatic hyperplasia (BPH) using microwave thermotherapy by, or under the supervision of, a trained medical practitioner.

The objective is to coagulate the hypertrophic tissue by the heat produced when the microwaves are absorbed into the tissue.

3. INDICATIONS

The purpose of CoreTherm Treatment is to achieve coagulation necrosis (debulking) of epithelial as well as stromal hyperplasia

- Patients with diagnosed symptomatic benign prostatic hyperplasia (BPH)
- Prostate size ≥20 g and prostate length ≥25 mm

4. CONTRAINDICATIONS

- Urethral stricture
- Patient with penile or urinary sphincter implants
- Previous radiation of pelvic area.
- Prostate is less than 20 g in weight and/or less than 25 mm in length

[1] Bolmsjö M, Schelin S, Wagrell L, Larson T, de la Rosette JJ and Mattiasson A: Cell-kill modeling of microwave thermotherapy for treatment of benign prostatic hyperplasia. J Endourol. 14: 627-35, 2000.

5. PRECAUTIONS

The safety and effectiveness of CoreTherm Treatment has not been established in patients with:

- Active prostatitis
- Prostate cancer
- Urinary tract infections
- Significant median lobe or bladder neck sclerosis
- Previous prostate or rectal surgery
- Neurogenic LUTS disorder
- Interest in the preservation of fertility
- Implanted active pacemakers or defibrillators

6. SIDE EFFECTS

- **Increased PSA Levels**
  Prostate specific antigen (PSA) levels will increase significantly in the first three months after treatment. The results of PSA testing during this period are therefore unreliable.

7. ADVERSE EVENTS

- **Micturition Urge and frequency**
  Many patients will experience a mild to moderate micturition urge and frequency during, and for a period after, the treatment session.
- **Urinary Retention**
  In the early post-treatment period, urinary retention is common. Indwelling catheterization is therefore used for approximately 3-6 weeks. Three weeks after CoreTherm treatment, the tendency to retain urine can be expected to be low.
- **Urinary Tract Infection**
  This is a commonly reported adverse event following CoreTherm treatment due to the use of a urinary catheter.
- **Urethral disorder**
  This is a well-known adverse event following the use of a urinary catheter and has been reported in a low frequency following CoreTherm treatment.
- **Bladder calculus**
  Bladder calculus has been reported in a low frequency following the CoreTherm treatment
- **Hematuria**
  Mild hematuria within 24 hours after completion of CoreTherm treatment is seen in many patients. In the post-treatment period, there is a low frequency of hematuria following CoreTherm treatment.
- **Retrograde and/or Dry Ejaculation**
  These events have been reported following CoreTherm treatment.
- **Sexual Dysfunction**
  This event is reported in a low frequency following CoreTherm treatment.
- **Transient Urinary Incontinence**
  Occasionally, mild to moderate incontinence may occur during the first weeks following CoreTherm treatment.
- **Prostatic disorder**
  Prostatic disorder has been reported in a low frequency following the CoreTherm treatment.
- **Epididymitis**
  Epididymitis has been reported in a low frequency following the CoreTherm treatment.

8. WARNINGS

Warning notices alert you the risk of physical injury. Following instructions must be followed to ensure the safety of the patient and operator.

8.1 Patient

- **Patient Injury**
  The use of damaged equipment may injure the patient. When preparing the patient for treatment, always check the intraprostatic temperature probe, the rectal temperature probe, the penis safety probe and the microwave antenna for cracks or any sign of physical damage. Exchange any item of damaged equipment for a fully operational, undamaged item before initiating the treatment.
- **Over sedation of patient**
  Do not over sedate the patient. His perception of pain is an important safety mechanism to ensure that excessive heat is not applied to the tissue. Do not administer a general or spinal anaesthetic.

8.2 Accessories

- **Improper Insertion of the CoreTherm Catheter**
  Exercise extreme care when inserting the CoreTherm catheter into the patient's urethra, otherwise perforation and subsequent infection of the urethra may result If the CoreTherm catheter is incorrectly placed or moves during treatment, or if the antenna comes loose, the patient's external sphincter may overheat, causing temporary or chronic incontinence. Use transrectal ultrasound (TRUS) to verify that the CoreTherm catheter is correctly positioned and check the position of the catheter regularly during the treatment to ensure that it has not moved. To further reduce the risk of external sphincter injury, the CoreTherm catheter has a narrow focus which concentrates the heat to a region close to the neck of

the bladder and continuing downwards towards the apex of the prostate.

- **Overheating of the Prostate Tissue**
  To avoid the risk of burn injuries to the bulbar urethra or the external sphincter, the temperature of the CoreTherm catheter is measured by a sensor placed close to the position of the external sphincter, i.e. approximately midway between the penis and the prostate. Microwave power is shut down if this temperature exceeds 42°C. High temperatures in the CoreTherm catheter may be caused by excessive power loss in the coaxial cable of the microwave antenna, or if the water circulating through the catheter is drained through leakage.

- **Overheating of the CoreTherm Catheter**
  The CoreTherm catheter can overheat if the temperature of the circulating water exceeds the preset safety limit of 42°C. The temperature of the circulating water is measured by a sensor in the intraprostatic temperature probe and microwave power is shut off automatically if the temperature exceeds 40°C. Monitor the temperature of the circulation water regularly throughout the treatment. The circulating water may leak if the CoreTherm catheter malfunctions or is damaged, and this may cause the urethra or external sphincter to overheat. The automatic power shut off prevents excessive CoreTherm catheter temperatures. Use only sterile water in the water reservoir. Do not use a saline liquid because it absorbs microwaves and could cause the CoreTherm catheter to overheat.

- **Excessive Temperature at the Penoscrotal Angle**
  To avoid the risk of burn injuries to the penis or urethra if the CoreTherm catheter moves during treatment or if the penile temperature exceeds the safety limit of 40°C, the penis safety probe shuts off the microwave power if the temperature exceeds preset limits. You must regularly monitor the penile temperature and check the position of the catheter throughout the treatment. An elevated temperature registered by the penis safety probe may indicate that the catheter/microwave antenna is not correctly positioned. In this event you must immediately check the position of the catheter/microwave antenna and the circulation system.

- **Reuse of the CoreTherm Catheter**
  The CoreTherm catheter is intended for single use only, otherwise cross-patient urinary infection could result. Each CoreTherm catheter has a unique catheter number, and the software includes a lock which prevents reuse of a catheter. Do not attempt to use a CoreTherm catheter for more than one treatment session.

- **Probe Calibration**
  The accurate measurement of temperatures is crucial to the performance of safe and efficient CoreTherm Treatments. Not calibrated or incorrectly calibrated temperature probes will result in erroneous temperature readings that may jeopardize the safety of the patient and cause permanent injury. It is therefore important that the manufacturer's probe calibration instructions given in this handbook are strictly observed, see chapter 29 MAINTENANCE OF THE PROBES.

- **Incorrect Positioning of the Intraprostatic Temperature Probe**
  If the intraprostatic temperature probe is incorrectly positioned in the patient's prostate, the temperature feedback may be inaccurate. This could result in the application of insufficient or excessive heat to the prostate. Ensure that the intraprostatic temperature probe is correctly positioned. If necessary, use transrectal ultrasound (TRUS) to verify that the probe is correctly positioned.

- **Insufficient retraction of the intraprostatic temperature probe**
  Insufficient retraction of the intraprostatic temperature probe before the catheter is removed may cause patient injuries. It is therefore important to retract the intraprostatic temperature probe at least 50 mm before the CoreTherm catheter is removed.

- **Cleaning Agents**
  The use of cleaning agents other than those stipulated in the cleaning instructions may be harmful to the patient or cause damage to the equipment and must not be used.

- **Insufficient Cleaning/Sterilization**
  Ensure that all temperature probes and the microwave antenna are properly cleaned, disinfected and, in the case of the intraprostatic temperature probe, sterilized before use in accordance with the instructions given in this handbook, otherwise infection may result.

- **Excessive Rectal Temperature**
  To avoid the risk of fistulas, the rectal temperature should not exceed 43°C during treatment. The rectal temperature probe shuts off the microwave power if the temperature exceeds pre- set limits. You must monitor the rectal temperature and check the position of the probe regularly throughout the treatment.

- **Balloon rupture**
  Please make sure to check the balloon with 20 ml of air before inserting it into the patient. While inside the patient's bladder, inject 20 ml of sterile water slowly in order to prevent rupture of the balloon. Balloon rupture could lead to sliding of the catheter downwards and cause damage on the external sphincter and the urethra.

- **Use of Saline Solution**
  Do not use Saline solution when filling the balloon and water reservoir as this may result in increased temperatures due to interaction between the microwaves and the ions.

8.3 CoreTherm device

- **Danger of microwave radiation**
  Microwave power must not be emitted under any circumstances when the CoreTherm catheter and/or the microwave antenna are not correctly positioned within the body, as this may cause injuries to the patient and/or the operator.
- **Danger of Electrical Shock**
  Do not connect a printer or other external electrical equipment to the CoreTherm / SE System during treatment, as this may compromise the electrical insulation of the patient from the mains electrical supply. A printer or other external equipment must be connected only when the laptop is disconnected from the CoreTherm / SE System and placed on a desk.
- **Lethal Voltages**
  Lethal voltages are present in this equipment when it is connected to the mains electrical supply. Disconnect the equipment from the mains electrical supply before removing the covers or attempting any service or repair activity, otherwise death or personal injury may result.
- **Risk of Explosion**
  The CoreTherm / SE System is not designed for use in potentially explosive environments. It must not be operated in the presence of flammable liquids or gases.
- **Incompatible Equipment and Software Programs**

  1. The CoreTherm / SE System may malfunction if transmitting devices such as mobile telephones or two-way radios are used near to the equipment.
  2. Do not install any other software on to the computer as this may cause the CoreTherm / SE System to malfunction.
  3. The computer is configured for use with CoreTherm software only. Do not attempt to run other applications. Any action that results in the treatment window being completely or partly covered by another window will stop the treatment.
  4. Do not adjust or replace the operating system of the computer as this may impair the correct functioning of the unit. All setup and configu- ration of the software must be per- formed by authorized service personnel.

- **Hot Surfaces**
  The surfaces of the calibration oven in the pull-out drawer of the CoreTherm SE control unit are hot. The temperature probes are also hot during and after calibration. Do not touch the hot surfaces of the probes or the calibration oven. Exercise caution when calibrating the temperature probes otherwise burn injuries may result. Do not insert your fingers into the oven.
- **Injury to Operator**
  There is a risk of trapping the fingers when opening and closing the pull-out drawer of the CoreTherm / SE control unit. Exercise caution when operating the drawer, otherwise injury to the operator may result.
- **Overturning the Control Unit**
  When positioning the the CoreTherm Control Unit, make sure there are no inclination on the floor. Otherwise the unit may overturn and injure medical staff or the patient.

9. CAUTION NOTICES

Caution notices indicate a hazard to the equipment. The nature of the hazard and the means by which it can be avoided are stated below.

- **Loss of Data**
  If the unit is switched off while the program is accessing the hard drive, data may be lost or corrupted. To prevent loss or corruption of data, always quit the program prior to turning off the unit.
- **Liquid Ingress**
  Damage may result if liquid can enter the equipment through accidental spillage or careless cleaning. The laptop is particularly sensitive to liquid ingress.
- **Damage to Connectors**
  Do not attempt to close the pull-out drawer of the CoreTherm / SE control unit while any of the probes or the microwave antenna are still connected to the control unit. Otherwise it may result in a damage to the connectors.

10. DIRECTIONS FOR USE

10.1 Investigations before CoreTherm Treatment

The standard investigations for BPH, to be conducted prior to CoreTherm Treatment are:

- patient history
- rectal palpation
- symptom score (including bother score)
- micturition list
- physical investigation
- flow measurement or time for first dl
- residual urine analyses
- urinalysis, including hematuria and bacteriuria tests
- S-creatinine
- prostate specific antigen (PSA), at least for patients under 70 years of age
- transrectal ultrasound (TRUS) for prostate volume measurement

Optional Investigations

- urodynamics
- urethra-cystoscopy

11. ABOUT THE CORETHERM / SE SYSTEM

The CoreTherm / SE System is a portable unit equipped with all the components necessary to perform CoreTherm Treatment. It includes a laptop computer with software designed to monitor treatments, and to assist with treatment planning. The main components of the CoreTherm / SE System are:

1. Control unit

2. Treatment accessories

3. Safety probes

4. CoreTherm software

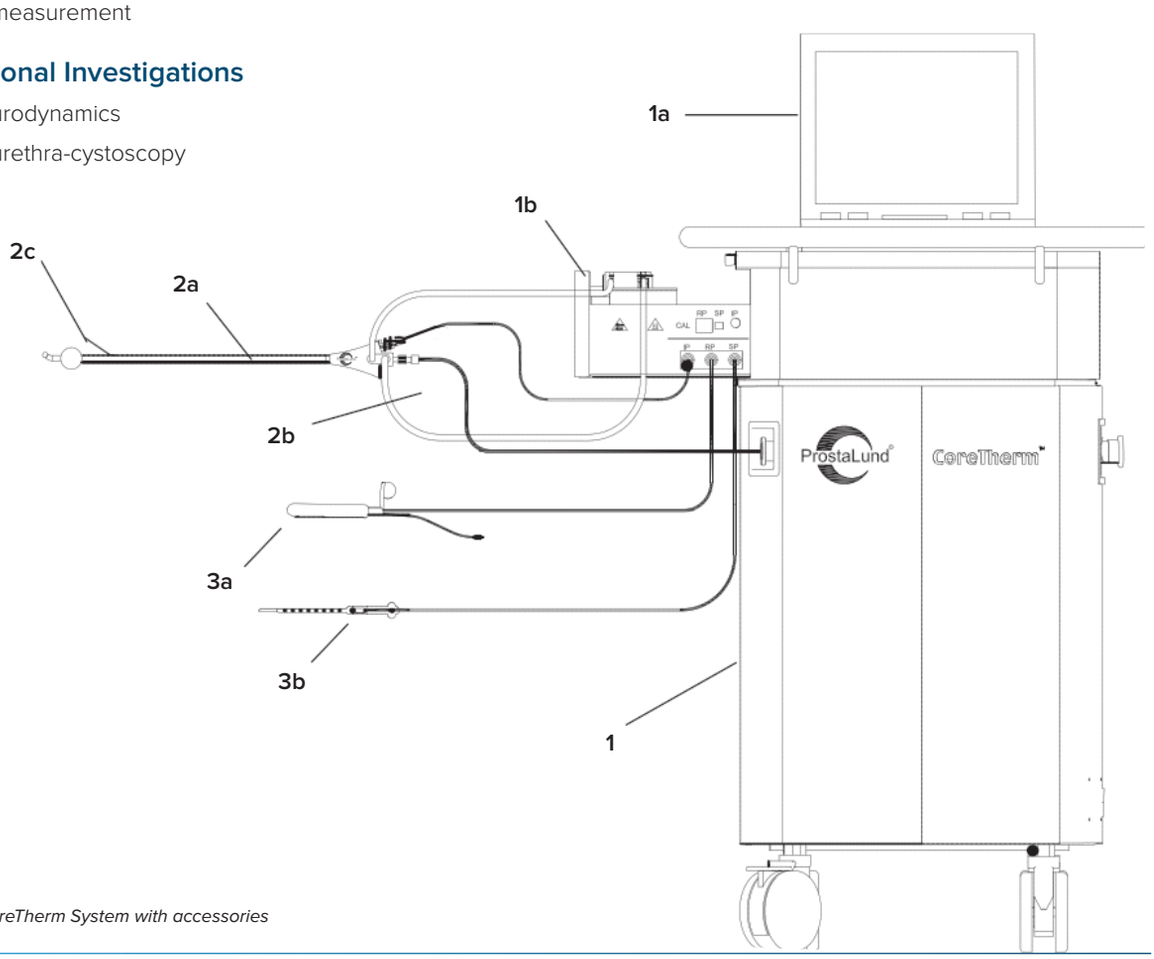


Figure. CoreTherm System with accessories

1. Control Unit

a) Computer (Laptop)

b) Pull Out Drawer

2. Treatment Accessories

a) CoreTherm Catheter

b) Microwave Antenna

c) Intraprostatic Temperature Probe

3. Safety probes

a) Rectal Temperature Probe

b) Penis Safety Probe

1. Control Unit

The control unit (1) houses the microwave generator, control electronics, calibration oven and the antenna circulation system.
It has four wheels and a handle for ease of transportation. The two front wheels have integrated brakes that can be set/ released by the operator. The unit requires an external mains electrical supply only and does not need a dedicated treatment area.

1a) Computer (Laptop)

The computer (1a) is used to monitor the CoreTherm Treatment and runs under the Windows XP operating system. It is a laptop computer which is placed on the top of the control unit during treatment. The computer must be removed from the control unit if a printer is to be connected.

1b) Pull-Out Drawer

The pull-out drawer (1b) on the left side of the CoreTherm / SE System is part of the control unit. It contains the heat exchange plate, the water pump, the connections for the temperature probes, and the calibration oven.

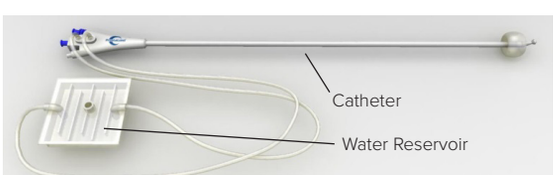
2. Treatment accessories

There are two sets of CoreTherm catheter, Antenna and Intraprostatic probes:

- Standard accessories coloured blue
Set for treating prostate sizes >30 g and a prostate length ≥35 mm

- Short accessories coloured yellow for small prostates
Set for treating prostate sizes >20 g and <50 g and a prostate length ≥25 mm

2a) CoreTherm Catheter



The CoreTherm catheter´s (2a) is a single use device that has separate channels for the Microwave Antenna, the Intraprostatic temperature Probe, the water inlet and outlet and for inflating the balloon to be used with CoreTherm / SE System.

The CoreTherm catheter is fitted with a balloon close to its tip. The balloon resides inside the patient's bladder and is inflated to keep the catheter anchored at the neck of the bladder during treatment.

The purpose of the CoreTherm catheter is to house the Microwave Antenna and the Intraprostatic temperature Probe. During the treatment the Antenna cable is temperate by water passing through the CoreTherm catheter. The catheter, the water tubes and the water reservoir are permanently connected together and must not be separated. The CoreTherm catheter is supplied in a sealed and sterile package with a unique catheter number.

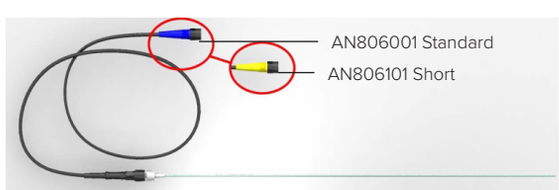
The connectors are color coded blue for standard accessories and yellow for accessories for small prostates.

CA804220 Standard CA804120 Short

2b) Microwave Antenna

The Microwave Antenna (2b) directs the microwave radiation into the prostate tissue. It has a Luer fitting with an integrated locking nut that secures the antenna to the CoreTherm catheter. The Antenna is inserted into the catheter before the catheter is introduced into the patient's urethra.

The connector of the microwave antenna to the PLC unit is color coded blue for standard accessories and yellow for accessories for small prostates.



The microwave antenna is reusable. Recommended reuse life is 10 times.

2c) Intraprostatic Temperature Probe

The Intraprostatic temperature Probe (2c) records the internal prostate temperature during treatment. The intraprostatic temperature probe is a plastic tube containing temperature sensors. The tube has a Luer fitting with an integrated locking nut that secures the probe to the CoreTherm catheter.

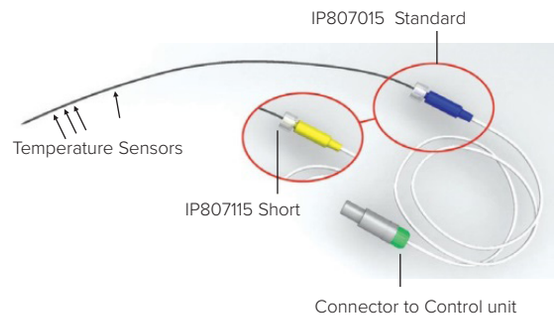
Three temperature sensors are located at the tip of the probe. A fourth sensor, further down from the tip, measures the temperature of the water circulating in the catheter. The intraprostatic temperature probe has a color coded (green) control unit connector. The connector has a hardware key that prevents the incorrect attachment of the probe to the control unit.

An electronic chip located in the connector contains a unique serial number that identifies the specific temperature probe in use.

CoreTherm System

CoreTherm System is not able to read the serial number automatically

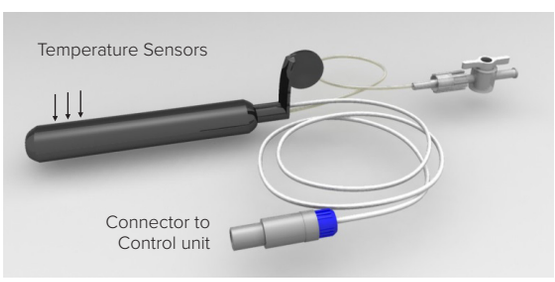
The connector to the Intraprostatic temperature probe is color coded blue for standard accessories and yellow for accessories for small prostates.



Maximum reuse life of the intraprostatic temperature probe is 10 times.

3. Safety probes

3a) Rectal Temperature Probe



The rectal temperature probe (3a) records the temperature in the patient's rectum during treatment.

The rectal temperature probe contains three temperature sensors on the anterior side and is fitted with a balloon on the posterior side. The sensors are located at the tip on the anterior side of the probe.

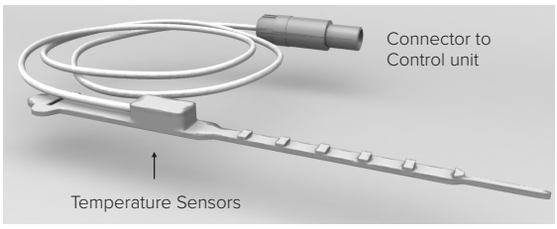
The rectal temperature probe has a color coded (blue) control unit connector. The connector has a hardware key that prevents the incorrect attachment of the probe to the control unit.

An electronic chip in the connector contains a unique serial number to identify the specific rectal temperature probe in use for the software.

The balloon can be inflated with 0 to 5 ml of air during treatment, to keep the rectal temperature probe in place. But this is not usually necessary and is not recommended as a general procedure.

Recommended reuse life of the rectal temperature probe is 10 times.

3b) Penis Safety Probe



The penis safety probe (3b) records the temperature at the base of the penis during treatment. The penis safety probe contains a temperature sensor and an electronic chip. The electronic chip contains a unique serial number to identify the specific penis safety probe in use for the software. The probe has a color coded (grey) control unit connector with a hardware key that prevents the incorrect attachment of the probe to the control unit.

Recommended reuse life of the penis safety probe is 10 times.

4. CoreTherm Software

The functions provided by the CoreTherm / SE System are accessed from software running under the Microsoft® Windows XP operating system on the laptop computer. The software provides the user interface and is used to enter treatment related parameters and settings. In addition, during the treatment, the software monitors various parameters such as temperatures and microwave power.

The software provides several integrated functions:

- a login function to prevent unauthorized use
- a patient records database
- an International Prostate Symptom Score (IPSS) questionnaire
- a function to run and record treatments and view the details of previous treatments
- tools with calibration functions, backup functions and user profile handling.

12. PREPARING FOR TREATMENT

This chapter describes the procedures to be performed before a CoreTherm Treatment session commences. In addition to the CoreTherm / SE System, you will need an ultrasound scanner to check the positions of the catheter prior to and during treatment.

12.1 Pre-operative Preparation of the Patient

Informing the patient

Prior to treatment the presiding physician should ensure that the patient has received adequate information about CoreTherm Treatment. It is important for the patient to be given the following information in particular:

- the risks and benefits of the treatment
- how the treatment is to be performed
- the likely duration of the procedure
- the normal level of pain or discomfort that he should expect to experience
- the importance of communicating any unusual pain during treatment
- the need to remain as still as possible during the treatment.
- Questions about any serious patient health circumstances. Any new health events? Any new medications, intolerance or allergy?

During treatment

- During the treatment the patient may experience an uncomfortable sensation of heat and a moderate or strong urge to urinate. However, the urge to urinate is “false” because the urinary bladder is just emptied. Ordinarily the urge discomfort is annoying but not exactly painful and will decrease as soon as the treatment is finished. It is important to clearly inform the patient of these symptoms before treatment commences.

After treatment

- The patient should also be informed that he will be catheterized after treatment, usually 3-6 weeks, and that this will cause a relatively high degree of discomfort, particularly in the first 24 hours.
- Advise the patient that the urge to urinate may occur after the catheter has been removed, and that ordinarily the urge will disappear within a month.
- It is also quite common for tissue sloughing outside the catheter to occur during the weeks after treatment and in some cases to be discharged with the urine in the form of small pieces of dead tissue after catheter removal.
- It is also usual for a small amount of hematuria to occur after the treatment.
- Encourage the patient to tell you if the discomfort becomes painful.
- It is highly advantageous to administer prophylactic medication before treatment to prevent eventual discomfort. While the whole treatment last less than 15 minutes and eventual discomfort is anticipated just for a few minutes in the end of treatment “on demand” medication like pain killer or sedatives have too short time to functionate.
- During the catheter period, lasting 3-6 weeks after treatment, encourage the patient to seek medical attention if he experiences catheter difficulties when emptying his bladder, develops a fever or shows signs of urinary tract infection.
- After the catheter has been removed you should instruct the patient to seek immediate medical attention on difficulties to urinate or urinary retention occurs. You should also instruct the patient to without delay go to the hospital if high fever or general symptoms suggesting an eventual urosepsis are suspected.

12.2 Pre-medication

There are no specific restrictions about eating or drinking before treatment while the patient is fully awake and capable during the less than 15 minutes procedure. For the patient’s own convenience, a heavy meal within a few hours before treatment should be avoided. Not mandatory, but if possible, the patient is advised to empty his bowel before treatment commences.

Premedication should be given at least two hours before starting treatment. It is recommended that antibiotics, analgesics, muscarinic receptor inhibitors and anti-inflammatory drugs be administered, if there are no contraindications, before starting treatment.

For intraprostatic injection of local anaesthesia and adrenaline Schelin Catheter (Art No SK812100) is recommended, see detailed instructions in Schelin Catheter IFU L-2015-021.

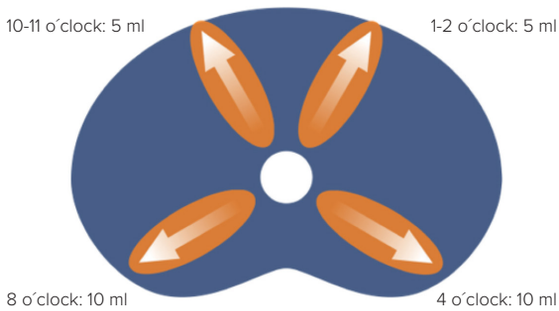
1. Schelin Catheter is a sterile single use device and shall be handled aseptic and make sure that the packaging is not damaged.
2. Visually inspect the Schelin Catheter for any damage. In particular, check that there is no balloon leakage by filling the catheter with 20ml of air by use of a medical syringe with luer lock connection. Deflate the balloon before moving on to next step.
3. Check that the opening for the injection needle should be located on the line along the shaft. Make sure that the line is not rotated.
4. Disinfect the genitalia.
5. Administer a local anesthetic gel into the urethra.
6. Insert the Schelin catheter into the urethra with the angeled tip facing forward. The entire length of the catheter should be inserted, in the same way as a regular catheter. Connect a catheter bag to empty the bladder.

7. Once you are sure that the catheter is positioned in the bladder, fill the balloon with 20 ml of sterile water from a sterile syringe.
8. Slide the catheter in and out a few times with the balloon filled to confirm that the catheter balloon is freely movable in the bladder and to prevent the catheter from being twisted inside the patient's urethra.
9. Administer intraprostatic injections of anaesthesia in all 4 quadrants at 1-2, 4, 8 and 10-11 o'clock, see Figure. Fully inserted in the deep position (45 mm), the needle tip meets the base area of the prostate, regardless of the prostate size. The majority of the blood flow enters and leaves the prostate in this area.
10. Rotate the catheter into desired angle for injection. This is done by carefully pushing the catheter forward, rotating it and gently stretching it. It may be necessary to push the catheter back and forth a couple of times to guarantee that the catheter shaft is not twisted inside the patient´s urethra. When the disired rotational angel has been obtained carefully stretch the catheter so the balloon rests against the bladder neck.
11. The patient will only experience a sting when the needle is inserted directly into its deep position. When the needle is then withdrawn and additional local anaesthetic is injected, the patient will not feel anything.

    NOTE: Heart palpitations may occur while the adrenaline injections are being administered. If the heart rate seems to increase during injection, pause the injection. A changed needle position and preceding aspiration should be administered before the injection continues. The pulse will generally reverse within 1 minute if the injection is paused.

12. Before each injection: aspirate and check that the fluid is not bloody. If blood is present, reposition the needle and aspirate again. When no blood is present, it is fine to start injecting local anaesthesia into the prostate according to the schedule.
13. When the anaesthetic / adrenaline is injected according to plan, the needle is withdrawn into the catheter and the balloon is emptied according to the instructions for use L-2015-021 and the Schelin catheter can be removed.
14. Before inserting the CoreTherm catheter, administer another dose of local anesthetic gel into the urethra.

Figure with intraprostatic injections.



13. PREPARING THE CORETHERM / SE SYSTEM

13.1 Positioning the Control Unit

1. Place the CoreTherm / SE control unit in close proximity to the treatment table, at a position where all probes and connectors can easily reach between the control unit and the patient, and where the control unit can be connected to the nearest, convenient, mains electrical supply.
2. Lock the wheels of the control unit so that it is immobilized.
3. Connect the CoreTherm / SE unit to the nearest, convenient, mains electrical socket

13.2 Switching the CoreTherm / SE System on

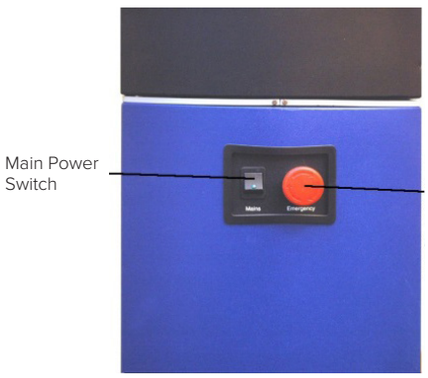
1 Ensure that the laptop computer is properly placed on top of the control unit and correctly connected to the control unit of the CoreTherm / SE Systems.

NOTE: The laptop computer must be connected to the docking station or the internal power supply cable of the control unit.

2. Press the main power switch on the right side of the CoreTherm SE control unit.
3. Switch on the computer by pressing the On/ Off switch. Once the computer has started the CoreTherm software will be automatically launched.

NOTE: In an emergency, press the Emergency Stop button on the control unit to disconnect the entire system from the mains electrical supply. To release the Emergency Stop, rotate the button.

14. PREPARING THE PATIENT FOR TREATMENT



This section gives instructions for preparing the treatment area and the clinical equipment prior to a CoreTherm Treatment session. You should have an assistant to help with these procedures.

1. Spread a sterile cloth on the treatment table.
2. Make sure you have the correct accessory set.

14.1 Preparing the Accessories

CoreTherm Catheter

CoreTherm catheter is supplied in a sterile packaging and is a single use device.

1. Have your assistant offer the sealed, sterile package containing the CoreTherm catheter. Check that the package is undamaged. If its sterility is compromised in any way, discard the package and continue the session with a new, sterile CoreTherm catheter.
2. Handle the CoreTherm catheter using aseptic technique. Remove the catheter from its packaging and note the catheter number.

   NOTE: Later in the procedure you must enter the catheter number in the Treatment Settings Page.

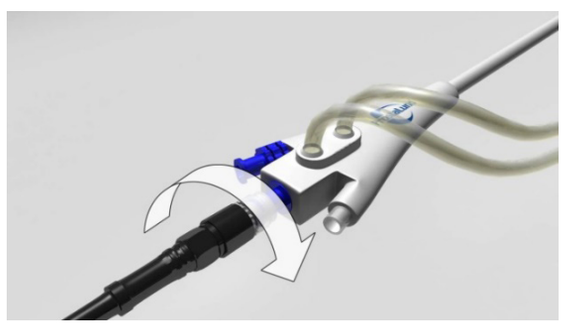
3. Examine the CoreTherm catheter. In particular, check the balloon for leakage by inflating it with 20 ml of air. If there is any sign of damage, discard the CoreTherm catheter and continue the session with a new, sterile catheter. When the catheter tip is directed upwards, the outlet for the intraprostatic temperature probe shall be in the 1 o'clock position.

Microwave Antenna and Safety probes

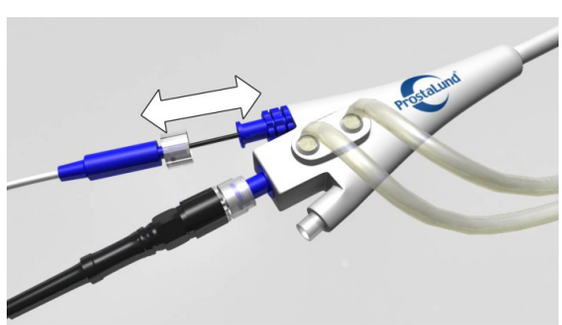
The Microwave Antenna, Rectal probe and Penis safety probe are supplied in a not sterile packaging and can be used more than once when disinfected. See chapter 28 Disinfection instruction.

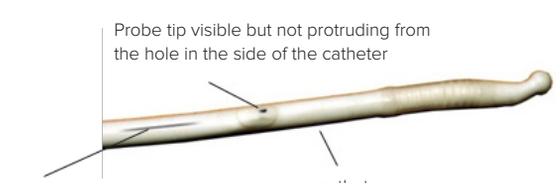
The Intraprostatic temperature probe is supplied in a not sterile packaging and must be sterilized before use, see chapter 28.3 Sterilization.

1. Inspect the Intraprostatic temperature probe, the Rectal temperature probe, the Penis safety probe and the Microwave antenna for cracks or any sign of physical damage. Exchange any item of damaged equipment for a fully operational, undamaged item before continuing the treatment.
2. Insert the disinfected Microwave antenna into the CoreTherm catheter and secure the antenna by turning the locking nut in the clockwise direction. Do not lubricate the antenna.



3. Insert the sterile intraprostatic temperature probe fully into the CoreTherm catheter, and then withdraw the probe so that its tip is visible but not protruding from the catheter. Do not secure the probe to the CoreTherm catheter yet.





Intraprostatic temperature probe inserted into the catheter

4. Fill the circulation system with 75 ml of sterile water. Check the position of the catheter regularly during the treatment by pulling it softly, in order to make sure that the catheter has not migrated.

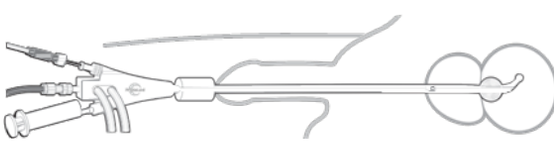
5. Adminster local anasthetic gel into urethra and introduce the CoreTherm catheter into the urethra, with the tip of the catheter all the way into the bladder in a similar manner to the insertion of a standard catheter.

   NOTE: It is important that the tip of the catheter is directed upwards when the catheter is in the bladder. This will ensure that the intraprostatic temperature probe is inserted correctly into the left lobe of the prostate.

6. When the CoreTherm catheter is fully inserted, fill the balloon slowly with 20ml of sterile water from a sterile syringe. Then it is important to check if the balloon is freely movable inside the bladder. Normally the balloon is filled with 20ml of sterile water. If the patient had a former TURP or TUMT, a special work up must be done. Urodynamic examination to verify obstruction and a cystoscopy to examine the bladder neck to exclude an open cavity in the bladder neck must be done. If a treatment is decided the treatment catheter balloon is filled with 30 – 40ml of sterile water and its correct position is always verified by TRUS before treatment start.

   NOTE: Do not use saline.

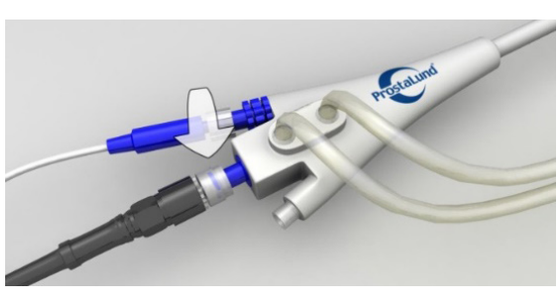
7. Gently withdraw the CoreTherm catheter until the balloon meets the bladder neck and is thus secured in place.



8. Hold the CoreTherm catheter to straighten it and insert the intraprostatic temperature probe into the prostate. Advise the patient that he may experience a slight pricking sensation.

9. Check the position of the catheter regularly during the treatment by pulling it softly, in order to make sure that the catheter has not migrated.

10. When fully inserted, secure the intraprostatic temperature probe to the CoreTherm catheter by turning the lock nut of the probe connector in the clockwise direction.



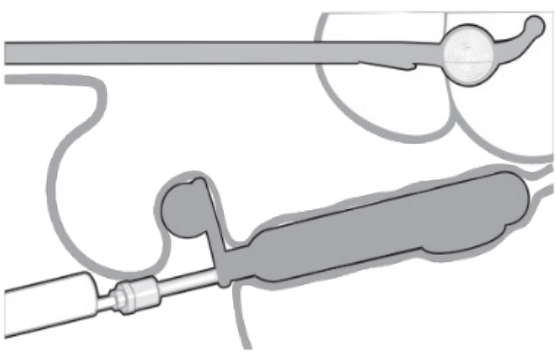
11. Verify the position of the CoreTherm catheter (balloon) and the intraprostatic temperature probe by performing an ultrasound examination.

Insertion of Rectal probe

1. Position the patient to receive the Rectal temperature probe. The patient can remain in the supine position with one leg drawn up or lie on his left side. Have a rolled-up towel available to stabilize the rectal probe.

2. Cover the Rectal temperature probe with a condom and apply a lubricant gel to the outer surface of the condom. Then, with the handle of the probe pointing vertically upward, carefully introduce the probe into the rectum.

   NOTE: Do not apply gel to the inside of the condom.

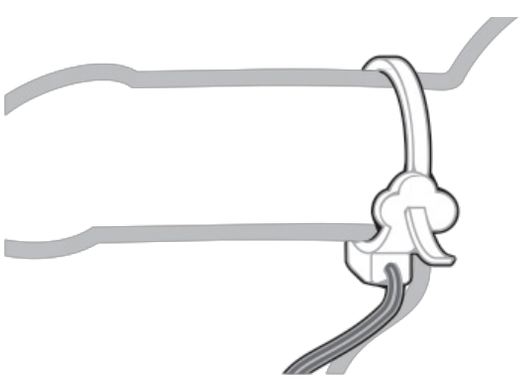


3. Place the rolled-up hand towel under the patient to prevent ejection of the rectal temperature probe when the patient is laid flat.

   NOTE: The balloon of the rectal temperature probe can be filled with up to 5 ml of air. However, this is not usually necessary and is not recommended as a general procedure.

Attachment of Penis Safety probe

Place the penis safety probe around the base of the penis, with the temperature sensor against the urethra and at the penoscrotal angle beneath the penis. Fasten the strap and ensure that it is properly connected.



Check of positioning of all accessories

1. After the CoreTherm catheter and all the temperature probes have been properly positioned, confirm that the Microwave antenna is still securely connected to the CoreTherm catheter by turning the locking nut on the microwave antenna cable in the clockwise direction.

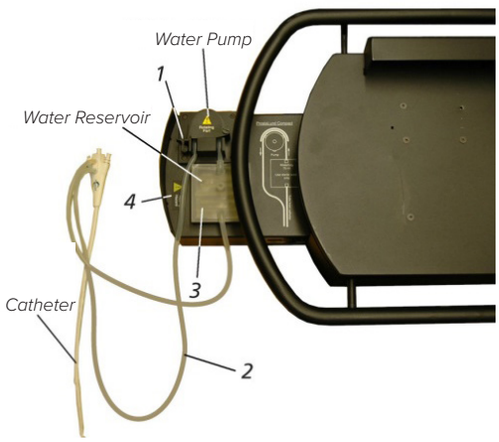
   NOTE: Do not cover the genitals or the CoreTherm catheter during the treatment as this should complicate the detection of for example catheter or antenna sliding.

2. The temperature probes, the microwave antenna and the water bag can now be connected to the CoreTherm SE control unit as described below.

   NOTE: The CoreTherm catheter, the temperature probes, and the microwave antenna must be prepared and inserted into the patient, before being connected to the CoreTherm / SE control unit.

15. CONNECTING THE PROBES TO THE CONTROL UNIT

The probe connecting points and the heat exchange plate for the water circulation are located in the pull-out drawer on the left side of the control unit. The connector of the Microwave antenna is located on the left side of the control unit. To gain access to the probe connecting points, carefully push the drawer inwards slightly, then pull it out.

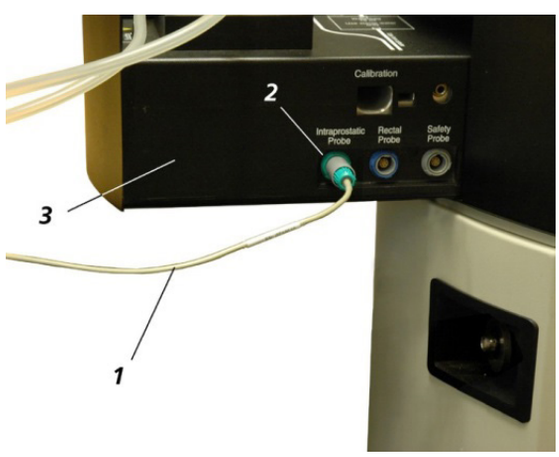


Connecting the Water Unit to the Pump

- Release the clamp securing the pump housing by moving it left and towards the back of the unit.
- Slide the access cover of the pump (1) to the right.
- Place the water reservoir (3) on the heat exchange plate in the pull-out drawer (4).

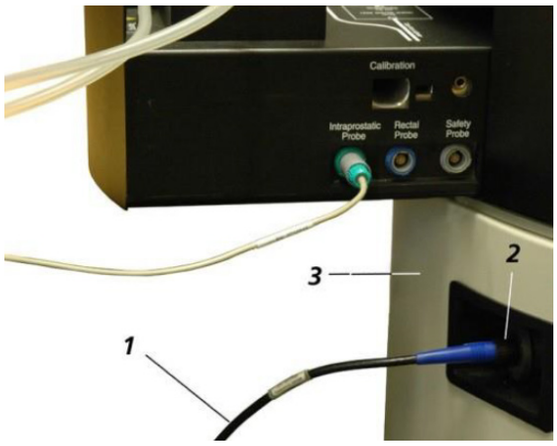
  NOTE: Make sure the water reservoir lies flat on the heat exchange plate.

- Place the water tube (2) around the pump (1) and close the access cover.
- Depress the clamp to secure the cover.



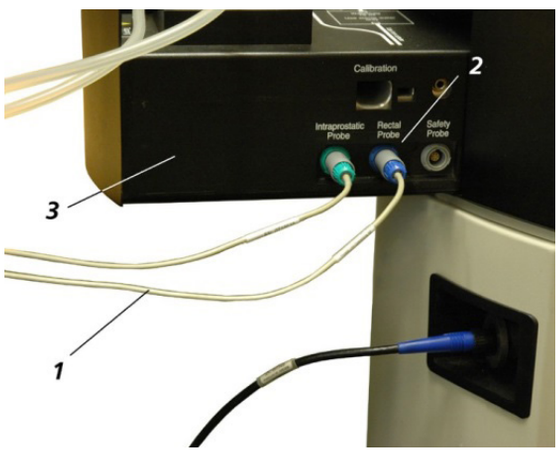
Connecting the Intraprostatic Temperature Probe

- Connect the intraprostatic temperature probe (1) to the green socket (2) of the pull-out drawer (3). An audible click will be heard when the connection is properly made.



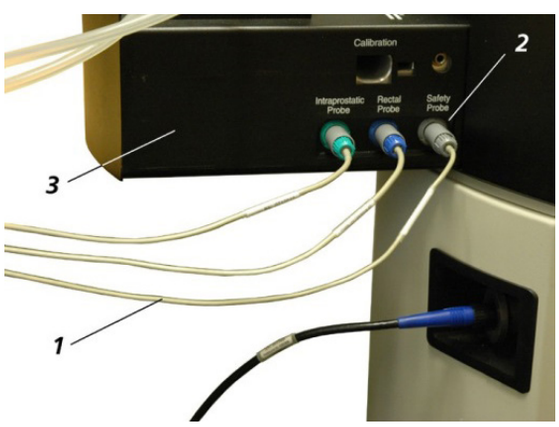
Connecting the Microwave Antenna

- Connect the microwave antenna (1) to the connector (2) on the left side of the control unit (3).
- Rotate the connector by 90 degrees to lock it in place.



Connecting the Rectal Temperature Probe

- Connect the rectal temperature probe (1) to the blue socket (2) of the pull-out drawer (3). An audible click will be heard when the connection is properly made.



Connecting the Penis Safety Probe

- Connect the penis safety probe (1) to the grey socket (2) of the pull-out drawer (3). An audible click will be heard when the connection is properly made.
- This concludes the pre-treatment preparations. The CoreTherm Treatment session can now commence as described in Running a CoreTherm Treatment session.

16. RUNNING A CORETHERM-TREATMENT SESSION

This chapter describes the procedures for administering a CoreTherm-treatment session.

16.1 Safety Precautions

Reported cases of treatment-related complications are rare. However, complications may occur if the treatment is not performed carefully and correctly in accordance with the instructions given here. Possible complications are balloon rupture and treatment catheter migration (external sphincter damage) and serious overtreatment.

You must remain with the patient throughout the duration of the treatment. You must also ensure that the following precautions are observed throughout the treatment.

16.2 Calculations of Tissue Necrosis

Before starting a CoreTherm Concept Treatment session (with Adrenalin), the presiding physician should keep in mind that the recommendations for calculated tissue necrosis are approximately 20% of the baseline prostate weight. These recommendations are based on clinical experience.

Adrenalin injections by the Schelin Catheter will bloc the intraprostatic blood flow to almost zero. Without the cooling effect from a high blood flow there will be an enhanced heat spread by conduction and it has been showed that the software calculations will underestimate the treatment effect by about 50%. Thus 20% calculated cell kill will approximately result in a 30 % volume reduction.

NOTE: The calculated tissue necrosis is an estimate: actual tissue necrosis may differ from the calculated value. The calculated tissue necrosis should therefore be used as a guide to determine when to stop the treatment. However, other important factors to consider in this regard are the intraprostatic temperature, the duration of the treatment and patient perception.

16.3 Back-up calculation for Tissue Necrosis using Energy Points

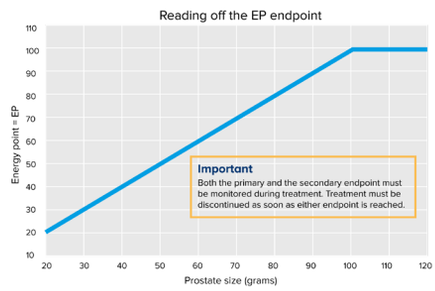
A back-up calculation, secondary endpoint, should be performed to ensure that overtreatment is not conducted. It should be used to limit the amount of energy given to the patient, based on the prostate volume. It has been shown that following this procedure will give approximately 20 % necrosis to the prostate tissue. This endpoint should always be used in case of illogical temperature curves of the intraprostatic temperature probe during treatment but should also be used as definitive endpoint even if calculated cell kill has not reached 20 %.

NOTE: This is applicable only when the patient is pretreated with adrenaline or equivalent, administrated into the prostate according to the procedure described in the Instruction for Use for the Schelin Catheter. If adrenaline is not used, the different rate of intraprostatic blood flow excludes the application of 'Energy Points' as an endpoint.

Use the graph on the form below to determine the number of Energy Points required for the volume of the prostate being treated.

Energy point (EP) for different prostate sizes

1. Proceed as follows:
Determine the EP endpoint from the diagram below. For example, if the prostate size is 80 grams, EP = 80.



2. Write down the microwave power minute by minute and the corresponding minute EP, which is equal to the microwave power divided by 10. Add the different minute EP points in the right-hand column. Once you have reached the endpoint (which you determine from the diagram above), you can end the treatment.

Energy (watts)	Time (min)	EP/ min	Accumulated EP
40	1	4	4
50	1	5	9
60	1	6	15
70	1	7	22
80	1	8	30
80	1	8	38
80	1	8	46
80	1	8	54
60	1	6	60
60	1	6	66
60	1	6	72
50	1	5	77
60	30 sec.	3	80
0			

Treatment is ended

Total time
12.5

Acc. EP
80

Tips

- For short catheters, start treatment at 30 watts (EP/min = 3)
- For standard catheters, start treatment at 40 watts (EP/min = 4)
- Increase and decrease the energy (watts) in full-minute intervals for simple calculation of minute EP.
- Target: intraprostatic temperature of at least 55 degrees to obtain a quick cell kill and gentle treatment.
- Choose the right treatment catheter:

Catheter	Prostate length (mm)	Prostate size
Short (yellow)	Larger than 25 mm	20–50 grams
Standard (blue)	Larger than 35 mm	30 grams and up

– Keep track of the treatment session on the form provided.

– Log any changes in the microwave power.

– Keep track of the accumulated energy points to know when to stop the treatment.

– Entering the 'Energy Points' at the end of each minute may be the most simple and reliable method of ensuring an accurate record.

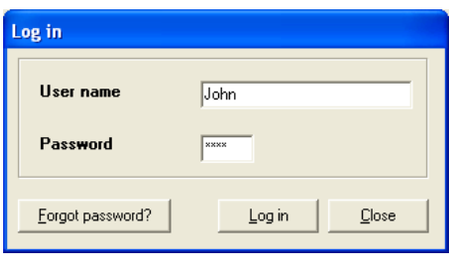
NOTE: The Energy Point calculation is used as a secondary endpoint for the treatment in cases where the pattern of the temperature curves renders the cell-kill calculation unreliable.

17. START TREATMENT

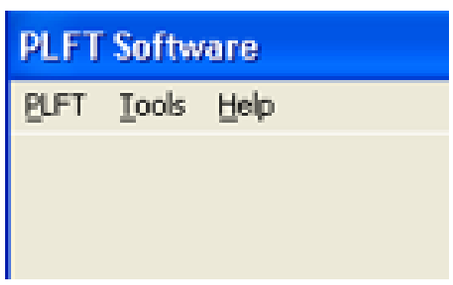
17.1 Starting Up and Logging In

1. After switching on the computer the CoreTherm SW will be automatically launched and the login dialog will be displayed. The login dialog can always be found under PLFT on the menu.

2. Type your Username and Password into the respective fields of the Login dialog



3. Click on Log in.
   The Login dialog closes. After a successful log in, the CoreTherm Software page opens. You now have full access to the CoreTherm Treatment software. If you have forgotten your password, refer to User Profiles and Passwords on page 60.



The CoreTherm Software page gives access to all the functions of the program by means of the CoreTherm, Tools and Help menus on the menu bar at the top of the page.

17.2 Patient registration

Registering a New Patient

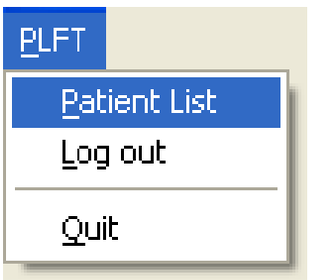
If the patient is not yet registered in the CoreTherm Treatment software (i.e. a new patient), his demographic data must be entered.

NOTE: If the patient is already registered, see Choosing the Patient to be treated page 26.

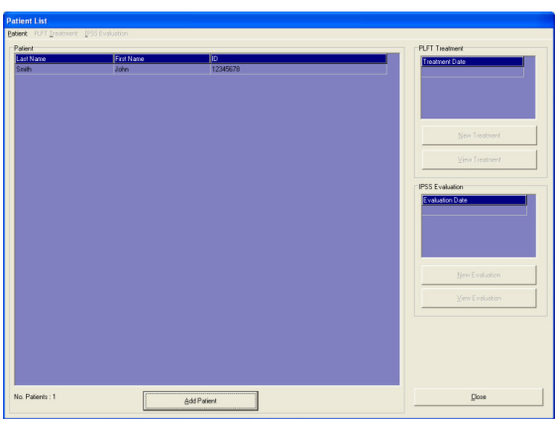
This command opens a list of the last names, first names and ID-codes of all patients in the database. The Patient List can be sorted based on last name, ID-code, treatment date or date of creation criteria. Commands in the Patient List allow you to:

- manage patient and treatment records
- perform new treatments
- view the details of previous treatments
- register and view IPSS evaluations.

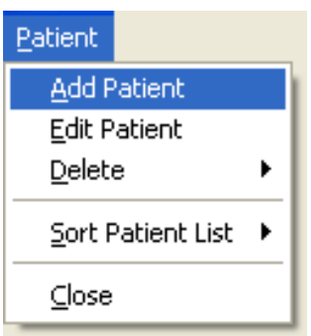
1. From the PLFT Menu on the CoreTherm Software page, choose Patient List.



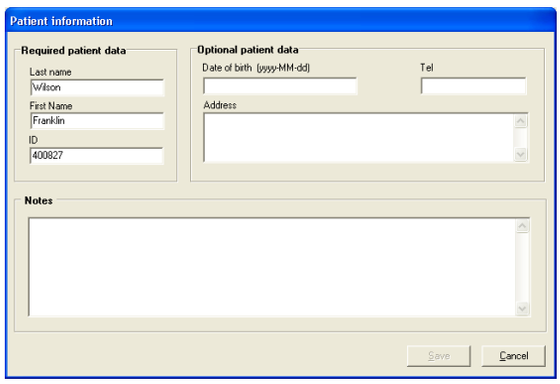
The Patient List opens.



2. Choose Add Patient from the Patient Menu.
   The Add Patient dialog opens.



3. In the Required patient data frame, enter the patient's Last Name, First Name and ID-code. These fields are mandatory: treatment cannot continue until they have been filled in.



4. If desired, complete the other fields of the Patient information dialog. They are optional.

   NOTE: If necessary, you can change some of the patient's information later by choosing Edit from the Patient Menu. However, the Last Name, First Name and ID fields cannot be edited once the treatment has been performed.

5. When you have finished entering the new patient's data, click on Save. The Add Patient dialog closes and details of the new patient now appear in the Patient List. You can also edit and delete patient records at the Patient List. See Using the Patient List on page 32.

Choosing the Patient to be Treated

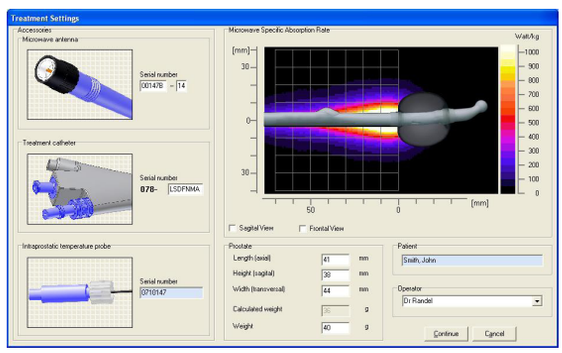
1. With the Patient List open, select the patient to be treated by clicking on his entry in the list.

Last Name	First Name	ID
Jones	Henry	576576
Smith	John	123123
Johnson	Mike	345123
Wilson	Franklin	400827

If desired, you can review earlier treatment dates or the dates of previous IPSS evaluations. See Managing Patient Records on page 32.

17.3 Entering the Treatment Information

1. At the PLFT Treatment Menu, click on the Treatment command and choose New Treatment from the sub-menu. The Treatment Settings page opens.



This figure shows the standard accessory set.

2. Check that the Treatment Settings page shows the correct name of the selected patient.

3. Enter the length and weight of the prostate as determined by TRUS. Alternatively, you can enter the length, width and height of the prostate and the software will then calculate its size (weight). Prostate length is a mandatory field - treatment cannot continue until it has been filled in. When the treatment settings have been filled, it is possible to show a schematic illustration, either sagittal or frontal views, of the prostate and compare it to the SAR image for the microwave antenna in use.

4. Enter your name by choosing it from the Operator list, or by typing your name into the field.

5. In the Antenna Serial Number field, type the serial number of the microwave antenna in use.

6. In the Catheter Number field, type the number of the CoreTherm catheter (also referred to as the treatment number) in use.

CoreTherm System

In the Intraprostatic Temperature Probe field enter the serial number.

Have any changes in accessories been made?	
Option	**Functionality**
No accessories unchanged	The default values remain and the ‘Accessories’ part of the window will be locked for editing. The ‘Cancel’ and ‘Confirm accessories and continue’ buttons are available.
Yes accessories changed	The ‘Accessories’ part of the window will be available for writing. The ‘Cancel’ and ‘Confirm accessories and continue’ buttons are available.

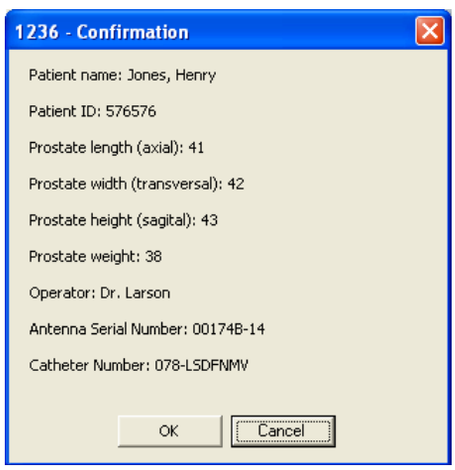
Accessories	
Option	**Functionality**
Microwave antenna	It is possible to enter a serial number of the current microwave antenna. The graphical picture will display the color coding of the entered serial number
Treatment catheter	It is possible to enter the number of the current treatment catheter. The graphical picture will display the color coding of the entered number.
Intraprostatic temperature probe	The serial number of the current intraprostatic temperature probe is presented. The graphical picture will display the color coding of the entered serial number. **CoreTherm System It is possible to enter a serial number of the current intra-prostatic temperature probe. The graphical picture will display the color of the entered serial number**

Buttons	
Cancel	Cancel the action, closes the window and displays the treatment window keeping the CoreTherm machine turned off.
Confirm accessories and continue	Performs accessories check, closes the window and starts the treatment.

Error and Warning messages

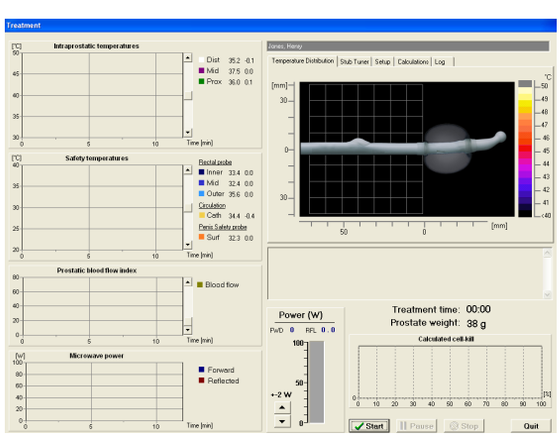
There are several error and warning messages that could arise during the operation of the software. The difference between an error and a warning message is that it is not possible to continue if an error message is popped up.

1. Click on Continue. A confirmation dialog opens



The dialog summarizes the information that you have entered. If the criteria for CoreTherm have not been met (i.e. the prostate length or weight are below permissible limits), a warning message is included with the dialog information.

2. Click on OK to close the confirmation dialog and open the Treatment Page. Alternatively, click on Cancel to change the patient's information or terminate the treatment.

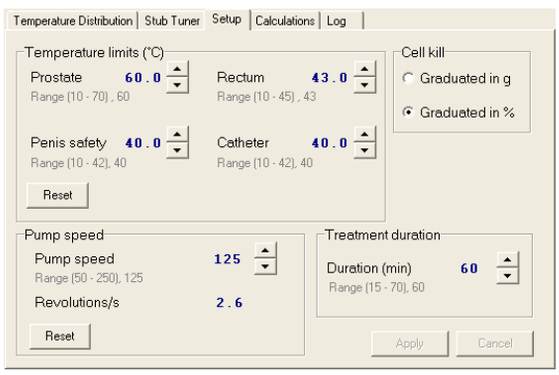


When the Treatment Page opens, the pump that circulates the water to temperate the microwave antenna cable starts automatically. Also, initial temperature values are displayed in the fields beside the temperature graphs. However, no microwave power is emitted until the treatment is started, so the temperature graphs are not updated at this time.

17.4 Checking/Adjusting the Default Treatment Settings

Default values for the temperature safety limits are displayed in the multi-panel window on the Treatment Page. You must check the default values and, if necessary, adjust them to obtain the optimal treatment protocol.

1. Click on the Setup tab of the multi-panel window on the Treatment Page. The Setup Panel opens.



NOTE: If the patient is pre-treated with adrenalin or equivalent, administrated into the prostate, Treatment duration timing is recommended to be adjusted to maximum 20 minutes.

2. Check the default settings shown in the Prostate, Rectum, Safety and Catheter fields of the Temperature limits frame. If necessary, adjust the maximum temperature limits by using the up/down arrow buttons beside the respective field. To restore the default temperature settings, click on the Reset button in the Temperature limits frame.

3. Check the Pump speed. If necessary, adjust the speed by using the up/down arrow buttons beside the pump speed value. To restore the default pump speed, click on the Reset button in the Pump speed frame.

4. Check the default Treatment duration. If necessary, adjust the maximum time limit by using the up/down arrow buttons beside the treatment duration value.

5. In the Cell kill frame, choose the way in which the cell-kill curve is to be displayed on the Calculated Cell kill graph:

- to display cell kill as an absolute value, click on the Graduated in "g" check box to activate it
- to display cell kill as a percentage of prostate weight, click on the Graduated in "%" check box to activate it.

6. When you are satisfied that all default treatment settings are correct, click on the Apply button.

   NOTE: The default values can be changed during the treatment.

   NOTE: If you forget to click the Apply button the old settings will still be valid.

18. RUNNING THE TREATMENT SESSION

Before you start any treatment, make sure that you know where the Emergency Stop button is located on the control unit, and that you know how to operate it. See Preparing the CoreTherm / SE System on page 17.

18.1 Start Up Checks

1. Check that the clinical procedures have been correctly performed.
2. Perform an ultrasound examination to check that the CoreTherm catheter is correctly fitted and to verify that the balloon is inflated in the bladder. Also verify the position for the intraprostatic temperature probe during the ultrasound.
3. Check that all cables and water tubes are properly connected to the control unit.
4. Check that the water tube is correctly fitted to the pump.
5. Check that the water reservoir is filled with sterile water and correctly placed on the heat exchange plate.
6. Check that the correct patient is named in the name field at the top of the Treatment Page.
7. Check that the treatment data have been correctly entered.
8. Check that the treatment setup information has been correctly entered.

Pre-Treatment Temperature Check

1. Before starting the treatment, check that the patient's temperatures displayed on the Treatment Page are normal.
   Typical temperatures are:
   - intraprostatic temperature 35°C to 37°C
   - rectal temperature 35°C to 37°C
   - penis safety temperature 28°C to 35°C.
2. If any of the displayed temperatures deviates from expected values, check the position of the probes. If the problem remains unresolved, the actual probe may need to be calibrated. Exchange the probe and calibrate it before using it again.

   NOTE: If the intraprostatic temperature probe needs to be exchanged, the CoreTherm catheter should be removed without compromising sterility before a new intraprostatic temperature probe is inserted into the catheter.

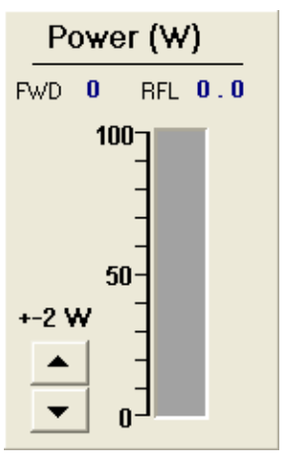
18.2 Starting the Treatment

Click on the button on the Treatment Page.

Adjusting the Microwave Power

The treatment strategy is to reach the therapeutic temperature, above 50°C for as many minutes that is required to kill 20% of the tissue in the gland. The microwave power level is set in the Power (W) field on the Treatment Page. You adjust the power output by clicking the up/down arrow buttons in this field.

The power increases or decreases by 2 W per click. Alternatively, click directly on the vertical bar to increase the micro- wave power level by 10 W per click or to decrease the microwave power to the level corresponding to the mouse click (the microwave power can be decreased from 80 W to 0 W by one click).



NOTE: For safety reasons the power level is set to 0 W by default when the treatment starts.

It is recommended that the operator and all other personnel should remain at a distance of at least 15 cm from the cable of the microwave antenna while microwave power is on. There is no immediate risk to personnel, but prolonged exposure to microwave radiation should be avoided.

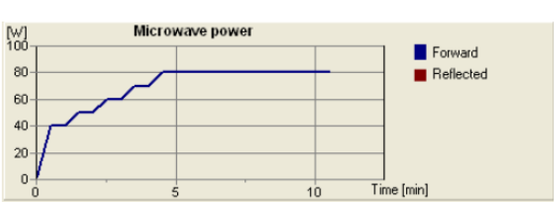
Setting the Initial Power Level

It is recommended to set the power level at 40W (30W if you use accessories for small prostates) and plan to increase the power in steps of 10W each treatment minute.

Treatment time	Standard accessories	Short accessories
1st treatment minute	40W	30W
2nd treatment minute	50W	40W
3rd treatment minute	60W	50W
4th treatment minute	70W	60W
5th treatment minute	80W	70W
6th treatment minute	80W	80W
Following minutes	80W	80W

Checking the Microwave Power Level

The Microwave Power graph on the Treatment Page shows the microwave power (in Watts) in relation to time (in minutes) throughout the treatment.

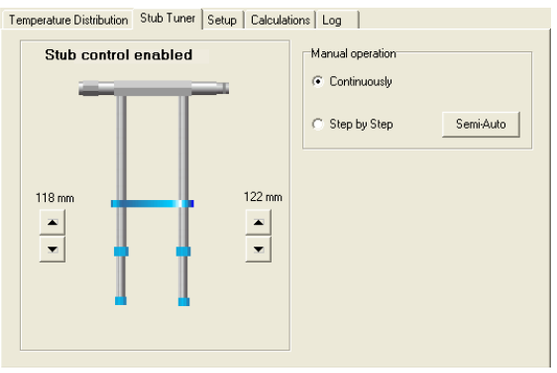


Observe the microwave power graph at regular intervals to ensure that the desired power setting is maintained.

Adjusting Reflected Power

During treatment, the microwave power display shows the forward (FWD) and reflected (RFL) power. Reflected microwave power does not contribute to prostate heating and should be kept as low as possible. If reflected power becomes excessive, a warning dialog is displayed and remains in view until reflected power has decreased. A reflected power level of close to zero can be achieved by adjusting the stub tuner.

1. Click on the Stub Tuner tab in the multi-page window. The Stub Tuner panel opens.



The Stub Tuner can be adjusted semi-automatically or manually. Adjusting the Stub Tuner Semi-Automatically

2. Click on the Semi-Auto button. The Stub Tuner minimizes the reflected power automatically. Adjusting the Stub Tuner Manually Manual tuning can be done continuously or in steps.

3. For continuous manual adjustment, activate the Continuously button in the Manual operation frame, then use the up/down arrow buttons to adjust the height of the two tuners until reflected power is at a minimum.

4. For stepped manual adjustment, activate the Step by Step button in the Manual operation frame, then use the up/ down arrow buttons to adjust the height of the two tuners until reflected power is at a minimum.

NOTE: During treatment the stub tuner is disabled periodically for 3 seconds. During this time the stub tuner cannot be adjusted. If the reflected power cannot be reduced, or if it is difficult to reduce, this may indicate that the microwave antenna is defective and must not be used.

Observing Temperatures, Blood Flow and Other Data

During the treatment session the temperatures are registered by the graphs on the Treatment Page at 30-second intervals.

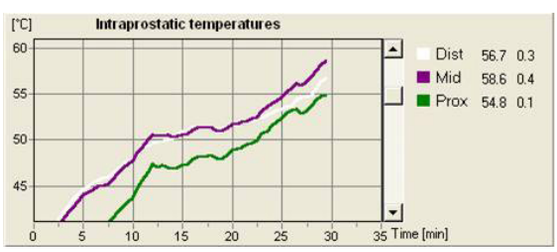
You must check these temperatures regularly throughout the treatment session. You must also check the patient's pulse and blood pressure at regular intervals. See Guidelines on Monitoring the Treatment Session on page 26.

Intraprostatic Temperature

The Intraprostatic temperatures graph shows the intraprostatic temperature (in Centigrade) in relation to time (in minutes) throughout the treatment.

The three lines on the graph represent the temperatures measured at the three sensors in the intraprostatic probe:

- the white line represents the distal (tip) sensor
- the purple line represents the mid sensor
- the green line represents the proximal sensor.



The temperatures represented by the white and purple lines are the basis for the cell kill calculations shown in the Calculated Cell-kill graph.

The temperatures measured at the distal, mid and proximal sensors are also given dynamically in the respective row on the right of the Intraprostatic temperatures graph. The left column shows the current measured temperature at each sensor, and the right column shows the difference in the readings compared to the previous measurement.

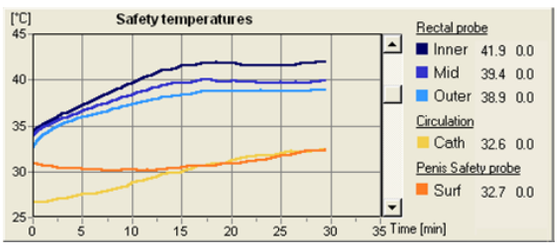
Safety Temperatures

The Safety temperatures graph shows the rectal temperatures, CoreTherm catheter temperature and penis surface temperature (in degrees Celsius) in relation to time (in minutes), throughout the treatment.

The five lines on the graph represent the temperatures measured at various probes:

- the light blue line represents the outer sensor of the rectal temperature probe
- the royal blue line represents the mid sensor of the rectal temperature probe
- the dark blue line represents the inner sensor of the rectal temperature probe

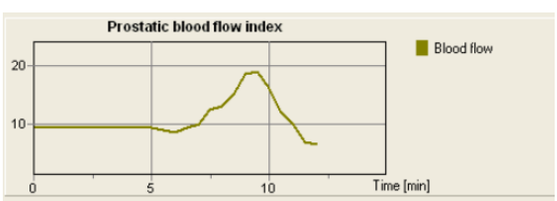
- the yellow line represents the catheter sensor in the CoreTherm catheter
- the orange line represents the penis safety sensor.



The temperatures measured at the various sensors in the rectal temperature probe, the CoreTherm catheter and the penis safety probe are also given dynamically in the respective row on the right of the Safety temperatures graph. The left column shows the current measured temperature at each sensor, and the right column shows the difference in the reading's compared to the previous measurement.

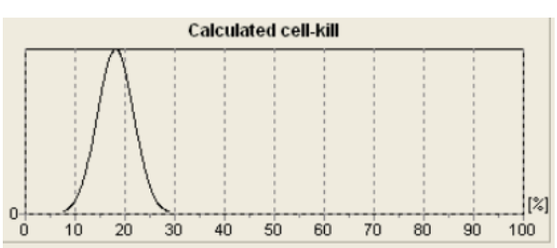
Blood Flow

The curve of the Prostatic blood flow index shows the calculated intraprostatic blood flow (in arbitrary units) in relation to time (in minutes) throughout the treatment.



Cell Kill Calculations

The calculated cell kill achieved during the CoreTherm Treatment session is shown by the Calculated Cell kill graph on the Treatment Page. Cell-kill is updated every 30 seconds. The graduation of the graph depends upon the choice (Graduated in g or Graduated in %), previously made in the Cell kill frame on the Setup tab of the multi-panel window.



The calculated cell kill value is the center value of the graph, i.e. the top point of the curve. The bell-shaped curve is intended to illustrate that the actual tissue necrosis may differ from the calculated value, although the probability that the actual tissue necrosis shall deviate considerably from the calculated value is low.

Other Treatment Data

During the CoreTherm Treatment session, the Treatment Page shows the elapsed Treatment time (in minutes and seconds), and the pretreatment Prostate weight (in g), immediately above the Calculated Cell kill graph.

Treatment time:	12:07
Prostate weight:	59 g

19. GUIDELINES ON MONITORING THE TREATMENT SESSION

Patient Comfort

As far as possible, a relaxed environment should be maintained throughout the treatment. Moreover, it is important to comfort the patient and pay attention to signs of pain or the urge to urinate, as well as sympathetic/parasympathetic reactions.

Logical Temperature Values

It is most important to check that the intraprostatic temperatures appear logical. Ordinarily the white or purple line on the Intraprostatic temperatures graph shows the highest temperatures. Initially, when microwave power is set to 0, the green line will register 35°C to 37°C, the purple line will indicate a slightly higher value, and the white line will approximately show the body temperature.

During the treatment the white, purple and green lines should show a gradual increase in temperature. If the temperature lines on the graph do not develop in this manner but remain illogical after several minutes of treatment, finish the treatment according to the secondary endpoint target.

Positioning of the Intraprostatic Temperature Probe

If the intraprostatic temperature probe is inserted into the prostate without holding the CoreTherm catheter straightened so the balloon rests at the bladder neck, the catheter may turn in the urethra/bladder. Consequently, the temperature probe will take a wrong path into the prostate. If the intraprostatic temperature probe is not correctly positioned, the calculated tissue necrosis may be overestimated or underestimated. If the prostate is small, the margins

for error are small. Hence extra care should be given to ensure that the intraprostatic temperature probe is correctly positioned.

With the aid of TRUS, and with the patient lying on his left side, it is relatively easy to control the position of the intraprostatic temperature probe as follows:

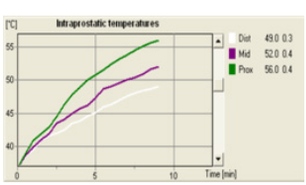
1. Your assistant should unfasten the nut that secures the intraprostatic temperature probe.
2. Push the probe in and out with a short, sharp movement (2 to 3 mm). The temperature probe can then be clearly seen in the ultrasound image, transversally and sagittal.
3. Identify the tip of the probe and verify that it is correctly positioned.

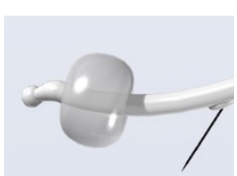
If logical temperatures are shown on the computer screen after the treatment has been started, then the temperature probe is positioned correctly. However, in some circumstances, the lines on the Intraprostatic temperature graph may be illogical even when the intraprostatic temperature probe is positioned correctly. This is the result of other factors, such as uneven circulation in the prostate or the intraprostatic temperature sensor being obscured by an intraprostatic stone or by a large blood vessel.

It is important to be aware that tissue necrosis may occur, even though the temperature and calculation of tissue necrosis cannot be reliably monitored on the computer screen.

Illogical Temperature Values

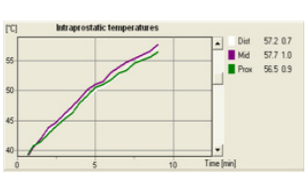
Green curve is highest

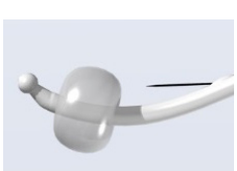




May indicate that the IP probe is exiting downward/backward if the catheter is curved. Adjust the probe counterclockwise 45 degrees or more. Cell kill calculation may be underestimated. Finish treatment according to secondary endpoint.

Parallel curves

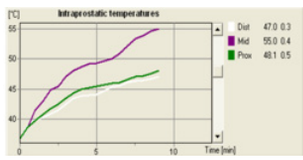


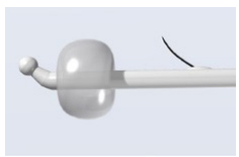


All 3 curves are parallel or very close together.

Cell kill calculation may be overestimated. Finish treatment according to secondary endpoint.

Large deviation between distal and mid curves

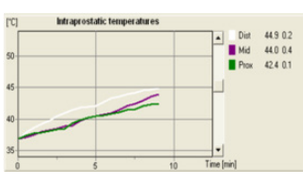


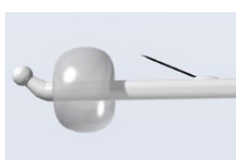


May indicate that the tension of the catheter has been to high when IP probe has been inserted. The IP probe will be bent backward when the tension is relieved.

May also indicate that the IP probe is exiting to much toward 3-4 o'clock or exiting with a too high angle due to a permanent bend if it has been used too many times. Cell kill calculation may be underestimated. Finish treatment according to secondary endpoint.

Intraprostatic temperatures remain low in spite of high power





Prostatic blood flow may be very high.

Abnormally high blood flow may occur for many reasons, most commonly highly vascularized prostatic tissue or systemic hypertension. Also, tissue heating gives rise to local vasodilatation which, in turn, may lead to increased intraprostatic blood flow during the early stages of treatment. This effect may continue until a point when the temperature increase begins to cause local coagulation and embolization. High blood flow is the most common limiting factor that impedes the ability to reach therapeutic temperatures (>48°C).

A particular sensor may be positioned very close to a blood vessel. If the patient has been pre-treated with adrenaline and the temperatures is not rising despite high energy: Finish treatment according to secondary endpoint.

Adjusting Microwave Power to Compensate for Temperature Changes

Adjust the microwave power according to plan by 10W every minute to achieve the therapeutic temperatures in the prostate. If any temperature increases quickly and are close to the preset limits it may be a good idea to step away from the plan and maintain or reduce the power level. If any preset limit is exceeded the system shuts off and you need to restart treatment.

Treatment Duration

The aim during treatment is for the maximum temperature to rise to approximately 55°C to 70°C to ensure that, within 13.5 minutes or less, an effective treatment is achieved.

Since the patient has been pre-treated with adrenalin, the blood flow in the prostate will be low, and the treatment duration time will be somewhere between 6 and 13.5 minutes. With the secondary treatment endpoint plan you can see how long the treatment maximum will last if performed according to plan.

Rectal Temperature

For reasons of safety, the temperature in the rectum is also monitored. When administering a CoreTherm treatment it is important to remember that the patient's rectum reacts relatively slowly to changes in temperature. When rectal temperature approaches 43°C, it is a good idea to reduce the microwave power to avoid interruptions of the treatment. This is because rectal temperature continues to rise for a short time after the power has been reduced.

The distance between the rectum and the microwave antenna varies in different patients. If the distance is short, the rectal temperature approaches 43°C more rapidly and is thus a limiting factor throughout the treatment. Throughout the procedure the treatment must therefore be administered by adjusting the microwave power level with respect to the rectal temperature. It is important to check the position of the rectal temperature probe regularly throughout treatment.

Penile Temperature

For reasons of safety, the temperature of the outside of the penis is also measured. If the sensor in the penis safety probe detects an elevated temperature, this may indicate that the circulation system of the CoreTherm catheter is not working properly, or that the CoreTherm catheter and/or microwave antenna has moved. In the event of an elevated penile temperature, immediately check the circulation system and the positions of the CoreTherm catheter and/or microwave antenna. It is important to check the position of the penis safety probe regularly throughout the treatment.

Catheter temperature

The intraprostatic temperature probe has a fourth temperature sensor that measures the temperature of the circulating water. An elevated temperature in the circulating water may indicate leakage in the circulation system or a defect in the heat exchange plate. In the event of an elevated catheter temperature, immediately check the circulation system and the heat exchange plate.

20. DIFFERENT TREATMENT CHARACTERISTICS

Small prostate volumes

If a patient's prostate is between 20 and 50 g, you can use the accessory set for small prostates.

Large prostate volumes

If the prostate volume is larger, the treatment time may be longer. Still, do not treat longer than the secondary endpoint target.

NOTE: It is very important to select the right accessories with regards to the prostate size.

Low blood flow

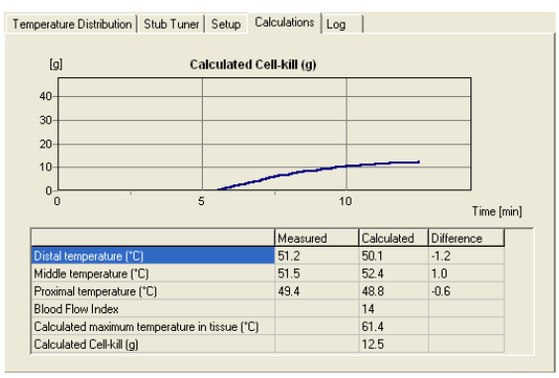
With calculated low blood flow, a rapid rise in the intraprostatic temperature is expected. The treatment should be completed within 6 to 13.5 minutes. Since the patient has been pre-treated with adrenalin, the blood flow in the prostate is expected to be low.

High blood flow

With calculated high blood flow, it is possible that cell kill values will be low. Finish the treatment according to secondary endpoint.

Viewing the Calculations During Treatment

During the treatment session, you can observe how the treatment's cell-kill calculations progress. Click on the Calculations tab on the Treatment Page. The calculations are displayed as shown below.



Error Messages

If an error or warning message occurs during the treatment, it remains on display in a message dialog until the cause of the message has been resolved. For detailed information, see 32. ERROR/WARNING MESSAGES BEFORE SET UP OF THE TREATMENT

21. STOPPING TREATMENT

Pausing the Treatment

A CoreTherm Treatment session can be temporarily halted: for example, if it is necessary to switch off the microwave power for any reason.

The program is automatically set to the pause mode if a temperature limit is exceeded.

1. To pause a treatment, click on the Pause button on the Treatment Page. Microwave power is automatically switched off and the treatment timer is stopped. However, the temperature readings and cell kill calculations continue as normal.

2. To resume the treatment, click on the Start button. The microwave power has to be manually set again.

Stopping the Treatment

A CoreTherm Treatment session can be stopped in two ways:

- automatic stop at the end of the preset maximum time
- manual stop by using the Stop button.

When the treatment is stopped, the temperature readings and the cell-kill calculations cease. However, it is still possible to continue the treatment by pressing the Start button.

NOTE: In an emergency, press the Emergency Stop button on the control unit. This disconnects the entire system from the mains electrical power. The microwave generator is immediately switched off when the Stop button is clicked.

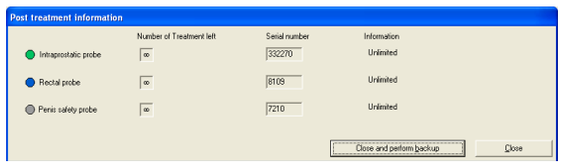
Saving Treatment Data

The treatment data are saved when you close the Treatment Page and confirm your intention to exit the page.

Return to the Patient List

1. Click on Quit on the Treatment Page. You are prompted to confirm that you want to exit the Treatment Page.

2. Click on OK in the confirmation dialog. The treatment data are saved. When leaving a treatment session, a post treatment dialog is displayed. The dialog gives a summary status of all three probes and allows you to perform a backup. A backup can alternatively be run later by selecting Backup in the Tools menu.



The following information is available in the Post Treatment dialog:

- Number of treatments left
- Serial number
- Information (Unlimited, OK, Expired, Needs calibration)

CoreTherm System

2. Click on OK in the confirmation dialog. The treatment data are saved. You are prompted if you want to perform a backup. It is strongly recommended to perform a backup after each treatment. It is also possible to perform a backup later by selecting the Backup in the Tools menu

This concludes the treatment procedure. You can now end the session as described in Finishing the Treatment.

NOTE: You will not be prompted to perform a backup if the treatment session is shorter than 10 minutes.

22. SWITCHING THE CORETHERM / SE SYSTEM OFF

Exit the CoreTherm software by using the Quit command in the PLFT Menu. By closing the application, the computer will be automatically switched off.

CoreTherm System

Exit the CoreTherm software by using the Quit command in the PLFT Menu then Switch off the computer by selecting Shut Down from the Windows Start Menu

Set the main power switch on the right side of the control unit to the OFF (0) position.

NOTE: In an emergency, press the Emergency Stop button on the control unit. Do not attempt to quit the program first.

22.1 Disconnecting the temperature probes and the CoreTherm catheter

When the treatment session has finished, the temperature probes and CoreTherm catheter can be disconnected from the CoreTherm / SE control

unit and removed from the patient. Always stop the treatment before extracting the CoreTherm catheter from the patient's body. Microwave power must not be emitted under any circumstances when the CoreTherm catheter and/or the microwave antenna are not correctly positioned within the body.

22.2 Disconnecting the Probes from the CoreTherm / SE System

1. Disconnect the penis safety probe from the grey socket of the control unit by pulling it outwards.
2. Disconnect the rectal temperature probe from the blue socket of the control unit by pulling it outwards.
3. Disconnect the microwave antenna from the connector on the left side of the control unit by rotating it 90° counter clock-wise and pulling it outwards.
4. Disconnect the intraprostatic temperature probe from the green socket of the control unit by pulling it outwards.
5. To disconnect the water tube - slide the access cover of the pump to the right, remove the water tube from the pump and allow the access cover to shut. Then remove the water reservoir from the heat exchange plate in the drawer.

22.3 Removing the Probes and the CoreTherm catheter from the Patient

1. Remove the penis safety probe from the base of the patient´s penis.
2. Carefully withdraw the rectal temperature probe from the patient. But first deflate the balloon, if it has been inflated.
3. Release the intraprostatic temperature probe from the CoreTherm catheter by turning its lock nut in the counter-clockwise direction. Then carefully withdraw the probe until it entirely resides in the catheter (minimum 50 mm).
4. Drain the water from the balloon of the CoreTherm catheter. Then gently remove the catheter from the patient's urethra. When the catheter is withdrawn, it is quite normal for the patient to experience some bleeding from the urethra, due to abrasions caused by the temperature probe. No particular measures are necessary: the bleeding should cease spontaneously after approximately 10 minutes.
5. Unlock the microwave antenna from the CoreTherm catheter as follows:
   - hold the Luer-lock on the antenna in one hand
   - hold the Luer part of the CoreTherm catheter in the other hand
   - gently turn the Luer-lock on the antenna in the counter- clockwise direction
   - when the Luer-lock is open, withdraw the microwave antenna from the CoreTherm catheter.
6. Ensure that no parts of the CoreTherm catheter remain attached to the Luer-lock of the microwave antenna. Immediately after the CoreTherm catheter has been removed, the patient should be fitted with an indwelling catheter e.g. a CoreFlow catheter. When fitting the catheter, it is not unusual for a quantity of coagulum and bloodstained urine to be discharged. The catheter should therefore not be plugged. The use of suprapubic drainage instead of indwelling catheter is strongly warned against due to the risk of permanent occlusion of the urethra. The patient should be prescribed bladder training from the outset. There are two reasons for this: urine counteracts the formation of coagulum due to the fibrinolytic effect of urine and the patient will feel less discomfort if the balloon and tip of the catheter are surrounded by urine. It is important to encourage the patient to drink plentiful amounts of water after the treatment.

22.4 Disposal of the Clinical Equipment

The CoreTherm catheter is intended for use in one treatment only. It must be discarded after use.

The intraprostatic temperature probe must be cleaned and sterilized before it is used for another treatment session. See **28.3 Sterilization.**

The microwave antenna, the rectal temperature probe and the penis safety probe must be cleaned and disinfected before they are used for another treatment session. See **28.2 Cleaning and Disinfection.**

23. AFTER CORETHERM TREATMENT

It is recommended that a prophylactic antibiotic should be administered in accordance with the clinical routines of the department.

For the first week after CoreTherm Treatment it is important for the patient to avoid physical exertion.

It is recommended that the patient should remain catheterized (with indwelling catheter), for at least 3 to 6 weeks after treatment.

Patients often experience urgency in the first week after treatment. This will diminish gradually, although it is not unusual for the feeling to persist for up to a month. During the first few months after treatment it is not unusual for small pieces of tissue from lesioned and necrotic prostate and prostatic urethra

to be discharged with the urine, and occasionally, macroscopic hematuria. After removal of the catheter, a small risk of urine retention is still present. It is therefore important to inform the patient about this risk.

24. FOLLOW UP

Three to four months after CoreTherm Treatment, the following checks should be made on the patient:

- IPSS + bother score
- Flow +/- residual urine.

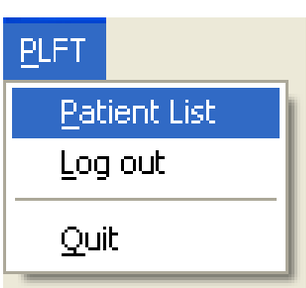
Three to four months after treatment, the patient's symptoms will be reduced significantly, and this trend may continue for up to a year after CoreTherm Treatment before the final improvement has been reached.

25. MANAGING PATIENT RECORDS

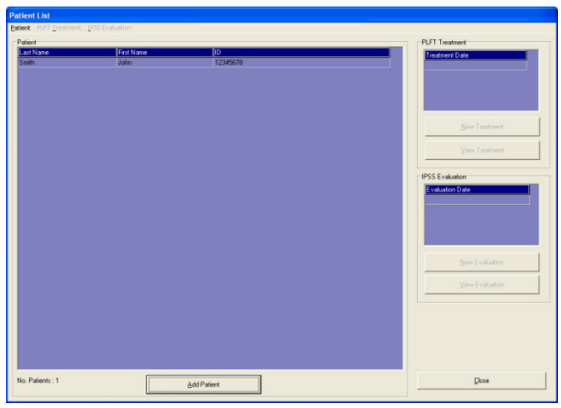
The CoreTherm software allows you to maintain records of the CoreTherm Treatment sessions of all patients. This section will help you manage your patient records.

Using the Patient List

Patient records are managed by means of the Patient List, a summary of all patient records in the database. It displays the last name, first name and ID-code of each patient.



1. Choose Patient List from the PLFT Menu on the CoreTherm Software Page.
2. The Patient List opens. Once the Patient List is displayed the Add Patient button is automatically selected and a patient can be added by simply pressing the Enter key or by clicking on the button. When the Patient List window is displayed no patient is preselected and consequently all patient related functions are disabled. Select a patient in order to enable these functions.



CoreTherm System

To add patient, you have to use the Add Patient command from the Patient Menu.

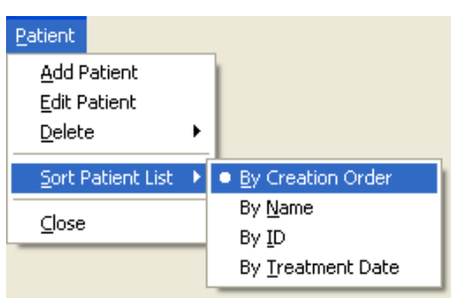
The contents of the Patient List can be sorted, edited and deleted by using the commands in the Patient Menu.

Sorting the Patient List

You can sort the Patient List in order of:

- date of creation of the patient's record
- patient's name
- patient's ID-code
- date of the treatment.

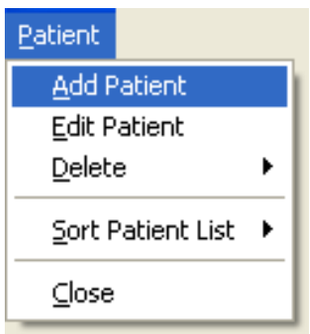
Choose Sort Patient List from the Patient Menu, then choose the desired sort option from the sub-menu.



When you release the mouse button, the Patient List is refreshed to present information in the order that you have selected.

Adding a Patient's Record

A new patient record can be added to the Patient List by using the Add Patient command in the Patient Menu or the Add Patient button.



CoreTherm System

The Add Patient button is not available in CoreTherm System

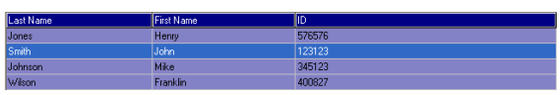
When adding a new record, the patient's first name, last name and ID-code are mandatory. The patient's date of birth, address, telephone number and notes are optional. See **17.2 Patient registration.**

Editing a Patient's Record

You can change (edit), the information in an existing patient record.

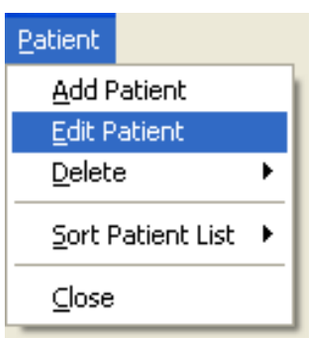
NOTE: The patient's name and ID-code can only be edited before the treatment has been performed. These data cannot be changed once the treatment has started.

1. In the Patient List, choose the patient whose record is to be edited.



Last Name	First Name	ID
Jones	Henry	576576
Smith	John	123123
Johnson	Mike	345123
Wilson	Franklin	400827

2. Choose Edit Patient from the Patient Menu. The Edit Patient dialog opens.



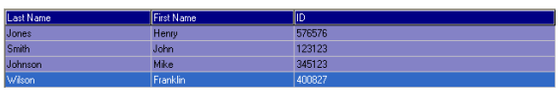
3. Change the details of the patient's record as necessary.
4. Save the changes to the patient's record and close the Edit Patient dialog. The Patient List is updated to show the changed information.

Deleting a Patient's Record

Patient-related information can be deleted from the database in three ways:

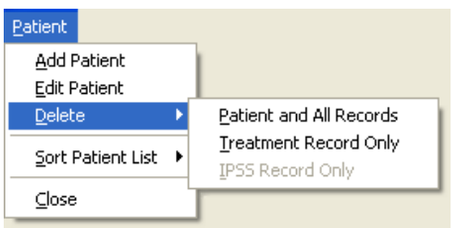
- delete a patient and all his records entirely
- delete one treatment record only
- delete one IPSS record only

1. In the Patient List, choose the patient whose record is to be deleted.



Last Name	First Name	ID
Jones	Henry	576576
Smith	John	123123
Johnson	Mike	345123
Wilson	Franklin	400827

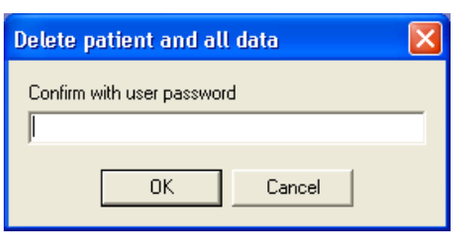
2. Choose Delete from the Patient Menu.



3. In the Delete sub-menu, specify the information that is to be deleted:

- if you want to remove the patient and all his records from the database, choose Patient and All Records
- if you only want to remove one treatment record from the database, choose Treatment Record Only
- if you only want to remove one IPSS record from the database, choose IPSS Record Only.
- When you release the mouse button, the Password dialog opens.

NOTE: If several treatments or IPSS evaluations are available for a patient, make sure you select the correct date for the data you want to delete.



4. Enter the password used to log in and click OK. The Pass- word dialog closes and the deletion is effectuated. The deleted information is removed from the Patient List.

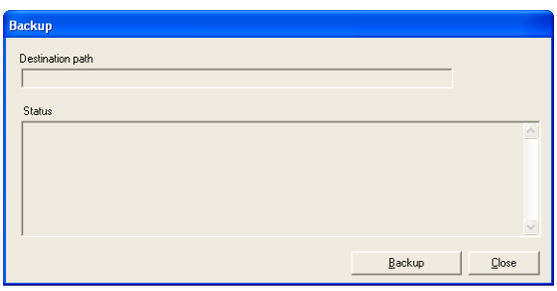
Back-up

This command allows you to make a back-up of all database tables, to facilitate recovery of the system. The Post Treatment window enables you to do a backup after each treatment.

It is strongly recommended to do a backup after each treatment.

CoreTherm System

It is possible for the user to change the path where the back-up files are stored.



26. VIEWING TREATMENTS

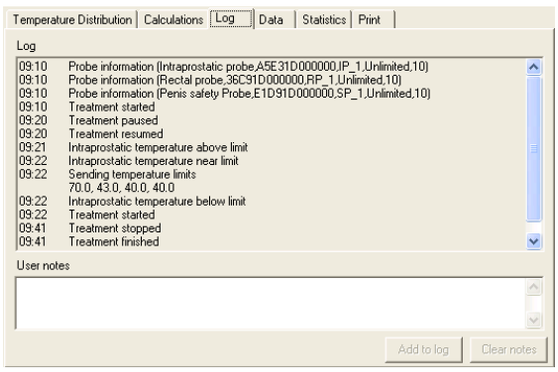
From the Patient List you can review the details of previous treatments.

1. In the Patient List, select the patient whose treatment details you want to view.
2. In the Treatment Menu, click on View Treatment.

The Treatment Page opens in view mode. You can now review and print the treatment details by selecting the appropriate tab in the multi-panel window.

Viewing the Log List

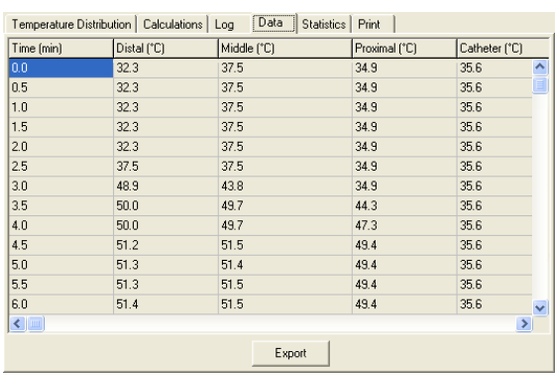
Click on the Log tab in the multi-panel window. The Log List opens in the panel.



The Log List contains information about all events that have occurred during the treatment. It includes any notes that may have been typed, and any warning/ error messages. The Log List is primarily intended for use as a troubleshooting aid. In order to add a note to the log list you have to push the button Add to log to save the note. It is only possible to add notes in treatment mode.

Viewing the Data Summary

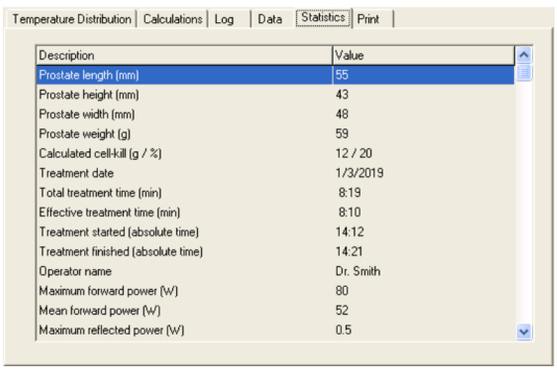
Click on the Data tab in the multi-panel window. The Data panel opens.



The Data panel contains a summary of all the temperature readings measured during the treatment, recorded at 30 second intervals. The Data panel is intended for troubleshooting and research purposes. By pressing the Export button, the user can export treatment data as a text file with the data separated by semicolon.

Viewing Statistics

Click on the Statistics tab in the multi-panel window. The Statistics panel opens.

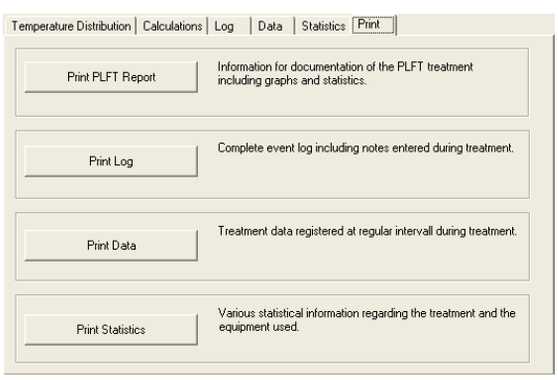


The Statistics panel contains a summary of treatment and device-related information for the current treatment.

Printing the Treatment Information

You can print selected treatment information on hardcopy.

1. Click on the Print tab in the multi-panel window. The Print panel opens.



2. Click on Print PLFT Report to print a full record of the treatment, including the temperature graphs. The PLFT Report is intended to be filed with the patient's medical records.
3. Click on Print Log to print the contents of the Log List.
4. Click on Print Data to print the contents of the Data panel.
5. Click on Print Statistics to print the contents of the Statistics panel. When you choose to print the selected page(s), a conventional Windows Print Setup dialog opens automatically.

   NOTE: The laptop computer must be disconnected from the CoreTherm / SE unit in order to connect a printer.

27. SYMPTOM SCORE

Devising Symptom Scores

The AUA symptom score and the International Prostate Symptom Score (IPSS) are equivalent. In the CoreTherm software and in this document, we use the term IPSS.

The IPSS symptom score contains seven questions that have graded responses ranging between 0 and 5. The responses are then totaled to give a final IPSS score ranging between 0 and 35.

Points	Significance
0-7	Mild symptoms
8-19	Moderate Symptoms
20-35	Serious Symptoms

An eighth question asks how the ailment is affecting the patient's quality of life. The response is graded between 0 and 6. This is called Bother Score.

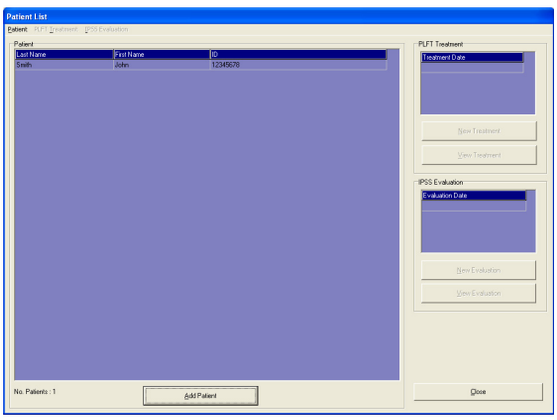
The CoreTherm software provides a Symptom Score page with two functions:

- display a record of a patient's previous symptom score on a particular date
- record a new symptom score for a patient

NOTE: The IPSS symptom score shall be patient administered, meaning that the patient shall fill in his own score. The CoreTherm IPSS evaluation page is intended for recording purpose only.

To Register an IPSS Symptom Score

1. In the Patient List, choose the patient for whom a symptom score is to be registered.

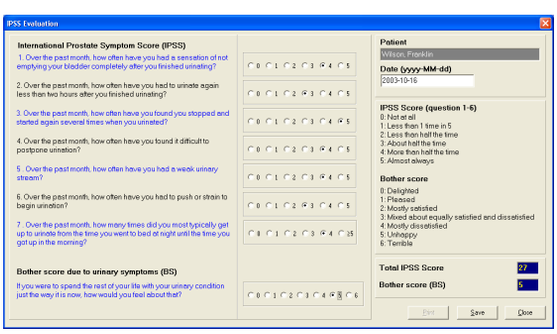


2. Choose New Evaluation from the IPSS Evaluation Menu on the Patient List page.

CoreTherm System

IPSS Evaluation is accessible through a different panel.

The IPSS Evaluation page opens.



3. Against each question, enter the symptom score by clicking the button that represents the corresponding value. The total IPSS symptom score is displayed automatically.
4. When you have entered appropriate values for all the symptom score questions, click on Save to store the information in the database.
5. If you want to print the symptom score on hardcopy, click on Print.

   NOTE: The laptop computer must be disconnected from the CoreTherm SE unit in order to connect a printer.

Viewing Symptom Scores

1. In the Patient List, choose the patient whose symptom score is to be viewed.
2. Choose an evaluation by date.
3. Choose View Evaluation from the IPSS Evaluation Menu in the Patient List.

CoreTherm System

IPSS Evaluation is accessible through a different panel.

The patient's symptom evaluation is displayed on his IPSS Evaluation page.

4. If you want to print the evaluation on hardcopy, click on Print.

NOTE: The laptop computer must be disconnected from the CoreTherm SE unit in order to connect a printer.

28. CARE AND MAINTENANCE

This chapter gives procedures for the proper care and maintenance of the CoreTherm equipment.

28.1 Care of Temperature Probes and Antenna

Probe and Antenna Statistics

This command provides various statistical information about selected probes and antenna (e.g. last date of calibration, total number of treatments, total treatment time, etc.). It is not necessary to connect the probes or antenna to the CoreTherm/ SE Systems control unit to obtain this information. See **30. PROBE AND ANTENNA STATISTICS.**

Temperature Probes

The intraprostatic temperature probe, the rectal temperature probe and the penis safety probe can all be reused, provided that the instructions given in this section are followed. Since all temperature probes are delicate instruments, it is very important that they are handled with care.

- Do not bend the intraprostatic temperature probe by more than a radius of 50 mm.
- Keep the probes rolled in loose loops in the instrument case to protect the internal wires.
- The plug is permanently attached to the probe cable. Do not remove it.
- The temperature probes are delivered unsterile. All probes need to be cleaned and disinfected before use. In addition, the intraprostatic temperature probe needs to be sterilized before use, see **28.2 Cleaning and Disinfection** and **28.3 Sterilization**

- The temperature probes also need to be calibrated at regular intervals in order to ensure accurate temperature measurements. It is therefore important to follow the calibration instructions in section Calibrating the Temperature Probes, see **chapter 29 MAINTENANCE OF THE PROBES.**

NOTE: All probes are delivered uncalibrated and must be calibrated before use.

Recommended reuse life for the temperature probes are 10 times. However, the functionality of the probes should be checked before each treatment:

- Check the front face of the probes and the probe cable for cracks or physical damage, as this may impair the performance and safety of the equipment.
- Check the plug of the probe.
- When the probes are applied to the patient, check that the patient´s temperatures displayed on the Treatment Page are normal, before starting the treatment. See Pre-Treatment Temperature Check under chapter **18 RUNNING THE TREATMENT SESSION** for further instructions.

Microwave Antenna

The microwave antenna can be reused provided that the instructions given in this section are followed. Since the microwave antenna is a delicate instrument, it is very important that it is handled with care.

- Do not bend the antenna by more than a radius of 60 mm.
- Do not bend the radiating part of the antenna (the most distal part of the antenna).
- Always store the antenna in its instrument case.
- Before each treatment the microwave antenna needs to be cleaned and disinfected, see **28.2 Cleaning and Disinfection.**

Recommended reuse life of the antenna is 10 times. However, the functionality of the antenna should be checked before each treatment:

- Check the front face and the cable of the antenna for cracks or any signs of physical damage, as this may impair the performance and safety of the equipment
- If the reflected microwave power cannot be reduced or is difficult to reduce by using the stub tuner, this may indicate that the microwave antenna is defective and must not be used.

28.2 Cleaning and Disinfection

Control Unit and the Pull Out Drawer

The control unit and the pull out drawer should be wiped gently with a damp cloth. Use a warm water and soap solution, taking care not to allow water into the connectors.

NOTE: After cleaning, make sure that no blood residue is left in the Luer Lock or in any other areas.

Keyboard, Computer Screen, Connectors and Cables

The keyboard, computer screen, connectors and cables should be cleaned using a cloth which has been dampened in alcohol.

Reusable Temperature Probes

The intraprostatic temperature probe, the rectal temperature probe and the penis safety probe can be used more than once and are supplied in non-sterile packaging. The probes should be used a maximum of ten times before discarding. These probes must be cleaned and disinfected after each use.

NOTE: The intraprostatic temperature probe must be cleaned, disinfected and sterilized prior every use. Read sterilization 28.3

Automatic cleaning and Thermal disinfection

1. Remove blood stains and gross soil from the probe using a soft brush with synthetic fibers under running lukewarm tap water. Water quality to be used shall comply to AAIM TIR34. A small pipe brush can be used for the narrower areas.
2. Use only validated washer-disinfector machines with approved efficacy (e. g. CE mark or FDA clearance and validation according to ISO 15883).
3. Use only cleaning agent intended for use in washer-disinfector (e. g. 5ml/L Neodisher® MediClean Forte). Do not exceed the concentration, temperature, and contact time recommended by the detergent manufacturer.
4. Load the probe into the washer-disinfector. Avoid contact between the probe and the other devices as movement during washing could cause damage and washing action could be obstructed.
5. Make sure not to bend the intraprostatic temperature probe to a radius less than 50 mm.
6. Run the washer-disinfector cycle. Water quality to be used shall comply to AAIM TIR34. A thermal disinfection program of at least 5 minutes in 90°C is required.
7. Upon completion, visually inspect the probe for any damages or remaining soil or blood stains. If soil or blood stain remains, repeat the cleaning process.
8. If additional drying is required, arrange instruments in a clean area or use a soft, lint-free cloth.

Note: Chemical disinfection programs are not recommended due to the potential for chemical

residues to remain on the probe. These residues could interfere with sterilization efficacy.

Microwave Antenna

The microwave antenna is reusable and should be cleaned and disinfected after each and every use. Clean the antenna by gently wiping it with a damp cloth, using a soap and water solution. Then gently wipe the antenna with a cloth dampened in an 70 % alcohol solution.

28.3 Sterilization

The intraprostatic temperature probe can be reused and is supplied in non-sterile packaging. Before using a intraprostatic temperature probe, after cleaning and disinfecting, the probe shall be sterilized according to the instructions below.

Autoclave sterilization

Dynamic-Air-Removal Steam Sterilization process follows the ISO 17665-1 standard for steam sterilization according to following parameters:

1. Place the cleaned probe in a Tyvek® bag.
2. Place the bag with the probe in the Autoclave.
3. Sterilize according to the following cycle:

28.4 Service and Repair

The CoreTherm / SE unit must be disconnected from all electrical sources before it is opened for any adjustment, replacement, maintenance and/or repair. Except for work to be performed by the operator as described in this manual, all service must be performed by your authorized service representative.

Temperature:	121°C
Pre-vacuum	
Time:	min 15 minutes (max 30 minutes)
Minimum dimension of packaging:	205x270 mm

Mandatory preventive maintenance is performed annually on the unit to ensure proper functionality.

28.5 Storage

The CoreTherm / SE unit and the reusable probes must be stored in a clean and dry place, where the temperature does not fall below 5°C or rise above 40°C. Avoid exposing the units to direct sunlight. The intraprostatic temperature probe, the rectal temperature probe, the penis safety probe and the microwave antenna are delicate instruments and should be handled with care. The CoreTherm catheter must be stored in a place with temperature 10-30°C, or 50-80°F at 10-80% atmospheric humidity. Expire date is labeled on the package.

Do not bend the intraprostatic temperature probe with a radius less than 50 mm.

Do not bend the microwave antenna with aradius less than 60mm.

29. MAINTENANCE OF THE PROBES

Calibrating the Temperature Probes

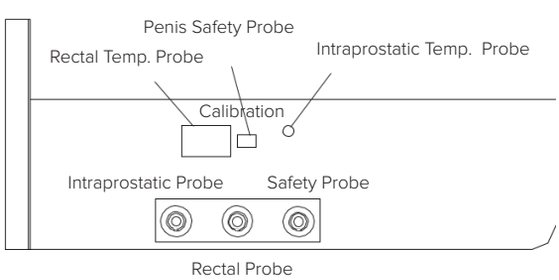
The accurate calibration of the temperature probes in accordance with the manufacturer's instructions is crucial to the performance of safe and accurate CoreTherm Treatments.

The probes should be checked before every treatment to ensure that they show correct temperatures. Calibration can be performed as an automatic procedure using the built-in calibration oven or as a manual procedure by using external reference temperatures.

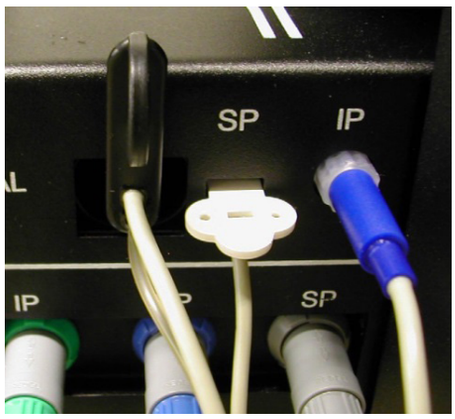
Automatic Calibration

The built-in calibration oven is located in the pull-out drawer of the CoreTherm / SE control unit. The drawer has one reference temperature chamber for each type of probe (intraprostatic, rectal temperature and penis safety).

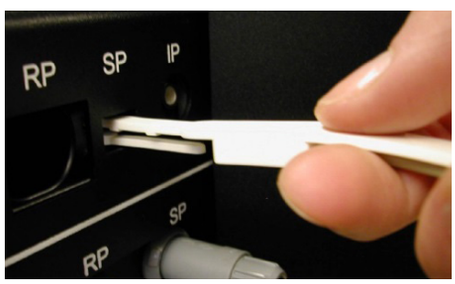
1. Before calibration, check the front face of the probe and the probe cable for cracks or damage. Discard the probe if it is damaged in any way.
2. Connect the probe to be calibrated to the CoreTherm / SE control unit.



3. Only one probe of the same type can be calibrated at a time. Place the probe/s to be calibrated in the corresponding reference temperature chamber.



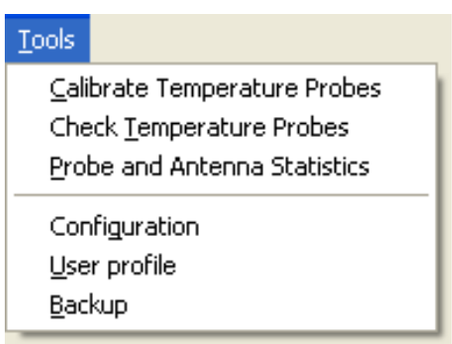
4. When placing the intraprostatic temperature probe, make sure to insert it all the way.
5. When placing the rectal temperature probe, the handle should point upwards. Make sure to insert the probe all the way.
6. When placing the penis safety probe, the strap must be folded. The sensor side should be at the top. Make sure to insert the probe all the way.



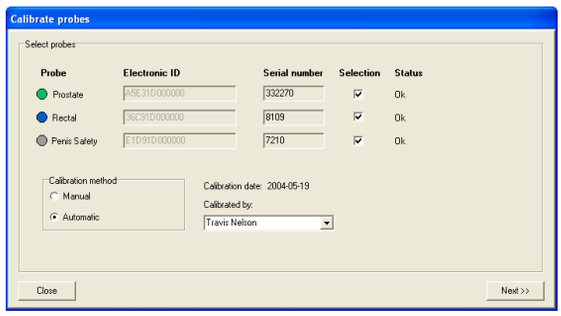
7. It is important that the probes remain in the reference temperature chamber during the entire calibration procedure.

Warning - Hot Surfaces

8. From the Tools Menu on the CoreTherm Software Page, choose Calibrate Temperature Probes.



The Calibrate Probes dialog opens, displaying the Select probes frame.



CoreTherm System

The Status field does not appear in CoreTherm System.

The electronic identification (EID) is used by the computer to identify the connected probe by the software. The EID is generated by a built-in electronic circuit in the probe connector, and displayed in the corresponding Electronic ID field as follows:

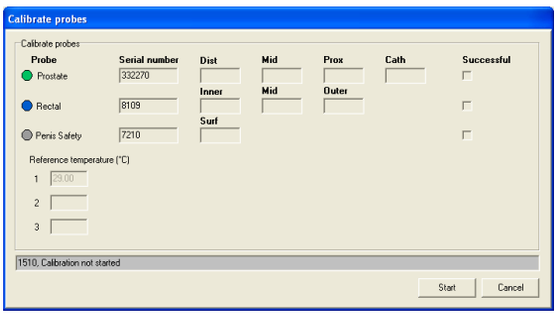
- the Electronic ID field is filled automatically for connected probes
- if a probe is damaged or not properly connected, the reason is indicated in the Status field

CoreTherm System

If a probe is damaged or not properly connected the legend NC is displayed in the Electronic ID field.

- if a connected probe has been calibrated before, its serial number is displayed in the Serial number field
- if the connected probe has not been calibrated before, the serial number field is left blank.

9. If the connected probe has not been calibrated before, type the probe's serial number into the Serial number field.
10. Confirm that the probe(s) to be calibrated are marked in the corresponding Selection checkbox.
11. In the Calibration method frame, activate the Automatic button.
12. Choose your name from the Calibrated by drop-down list or type your name into the field.
13. Click on Next to continue. The Calibrate Probes dialog displays the Calibrate probes frame for an automatic calibration.



CoreTherm System

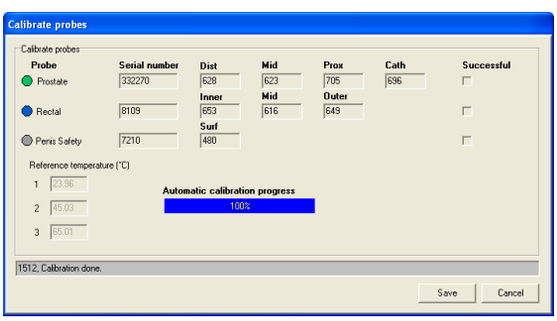
The Successful check box is named Done in CoreTherm System.

14. Click on Start.

    NOTE: The calibration procedure starts only if the temperature of the calibration oven is within the range 15°C to 30°C.

Automatic probe calibration commences, and:

- while the calibration is running, a bar indicates the progress of the calibration
- during calibration, the reference temperatures are automatically filled in the corresponding fields
- when automatic calibration is finished, the message field at the bottom of the Calibrate Probes dialog shows the message 1512, Calibration done.



15. When the automatic calibration is successfully concluded, click on Save to store the new calibration constants. A message confirming that the new calibration constants have been saved is displayed in the message field at the bottom of the Calibrate Probes dialog. The Successful/ Done box for each probe is checked, which shows that the calibration has been successful. It is recommended that the Check probes procedure is performed after calibration. See Checking the temperature probes.

Automatically Calibrating More Probes

To calibrate other probes automatically:

1. Disconnect the calibrated/checked probe(s) from the CoreTherm / SE control unit.
2. Connect the next probe(s) to be checked/ calibrated to the control unit.
3. Repeat the calibration procedure given in steps 3 to 15 above.

Manual Calibration

The rectal temperature probe and the penis safety probe should be calibrated at three temperatures between 20°C and 60°C (for example 20°C, 35°C and 50°C).

CoreTherm SE System

The intraprostatic temperature probe should be calibrated at three temperatures between 20°C and 70°C (for example 25°C, 45°C and 65°C).

NOTE: The three reference temperatures, T1, T2 and T3 have to be within the following ranges:

$15°C \leq T1 \leq 30°C$

$30°C < T2 < 70°C$,

$0°C < T2 < T3 \leq 70°C$.

The rectal temperature probe and the penis safety probe can be calibrated together. It is recommended that the intraprostatic temperature probe should be calibrated separately.

Preparing for Manual Calibration

1. Connect the probe(s) to be calibrated to the control unit of the CoreTherm / SE System.
2. Prepare three insulated flasks with water samples, each at a different temperature depending on the probe(s) to be calibrated. Ensure that the water level in each flask is sufficient to entirely immerse all the sensors of the respective probe.

It is important to use a calibrated reference thermometer and that correct temperature is entered into the Reference Temperature field.

Calibrating a Probe Manually

1. Before calibration, check the front face and cable of each probe for cracks or damage. Discard the probe if it is damaged in any way.
2. From the Tools Menu on the CoreTherm Software Page, choose

Calibrate Temperature Probes

The Calibrate Probes dialog opens, displaying the Select probes frame as shown previously:

- the Electronic ID field is filled automatically for connected probes

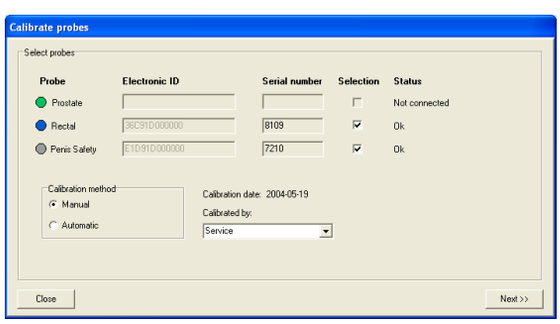
- if a probe is damaged or not properly connected, a message is displayed in the Status field

CoreTherm SE System

If a probe is damaged or not properly connected, the legend NC is displayed in the Electronic ID field.

- if a connected probe has been calibrated before, its serial number is displayed in the Serial number field
- if the connected probe has not been calibrated before, the field is left blank.

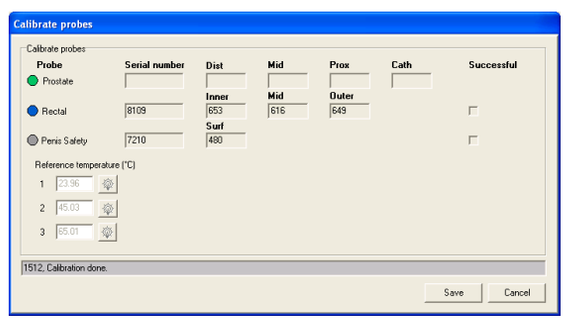
3. If the connected probe has not been calibrated before, type the probe's serial number into the Serial number field.
4. Confirm that the probe(s) to be calibrated are marked in the corresponding Selection checkbox.
5. In the Calibration Method field, choose Manual.
6. Type your name into the Calibrated by field or choose your name from the drop-down list.
7. Click on Next. The Calibrate Probes dialog displays the Calibrated Probes frame for a manual calibration.



CoreTherm System

The Successful check box is named Done in CoreTherm System.

8. Click on Start.
9. Use the thermos flask that has been filled with the prepared water sample of the lowest temperature.
10. Stir the water well. Then place a calibrated reference thermometer and the probe(s) to be calibrated into the water. If a rectal temperature probe is to be calibrated, protect it with a condom before placing the probe in the water.
11. If a rectal and/or penis safety probe is being calibrated, wait 15 minutes for the probe(s) to reach the temperature of the water in the thermos flask. If an intraprostatic temperature probe is being calibrated, wait 1 minute for the probe to reach the temperature of the water in the thermos flask. It is important that the probes are kept in the thermos flask the time intervals mentioned above, in order for the sensors to equilibrate with the water temperature.
12. Read the water temperature as measured by the reference thermometer. Enter this value in Reference Temperature field 1 and click on the adjacent button.
13. Change the thermos flask and repeat steps 7 to 9 above. Enter the temperature of each water sample into Reference Temperature fields 2 and 3 respectively.



14. When you have obtained and entered all three measured temperature values, click on Save. It is recommended that the Check probes procedure is performed after calibration. See Checking the temperature probes.

Calibrating More Probes

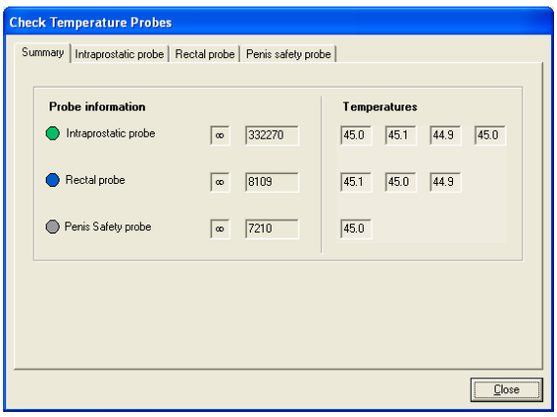
To calibrate other probes:

1. Disconnect the calibrated/checked probe(s) from the CoreTherm / SE control unit.
2. Connect the next probe(s) to be checked/ calibrated to the control unit.
3. Repeat the calibration procedure given in steps 3 to 16 above.

Checking the Temperature Probes

The temperature probes can be checked by using the Check Temperature Probes function. It is recommended that the temperature probes are checked at frequent intervals (every week) to ensure that they are operating correctly.

The Check Temperature Probes opens with the Summary tab displayed. Additional information can be found under the tab for each probe.



CoreTherm System

The Check Temperature Probes dialog contains only the information in the Summary tab. No other tabs are available.

The detailed tab for each probe holds the following information:

- Electronic identification (unique number for system identification)
- Serial number (serial number of the probe)
- Status (Connected, Not connected, Not calibrated, Error, Expired)
- Temperatures for the respective sensors
- Type (Unlimited, Limited lifetime, Reusable after calibration)
- Number of treatments left
- Last calibration date
- Calibration LOT (applicable for factory calibrated probes only)
- Calibrated by (as entered in the calibration dialog)
- Calibration method (Manual, Automatic, Factory)
- Total number of treatments
- Total number of treatments since last calibration

NOTE: To verify that the probes are properly calibrated, the check should be performed for at least two, and preferably three, different temperatures.

1. Connect the probe(s) to be checked to the CoreTherm / SE control unit.

2. Prepare two or three thermos flasks with water samples.

   NOTE: The check should be done between 20°C and 65°C.

   Examples:

   Two water samples:

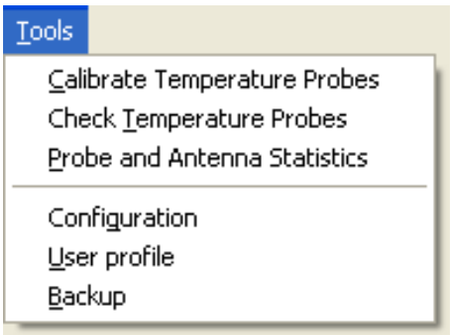
   approx. 30°C and 50°C.

   Three water samples: approx. 25°C, 45°C and 65°C.

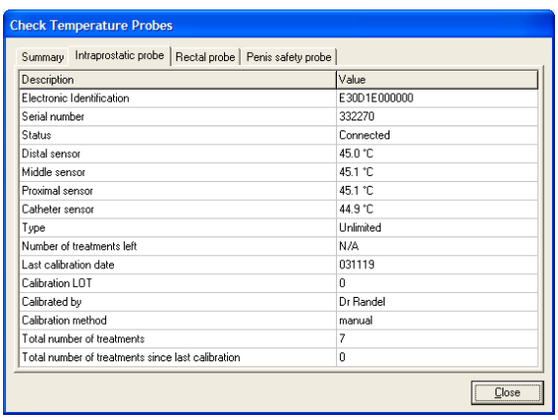
   It is important to use a calibrated reference thermometer.

3. From the Tools Menu on the CoreTherm software page, choose

Check Temperature Probes



The Check Temperature Probes dialog opens.



1. Temperatures are registered and displayed continuously until the probe is disconnected from the CoreTherm / SE control unit or until you click the Close button.

2. Use one of the prepared water samples.

3. Stir the water well. Then place the reference thermometer and the probe(s) to be checked into the water. If a rectal temperature probe is to be checked, protect it with a condom before placing the probe in the water.

4. If a rectal temperature probe is being checked, wait until the temperature displayed in the Check Temperature Probes dialog has stabilized (it takes approx. 15 minutes for the probe to reach the temperature of the water in the insulated flask). If a penis safety probe is being checked, wait until the temperature displayed in the Check Temperature Probes dialog has stabilized (it takes approx. 10 minutes for the probe to reach the temperature of the water in the insulated flask). If an intraprostatic temperature probe is being checked, wait until the temperature displayed in the Check Temperature Probes

dialog has stabilized (it takes approx. 1 minute for the probe to reach the temperature of the water in the thermos flask).

It is important that the probes are kept in the thermos flask during the time intervals mentioned above, in order for the sensors to equilibrate with the water temperature.

5. Read the water temperature as measured by the reference thermometer and compare it with the measurement displayed in the Check Temperature Probes dialog. The displayed temperatures should be within +/- 1°C compared to the reference thermometer.

   It is important to use a calibrated reference thermometer.

6. Repeat the procedure with the next water sample.

You can disconnect any probe from the CoreTherm / SE control unit and connect a new probe without closing the Check Temperature Probes dialog. The temperature of the new probe is displayed automatically when it is connected.

30. PROBE AND ANTENNA STATISTICS

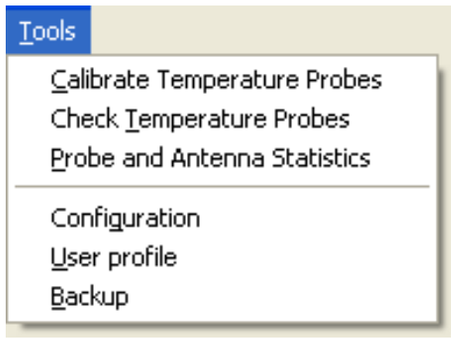
The CoreTherm software includes a Probe and Antenna Statistics function that allows you to view the history of a temperature probe or microwave antenna. You can see:

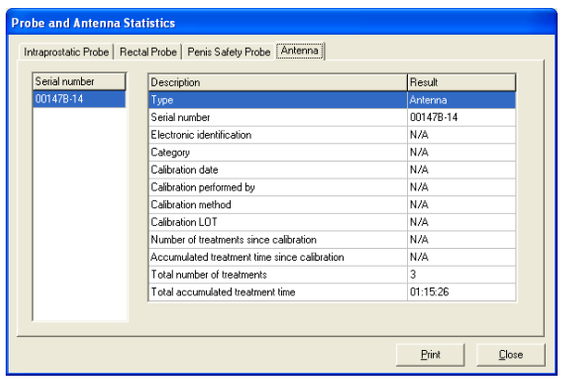
- the last date of calibration (not applicable to antenna)
- who performed the calibration (not applicable to antenna)
- the calibration method (not applicable to antenna)
- the accumulated treatment time since the last calibration (not applicable to antenna)
- the number of treatments since the last calibration (not applicable to antenna)
- the total accumulated treatment time of the probe/antenna
- the total number of treatments that the probe/antenna has performed
- the serial number of the probe/antenna

CoreTherm SE System

- Calibration LOT (not applicable to antenna);
- Category (Unlimited, Reusable after calibration, Limited lifetime).

1. From the Tools Menu on the CoreTherm Software page, choose Probe and Antenna Statistics. The Probe and Antenna Statistics dialog opens.





2. Click on the tab corresponding to the type of probe/antenna about which you require information:

   Intraprostatic probe

   Rectal probe

   Penis Safety probe

   Antenna

3. From the serial number list, choose the serial number of the particular probe or antenna about which you require information. Only probes/antenna that have already been used (and thus registered in the CoreTherm software database), appear in the list.

   The information about the selected probe or antenna is displayed automatically in the Description and Result columns.

4. To print the information, click on the Print button.

NOTE: It is not necessary to connect the probe or antenna to the control unit of the CoreTherm / SE System. The information is retrieved from the CoreTherm software.

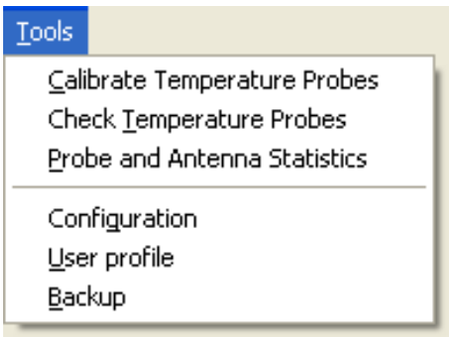
31. USER PROFILES AND PASSWORDS

User Profiles

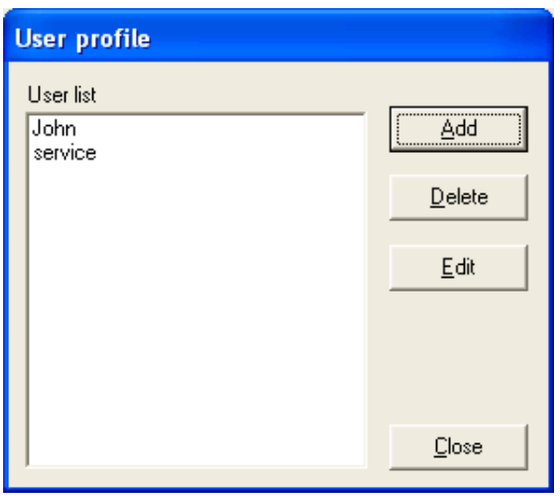
When you log in to the CoreTherm software, you are required to enter a unique username and password.

These are stored by the software as part of your User Profile. User profiles can be added, edited or deleted.

1. From the Tools Menu on the CoreTherm Software page, choose User profile.



The User Profile dialog opens.



Adding a User Profile

1. Click on the Add button.
2. Type a Username and Password for the new user profile. The password must be entered twice as confirmation, since each password character is masked with an asterisk (*).

Editing a User Profile

1. From the User Profile list, choose the user profile that you want to change. Then click on Edit.
2. Amend the Username and/or Password.
3. Click on Save to store the new settings. The password must be entered twice in confirmation.

Deleting a User Profile

1. From the User Profile list, choose the user profile that you want to delete.
2. Click on Delete. You are prompted to confirm that the selected User Profile is to be deleted.

NOTE: The present User Profile (as used to log in to the CoreTherm program), cannot be deleted.

Passwords

If you forget your password, there are two options:

- your authorized service representative can retrieve your password
- in exceptional circumstances you can use a common password to obtain restricted access to the CoreTherm software.

Retrieving a Password

1. With the Login dialog open, type your username into the Username field.
2. Click on the Forgot Password? button. The CoreTherm software displays a code.
3. Call your authorized service representative. The service personnel will use the code to retrieve your password.

Using the Common Password

There may be circumstances when a treatment must be performed, even if a valid password is not available or cannot be retrieved in time. In this event:

1. With the Login dialog open, type the word prostalund into the Username field. Leave the Password field blank.

NOTE: The word prostalund must be typed without upper-case letters. It is case-sensitive. A restricted log in procedure takes place, after which, only the Treatment command in the PLFT Menu is enabled on the CoreTherm Software page.

2. Choose the Treatment command.
   The Add Patient dialog opens, allowing you to register the patient. Thereafter the Treatment Settings dialog and the Treatment Page can be accessed. When the treatment is finished, you are automatically logged out.

   This facility gives access to the treatment function only. To maintain patient integrity, you cannot gain access to the Patient List page or any other function.

Equipment Failure

If you believe the correct function or operating safety of the CoreTherm / SE System is impaired in any way, disconnect it from the mains electrical supply and secure it against further use. Do not remove the instrument cover. Contact your authorized service representative or hospital technician.

32. ERROR/MESSAGES BEFORE SETUP OF THE TREATMENT

Error messages may appear during set up of treatment.

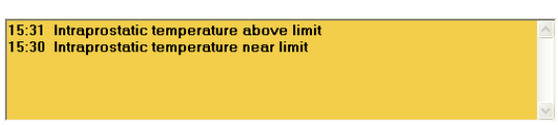
The possible error messages and appropriate operator actions are listed in the following tables

Accessories	
Text	**Action**
Error: You need to close all other applications in order to run this program.	Close all other applications and restart CoreTherm SE.
Error: This ID already exists and belongs to Last name X First name X ID X Proceed to treatment for this patient?	Choose new ID or continue treatment with pro- posed patient.
Unknown user	Enter a correct username (N.B. usernames are case sensitive).
Wrong password	Enter a correct password (N.B. passwords are case sensitive).
Error: Check prostate length	Enter a correct prostate length.
Error: Check prostate weight	Enter a correct prostate weight.
Error: Check operator name	Enter a correct operator name.
Error: Check antenna serial number	Enter a correct antenna serial number.
Error: The S.A.R of the antenna cannot be found in the database table.	Enter a correct serial number for an antenna supported by the system. If the problem persists, contact your authorized service representative
Error: Check catheter number alternatively Error: Check catheter number (used YYYY-MM-DD)	Enter a correct catheter number.
Warning: The prostate length and/or weight are below recommended limits.	Make sure the length and weight are entered correctly
Error: You cannot delete the profile you currently use!	Log in with another user profile to delete the pro- file currently in use.
Error: Select the user profile to edit.	Select a profile and click on edit/delete.
Error: The username must be at least 4 characters.	Enter a valid username.

Accessories	
Text	**Action**
“prostalund” is a reserved word and cannot be used.	Enter a valid username not equal to ‘prostalund’.
The password must be at least 4 characters.	Enter a valid password.
Password strings not identical.	Enter a valid password confirmation.
Password can only contain characters of ‘’a- z’’,’’A-Z’’,’’0-9’’’	Enter a valid password.
Error: Check IP serial number	Enter a correct IP serial number
Error: No IP Connected	The IP is not connected or not recognized by the software.
Error: Accessory mismatch	The accessories chosen are mixed (i.e. the user is combining accessories for treating standard size prostates with accessories for treating small prostates)
Prostate weight is below recommended limit	The entered weight of the prostate is less than the recommended value for the treatment.
Prostate weight is below recommended limit for selected accessories	The entered weight of the prostate is less than the recommended value for the current accessories.
Prostate length is below recommended limit	The entered length of the prostate is less than the recommended value for the treatment.
Prostate length is below recommended limit for selected accessories	The entered length of the prostate is less than the recommended value for the current accessories.
Prostate weight is above recommended limit for selected accessories	The entered weight of the prostate is higher than the recommended value for the current accessories.

Error/Warning Messages During Treatment

Error messages may appear during treatment. An example is shown below.



Temperatures Above Safety Limits	
Text	**Action**
Intraprostatic temperature above limit	The intraprostatic temperature has exceeded the preset limit (60°C unless changed by the operator). The microwave power is shut off and the treatment is paused. Find the cause of the excessive temperature and check the position of the intrapros-tatic temperature probe. If no hazard exists, restart the treatment when the intraprostatic temperature has decreased below the temperature limit. Always decrease the microwave power when restarting the treatment.
Rectal temperature above limit	The rectal temperature has exceeded the preset limit (43°C unless changed by the operator). The microwave power is shut off and the treatment is paused. Find the cause of the excessive temperature and check the position of the rectal temperature probe. If no hazard exists, restart the treatment when the rectal temperature has decreased below the temperature limit. Always decrease the microwave power when restarting the treatment.
Penis safety temperature above limit	The penis safety temperature has exceeded the preset limit (40°C unless changed by the operator). The microwave power is shut off and the treatment is paused. Find the cause of the excessive temperature and check the position of the penis safety probe, the CoreTherm catheter and the microwave antenna. Also check the circulation system and the water level. If no hazard exists, restart the treatment when the penis temperature has decreased below the temperature limit. Always decrease the microwave power when restarting the treatment.
Catheter temperature above limit	The temperature of the circulating water has exceeded the preset limit (40°C unless changed by the operator). The microwave power is shut off and the treatment is paused. Find the cause of the excessive temperature. Al- ways check the circulation system, the water level and the connection of the microwave antenna to the CoreTherm catheter. If no hazard exists, restart the treatment when the temperature of the circulating water has decreased below the temperature limit. Always decrease the microwave power when restarting the treatment.

Temperatures Close to Safety Limits

Text	Action
Intraprostatic temperature near limit	This warning message is displayed if the temperature is within 1 degree of the maximum preset intraprostatic temperature. The treatment continues. Decrease the microwave power to prevent pausing the treatment.
Rectal temperature near limit	This warning message is displayed if the temperature is within 1 degree of the maximum preset rectal temperature. The treatment continues. Decrease the microwave power to prevent pausing the treatment.
Penis safety temperature near limit	This warning message is displayed if the temperature is within 1 degree of the maximum preset penis safety temperature. The treatment continues. Decrease the microwave power. Check the position of the penis safety probe, the CoreTherm catheter and the microwave antenna. Also check the circulation system and the water level.
Catheter temperature near limit	This warning message is displayed if the temperature in the circulating water is within 1 degree of the maximum preset CoreTherm catheter temperature. The treatment continues. Decrease the microwave power. Check the circulation system, the water level, and the connection of the microwave antenna to the CoreTherm catheter.

Missing Probes

Text	Action
Intraprostatic temperature probe not connected	There is no intraprostatic temperature probe connected to the CoreTherm / SE control unit, or the probe is broken. Re-insert or replace the intraprostatic temperature probe.
Rectal temperature probe not connected	There is no rectal temperature probe connected to the CoreTherm / SE control unit, or the probe is broken. Reinsert or replace the rectal temperature probe.
Penis safety probe not connected	There is no penis safety probe connected to the CoreTherm / SE control unit, or the probe is broken. Reinsert or replace the penis safety probe.

Probes Not Calibrated

Text	Action
Intraprostatic temperature probe not calibrated	The intraprostatic temperature probe connected to the CoreTherm / SE control unit is not calibrated. Replace with a properly calibrated intraprostatic temperature probe. See Calibrating the Temperature Probes.
Rectal temperature probe not calibrated	The rectal temperature probe connected to the CoreTherm / SE control unit is not calibrated. Replace with a properly calibrated rectal temperature probe. See Calibrating the Temperature Probes.
Penis safety probe not calibrated	The penis safety probe connected to the CoreTherm / SE control unit is not calibrated. Replace with a properly calibrated penis safety probe. See Calibrating the Temperature Probes.

Probe Expiration

Text	Action
Intraprostatic temperature probe expired	The intraprostatic temperature probe connected to the CoreTherm / SE control unit has expired. Replace with a properly calibrated intraprostatic temperature probe.
Rectal temperature probe expired	The rectal temperature probe connected to the CoreTherm / SE control unit has expired. Replace with a properly calibrated rectal temperature probe.
Penis safety probe expired	The penis safety probe connected to the CoreTherm / SE control unit has expired. Replace with a properly calibrated penis safety probe.

Temperatures Out of Range

Text	Action
Intraprostatic temperature out of range	The intraprostatic temperature probe connected to the CoreTherm / SE control unit is measuring unphysiological temperatures. This may indicate that the probe is broken. It is not possible to start or continue a treatment. Replace with a properly calibrated, intact intraprostatic temperature probe.
Rectal temperature out of range	The rectal temperature probe connected to the CoreTherm / SE control unit is measuring unphysiological temperatures. This may indicate that the probe is broken. It is not possible to start or continue a treatment. Replace with a properly calibrated, intact rectal temperature probe.
Penis safety temperature out of range	The penis safety probe connected to the CoreTherm / SE control unit is measuring unphysiological temperatures. This may indicate that the probe is broken. It is not possible to start or continue a treatment. Replace with a properly calibrated, intact penis safety probe.

Miscellaneous Error Messages	
Text	**Action**
Pump house open	The pump housing is open. The treatment is paused. Check the pump housing.
Pump speed out of range	The water pump is rotating too slowly or detecting an illogical high value. The treatment is paused. Check that the water tube is properly mounted in the pump housing.
Too high reflected power	Adjust the stub tuner (on the Stub Tuner panel) to reduce the reflected power. If reflected power cannot be reduced, or if it is difficult to reduce, this may indicate that the microwave antenna is defective and must not be used.
Operating time exceeded	The system has been in treatment mode for too long (>150 minutes). The system is set to idle mode.
Treatment time exceeded	The treatment time has exceeded the preset effective treatment time, or the maximal treatment time (70 minutes). The treatment is stopped. If desired, try to prolong the effective treatment time by using the Setup Panel on the Treatment Page.
Power meter discrepancy	The internal power meter is not operating properly. The treatment is stopped. The CoreTherm / SE control unit needs service. Please contact your authorized service representative.
Power readings out of range	The internal power meter is measuring illogical power levels. The treatment is stopped. The CoreTherm / SE control unit needs service. Please contact your authorized service representative.
Heat exchanger temperature out of range	The heat exchanger is overloaded. Please contact your authorized service representative.
Internal error, system communication	Internal hardware failure. The treatment is aborted. If the message recurs repeatedly, it indicates that the CoreTherm / SE control unit needs service. Please contact your authorized service representative.
Internal error, system reset	Internal hardware failure. The treatment is aborted. If the message recurs repeatedly, it indicates that the CoreTherm / SE control unit needs service. Please contact your authorized service representative.
Communication error	Communication failure. The treatment is aborted. Check that the computer is properly connected to the CoreTherm / SE control unit.

In addition to the faults listed above, the Operating System can issue fault messages if a hardware or software error is detected by the operating system. If this occurs, treatment is shut down within 30 seconds.

A history of error messages that have occurred during treatment can be seen in the Log List on the Treatment Page.

Error/Warning Messages During Maintaining Your System	
Text	**Action**
Error: Calibration file not found. Load default values?	Message given when an automatic calibration is chosen (user presses ‘next’) and the file containing regulation parameters for the calibration oven cannot be found. Press yes to load the default values.
Error: Error in reading time constants. Load default values?	Message given when an automatic calibration is chosen (user presses ‘next’) and the file containing regulation parameters for the calibration oven contains time constants that cannot be converted. Press yes to load the default values.
Error: Error in reading reference temperatures. Load default values?	Message given when an automatic calibration is chosen (user presses ‘next’) and the file containing regulation parameters for the calibration oven contains reference temperatures that cannot be converted. Press yes to load the default values.
Error: Error in reading regulation parameters. Load default values?	Message given when an automatic calibration is chosen (user presses ‘next’) and the file containing regulation parameters for the calibration oven contains regulation parameters that cannot be converted. Press yes to load the default values.
Error: Value in calibration file out of range. Load default values?	Message given when an automatic calibration is chosen (user presses ‘next’) and the file containing regulation parameters for the calibration contains parameters out of range. Press yes to load the default values.
Value out of range	Enter reference temperatures that comply: 15°C ≤ T1≤ 30°C< T2 < T3 ≤ 70°C.
No valid probes left to calibrate. Calibration aborted.	Reperform calibration. Check probe(s) functionality.
Oven temperature too high	If this message is displayed repeatedly during the calibration procedure, this may indicate that the calibration oven is defective. Please contact your authorized service representative.
Exception raised during calculations! Please abort.	Reperform calibration.
Error while opening the log files. Calibration aborted.	Restart application and then reperform calibration. If failure persists, contact your authorized service representative
Internal error, system reset. Calibration aborted	Restart device and computer. Reperform calibration.
Oven timeout. Calibration aborted.	Restart device and computer. Reperform calibration.
Calibration error. Please check the user manual.	Reperform calibration.
Insufficient disk capacity	The user can try again with another media/drive or contact the company service representative if the error remains.

Error/Warning Messages During Maintaining Your System	
Text	**Action**
Incomplete backup	Try performing the backup again. If the problem persists, please contact your authorized service representative.
Calibration error. Please check the user manual	Try saving again. If this doesn't solve the problem, try recalibrating the probe. Make sure that the probe is not defect. If the problem persists, please contact your authorized service representative.

Other Error/Warning Messages	
Text	**Action**
Error: Incompatible Controller version	Contact your authorized service representative
Error: Database error	Contact your authorized service representative
Error: Database integrity error, treatment function disabled	Contact your authorized service representative
This program has been modified and its execution will abort immediately.	Contact your authorized service representative
Error: Error, BMP file not found.	Contact your authorized service representative

33. ORDERING INFORMATION

Device	Article Number
CoreTherm Catheter	CA 804220 (standard) CA 804120 (short)
Microwave Antenna	AN 806001 (standard) AN 806101 (short)
Intraprostatic temperature Probe	IP 807015 (Autoclavable standard) IP 807115 (Autoclavable short)
Rectal temperature Probe	RP 809601
Penis Safety Probe	SP 808601

Contact Information

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Medical Device CE 0123

34. SYMBOLS

The following symbols are used to label the CoreTherm / SE System with accessories

CoreTherm/SE

Symbols Electrical safety

Symbol	Description
	Read instructions for use before starting to use device
	Consult the instruction for use for important cautionary information such as warnings and precaution.
	Manufacturer
	Type BF applied part
	Protective earth (ground)
	Equipotentiality
	Non-ionizing radiation
	Trapping hazard when closing the drawer
	Hot surface
	Product should not be disposed of with other household waste

Symbols for Accessories

Symbol	Description
	Read Instructions For Use
	Indicates the date when the medical device was manufactured
	Date of expiry
	Sterilized by Ethylene oxide
	Article Number
	Serial Number
	Temperature limits
	Range of humidity
	Do not use if the product sterile barrier system or its packaging is compromised
	Do not re-use. Single use device
	Batch number

Disposal

At the end of the product life the CoreTherm / SE system must be disposed in compliance with your local waste control regulations. Pay extra attention to electronic component regulations. Reuse components or recycle components as far as possible. Hint: Save the packaging for future use (e.g. when sending the device for service).

Material

The different materials must be separated and recycled.

- The CoreTherm / SE system does not contain any hazardous materials.
- The majority of the metal parts with the exception of electric and electronic components are made of stainless steel. Some parts of the calibration oven and the cooling system are made out of aluminum.
- The Laptop and the printer should be handled as electronic waste
- The Cover is made out of PVC
- Packaging: Plywood and Ethafoam

Scrapping the System

When you want to scrap your CoreTherm / SE system, please inform ProstaLund who wants to update the status of the system in the service file. ProstaLund is willing to take care of your system at a certain fee when it is ready to be scrapped.

35. TECHNICAL SPECIFICATIONS

This chapter contains technical specification for CoreTherm / SE System.

CoreTherm / SE System - General Specifications	
Operating Temperature Range	+10°C to +30°C (+50°F to +86°F)
Storage Temperature Range	+5°C to +40°C (+41°F to +104°F)
Operating Relative Humidity range (non-condensing)	30% to 75%
Storage Relative Humidity range (non-condensing)	30% to 75%
Maximum operating altitude	2000m
Mains Supply Voltages	100 V to 120 V at 50 Hz or 60 Hz 220 V to 240 V at 50 Hz
Fuses	2 x 10 A, slow blow (100 V to 120 V) 2 x 5 A, slow blow (220 V to 240 V)
Power Consumption	700 VA
Power Output	0 W to 80 W
Operating Frequency	915 MHz
Matched Load	50 ohms
Dimensions	Height 922 mm Depth 453 mm Width 605 mm Width with the pull out drawer out 735 mm
Weight	100kg (220lb) CoreTherm 82kg (180lb) CoreTherm SE

Protection Against Electrical Shock

In accordance with IEC 60601-1, Class 1, Type BF equipment. Applied parts - protection against electrical shock in accordance with IEC 60601-1.

Electromagnetic Compatibility (EMC) and Stray Radiation

The CoreTherm SE System complies with the requirements of the publication IEC 60601-1-2:2001, with the exception of the 915 MHz frequency, which is the operating frequency of the unit. In region 2 (including USA), 915 MHz is an unrestricted frequency. The CoreTherm SE System has been tested according to IEC 60601-1-2:2001, CISPR11 with regards to electromagnetic compatibility. Furthermore, the CoreTherm SE System has been tested according to IEC 60601-1-2:2001, IEC 60601-2-6 and IEEE C95.1 (ANSI):1999 with regards to stray radiation. The compliance to various test variables is reported in tables 1-4 below.

Installation and operation

The following warnings should be considered prior to installation and operation of the CoreTherm SE System.

- **Warning**: The CoreTherm SE System may disturb other medical devices. In order to minimize the risk to disturb other equipment in the surrounding, a separation distance of at least 1 meter from the CoreTherm SE System including cables should be maintained.
- **Warning**: Portable and mobile RF communications equipment can affect the CoreTherm SE System.
- **Warning**: Usage of replacement parts not supplied by ProstaLund for internal components may result in increased emissions and decreased immunity of the CoreTherm SE System.
- **Warning**: The CoreTherm SE System shall not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the CoreTherm SE System shall be observed to verify normal operation in the configuration in which it is use.
- **Warning**: The usage of other accessories and cables than those stated in the instructions for use and provided by ProstaLund may result in increased emissions or decreased immunity of the CoreTherm SE System.

The Coretherm / SE has been tested with respect to electromagnetic phenomena representative to the environment in a professional healthcare environment. It is however possible that the Coretherm/SE temperature and power measurements can be affected by external disturbances. At all-time the device should be observed to verify normal operation.

Any incident of EMI should be reported to the manufacturer.

The following warnings should be considered prior to installation and operation of the CoreTherm SE System.

Guidance and manufacturer's declaration - electromagnetic emissions

The CoreTherm SE system is intended for use in the electromagnetic environment specified below. The customer or the user of the CoreTherm SE system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The CoreTherm SE system must emit electromagnetic energy in or- der to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The CoreTherm SE system is suitable for use in all establish- ments, including domestic establishments and those directly connected to the public low-voltage power supply
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity

The CoreTherm SE system is intended for use in the electromagnetic environment specified below. The customer or the user of the CoreTherm SE system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV mains plug input/output lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Line to line: ±1 kV Line to ground: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4- 11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles T 70 % UT (30% dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	0 VAC (100 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles 0 VAC (100 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CoreTherm SE system requires continued operation during power mains interruptions, it is recommended that the CoreTherm SE system be powered from anz uninterruptible power supply or a battery.

Guidance and manufacturer's declaration - electromagnetic immunity

The CoreTherm SE system is intended for use in the electromagnetic environment specified below. The customer or the user of the CoreTherm SE system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The CoreTherm SE system is intended for use in the electromagnetic environment specified below. The customer or the user of the CoreTherm SE system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000- 4-6 Radiated RF IEC 61000- 4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CoreTherm SE system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2√P d = 1.2√P 80MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and manufacturer's declaration - electromagnetic immunity

The CoreTherm SE system is intended for use in the electromagnetic environment specified below. The customer or the user of the CoreTherm SE system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CoreTherm SE System SE system is used exceeds the applicable RF compliance level above, the CoreTherm SE System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CoreTherm SE System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the CoreTherm SE System SE unit

The CoreTherm SE System SE system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CoreTherm SE System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the CoreTherm SE System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

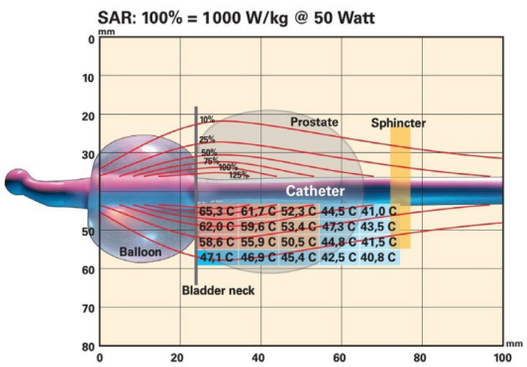
NOTE: The output power from mobile telephones is typically 1W.

Protection Against Water Ingress

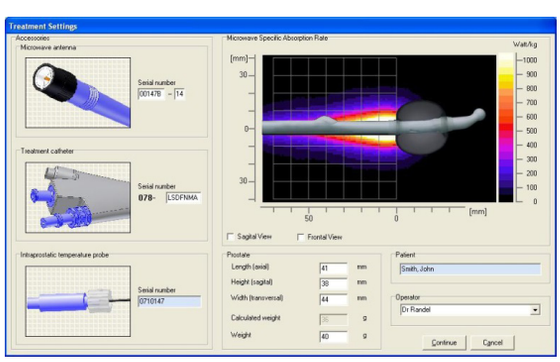
IP20, ordinary equipment without protection against water ingress.

SAR distribution for the CoreTherm / SE System

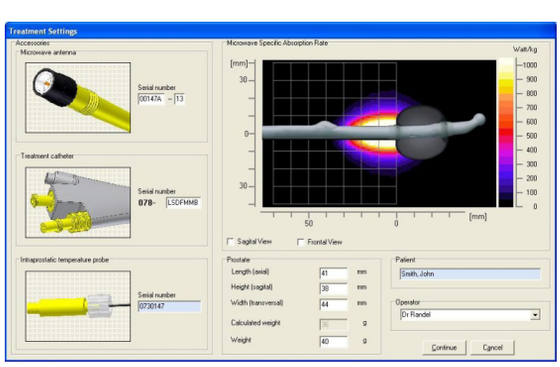
The Specific Absorption Rate (SAR) distribution, expressed as W/kg, for the CoreTherm / SE System antenna and catheter is shown in the figure below.



The figure shows the iso-contours 10%, 25%, 50%, 75%, 100% and 125%, where the 100% iso-contour corresponds to a SAR value of 1000 W/kg when 50 Watt microwave power is applied. The SAR distribution is also displayed in the Treatment Settings dialog in the CoreTherm software as shown below.



Display for standard accessory set.



Display for accessory set for small prostates.

In the Treatment Settings dialog, the SAR iso-contours are illustrated by colors. The purpose of the SAR image in the Treatment Settings dialog is to give the operator an understanding of the relation between the SAR distribution and the size of the prostate.

36. ELECTRICAL SAFETY

The CoreTherm / SE System has been designed in accordance with IEC publication 601-1 (Medical Electrical Equipment). You must ensure that the following electrical safety requirements are observed

Installation

The CoreTherm / SE System must be installed and tested prior to use by suitably qualified personnel.

Mains Power Supply

Ensure that the mains voltage indicated by the label on the side of the CoreTherm / SE System matches the available mains supply voltage.

Use only the mains electrical power cable supplied with the CoreTherm / SE System. This cable must be fitted with a hospital approved three-pole mains plug which has a protective ground conductor. Never use an extension cable with the mains electrical power cable. The length of the extended cable increases the resistance of the protective ground conductor beyond an acceptable level. Always keep power cables, sockets and plugs clean and dry.

Grounding

The equipment must be connected only to an AC power supply which has a protective ground conductor in accordance with IEC requirements or applicable local regulations. The grounding system in the treatment area should be checked regularly by a qualified engineer or hospital safety personnel.

Any interruption of the protective earth conductor inside or outside the equipment, or disconnection of the protective earth terminal, is likely to make the apparatus dangerous. Intentional interruption is prohibited. The protective earth (ground) conductor must be checked regularly.

Leakage Current

When more than one apparatus is connected to a patient, attention must be paid to the summation of leakage currents. Whenever it is likely that the protection has been impaired, the CoreTherm / SE System must be made inoperative and secured against inadvertent operation. The protection is likely to be impaired if, for example, the apparatus:

- shows visible damage
- fails to perform the intended treatments
- has been subjected to prolonged storage under unfavorable conditions
- has been subjected to severe transport stress

Connecting Other Equipment

Do not connect a printer or other external electrical equipment to the CoreTherm / SE System during treatment, as this may compromise the electrical insulation of the patient from the mains electrical supply. A printer or other external equipment must be connected only when the laptop is disconnected from the CoreTherm / SE System and placed on a desk.

Service and Repair

The CoreTherm / SE System must be disconnected from all electrical sources before it is opened for any adjustment, replacement, maintenance and/or repair. Except for work to be performed by the operator as described in this manual, all service must be performed by ProstaLund AB or its authorized representatives.

ProstaLund AB reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by non-authorized parties. After repair, the safety of all equipment should be verified by a qualified electronics engineer or hospital technician.

Fuses

Make sure that only fuses with the required rated current and of the specified type are used for replacement. The use of makeshift fuses and short-circuiting of fuse holders are prohibited. See Fuses.

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CoreTherm

EVIDENCE-BASED TREATMENT FOR BPH