Exablate

Exablate 2100V1

Prostate System

Operator's Manual

Software Version 8.1

INSIGHTEC

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REVISION INFORMATION

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This is the **Revision 1** release of the Exablate Prostate Operator's Manual for Software Version 8.1, applicable for 1.5- and 3-Tesla MR system(s). Contact INSIGHTEC Marketing Support to determine if this is the most current release of this operator's manual.

Each page of this manual has a chapter revision level and date at the bottom. This indicates the release level and date for the individual chapters. Note that when the manual is updated, not all of the chapters are necessarily updated, so some chapters may have a revision level earlier than the release revision level for the manual (the revision level designation for the manual is that which appears on the top of the second page of this manual). The following table provides a complete list of the revision information, by chapter, for this release of the operator's manual.

CHAPTER #	CHAPTER NAME	CHAPTER REVISION & DATE
Chapter 1	System Overview	1.0, 04/2021
Chapter 2	Safety	1.0, 04/2021
Chapter 3	Getting Started	1.0, 04/2021
Chapter 4	System Start-Up	1.0, 04/2021
Chapter 5	Treatment Tools	1.0, 04/2021
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1. SYSTEM OVERVIEW

1.1. Introduction

INSIGHTEC Exablate Prostate delivers MR-guided focused ultrasound energy into the prostate in a minimally invasive manner by utilizing an endorectal transducer. In a matter of seconds, the tissue at the focal spot of the ultrasound beam is heated to the point of irreversible thermal coagulation, while nearby tissue remains unaffected. Over time, the body gradually absorbs the ablated tissue. This procedure is typically performed in an outpatient setting using either Epidural anesthesia (combined with conscious sedation) or general anesthesia. The patient is usually able to return to normal activity the following day.

The Exablate Prostate's focused ultrasound system operates inside a Magnetic Resonance Imaging (MRI) scanner, used to provide images of the patient's anatomy, and prepare an appropriate treatment plan. The MRI also measures temperature changes inside the body during Focused Ultrasound (FUS) treatment. The system acquires MR images and runs dedicated sequences to display temperature maps. The temperature maps are used to calculate the extent of thermal ablation and to help ensure safety and efficacy.

1.2. Document Conventions

Notes, Cautions and Warnings are used throughout this manual to highlight important points of information that could affect the health and safety of the patient and operator, as well as information intended to preserve system integrity. The following conventions are used to highlight these messages:

NOTE:

Notes provide information to aid in obtaining optimum equipment performance.

CAUTION:
Cautions indicate instructions or cautionary notes that, if not followed, may result in damage to the equipment or to the quality of treatment.

WARNING:
Warnings indicate precautions and instructions which, if not followed, may result in personal injury or even death .

1.3. Scope of This Manual

This operator's manual covers the following systems:

- MR scanner: 1.5 and 3-Tesla
- System Model: 2100V1

- Cradle Type: 3.0 (Prostate)
- Software version: 8.1

System Specifications:

- Transducer: 990 transmit elements flat phase array
- Transducer aperture (diameter): 34x22mm
- Focal distance: 15-60mm (achieved by electronic steering)
- Frequencies: 2.3±0.25Mhz
- Maximal Energy per macro-spot: 30KJ
- Maximal energy per sub-spot: 2.2KJ
- Energy specifications:
  - Energy density in target: 400~800J/cm^2
  - Ultrasound output: ~45W
  - Max output pulse width: 512sec
- Effective radiating area (ERA): 748mm^2
- Focal region size: Variable
- Focal control: Electronic
- Tissue destruction mechanism: Thermal coagulative necrosis
- Imaging during treatment: PRF MR Images at 3-6seconds interval
- Temperature measurement: Proton Resonance Frequency (PRF) MR thermometry
- Reflection monitoring: None
- Cavitation monitoring: Real time display
- Treatment outcome monitoring method: Using real-time thermometry the operator gets real time feedback on treatment outcome, as temperature is correlated to tissue viability.
- Independent assessment using standard MR imaging sequences is done during and after treatment, to assess lesion size and location.
- System Electrical Specifications:
  - Rated power voltages/currents: 208V (30A) / 380-400V (15A) / 480V (13A)

- Number of phases: Input 3-phase (5 wire)
- Rated power frequency: 50/60Hz
- Rated power input: ~10Kva
- Protection against electric shock: Applied Part Type BF

- Exablate Table Specifications:
  - Dimensions (L x W x H): 231±1 x 65±1 x 110.5±1 cm
  - Height in lowest position: 90cm
  - Weight: 230Kg
- Cleaning and High-Level Disinfection Cart Specifications:
  - Dimensions (L x W x H): 80±1 x 58±1 x 118±1 cm
  - Net weight: 25Kg
  - Full weight (with liquids): 39Kg

1.4. System Components

The Exablate Prostate system consists of the following integrated components:

- Operating console (located in the control room)
- Patient table (located in the MR treatment room)
- Equipment cabinet with Control PC (located in the equipment room)
- Water system (primary circuit located in the equipment room; secondary circuit located on the patient table)
- Power Distribution Unit (PDU)
- Cleaning and High-Level Disinfection (HLD) cart

1.4.1. Operating Console

The Exablate Prostate console (see Figure 1-1) allows the operator to control and monitor both the system and the treatment. It is positioned alongside the **GE (General Electric) MRI** workstation in the control room.

The WorkStation (WS) comprises the Exablate software installed on a Windows-based PC (Windows 7/10 operating system), a monitor, a keyboard, and a mouse. The Exablate console also consists of an emergency stop button (colored red) that halts the power to the system in case of emergency.

Figure 1-1: Operating Console of 2100V1

1.4.2. Patient Table

The Patient Table (see Figure 1-2), on which the patient lies during treatment, incorporates a probe (see Figure 1-3, **A**) containing a phased array focused ultrasound transducer (Figure 1 4) mounted on a mechanical positioner (see Figure 1-3, **B**). In addition, it houses a motion unit (see Figure 1-3, **C**) and the electronics needed to activate the transducer.

Prior to treatment, the patient table is docked to the MR Scanner. A quick-coupler cable connects the patient table to the equipment cabinet.

Figure 1-2: The Patient Table of Exablate 2100V1

The following legend explains the components shown in Figure 1-3:

A – Probe

B – Positioner

C – Motion unit

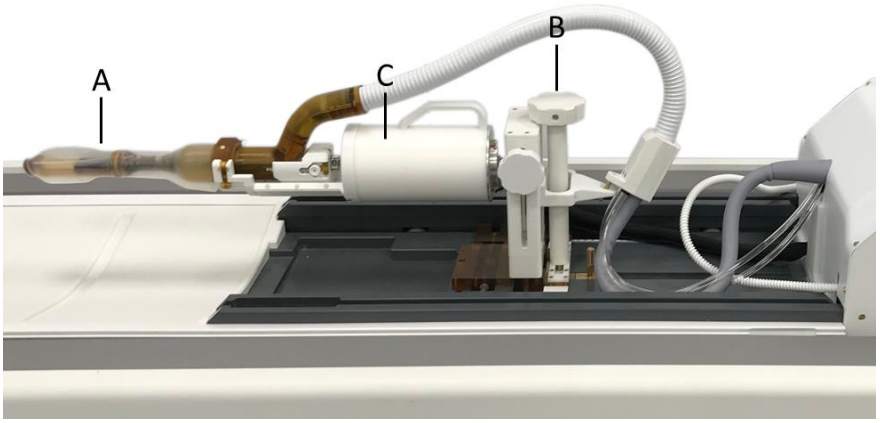

Figure 1-3: A closer look on the Patient Table

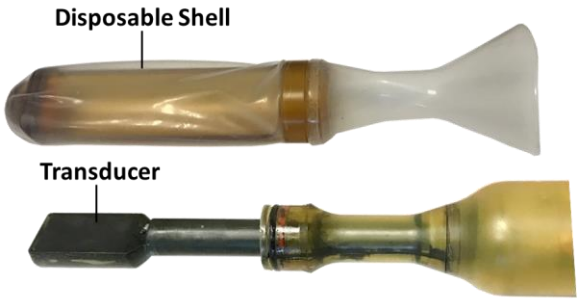

Figure 1-4: Exablate Prostate Probe

1.4.2.1. Positioner

A positioner (see Figure 1-3, **B**) mechanically attached to the cradle fixes the probe in place during the treatment. However, it still allows automatic mechanical movement of the transducer inside the shell in two dimensions. The positioner is designed so it would reduce pressure on the anus and eliminate any motion in the anus during the treatment.

The positioner has six degrees of freedom to easily adjust it to the probe location after insertion.

1.4.2.2. Probe Shell

The probe shell (see Figure 1-4) function is to keep the rectum and the anus safe while allowing energy delivery with minimum acoustic attenuation and dispersion and free mechanic transducer motion. The shell's dimensions and shape were designed to facilitate its insertion/extraction through the anus. The shell has no sharp edges nor steps that could have harm the rectal wall, and its oblique tip is intended to facilitate safe insertion. The transducer is locked in its position inside the shell while inserting or extracting it.

1.4.2.3. Transducer

The 990-elements phased array transducer was designed to be small yet powerful. It delivers ultrasound energy in a frequency of 2.3 MHz for high energy absorption in the prostate tissue. It can deliver up to 60W (acoustic); yet power is currently limited to 45W to avoid cavitation. The focus of the US beam transmitted by the transducer at the working distance of 15mm to 60mm is ~1mm to ~2.5mm in diameter (according to approximated measures of -6db contour), thus it creates well defined spot margins. This feature is important for full tumor ablation, even when adjacent to vulnerable structures such as the nerve bundles and the urethra.

The 990 elements of the phased array transducer enable electrical steering of the US beam 15mm-60mm away from the transducer (A/P), +/-5 degrees transversally (R/L) and +/-10 degrees longitudinally (S/I); this ability have a few implications, in addition to simple spot relocation. First, it increases the transducer possible treatment range (mechanical 50mm in S/I and ±40 degrees roll) to allow total prostate coverage, without passing the beam through the anus muscle. Second, it enables creating spots of various sizes and shapes without moving the transducer, using a 'bean' shape building block. This allows good control of the planned spots to maximize efficacy and safety.

1.4.2.4. MR Tracking Coils

The prostate motion system location control is based on relative encoders with index only. As an additional safety measure, an MR tracking subsystem is used to verify the transducer spatial location before every sonication and to re-aim it accordingly if necessary. The MR tracking subsystem includes four miniature

tracking coils, named 'trackers', that are embedded in the four corners of the transducer's housing. The signal acquired by the four trackers is analyzed to define the position of the transducer in the MR coordinates.

1.4.2.5. Robotic Motion Unit

The transducer has two mechanical degrees of automatic motion: linear motion of 50mm along the horizontal (S/I) axis and angular motion of ±40 degrees around the roll (Axial) axis, enabling access to whole desired treatment volume in the prostate gland. The automatic motion is achieved by a motion unit (Figure 1-3, C), attached to the prostate positioner on one end and to the probe on the other end. The motion system consists of piezoelectric motors activating the two degrees of freedom of the mechanical motion described above.

1.4.2.6. Probe Preparation Station

During the system preparation stage, the probe must be secured to avoid the hazard of its being damaged or broken. In addition, the degassing process is more efficient when the probe is vertical, facing down, as the tube opening is adjacent to the probe's neck and this way the air bubbles go up to it. For those purposes, the system includes a probe holder, as seen in Figure 1-5.

Figure 1-5: Probe in Preparation Station

1.4.2.7. Patient Legs Support

During the treatment, the patient's body must stay immobilized to avoid miss-targeting and thermal artifacts. Epidural/general anesthesia keeps the patient lower body temporary immobile throughout the treatment duration, yet legs support is required for holding them slightly spaced and elevated and with some knee flexion. This position allows room for the positioner while still enabling entrance to the MR bore.

The specially designed patient leg holders provide patient immobilization while uncompromising patient comfort. The supporting Leg Holders are attached to the cradle and are adjustable in S/I and can also be rotated as necessary.

Figure 1-6: Patient Leg Support

1.4.3. Equipment Cabinet

The Equipment Cabinet (Figure 1-7), installed in the equipment room of the MR suite, houses the electronics and amplifiers required for powering the system, along with the Control Personal Computer (CPC). It includes the electronic interface to the patient's bed, to the MR scanner and to the operators' workstation, as well as the safety monitoring function of the system. The CPC coordinates the transducer power output and focusing and controls its mechanical motion and electrical steering.

CAUTION:

Do not interact with the equipment cabinet. Only authorized INSIGHTEC service personnel are qualified to operate this unit.

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Figure 1-7: Exablate Prostate Equipment Cabinet

1.4.4. Water System

Exablate Prostate contains a water subsystem that incorporates a semi-closed water circulation loop, designed to provide several requirements for prostate treatment:

- Filling, draining, circulating and degassing the water within the balloon during treatment preparations.
- Circulating and degassing the water during treatment to keep water within the balloon cooled and degassed.
- Support the cleaning and high-level disinfection procedure between treatments.

The water system is made of a primary circuit at the equipment room, including a cooling unit (see Figure 1-8), and a secondary water circuit assembled on the table (see Figure 1-9). The operator controls the water subsystem using a control panel positioned on the patient table (see Figure 1-10) to manually operate filling and draining of the balloon.

Two elements on the left side of the Exablate console (see Figure 1-11) indicate the operation status of the water system: The **Circulation Controller**, that illuminates continuously when water is circulating, and the **Cooling Indicator**, that illuminates continuously when water is cooled.

NOTE:

The circulation is automatically controlled by the system. Do not interact with the circulation controller.

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The endorectal probe includes tubing which connects it to the water subsystem. The tubing feed the water into a disposable silicon balloon enclosing the transducer.

The balloon is made of a biomedical-grade silicone. The system circulates the water, monitors and controls the water temperature and vacuum level, and warns the user in case of malfunction. The water system also provides an acoustic transmitting media. The degassed water inside the balloon and gel smeared on the balloon's surface provide acoustic coupling during the treatment.

The Exablate Prostate water subsystem is designed to keep the rectal wall safe through cooling and circulation.

At the beginning of the treatment, the system initiates an active cooling unit, which is intended to maintain the water temperature around 14°C. During sonications, water is circulated at a rate of at least one liter/min to minimize thermal accumulation around the probe. During the treatment, the Workstation controls water system status automatically.

See Appendix B for water system use and maintenance.

Figure 1-8: Exablate Prostate Cooling Unit (2100V1 Forward Production)

Figure 1-9: Exablate Prostate Secondary Water Circuit

Figure 1-10: Exablate Prostate water system display

Figure 1-11: Exablate Prostate console

1.4.5. Power Distribution Unit (PDU)

The power distribution unit is an input power isolation transformer. Its purpose is to provide protection from electrical power hazards.

CAUTION:

Do not interact with the power distribution unit. Only authorized INSIGHTEC service personnel are qualified to operate this unit.

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1.4.6. Cleaning and High-Level Disinfection (HLD) Cart

The cleaning and high-level disinfection cart was specifically designed to facilitate the probe and water system cleaning and high-level disinfection process (see Appendix C for further details).

Figure 1-12: Cleaning and High-Level Disinfection Cart

1.5. Exablate Prostate Accessory List

NAME	P/N	DESCRIPTION
EXABLATE PROSTATE DISPOSABLES		
Prostate Patient Treatment Kit	SET000546-BC	The Treatment Kit includes all disposable items required to perform an Exablate Prostate treatment.

WARNING:

- All single use, disposable items (described below) must be discarded immediately after treatment (see Appendix C for further details) and should not be reused.

- Failure to do so may degrade the quality of treatment and may even cause harm to the patient.

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Each Exablate Prostate treatment kit includes the following single use, disposable items:

NAME	P/N	QTY
Disposable shell	ASM500065	1
Balloon assembly locking pin	ASM001757	2
O-ring (white)	MPR001502	2
Probe cable cover	BUY000900	1
Probe cover	MEC500356	1
Motion unit cover	MEC500357	1
Cradle cover	BUY000938	1
Leg sleeves	BUY000939	2
Surgical tape	MPR000149	1
US Gel (pouch, sterile)	DTP000066-AA	6
*Purified Water 1L	ASM000761-AA-CE	1

*Can be shipped separately.

In addition, the following single use, disposable items*, are used for storage of the Exablate probe **between** treatments:

NAME	P/N	QTY
Probe storage bag	BUY000941	100 (per package)
Probe storage label	BUY000943	100 (per package)

*Should be purchased separately.

2. SAFETY

2.1. Exablate Safety Considerations

Exablate Prostate was designed and manufactured to ensure maximum safety of operation. Maintain the system in strict compliance with the safety precautions, warnings, and operating instructions in this manual. The Exablate Prostate should be installed, maintained, and serviced by only **INSIGHTEC** personnel, or other qualified personnel approved in writing by INSIGHTEC.

The Exablate Prostate, in whole or in part, should not be modified in any way without the prior written approval of INSIGHTEC.

The Exablate Prostate system must be used under the supervision of a physician who has successfully completed the INSIGHTEC training program.

The owner should ascertain that only fully qualified, properly trained and certified personnel according to INSIGHTEC training program, are authorized to operate this equipment.

Only trained and certified clinicians, specializing in Urology, Radiology and/or Radiation Oncology should use the Exablate Prostate system for treatment of patients.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the country regulatory authority.

It is important to keep this manual near the system. It should be studied and reviewed periodically by all authorized operators. However, INSIGHTEC makes no representation that the act of reading this operator's manual renders any user qualified to test, calibrate, or operate the system.

Unauthorized personnel should not be allowed access to the system.

If the system does not operate properly or fails to respond as expected to the controls as described in this manual, tend to the safety of the patient first, and then attend to the system.

The Exablate 2100V1 is compliant with Directive 2011/65/EU of the European Parliament (Restrictions of Hazardous Substances, RoHS).

As required by IEC60601-1 (3.1 edition) to define:

- System applied part list: FUS cradle.
- System accessory part list: Leg supports, endorectal silicon probe cover (single-use, non-sterile introduced), water-based US gel (single-use, non-sterile introduced) and purified water bottles (single-use, non-sterile introduced).

2.1.1. Use of Exablate System within the MRI Environment

The Exablate Prostate Patient Table is MR Safe

2.1.2. Use of MR Equipment

Personnel operating the MR equipment must have a thorough understanding of the proper operation of the system.

Do not operate the MR equipment before reading the appropriate user manuals and gaining a clear understanding of the operation of the system. If any part of the MR system's manual is not clear, contact the MR equipment's technical and/or clinical service personnel for clarification.

For the safety of the patients, operating personnel and technical personnel, all operating instructions and particularly the safety instructions therein must be strictly adhered to.

2.1.3. System Service

- The Exablate system should be installed, maintained, and serviced by INSIGHTEC personnel, or other qualified personnel certified by INSIGHTEC.
- Periodic maintenance should be performed regularly according to INSIGHTEC service standards by INSIGHTEC or by INSIGHTEC certified personnel.
- An Exablate Prostate system should be serviced every six months.

WARNING:

If a system is not appropriately serviced and maintained, it should not be clinically operated.

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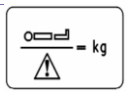
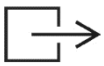
2.2. Symbols Used in the System

Symbol	Symbol Title	Description	Standard Reference
CE	CE mark	Designates that the product labeled is authorized for sale in EU.	EU 2017/745

Symbol	Symbol Title	Description	Standard Reference
EC REP	Authorized representative in the European Community	This symbol shall be accompanied by the name and address of the authorized representative in the European Community.	ISO 15223-1: 2016, clause 5.1.2
Rx only	Prescription devices	Caution: Federal law restricts this device to sale by or on the order of a physician / special practitioner.	21 CFR 801.109 21 CFR 801.15(c)(1)(i)F
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1: 2016, clause 5.1.1
	Date of manufacture	This symbol shall be accompanied by a date to indicate the date of manufacture.	ISO 15223-1: 2016, clause 5.1.3
	Use-by date	This symbol shall be accompanied by a date to indicate the expiration date.	ISO 15223-1: 2016, clause 5.1.4
LOT	Batch code	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.	ISO 15223-1: 2016, clause 5.15
SN	Serial number	This symbol shall be accompanied by the manufacturer's serial number.	ISO 15223-1: 2016, clause 5.1.7
REF	Catalogue number	The manufacturer's catalogue number shall be adjacent to the symbol.	ISO 15223-1: 2016, clause 5.1.6
Model	Model/ Type designation	The name and/or number used to represent one medical device, or a family of medical devices to group many variations that have shared characteristics.	IMDRF/RPS WG/N 19:2016
	Keep away from sunlight/ Keep away from heat	Indicates a medical device that needs protection from light sources.	ISO 15223-1: 2016, clause 5.3.2

Symbol	Symbol Title	Description	Standard Reference
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1: 2016, clause 5.3.4
	Lower limit of temperature	The lower limit of temperature shall be indicated adjacent to the lower horizontal line.	ISO 15223-1: 2016, clause 5.3.5
	Temperature limit	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1: 2016, clause 5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1: 2016, clause 5.3.8
	This way up	This way up	ISO 7000-0623
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1: 2016, clause 5.4.2 IEC 60601-1 Ed 3.1 Table D1 (28)
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself	ISO 15223-1: 2016, clause 5.4.4 IEC 60601-1 Ed 3.1 Table D.1 (10)
	General Warning (There is a certain danger)	To be placed together with a supplementary symbol or text.	IEC 60601-1 Ed 3.1 Table D.2 (2)
	General mandatory action	To be placed together with a supplementary symbol or text	IEC 60601-Ed 3.1 Table D.2 (9)
	Follow instructions for use	Refer to instruction manual/ booklet	IEC 60601-Ed 3.1 Corrigendum 1 Table D.2 (10)

Symbol	Symbol Title	Description	Standard Reference
	Warning, electricity	Dangerous voltage	IEC 60601-1 Ed3.1 Table D.2 (3)
	WEEE- waste of electrical and electronic equipment	Discard the electrical and electronic equipment according to local regulation policy	Directive 2012/19/EU
	Type BF applied part	Degree of Protection against electric shock (Type BF)	IEC 60601-1 3.1Ed Table D.1 (20)
	Type B Applied Part	Type B Applied Part	IEC 60601-1 3.1Ed Table D.1 (19)
	Body weight	To identify the control or the indicator to enter or call up the body weight of a person	IEC 60417-5665
	Safe working load	Safe working load	IEC 60417
	Alternating current	Indicating the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	IEC 60601-1 3.1Ed Table D.1 (1)
	Three-phase alternating current	Indicating the rating plate that the equipment is suitable for three phases alternating current only; to identify relevant terminals.	IEC 60601-1 3.1Ed Table D.1 (2)
	Three-phase alternating current with neutral conductor	Indicating the rating plate that the equipment is suitable for three phases alternating current with neutral conductor only; to identify relevant terminals.	IEC 60601-1 3.1Ed Table D.1 (3)

Symbol	Symbol Title	Description	Standard Reference
	Protective earth (ground)	Identifying any terminal, intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.	IEC 60601-1 3.1Ed Table D.1 (6)
	Input; entrance	Indicating an entrance (e.g. hydraulic pump).	ISO 7000-0794
	Output; exit	Indicating an exit (e.g. hydraulic pump).	ISO 7000-0795
	Method of sterilization	Method of sterilization using ethylene oxide.	ISO 15223-1: 2016, clause 5.2.3
	MR Safe	Indicates that the device is safe- it poses no risks in any MR environment.	ASTM F 2503-13

2.3. Safety Instructions

WARNING:

Before using the Exablate Prostate system:

- Read and understand each of the following safety warnings.
- Refer to the safety information supplied with the MRI System.
- The Exablate Prostate is type BF applied part.
- It is properly grounded by design and by the installation process.
- It is important for the safety of the patient and operator to maintain proper system grounding. Connect the system as instructed, and do not disconnect any of the system installation connections.
- The use of accessories, transducers and cables other than those specified or provided by Insightec with this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

[W-4]

2.3.1. MR Coils

The Exablate Prostate system can be used with most of the MR coils provided by GE Medical Systems (e.g., Cardiac or Torso-Phased Array). The particular coil will be selected during system installation and only this coil should be used from this point on. Read the appropriate operating guides of the coils to ensure correct use.

2.3.2. Patient Positioning

After the patient is lying comfortably on the patient table, insulate the patient from the MR scanner with appropriate thermal-resistant pads to prevent potential RF burns. Place the pads along the patient's sides to insulate the patient from the scanner walls. To prevent patient's legs or knees from touching the scanner walls or ceiling, insulate those body parts with thermal-resistant pads.

Verify that an open space of more than ½" (1¼ cm) exists between all system components and patient to the sides and top of the scanner.

The maximum allowed patient weight is 135 kg.

Ensure that patient's body is strapped to the table to avoid an accidental fall of the patient and/or any objects from the patient table.

WARNING:

Pay strict attention that no air has entered the transducer interface and that it is completely filled with water in preparation and continuously during the treatment. Incorrect coupling may cause reduced focal zone temperatures, defocusing and misalignment of the focal spot and/or severe damage to system components.

[W-5]

2.3.3. Patient Protection

For MRI safety, refer to the **Safety** section of the MR system operator's manual.

Ensure that the patient does not have any metallic implants, including but not limited to pacemakers and neuron-stimulators.

Metal objects are forbidden in the magnet room. Verify that there are no rings, clips, loose change, or any other metal objects on the patient.

WARNING:

Refer to safety guidelines issued by the MRI safety procedures and restrictions that may apply to the specific site.

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Do not leave a patient unattended in the magnet room.

The **MRI Stop Scan** button must be given to all patients who are not under general anesthesia. Pressing the button immediately interrupts treatment. Additionally, two **Stop Sonication** buttons are available on the Exablate system:

- One is on the operator's console.
- One is controlled by the staff member in the treatment room.

If the patient is not under general anesthesia, instruct him to press the **MRI Stop Scan** button when feeling pain or heat.

The patient will require hearing protection.

The Exablate Prostate console controls the connection between the ultrasound transducer and the rest of the system. The system power should be turned off before leaving the console to prevent undesired activation of the transducer.

The Sonication Power-On light in the magnet room indicates that the transducer is applying ultrasound energy. This light must be in clear view of the nurse and the console operator. Never move the patient or place your hand near the transducer while the sonication power-on light is on.

The patient is not always in view of the console operator. Be sure that medical personnel are in the magnet room during the procedure.

Verify that the patient’s fingers and clothing (hospital gowns) do not get caught in the equipment during positioning or cradle motion.

During treatment, frequently ask the patient if he/she is in any pain or discomfort.

To increase patient comfort and reduce the risk of patient hypothermia, body warmth should be maintained by accessories or systems provided by the site.

The use of any medication and/or imaging contrast should be applied after considering possible effects on ultrasound energy absorption or thermal imaging.

The Exablate system creates heat in the target, which may cause thermal ablation based on temperature rise levels and duration. Such ablation (referred to as thermal dose) will be created by temperature of 43°C for 240 minutes, by 54°C for 3 seconds, or by 57°C for one second [Sapareto and Dewey]. Carefully examine

the thermal images and the thermal dose contours after each sonication to avoid possible damage to unintended tissues

Cavitation refers to formation and collapse of bubbles (created from dissolved gas), which fill cavities that are created in low pressure regions.

As a result, bio-effects may occur due to these bubbles and are dependent on the extent and type of cavitation.

2.3.4. Patient Emergencies

Each Exablate Prostate site must develop appropriate patient emergency procedures.

All personnel who operate the system must study and practice patient emergency procedures.

If there is any sign of risk to the patient, proceed as follows:

1. Press the Emergency Stop button mounted on the wall in the operator's control room or the one in the magnet room to shut down the MR and the Exablate Prostate systems.
2. If necessary, notify emergency personnel.
3. Squeeze the cradle release handle and pull the cradle onto the patient table. If the cradle does not release, use moderate force to pull out the cradle.
4. If it becomes necessary to remove the table from the room, detach the quick-coupler cables and hoses and remove the patient table from the magnet room. The patient table is not very maneuverable. To avoid this limitation, perform one of the following options:
   - Keep a non-magnetic gurney in the magnet room, or
   - Keep a regular gurney outside of the magnet room.
5. Release the patient from the transducer interface as expediently as possible.
6. Attend to the patient, following established hospital emergency protocols.

2.3.4.1. Patient Emergency Release

In case of an emergency, the following **patient release procedure** should be followed:

1. Retract the cradle outside of the MR.
2. On the Motion Unit controller, press on **Enable** + **Home**. The probe will move in its shell to a protected extraction position.
3. On the water system display, press **Extract** to drain the balloon back to the insertion volume. This will also **pause** the water circulation in the balloon.

NOTE:

The water system is drained by the water system display. In case of complete power loss, or other malfunction of the automated water system, continue with the manual patient release procedure (steps 4-6).

[N-3]

4. Release the large hand screw that fixes the Positioner to the cradle and retract the entire Positioner along with the probe backwards from the patient.
5. Release the hand screw that fixes the Motion Unit to the Positioner and lower the probe until it lies safely on the cradle.
6. Carefully remove the patient from the table.

WARNING:

Life-support, resuscitation or any other equipment based on ferromagnetic components is not allowed in the magnet room.

[W-7]

2.3.5. System Stability

The Exablate system complies with Regulation (EU) 2017/745, General Safety and Performance Requirements, and 2006/42/EC Machinery standard regarding stability requirements.

The system table and cradle move in/out of the MR bore on wheels equipped with stoppers. The table can be manually raised or lowered as required by pressing the foot pedal, to a maximum range of 225mm. To ensure the patient's secure and safe positioning on the table, proceed as follows:

1. Always ensure that the patient, while on the table, is safely harnessed with the cross-tying safety belts.
2. Only remove the patient from the table when the table is in final lowering position and its wheels are at STOP position.
3. Do not try to move the cradle when the table is not docked to the MRI, as the cradle is locked in place (on table) when the table not docked to MRI.

The system operator is obliged to meet instructions and take the stability safety precautions in a timely and complying manner as to keep moving parts from collisions, falls, slipping and tripping.

2.4. Water System Precautions

The water system is used to keep the rectal wall cool during treatment. The water temperature is monitored by the system and is displayed on the workstation screen.

During treatment, the operator must be aware of the following:

- Attend to any system alert to a malfunction in the water system.
- Confirm that the circulation has restarted in between sonications and that the water temperature is adequate.

2.4.1. Temperature Rise Precautions

A malfunction in the water system during operation could cause the water to warm up rather than being cooled to the proper operating temperature. This situation may cause one or both of the following hazards:

- Harm to the patient
- Damage to the transducer

The Water system status (Cooling / Paused) and water temperature are presented in the Exablate Prostate Workstation Device Status Bar. When the temperature of the water is higher than the desired set point by 2 degrees or more, the workstation will alert the operator. If this happens, verify water system status is set to 'Cooling' and wait for it to cool down to the desired temperature, before continuing the treatment.

If the problem persists, contact technical support.

WARNING:

The balloon water may start warming as a result of a prolonged sonication sequence. Keep a close watch on the water temperature at the Exablate workstation console and avoid sonicating when water temperature is above the desired level.

[W-8]

2.4.2. Balloon Volume Precautions

The balloon covering the probe is designated to hold circulating cold water for keeping the rectal wall safe. During the treatment, it is inflated to provide acoustic coupling with the rectal wall. However, during insertion, extraction or repositioning of the probe, the balloon should be drained to minimize the probe diameter while passing through the anus.

NOTE:

In order to avoid over draining when draining water from the balloon, observe water volume displayed on the water system control panel.

[N-4]

WARNING:

To avoid risk of damage to the anus, always make sure the balloon is at the desired insertion volume in any of the following actions:

- Probe insertion
- Probe repositioning
- Probe extraction

[W-9]

2.5. Operator Precautions

WARNING:

To avoid the risk of electrical shock, this system must only be connected to a supply main with protective ground (earth).

[W-10]

The Exablate Prostate console is designed to protect the patient and the operator from accidental exposure to ultrasound energy.

Review and follow all operator instructions included with the console.

The operator and nurse must each be able to freely activate a Stop Sonication button at any time during the procedure. Pressing the Stop Sonication button immediately stops the sonication. Releasing the button enables the treatment to resume.

The Exablate Prostate console controls the connection between the ultrasound transducer and the rest of the system. The system power should be turned off before leaving the console to prevent undesired activation of the transducer.

The transducer surface is very delicate, therefore clean it only with alcohol, a soft cloth and avoid any contact of sharp objects. When not in use, cover the transducer with the dedicated cover to avoid accidental damage.

After each treatment, the transducer should undergo a cleaning and high-level disinfection (HLD) procedure, as described in Appendix C of this manual.

Prior to every application of energy ensure that the water interface is full.

The **Sonication Power-On** light in the magnet room indicates that the transducer is applying ultrasound energy. This light must be in clear view of the nurse and the console operator. Never move the patient or place your hand near the transducer while the sonication power-on light is illuminated.

It is hereby stated that no patients or operators are exposed to any hazardous material.

No modification of this equipment by non-authorized personnel is allowed.

2.6. System Security and Malware Protection

The Exablate system is a standalone system that is not connected to external networks (including the hospital network) and is connected to the MRI via a private MRI-equipment hub that is obscured from the hospital backbone network.

The WS PC has two connections. One is direct communication with the MRI internal equipment network. This local point-to-point connection has no direct access to external hospital network and is solely used by the Exablate system and the MRI scanner. The second connection is between the Exablate WS and the Exablate Control PC, which is also an internal, point-to-point connection.

For MRI security and malware protection, refer to the MR system operator's manual.

CAUTION:

Do not insert into the USB ports any unauthorized devices, including radiofrequency (RF) transmitters, nor use the USB ports to charge other equipment.

[C-2]

The Exablate system also has additional mechanisms to ensure file and data integrity. These mechanism include hard drive integrity protection as well as prevention of any unauthorized change or modification to the system configuration files.

All Exablate software related updates and/or modifications are performed by only INSIGHTEC personnel, or other qualified personnel approved in writing by INSIGHTEC.

2.7. Electromagnetic Compatibility (EMC) Precautions

CAUTION:

The Exablate system requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided below:

- The Exablate system should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.
- Be aware that portable and mobile RF communication equipment can affect the Exablate system.
- The Exablate system should not be used adjacent to Portable RF readers. If use of adjacent RFID readers is necessary, Insightec service must be informed to verify normal operation in the configuration in which it will be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Exablate System, including cables specified by Insightec. Otherwise, degradation of the performance of this equipment could result.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment, this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- In case of system power loss due to AC inputs mains Voltage interruption, the system will shut down. Wait for a stable return of the AC power and restart the system to repeat the planning stage and resume the treatment. If the return of power is delayed, and you decide to abort the treatment, proceed to patient release procedure, as described in the operator's manual.

[C-3]

A Statement on Exablate System Essential Performance:

The essential performances of Exablate Prostate are:

1. Safety Monitoring
    a. Monitors and Verifies the sonication is executed as planned

b. Verifies that the monitoring is running continuously.

c. If failure of any of the above does NOT stop the sonication/halts the CSA (Control System Application), the system is NOT safe.

2. Transducer Motion:

a. Control of the Transducer robotic arm movement.

b. Verification that the Transducer robotic arm is at the correct location and orientation

c. Verification that transducer robotic arm position monitoring is performed continuously.

d. If failure of any of the above does NOT stop the energy sonication and halts the movement, the system is NOT safe.

2.7.1. Summary of EMC Test Results

Test	Standard	Class/Severity Level	Test Result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements (Risk Management file)	Section 4.1	-	Complies
Instruction for use	Section 5.2.1	-	Complies
Technical description	Section 5.2.2	-	Complies
Emission (IEC 60601-1-2 sections 7.1-7.2)			
Conducted emission Freq. range: 150 kHz - 30 MHz	CISPR 11	Group 1 Class A on AC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class A	Complies
Immunity (IEC 60601-1-2 sections 8.9-8.10)			
Immunity from Electrostatic discharge (ESD)	IEC/EN 61000-4-2	± 8 kV contact discharges & ± 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC/EN 61000-4-3	1.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC/EN 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies

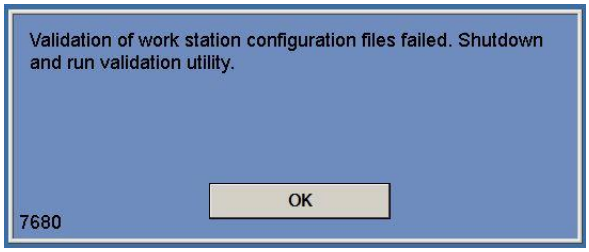
Test	Standard	Class/Severity Level	Test Result
Immunity from Electrical Fast transient (EFT)	IEC/EN 61000-4-4	± 2 kV on AC main 3 phase ± 1 kV on 5 power & signal cables Tr/Th – 5/50 ns 100 kHz	Complies
Immunity from Surge	IEC/EN 61000-4-5	± 2 CM / ± 1 kV DM on AC mains, 3 phases Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC/EN 61000-4-6	3.0 & 6.0 VRMS 0.15÷80 MHz, 80% AM, 1 kHz on AC mains, 3 phases & 4 power & signal cables	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC/EN 61000-4-11	AC mains: 0 % - 10 ms & 20 ms; 70% - 500 ms; 0% - 5 s	Complies

2.8. Cyber-Security

2.8.1. Cyber-Security Related Precautions

1. Only authorized personnel are allowed to physically access the Exablate workstation.
2. Maintain physical access control to the MR control room and the Workstation.
3. Maintain physical access restriction to the MR service area and the Equipment Cabinet.
4. Exablate Workstation username & password should not be printed or shared with anyone, except for authorized users.
5. In case the WS and/or CPC hard drive/s physical security cannot be guaranteed in the MR control room or the Equipment Cabinet room, detach with the dedicated keys the WS and/or CPC hard drive/s when the system is not in use and store them in a safe and accessible controlled location.
6. USB devices (such as Disk on Key) should be used on Exablate workstation only by authorized personnel. USB devices require prior malware scan (by Anti-Virus/Anti-Malware).
7. Do not use the USB port to charge other equipment.
8. Do not insert into USB ports unauthorized devices including radiofrequency (RF) transmitters.
9. Always shut down the Exablate system after completing a treatment/session (unless it is followed by another consecutive session).

10. In case of a security event resulted in unauthorized changes to the configuration files (e.g., Ini-file modification), the following alert message will appear on the workstation screen:



Contact the local IT and Insightec service representative and do not use the system nor treat patients until the issue is resolved.

11. Shut down the system and disconnect the Workstation from the socket, to disable sonications, upon detection of abnormal or unstable behavior, cybersecurity vulnerability or a security incident in the Exablate device. Report on security incidents and near misses, including those involving portable information assets, to your local IT and your Insightec service representative.
12. Monitor the temperature maps during sonication. If an unexpected thermal rise is found outside the target location, stop the sonication immediately.
13. Cybersecurity and software updates should only be implemented by authorized Insightec technicians/personnel.
14. Users should not accept or implement any updates on the Workstation or CPC.

2.8.2. Cyber-Security Related Notes and Instructions

1. Every Treatment export includes system login audit logs and Anti-Virus event logs.
    a. Login audit logs to the WS and the CPC can be found in a windows event viewer called 'WsSecurity.evt' and 'CpcSecurity.evt'.
    b. Anti-Virus event logs can be found in text files called 'OnAcessScanLog.txt', 'OndDemandScanLog.txt' and 'AccessProtectionLog.txt'.
2. It is strongly recommended that local IT personnel evaluate periodically the system login audit logs and Anti-Virus event logs of treatment exports and estimate if there is any suspicion of cyber security events.
3. It is recommended to contact your insightec representative to modify the initial password and replace it with a strong password which fits your local password policy.

2.9. Environmental Requirements

System Operating Conditions:

Atmospheric pressure: 700 to 1060 kPa

Altitude: -30 m (-100 ft.) to +3000 m (+9800 ft.)

Operator + Equipment room:

Temperature range: +15 to 32°C

Relative humidity: 30 to 70% (non-condensing)

Magnet room:

Temperature range: +15 to 24°C

Relative humidity: 30 to 60% (non-condensing)

System Storage & Transportation Conditions:

Atmospheric pressure: 700 to 1060 kPa

Temperature range: +5 to 40°C

Relative humidity: Up to 90%

Treatment Kit Storage & Transportation Conditions:

Storage conditions:

Temperature range: +14 to 30°C

Relative humidity: 40 to 80%

*Kit shall be stored in a shaded place.

Transportation conditions:

Temperature range: -30 to +60°C

Relative humidity: 15 to 90%

3. GETTING STRTED

3.1. System Power On

NOTE:

Refer to the relevant operator's manual in case a Storage Cabinet is used to store the Exablate Prostate cradle.

[N-5]

WARNING:

Ensure that all system components and accessories are present and intact, **before** starting the treatment.

[W-46]

Start up the system in the following sequence:

1. **Confirm that the MR console had been rebooted at the beginning of the day. If it had not - please reboot it.**
2. Undock the imaging table.
3. Connect the patient table to the MR scanner (see Figure 3-1):
   - Dock the patient table to the MRI scanner.
   - Lock the connector lever by pulling it toward the magnet bore.

WARNING:

- Do not un-dock the table when the connector lever is secured.
- Ensure that the patient table is connected to the MRI and the connector lever is secured before turning on the main power switch. Do not disconnect the table when the main power is on except in an emergency.

[W-12]

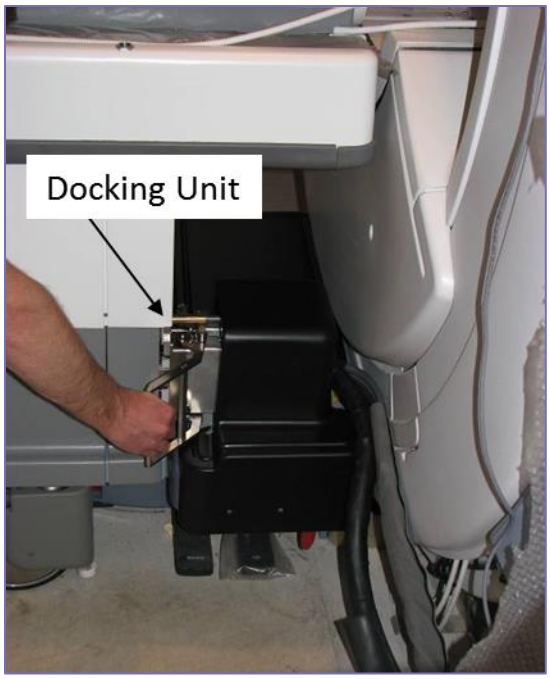


Figure 3-1: Exablate 2100V1 Connection of the Table To the MRI

4. Prepare **a new** water pouch assembly and connect to the table (see Figure 3-2):
   - Open the cap of a water pouch and remove the small white ring (if applicable).
   - Screw and tighten the fitting on the water pouch.
   - Connect one side of the water hose to the fitting on the water pouch and the other side to the fitting on the table. Hang the water pouch on the dedicated hanger.

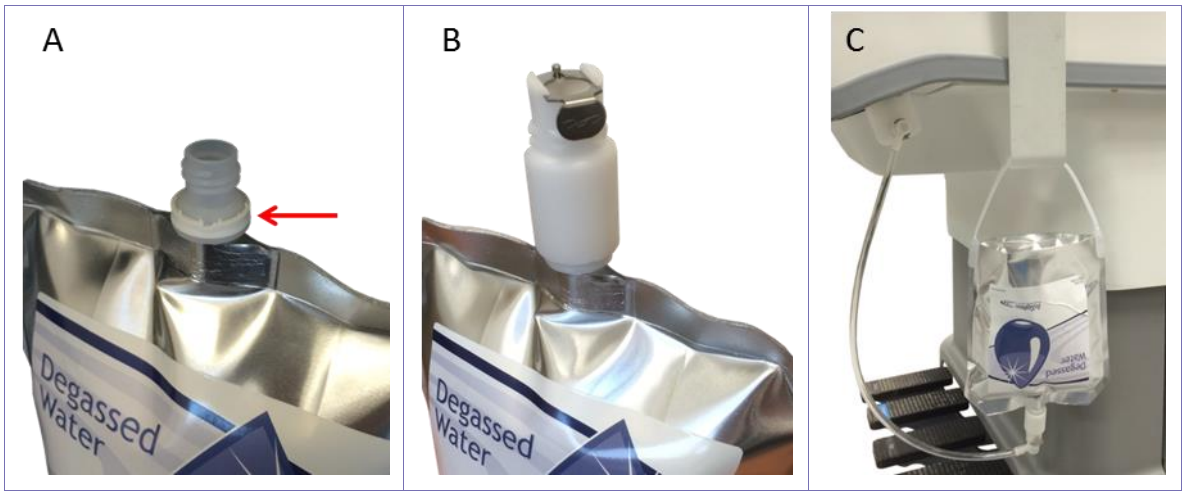


Figure 3-2: Exablate Prostate Preparation of the Water Pouch Assembly

A – Open cap and remove the white ring shown with red arrow (if applicable)
B – Screw and tighten the fitting
C – Connect hose to the fitting and to the table and hang the water pouch

5. Remove all disks or USB devices from the console computer.
6. Turn on the system by pressing the **Power On** switch located on the operator's console.
7. The **Begin Logon** notice appears. Press **Ctrl+Alt+Del** to access the logon information dialog box. Enter your username and password. (Windows logon parameters are case sensitive). Click **OK** to continue.
8. The Exablate application selection window will appear. Click the **Treat** or **Start** button of the desired application, to enter the **Start-Up** screen and start the treatment (see Figure 3-3).

Figure 3-3: Application Selection Screen

9. The Exablate disclaimer popup window opens; click **OK** to continue.

3.2. Probe Preparation for Treatment

For this stage, a new treatment kit is required.

Use only powder-free gloves when handling the probe; powder particles may absorb the US energy and damage the rectal wall.

NOTE:

Verify that there is no balloon already covering the probe. If there is, refer to the Cleaning and High-Level Disinfection Procedure in Appendix C and continue after cleaning the system.

[N-6]

1. Place a new **disposable** (white) **O-ring** over the **groove in the probe** (see Figure 3-4).
2. Gently Place a new **disposable shell** assembly (see Figure 3-4) over the **probe**.

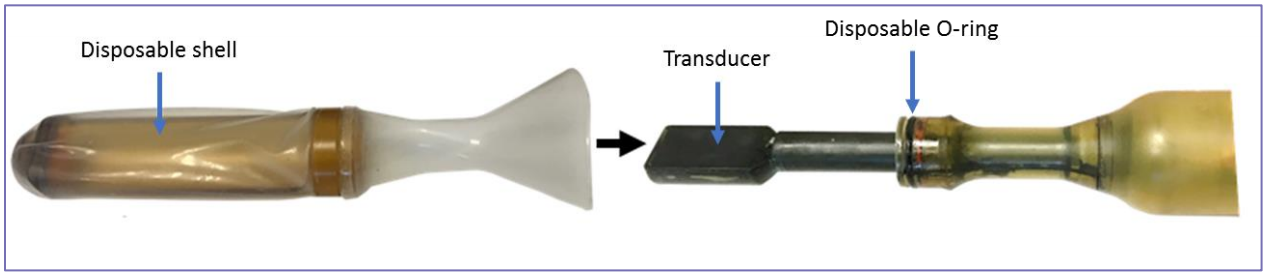


Figure 3-4: Probe Disposable Shell and Transducer

3. Both the **disposable shell** assembly and the base of the probe have small holes that must exactly overlap once the shell is on the probe. Fold the endorectal balloon back over the probe to allow for visibility. Carefully align both holes.
4. Insert a **locking pin** through the hole in the **disposable shell** and push it down till it sits flat against the shell. Verify that the disposable shell is **properly locked** to the probe.
5. Pull the flipped part of the endorectal balloon over the neck of the probe. Care must be taken to ensure the cord attached to the locking pin exits the endorectal balloon towards the motion unit and does not touch the patient.
6. Cover the motion unit and positioner with the disposable motion unit cover (supplied in the treatment kit).
7. Cover entire probe cable with the disposable probe cable drape.

Then, cover the rear part of the probe (starting from the neck of the probe and towards its cable) with the probe cover drape.

8. Place the probe in the Preparation Station in the upright position.
9. Make sure a new **water pouch** is attached to the system.
10. On the Water System display, select (press on) **Prepare**.
11. Press the **Fill** button continuously, until the balloon is ~1/2 full.
12. Press on **Start Circulation** button to start water circulation. Verify there are no water leaks. In case leaks are detected, restart the procedure using a new disposable shell.

NOTE:

If the water system buzzer sounds, press **Mute** on the water system control panel or **Reset** to continue. Alternatively, you can press the blue button on the workstation console once for mute and again to reset. See appendix B for details.

[N-7]

13. Press the **Fill** and **Drain** buttons alternately, waiting several seconds between cycles, until the balloon is full and degassed. Make sure that there are no visible bubbles inside the balloon.
14. Bring the balloon to the desired insertion volume and press **Insert** on the water system's display. This will set the current water volume as the reference volume for insertion and extraction of the probe, and will also pause the water circulation in the balloon.
15. Press on **Start Circulation** to resume water circulation. Verify that the water system is in Treat mode before starting the treatment.

3.3. Patient Preparatory Procedures

1. The patient will undergo assessment for anesthesia by the attending physician (including the usage of NSAIDs in patients with increased risk for DVT)
2. It is recommended to prepare the patient in a similar manner to what is done for colonoscopy. In the morning of the treatment, apply a cleansing enema before inducing anesthesia.
3. Insert an I.V. line.
4. The attending physician should perform a rectal examination.

NOTE:

If any feces residuals are present, perform a cleansing enema.

[N-8]

5. Administer general or epidural anesthesia (based on clinical decision). Vital signs monitoring will be according to clinical standard of care for the applied anesthesia and the attending physician's decision, using MR compatible equipment. In any case, peripheral oxygen saturation and heart rate will be monitored throughout the procedure.
6. Insert a urinary catheter (either a trans-urethra Foley or a supra-pubic, based on a clinical decision) to ensure continuous adequate bladder emptying.
7. It is recommended to wrap patient legs with compression stockings, to reduce risk for DVT.

   Then, cover patient legs with the leg sleeves (supplied in the treatment kit).

3.4. Patient Positioning and Probe Insertion

Once **probe preparation** for treatment is complete, perform the following steps for **probe insertion**:

1. Verify that the desired balloon volume is set and that the water system is in **Treat** mode and **circulating**.
2. Place the posterior part of the imaging coil on the Exablate Prostate table. Verify that an open space of more than ½" (1¼ cm) exists between the sides and top of the scanner, coil cable and the coil itself.
3. Insert the imaging coil and the tracking coil cables connectors into the matching connectors within the magnet bore. Verify that no loops were created by any cables (transducer cables, MR coil).
4. Place mattresses/padding on table, then cover it with the disposable cradle cover. Verify that the mattresses/padding, cradle cover and any other disposable cover do not interfere with the cradle movement in and out of the MR bore.

5. Position the patient in a supine, head-first position on the Exablate Prostate table. During preparation, the patient should be supported by the attending medical team.

NOTE:

- Insulate the patient from the MR scanner with appropriate thermal-resistant pads to prevent potential RF burns.
- Avoid direct contact of the coil's cables with the patient. The coil's cables should be place such that no arching loops are created; all other electrical cables on the cradle must be firmly secured to the cradle mechanics and isolated from contact with the patient.

[N-9]

6. On the water system display, press on **Pause Circulation** (**before** inserting the probe).
7. Lock the transducer in its shell by moving it maximum forward in horizontal orientation. Rotate it a bit until you feel and hear a 'click'.

WARNING:

Verify that the probe is not mechanically damaged prior to every use.

[W-13]

8. Cover the balloon with a thick layer of ultra-sound gel and gently spread it over the balloon. Remove any visible air bubbles in the gel.
9. Insert the endorectal probe through the anus, until the anus is at the narrow part of the probe (the probe neck).
10. Connect the probe to the **Motion Unit** by bringing the **Positioner** forward towards the probe.

    Verify than none of the drapes/covers get stuck between the probe and the motion unit connectors.
11. Lock and tighten the **Positioner** (hand screws) to the cradle and the **Motion Unit** to the **Positioner**. It is possible to set the **Motion Unit** at an initial rotation of up to ±20 degrees, according to the desired treatment location.
12. Connect the **Probe Cable** pin to the **Positioner**.
13. On the **Motion Unit** controller, press on **Enable** + **Connect**.
14. On the **Motion Unit** controller, press on **Enable** + **Home**.

WARNING:

In case of any hazard or risk to the patient, team or system, press on **any single** button on the **Motion Unit** controller, to immediately stop its movement.

[W-45]

15. On the water system display, press on **+60cc** button and then on **Start Circulation**.

WARNING:

System will alert when pressure in the balloon exceeds 200mmHg. In such a case of over-pressure in the balloon, drain water from it to reduce the pressure on the rectal wall.

[W-14]

16. Place the anterior part of the imaging coil above the prostate area (aligned with the posterior part) and strap it to the table.
17. Strap the patients' legs in the leg holders. Verify proper padding of the leg holders throughout entire treatment (i.e., pads are intact and fully covering the holders, no pressure points on patient's legs, etc.).
18. On the **Motion Unit** controller, press **Enable** + **Test** to verify that the probe motion is not obstructed. If the Motion Test finishes successfully, a green LED will light up next to the Test button. If it fails, the LED will light in orange. In this case, clear any obstructing elements.
19. Set a landmark on the estimated location of the prostate and insert the table into the MR bore. Ensure that nothing hinders the movement of the table mechanism as it goes in and out of the scanner.

NOTE:

Proper landmark allows the Exablate system to take trackers readings correctly. It also assures high imaging signal in the targeted area.

[N-10]

WARNING:

Pay attention to verify that no air has entered the balloon. Air bubbles inside the balloon may reduce target zone temperatures, cause defocusing and misalignment of the spot and/or severely damage system components.

[W-47]

3.5. Patient Release

At the end of the treatment, release the patient as follows:

1. Exit the treatment in the Exablate workstation.
2. Take the cradle out of the MR bore back to home position.
3. On the **Motion Unit** controller, press on **Enable** + **Home**. This will bring the transducer back to its home position, which is the safest position for extraction.
4. On the **Water System** display, press **Extract**. This will pause the circulation, drain the balloon back to the initial insertion volume, and will move the water system display to the **Home** screen.
5. Release the large hand screw that fixes the **Positioner** to the cradle and retract the entire **Positioner** along with the probe backwards from the patient.
6. Release the hand screw that fixes the **Motion Unit** to the **Positioner** and lower the probe until it lies safely on the cradle.
7. Disconnect the imaging coil and the tracking coil cables from their connectors within the magnet bore.
8. Lower the table and carefully remove the patient from the table.
9. Remove all single-use items from the probe and discard as per hospital policy.
10. Perform cleaning and high-level disinfection of the water system (see Appendix C for details).

WARNING:

All single-use items (e.g., disposable shell assembly, drapes and covers) MUST be disposed of properly after each use according to the institution rules and procedures.

[W-15]

3.6. Shutdown

To shut the system down, proceed as follows:

1. Click the **Quit** 

button on the **System** toolbar to return to the **Startup** screen.
2. Click the **Power**  button; the system responds with the **Shutdown Confirmation** message.
3. Click **Yes** to continue; the automatic shutdown procedure is initiated. This takes a few minutes.
4. Disconnect the coupler cables and hoses from the table only when the console has automatically powered down, and the power-on light has been turned **OFF**; unlock the quick-coupler levers and gently slide the cable/hose quick-coupler out.

5. Undock the table.
6. To prevent damage to the transducer, at the end of the working day (after cleaning the system), verify that the transducer is dry, and cover it with a mechanical protective cover.

CAUTION:

Do not leave the transducer filled with water unattended or for more than 20 hours.

[C-4]

7. When not in use, cover the patient table with the protective table cover.

3.7. Daily Quality Assurance (DQA) Test Procedure

The DQA procedure should be conducted at the start of each day, prior to each treatment, to verify proper operation of the Exablate Prostate system.

The instructions below provide a general outline of the DQA procedure.

The accessories required for the DQA procedure are:

- Phantom gel (SET000885-CE) – solid, water based, crossed linked gel mimicking Prostate tissue. This gel is disposable.
- Phantom holder (ASM001513) – holds the phantom gel during DQA procedure.
- A single-use, disposable treatment kit (SET000546-BC-CE).

The DQA test procedure is a simulated treatment using a tissue-mimicking phantom. This phantom has the unique property of heating due to ultrasound energy absorption, similar to that of a real tissue.

3.7.1. DQA Set Up Procedure

Prior to starting the DQA confirm:

1. Reboot the MR System if it has not been rebooted that day.
2. Power on the system (see Section 3.1).
3. Visually check the integrity of the transducer:
   - For loose fittings or cracks
4. Check for any loose or damaged connectors or water tubes on the patient table
5. Ensure that the patient table is completely set up and ready for the patient.

6. Place the posterior part of the imaging coil on the table, adjacent to the cradle's hole.
7. Insert the coil's cable connector into the matching connector within the magnet bore.
8. Insert the tracking coils cable connector (attached to the cradle) into the matching connector within the magnet bore.
9. Set up the probe as described in Section 3.2.
10. Place the phantom holder at the center of the coil.
11. Once attached to the Motion Unit, position the balloon in the middle of the phantom holder.
12. Lock the Positioner to the cradle and the Motion Unit to the Positioner.
13. Connect the probe cable pin to the Positioner.
14. On the Motion Unit controller, press on Enable + Connect.
15. On the Motion Unit controller, press on Enable + Home.
16. Cover the balloon with a generous layer of ultrasound coupling gel. Verify no bubbles are captured in the gel.
17. Place the phantom gel on the phantom holder, over the balloon; make sure it is centered over the balloon. Strap the phantom gel to the phantom holder.
18. On the Water System display, verify that it is in **Treat** mode and press on **+15cc**, several times if needed, until the balloon creates proper acoustic interface with the phantom gel.
19. Place the anterior part of the imaging coil over the center of the phantom holder.
20. Set a landmark on the center of the phantom and insert the table into the MR bore. Ensure that nothing hinders the movement of the table mechanism as it goes in and out of the scanner.
21. Insert the table to the MR bore.
22. Open new exam on the MR console and run Localizer scan
23. Start new treatment on Exablate workstation.
24. Perform a short treatment including at least 1 Macro-spot (with 3+ sub-spots). Check that the system operates properly, that the spot is within 1 mm of the target location and that thermal dose is achieved.
25. Verify that the Region of Treatment (ROT) is reaching required ablative temperatures (> 65 ^{o}C) during Macro-spot sonication.

CAUTION:

If any of the above inspections or tests fail to meet the expected values, discontinue use of the system until it has been thoroughly inspected by authorized INSIGHTEC service personnel.

Do not treat patients if the DQA was not completed successfully!

[C-5]

NOTE:

Exablate Prostate treatments create many new series on the MR scanner. It is advisable that during DQA, sufficient disk space be available on the MR workstation.

[N-11]

3.8. Storage and Maintenance of the DQA Phantom Gel

The DQA phantom gel is a solid water based cross-linked gel, embedded in a rounded plastic container, and protected by a Mylar membrane.

1. Always check the expiration date on the DQA phantom gel **before** using it; If it is expired, order a new phantom gel. Expired phantom gel should not be used.
2. Inspect the phantom for cracks and chips; if any appear, order a new phantom gel.
3. If the surface of the phantom is defective, a replacement phantom must be ordered from INSIGHTEC immediately. The defect may trap air and cause beam deflection.
4. Verify that the Mylar membrane protecting the phantom gel is intact and tightened. In any case of holes in the Mylar membrane, bacteria may quickly destroy the phantom.
5. Close the bottom cover of the phantom gel and store it in a cool, dark location.

NOTE:

The DQA phantom gel is fragile, Handle with care.

[N-12]

4. SYSTEM START-UP

4.1. Start-Up Screen

Turn on the power to the system and log on (see Chapter Figure 4-1); the Start-Up screen appears:

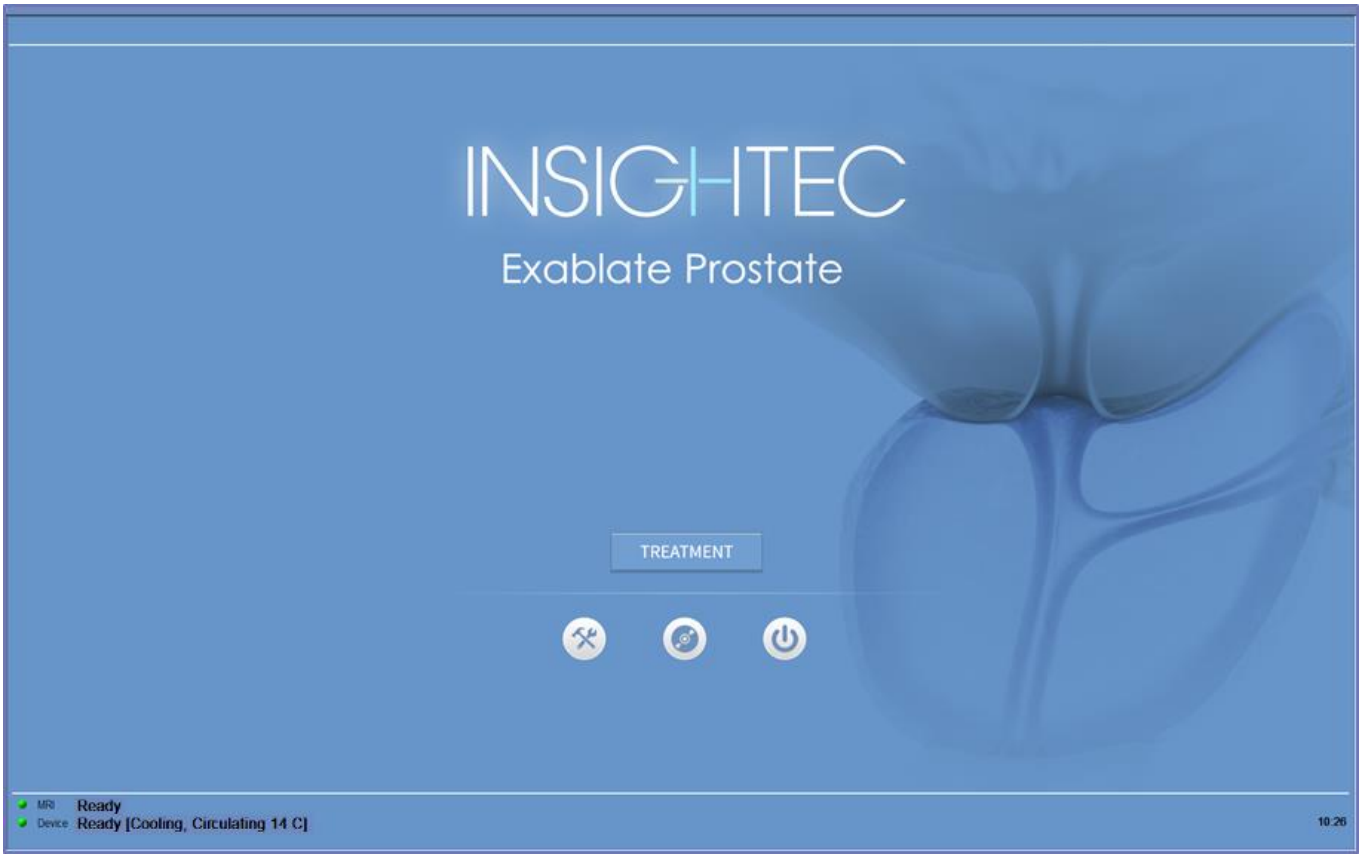


Figure 4-1: Start-Up Screen

The **Start-Up** screen contains a **Treatment Start** button, Three **Command** buttons and a **Status Bar**.

4.2. Treatment Options

Pressing the **Treatment** button activates the application-specific treatment.

4.2.1. Start Treatment

TREATMENT	**Start Treatment**	Click this button to begin the treatment

4.2.2. Command Buttons

The command buttons that appear in the lower half of the **Start-Up** screen are:

	**Utilities**	Click this button to access **Utilities** mode (see Chapter 10).
	**Data Management**	Click this button to access data management operations (see Chapter 11).
	**Shutdown**	Click this button to shut down the Exablate Prostate system.

4.2.3. Status Bar

The status bar shows the operational status of the Exablate Prostate and the water system (Device), and the status of the MRI (MR).

Figure 4-2: Device and MR Status Bar

Verify that the buttons in the status bar are green. When the buttons are red, follow the system's instructions.

4.3. Begin Treatment Procedure

After turning on the power to the system and positioning the patient, the treatment procedure is initiated from the console, as well as the balloon water cooling.

1. Click TREATMENT on the **Start-Up** screen; the treatment data dialog box is opened (see Figure 4-3)
2. Type the physician's name in the **Physician Name** text box. This step is required, and the system will respond with an error message if you attempt to advance to the next stage without a name in this text box. The physician name consists of letters only (no numbers or symbols).

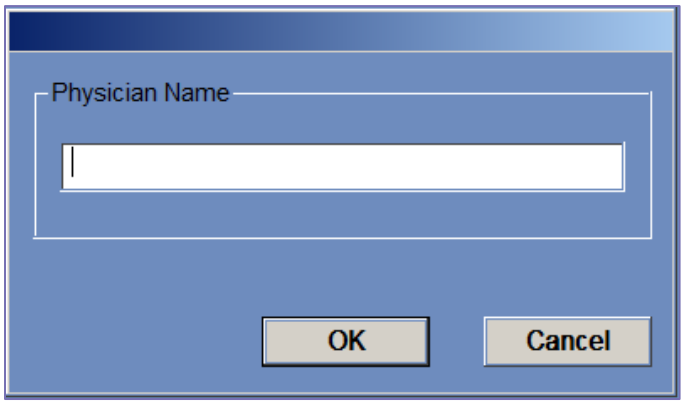


Figure 4-3: Treatment Data Dialog Box

5. TREATMENT TOOLS

5.1. Treatment Tools - Overview

This chapter describes the elements which appear on the **Treatment** screen throughout the treatment cycle. This includes **Treatment Stages**, **Utilities**, **Imaging**, **Navigation** and **Overlay tools**, **Cursor Coordinates**, **Image Strips** and the **Selected Image** window.

Along the left side of the **Treatment** screen, several tools are displayed to help plan and conduct the treatment. Different tools are available to the operator depending upon the stage of the treatment and are described in each of the following sections. The following descriptions refer to the general tools that are not specific to one stage or another.

5.2. Treatment Screen

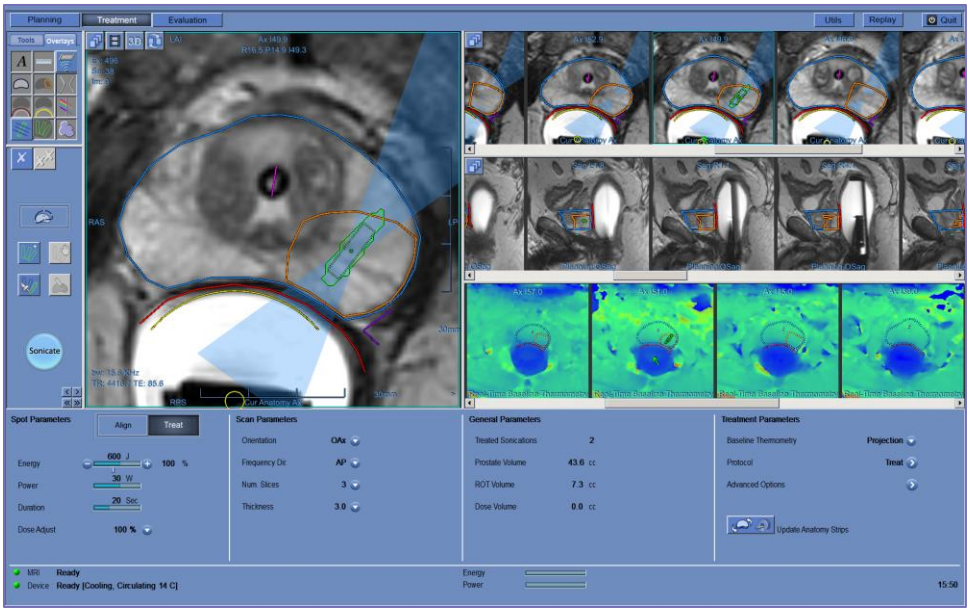


Figure 5-1: Treatment Screen

5.2.1. Exablate Main Toolbar

This toolbar consists of buttons that correspond to the stages of the **Treatment** and the **Utilities** buttons.

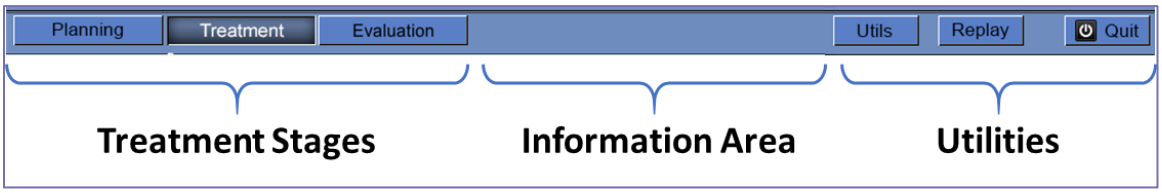


Figure 5-2: The Exablate Main Toolbar

5.2.2. Treatment Stages

5.2.2.1. Planning Stage

This stage enables the operator to:

1. **Automatically track** and determine the transducer's home position and orientation relative to the patient's anatomy.
2. **Adjust probe positioning** so that the desired region of treatment is fully accessible.
3. Determine and fix the **Central Frequency** automatically so it will be used in subsequent MR images throughout the procedure, to minimize imaging and thermal shifts.
4. **Acquire and review a Bubble Detection scan** to verify the balloon – rectal wall interface is clear of significant air bubbles.
5. **Approve Positioning**.
6. Prescribe and acquire **MR Planning images** (or alternatively scan planning images on the MR and retrieve the relevant series to the Exablate workstation) as well as additional series that might assist with **target identification** (e.g. Diffusion Weighted Imaging).
7. Acquire and examine the **Baseline Anatomy Scan** which serves as the reference for movement detection and for balloon boundaries detection.
8. Define the **Rectal Wall**, **Prostate Capsule**, **Target Volume** and the desired **Region of Treatment**.
9. Run the automatic **Balloon Boundaries** detection.
10. Define sensitive areas that will limit or eliminate the acoustic energy adjacent to them, by drawing the **Urethra**, **Nerve Bundles**, **Sphincter** and **Bladder** (optional).
11. Define the required **Treatment Protocol** (optional).
12. **Transfer the accumulated dose** to newly scanned Planning images (in case of large movement).

5.2.2.2. Treatment Stage

This stage enables the operator to:

1. **Verify** that the location of the thermal focal point is in the selected target and that the sonication intensity levels deliver the expected results.
2. Adjust the **Spot's Parameters** and **Thermal scan parameters**.
3. **Automatically Plan Macro-Spots** based on the defined **Region of Treatment** and the selected treatment protocol while taking into consideration the LEDR's limitations.
4. Perform therapeutic **Treatment Sonications**.

5.2.2.3. Evaluation Stage

This stage enables the operator to:

1. Plan and acquire **Pre- and Post-Contrast MR Treatment Evaluation images** (or alternatively scan images on the MR and retrieve the relevant series to the Exablate workstation).
2. **Measure the Non-Perfused Volume** and assess treatment outcome.

5.2.3. Information Area

In this area warning messages and treatment/progress status information are displayed for the operator.

5.2.4. Utilities

Utils – Provides access to optional tools during the Treatment stage.

Replay – Views and analyzes the results of previous sonications.

Exit – Aborts the treatment and returns to the Startup screen.

5.2.5. Image Strips

Three rows of image strips appear on the screen. Any content that has been loaded into the system can be displayed, using the navigation tools next to each strip (see Figure 5-1).

5.2.6. Selected Image Window

The **Selected Image** window is the "workspace" for planning and conducting treatments. When clicking on an image in the image strips, this image is displayed in the selected image window.

NOTE:

All user editing and interaction with graphical objects is performed only on the selected image window.

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5.2.7. Imaging Tools

This section describes the button, name and function of each of the imaging tools.

Zoom

To see a close-up of an image, click this button. To zoom in, drag the mouse up. To zoom out, drag the mouse down. Any change in one image is automatically reflected in all the other images on the same type of strip.
Alternatively, click the left mouse button and drag the mouse as above to change the zoom.

Pan

To navigate around a zoomed image, click this button and then move the cursor to the image you wish to navigate to. Drag to pan the image. Alternatively, right click and drag to pan the image. Any change is automatically reflected in all the other images on the same type of strip.

Measure Distance

Click this button to measure the actual distance between two points. This function is applicable only to the selected image window.

To measure distance:

1. Click an image from the image strips to view in the selected image window.
2. Click on the first point to measure.
3. Move to the second point and click again.
4. Double click to complete the Measure command.
5. If needed, edit the measurement line by moving its tip

Exablate calculates and displays the distance between the two points. Distance label can be moved if required.

Measure Area

Click this button to measure the attributes of a drawn polygon. This function is applicable only to the selected image window.

To measure an area, draw a polygon:

1. Click on the first point of the polygon to be measured.
2. Continue to draw the outline of the polygon with single clicks.
3. Close the polygon by clicking again on the first point.

The polygon's average pixel value, the standard deviation of pixel values within the polygon and its area are calculated and displayed. Label can be moved if needed.

Note

On a temperature map, the pixel value is the temperature value. The average temperature within a polygon is displayed in the temperature graph (see Section 7.3.6).

Measure Angle

Click this button to measure an angle, or to place a right angle on the image. This function is applicable only to the selected image window.

To measure an angle:

1. Select **Angle** from the menu
2. Click on the first point of the angle to be measured.
3. Move to the second and third point and click again
4. Double click to complete the **Measure** command.
   Exablate calculates and displays the angle.

Windowing

To change the image windowing (brightness or contrast), click this button. Drag the mouse up to brighten and down to darken the image. Drag the mouse left to increase the contrast and right to decrease the contrast. The change is automatically reflected in all of the other images on the same type of strip.

Alternatively, click the middle mouse button and move the mouse as above to change the brightness or contrast.

Reset Windowing

Click this button to restore all images to default zoom, pan, contrast, and brightness settings. **Reset** applies to the entire image slice in all strips simultaneously.

Centering

Click this button and then select a location in any image. By clicking on it, the images with this point will appear at the center of the strips.

	**Screen Snapshot**	Click this button to take a snapshot of the screen and save it with the treatment database. When the specific treatment is exported, the screen-dumps associated with it are copied to the CD.
	**Animation**	Click this button to display the selected series as a cine.
	**3D View**	Click this button to show the treatment data in three dimensions, to clinically assess the treatment plan.
	**Image Toggling**	Click on the image toggling button to iteratively pass between the Previous and Current Anatomy images in the selected image window (see Section 7.2.8).

5.2.8. Overlays

This section describes the overlay tools, which toggle the graphic overlays on the MR images.

	**Text Overlay**	Click this button to show or hide the **text overlays** on the images.
	**Measurement Lines**	Click this button to show or hide the **Measurement** graphical overlays on the images.
	**Treatment Envelope**	Click this button to display the **Treatable area** (as governed by the position and available motion range of the transducer).
	**Prostate Capsule**	Click this button to show or hide the contour of the **Prostate Capsule**.
	**Target Volume**	Click this button to show or hide the **Target Volume** contour.
	**Region of Treatment (ROT)**	Click this button to show or hide the contour of the **Region of Treatment (ROT)**.
	**Energy Pass Zone**	Select a spot and click this button to view or hide the **rays** from the transducer to the spot.

	**Rectal Wall**	Click this button to show or hide the drawn **Rectal Wall** contours.
	**Balloon Boundaries**	Click this button to show or hide the **Balloon Boundaries**.
	**Low Energy Density Regions (LEDR)**	Click this button to show or hide the Low Energy Density Region **(LEDR)** overlays (urethra, nerve bundles, sphincter, and bladder).
	**Thermal Scan Planes**	Click this button to display the locations of the **MR thermal slices** on the selected image window and on the image strips. The lines display the intersection between the planned images and the thermal scan images for selected sonication spots.
	**Sonication Spots**	Click this button to select **sonication spots display** (Show/Hide all spots).
	**Dose**	Click this button to show or hide the accumulated dose. The accumulated dose appears as a blue overlay on the image. In the **Thermal Evaluation** screen, the dose from the last sonication is displayed in green.

5.2.9. Navigation Tools

Navigation tools are used to select the content of the image strips which will be displayed, and to scroll within the strips.

	**Image Strip Selection**	Click this button to select the images in one of the three image strip windows to be displayed from the pull-down menu. Options may vary between stages depending on the data available.
	**Image Scroll Buttons**	Use this button to scroll through an image series. The single arrows scroll single images, and the double arrows scroll to the first or last image. Alternatively, use the scroll bar under the image strips. To navigate through an image series, you can use the Right and Left arrows buttons on the keyboard.
	**Temperature Maps Scroll Buttons**	For multi-slice thermal scans, use this button to scroll between different slices of the temperature maps in the selected image window. Alternatively, select the desired slice in the image strips. To

navigate through different slices, you can use the Up and Down arrows buttons on the keyboard.

5.2.10. Image Overlays

5.2.10.1. Image Annotations

The image annotations consist of the orientations, patient details, scan parameters, scaling bar and image type. MR magnitude images (Sonication Anatomy) consist of slice location while Temperature Maps consist of the acquisition time.

5.2.10.2. Cursor Coordinates

The cursor coordinates show the location of the anatomical feature pointed in three axes on all image windows.

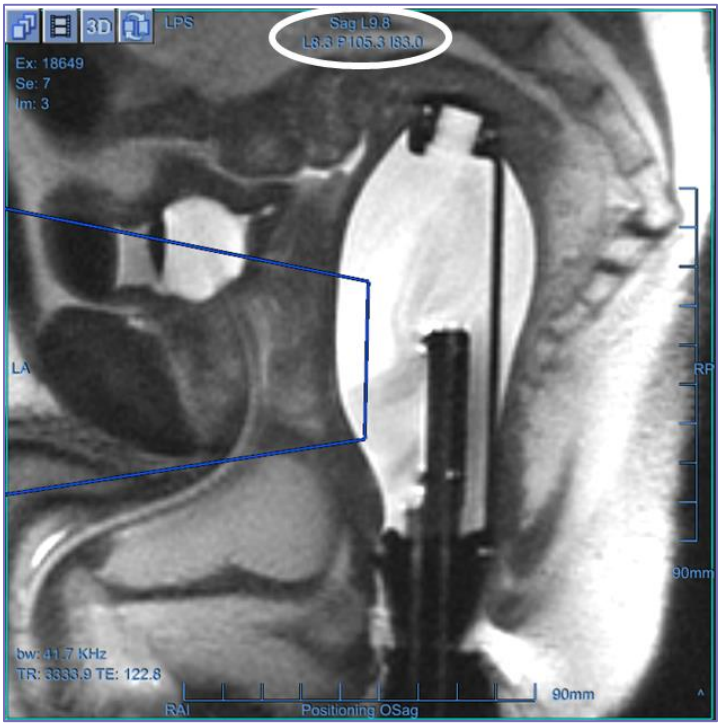

Figure 5-3: Cursor Coordinates

5.2.10.3. Shadow Cursor

While pointing the cursor at any image location, an additional small green cursor will appear on all images in which this point appears in all orientations.

5.2.10.4. Three-Dimensional Display

At any stage, press the  button to open the Three-Dimensional Display screen (see Figure 5-4).

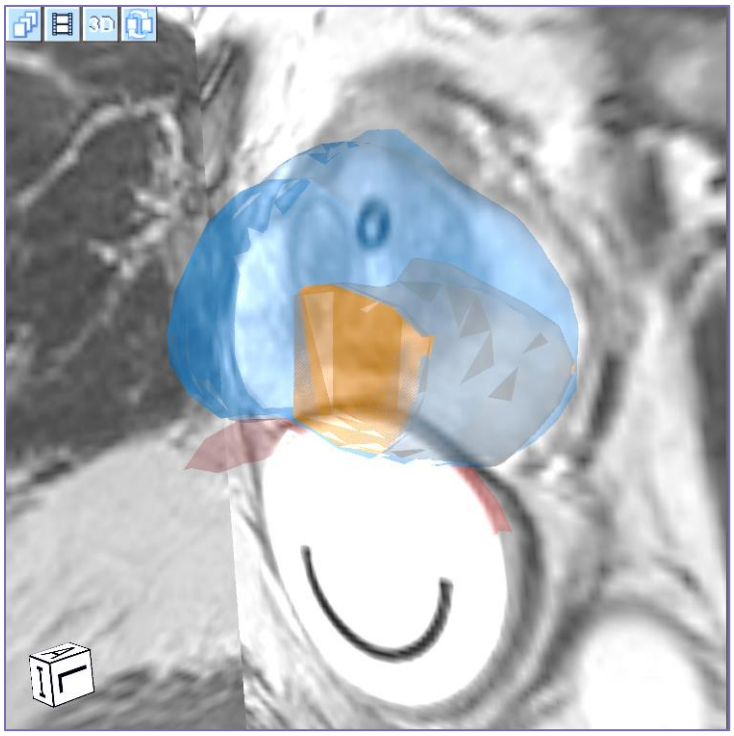

Figure 5-4: Three-Dimensional Display Screen

During the **Three-Dimensional Display** mode, the following elements are used:

	**Orientation Box**	The orientation box gives information on the three-dimensional display of the patient orientation.
	**Default View**	Click this button to return to the default three-dimensional display.

	**Coronal View**	Click this button to display the coronal images on the three-dimensional Display. Click it again to turn off the coronal images display.
	**Axial View**	Click this button to display the axial images on the three-dimensional Display. Click it again to turn off the axial images display.
	**Sagittal View**	Click this button to display the sagittal images on the three-dimensional Display. Click it again to turn off the sagittal images display.
	**3D Scroll Bars**	Click on the 3-D Scroll bar button and drag it up and down to scroll between the displayed images.

Press the middle mouse button, click and drag the mouse to rotate the **Three-Dimensional Display**. As in regular display mode use the mouse right click to Pan, and click the Left mouse to zoom (see more in Section 5.2.7).

To exit the three-dimensional display mode, press the  button or alternatively click on any other image on the strips.

6. PLANNING STAGE

6.1. Planning Stage - Overview

The **Planning** stage is the first stage of an Exablate Prostate treatment procedure.

This stage provides the system with all necessary data relates to imaging and treatment planning.

NOTE:

During **Planning** stage, there are several different treatment flows that can be executed by the operator. This chapter reviews a suggested treatment flow to cover all the features that were integrated within this stage.

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The operator is not obliged to follow this suggested flow but must complete the following tasks to proceed to the next stage:

1. **Automatically track** and determine the transducer's home position and orientation relative to the patient's anatomy.
2. **Adjust probe positioning** so that the desired region of treatment is fully accessible.
3. Determine and fix the **Central Frequency** automatically so it will be used in subsequent MR images throughout the procedure, to minimize imaging and thermal shifts.
4. **Acquire and review a Bubble Detection scan** to verify the balloon – rectal wall interface is clear of significant air bubbles.
5. **Approve Positioning**.
6. Prescribe and acquire **MR Planning images** (or alternatively scan planning images on the MR and retrieve the relevant series to the Exablate workstation).
7. Acquire and examine the **Baseline Anatomy** scan which serves as the reference for movement detection and for balloon boundaries detection.
8. Define the **Rectal Wall** and the **Prostate Capsule**
9. Define the **Target Volume** and automatically expand it by customizable margins to form the **Region of Treatment**, OR directly define the desired **Region of Treatment**.
10. Run the automatic **Balloon Boundaries** detection.

The rest of tasks and features are considered as optional:

1. Define sensitive areas that will limit or eliminate the acoustic energy adjacent to them, by drawing the **Urethra**, **Nerve Bundles**, **Sphincter** and **Bladder** (optional).
2. Define the required **Treatment Protocol** (optional).
3. **Transfer the accumulated dose** to newly scanned Planning images (in case of large movement).

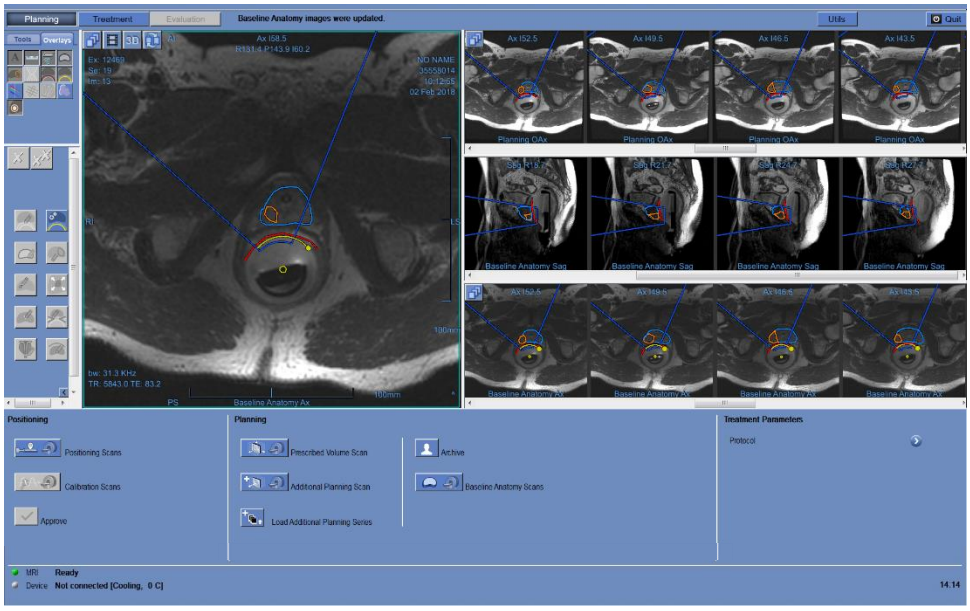

Figure 6-1: Planning Screen

6.2. Planning Stage General Action Elements

During the Planning stage, the following new general Action elements are used (see Chapter 5 for an explanation of the Imaging tools previously used).

	**Delete Selected Object**	Click this button to remove the selected object.
	**Delete All Objects**	Click this button to remove all objects of the same type as the selected object.

6.3. Baseline Thermometry

Baseline Thermometry establishes the prostate temperature profile before the treatment sonications are executed. The Baseline Thermometry maps serve as baseline for the thermometry performed during sonications, and as a baseline for **Macro spots** planning and prediction.

6.4. Positioning Verification

Under the **Positioning** procedure, the following elements are used:

	**Positioning Scans**	Click this button to perform a scan on the MR that will automatically track the transducer's current location, then scan Sagittal and Axial Positioning images and load them in the strips.
	**Calibration Scans**	Click this button to perform a scan on the MR to automatically detect an optimized **MR Central Frequency** value, to minimize imaging frequency shifts. In addition, the system will automatically acquire a **Bubble Detection** strip.
	**Approve Positioning**	Click this button only once patient and probe positioning are final, and once both Positioning and Calibration scans were performed and validated. The system will initiate a **Motion Test** to verify that the probe motion is unobstructed.

6.4.1. Validate Treatment Envelope Coverage

Verify that the transducer position provides full coverage of volume designed to be treated.

The **Treatment Envelope** represents the volume that can be reached and treated based on transducer position, and taking into account mechanical motion and electrical steering capabilities. The Treatment Envelope is overlaying the scanned Positioning images (see Figure 6-2).

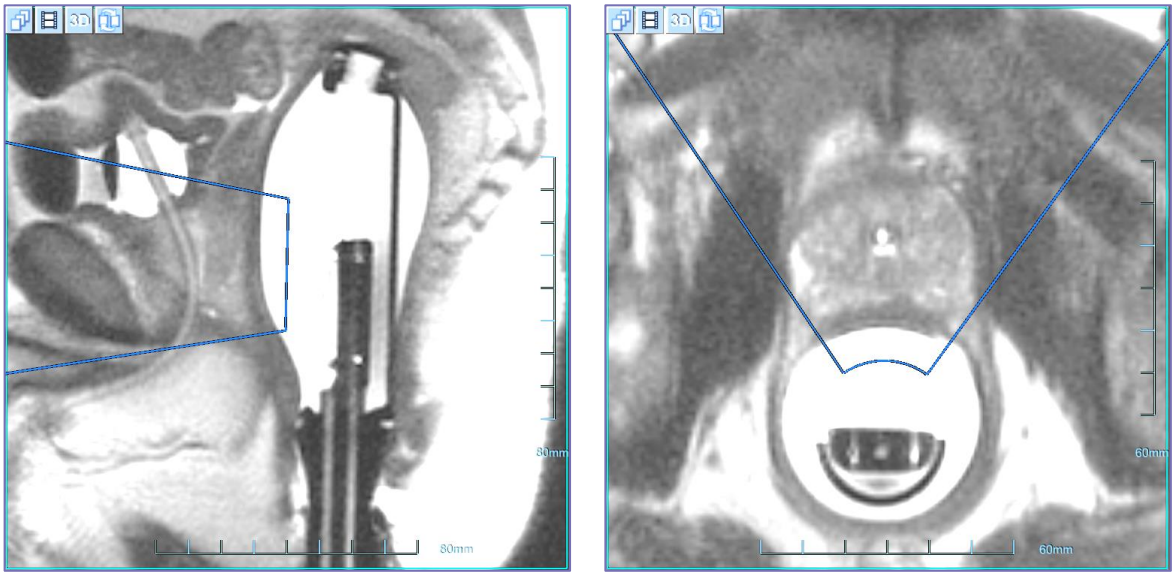

Figure 6-2: Treatment Envelope (blue) displayed on Sagittal Positioning image (left) and on Axial Positioning image (right)

1. On the MR workstation, start a new MR exam and perform a Localizer scan to define the patient's entry and position.
2. Click  and confirm the patient's name and position, as they appear in the pop-up message on the operating console screen.
3. The MR performs tracking scans to automatically detect the transducer location, following by Sagittal and Axial Positioning scans.
4. On the Axial Positioning images, verify that the treatment envelope covers the entire designated region of treatment.

- If the treatment envelope does not fully cover the entire designated region of treatment on the Axial images, use the angle measurement tool  to measure the required degree of the probe rotation.

5. On the Sagittal Positioning images, verify that the treatment envelope covers the entire designated region of treatment.

- If the treatment envelope does not fully cover the entire designated region of treatment on the Sagittal images, use the line measurement tool  to measure the required degree of the probe insertion or extraction.

6. Perform the required reposition of the probe (rotation and/or linear displacement) using the Positioner mechanism and the rulers that are attached to the cradle and the motion unit.
7. From the motion unit controller, run the Motion Test procedure to verify that the probe motion is not obstructed in its new position.
8. Repeat the procedure in this section, starting in Step 2.

6.4.2. Acquire Calibration Scans

Detecting the optimal value of the **MRI Central Frequency** prior to the treatment can reduce thermal imaging shifts during sonications.

During the Calibration scans, the system detects the optimal MRI Central Frequency. This procedure will occur automatically by the system.

1. Click  to initiate the **Calibration** scans.
2. The MR performs tracking scans to automatically detect the transducer location, followed by an MRI Central Frequency scan.
3. Next, a **Bubble Detection** series will be scanned and loaded to the 3rd strip. Review the images to ensure the following:

- No image folds (tissue that overlap tissue)
- No bad signal or excessive noise
- No artifacts of any kind

4. If the images exhibit any of the above issues, repeat the Calibration scans by clicking  .

6.4.3. Verify Acoustic Coupling

Verify proper acoustic coupling between the balloon and the rectal wall.

Inadequate coupling (which may result from air bubbles, fecal residues etc.) between the balloon and the rectal wall may either reflect or absorb part of the ultrasound energy, as well as create thermal imaging artifacts.

1. Carefully review the **Bubble Detection** images (either directly on the Exablate Workstation or on the MR) and ensure no significant air bubbles are found in the interface between the endorectal balloon and the rectal wall.

NOTE:

The **Bubble Detection** images are suitable for this objective as air bubbles in the balloon-rectal wall interface cause an enlarged artifact and are thus easy to identify. See Figure 6-3 for an example.

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2. In case significant air bubbles are detected, attempt the following techniques (noted here in an escalating order):

- Without draining the balloon or extracting the probe, rotate the motion unit from side to side, attempting to sweep the air bubbles outside of the acoustic window.
- Without draining the balloon or extracting the probe, cover your finger with ultra-sound gel, insert the finger into the gap between the balloon and the rectal wall and sweep your finger in an attempt to replace the air with fresh gel. Pay attention not to scratch or puncture the balloon in the process.
- Fill the balloon with another 30 CC of water, attempting to push the air bubbles into regions of lower pressure, outside of the acoustic window.
- As a last resort, drain the probe back to reference (insertion) volume, completely extract the probe, clean it, apply new US gel and re-insert the probe. Fill the balloon with 60cc of water.

NOTE:

After re-positioning the probe (also for the purpose of removing air bubbles), re-start the Positioning verification procedure (see Section 6.4).

[N-16]

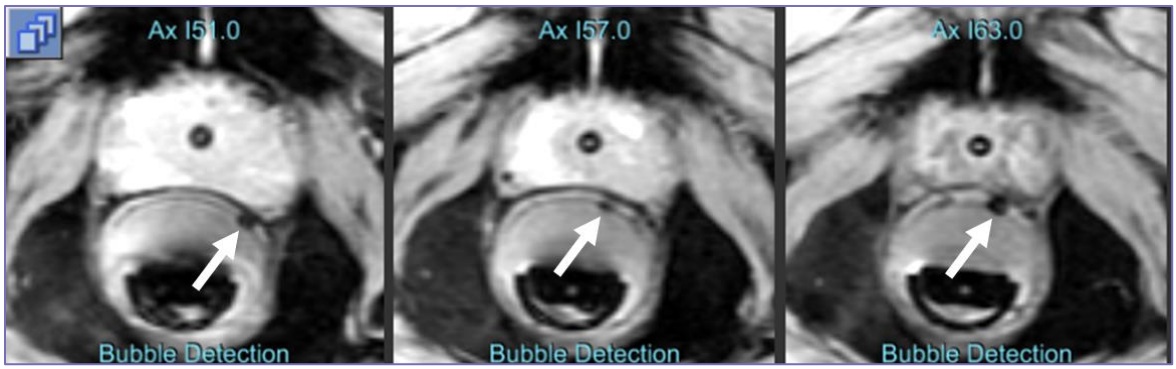


Figure 6-3: Air bubbles as seen in a Bubble Detection scan

6.4.4. Approve Positioning

1. Once patient and probe positioning are final, and once both **Positioning Scans** and **Calibration Scans** were performed and validated, press the **Approve Positioning** button.
2. The system initiates a **Motion Test** to verify that the probe can reach the full range of motion.

- In case of a motion failure, go inside the MR room and press **Enable** + **Motion Test** on the **Motion Unit Controller**. Carefully view the motion test and verify there are no physical obstructions that interfere with the motion of the probe (e.g., blankets, patient legs etc.).

6.5. Acquisition of MR Planning images

The Exablate Prostate workstation supports several ways to prescribe, acquire and load MR planning images, which serve as a base for treatment planning.

1. Automatic prescription and acquisition of Axial Planning images, scanned perpendicular to the transducer axes. Sagittal and Coronal Planning images are produced by reformatting the scanned Axial series and create and orthogonal set, according to transducer axes.
2. Manually prepare and acquire the planning images (in all 3 planes) completely using the MR workstation user interface. Load all scanned series to the Exablate workstation, or load some orientations only (e.g., to replace reformatted strips).
3. Manually scanning an Axial Planning series on the MR and loading it to the workstation. Sagittal and Coronal Planning images are produced by reformatting the loaded Axial series and create and orthogonal set, according to transducer axes.

6.5.1. User Interface Elements

During the procedure of acquiring, reformatting and loading MR Planning images, the following elements are used:

	**Prescribed Volume Scan**	Click this button to prescribe and run the Axial Planning images scan, according to the range defined by the Scanning Range lines. This scan will use the optimal central frequency that was identified by the system. When the scan ends, the new scanned MR series will appear in the upper Exablate workstation image strip. The system will automatically produce Sagittal and Coronal series by reformatting the scanned Axial series. The Sagittal and Coronal reformatted series will appear in the 2nd and 3rd image strips. ***Note*** Following the Axial Planning series scan, the system will automatically initiate the **Baseline Anatomy** Axial and Sagittal scans (see Section 6.6).
	**Archive**	Click this button to open the images Loading Form (“Archive”). The following button appears in the images loading form.
	**Load**	Click this button to load the series that appear in the selected series frame to the strips on the screen.

6.5.2. Define the Scanning Range

After approving Positioning, two cyan lines appear on the Sagittal Positioning image, representing the Scanning range (From-To) of Planning images which will be executed automatically by the Exablate workstation. The lines are perpendicular to the transducer axis (see Figure 6-4).

NOTE:

- The range of Planning images should cover the entire prostate and include proper margins.
- It is recommended to define the minimal range required to fulfill the clinical needs, to minimize the expected scanning duration.

[N-17]

To customize the Scanning Range, drag the graphical line objects up/down to enlarge or reduce the coverage area. There is no significance to switching between the lines.

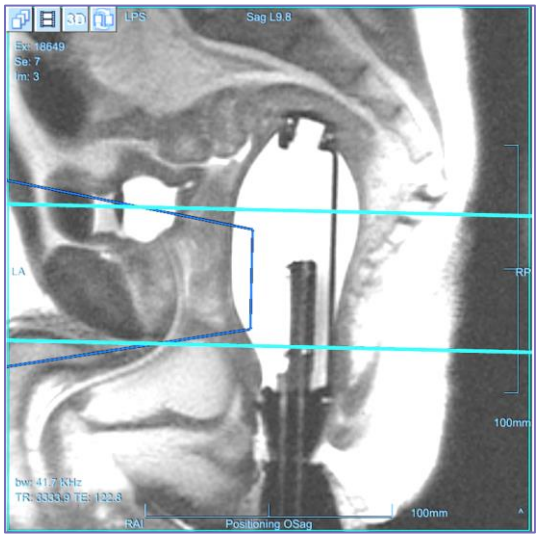


Figure 6-4: Scan Range lines

6.5.3. Automatic Acquisition of Planning Images

1.  Press this button in order to perform an Axial scan covering the range that is defined by the Scan Range Lines (see Section 6.5.2).
2. The automatic Axial scan will automatically be prescribed with the optimal Central Frequency value that has been previously found (see Section 6.4.2), and with recommended parameters (e.g., slice thickness of 3mm and zero spacing).
3. Once the MR completes scanning this series, the set of images will be retrieved automatically and displayed on the 1st **Image Strips** of the Exablate workstation.
4. The Exablate workstation will automatically produce Sagittal and Coronal series by reformatting the scanned Axial series.
5. The Sagittal and Coronal reformatted series will appear in the 2nd and 3rd image strips.

NOTE:

Sequentially to the Axial series scanned by the "Scan Prescribed Volume" option, additional two scans will start running on the MR. These scans are the Axial and Sagittal **Baseline Anatomy Scans** (see Section 6.6).

[N-18]

6.5.4. Manual Acquisition of MR Planning Images

As an alternative option for acquiring the planning images from the Exablate workstation, you may prepare and acquire the planning images completely using the MR workstation user interface.

1. Prepare and scan the desired planning orientations on the MR. Follow these imaging guidelines:

- Prescribe high quality, high resolution sets of T2w images.
- The Axial series should have a slice thickness of 3mm and zero spacing.
- We recommend acquiring images that are perpendicular to the transducer axes. It is easier to view and comprehend the overlaying spots on such images.

2. After acquiring the scans, confirm that:

- The target to be treated is visualized
- Verify that the patient has not moved during imaging and that there are no imaging artifacts that could influence identification of anatomy structures.

3.  Press this button and open the loading form (see Figure 6-5).

4.  After acquiring each of the scans (or alternatively after all were scanned), press this button. The new series that has just been scanned on the MR will appear on the ***MR Series List*** of the ***Selected Exam***.

5. Click on each one of the selected series you would like to upload as Planning Images. As a default, all images within the selected series will be used by the system.

6. If only part of the series is needed, Click the desired image numbers as follows:

- Select an image and then press **Shift** and select another image, to select any number of contiguous images.
- Select an image and press **Ctrl** to select additional non-contiguous images.

7. The selected series will appear on the ***Selected Images List***.

8.  To change the selection, press this button and select a different set of images. These images replace the previously selected ones.
9.  Press this button to upload and display the selected images in the strips.

NOTE:

You can start planning the treatment as soon as the Axial Planning series is loaded, and acquire the rest of the orientations while drawing the treatment plan (see Section 6.7).

[N-19]

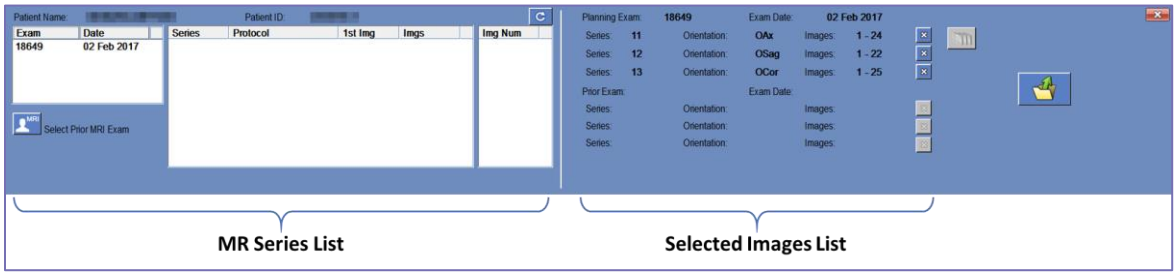


Figure 6-5: Planning stage – Loading Form

6.5.5. Reformat of Axial Planning Images

It is possible to manually scan an **Axial Planning** series on the MR and load it to the workstation, while **Sagittal** and **Coronal Planning** images will be produced by reformatting the loaded **Axial** series and create and orthogonal set, according to transducer axes.

1. Follow the procedure described in Section 6.5.4, while scanning and loading an Axial series only.
2.  Press this button to reformat the Axial series into Sagittal and Coronal series.
3. System produces two perpendicular series with 3mm thickness and zero spacing between the images.
4. The newly produced series will appear in the ***Selected Images List*** with an "R" suffix to denote those series were produced by reformatting.
5.  Press this button to upload and display the selected images in the strips.

6.5.6. Loading Additional Planning Images (Optional)

The Exablate workstation enables to load intra-operative diagnostic MR images (e.g. Diffusion Weighted Imaging), to aid in identifying the **Target Volume**.

The Exablate Prostate workstation supports several ways to prescribe, acquire and load additional MR planning images:

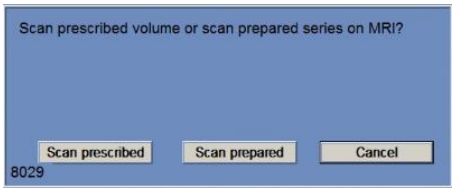
1. Automatic prescription and acquisition of Axial Diffusion-Weighted Images, scanned perpendicular to the transducer axes.
2. Manual preparation of the additional planning images scan on the MR console (including desired imaging type, scan range, etc.). The acquisition of the images is performed from the Exablate workstation (after preparing and defining the scan on the MRI workstation).
3. Manually scanning additional planning images series on the MR and loading it to the workstation.

6.5.6.1. User Interface Elements

During the procedure of acquiring, reformatting and loading MR Planning images, the following elements are used for acquiring the additional planning images:

Scan Additional Planning Series

Click this button either to automatically prescribe the additional planning series or to scan the prepared series on the MR console.



After clicking the **Scan Additional Planning Series**, a pop-up message will appear, with the following options:

- **Scan prescribed** - click this button to automatically prescribe and run a Diffusion Weighted Imaging (DWI) scan, according to the range defined by the Scanning Range lines. This scan will use the optimal central frequency that was identified by the system.
  When the scan ends, the new scanned MR series will appear in the 3rd Exablate workstation image strip.

- **Scan prepared** - click this button to acquire (scan) the **manually prepared** additional planning series on the MRI. This scan will use the manually defined imaging type and

scan range but will use the optimal central frequency that was identified by the Exablate system.
When the scan ends, the new scanned MR series will appear in the 3rd Exablate workstation image strip.

- **Cancel** - click this button to exit the pop-up message back to the Planning stage screen, **without** scanning additional planning series.

Load Additional Planning Series — Click this button to load the manually scanned additional planning series from the MRI to the Exablate workstation (select the series in the MR console browser, prior to loading it). The loaded MR series will appear in the 3rd Exablate workstation image strip.

6.5.7. Loading Prior Exams (Optional)

 The Exablate workstation enables to load diagnostic MR images, acquired from a previous (pre-treatment) session, to aid in defining the region of treatment.

1. Press this button to open the loading form.
2. 

Press this button; the system will prompt the user to select an MR exam from the MR.
3. The MR exam information appears in the **Prior Exam** frame. Verify that the correct images are used.
4.  Press this button to upload and display the selected images in the strips.

6.6. Acquisition of Baseline Anatomy Scans

In case MR Planning images were not acquired automatically by the Exablate workstation (by the **Scan Prescribed Volume**  button), you should manually initiate the Baseline Anatomy scans (acquired automatically as a set of Axial and Sagittal series) immediately after loading the Planning images.

The Axial Baseline Anatomy scan should ideally be acquired as close as possible to the Axial Planning images, to avoid any movements between the two scans.

The Axial Baseline Anatomy scan serves as the reference for movement detection (see Section 7.2.9) and for balloon boundaries detection (see Section 6.7.5).

NOTE:

In case the Planning images were acquired automatically through the Exablate workstation (using Scan Prescribed Volume), the system automatically scans the Baseline Anatomy series. Do NOT manually repeat the scan in such a case, as the Baseline Anatomy strips will be replaced with the newly scanned ones.

[N-20]

6.6.1. User Interface Elements

Baseline Anatomy Scans Click to initiate the Baseline Anatomy scans (Axial and Sagittal).

1. After manually loading Planning images, close the loading form.
2.  Press this button to initiate the Baseline Anatomy scans.
3. The Axial Baseline Anatomy scan replicates the scan range and slice locations of the Axial Planning images, while the Sagittal Baseline Anatomy scan includes 5-6 slices that are centered around the treatment envelope.
4. Once the MR completes scanning the series, the set of images will be retrieved automatically and displayed in the 2nd image strip (Sagittal Baseline Anatomy) and the 3rd image strip (Axial Baseline Anatomy) of the Exablate workstation.

6.7. Defining a Treatment Plan

After loading the Planning images to the image strips and acquiring the Baseline Anatomy scans, you should define the treatment plan by drawing the prostate capsule, rectal wall, region of treatment (ROT), and detecting the balloon boundaries. Optional drawings include the target volume, and the following low energy density regions (LEDRs): urethra, sphincter, nerve bundles and bladder.

Target Volume can only be drawn on a **Diffusion-Weighted Imaging (DWI) series**. All other manual **drawings** are performed on the **Planning images**, while balloon **boundaries detection** is performed on the Axial **Baseline Anatomy** images.

6.7.1. Action Tools

	**Draw Rectal Wall**	Press this button to draw the **rectal wall**.
	**Detect Balloon Boundaries**	Press this button to automatically detect the **balloon boundaries**.
	**Draw Prostate Capsule**	Press this button to draw the outline of the **prostate capsule**.
	**Draw ROT**	Press this button to draw the outline of the volume to be treated (**ROT**).
	**Draw Target Volume**	Press this button to draw the **Target Volume.**
	**Expand Target Volume to ROT**	Press this button to expand the drawn **Target Volume** by customizable margins (under the **Treatment Protocol** dialog) to automatically create the volume to be treated (**ROT**).
	**Drawn Urethra**	Press this button to draw the **urethra** LEDR (optional).
	**Draw Sphincter**	Press this button to draw the **sphincter** LEDR (optional).
	**Draw Nerve Bundles**	Press this button to draw the **nerve bundles** LEDR (optional).
	**Draw Bladder**	Press this button to draw the **bladder** LEDR (optional).

6.7.2. Draw the Rectal Wall

The rectal wall is a mandatory drawing; the Exablate workstation will not allow you to proceed to Treatment stage prior to drawing it.

The Exablate workstation uses the rectal wall drawing when planning the sonications to ensure that no thermal dose reaches it. The system will warn you if you add or drag a sonication so that it's predicted dose is less than 1mm away from the rectal wall drawing.

Always draw the rectal wall at the interface between the rectal wall and the prostate (NOT at the interface between the rectum and the balloon, see Figure 6-7).

1. Press on an **Axial Planning image** (the drawing starting point) to display it in the selected image window.
2.  Press this button in the selected image window, click on the desired location to start the **rectal wall** outline.
3. Move the cursor in one direction, while pressing the left mouse button or by clicking on successive points to create the **rectal wall** outline.
4. Press the box at the end of the line to close the **rectal wall** drawing.
5. The **rectal wall** drawing should extend about 1cm out of the treatment envelope in Axial view.
6. Continue to define the **rectal wall** on all additional slices (draw on every second or third Axial slice).
7. Unclick the **Draw Rectal Wall** button or alternatively click on another drawing button and the system will automatically interpolate the drawing. Verify the automatic interpolation of the **rectal wall** is correct in all Axial slices.
8. Move the drawing by pressing and dragging it. Delete the drawing by pressing it and the **Delete** (or **Delete All**) button.

6.7.3. Draw the Prostate Capsule

The prostate capsule is a mandatory drawing; the Exablate workstation will not allow you to proceed to Treatment stage prior to drawing it.

The prostate capsule is used by the workstation to detect prostate movements and deformations during the treatment (for more information on prostate movement detection refer to Section 7.2.9).

The prostate drawing is also used to limit the predicted thermal dose from extending too far beyond it (e.g. up to the bones and muscles), and for other temperature related calculations.

1. Click on an **Axial Planning image** (the drawing starting point) to display it in the selected image window.
2.  **Press this button** in the selected image window, click on the desired location to start the **prostate capsule** outline.
3. Move the cursor in one direction, while pressing the left mouse button or by clicking on successive points to create the **prostate capsule** outline.
4. Complete a non-intersecting polygon.
5. Click the box at the end of the line to close the **prostate capsule** polygon.

6. Continue to define the **prostate capsule** on all additional slices (draw on every second or third Axial slice).
7. Unclick the **Draw Prostate Capsule** button or alternatively click on another drawing button and the system will automatically interpolate the drawing. Verify the automatic interpolation of the prostate capsule is correct in all Axial slices.
8. Move the drawing by clicking and dragging it. Delete the drawing by clicking it and the **Delete** (or **Delete All**) button.

6.7.4. Define the Region of Treatment (ROT)

The ROT is a mandatory drawing; the Exablate workstation will not allow you to proceed to Treatment stage prior to drawing it.

The ROT drawing defines the volume to be treated within the prostate capsule. The workstation planner covers the ROT volume with Macro spots, while taking into account LEDR limitations (see Section 6.7.6).

There are two options for defining the ROT:

Option 1: Automatically expand the Target Volume with customizable margins

1. Click on an image from the **Axial Planning** or **Additional Planning Series** (the drawing starting point) to display it in the selected image window.

The Target Volume can be defined either on Axial Planning Images or on the Additional Planning Images (e.g., DWI), but not on both simultaneously.

2.  **Press this button** in the selected image window, click on the desired location to start the **Target Volume** outline.
3. Move the cursor in one direction, while pressing the left mouse button or by clicking on successive points to create the **Target Volume** outline.
4. Complete a non-intersecting polygon.
5. Click the box at the end of the line to close the **Target Volume** polygon.
6. Continue to define the **Target Volume** on all additional slices (as required). Do not add intentional margins.
7. Unclick the **Draw Target Volume** button or alternatively click on another drawing button and the system will automatically interpolate the drawing. Verify the automatic interpolation of the prostate capsule is correct in all Axial slices.
8. Move the drawing by clicking and dragging it. Delete the drawing by clicking it and the **Delete** (or **Delete All**) button.

9.  **Press this button** to automatically expand the **Target Volume** and create a **Region of Treatment (ROT)**. The system will use the **Target Volume** drawing and automatically add margins as defined in the **Treatment Protocol** (see section 6.8 for more details).

WARNING:

Carefully examine the automatically generated **ROT** on all relevant slices to make sure it corresponds with your desired treatment volume.

[W-37]

Option 2: Directly draw the ROT

1. Press on an **Axial Planning** image (the drawing starting point) to display it in the selected image window.
2.  Press this button in the selected image window, click on the desired location to start the **ROT** outline.
3. Move the cursor in one direction, while pressing the left mouse button or by clicking on successive points to create the **ROT** outline.
4. Complete a non-intersecting polygon.
5. Press the box at the end of the line to close the **ROT** polygon.
6. Continue to define the **ROT** on all required slices.
7. Unclick the **Draw ROT** button or alternatively click on another drawing button and the system will automatically interpolate the drawing. Verify the automatic interpolation of the **ROT** is correct in all Axial slices.
8. Move the drawing by clicking and dragging it. Delete the drawing by clicking it and the **Delete** (or **Delete All**) button.

6.7.5. Automatic Balloon Boundaries Detection

The balloon boundaries are a mandatory element; the Exablate workstation will not allow you to proceed to Treatment stage prior to setting it.

Balloon boundaries mark the interface between the balloon and the rectal wall. They are used by the Exablate workstation for Baseline Thermometry calculations, as the balloon boundary has the know temperature of the endo-rectal balloon water.

1.  Press this button to run the automatic **balloon boundaries** detection algorithm on the Baseline Anatomy images (see Figure 6-6).
2. Yellow arcs will appear on all Axial Baseline Anatomy images that include a rectal wall drawing.
3. Review the results to verify correct marking of the balloon boundary arcs on all Axial Baseline Anatomy slices.
4. Where needed, correct the **balloon boundary** arc by changing its radius (clicking the arc handle and dragging it) or by displacing the arc (click the arc itself and drag it).
5. **Balloon boundary** arcs cannot be deleted.
6. To revert the **balloon boundaries** to the originally detected locations, press this button  again.

NOTE:

The automatic balloon boundaries detection should be performed only after the Baseline Anatomy scans were executed and once the rectal wall has been drawn, as the detection algorithm uses the rectal wall drawing as input.

[N-21]

WARNING:

- The Automatic Balloon Boundaries Detection algorithm can only assist the operator in marking the balloon boundaries. Therefore, after running this feature, pay strict attention and review all the Axial Baseline Anatomy images to ensure accurate identification.
- After each run of this feature, you must review the computation results.

[W-16]

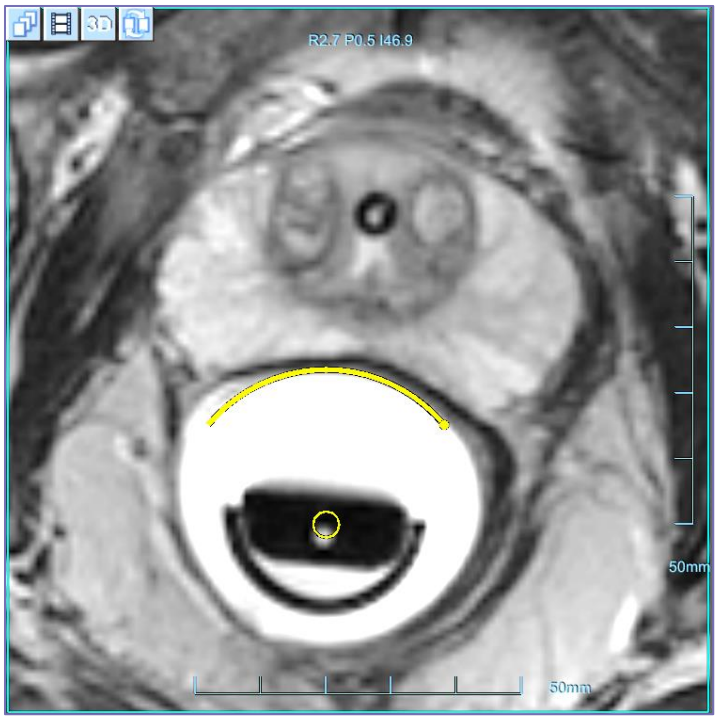


Figure 6-6: Balloon Boundaries (yellow arc)

6.7.6. Draw Limited Energy Density Regions (LEDR's) - Optional

When there is a need to prevent the predicted dose from reaching sensitive regions, corresponding LEDR contours should be drawn on all relevant images.

The LEDR's are optional drawings that mark sensitive structures. They are defined by a safety margin (measured in millimeters). The system plans and validates spots according to the distance of the predicted dose from the different LEDR's.

The following LEDR's are available for drawing:

- **Urethra:** draw the **Urethra LEDR** on **Axial Planning images**. By default, the system will keep the predicted dose at a safety distance of **3mm** from the drawing.
- **Sphincter (Apex and/or base):** draw the **Sphincter LEDR** on **Coronal Planning images**. The system will keep the predicted dose at a safety distance of **5mm** from the drawing.
- **Nerves:** draw the **Nerves LEDR** on **Axial Planning images**. The system will keep the predicted dose at a safety distance of **3mm** from the drawing.

- **Bladder:** draw the **Bladder LEDR** on Axial **Planning images**. The system will keep the predicted dose at a safety distance of **2mm** from the drawing.

1. Click on the desired **Planning image** (the drawing starting point) to display it in the selected image window.
2. Click the relevant **LEDR Drawing** button (see options in Section 6.7.1). In the selected image window, click on the desired location to start the **LEDR** outline.
3. Move the cursor in one direction, while pressing the left mouse button or by clicking on successive points to create the **LEDR** outline.
4. Click the box at the end of the line to close the **LEDR** drawing.
5. Continue to define the **LEDR** on all required slices.
6. Unclick the **LEDR** button or alternatively click on another drawing button and the system will automatically interpolate the drawing. Verify the automatic interpolation of the **LEDR** is correct in all slices.
7. Move the drawing by clicking and dragging it. Delete the drawing by clicking it and the **Delete** (or **Delete All**) button.

WARNING:

- Proper drawing of LEDR contours can prevent injury to the patient during treatment. The treating physician should identify the sensitive regions which are candidates for LEDR drawings.
- If Interpolation was used when drawing the rectal wall and LEDR's, manually check the interpolation results in all slices. If the interpolation action failed to achieve the desired results, delete the interpolated contours, and manually draw additional contours in the necessary locations.

[W-17]

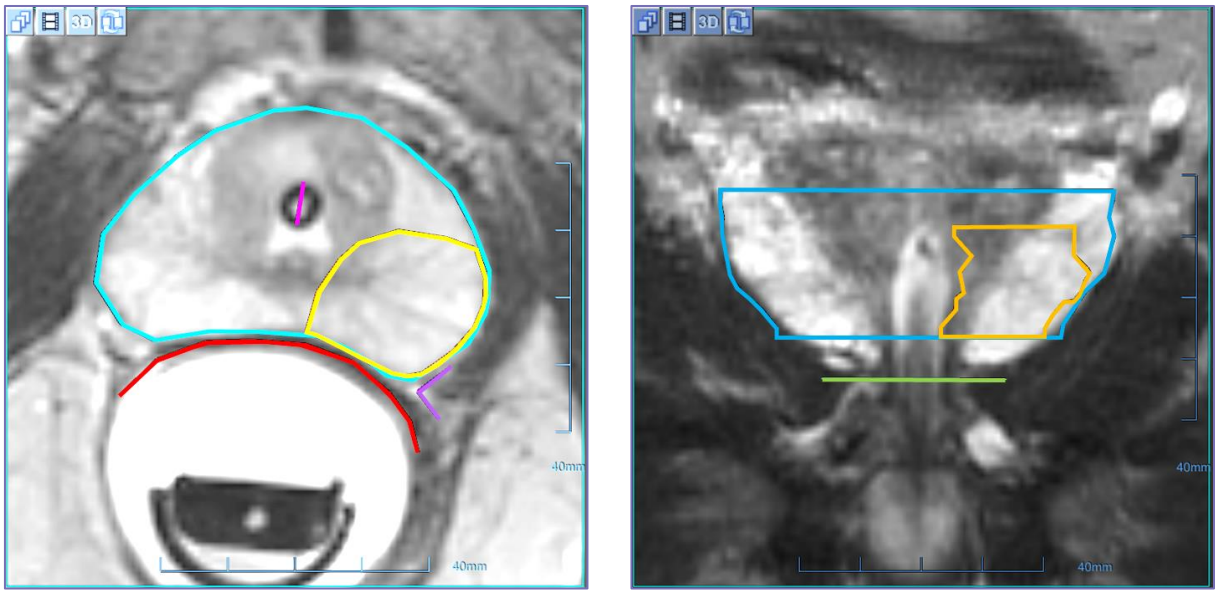


Figure 6-7: Planning images with drawing overlays (left – Axial, right – Coronal)

6.8. Selecting a Treatment Protocol (Optional)

Selecting a **Treatment Protocol** enables the system to adjust parameters according to specific treatment characteristics or while performing Daily Quality Assurance (**DQA**).

Selecting a **Treatment Protocol** is optional, as the system will use a default protocol (named **Treat**) with default values (see below).

To select or update the **Treatment Protocol**, use the following element, found under the Treatment Parameters section in **Planning** and **Treatment** stages:

Figure 6-8: Treatment Protocol control

6.8.1. Changing Treatment Protocol Parameters

1. Press the button next to the protocol name to open the **Treatment Protocol Dialog** box:

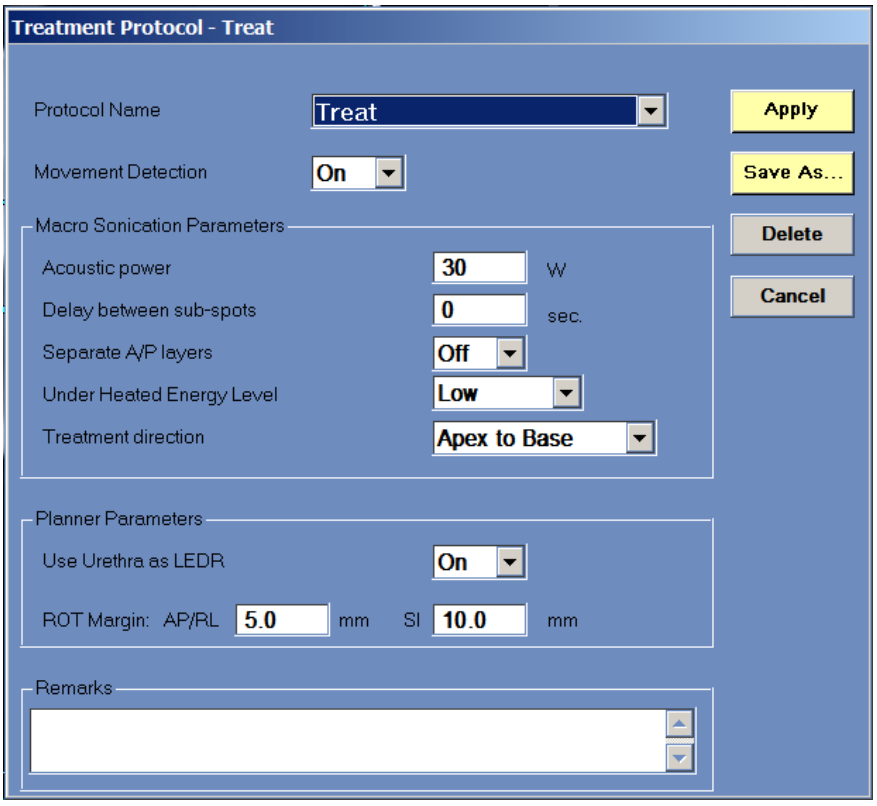


Figure 6-9: Treatment Protocol Dialog

2. From the **Protocol Name** pull-down list, select the **Treatment** or **DQA** protocol, per the specific procedure you would like to perform; the default parameters for the selected protocol appear in the dialog box.
3. Treatment Protocol parameters include the following:

- **Movement Detection**

  Set the automatic movement detection feature ON or OFF. Value in the default **Treat** protocol is ON.

- **Acoustic Power**

  Set the acoustic power which the system will use to plan spots. Valid range is 10-45W, value in the default **Treat** protocol is 30W.

- **Delay Between Sub-Spots**

  Enables to add a delay between Macro sub-spots.

When larger than zero, the system enlarges the nominal delay between sub-spots while sonicating a Macro-spot, effectively adding a "cooling time" between the sub-spots. Valid range is 0-60 seconds, while the value in the default **Treat** protocol is zero.

- **Separate A/P Layers**

  Set this field to ON and the system will plan Macro spot while separating between the anterior and posterior layers of the sonication. During the sonication, the system will first perform all anterior spots, then continue with the posterior spots. Value in the default **Treat** protocol is OFF.

- **Under-Heated Energy Level**

  Sets a limit to the energy that the system can add when using the repeat under-heated regions feature (see Section 7.4.6).

  Optional values are Low, Mid and High. Value in the default **Treat** protocol is Low.

- **Treatment Direction**

  Sets the direction in which the treatment advances. After each sonication, the system performs a movement detection test on the next slice according to the treatment direction defined here.

  Values are either apex to base or base to apex. Value in the default **Treat** protocol is apex to base.

- **Use Urethra as LEDR**

  This field defines whether the Urethra drawing will be regarded by the system as a **Low Energy Density Region (LEDR)**. When set to ON, the system will automatically keep 3mm safety margins around the drawing when planning spots (see section 6.7.6). When set to OFF, the Urethra drawing will be visible and available as a handle while in **Deformation Mode** (see section 7.2.9).

  Value in the default **Treat** protocol is ON.

WARNING:

When set to OFF, the Urethra drawing will be visible however the system will NOT keep safety limits from it. Carefully examine the predicted dose location of planned spots prior to performing a sonication.

[W-18]

- **ROT Margin**

  Set the margins used by the system when automatically expanding a **Target Volume** to create a **Region of Treatment (ROT)**. It is possible to set different margins for AP/RL and for S/I expansions.

  Values in the default **Treat** protocol are 10mm in AP/RL and 10mm in S/I.

- **Remarks Area**

  Type remarks to keep your notes per Treatment Protocol.

4. Close the **Treatment Protocol** Dialog box:

- If no changes were made to the protocol, click **Cancel** or **Apply**.
- If changes were made to the protocol, click **Save As** to access the **Save Protocol** dialog box.
- Type in the name of the new **Treatment Protocol**.
- Click **Delete** to delete any current user-defined protocols.
- Click **Cancel** to discard the new information and return to the **Main** screen.

NOTE:

The system's preset treatment protocols cannot be deleted from the list of protocols, and if edited they must be saved under a different name.

[N-22]

6.8.2. System Preset Treatment Protocols

In addition to the default **Treat** protocol, the system offers four additional pre-defined protocols which parameters were optimized for specific scenarios:

- **Excessive Posterior Heating**

  This protocol should be used in cases in which posterior heating is blocking the energy from heating the anterior part of the region of treatment.

  When selecting this protocol, the system changes the following fields from their default values:

  Separate A/P layers = ON

  Acoustic power = 20W

  Delay between sub-spots = 10 seconds

- **DQA**

  This protocol should be used when running a Daily Quality Assurance (DQA).

  When selecting this protocol, the system changes the following fields from their default values:

  Movement detection = OFF

  Balloon boundaries are automatically set to 2mm below the drawn rectal wall, replacing any image-based identification or tracking

  System will not warn about balloon water temperature that is too high or too low.

WARNING:

- **DQA** treatment protocol should only be used when running a Daily Quality Assurance session.
- Do NOT use the **DQA** protocol in actual treatments.

[W-1]

- **Treat – Repeat Aggressive** & **Treat – Repeat Mild**

  These two protocols should be used when there is a need to change the intensity (energy) levels of the **Repeat Under-Heated Regions** feature.

  When selecting one of these protocols, the system either increases (Repeat Aggressive) or decreases (Repeat Mild) the permissible energy levels of this feature.

  It is recommended to use these protocols **only** after applying the default Repeat Under-Heated Regions feature (under the **Treat** protocol), and only in case it did not provide the desired outcome.

6.9. Re-Draw / Dose Transfer (Optional)

In the event of a large patient movement and a need to acquire new Planning images, it is possible to manually define a rigid registration between the new MR images and the prior MR images, based on anatomical structures (the prostate capsule). By doing this, the system will automatically copy the accumulated dose volume to the new MR images.

6.9.1. Acquiring New Planning Images

1. Planning In case sonications were already performed, go back to Planning stage by pressing on the main toolbar.
2. Acquire new Planning images – see Section 6.5.
3. Acquire a new Baseline Anatomy scan – see Section 6.6.

6.9.2. Dose Transfer Procedure

After loading a new Axial series of MR planning images, all the previously drawn objects except for the prostate capsule and the ROT are deleted.

The prostate capsule, ROT and the accumulated dose are automatically copied to the new MR Planning images.

1. At this stage, the **prostate capsule** as well as the **ROT** are rigid structures and cannot be moved or edited slice by slice.
2. Carefully review the **prostate capsule** and the **ROT** volumes. Drag and rotate each of them to achieve the best possible fit to the anatomy as demonstrated in the new Planning images. Rotation can be achieved by clicking and dragging the handle (see Figure 6-10).
3. Perform adjustments in all orientations (Axial, Sagittal and Coronal). The accumulated dose volume will be adjusted accordingly.
4. In case an accurate adjustment cannot be achieved, the **prostate capsule** and **ROT** structures can be completely deleted and re-drawn.

NOTE:

In case both prostate capsule and ROT are deleted, you will no longer be able to adjust the accumulated dose location.

[N-23]

WARNING:

The dose transfer procedure refers to the prostate capsule and the ROT as rigid structures, and thus may fail to achieve accurate results in case of significant deformations. In such cases, delete the previously prostate capsule and ROT objects, and draw new ones.

[W-19]

5. Rectal wall, balloon boundaries and all LEDR drawings were deleted. Re-draw the rectal wall and all necessary LEDR contours, and detect balloon boundaries before continuing (see Section 6.7).
6. Proceed to **Treatment** stage to resume the treatment. The system will ask whether to keep the accumulated dose or to delete it.

WARNING:

Carefully review the dose transfer procedure result before deciding whether to keep or to delete the accumulated dose. Inaccurate adjustment of the accumulated dose overlay may be misleading when attempting to estimate the region of treatment dose coverage.

[W-20]

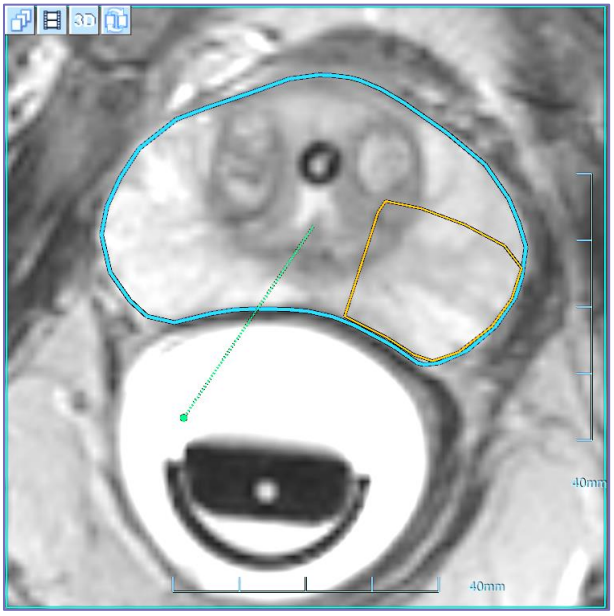


Figure 6-10: Dose Transfer procedure

6.10. Advancing to Treatment Stage

Before advancing to the **Treatment Stage**, carefully check all orientations and verify:

- The **ROT** covers the target tissue including the required margins (determined by protocol and clinical considerations).
- The **ROT** is completely within the **Treatment Envelope**.
- If it is necessary to correct the **ROT**, select it and modify it.

Confirm that both the patient and the nurse have been instructed in the use of the **Stop MR Scan** button and that the patient is holding it and understands how to operate it (in case anesthesia and sedation allow it).

1. 

Press this button on the main toolbar to advance to the next stage in the treatment procedure.
2. The MR performs tracking scans to automatically detect the transducer location.

7. TREATMENT STAGE

7.1. Overview

Treatment Stage is the stage where the actual treatment is performed. If needed, the user can change the plan and the sonication parameters throughout the treatment.

This stage enables the operator to:

1. **Verify** that the location of the thermal focal point is in the selected target and that the sonication intensity levels deliver the expected results.
2. Adjust the **Spot's Parameters** and **Thermal scan parameters**.
3. **Automatically Plan Macro-Spots** based on the defined ROT and the selected treatment protocol while taking into consideration the LEDR's limitations.
4. Perform therapeutic **Treatment Sonications**.

Treatment Stage includes two screens which cover the three phases within the sonication cycle:

1. **Treatment Stage Main Screen:** This screen (see Figure 7-1) enables the user to conduct the **Pre-Sonication phase** and provides the means to prepare and plan the spot prior to the actual delivery of energy.
2. **Thermal Evaluation Screen:** This screen (see Figure 7-4) enables the user to perform the Sonication & Post Sonication phases. During the sonication time, the system displays the temperature maps and the magnitude images acquired in real time. When the act of applying the energy has been completed, the system provides a set of tools to perform retrospective analysis and adjustments, as necessary.

7.2. Treatment Stage Main Screen

The **Treatment stage** contains the following new elements (see Chapter 5 for an explanation of the **Imaging** tools previously used).

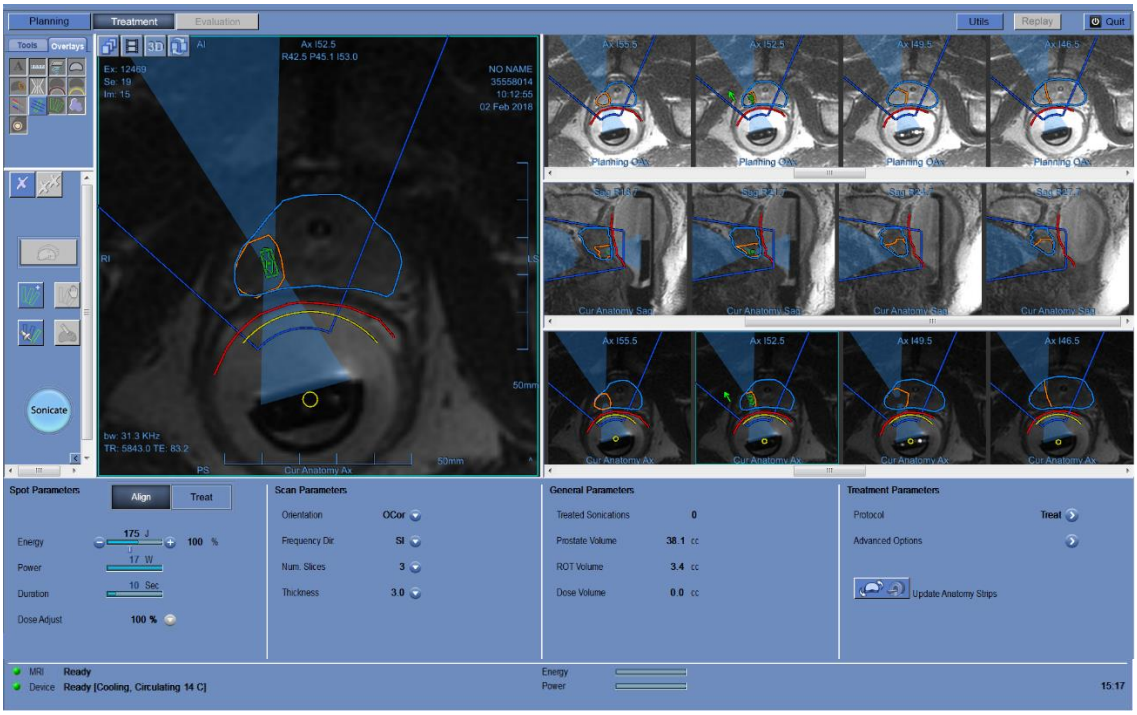


Figure 7-1: Treatment Stage Main Screen

7.2.1. Action Tools

Align	**Align Mode**	Select the **Align Mode** to perform a geometrical location verification.
Treat	**Treat Mode**	Select the **Treat Mode** to perform thermal dose verification and therapeutic sonications.
	**Add Sonication Spot**	Use this button to add a sonication spot; the spot is added at the location clicked on the MR image. For **Macro-spots**, the location clicked within the ROT will define the Macro-spot **direction**.
	**Stop Planner**	Click to stop the Macro-spot planning process.

	**Set Spot as Current Spot**	Click this button to set the selected spot as the **Current Spot** to be treated.
	**Deformation Mode**	Click to enter **Deformation Mode**, in which the capsule can be deformed to match the anatomy as seen on Axial **Current Anatomy** images.
	**Start Sonication**	Click this button to perform a sonication. This command is enabled only after a sonication spot is defined in the **Treatment stage** and both the MR and device lights in the status bar are green.
	**Draw Under-Heated Regions**	While in the **Repeat Under-Heated Regions mode**, press this button to draw the under-heated region polygon.

7.2.2. Treatment Modes

Under Treatment stage, the Exablate Prostate workstation offers two **Treatment Modes**:

- **Align**: Where the hot spot center location is evaluated and adjusted. Default spot parameters are set to produce a sub-therapeutic sonication.

  It is required to successfully complete at least one geometrical verification sonication in **Align** mode prior to advancing to the next mode.

- **Treat:** Where the system aims to reach an adequate level of temperatures within the targeted region that will ensure controllable lesioning of the tissue.

WARNING

Do not advance to Treat Mode unless you are certain that the heated area is within the expected target location.

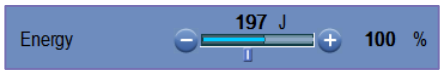
[W-21]

7.2.3. Spot Parameters Frame

If necessary, change the parameters of the sonication as described below.

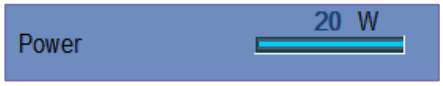
The changes made in the parameters below affect only the selected spot (or Macro sub-spot), except for the Dose Adjust value which is a global setting that affects all spots.

Confirm the changes by clicking the **Apply** button or **Cancel** them to retrieve previous values.



Set the Acoustic **Energy** of the selected spot or sub-spot. Change the value by clicking the ⊕ or ⊖ buttons.

Changing the **Energy** affects the **Acoustic Power** while maintaining the original sonication **Duration**.



Presents the Acoustic **Power** of the selected spot or sub-spot.

To control the **Power** directly (while maintaining the original spot **Energy** and affecting the spot **Duration** – use the **Treatment Protocol** dialog – see Section 6.8.1).

Presents the selected **Spot Duration**.

Presents the current global **Dose Adjust** level and enables to reset it back to 100% (see Section 7.4.4).

WARNING

Verify desired sonication parameters before performing the sonication. Unintended sonication parameters may result in ablation of unintended tissue. Confirm spot location and the predicted dose before each sonication.

[W-22]

7.2.4. Scan Parameters Frame

This section controls the parameters of the **Thermal Scan** to be acquired during the next planned sonication.

Select one of three oblique orientations (**OCor**, **OAx**, **OSag**). The thermal scans will always be acquired according to the transducer axes.

Select the frequency direction from one of three settings: **RL**, **AP**, or **SI**.

Select Number of Slices for single-slice or multi-slice thermal imaging:

1 (Single-Slice) is using TMAP protocols of thermal imaging intersecting with the center of the planned spot.

3 or **5** (Multi-Slice) are using EPI protocols for volumetric thermal imaging. A few parallel scan slices will be taken while the center slice will intersect with the center of the planned spot.

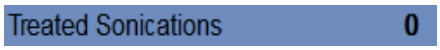
Select the slice thickness (in millimeters) from one of the settings: **3** or **5**.

NOTE:

For each selected sonication, the thermal scan grid lines (blue color line/s) can displayed on the screen, according to the thermal scan parameters. Press this button  to show or hide them.

[N-24]

7.2.5. General Parameters Frame



The system automatically indicates the number of sonications already conducted.

The system automatically calculates the prostate volume based on the prostate capsule drawing.

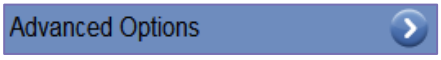
The system automatically calculates the ROT volume based on the ROT drawing.

The system automatically calculates and indicates what volume has been treated so far, based on the accumulated dose volume that was accepted by the operator in previous sonications.

Thermal dose is an automatically calculated volume that reached 54°C for three seconds (or thermally equivalent), based on the real time thermal imaging. This volume is considered ablated, based on physical models.

7.2.6. Treatment Parameters Frame

Control the Treatment Protocol. Refer to Section 6.8.



If required, click to open the Advanced Option dialog box (refer to Appendix A for details).

Update (Current) Anatomy Strips Click to acquire updated Current Anatomy strips (Axial and Sagittal) and run the movement detection algorithm to compare the Axial scans with the Axial Previous Anatomy scans (refer to Section 7.2.8).

7.2.7. Spot Colors

The sonication spots are colored to provide additional feedback about their validity and status.

- **Green** – A valid spot that is ready to be sonicated.
- **Yellow** – Warns the user that the distance between the predicted dose of the spot and an LEDR is below the recommended threshold.
- **Red** – The spot is invalid and cannot be sonicated. Either the spot is too close to an LEDR, or spot parameters are not valid. Edit the spot to make it yellow or green.

NOTE:

When a spot is **yellow** or **red**, the reason will be displayed in the information box when clicking and selecting the spot.

[N-25]

CAUTION

When a spot is **Yellow**, carefully review the spot and evaluate the risk versus the clinical benefit prior to performing the sonication.

[C-6]

7.2.8. Current and Previous Anatomy Scans

While in Treatment stage, the Axial **Current Anatomy** scans effectively replace the original Axial **Planning** images as the main working strip for updating the treatment plan (to account for prostate deformations – see Section 7.2.10), planning new spots and evaluating the progress of the treatment.

After each sonication, the system automatically acquires a new set of **Current Anatomy** (both **Axial** and **Sagittal**) images, which replaces the last acquired set (which is now renamed to **Previous Anatomy**).

To manually update the **Current Anatomy** strips (**on-demand**), press this button  . This feature is useful in case you suspect that movement (either of the probe and/or of the prostate) has occurred since the previous update of the strips. Once the button is pressed, the system will:

- Bring the transducer back to its **Home position** and initiate a **tracking scan** to update the probe location.
- Initiate an **Axial Current Anatomy** scan and load the images in the 1st **Images Strip**.
- Initiate a **Sagittal Current Anatomy** scan and load the images in the 2nd **Images Strip**.

Both **Current** and **Previous** Anatomy strips are scanned with the exact range and slices of the **Baseline Anatomy** scan, performed in **Planning** stage (see Section 6.6).

7.2.9. Automatic Movement Detection

The **Automatic Movement** Detection feature can assist the operator in detecting prostate movements during the treatment. The Baseline Anatomy scan (performed automatically by the system when acquiring the Planning images, or manually by pressing this button ), serves as the movement detection reference.

The movement detection algorithm uses tracking fiducials that are derived automatically from the **prostate capsule** drawing (see Figure 7-2).

WARNING

An automatic algorithm is used for prostate movement detection. This algorithm is designed to assist the operator to identify movement. However, the Movement Detection option does not replace the operator and does not relieve the operator from responsibility to properly identify movement.

[N-26]

After acquiring Axial **Current Anatomy** images, the system automatically attempts to **detect prostate movements** by comparing a slice from the newly scanned **Current Anatomy** strip with the corresponding slice from the **Previous Anatomy** strip.

The actual slice that the system selects to run the movement detection test on, is the slice that the system assumes will be the next one that will be sonicated:

- Right after performing a sonication, the suggested slice would be the adjacent one according to the treatment direction that is defined in the **Treatment Protocol** (see Section 6.8).
- In case another spot already exists (was added prior to the current sonication), the system assumes that the next slice would be the one with the previously added spot.

NOTE:

The movement detection test is performed on Axial slices only, and therefore is not sensitive to movements in S/I. Use the **Sagittal** Current and Previous Anatomy strips to assess S/I movements.

[N-27]

In case a **significant** (larger than 1mm) movement was detected, and while the movement detection feature is set to ON in the **Treatment Protocol**, the system will issue an alert pop-up message.

When a significant movement is detected, the **Sonicate** button will be **disabled** until the user enters **Deformation Mode** to update the treatment plan (see Section 7.2.10).

To evaluate prostate movements, use the **Toggling** tool  to display alternating images of the Current and Previous Anatomy strips.

NOTE:

To evaluate prostate movements between the **Current** and **Baseline Anatomy** scans, press the **Toggling** button while in **Planning** stage rather than in Treatment stage.

[N-28]

Reference Tracking Fiducials can be edited in case specific ones generate false alarms. To edit **Tracking Fiducials**:

1. 

Press this button to return to Planning stage.
2. The **Reference Tracking Fiducials** are displayed on the **Axial Baseline Anatomy** strip.
3. Edit the fiducials by dragging or deleting.

NOTE:

For optimal results, **Tracking Fiducials** should be placed over the **Prostate Capsule** edge.

[N-29]

4. To generate a new set of tracking fiducials, edit the **Prostate Capsule** drawing on the **Axial Planning images**.

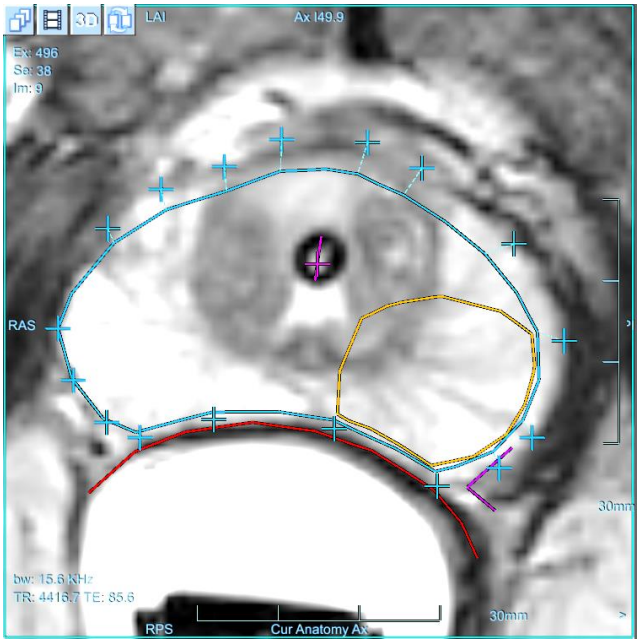


Figure 7-2: Movement Detection Fiducials

WARNING

- Make sure you monitor patient and prostate movements during sonications using the real-time **sonication anatomy** images to confirm no movement; the **Automatic Movement Detection** feature should be used as an additional advisory element.
- Monitoring prostate and patient movements is important to assure accurate sonication targeting.
- Monitor the prostate capsule, rectal wall, and LEDR drawings during the treatment to facilitate the detection of prostate movement.

[W-23]

7.2.10. Deformation Mode

Deformation Mode enables you to update the treatment plan, by adjusting the **Prostate Capsule** contour so that it matches the anatomy, as seen on the **Axial Current Anatomy** images.

The **Rectal Wall**, **ROT** and all drawn **LEDR contours** will be deformed as well, according to the deformation applied on the prostate capsule.

Deformation Mode can only be accessed while an image from the **Axial Current Anatomy** strip is selected. While in **Deformation Mode**, the **Balloon Boundaries** are also editable, enabling you to adjust it according to the most up-to-date location of the balloon.

NOTE:

Planning a Macro-spot after updating the treatment plan in **Deformation Mode** enables the system to plan an optimal spots arrangement that considers the updated location of all contours. This flow is preferable to planning a spot, and only then entering **Deformation Mode**.

[N-30]

1.  Click this button to enter **Deformation Mode**.
2. The **Prostate Capsule** contour will appear **dashed** and with 4 **handles**. Another handle will appear at the center of the **Urethra LEDR** (in case it was drawn, see Figure 6-8).
3. Click a handle and hold while dragging the mouse to deform the contour.
4. To update the **Balloon Boundary** arc, click and drag the arc handle to change its radius, or click and drag the arc itself to displace it.
5.  Click this button to exit **Deformation Mode** and **Apply Deformation**. All images in the **Axial Current Anatomy** strip will be updated according to the applied deformation.
6. **Repeat** the process on other slices, as required. The deformation will be interpolated between all edited slices.
7.  Click this button to add a spot on the desired **Axial Current Anatomy** slice.

NOTE:

In case a very large or irregular deformation occurred, if the **Prostate Capsule** contour cannot be corrected accurately in **Deformation Mode**, return to Planning stage and perform a **Re-Draw** procedure (see Section 6.9).

[N-31]

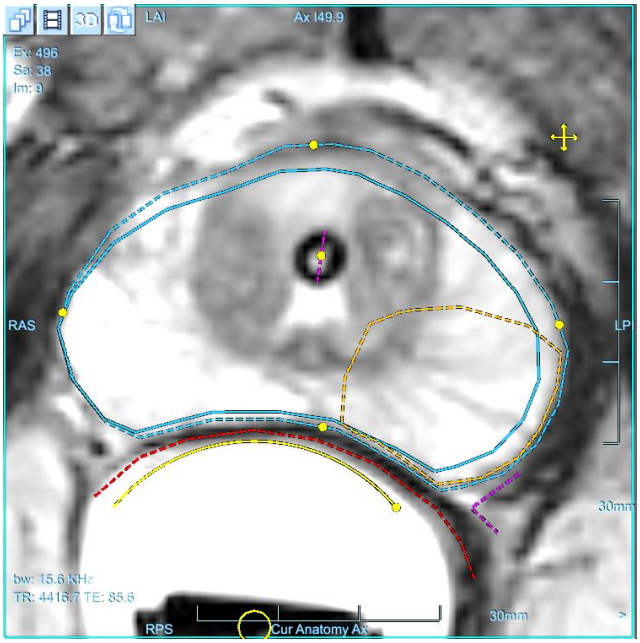


Figure 7-3: Deformation Mode

7.2.11. Handling Probe Movements

At different time points (e.g., Positioning scans, advancing to Treatment Stage, prior to every sonication and more), the system automatically initiates **tracking scans** to automatically detect the transducer location.

This important feature enables the Exablate Prostate system to track the probe exact position, identify significant movements of the probe, and even correct the transducer aiming (by means of **electronic steering**) according to the identified displacement (in case of small probe movements – lower than 3mm and 3 degrees).

When a significant (larger than 3mm or 3 degrees) probe movement is identified, the system will notify you and recommend on updating the **Current Anatomy Scans**, a procedure which also runs a **tracking scan** to update the system with the current probe location.

In case the system identifies a large transducer movement, verify that:

- Probe connections to the Motion Unit and the Positioner have not been loosened.
- The balloon water is not leaking.
- Patient is not moving (anesthesia and/or sedation level is sufficient).

7.3. Thermal Evaluation Screen

After the sonication energy is applied, the system displays the **Thermal Evaluation** screen:

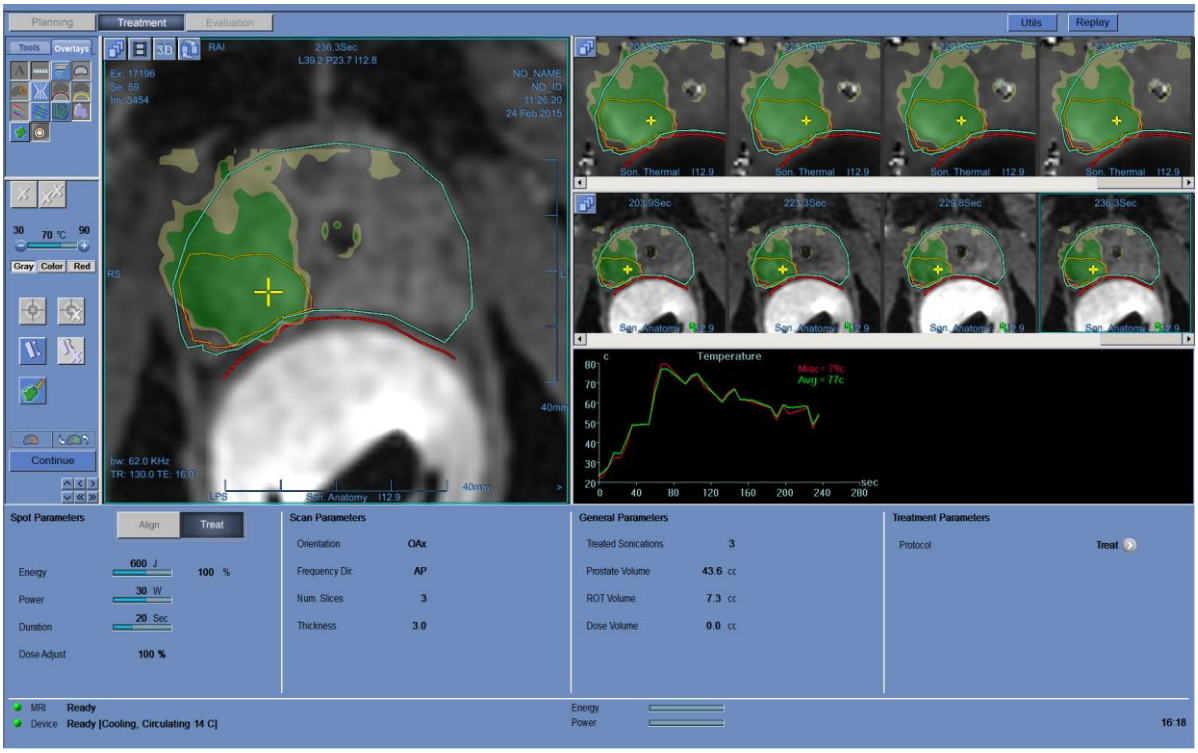


Figure 7-4: Thermal Evaluation Screen Elements

7.3.1. Image Strips

The top image strip shows the temperature maps acquired during the sonication.

The bottom strip displays the set of MR magnitude images taken during the sonication. The **Image Strip**  selection menu may be used to manually change this default setting.

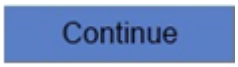
For multi-slice thermal scans, the central slice is displayed.

The **Selected Image** window shows the MR image acquired closest to the end of the sonication. The calculated thermal dose contours are superimposed on the post-sonication temperature maps.

To navigate through the MR images along time, use the **Keyboard Right and Left Arrows**  or the buttons, or alternatively click on the desirable image.

For multi-slice thermal scans, use the **Keyboard UP and Down Arrows**  or buttons to navigate between different slices of the temperature maps. Annotation on the bottom of the selected image (main image) will indicate the scan location.

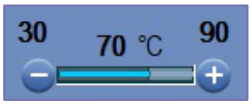
7.3.2. Thermal Evaluation Action Tools

	**Spot Location Adjustment**	To perform spot location adjustment, select the temperature map with the hottest spot to the Selected Image window.
	**Reset Spot Location Adjustment**	Click to reset all accumulated adjustment of the treatment
	**Dose Adjustment**	Click to display the predicted dose overlay (in white) and adjust it to the measured thermal dose. Enabled after every sonication.
	**Reset Dose Adjustment**	Click to reset the Dose Adjust value.
	**Draw Dose Polygon**	In case of erroneous thermal dose regions (caused by noise or artifacts), mark the thermal dose on the temperature map as follows: Click on a temperature map with thermal dose to display it in the selected image window. Click once on the Draw Dose Polygons button; the polygon will be automatically drawn along the Prostate Capsule contour. If it becomes necessary to refine or redefine the drawn polygon, move it by clicking it and dragging, or delete by clicking it and then clicking the Delete button. Pressing the button again (for the 2nd time) will allow you to manually draw the polygon.  When clicking on this button, only the thermal dose inside the Dose Polygons will be accumulated.

7.3.3. Continue Treatment Tools

	**Continue to Main Treatment Screen**	Click this button to exit the **Thermal Evaluation Screen** and continue to the **Main Treatment Screen**, to advance to the next sonication. **Note** By clicking this button, you accept the **Thermal Outcome** (**Measured Thermal Dose** accumulation) from this sonication. This action will affect the **Accumulated Measured Thermal Dose**. Carefully examine the sonication outcomes before clicking the continue button.
	**Repeat Sonication**	Click this button to repeat the last performed sonication. Click  to proceed.
	**Repeat Under-Heated Regions**	Click this button to enter **Repeat Under-Heated Regions** mode. See Section 7.4.6. Click  to proceed.

7.3.4. Temperature Scaling Tools

	**Temperature Scale Viewing**	Click on different tabs for different scaling: Gray displays temperature maps in grayscale. Color displays temperature maps in color. Red displays a red overlay on the grayscale image. The red overlay displays all the areas where the temperature is above a pre-determined temperature threshold.
	**Temperature Threshold**	To view the desired temperature scale, set the temperature threshold by clicking the  or  buttons. The selected value appears on the scale.

7.3.5. Measured Sonication Parameters Indicators

This frame indicates the actual measured acoustic energy and power of the last sonication.

Figure 7-5: Measured Sonication Parameters Indicators

7.3.6. Temperature Graph

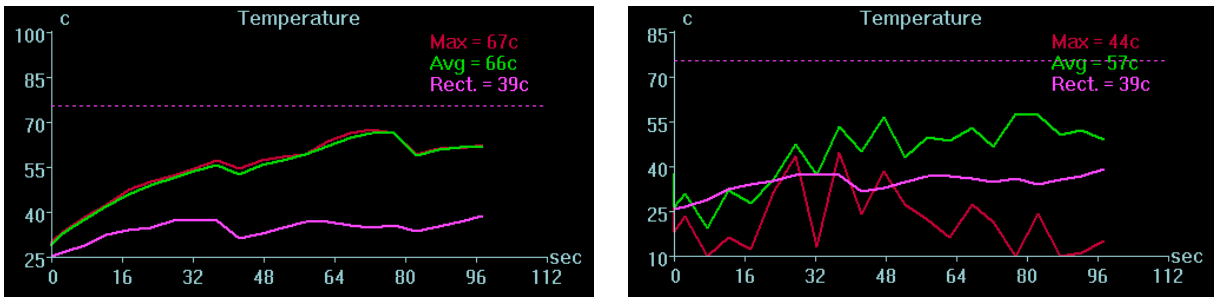


Figure 7-6: Temperature Graphs (left – nominal, right – thermal noise)

During the sonication, a cross-shaped cursor automatically appears on the hottest spot. The temperature graph shows the temperature change during a sonication at the cursor location.

Inspect the temperature map for noise that was miscalculated as Thermal Dose. Noise can be identified by searching for pixels that have inconsistent temperature readings in relation to their neighbors. Utilize the temperature graph to locate these pixels by looking for pixels with "temperature jumps" (Figure 7-6, right).

The graph shows:

- **Red Line** – the evolution of the temperature at the cursor location, during and after sonication.
- **Green Line** – the average temperature around that cursor.
- **Magenta Line** – the maximum measured temperature adjacent to the rectal wall drawing
- **Dashed (Magenta) Line** – a (visual) marker indicating the temperature of 75 ^{o}c.
- **Azure Line** – the average temperature within a measurement polygon.
- The highest temperature reached by each graph line is displayed on the upper right position of the frame.

NOTE:

The graph may be used to display the temperature history of any location by moving the cross-shaped cursor with the mouse.

[N-32]

7.3.7. Acoustic Spectrum

To enhance treatment safety monitoring, an **Acoustic Spectrum Data** graphs is displayed during the sonication; it is displayed as soon as the sonication begins.

This graph presents the spectrum of frequencies that are transmitted back to the transducer, which assists in detecting the potential creation of microbubbles – a first sign of **cavitation effects**.

Acoustic spectrum peak exceeding the 1mV threshold line at a frequency of 1.15MHz, is indicative of potential start of cavitation effect.

If this occurs during a sonication, press the Stop Sonication button to instantly stop the sonication, reduce the **acoustic power** (by ~10%) and repeat the sonication. If needed, keep gradually reducing the acoustic power until the "peak" of the acoustic graph is well below the 1mV threshold line.

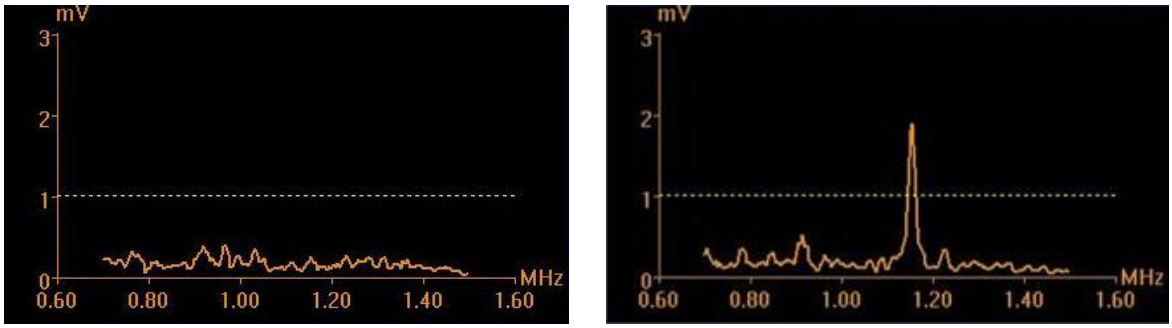


Figure 7-7: Acoustic Spectrum Graphs (left - typical, right – Cavitation effect)

7.4. Treatment Procedure

7.4.1. General Sonication Flow

1. Add a Macro-spot in the desired ROT slice. For safety considerations of sphincters preservation, it is advisable to keep the sonications execution order from the sphincter and away.
2. Examine the next spot to be sonicated:

- When highlighted in **green**, the spot is valid and may be treated.

- When highlighted in **yellow**, the spots predicted dose is closer to an **LEDR** than the recommended threshold. Check the location of the spot and its parameters and assess if the clinical situation allows this sonication.

NOTE:

When a spot is not green, the reason is displayed in the information box at the top-right side of the screen by clicking on the spot.

[N-33]

3. Based upon the examination of the actual (measured) dose of previous sonications, changes to the treatment plan are possible at any stage during a treatment:

- Sonication parameters (such as **Energy**, **Power**, **Delay between sub-spots**, **Separating Anterior and Posterior Sub-Spot Layers**).
- Change Thermal scan parameters (MR protocol, Frequency direction).
- Utilizing the **Repeat Under-Heated Regions** mode.

WARNING

Before each sonication, confirm that the water system is functioning properly and that:

- There is no significant water loss from the balloon by visually reviewing the Axial and Sagittal Current Anatomy scans.
- The blue Circulation Controller on the operator's console is illuminated continuously, meaning water is circulating.

[W-24]

4. 

Click this button to apply the ultrasound energy.
5. During the sonication, the following factors should be monitored:

- The **evolving temperature rise and dose** during sonication.
- Patient movements, by observing the **Rectal Wall** and **Prostate Capsule** drawings on the updated MR anatomical images.
- The real-time images to **ensure coupling** and verify no air bubbles entered the interface between the balloon and the rectal wall.
- **Spectrum signal** during the transmission of the acoustic energy.

WARNING

- If there is a need to stop the sonication process, press the Stop Sonication button.
- Monitor the temperature maps during the sonication. If an unexpected thermal rise or dose is found outside the target location, stop the sonication.

[W-25]

6. After the sonication, the **Thermal Evaluation** screen opens with the actual thermal dose contours overlaid on the image (see Figure 7-4). Review the results as described in **Thermal Dose Verification** (see Section 7.4.4).

WARNING

- Monitor the thermal rise and dose buildup at the target location, and at the relevant pass zone with special attention to the rectal wall.
- In case temperature on the rectal wall exceeds 75°C, press the Stop Sonication button and reduce the energy of the following sonication.
- The geometric verification procedure must be repeated if the thermal hot spot is not noticed on thermal imaging sequence during treatment.

[W-26]

7. The system will automatically initiate **Current Anatomy Scans** on the MR.
8. The system will notify the user in case the targeted area was not fully covered with dose (above pre-defined threshold).
9. If required, choose to repeat the sonication using the **Repeat Under-Heated Regions** (refer to Section 7.4.6)
10. Click Continue to **accept the measured dose** and return to the **Treatment Main Screen**.

NOTE

After continuing to the next sonication, the operator will NOT be able to edit the **Accumulated Measured Dose** of previous sonications. Use **Dose Polygons** in case only part of the measured dose should be accumulated.

[N-34]

WARNING

If there is a need to increase treatment energy, do so in gradual steps and monitor any thermal rise after each sonication.

[W-27]

11. The system will detect and notify about movements on the next slice, according to the **Treatment Direction** defined in the **Treatment Protocol**.
12. If required, enter **Deformation Mode** to update the treatment plan on the **Axial Current Anatomy** strip (refer to Section 7.2.10).
13. Repeat the procedure until the entire **ROT** is covered with **Thermal Dose**.
14. If required, click **Replay** to view the results of previous sonications.

7.4.2. Adding a new Sonication Spot

 Click this button and add a new sonication spot in the **Selected Image** window. Spots can be added on a **Current Anatomy** image only.

- In **Align Mode**: It is possible to add a Regular spot only. Make sure to add the spot at the center of the **ROT**.
- In **Treat Mode**: There are three optional spot types that could be added:
  - **Macro-spot**: Click within the **ROT** polygon and the system will initiate planning a sub-spots arrangement that will cover the **ROT** while taking into consideration all **LEDR** limitations. Click in the **ROT** at the side that you with the **Macro-spot** to start at.
  - **Regular Spot:** Adding a Regular spot is possible not only within the **ROT** but within the entire **prostate capsule**.
  - **Macro Sub-spot:** Select an existing **Macro-spot**, then select this option to add a **Macro sub-spot** to the selected Macro. The added sub-spot will be sonicated according to its relative rotation degree.

7.4.3. Geometric Verification (Align Mode)

Geometric Verification is used to confirm that the thermal spot can be identified and is located at the intended location. In this mode, the system will suggest spot parameters that are estimated to result in sub-lethal temperature rise at the target.

7.4.3.1. Perform a Geometric Verification Sonication

WARNING

In case of an unanticipated system action or patient reaction, the operator, the nurse or the patient (if applicable) can immediately interrupt the treatment at any time with the **MRI Stop Scan** or **Stop Sonication** buttons.

[W-28]

1. 

The system automatically defines the required sonication parameters for geometric verification while using the **Align Mode**. Sonication parameters should be examined in the **Spot Parameters** and **Scan Parameters** frames.

NOTE:

- In this mode, it is possible to add only a **Regular** spot.
- The default scan orientation will be **OCor**.
- Initial parameters for first sonication are **20W**, **10sec**.

[N-35]

2. Confirm that the sonication parameters are adequate to assure that the thermal rise will be below dose threshold.
3. Notify the team that a verification sonication is about to begin.

WARNING

Before each sonication, confirm that the water system is functioning properly and that:

- There is no significant water loss from the balloon by visually reviewing the **Axial and Sagittal Current Anatomy scans**.
- The blue **Circulation Controller** on the operator's console is illuminated continuously, meaning water is circulating.

[W-29]

4. 

Click the **Sonicate** button to apply the ultrasound energy. The system transfers the sonication location to the MR.
5. The sonication will start with the MR scanning images and then starts transmitting ultrasound energy.

During the sonication, the following factors should be monitored:

- The **evolving temperature rise and dose** during sonication.
- Patient movements, by observing the **Rectal Wall** and **Prostate Capsule** drawings on the updated MR anatomical images.
- The real-time images to **ensure coupling** and verify no air bubbles entered the interface between the balloon and the rectal wall.
- **Spectrum signal** during the transmission of the acoustic energy.

WARNING

- In case of an unanticipated system action or patient reaction, the operator, the nurse or the patient (if applicable) can immediately interrupt the treatment at any time with the **MRI Stop Scan** or **Stop Sonication** buttons.
- At any point if any undesired signs appear, the **Stop Sonication** button must be pressed immediately.

[W-30]

6. When the thermal imaging is complete after the sonication, the screen is automatically replaced by the Thermal Evaluation screen (see Figure 7-4).
7. System automatically initiates Current Anatomy Scans on the MR (in the background). The updated strips will be displayed when returning to the Treatment Main Screen (see Figure 7-1).

7.4.3.2. Geometric Adjustment

The **Adjust** function enables correction of the transducer's electronic position according to the offset between the sonication location and the planned spot location.

Every sonication has a pre-set frequency direction, along one of the plane's main axes. The frequency direction is indicated by an orange arrow located in the lower right corner of the thermal image. In Multi-Slice thermal imaging, the location of the thermal spot along the phase direction (which is perpendicular to the frequency direction) is sensitive to imaging shifts which do not represent the true location of the thermal spot.

NOTE

The Exablate Prostate enables geometrical adjustments to be performed **only in the S/I direction**. In case a significant shift is identified in the R/L direction, please contact your service representative.

[N-36]

1. Select the **Red Temperature Scaling Tool** (Section 7.3.4) and reduce the temperature threshold until a tight hot spot is clearly visible.
2. If a hot spot can be adequately identified, verify that it is within 1.0 mm of the planned location (the spot circle). If it is, continue to the **Thermal Dose Verification Procedure** (see Section 7.4.4).
3.  If the hot spot is over the 1.0 mm margin click this button, then click on the hot spot center in the **Selected Image** window, to adjust to the correct position.
4. A pop-up message will show the required adjustment in spot's location.
5. 

Click **Accept** or **Reject** adjustment and then click this button to return to the **Treatment Main Screen**.

WARNING

- Take extreme caution before performing an adjustment:
- If adjustment is required, it must be performed. However, do not perform an adjustment unless you can clearly see the entire hot spot and be certain that the adjustment is necessary.
- If the adjustment is over 2mm, before performing it apply another sonication with a different frequency direction to confirm that the shift is real and not the result of an MR central frequency shift.
- Failure to do so may increase the risk of treating unintentional tissue.

[W-31]

6. If a hot spot from the sonication cannot be adequately identified, do the following:

- Confirm that no air has entered the balloon-rectal wall interface.
- Verify that the energy measured in the last sonication, displayed in the **Sonication Measured Parameters Indicators** (see Figure 7-5), is similar to the energy requested.
- Increase the sonication energy level in small increments, repeating the geometric verification sonication until a hot spot is observed.

7. After the Geometric Verification Procedure is successfully completed, advance to the Thermal **Dose Verification Procedure** (see Section 7.4.4).

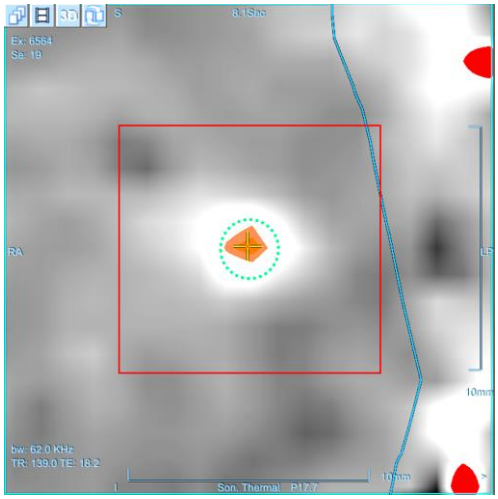


Figure 7-8: Geometrical Adjustment Procedure

WARNING

- Do not continue with the treatment if a hot spot is not adequately visible.
- The geometric verification procedure must be repeated if one or more of the following incidents occur during treatment:
  - Repositioning of the probe.
  - New planning images are loaded.
  - Thermal hot spot is not noticed on thermal imaging sequence during treatment.
  - Spot placed in new target location (e.g., bilateral treatment).

- This is effectively the beginning of the treatment. Select the spot parameters as though you are beginning a treatment.

[W-32]

NOTE

- If the spot appears red, it is invalid and cannot be sonicated.
- If the spot appears yellow, be cautious. Try to optimize the location and/or the sonication's parameters.

[N-37]

7.4.4. Thermal Dose Verification (Treat Mode)

Thermal Dose Verification is used to confirm the tissue response is as expected at therapeutic level energies.

Since different prostates might have different heating characteristics, you may need to adjust the sonication energy level for each patient. This adjustment ensures that the sonication's predicted thermal dose will match the measured thermal dose.

Switch to Treat **Mode**.

NOTE

- The default scan orientation is **OAx**.
- Default **Power** for sonications is **30W**.

[N-38]

1.  Click this button and select **Regular** spot. Add the spot at the center of the **ROT**. Spots can be added on the **Current Anatomy** strip only.
2. Follow the same monitoring guidelines as in the **Geometric Verification Sonication Procedure**.

3. 

Click the **Sonicate** button to apply the ultrasound energy; the system transfers the sonication location to the MR.
4. Monitor the following during the sonication:

- The **evolving temperature rise and dose** during sonication. Pay special attention to the temperature on the **rectal wall**.
- Patient movements, by observing the **Rectal Wall** and **Prostate Capsule drawings** on the updated MR anatomical images.
- The real-time images to **ensure coupling** and verify no air bubbles entered the interface between the balloon and the rectal wall.
- **Spectrum signal** during the transmission of the acoustic energy.

WARNING

- Monitor the **thermal rise and dose buildup** at the target location, and at the relevant pass zone with special attention to the **rectal wall**.
- In case temperature on the **rectal wall** exceeds 75°C, press the **Stop Sonication** button and reduce the energy of the following sonication.
- If an unexpected thermal rise is found outside the target location, stop the sonication.

[W-33]

5. After the sonication ends, the **Thermal Evaluation** screen opens (see Figure 7-4).
6. System automatically initiates **Current Anatomy** Scans on the MR (in the background). The updated strips will be displayed when returning to the **Treatment Main Screen** (see Figure 7-1).
7. Check whether there has been patient movement by observing the location of the **Rectal Wall**, **Prostate Capsule** and **LEDR** contours on the **Sonication Anatomical** images.
8.  If required, use this button to draw **Measurement Polygons** to evaluate the temperature rise.
9. Analyze the results and compare the size of the **obtained (measured) dose** with the **planned (predicted) dose**:

- Continue If they match, click **Continue** to accept the **Thermal outcome** and return to the **Treatment Main Screen** (see Figure 7-1).
-  If they do not match, click this button to adjust the thermal dose:
  - A white contoured thermal dose prediction is displayed in the **Selected Image** window.
  - Click and drag the mouse to change the white prediction size until it accurately overlaps the measured thermal dose.
  - The **Information Box** shows the adjustment value (percentage).
  -  Click this button to exit the dose adjust mode.
  - A message box prompts you to **Apply** or **Reject** the new dose adjustment value.

NOTE

- If the temperature map still contains an erroneous thermal dose (caused by residual artifacts or noise), click  to define which regions should be considered as dosed regions. See Section 7.3.2).
- The **Dose Adjust** value can also be seen and reset in the **Treatment Main Screen**, under the **Spot Parameters Frame**.

[N-39]

WARNING

Do not perform an adjustment unless you can clearly discern the temperature rise. Failure to do so may increase the risk of unintentionally treating non-targeted tissue.

[W-3]

10. Continue Click **Continue** to accept the Thermal outcome and return to the Treatment Main Screen (see Figure 7-1).
11. System will detect and notify about movements on the next slice, according to the **Treatment Direction** defined in the **Treatment Protocol**.

12. If required, enter **Deformation Mode** to update the treatment plan on the **Axial Current Anatomy** strip (refer to Section 7.2.10).

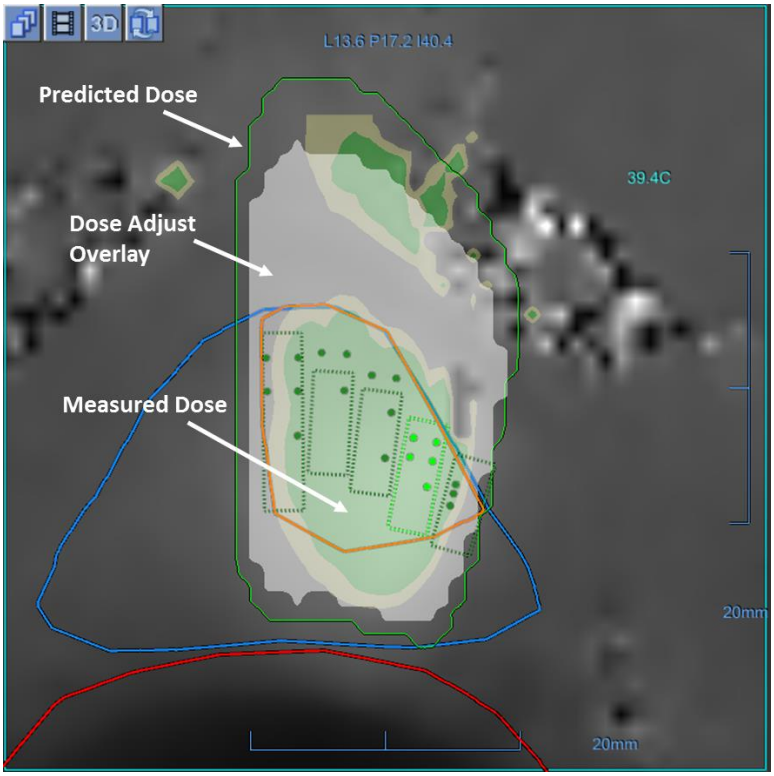


Figure 7-9: Thermal Dose Adjustment Procedure

7.4.5. Performing Macro-Spot Sonications

Macro-spot sonications can only be performed while in **Treat** Treat Mode, and once at least one sonication was performed in **Align Mode** Align.

NOTE

- The default scan orientation is **OAx**.
- Default **Power** for sonications is **30W**.

[N-40]

1.  Click this button and select **Macro** spot. Add the spot at the desired **ROT** slice by clicking inside it. Spots can be added on the **Current Anatomy** strip only.

NOTE

Clicking at the right or left half of the **ROT** slice polygon will affect the direction in which the Macro spot is planned and executed.

[N-41]

2. The system will automatically plan an optimized **Macro-spot** that covers the entire **ROT** slice while taking all **LEDR** limitations into consideration.
3. **Macro** spots can be edited by:

- Selecting the entire **Macro-spot** and dragging it. All **sub-spots** inside the Macro-spot will be dragged as well.
- Selecting the entire **Macro-spot** and changing its **Energy**. This will affect the **Power** of all sub-spots while keeping the same total **Duration**.
- Dragging, deleting and changing **Energy** is also applicable on specific **sub-spots**. Select the desired **sub-spot** and perform the required operation.
- To change the **Power** of a **Macro-spot** without affecting its **Energy** (but rather affecting its **Duration**), change the **Power** setting in the **Treatment Protocol** (see Section 6.8).

4. Following each Macro-spot editing, the system will re-predict and re-validate the Macro-spots (see Section 7.2.7).
5. 

Click the **Sonicate** button to apply the ultrasound energy; the system transfers the sonication location to the MR.
6. Monitor the following during the sonication:

- The **evolving temperature rise and dose** during sonication. Pay special attention to the temperature on the **rectal wall**.
- Patient movements, by observing the **Rectal Wall** and **Prostate Capsule drawings** on the updated MR anatomical images.
- The real-time images to **ensure coupling** and verify no air bubbles entered the interface between the balloon and the rectal wall.

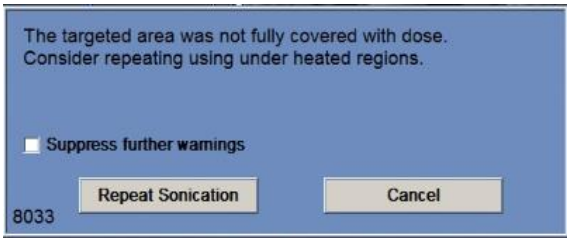
- **Spectrum signal** during the transmission of the acoustic energy.

WARNING

- Monitor the **thermal rise and dose buildup** at the target location, and at the relevant pass zone with special attention to the **rectal wall**.
- In case temperature on the **rectal wall** exceeds 75°C, press the **Stop Sonication** button and reduce the energy of the following sonication.
- If an unexpected thermal rise is found outside the target location, stop the sonication.

[W-34]

7. After the sonication ends, the **Thermal Evaluation** screen opens (see Figure 7-4).
8. System automatically initiates Current Anatomy Scans on the MR (in the background). The updated strips will be displayed when returning to the **Treatment Main Screen** (see Figure 7-1).
9. In case the targeted area was not fully covered with dose (above pre-defined threshold), the system will display the following pop-up message:



10. Click on **Repeat Sonication** to enter **Repeat Under-Heated Regions** Mode (see Section 7.4.6), after accepting thermal outcome and returning to the Treatment main screen or click on **Cancel** to proceed without repeating sonication.
11. If required, mark the **Suppress further warning** checkbox, to prevent the system from displaying this message again during the rest of the treatment.

In this case, the **Repeat Under-Heated Regions** Mode will be still **available**, but the notifying message will not be displayed.

12. Check whether there has been patient movement by observing the location of the **Rectal Wall**, **Prostate Capsule** and **LEDR** contours on the **Sonication Anatomical** images.

13.  If required, use this tool to draw **Measurement Polygons** to evaluate the temperature rise.
14. Analyze the results and compare the size of the **obtained (measured) dose** with the **planned (predicted) dose**.
15. If they do not match, there are several actions to select from:

-  Click this button and perform a **Dose Adjust** (refer to Section 7.4.4).
-  Click this button and then **Continue** to **repeat** the exact same sonication again (on the same slice).
-  Click this button (if not already selected) and then **Continue** to enter **Repeat Under-Heated Regions** Mode (see Section 7.4.6).

NOTE

- If the temperature map still contains an erroneous thermal dose (caused by residual artifacts or noise), click to define which regions should be considered as dosed regions. See Section 7.3.2).

[N-42]

16. 

If not done yet, click **Continue** to accept the **Thermal outcome** and return to the **Treatment Main Screen** (see Figure 7-1).
17. System will detect and notify about movements on the next slice, according to the **Treatment Direction** defined in the **Treatment Protocol**.
18. If required, enter **Deformation Mode** to update the treatment plan on the **Axial Current Anatomy** strip (refer to Section 7.2.10).
19. **Repeat** the procedure starting at Step 1. For efficacy considerations, it is recommended to perform **Macro-spots slice-by-slice** so that there is a sufficient **overlay** between them.

7.4.6. Repeat Under-Heated Regions (Optional)

While in **Thermal Evaluation** (see Figure 7-4), carefully review and analyze the results and compare the size of the **obtained (measured) dose** with the **planned (predicted) dose**.

In case the **measured dose** does not cover the entire **ROT**, you can enter a special mode that will attempt to treat these regions that did not heat sufficiently in the last sonication.

NOTE

Under-heated regions are defined as regions within the **ROT** that were originally covered with **predicted dose** (by the planner) but where not covered by the **auxiliary measured dose**. Noisy regions are excluded.

[N-43]

1.  While in the **Thermal Evaluation** screen, click this button and then **Continue** to return to the **Treatment Main Screen** while in the **Repeat Under-Heated Regions Mode**.
2. The system calculates (in the background) an **Effective Heating Map (EHM)** for the previously sonicated slice, by comparing between the **predicted heating map** and the actual **measured heating map**.
3. Back in the **Treatment Main Screen**, the system identifies the Under-Heated Regions on the last sonicated Axial slice (from the **Current Anatomy** strip).
4. The **Under-Heated Regions** are marked on the **Axial Current Anatomy** image with a brown-colored polygon:

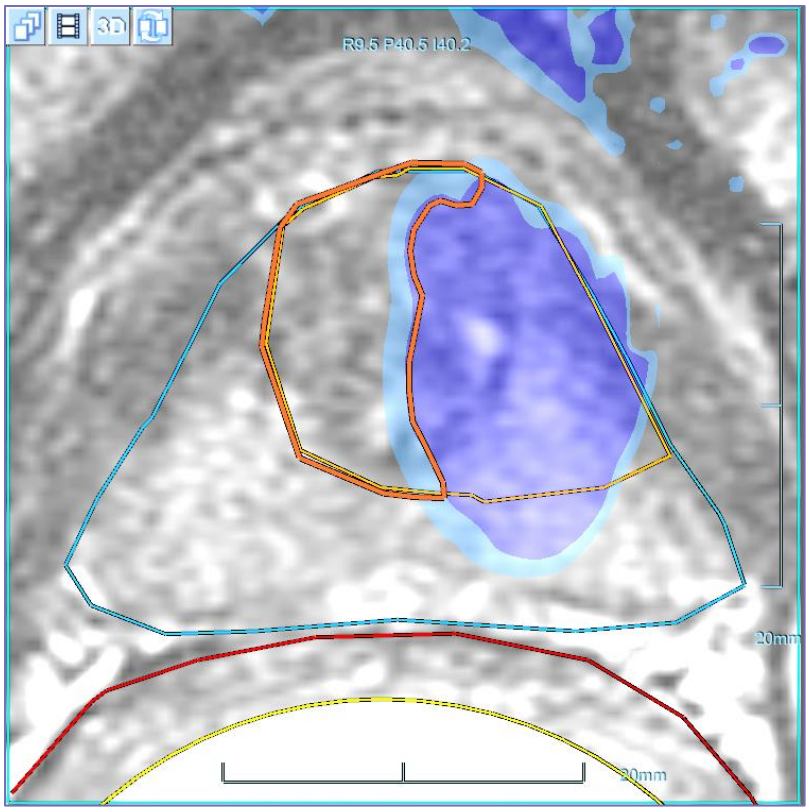


Figure 7-10: Under-Heated Regions Polygon

5. The **Under-Heated Regions** polygon can be edited either by dragging or by completely deleting and re-drawing it.
6.  To draw the **Under-Heated Regions** polygon, click this button. It is enabled only in this state. Drawing is enabled only on the slice of the previous **Macro-spot** (since the **EHM** was calculated only for this slice).

WARNING

When manually drawing the **Under-Heated Regions** polygon, make sure to draw it strictly within the original **ROT**. Otherwise, the system might plan spots that exceed the original **ROT** limits (while still restricted by the various LEDR's).

[W-35]

7.  Click this tool; a new option of **Repeat Under-Heated**, available only in this state, will be available. Select it from the sub-menu.
8. Click inside the **Under-Heated Regions** polygon. As with **nominal Macro-spots**, clicking on the right or left half of the polygon will affect the direction in which the **Macro-spot** is planned and executed.
9. 

Click the **Sonicate** button to apply the ultrasound energy; the system transfers the sonication location to the MR.

WARNING

Repeat Under-Heated Regions spots are limited in energy according to value set in the **Treatment Protocol** (see Section 6.8). When required, **gradually** allow the system to add more energetic spots until reaching the desired tissue response.

[W-36]

7.5. Conclusion of the Treatment Session

At the conclusion of the treatment session, you may select to advance to **Evaluation** Stage, in which **Treatment Evaluation** scans will be performed.

8. EVALUATION STAGE

8.1. Overview

Evaluation Stage enables the operator to evaluate treatment results based on post- treatment, contrast-enhanced imaging. The contrast-enhanced images display the Non-Perfused Volume (NPV) within the prostate tissue. Once the images are uploaded to Exablate Prostate workstation, they are overlaid with the accumulated thermal dose.

The user can either scan treatment evaluation images (with- and without-contrast) directly from the Exablate Prostate workstation or select post-treatment MR images from the MR console and import them to the workstation. These images can be reviewed later in **Replay** mode.

NOTE

Do not shut down the system prior to completing the post-treatment imaging and removing the patient from the MR. Otherwise transducer motion during system shutdown may cause severe imaging artifacts.

[N-44]

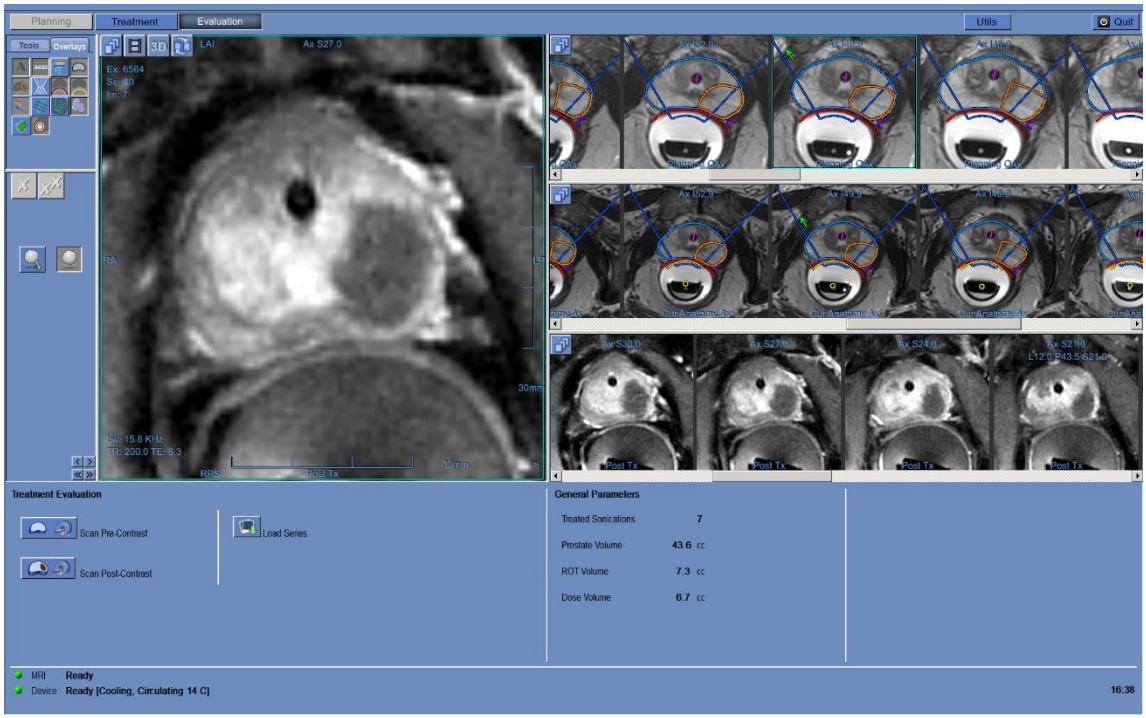


Figure 8-1: Evaluation Screen Elements

8.2. Action Tools

	**Scan Without Contrast**	Click this button to prescribe and run an **Axial Treatment Evaluation** scan, according to the range defined by the **Scanning Range lines**. This scan will use the optimal central frequency that was identified by the system. When the scan ends, the new scanned MR series will appear in the 3rd Exablate workstation **image strip**.
	**Scan with Contrast**	Click this button to prescribe and run an **Axial Treatment Evaluation** scan, according to the range defined by the **Scanning Range lines**. This scan will use the optimal central frequency that was identified by the system. When the scan ends, the new scanned MR series will appear in the 3rd Exablate workstation **image strip**.
	**Load Images from MR**	Click this button to select any series in the MR console browser. This series is then uploaded to the workstation and can be viewed in the 3rd image strip
	**Measure Volume**	Click this button to draw the area on all relevant MR images and display its volume.
	**Show/Hide Volume Measurement**	Click on this button to Show/Hide the volume measurement overlay.

8.3. Automatic Evaluation Scan Acquisition

1. Upon entering Evaluation Stage, the 3rd **Image Strip** is updated with the **Sagittal Current Anatomy** strip, showing the **Scan Range Lines** as previously set in the **Planning** stage (see Section 6.5.2).
2. Either leave the **Scan Range Lines** as previously defined or edit them, as necessary.
3.  Click this tool to perform a **T1w Axial Evaluation Scan (without contrast)**, covering the range that is defined by the **Scan Range Lines,** and using the optimal **Central Frequency** value that has been previously found (see Section 6.4.2).
4. The automatic Axial scan will be prescribed using recommended parameters (e.g., slice thickness of 3mm and zero spacing).
5. Once the MR completes scanning this series, the set of images will be retrieved automatically and displayed in the 3rd **Image Strip** of the Exablate workstation.

6.  Click this tool to perform a **T1w+C Axial Evaluation Scan (with contrast)**, covering the range that is defined by the **Scan Range Lines**, and using the optimal **Central Frequency** value that has been previously found (see Section 6.4.2).
7. On the MR console, subtract the no-contrast series from the contrast-enhanced series. To upload the subtraction series to the Exablate Prostate workstation, follow the procedure describe in the following section.

8.4. Manual Evaluation Scan Acquisition

 This feature allows uploading manually-scanned post-treatment MR series into the console in order to present the accumulated dose overlay and evaluate treatment effect.

1. To load a new series, click this tool.
2. While the MR console is in **Idle** status, select a series in the MR console browser by clicking it.
3. The MR series will be transferred to the operating console into the 3rd **Image Strip**.

8.5. Volume Measurement

1.  To **measure a volume** on the post treatment images, use this tool. The measured areas will be shown on each slice, and the total volume will be shown on the bottom right corner of the **Selected Image Window**.
2.  Click this tool to show or hide the volume measurement overlay.

NOTE

To review the post-treatment series in **Replay** mode, skip to the **last sonication** that was performed.

[N-45]

8.6. Exit Evaluation Stage

 Click this tool to exit **Evaluation Stage** and terminate the treatment.

9. REPLAY STAGE

9.1. Overview

Replay mode enables the operator to analyze the results of previous sonications. **Replay** can also be activated from **Data Management** to view past treatments.

Click the **Replay** button in the main toolbar to access the **Replay** screen. This screen is similar to the **Thermal Evaluation** screen displaying the results of the last performed sonication (see Figure 7-4). This way the operator can observe the acquired temperature maps and the temperature graph of all previous sonications.

If you access **Replay** from **Data Management** (see Chapter 11), the **Replay** screen displays the first sonication in the treatment.

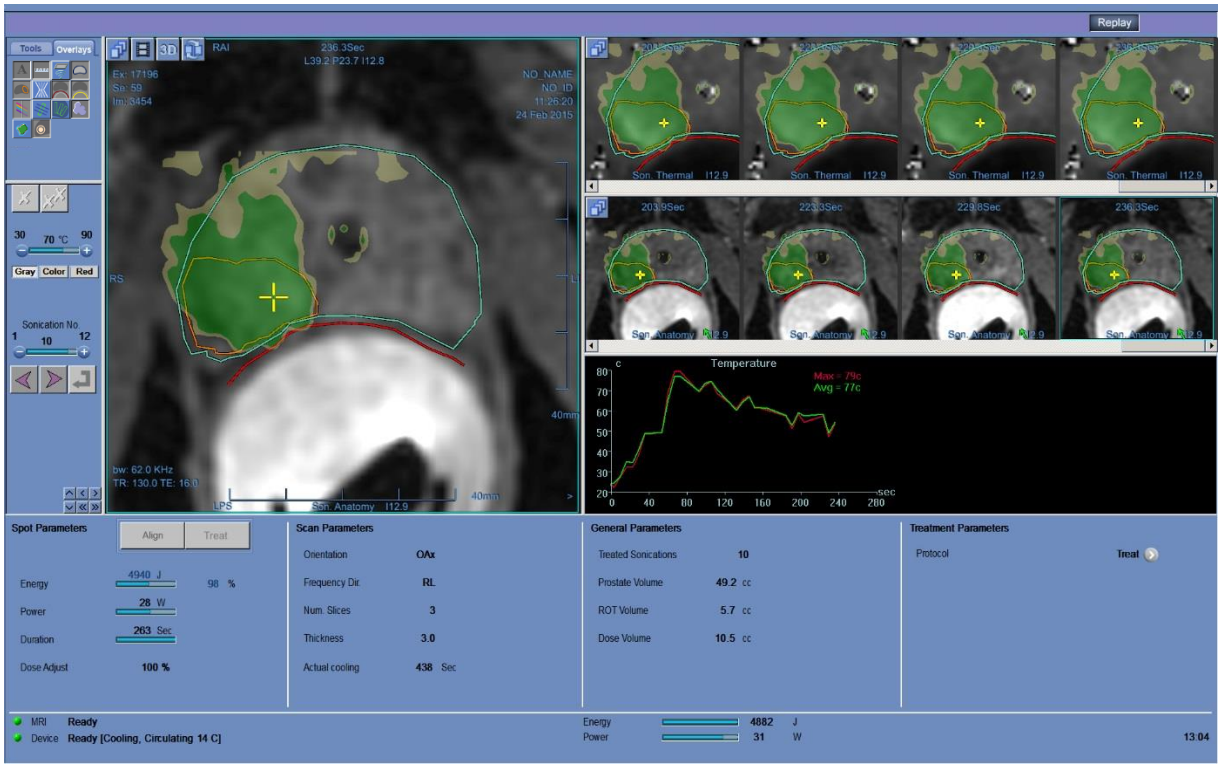
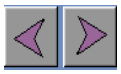


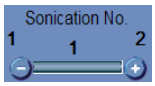
Figure 9-1: Replay Screen

9.2. Replay Action Tools



Next or Previous Sonication

Click this button to scroll through the sonications. The current sonication sequence number appears in the middle of the sonication bar.



Sonication No. Bar

Use the  and  buttons in the **Sonication No. Bar** to select to view a certain sonication and click this tool  .

9.3. Exit Replay

To leave **Replay**, click the **Replay** button in the main toolbar; the system transitions to the same screen from where you accessed **Replay**.

10. UTILITIES

10.1. Overview

The **Utilities** mode provides the means to perform actions that may be used during treatment but are not necessarily part of the nominal treatment flow.

The means include - MR operations, turning device On/Off, operate water system, connection to the site network and configuring Macro-spot planner modes.

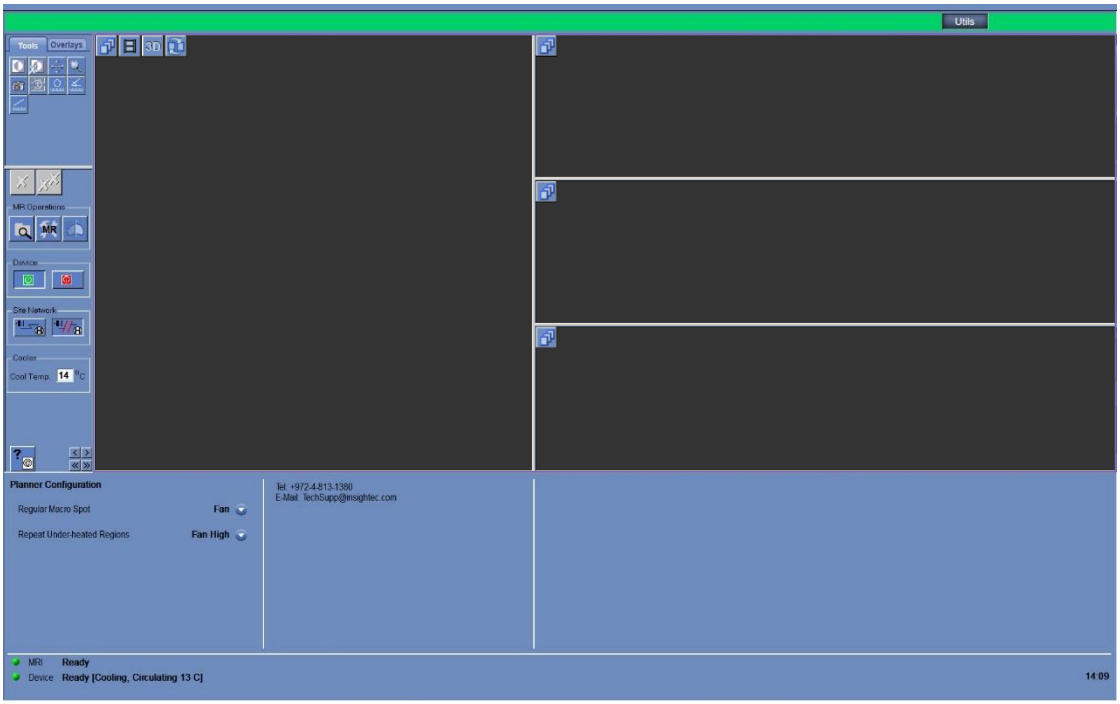


Figure 10-1: Utilities Screen

10.1.1. Utilities Action Tools

The tools relevant to this mode are (refer to Figure 10-1):

	**MR Operations – Select Exam**	Click the **Select Exam** button to select the active exam in the MR as the new treatment exam for the rest of the treatment.
	**MR Operations – Setup MRI**	Click the **Setup MRI** button to manually restore the connection to the MRI and/or the MR protocols in the GE MR system (in case they were changed or removed).

	**MR Operations – Optimize Coil Signal**	Click the **Optimize Coil Signal** button to improve imaging by optimizing coil channel averaging.
	**Turn Device On/Off**	 Click this tool to turn the device off.  Once shutdown is complete (as appears in the status bar), click this tool to turn the device on.
	**Connect/Disconnect to the Site network**	 Click this tool to connect the MR system to the hospital network.  Click this tool to disconnect from the hospital network.
	**Set water cooling temperature**	Set water cooling temperature. Do NOT change the default 14˚C unless performing research activity.
	**Copyright Notice**	Click this button to review the list of open source software that parts of the product may incorporate or be distributed with.
	**Planner Configuration**	Select the default planner mode used by the system for a **Macro-spot** and for a **Repeat Under-Heated Regions** spot.

10.2. Utilities Procedures

10.2.1. Select Exam

This procedure is used when it is required to synchronize the Exablate workstation with a new exam on the MR. To continue the treatment with the correct exam, a new MR exam must be opened and defined as the current exam.

1. Confirm that a new exam with at least one series comprising of some images has been manually scanned in the MR.
2.  Click on this tool; the system will automatically select the latest exam in the MR as the treatment exam. From this point on all thermal scans will be created using images from the new exam.

WARNING

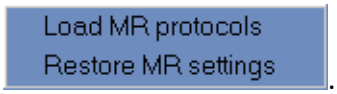
Before performing this procedure, the operator ***must*** confirm that both exams have the exact same landmark location and that there was no patient movement since the planning images were scanned.

[W-38]

10.2.2. Setup MR Protocols

This procedure should be used when the MR protocols stored in the GE MR system have been deleted or modified, or when communication with the MRI was lost.

1. 

Click the **MR** tool to open the **Setup MRI** drop down menu 

.
2. Select the desired option:

- Click **Load MR Protocols** to restore the MR treatment protocols from the workstation to the GE MR system.
- Click **Restore MR settings** to restore the connection between the Exablate system and the MRI, and to restore the MR treatment protocols.

10.2.3. Optimize Coil Signal


This procedure enables you to improve imaging by reading the correct **coil channels averaging coefficients** and updating them in the Exablate Prostate workstation.

- Click this tool and select any series from the **current exam**.
- Click the **Calc SNR** button to read and update **coil channel averaging coefficients**.

10.2.4. Turn System Hardware On/Off

This procedure is to be used when the equipment cabinet computer must be restarted in the middle of the procedure.


Click this tool to turn off the Exablate Prostate system; when the device shutdown is complete, the **Device Status** (in the status bar) appears as **Not connected**.

 Click this tool to turn on the Exablate Prostate system; when the device is on, the **Device Status** (in the status bar) appears as **Ready**.

10.2.5. Connect/Disconnect to the Site Network

The MR system should be disconnected from the hospital network during a treatment. In case of an urgent need to transfer data, use this option to connect/disconnect the MR to the site network.

1.  Click this tool to connect to the hospital network.
2.  As soon as the data transfer is completed, click this tool to disconnect the MR from the site network and continue the treatment.

CAUTION

Do not treat a patient while the MR is connected to the hospital network.

[C-7]

10.2.6. Change Macro-Spot Planner Configuration

Different Prostate tissues may have a different response to the acoustic energy and as a result, respond differently to various energy deposition regimens.

The Exablate Prostate system supports **Two Planner Modes**:

1. **Fan:** The Macro-spot planner adds the most energetic sub-spot first, while the energy per sub-spot is reduced for further sub-spots, due to the simulated accumulated heat effect. For the same reason, per each sub-spot, the most energetic focal point will be the most anterior one.
2. **Uniform:** The Macro-spot planner attempts to achieve **uniform** energy distribution within the **ROT** both by geometrically spreading the energy in a uniform grid and by attempting to distribute energy uniformly between all focal points.

Both Planner modes have an additional sub-mode (denoted by the suffix **High**), in which the planner will attempt to reach a higher temperature threshold within the **ROT**.

By default, a **Macro-spot** will be added in a **Fan** configuration, while a **Repeat Under-Heated Regions** spot will be added in a **Fan High** configuration.

Figure 10-2: Planner Configuration

Use the **Planner Configuration** controls to select the default planner mode used by the system for a **Macro-spot** and for a **Repeat Under-Heated Regions** spot.

10.2.7. Copyright Notice

Certain parts of this system may incorporate – or be distributed with – selected open-source software. Clicking the **Copyright Notice** button will open a Windows® text file listing such software.

10.3. Exit Utilities

To leave **Utilities**, click the **Utils** button in the main toolbar; the system will return to the stage that was active prior to entering **Utilities**.

11. DATA MANAGEMENT

11.1. Overview

Data Management provides the following options:

- Store treatment records
- Review treatment records
- Export treatment records to a CD or USB storage device
- Import treatment records from a CD or USB storage device

NOTE

This mode can be accessed only from the **Startup** screen and not during treatment, by clicking the **Data Management** button.

[N-46]

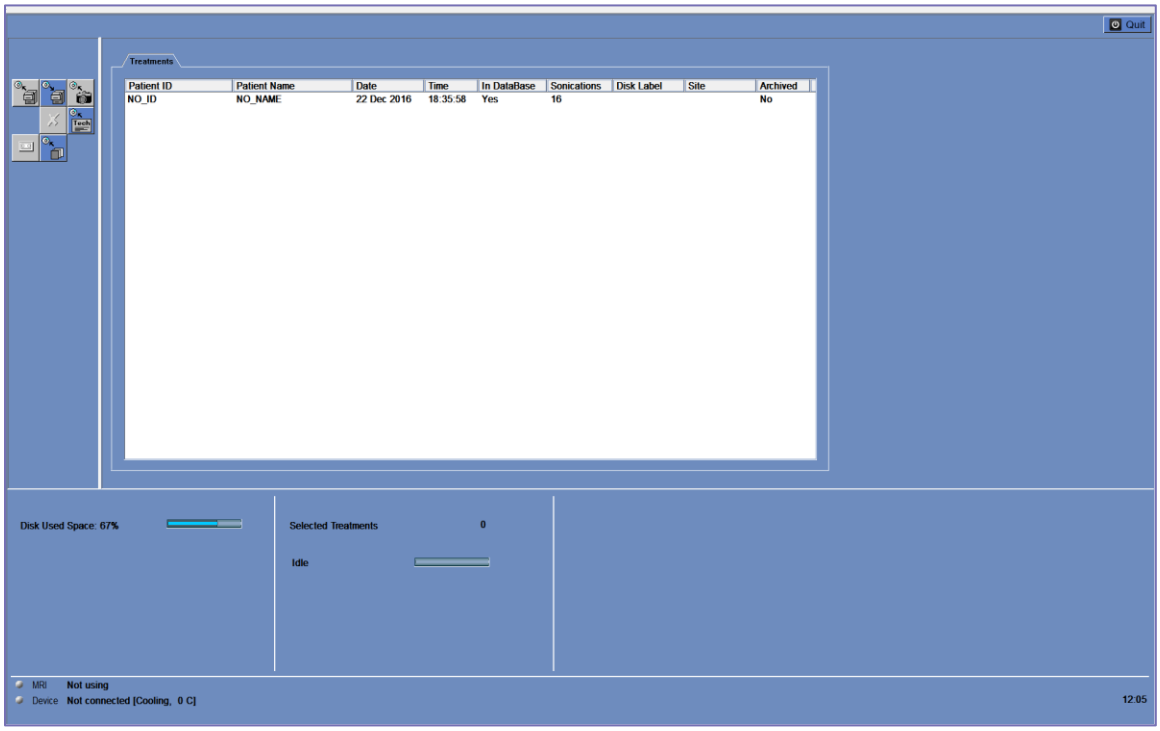


Figure 11-1: Data Management Screen

11.2. Selecting a Patient

1. Click the **Patient ID** number to select the treatment record.
2. Hold down the **Shift** key to select a continuous list of patient IDs
3. Hold down the **Ctrl** key to select specific patient IDs.

11.2.1. Action Tools

The following commands appear on the **Data Management** screen (see Figure 11-1):

	**Export**	Click this button to export all selected treatment records to the CD or USB device.
	**Import**	Click this button to import one or several treatment records that have been previously saved on a CD or USB device to the console, or treatments from another Exablate console.
	**Screen Dump**	Click this button to send the snapshots associated with the selected treatments to the CD or USB device.
	**Erase Selected Treatment**	Click this button to erase selected treatment records from the database but leave the record on the Patient list.
	**Technical Export**	Click this button to export technical log files to the CD or USB device.
	**Replay**	Click this button to access the **Replay** screen. **Replay** can be applied only if one treatment is selected.
	**Get Images**	Click this button to enter the **Download MR Images** dialog box. Images imported from the MR system can be copied using the Exablate CD drive or USB storage device.

NOTE

The Exablate system enables back-up storage of treatment data on certain electronic media (CD, DVD, USB or external hard-disk); however, it is the responsibility of the user, not INISGHTEC, to back-up treatment data as may be required by applicable laws and regulations and/or by the user's institutional policies and procedures. The back-up storage capabilities on the Exablate system are provided by INISGHTEC "as is" without any representations or warranties, including but not limited to warranties of merchantability and fitness for a particular purpose. INISGHTEC is not responsible for any data alteration or loss arising from malfunction, or any use of, electronic media used with the Exablate system.

[N-47]

11.2.2. Export to CD or USB Storage Device

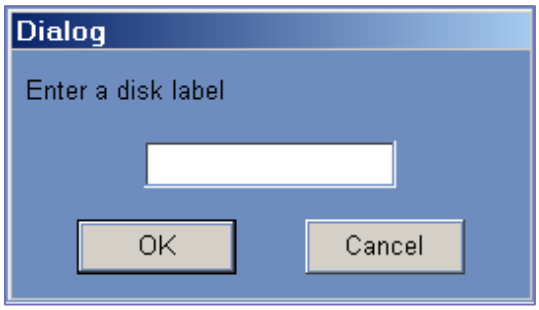


Figure 11-2: CD Disk Label Dialog Box

Export one or more treatment records from the local database to a CD or USB storage device as follows:

1. Insert a blank CD into the CD-R drive or connect a USB device.
2. Select a treatment or a set of treatments to export.
3.  Click this tool; select **To CD/DVD** or **To USB** from the drop-down menu and click **OK** to start export. The system responds with the **Disk Label** dialog box.
4. Type in a title for the disk/file and click **OK**.
5. Data will be exported to the CD or USB device. The export's progress can be viewed on the **Status Bar** (see Figure 11-1).
6. The CD is automatically ejected from the CD-R drive when the data export is complete.

11.2.3. Import Treatment Records from CD or USB Storage Device

To import one or more treatment records:

1. Place the CD with the treatment files in the CD drive or connect the appropriate USB device.
2.  Click this tool; select **From CD/DVD** or **From USB** from the drop-down menu.
3. The imported treatments will be copied to the local drive and will be shown in the Patient List (see Figure 11-1).

11.2.4. Screen Dump to CD or USB Storage Device

To store snapshots associated with the selected treatment:

1. Insert a CD or connect a USB device.
2.  Click this tool; select **To CD/DVD** or **To USB** from the drop-down menu.
3. The snapshots associated with the selected treatments will be copied to the selected storage option.

11.2.5. Erase Selected Treatment Record

Use this button to erase selected treatment records from the database but leave the treatment's details on the Patient list.

1. Select records to be erased from the Patient list.
2.  Click this tool to erase; records will be erased from the database, but treatment details will remain on the Patient list.

NOTE

- After deletion, the treatment record will not be available. Ensure that the treatment was exported prior to erasing it.
- Erased treatments will still be displayed in the Patient list. The column **In Database** will indicate the availability of treatment in the Database (see Figure 11-1).

[N-48]

11.2.6. Technical Export to CD or USB Storage Device

Export one or more treatment technical log files to a CD or a USB device as follows:

1. Insert a blank CD into the CD-R drive or connect a USB device.

Figure 11-3: CD Disk Label Dialog Box

2. 

Click this tool; select **To CD/DVD** or **To USB** from the drop-down menu, and in the **Technical Export** dialog box select a date to locate log files and click **OK** to start the export. Type in a title for the disk/file and click **OK**.
3. Technical data will be exported to the CD or USB device. The export progress can be viewed on the **Status Bar**.

11.2.7. Download MR Images

The Exablate system is equipped with a utility to export MR images to the CD or USB storage device.

To export MR images (refer to Figure 11-4):

1.  Click this tool and select **To CD/DVD** or **To USB** from the drop-down menu; the **Download MR Images** dialog box opens.
2. Select one exam from the **Exam List**. All relevant series will appear in **Series List** (this operation might take a while).

3. From the associated **Series List** select one or more series, using the **Shift** or **Ctrl** keys, or select the **Select All** option button.
4. Type in a new patient name and treatment ID or use the system default (patient's initials).

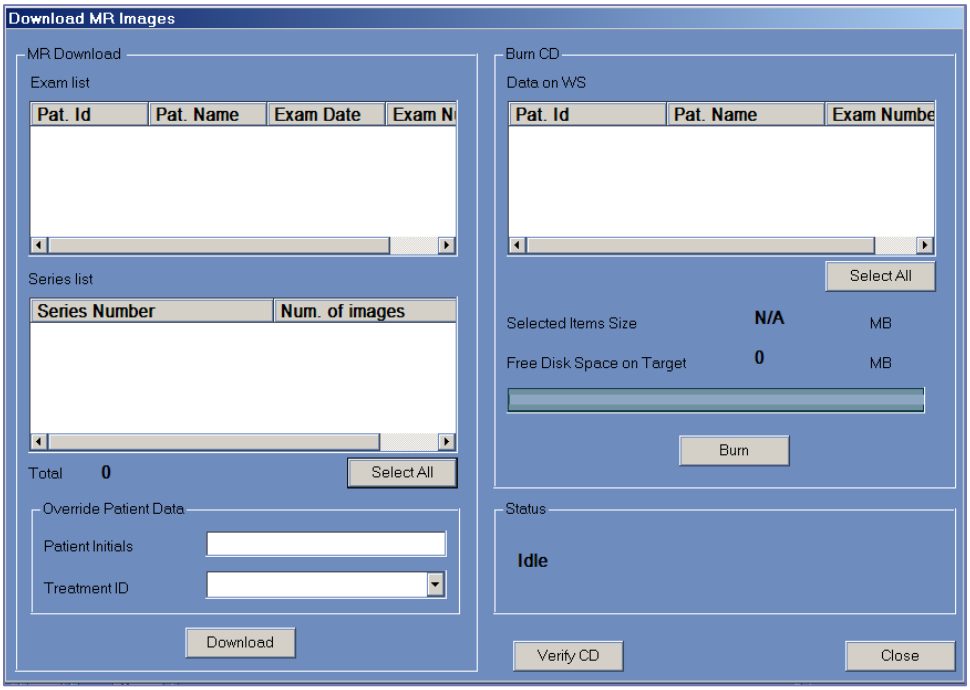


Figure 11-4: Download MR Images Screen

5. Download Click the **Download** button to copy the images to the Exablate system; the images will be stored on the workstation and will appear in the **Data on WS** list.
6. Burn Select the patients from **Data on WS** list and click the **Burn** button to export the images to a CD or to a USB device. The export process can be viewed in the **Status Bar** (see Figure 11-1).
7. The CD-R is automatically ejected from the CD drive when the data export is complete.

NOTE

The treatment files must come from an Exablate console. When treatment files are recorded on a different console, the patient's name and ID are not displayed to retain privacy.

[N-49]

11.3. External Database (Optional)

The Exablate system can be delivered with an additional external database. The optional database can be added to an existing system by INISGHTEC at a later stage as well.

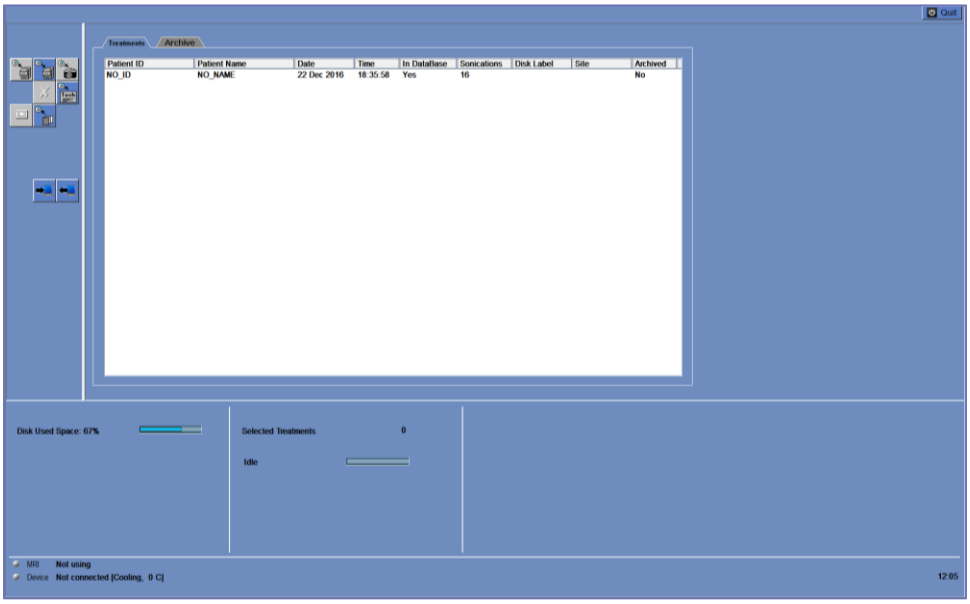


Figure 11-5: Data Management Screen – System with External Database

11.3.1. Action Tools

The following elements are added to the **Data Management** screen on systems with an **External Database** (see Figure 11-5):

	**Select Database**	Click a database tab to display the data on the Patient list.
	**Delete Complete Record**	Click this tool to delete selected treatment records from the database and from the Patient list.
	**Copy Records between Databases**	Copy a treatment record from the Local database to the Archive database, or vice versa.

11.3.2. Select Database

There are two tabs to select the active database.

- Click the **Treatments** tab to display Local Database data on Patient list and manage data.
- Click the **Archive** tab to display Archive Database data on Patient list and manage data.

11.3.3. Delete Complete Treatment Record

Use this button to delete selected treatment records from the database and from the patient list.

1. Select records for deletion from Patient list.
2.  Click this tool to delete selected records.

> ***NOTE***
>
> After deletion, no record of the treatment will be available. Ensure that treatment was exported prior to deletion.
>
> [N-50]

11.3.4. Records Management

To copy treatments from one database to the other, use the **Copy Records Between Databases** tool.

-  Click this tool to copy a treatment record from the Local database to the Archive database.
-  Click this tool to copy a treatment record from the Archive database to the Local database.

The Action Tools presented in Section 11.2.1 are available for use within the **Local Database**.

The commands **Screen Dump**, **Delete Complete Record**, **Erase Selected Treatment** and **Get Images** are available for use in the **Archive** database as well.

11.4. Exit Data Management

To leave **Data Management**, click the **Quit** button; the system will transition to the **Startup** screen.

APPENDIX A. ADVANCED OPTION MODE

A.1. Overview

WARNING

Improper use of the **Advanced Option Mode** may degrade the quality of treatment and may even result in personal injury.

[W-39]

Advanced Options Mode enables the operator to override the automatically generated treatment plan and manually set treatment parameters. This includes:

- Sonication parameters
- MR scan protocol parameters

When you access the **Advanced Options** dialog box, all displayed values are the current treatment values.

To change a parameter:

1. Click the button next to the parameter to be changed or adjusted; the parameter's value text box is activated.
2. Type in or select the required value.
3. Click on:

- **OK** to accept the changes
- **Cancel** to reject all changes and close the dialog box
- **Reset Values** to reset all changes

To return the parameter to system default:

1. Open the **Advanced Options** dialog box.
2. Click the box next to the parameter; the value text box is disabled, and the value is automatically generated by the system.

A.2. Sonication Parameters

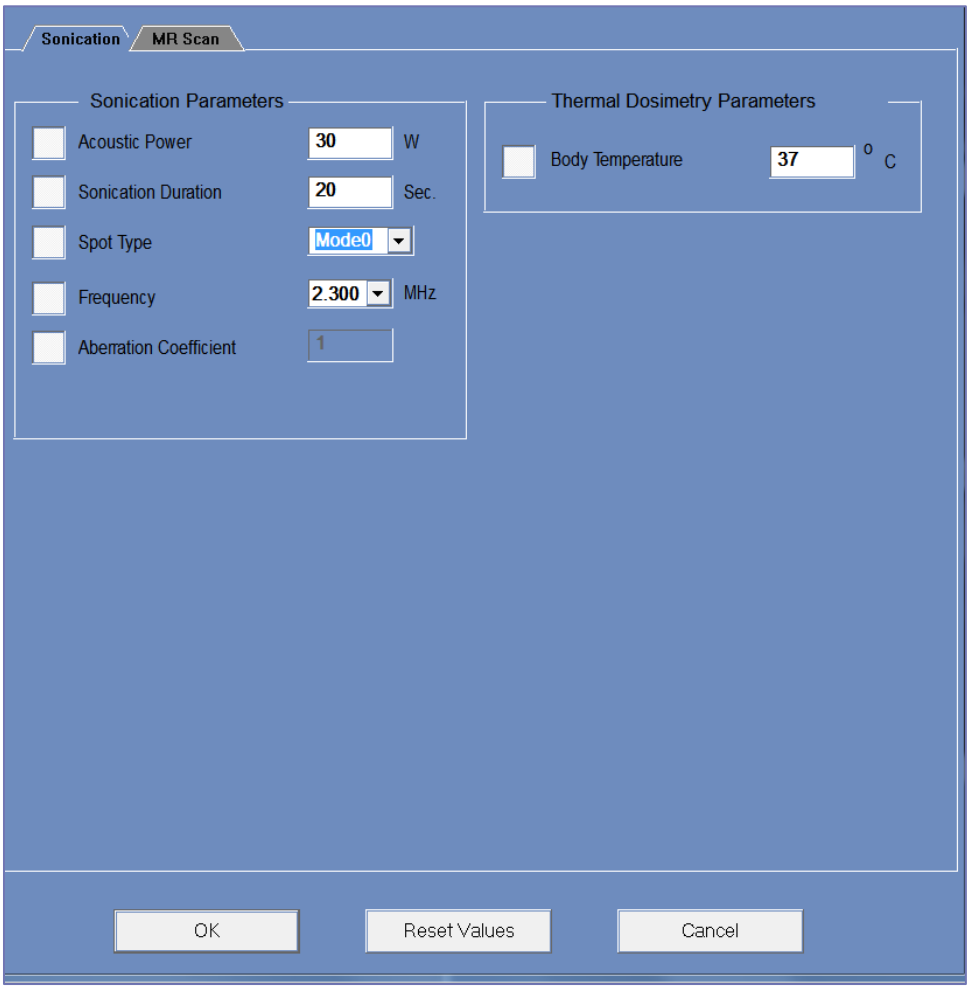


Figure A-1: Sonication Parameters Dialog Box

It is possible to change the following sonication parameters:

- Acoustic Power
- Sonication Duration
- Spot Type
- Frequency
- Aberration Coefficient
- Body temperature

A.3. MR Scan Parameters

Click the **MR Scan** tab to access the **MR Scan Parameters** dialog box:

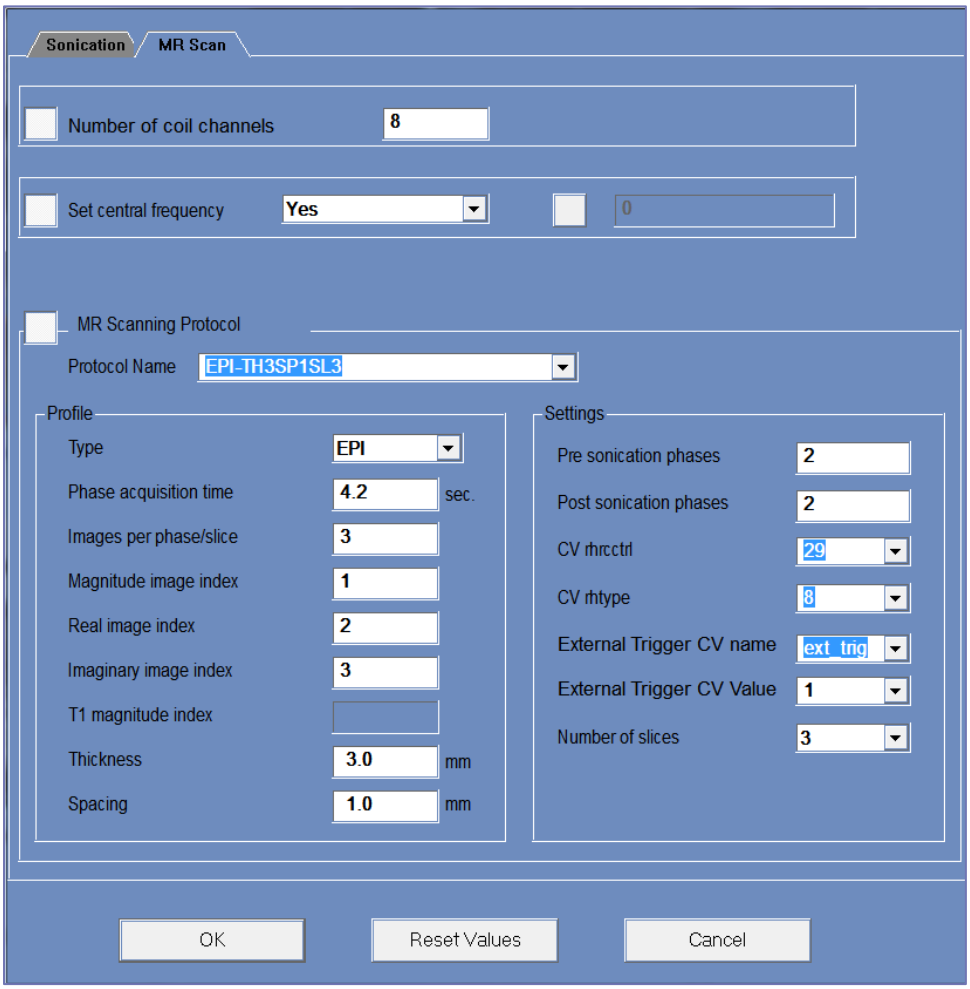


Figure A-2: MR Scan Parameters Dialog Box

A.3.1. Changing MR Parameters

1. Click the button next to **Number of coil channels**.
2. Select the number of **coil channels**.
3. Click the button next to **Set Central Frequency**.
4. Enable manual setting of **MR central frequency** to override automatic feature values.

5. Select a MR Scanning **Protocol**:

- Select from the **Thermal Mapping** Protocol list in the pull-down menu.
- Create a new thermal mapping PSD. Type the new protocol name in the **Protocol Name** text box.
- The parameters of the selected protocol appear automatically. If a user protocol is created, manually set all values for the protocol profile.

NOTE

Ensure that the user-defined protocol profile is correct and complete.

[N-2]

A.3.2. Profile Parameters Elements

- **Type**

  Select the sequence type: Dual Echo, Single Echo or EPI.

- **Phase Acquisition Time**

  The MR performs a single scan under the selected protocol in this time span.

- **Images per Phase**

  This sets the number of images created by the MR for each phase.

- **Magnitude Image Index**

  Determines which image in a series is the magnitude image.

- **Real Image Index**

  Determines which image in a series is the real image.

- **Imaginary Image Index**

  Determines which image in a series is the imaginary image.

- **T1 Magnitude Index**

  For dual echo sequences, determines which image in a series is the echo 1 magnitude image.

- **Thickness**

  Determines the slice thickness.

- **Spacing**

  For multi slices sequences, determines the slice spacing.

A.3.3. Parameter Settings

- **Pre-Sonication Phase**

  Use **Pre-Sonication Phase** to determine the number of “cold phases” created by the system before each sonication.

- **Post-Sonication Phase**

  Use the **Post-Sonication Phase** to determine the number of cooling phases the system scans after each sonication.

- **CV rhrcctrl**

  This defines the image types reconstructed for each phase. For reconstructing magnitude, real and imaginary images, use a value of **29**.

- **CV rhtype**

  For **EPI** sequences, use a value of **8**. This applies only to **EPI** sequences.

- **External Trigger CV Name**

  This defines the name of the external trigger.

- **External Trigger CV Value**

  For sequences with the **ext_trig CV**, use a value of **1**.

  For sequences without the **ext_trig CV**, use a value of **0**.

- **Number of Slices**

  For multi-slices thermal imaging, defines the number of slices per sonication.

APPENDIX B. WATER SYSTEM CLEANING AND HIGH-LEVEL DISINFECTION

B.1. Overview

The Exablate Prostate system is equipped with a water sub-system, as described in Section 1.4.4. Immediately post procedure and as part of regular maintenance of the system post usage, the overall prostate system should undergo a cleaning and high-level disinfection procedure.

B.2. Water System Troubleshooting

B.2.1. Handling Water System Errors

The system will automatically cease circulation when there is a chance of water leakage or excessive pressure in the balloon. This will cause the green **Water System** indicator to blink and activate a **warning buzzer**. To resume treatment, follow these instructions:

1. Press the **Circulation Controller** once to stop the warning buzzer. Resume circulation by pressing the **Circulation Controller** again.
2. If the error repeats itself, enter the magnet room and check the message on the **water system control panel**. Follow the **Troubleshooting Table** below for specific instructions.
3. If the problem persists, contact technical support.

B.2.2. Water System Troubleshooting Table

#	**Error Message** (on water system control panel)	**Description**	**Corrective action**
1.	**High XD temp**	The temperature of the water in the balloon is above 39°C.	■ Observe the temperature value on the water system control panel. ■ Touch the tubes entering the transducer; if it indeed feels hot, halt the treatment, and circulate water in cooling state for ~5 min.
2.	**Low XD temp**	The temperature of the water in the balloon is below 10°C.	■ Observe the temperature value on the water system control panel. ■ Observe the tubes entering the transducer; if it is covered with water

			condensation, circulate water in warming state for ~5 min.
3.	**High pressure**	The water pressure in the balloon is too high.	Drain 30 CC from the balloon, and more if the error persists (up to reference volume).
4.	**Low pressure**	The water pressure in the balloon is too low.	Fill 30 CC into the balloon, and more if the error persists.
5.	**High flow XD**	The flow rate of the circulating water is above threshold.	■ Check visually for bubbles in the balloon/hoses, the error might occur as long as there are bubbles in the system. ■ If it occurs during transducer preparation ignore it by pressing <Mute> on remote control. ■ Check for water leaks.
6.	**Low flow XD**	The flow rate of the circulating water is below threshold.	■ Check visually for bubbles in the balloon/hoses, the error might occur as long as there are bubbles in the system. ■ If it occurs during transducer preparation ignore it by pressing <Mute> on remote control. ■ Check for water leaks. ■ Check water filter on the table. ■ Check for bend/ pinched hoses.
7.	**Combined error**	General error, as a result of several errors at once.	■ Click “Reset” on the control panel.
8.	**Chiller low/high temp**	The water temperature of the chiller is not within boundaries.	■ Check temperature reading on chiller display (in equipment room).
9.	**Chiller low level**	The system diagnosed that there is coolant level drop inside the chiller coolant tank (in equipment room).	■ Check for coolant leaks around the table and along the hoses up to the chiller (in equipment room). ■ Coolant may evaporate. Add coolant to the chiller according to the level signs (in equipment room).

10.	**High flow chiller**	The coolant flow rate in the is above threshold.	■ Check for coolant leaks around the table and along the hoses up to the chiller (in equipment room). ■ Check visually for bubbles in the coolant, the error might reoccur as long as there are bubbles in the coolant.
11.	**Low flow chiller**	The coolant flow rate in the is below threshold.	■ Check the water hose connection to the table. ■ Check visually for bubbles in the coolant, the error might reoccur as long as there are bubbles in the coolant.
12.	**High/Low SU Temp**	Temperature in the Switching Unit (on patient table) is not within limits.	■ Click **Reset** on the remote control. ■ If the problem persists, contact technical support.

APPENDIX C. HIGH-LEVEL DISINFECTION PROCEDURE

C.1. Introduction

1. The Exablate 2100V1 ("Exablate") Prostate probe is considered a semi-critical device, as per Spaulding classification, and should undergo this cleaning and high-level disinfection (HLD) procedure, immediately at the point of use after every treatment.
2. Immediately after treatment, all single-use items: (1) probe shell, safety pin and white O-ring, (2) all drapes and covers, and (3) water pouch must be discarded in marked hazardous material containers and handled using applicable personal protective equipment (e.g., gloves, protective glasses, etc.), according to the policies of the medical facility.
3. Used cleaning and disinfection materials should be disposed of according to their manufacturer instructions and the medical facility policy.
4. Individuals handling cleaning and disinfecting agents must follow the instructions of the agent manufacturer, including instructions for personal protective equipment.
5. Follow the steps in this procedure consecutively and without delays in between.
6. Users should also refer to professional organizations' clinical practice guidelines or clinical guidelines of the Center for Disease Control (CDC).

C.2. List of Materials Required for Cleaning

1. Cleaning and disinfection cart, with **four (4) containers**:
    a. Container #1 for cleaning Solution
    b. Container #2 for water
    c. Container #3 for disinfectant
    d. Container #4 for water
2. Sodium hypochlorite (5.25-6.15%, also known as household bleach)
3. Purified water
4. Enzol® Enzymatic Detergent
5. Revital-Ox™ RESERT® HLD
6. Disposable disinfection wipes containing 0.2-0.4% benzalkonium chloride active ingredient (e.g., Clorox® disinfection wipes or equivalent product)
7. Lint free cloth

8. Probe storage cover + probe cover label

NOTE

Please do not use other materials for this procedure.

[N-51]

C.3. HLD Procedure

WARNING

HLD procedure must be performed using clean applicable **personal protective equipment**, according to the cleaning and disinfection materials' manufacturer instructions and the medical facility policy.

[W-40]

C.3.1 Cleaning and Disinfection Cart Preparation

NOTE

It is recommended to perform this step prior to treatment ending, to allow for the immediate probe cleaning and disinfection, when treatment ends.

[N-52]

1. Verify that the cleaning and disinfection cart is stable and that the four (4) containers are **intact** and are situated and **leveled** inside the cart openings, now and after each removal of the containers from cart.
2. **Remove (open)** both the **wide** and the **narrow** container caps.
3. **Completely** fill the four (4) cart containers with Sodium hypochlorite (5.25-6.15% household bleach), diluted approximately 1:100 with **potable water** (e.g., **25 cc** of Sodium hypochlorite for **2.5 liters** of water or **40 cc** of Sodium hypochlorite for **4 liters** of water).
4. Wait **five (5) minutes** and then completely drain the containers.
5. Rinse the containers, **twice**, by filling them with potable water and then drain completely.
6. **Fill** the containers **up to their lower marker**, according to the following instructions:

a. Fill container #1 (“cleaning solution”) with **20 ml of Enzol®** enzymatic detergent and **then** add approximately **2.5 liters** (85 oz) of **purified water**. Gently shake the container to mix the solution.

b. Fill container #3 (“disinfectant”) with approximately **2.5 liters** (85 oz) of **Revital-Ox™**.

c. Fill containers #2 and #4 with **purified water**, approximately **4 liters** (135 oz) in each.

C.3.2 Post-Treatment Procedure

1. Remove **disposable shell** from the probe - pull its balloon “dress” over the inflated part to expose the locking pin. **Release** the **pin** by firmly pulling its nylon cord, and then pull the disposable shell assembly from the probe. Remove **white O-ring** from the probe as well.
2. Dispose all **single-use** items according to the policies of the medical facility.
3. Place the cleaning and disinfection cart adjacent to the Exablate table and **attach (screw)** the **water fitting connector** (previously connected to the water pouch) to the **connector** in the back of the cleaning and disinfection cart.

C.3.3 Probe Cleaning

WARNING

The transducer surface is **very delicate**. Clean and handle it very gently during the procedure (e.g., when wiping the probe) and avoid any contact with sharp objects.

[W-41]

1. Press “**Clean**” on the Exablate table **water system display** (“display”) and choose “**HLD**”.
2. Press “**Next**” on the display (if the cleaning cart preparation, described above, was completed).
3. Verify that the table **water fitting connector** is properly attached to the connector at the back of the **cleaning and disinfection cart** and press “**Next**” on the display.
4. Use **two (2) disinfection** wipes (consecutively) to carefully wipe the probe for **two (2) minutes**, then press “**Next**”.
    a. If necessary, press “**Back**” on the display to go to previous screen.
5. **Lock** probe’s shell and soak the probe in the cleaning solution by inserting it into **container #1** (“cleaning solution”) for **six (6) minutes**, then press “**Next**”.
6. Remove the probe from container #1, **wait** until it stops dripping, and soak it in **water** by inserting it into **container #2** (“water”) for **three (3) minutes**, and then press “**Next**”.

7. Remove probe from container #2 and dry it entirely with a **lint free** cloth for **two (2) minutes**, and then press "**Next**".
8. Visually **inspect** the probe for visible soil/residues and press "**Next**".
    a. If soil/residues are found - repeat probe cleaning by pressing "**Repeat**" on the display.
    b. If other visible signs of deterioration such as corrosion, discoloration, pitting, or cracks are noticed, contact Technical Support.

C.3.4 Probe Disinfection

1. Use **two (2) disinfection** wipes (consecutively) to carefully wipe the probe for **two (2) minutes**, and then press "**Next**".
2. Dry the entire probe with a **lint-free** cloth for **two (2) minutes** (if necessary, continue until visually dry), and then press "**Next**".
3. Verify that the **white tray** of the cart is placed over **container #4**.
4. Connect the **water hose** (on the cleaning and disinfection cart) to **container #3** ("disinfectant"), as shown on display, and then press "**Next**".
5. Soak the probe in **Revital-Ox™** by inserting it into **container #3** ("disinfectant").
    a. **Verify that the probe and the water hose are properly connected to container #3.**
6. Press "**Start**" to begin **circulation** and wait for system to finish.
    a. The system will circulate automatically for **one (1) minute**.
    b. If necessary, press "**Stop**" to stop circulation (to resume press **"Start"** again).
7. When requested, confirm that the liquid level in container #3 is **up to its upper marker**. Add **disinfectant** if needed.
    a. To **quit** HLD, press "**Home**" and confirm pop-up message to return to "Home" screen.
8. Press "**Start**" to begin **circulation** and wait for system to finish.
    a. The system will circulate automatically for **approximately thirteen (13) minutes**.
    b. If necessary, press "**Pause**" to pause circulation.
    c. When circulation is **paused**, it is possible to do one of the following:
        i. Resume circulation by pressing "**Start**".
        ii. Return to previous screen by pressing "**Back**".
        iii. Go back to "**Home**" screen by pressing "**Home**" and confirming the pop-up message.

NOTE

If the temperature of the water in the system is below threshold, the system will first go through a warming stage ("Warming" will appear on top of the display), and only when completed, will the system **automatically** move to circulation.

[N-53]

C.3.5 Probe Rinsing

1. After probe disinfection is successfully completed, **carefully** disconnect **both** the **water hose** and the **probe** from container #3 and **wait** until the **probe** stops dripping.
2. Move the **white tray** of the cart over **container #3** and then connect **both** the **water hose** and the **probe** to **container #4** ("water").
    a. To **quit** HLD, press "**Home**" and confirm pop-up message to return to "Home" screen.
    b. **Verify that the probe and the water hose are properly connected to container #4.**
3. Press "**Start**" to begin **circulation** and wait for system to finish.
    a. The system will circulate automatically for **two and a half (2.5) minutes**.
    b. If necessary, press "**Pause**" to pause circulation.
    c. When circulation is **paused**, it is possible to do one of the following:
        i. Resume circulation by pressing "**Start**".
        ii. Go back to "Home" screen by pressing "**Home**" and confirming the pop-up message.

C.3.6 Post-HLD

1. After probe rinsing is completed, disconnect **both** the **water hose** and the **probe** from container #4, then press "**Next**".
2. Dry the entire probe with **three (3) lint-free** cloth for **three (3) minutes**, and then press "**Next**".
3. Cover the probe with **probe storage cover** and **secure** with the **cover label**.
4. Then, put the **mechanical protective cover** (P/N MEC501226) over the transducer (probe tip) and press "**Next**".
5. **Disconnect** the Exablate table **water fitting connector** from the **connector** in the back of the cleaning and disinfection cart.
6. **Dispose** of the cleaning and disinfection materials (contents of the 4 containers) according to the respective manufacturer instructions and the medical facility policy.

7. **Completely** fill the four (4) containers with Sodium hypochlorite (5.25-6.15%) diluted approximately 1:100 with **potable water** (e.g., **25 cc** of Sodium hypochlorite for **2.5 liters** of water or **40 cc** of Sodium hypochlorite for **4 liters** of water).
8. Wait for **five (5) minutes** and then completely drain the containers.
9. Rinse the containers, **twice**, by filling them with potable water and then drain completely.
10. Dry all the containers and caps with a **lint-free** cloth.
11. Allow the containers and caps to **air-dry** before storing them.
12. Press "**Finish**" on the display and confirm pop-up message to finish and exit HLD procedure.
13. If HLD procedure is completed **successfully**, an approval message will appear on display.
    a. Press "**OK**" to return to "Home" screen.
14. If the HLD procedure was **not completed successfully**, a warning message will appear on the display.
    a. Press "**OK**" to return to "Home" screen.
15. Continue to system shutdown, as described in Operator's Manual, or to probe and table preparation for treatment (**only if HLD completed successfully**).

WARNING

If HLD procedure failed to be completed successfully – do not treat patients and contact technical support at TechSupp@insightec.com, or by calling your local service/applications team!

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WARNING

After the issue is resolved by Technical Support, perform full HLD procedure successfully, before treating any patient.

[W-43]

WARNING

After six (6) months, contact Technical Support for maintenance.

[W-44]