Sonablate®

User Manual

Sonablate may only be used by physicians who successfully complete a SonaCare Medical Training Program.
Manufacturer

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Fax: 1-317-755-1352
E-mail: service@sonacaremedical.com

Europe – Authorized Representative

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: (+31) 70-345-8570
Fax: (+31) 70-346-7299

The CE Mark is only applicable to systems rated 230-240 Volts.

MEDICAL – ULTRASOUND EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS
ONLY IN ACCORDANCE WITH:

CAN/CSA C22.2 No. 60601-1(2008)
IEC60601-2-37(2007)

CONFIDENTIAL
This manual contains proprietary information of SonaCare Medical, LLC and it shall not be disclosed to a third party or reproduced in any form.

CO-202 Sonablate User Manual 3GV6, English with Sonablate Software V6 for Windows 7
Revision 1.0 as of 17-Dec-15
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CHAPTER 1: INTRODUCTION

Preface

Sonablate® (Sonablate) User Manual contains detailed instructions on how to use Sonablate, which is designed to ablate prostatic tissue using ultrasound energy. Sonablate is manufactured by Focus Surgery, Inc. (Focus Surgery), a wholly owned subsidiary of SonaCare Medical, LLC. (SonaCare Medical).

Indication for Use: The Sonablate is indicated for the transrectal high intensity focused ultrasound (HIFU) ablation of prostatic tissue.

Manual Overview

This manual provides Sonablate users with a basic understanding of the technology and functioning of the system, including instructions to prepare, operate, and maintain the equipment and to maintain patient and operator safety. It is mandatory to participate in hands-on training for the safe operation and use of this device.

The Appendices provide supplemental information, including specifications about the system and accompanying accessories, device error messages, service contacts and locations.

The symbol below is attached to the primary Sonablate system components to notify the reader to consult the operating instructions for information needed for the proper use of the device. This User Manual is the primary instruction for use for Sonablate. The label is located on the console, probe, and Sonachill unit.

![Label: “Consult Instructions for Use”](image)

The symbol below is also included on several components advising the reader to consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.

![Label: “Caution”](image)
To safely and correctly use this device, and maintain its performance, the operator must understand fully the operation procedure of the equipment, its functions and maintenance. It is mandatory to read and understand the User Manual and fully comply with the safety instructions.

Note the following precautionary notices and definitions, which are found throughout the User Manual:

<table>
<thead>
<tr>
<th>Precautionary Notice</th>
<th>Meaning (Definition)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WARNING</strong></td>
<td>Any condition or action which, if not strictly observed, could result in direct danger, such as serious personal injury or possible death, or serious property damage, such as total loss of equipment or fire.</td>
</tr>
<tr>
<td><strong>CAUTION</strong></td>
<td>Indicates any condition or action which, if not strictly observed, could result in possible danger such as partial equipment damage or data loss.</td>
</tr>
<tr>
<td><strong>NOTICE</strong></td>
<td>Some declarative statements are of significant importance and are shown with an icon to add emphasis.</td>
</tr>
</tbody>
</table>

**NOTICE**
Federal (USA) law restricts this device to sale by or on the order of a physician.

**WARNING**
Do not use it in the presence uncontrolled or excessive levels of an explosive gas, flammable liquids, or flammable anesthetic agents.
CAUTION

Do not block the openings for air ventilation located on the side and rear covers or equipment failure might result due to overheating.

During operation of the system, maintain a free space of at least 10 cm on all sides of the console.

Trademarks and Patents

Sonablate® (Sonablate) is a trademark and patent protected medical device manufactured by Focus Surgery and operating under proprietary software. The purchase or use of Sonablate allows the owner or user a limited-use software license to use the software packages solely for the operation of Sonablate. No other rights, ownership, or exclusivity in the use of any of these software packages are conveyed in the purchase or use of Sonablate.

There are several SonaCare Medical trademarks, both registered and pending registration, as well as other trademarks used in this document. Unregistered use of SonaCare Medical trademarks may result in penalties or suspension of the license to use Sonablate and software. CHEMets, Co-routine for Java, Java, Snag-It and Windows are not trademarks of SonaCare Medical.

Registered Trademarks

<table>
<thead>
<tr>
<th>Trademark</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIM® (Reflectivity Index Measurement)</td>
<td>SonaCare Medical, LLC; Focus Surgery, Inc.</td>
</tr>
<tr>
<td>Sonablate®</td>
<td>SonaCare Medical, LLC; Focus Surgery, Inc.</td>
</tr>
<tr>
<td>Sonachill™</td>
<td>SonaCare Medical, LLC; Focus Surgery, Inc.</td>
</tr>
<tr>
<td>TCM®</td>
<td>SonaCare Medical, LLC; Focus Surgery, Inc.</td>
</tr>
<tr>
<td>Sonasource®</td>
<td>SonaCare Medical, LLC; Focus Surgery, Inc.</td>
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U.S. Patent Listing

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<td>5,066,761</td>
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International Patent Listing

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<th>Patent Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>WO9316641</td>
<td>AU9337279</td>
</tr>
<tr>
<td>719,871 Australia</td>
<td></td>
</tr>
</tbody>
</table>
Warranty Information

SonaCare Medical warrants that under normal use and service in accordance with this User Manual, the equipment shall, at the time of installation and for a period equal to one (1) year after installation (Warranty Term), be free from defects in material or workmanship (Limited Warranty).

If during the Warranty Term you submit a valid Limited Warranty claim to SonaCare Medical, SonaCare Medical will, at its option, repair or replace the non-conforming equipment or parts. Replacement parts may be new or reconditioned.

All equipment and parts that are replaced will become the property of SonaCare Medical. Any repaired or replaced equipment or part will be covered by the Limited Warranty only for the remainder of the original Warranty Term, unless otherwise specified in writing by SonaCare Medical.

All other warranties are hereby explicitly disclaimed by SonaCare Medical. THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ANY WARRANTY OF NON-INFRINGEMENT. IN NO EVENT SHALL SONACARE MEDICAL AND ITS AFFILIATES BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES AND CUSTOMER’S REMEDIES SHALL BE LIMITED TO REPAIR OR REPLACEMENT OF NONCONFORMING EQUIPMENT OR PARTS.

This Limited Warranty does not apply if: (a) the equipment has not been used in accordance with this User Manual (or other applicable manufacturer’s instructions, documentation or labeling) and the approval(s) granted by the applicable governmental or regulatory agencies, and in compliance with applicable laws and regulations; (b) the equipment has been subjected to tampering, misuse, abnormal conditions, unusual stress, power failure, environmental or stress testing, conditions exceeding design tolerance, or negligent handling, storage or operation; (c) the equipment has been serviced by anyone who is not an Authorized Service Provider and/or replacement parts have been used that were not manufactured or certified by SonaCare Medical; or (d) there has been unauthorized alteration of or modification to the equipment or use of the equipment in combination with any software or other materials not specified, furnished or approved in writing by SonaCare Medical.

SonaCare Medical shall not be responsible for any loss of software, firmware, information or memory data of customer contained in, stored on or integrated with any equipment or parts repaired or replaced by SonaCare Medical under warranty or not.

SonaCare Medical aims for the use of Sonablate to be successful and trouble-free throughout the useful life of the system. However, periodic repairs may need to be made and periodic maintenance will need to be performed, both by an Authorized Service Provider of the
manufacturer or distributor. Due to the complex nature of the system and the importance of safety to patients and users, all service work must be performed by an Authorized Service Representative. Contact information for these Authorized Service Providers is available from SonaCare Medical and on the website.

When disposal of the equipment or parts is required, the electrical or electronic components of the equipment must not be disposed into the municipal waste. This equipment must be recycled or discarded according to applicable local and national regulations. The WEEE label is located on the console, probe, and Sonachill unit.

Figure 3. Label: Waste Electrical and Electronic Equipment Directive (WEEE Directive)
Sonablate is a medical device which uses high intensity focused ultrasound (HIFU) energy to cause thermal coagulative necrosis in the selected region of tissue at a specific distance from a focused transducer element(s).

A unique feature of Sonablate is the transrectal ultrasound scanning and ablation design of the single ultrasound transducer capable of performing both imaging and ablation. This dual-function piezoelectric transducer, housed in a transrectal probe, allows accurate placement of the ablation focus and real-time imaging during ablation that are updated after every ablation cycle.

**Technology Principles**

As surgical tools, both HIFU and lasers achieve their effect by focusing specific frequencies of energy to create heat, leading to a variety of tissue effects. Focusing a laser is accomplished at the source of transmission using coherent beams comprised of extremely short wavelengths ($\lambda$) between approximately $4-10 \times 10^{-7}$ m.

In the field of acoustics, focusing occurs at a point where multiple beams converge; the useful wavelength $\lambda$ is typically $1-15 \times 10^{-4}$ m. In acoustics, the term frequency (F, in Hz), which is inversely related to wavelength by the formula $F = c/\lambda$, is used and the applicable range for focused ultrasound is 1-10 MHz (c is the speed of sound in tissue). The effect on tissue itself is both a function of the frequency (or wavelength) and, more importantly, the intensity (I, in Watts/cm$^2$) of the applied energy. Energy intensity is controlled by the input or excitation voltage and the duration of the energy pulse. Given the ability to achieve comparable energy intensity, most of the primary effects of lasers (cutting, burning, vaporizing, coagulating, ablating, heating, photo activation) can be accomplished similarly with focused ultrasound.

Focused ultrasound, however, has a distinct advantage over laser energy sources: it can travel through and be focused within media that are predominantly aqueous, including tissue. Therefore, the tissue in the region where sound waves converge (focal region) can be subjected to significantly higher energy levels than the intervening tissue. Using focused ultrasound can spare intervening tissue that would be otherwise destroyed by direct contact with laser light. Deep tissue effects, such as heating, ablating and photo-activation are therefore particularly suited to focused ultrasound.

The ability to focus ultrasound within tissue is subject to a number of constraints, the most dramatic being the loss of energy (attenuation) as the sound waves travel through various tissues. For this reason, the energy which is delivered at the ablation focus (site intensity) will be lower than the energy emitted by the HIFU transducer (free-field intensity).
The significant variables that determine the relationship between the site and free-field intensity are the ultrasound frequency, the attenuation coefficient of the intervening tissue and the tissue depth. The relationship among these variables can be described mathematically as:

$$I = I_0 T_i e^{-(\alpha F l)}$$

where $I$ is the focal site intensity (W/cm$^2$), $I_0$ is the free-field intensity (W/cm$^2$), $\alpha$ is the intensity attenuation coefficient (Np/MHz/cm), $F$ is the ultrasound frequency (MHz), $l$ is the tissue depth (cm) and $T_i$ is the transducer index that handles the focusing effect of the transducer. Obviously, different tissue types and tissue depths, which affect the attenuation, are critical to the delivery of appropriate intensity levels at the targeted tissue.

Hyperthermia is a form of tissue heating that previously has received the greatest attention in urology. During hyperthermia procedures, for example, broadly focused microwave energy of low intensity is used to raise the temperature of several cubic centimeters of tissue to the range of 42-45° C over an extended period of five to 60 minutes. The theory assumes that raising tissue temperatures slightly above the threshold for viable prostatic tissue will destroy sufficient tissue to affect a decrease in overall gland volume. In attempting to gradually raise the temperature of large volumes of tissue, it has proven difficult to heat the required region without causing temperature elevations to surrounding tissue.

In contrast, Sonablate destroys prostatic tissue using ultrasound ablation. As opposed to hyperthermia, the strategy for ultrasonic ablation is to focus high intensity ultrasonic energy on a very small volume of tissue (few cubic millimeters) for short bursts of time (three seconds). Since the targeted tissue volume is small, conduction and perfusion provide rapid cooling of surrounding tissue, while the targeted region is necrosed instantaneously.

Extensive research has been conducted to determine the appropriate energy intensity required to create small focal lesions in the prostate and appropriate duty cycle to ensure sufficient cooling of surrounding tissue. Overlapping of the split-beam HIFU focal lesions, in both linear and lateral directions, results in a volume lesion of several cubic centimeters.

**System Overview**

The Sonablate system consists of:

- Sonasource Console – the main chassis of the system
- Probe – two transrectal probes supplied per console
- Probe Arm – for probe support and positioning
- Multi-axis Stepper (stepper) – for probe support and positioning
- Sonachill (pump/chiller) – for circulating and cooling water
- Disposable/reusable accessories
Sonablate® Probe High Frequency 30/40

Sonablate® Probe High Frequency 30/40 (Probe) is an applied part, intended for contact with the patient.

The probe provides for independent imaging and ablation at two different focal lengths (3 cm and 4 cm). The probe is capable of:

- Ultrasonically imaging the prostate gland in the transverse and sagittal (longitudinal) planes.
- HIFU ablation of the prostate according to the on-screen planned ablation zone in the transverse and sagittal (longitudinal) planes.

(Refer to Probe Specifications for more information)
CHAPTER 3: SAFETY AND GENERAL INFORMATION

The following are guidelines for the safe use and operation of Sonablate. The system is to be used under direct supervision of a trained physician and only for the specified indication.

General Safety

Sonablate contains no user-serviceable parts. Any repair that may be needed must be performed by authorized service personnel only.

Unauthorized changes, modifications or upgrades to any part of Sonablate could have hazardous consequences. Changes or modifications must not be made unless specifically authorized by the manufacturer and completed by authorized service personnel.

WARNING

Do not change or modify any part of Sonablate without authorization of the manufacturer.

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Electrical Safety

The use of improper types of fire extinguishers presents electrical shock and burn hazards. To avoid this danger, a fire extinguisher specifically rated for electrical fires should be available in all rooms where electronic medical devices are used.

The medical center’s administration is responsible for developing an effective emergency procedure in the event of fire. Such a program should provide emergency evacuation procedures, training in the proper use of fire extinguishers and directions for the notification of firefighting personnel.

WARNING

In case of fire in the unit, use fire extinguishers specifically rated for electrical fires.

Failure to comply may result in serious injury or death.

M384

The system contains high voltage power supplies which are capable of inflicting serious injury or death from electric shock. To avoid this hazard, operators must never remove the cabinet
covers. Under no circumstances should persons other than Authorized Service Personnel undertake the installation, maintenance or repair of the system.

Power can be interrupted by overloads that blow fuses or trip circuit breakers or loss of power at the service outlet. Should a loss of power occur, disconnect the main power cord until power is restored. If a fuse is blown repeatedly or a circuit breaker trips after being reset, it may indicate an equipment malfunction. Do not attempt to operate the system until the unit has been inspected by an Authorized Service Representative.

Many medical center circuits are monitored by ground fault alarms, which are intended to warn of current leakage that may damage sensitive medical equipment or allow conditions hazardous to patient health. Should a ground fault alarm into which the system is connected activate, immediately terminate ablation by pressing the emergency stop button, disconnect the main power cord and do not attempt to operate the unit until the cause of alarm activation has been identified and corrected. Depending upon the type of electrical fault, the system may present electrical shock or fire hazard. Operation should not be attempted until the faulty circuit has been repaired.

Food or beverages should not be placed on the system or in its immediate vicinity. Fluids that inadvertently come into contact with electrical components may cause damage to the system or present electrical safety hazards.

The USB port for the computer, which is installed on the rear of some consoles, is intended only for passive devices, such as storage flash or jump drives or a wireless dongle for an external mouse.

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not plug an externally powered device, such as a printer or scanner, in the USB port. Exceptions may be made only with manufacturer approval for devices with proven compliance to IEC 60601-1.</td>
</tr>
</tbody>
</table>

EMC Statement, Guidance, and Essential Performance

Sonablate system has been designed and tested to comply with the 3rd edition of IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance. Included are the electromagnetic compatibility (EMC) requirements as defined by IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.
NOTICE

The primary functions of Sonablate are HIFU delivery, ultrasound imaging, and ablation planning. The following are essential performance of Sonablate:

- An updated image during the ablation duty cycle is accurately paired and displayed with the image used for planning. The Doctor monitors the updated images for the effects of HIFU, for movement and rectal wall distance, and for changes in reflectivity caused by various factors. An accurate pairing of updated images during ablation is essential for the Doctor to effectively monitor the ablation progress and conduct ablation planning.

- During HIFU delivery, the focal site acoustic intensity, depth, and duration of the HIFU is created as intended. This function is a product of the fixed transducer design driven by the system's hardware and software and is essential for HIFU delivery.

- During HIFU delivery, it is essential that the lesion is placed at the intended location as planned. Motion control of the transducer is a functional design of the system hardware and software.

- For the ultrasound image that is displayed without obvious obstruction, it is essential to be accurate and that the physical anatomy is distinguishable by the physician. This function is a product of the fixed transducer design driven by the system hardware and software.

- During HIFU delivery, the intended volume of ablation is created. This function is a product of the fixed transducer design driven by the system hardware and software and is essential for HIFU delivery.
CAUTION

Sonablate needs to be installed and put into service according to the EMC information in the following tables:

- Guidance and manufacturer’s declaration – electromagnetic emissions
- Guidance and manufacturer’s declaration – electromagnetic immunity
- Recommended separation distances between portable and mobile RF communications equipment and Sonablate

M379

CAUTION

Portable and mobile RF communications equipment can affect Sonablate.

M380

CAUTION

The use of accessories, probes, and cables other than those specified, with the exception of probes and cables sold by the manufacturer of Sonablate as replacement parts, may result in increased emissions or decreased immunity of Sonablate.

M381

List of Cables and Accessories

<table>
<thead>
<tr>
<th>Item</th>
<th>Length</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC Main Power Cord</td>
<td>3.0m</td>
<td>Unshielded 3-conductor</td>
</tr>
<tr>
<td>Probe Cable</td>
<td>2.8m</td>
<td>Shielded, multi-conductor</td>
</tr>
<tr>
<td>Sonachill Cable</td>
<td>1.8m</td>
<td>Shielded 7-conductor</td>
</tr>
</tbody>
</table>

CAUTION

Sonablate should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, Sonablate should be observed to verify normal operation in which it will be used.

M382
## Guidance and manufacturer’s declaration – electromagnetic emissions

*Sonablate* is intended for use in the electromagnetic environment specified below. The customer or the user of *Sonablate* should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td><em>Sonablate</em> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td><em>Sonablate</em> is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

## Guidance and manufacturer’s declaration – electromagnetic immunity

*Sonablate* is intended for use in the electromagnetic environment specified below. The customer or the user of *Sonablate* should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>6 kV contact 8 kV air</td>
<td>6 kV contact 8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>2 kV for power supply lines 1 kV for input/output lines</td>
<td>2 kV for power supply lines 1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>1 kV differential mode 2 kV common mode</td>
<td>1 kV differential mode 2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5 % $U_T$ (&gt;95 % dip in $U_T$) for 0,5 cycle 40 % $U_T$ (60 % dip in $U_T$) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$) for 25 cycles &lt;5 % $U_T$ (&gt;95 % dip in $U_T$) for 5 sec</td>
<td>&lt;5 % $U_T$ (&gt;95 % dip in $U_T$) for 0,5 cycle 40 % $U_T$ (60 % dip in $U_T$) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$) for 25 cycles &lt;5 % $U_T$ (&gt;95 % dip in $U_T$) for 5 sec</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of <em>Sonablate</em> requires continued operation during power mains interruptions, it is recommended that <em>Sonablate</em> be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**NOTE** $U_T$ is the a.c. mains voltage prior to application of the test level.
Guidance and manufacturer’s declaration – electromagnetic immunity

*Sonablate* is intended for use in the electromagnetic environment specified below. The customer or the user of *Sonablate* should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 V</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
</tr>
</tbody>
</table>

Portable and mobile RF communications equipment should be used no closer to any part of *Sonablate*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:

\[
d = 1.2\sqrt{P}
\]

- 80 MHz to 800 MHz
- 800 MHz to 2.5 GHz

where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and \( d \) is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:

---

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

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

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

**b**  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Recommended separation distances between portable and mobile RF communications equipment and *Sonablate*

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>(d = 1.2\sqrt{P})</td>
<td>(d = 1.2\sqrt{P})</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.7</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \(d\) in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where \(P\) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

The Sonablate is a medical device and may only be operated by properly trained, qualified medical personnel who have obtained applicable credentials as may be required by regional or federal authorities.

Under no circumstances may any person other than authorized service personnel make any modifications to either the system hardware or software. Each of the system safety circuits has been specifically designed to minimize potential hazardous situations; these must never be bypassed, altered, or disabled.

The manufacturer and distributor assume no responsibility or liability for personal injury or property damage resulting from misuse of the systems.

Cybersecurity User Responsibilities

Cybersecurity is the process of preventing unauthorized access, modification, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient.

A local administrator, or service provider, is a user who is authorized by the owner (and, therefore, trusted) to perform security relevant functions that ordinary users are not authorized to perform.

The Sonablate system incorporates a Windows 7 computer which could be susceptible to unauthorized access and requires the local administrator to follow the suggested guidelines.

a) Sonablate login password should be customized as necessary to meet all applicable local IT policies, and shared with authorized users only. The local administrator should implement policies to change password on regular intervals.

b) The Sonablate system does not require to be connected to the local network for its intended use.
c) The Sonablate system is verified at the factory to assure virus/malware are not present. The local administrator should implement policies for periodic scan of the entire system.

d) USB flash drive or CD/DVD should be independently authorized (i.e., verified to ascertain that the media is free of virus/malware) by the local administrator prior to using it on the Sonablate system.

As periodic updates for Sonablate software, Windows software, and other software components and configuration on the system become available, the local administrator should evaluate these against the site’s needs and determine whether the update is suitable and/or applicable to their usage. The local administrator should only use update/installation materials from the manufacturer as provided by the manufacturer or a representative service provider.

**Operator Training**

Familiarity with diagnostic transrectal ultrasound imaging is imperative for the safe use of the device. Potential Sonablate physicians are expected to attend a SonaCare Medical training course that contains education on the technology, the HIFU procedure, and patient care.

The physician will undergo the next level of training, which includes HIFU simulator training and the completion of cases with a SonaCare trained technician onsite. Subsequent cases conducted independently by the trained physician may be monitored remotely by a SonaCare trained technician for supplemental guidance if the Sonalink feature is installed. Refer to Appendix E: Sonalink.

**Indication for Use**

The Sonablate is indicated for the transrectal high intensity focused ultrasound (HIFU) ablation of prostatic tissue.

**Contraindications**

- Presence of significant (>10mm) fluid-filled cavities (for example, cysts), large reflective surfaces (for example, significant calcifications >10mm, urethral stent) observed in the planned ablation zone. Varying attenuation among these tissues may cause an unpredictable size of lesion.
- Metal implants or stents in the urethra, within the area to be ablated
- Presence of brachytherapy seeds adjacent to the posterior prostate capsule, the Denovilliers’ fascia, or the rectal wall
- Preexisting inflammatory disease of the colon or rectum; including proctitis, ulcerative colitis.
- Prior significant rectal surgery
- Inability to insert or tolerate a transrectal ultrasound probe
- Active urinary tract infection
- Urethral stricture
- Latex allergy. Note: Ablation with Sonablate requires that the transrectal probe be covered with a sheath prior to insertion, and the sheath provided for use is made from natural rubber latex. For those patients who are allergic to latex, a non-latex ultrasound probe sheath is available as an option; please contact your distributor or SonaCare Medical.

**Warnings**

The effectiveness of the Sonablate in treating any specific prostate disease has not been established. The safety and effectiveness of Sonablate HIFU has not been established in patients with the following conditions:

- Interest in future fertility
- Bleeding disorder
- Clinical or histological evidence of urinary bladder cancer
- Renal impairment
- Functional bladder problems, including neurological disorders that might affect bladder function
- Post-void residual urine greater than 250ml
- Urinary retention requiring an indwelling catheter
- Enlarged median lobe of the prostate protruding into the urinary bladder
- Clinical evidence of prostatitis within six months prior to HIFU
- Bladder calculus
- Prostate > 40 cm³

- For patients who have previously received radiation to the pelvic region, follow the recommended values of the total acoustic power (TAP) levels for the rectal wall distance listed in the HIFU power table (Chapter 10, Table 1). Patients who have previously received radiation to the pelvic region have reduced vascularity and thus reduced ability to actively cool the prostate. In addition, the rectal wall could be damaged from the effects of radiation.

- Grounding reliability can be achieved only when connected to an equivalent receptacle marked as “hospital grade.” Use of prescribed power source will ascertain proper functioning of the entire system and operator safety.
Precautions

- Sonablate is not capable of ablating anterior prostate tissue > 4 cm from the transducer (due to physical limitations of the device).
- The Sonablate is designed as an acoustic ablation device and its ultrasound imaging is intended for precise ablation planning and monitoring. The device may not be used as a diagnostic imaging device.
- Do not use the probe if the probe has been dropped or shows evidence of physical damage. Doing so may result in further damage to the probe or inadequate performance due to potential damage to the internal components of the probe.
- Use only degassed water with oxygen content ≤ 3 ppm. It is essential to maintain the oxygen content below the prescribed level to prevent damage to the Ultrasound transducer and/or interference during imaging with the probe.
- Use appropriate ultrasound coupling gel to cover the sheath. Ultrasound gel is used to ascertain adequate coupling between the probe sheath and rectal wall. Inadequate coupling will result in imaging artifacts.
- Monitor the real-time updated image on the screen and watch for evidence of cavitation, patient movement, or sheath sagging which could realign the planned ablation zone.
- Ensure that the appropriate focal length transducer is being used so the appropriate ablation depth is achieved.
- Deflate sheath of excess water before removing the probe from the patient’s rectum. The probe sheath could potentially tear if not sufficiently deflated before removing the probe from the rectal cavity.
- Do not turn on HIFU ablation if the transducer is not surrounded by water. Doing so may permanently damage the transducer.
• It is recommended that probe rotation be minimized when the sheath is pressurized in order to prevent unnecessary rectal wall pressure which could potentially tear the sheath. Ensure that the transducer is in the midline position prior to inserting the probe into the patient’s rectum. Before removing the probe from the patient’s rectum, disconnect the probe from the console, which will free the transducer and help prevent rectal wall injury during probe removal.

**Adverse Effects**

The following adverse effects have been associated to varying degrees with prostate ablation using the Sonablate device. Find additional details in the Physician Instruction section of this manual, which focuses on the actual HIFU procedure, including pre- and post-care.

• Urinary Retention
• Proteinuria
• Hematospermia
• Hematuria
• Retrograde Ejaculation
• Urinary Tract Infection
• Rectal Wall Injury (thermal)
• Impotence/Sexual Dysfunction
• Dysuria
• Pain and Discomfort
• Incontinence
• Osteomyelitis
• Urethral stricture/bladder neck contracture
Operation of the Console

CAUTION

Do not block the fans located at the back of the console. Air must circulate through the unit during use for proper cooling of electronic components.

Before initial use, the main power cord must be attached and secured to the main appliance inlet and remain attached for operation. Refer to Appendix C for the AC Power On/Off Sequence and instructions.

The circuit breaker located on the back panel of the console acts as the main power disconnect and controls power to all high energy assemblies in the unit. In an emergency situation, toggle the circuit breaker to the off position or disconnect the main power cord from the console.

If the system does not operate properly or fails to respond, the operator should record the type of problem, specific circumstances under which it occurred, and any system error messages before attempting to restart the system. If the system continues to fail, the power must be turned off, the main power cord disconnected and Authorized Service Personnel contacted.

The system operator must be aware of the presence or the uncontrolled release of flammable anesthetics, or other flammable or explosive liquids, vapors, or gases and avoid a situation in which an unsafe concentration of a flammable substance is reached. If ignored, these substances may be ignited by electrical arcs that can occur during the normal operation of switches, circuit breakers or other system components. If unsafe concentrations of flammable substances are detected in the room, the power cord should not be connected and the system should not be turned on. Should unsafe concentrations of flammable substances be detected while the system is operating, do not disconnect the power. Stop the ablation by selecting the PAUSE button in the lower right hand portion of the screen and then remove the probe. Evacuate all persons immediately. Ventilate the room to clear the air of the flammable substance. Remove any liquids which are producing flammable vapors to a safe storage area.
WARNING

Do not operate the unit in the presence of uncontrolled or excessive concentrations of flammable or explosive liquids or gases.

Use of the Transrectal Probe

It is recommended to keep the ambient temperature in the procedure room at or below 23°C while using the system to allow the most efficient chilling of the water path circuit.

The probe should be visually inspected prior to use in order to prevent the use of a probe which contains cracks or other defects. If any defects are observed, the probe should not be used and should be returned to the service center for repair.

The probe is constructed of delicate components that may be damaged if dropped. Therefore, the probe should be considered unsafe under these circumstances. If connected, the probe must be disconnected from the system immediately. Any probe which has been dropped should be returned to the service center for inspection and repair.

The probe must only be operated in ablation mode with the transducer immersed in degassed water or after water has been introduced into the sheath for ablation. Firing the transducer in a non-aqueous environment will cause delamination of the transducer and may permanently damage the transducer.

CAUTION

Firing HIFU when the transducer element is not surrounded with degassed water will damage the transducer.

The sheath should be inflated to raise the level of rectal wall mucosa near the solid GREEN line shown on the imaging screen (in both transverse and longitudinal images) for ablation. The GREEN line is 1.0 cm from the transducer surface when the transducer is in the neutral position. (Figure 7)

A rectal wall distance of an additional 0.25 cm beyond the solid GREEN line (1.25 cm from transducer) is required before the transducer can safely be flipped. A RED marker (Figure 8) shown on the screen longitudinal images turns GREEN (Figure 9) when the rectal wall distance is at least 1.25 cm away from the transducer.
It is essential that the operator of *Sonablate* monitor the volume of water introduced into the probe tip and assure that the water is evacuated prior to removal of the probe from the patient’s rectum. Injury to the rectal wall or the rectal sphincter may occur if the probe is removed or rotated while pressurized.

The probe is designed to perform acoustic ablation of the prostate; its ultrasound imaging functions are intended solely for ablation planning and monitoring of the prostate.

The condom/sheath has been evaluated for its ability to transmit ultrasound for imaging and ablation. Only use the approved condom/sheath provided.

While the choice of anesthetic agent is up to each physician, it is important that the patient be sufficiently anesthetized and restrained to prevent any movement during the procedure.

---

**CAUTION**

The patient should be adequately anesthetized prior to initiation of HIFU ablation to ensure no discomfort or pain during the procedure. This will also help to maintain complete immobilization of the patient.
Cleaning

**CAUTION**

The entire Sonablate probe should not be submerged under water as water leakage into the body of the probe or cable connector will damage probe parts.

After each patient procedure and before disinfecting the probe, treat the sheath, gloves, and any waste materials as infectious.

Dispose of the waste material in accordance with infectious waste control procedures of the facility.

Reference the Cleaning and Disinfection section of this manual Chapter 16 for additional information.

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After each patient procedure and before disinfecting the probe, treat the sheath, gloves, and any waste materials as infectious.

Dispose of the waste material in accordance with infectious waste control procedures of the facility.

Reference the Cleaning and Disinfection section of this manual Chapter 16 for additional information.

**CAUTION**

Gas sterilization other than the Ethylene Oxide sterilization cycle described in Chapter 16, ultraviolet sterilization, heat sterilization, autoclaving and chlorine bleach may damage the Sonablate probe.

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Transporting the Console

The console must always be on a flat surface when not transporting and during operation. Prior to moving the console into storage or packing for transport, the console must be placed in the transport position as described below.
Before moving the console:

- The console should be powered OFF and the probe, Sonachill unit, and main power cord disconnected. If applicable, any storage media connected to a USB port should also be disconnected.
- Stow the monitor/keyboard as described and as shown (Figure 13).
  - Strap the keyboard to the tray with the provided Velcro cinch strap (Figure 10)
  - For temporary storage, the mouse may be placed in the holster on the tray, else store the mouse with other system accessories
  - Lift the monitor arm pin to swivel arm facing the rear of the console. The pin will engage and lock in the transport position (Figure 11)
  - Rotate the upper portion of the monitor arm and tilt the monitor and keyboard tray backward. If needed, the tensioning set-screw may be adjusted. (Figure 12)
- Engage the levers of the front casters to the “swivel lock position” such that the wheels remain parallel to the sides of the console when rolling, see Figure 14.
- Engage the levers of the rear castors to the “free swivel position” such that the wheels may turn for steering. For details of the brake lever operation, see Figure 14.
- Use the handle located on the rear of the console to push and steer the console.
  - Avoid wet, uneven, or any other dangerous surfaces.
  - If a ramp is required during the move, the maximum elevation of the ramp must be less than 10 degrees from the flat surface. Sufficient clearance should be established before moving console on ramp to not damage transformer cage.
  - Do not push or lean against the monitor arm at any time.

---

**WARNING**

Failure to comply with these instructions may result in instability and the console may fall if tilted. This may result in serious injury or equipment damage.

Do not attach or rest unapproved objects onto the console.

---

**CAUTION**

Always engage all caster levers to the “brake position” when movement of the console is completed.

(See Figure 14 for details.)
Figure 10: Strap the keyboard to the tray with provided Velcro cinch strap.

Figure 11: Lift pin as shown to unlock swivel

Figure 12: Swivel arm facing the rear. The pin locks the arm in place.
Transporting the Sonachill Unit

As indicated on the label on the Sonachill stand, shown in Figure 15, the stand must not be extended in such a way that it may tip over while moving. Do not tilt more than 10 degrees. The knob may be loosened and locked as shown to extend or lower the Sonachill stand. Prior to
moving the Sonachill into storage or packing for transport, the Sonachill must be fully lowered and locked by the handle shown below.

![Figure 15. Label: Sonachill stand](image)

### CAUTION

Keep the Sonachill stand in the lowered position at all times.

Always engage all castor levers to the “brake position” when movement of the chiller is completed.

If a ramp is required during the move, the maximum elevation of the ramp must be less than 10 degrees from the flat surface.

The Sonachill unit must always be on a flat surface when not transporting and during operation.
Handling the Probe

- Keep the probe in the tray and case when not in use.

![Figure 16. Probe in Probe Tray](image)

- Secure the probe arm to the probe stepper or the table rail before inserting and securing the probe into the probe arm cuff.
- The probe must always be secured by the probe arm (for ablation) or by the verification tank (for testing) before the probe is connected to the console.
- Keep all objects clear of the transducer window to protect the transducer.
- The probe should be held or moved by the probe body while positioning in the probe arm cuff or verification tank. Do not move or hold the probe by the cable or the tip.

**WARNING**

The probe is not a hand-held device and must not be held during the ablation procedure except with the support of the articulated probe arm.

Handling the Articulated Probe Arm

- The central locking knob is used to free all five arm joints. Use caution when loosening the central locking knob as it frees all five arm joints **(Figure 17)**.
- Secure the probe arm to the stepper or the operating table rail before inserting the probe into the probe arm cuff. Make sure the lockout safety device is installed on the probe arm rail clamp while in use.
- When adjusting probe position, use one hand to support the probe and a second hand to loosen or tighten the main locking knob.
- Disconnect and remove the probe before removing the probe arm.
Handling the Stepper

- Note that only surgical tables with a dropping leg section with attached surgical rails can be used with the stepper assembly.
  - An adapter is available to mount the stepper onto tables without a dropping leg section with rails.
- Latch the stepper to the surgical table during procedure preparations.
- Cover the probe arm rail clamp with the lockout safety device while in use.
- The stepper cannot be adjusted during ablation. Ablation must be paused to make stepper adjustments.
- Remove the probe arm before removing the stepper from the surgical table.

Handling the Printer

- Stop operation immediately if any liquid falls into the printer cabinet.
- Do not disassemble the printer.
- Do not touch the cutting blade of the printer.
- Keep fingers clear of the paper lid assembly.
CHAPTER 4: SYSTEM COMPONENTS AND START-UP

This section describes the various components of the Sonablate system and the procedure for system power up. The Sonablate system consists of a console, a transrectal probe with 2 different focal lengths, an articulated probe arm, a stepper, and a Sonachill unit. A typical system includes a second probe as a spare.

Operator Console

- The mobile operator's console consists of a cabinet on castors, a flat panel LCD color monitor, a keyboard, USB, and front access to a printer.
- Before using Sonablate, the wheel-brakes on the console's four casters should be locked. Refer to Figure 14 in section “Transporting the Console” for instructions on locking and unlocking casters.

System Setup and Initialization

![Figure 18. Back view of console](image-url)
As shown in Figure 18 and indicated by the symbol shown in Figure 19, a post is provided on the bottom right corner of the console for the connection of a potential equalization conductor.

![Figure 19. Ground label (located on console)](image)

**CAUTION**

Do not block the openings for air ventilation located on the side and rear covers or equipment failure might result due to overheating.

During operation of the system, there should be a free space of at least 10 cm on all sides of the console.

Before attaching the main power cord to a power outlet, check the back of the console to assure that the circuit breaker which acts as the main disconnect (located next to the main appliance inlet) is in the OFF position. Also, verify that the Power On/Off Switch (at the top rear of the console) is in the OFF position.

Once the system has been connected to a power outlet, turn the Circuit Breaker switch to the ON position, and press the Power On/Off Switch to the ON position. The computer will automatically start and Microsoft Windows will initialize the Windows software. A window will appear as shown in Figure 20.

After booting up the system, a screen will display which may show one or more options for logging in. Select the appropriate software icon to reflect which type of probe is being used, and complete the login process, following the instructions on the screen.

After login, the screen will display a Microsoft Windows Desktop environment with the Sonablate shortcut icon as shown in Figure 21.

Using the keyboard touchpad or mouse, double click the icon to start the program. Once the software is launched, the software icon will be visible on the screen. (Figure 22)
A message box will appear as the program is being loaded by the computer (Figure 23).

**CAUTION**

The probe connector must be completely removed from the receptacle located on the operator's console before powering the console.

The probe cable should only be connected to the console while *Sonablate* program is running.
Automatic System Check

Sonablate software automatically brings up a Test Safety Circuits window as shown in Figure 24. The user will have to run the safety test each time the system is powered up. The first and the last step of the safety test are manual and the rest of the steps are automatic.
The various components of the safety circuit test are as follows:

![Image](STEP_1.png) **Figure 25. First Step**

Press the red emergency stop button. On pressing the emergency stop button, the corresponding box will turn green if the emergency stop button is functioning properly.

![Image](STEP_2.png) **Figure 26. First Step Passed**

Subsequently, the next two system checks will run automatically and the corresponding boxes will turn green if the test results are normal.

![Image](STEP_3.png) **Figure 27. Automatic Steps**

This is the last step of the system check and involves raising the emergency stop button by turning the button in the clockwise direction. On doing so the corresponding box turns green.

![Image](STEP_4.png) **Figure 28. Last Step Passed**

On passing all the safety tests the system safety test box appears as shown below in **Figure 29**.
Click on the hide button to hide the box. If any of the tests fail, service is required.

### CAUTION

If the automatic system check fails, service is required.

**Flat Panel Color Monitor and Monitor Arm**

The monitor/keyboard arm *(Figure 30)* holds a flat panel LCD color monitor with speakers and keyboard. The monitor arm can be adjusted to optimize visibility and keyboard ergonomics.

An illuminated button on the front of the monitor can be used to power on/off the display. Additional monitor buttons can be used to adjust the display with an on-screen menu. Examples of monitor button controls are shown. The buttons and the displayed menu allow for the adjustment of typical options such as Contrast, Brightness, Horizontal Position, Vertical position, Color, and Volume. *(Figure 31)*
Red Emergency Stop Button

The red button is an Emergency Stop button (Figure 32). When pressed, the ablation is paused and the Sonachill unit is turned OFF. Ablation can be resumed from where it was stopped. To resume ablation, clear the alert message and release the Red Emergency Stop button by turning it clockwise, go to the Tools drop-down menu chose Pump and Chiller Status, then turn Sonachill pump ON, return to the Treat a Zone screen and click the Start HIFU button and confirm start of HIFU ablation when prompted. New reference images should be taken and ablation plan reviewed.

<table>
<thead>
<tr>
<th>Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press Red Emergency Stop button to suspend ablation in an emergency situation.</td>
</tr>
</tbody>
</table>

Keyboard

The alphanumeric keypad has a standard computer keyboard layout with touchpad (Figure 33).

A touchpad is located on the keyboard to move the cursor on the screen to the desired location. A standard cordless mouse may also be utilized on the slide-out mouse pad.
Thermal Printer

The printer is a thermal digital graphic printer.

To turn on the printer, press the ON/OFF switch. The Power light turns on. The printer paper can be loaded by opening the paper lid with the OPEN button and placing the paper roll in the paper tray. Pull out the first 15-20cm of the paper to remove any slacks in the roll. Close the paper port lid. Use only Sony UPP-110 series paper for best results. While using the digital printer, to print the image on the screen, press the Print Screen button on the keyboard. Alternatively, to print the image on the screen, click on the printer icon at the bottom of the screen.

Probes

Sonablate probe consists of a probe tip, front housing, probe body, and a probe cable connector (Figure 34). Incorporated into each probe are two custom piezoelectric transducers of different focal lengths that have the capability to both image and deliver high-intensity focused ultrasound ablation pulses. The probes are specifically labeled according to the focal lengths of the transducers, which are expressed in centimeters. The probe tip, which houses the transducer, is 3.3cm in diameter (tapering to 1.8 cm at the neck) and incorporates the transducer window for ultrasound imaging/ablation and an O-ring recess to secure the sheath. The button tip accommodates an O-ring (O-ring recess) that seals the sheath at the tip of the probe (Figure 35).
The front housing connects the probe tip and probe body.

The probe body contains the electromechanical components for precise transducer movement and ultrasound imaging.

The ergonomic handgrip and textured surface provide a secure method for holding the probe during probe preparation and insertion into the patient. The water ports are used to recirculate water through the watertight probe tip.
**WARNING**

The entire *Sonablate* probe should not be submerged under water as water leakage into the body of the probe or cable connector will damage probe parts.

After each patient procedure and before disinfecting the probe, treat the sheath, gloves, and any waste materials as infectious.

Dispose of the waste material in accordance with infectious waste control procedures of the facility.

Reference the Cleaning and Disinfection section of this manual Chapter 16 for additional information.

---

The probe cable connector is a multi-pin connector that plugs into the interconnect board located on the side panel of the operator's console. The cable is secured in place with a twist lock located on the connector. Connect the probe to the console after *Sonablate* program has finished the Automatic System Check. To connect the probe, insert the connector in the receptacle and immediately engage the twist lock. In a similar manner, unlock and immediately remove the probe connector from the receptacle before exiting from *Sonablate* program. Never leave the probe connector inserted into the receptacle with the lock disengaged.

---

**CAUTION**

Never leave the probe cable inserted into the receptacle on the console with the lock disengaged.

---

**Transducer Movement**

The piezoelectric transducer incorporated in the probe tip is aligned with the open transducer window. Through this window the transducer is able to obtain gray-scale images of the prostate volume and to deliver HIFU ablation to user selected regions of tissue.

The transducer moves in two separate reciprocal motions to provide ultrasound images of the prostate in the sagittal (longitudinal) and transverse (sector) planes. The transducer is extended and retracted in a linear motion parallel to the probe to provide longitudinal images. The term “linear” is frequently used to describe this motion in relation to software control and to differentiate transverse images by the corresponding linear position of the transducer. The
transducer is also rotated from side-to-side around the axis of probe to provide transverse images. The resultant display of each transverse image appears as a sector of a circle on the screen. The term “sector” is frequently used to describe this transducer motion in relation to software control and to differentiate longitudinal images by the corresponding sector angle position. The transducer moves precisely, under computer control, to specific positions to allow image updates and ablation within a three-dimensional volume of prostatic tissue.

**Articulated Probe Arm**

The articulated probe arm (Figure 36) is used to immobilize the probe during preprocedure imaging and during HIFU ablation.

**Stepper**

The stepper (Figure 37) is used to micro-position the probe and the articulated arm during preprocedure imaging and planning.

![Figure 36. Articulated probe arm](image1)

![Figure 37. Multi-Axis Stepper](image2)

![Figure 38. Probe Support System](image3)

**Sonachill**

The Sonachill (pump unit) is used for recirculating, degassing and indirectly cooling the sterile distilled water used in the probe tip. The Sonachill is connected to the back panel of Sonasource console via a connector cable. This connection provides the power to the Sonachill. The following main components of the Sonachill are:

- Peristaltic pump – 2 Heads
- Disposable water reservoir and recirculating tubing
- Indirect Cooling System
  - Solid state cooler
  - Disposable heat exchanger
- Various tubing and fittings
- In-Line degasser, consisting of the following components:
  - Vacuum pump
  - Air trap
  - Disposable water path including degassing filter and various fittings and tubing segments
  - Vacuum gauge

The Sonachill serves three vital functions: removal of air bubbles, recirculation of water and cooling of the water circulating around the transducer. Before starting and during the procedure, the peristaltic pump constantly recirculates the volume of water through the system and the in-line degasser creates negative pressure and removes air from the water. The chilled water path is a separate circuit which surrounds the water path while it passes through the heat exchanger.

The syringe connected to one of the water reservoir top connectors valve is used to change the level of the latex sheath by inflating and deflating the latex sheath by adding or removing water in the reservoir.

![Figure 39. Sonachill left side components](image)
The Sonachill unit also features a freezing monitoring of the liquid-to-air heat exchanger (chiller) using a thermistor. Based on the analog output from this thermistor, the software will automatically warn the user if the temperature of the water inside falls below 10ºC. This is done to prevent damage to the chiller.

WARNING

Never open the pump head while the motor is running. The moving rollers are a danger for pinching fingers.

Each Sonachill unit is uniquely identified with a serial number located on its label.
Refer to APPENDIX A: LABELING SYMBOLS for meaning of additional symbols used.

Refer to the “Hookup Diagram” as shown on the label (Figure 46) for the proper connection of tubing and operation of the Sonachill unit. Refer to the next chapter for additional details and instructions for maintaining and ensuring the water is degassed during operation.
 CHAPTER 5: SONACHILL INLINE DEGASSING SYSTEM

Overview

Sonablate requires the use of distilled or sterile and degassed water in the probe water-path to operate correctly, as the formation of cavitation bubbles during the ultrasound ablation can cause decreased ablation efficacy. Therefore, the water-path of Sonablate needs to be filled with distilled or sterile and degassed water during the system preparation steps.

The addition of the inline degassing system to the Sonachill unit enables the operator to degas water during the system preparation steps and continuously during the procedure, thus alleviating the operator from having to procure degassed water externally for the operation of the system.

Inline Degassing System Components

The inline degassing system of the Sonachill (Figure 44) consists of a vacuum pump (installed inside the Sonachill unit), a vacuum gauge, water trap and a disposable Water Path Kit.

Figure 44. Sonachill with inline degassing components
**Inline degassing system**

The water in the water circuit is degassed as it continuously flows through the degassing filter cartridge (Figure 45). The vacuum pump creates a low-pressure region inside the chamber of the degassing filter cartridge, forcing the diluted oxygen present in the water to permeate through the permeable capillary tubes located inside the cartridge. System components are sized in such a way that the flow rate through the probe is not compromised with the addition of the inline degasser cartridge, and such that the entire water volume present in the probe/tubing/chiller/reservoir system can be degassed from 7 ppm dissolved O2 content (typical O2 content of water) to less than 3 ppm dissolved O2 content in approximately 15 minutes. The vacuum gauge, attached directly to the filter, enables user verification of the vacuum level inside the system required for correct degassing operation. The label on back of the Sonachill demonstrates the water path flow through the system (Figure 46).

**Inline Degasser Setup**

Follow these instructions to set up the inline degasser system:

1. Place reservoir into the Sonachill holding bracket with the stopcocks on the top.
2. Attach tubing from water trap and vacuum gauge to open ports on filter and press filter assembly (Figure 45) into clip on underside of chiller.
3. Connect open end of chiller loop (green fitting) to left front metal fitting.
4. Open peristaltic pump heads and route one length of peristaltic tubing from right to left through each pump head. Take extra care to ensure tubing is placed from right to left.
5. Connect open end of peristaltic tubing (orange fitting) to metal fitting on the bottom of the chiller just behind the peristaltic pump heads.

![Degasser Filter cartridge](image)

*Figure 45. Degasser Filter cartridge*

**NOTICE**

The vacuum pump is powered by the same control circuitry that powers the peristaltic pump.
CAUTION

Use a new Water Path Kit for each procedure. Discard used Water Path Kits at the end of each procedure in accordance with the infectious waste control procedures of the facility.

M433

CAUTION

The system continuously degasses water in the water-path only if the pump is operating. Turning the pump off compromises the degassing performance of the Sonachill.

M434

Figure 46. Label: Sonachill Hookup Diagram (located on Sonachill rear)
Probe Preparation using the Inline Degasser

CAUTION

Ensure that the Filter Cartridge is not damaged. Ensure that the Water Reservoir and all Water Tubes are clean and not damaged. Replace the Water Path Kit prior to use.

M435

CAUTION

Do NOT operate the Sonachill pump unless the probe valves/tubing stopcocks are in the “Open” position. Activating the pump with the valves in the closed position may generate enough pressure in the water-path to burst the inline degasser filter cartridge or water-path tubing/connections.

M436

After a new Water Path Kit has been installed, dress Sonablate probe and prime the water-path following the instructions located in the Ablation Preparation section of this manual.

The use of degassed water is not necessary if the inline degasser option is installed; thus, regular distilled or sterile water (i.e. non-degassed) needs to be used for the probe, reservoir, syringe, and water-path tubing filling steps.

Water Analysis

Sonablate requires the use of distilled or sterile water with a dissolved oxygen content of \( \leq 3 \) parts per-million (PPM). This procedure verifies that the oxygen content does not exceed the 3ppm requirement. Although the use of any reliable test with sensitivity to detect oxygen content in the range of 1-8ppm is acceptable, it is recommended to use acid-based indigo-carmine reagents, which provide accurate results independent of normal mineral levels, water temperature, and barometric pressure. The CHEMets K-7512 test kit (CHEMetrics, Inc., Calverton VA) (Figure 47) is included with the system and can be used quickly to provide accurate analysis. The procedure for use of this kit is as follows.
CHEMets Test Procedure

Because exposure to the high oxygen content of the environment will tend to cause the sample to approach its saturation level, dipping, pouring, and sampling operations should be performed with as little agitation as possible.

<table>
<thead>
<tr>
<th><img src="image1.png" alt="Image" /></th>
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<tbody>
<tr>
<td><strong>NOTICE</strong></td>
</tr>
<tr>
<td>The dyes in both the sample ampoules and comparators may deteriorate upon prolonged exposure to light. Therefore, both should be used before expiration date and store in the CHEMets storage case when not in use.</td>
</tr>
</tbody>
</table>

Colored and/or turbid samples should not be subjected to analysis, since the color comparison may be obscured.

The CHEMets Water Tester kit is used to determine the level of dissolved oxygen in the degassed water.

1. Fill the sample cup to the 25ml mark with degassed water (Figure 48).

2. Place the CHEMets tapered tip ampoule into one of the depressions in the bottom of the sample cup. Snap the tip by pressing the ampoule toward the side of the sample cup. A vacuum in the test tube will draw water into the ampoule and begin to mix with the reagent. A small bubble of inert gas will remain in the ampoule to facilitate mixing.

![Image](image2.png)

Figure 47. Chemets Testing Kit and Storage case

![Image](image3.png)

Figure 48. Sample cup, Self-Filling Ampoules, and mixing
3. Remove the fluid-filled ampoule from the cup. Keeping the open end downward, cover the tip of the ampoule with a finger. Mix the contents of the ampoule by inverting it several times, allowing the bubble to travel from end to end each time.

4. Wipe all liquid from the exterior of the ampoule and wait for 2 minutes. The ampoule tip may be left uncovered during the chemical reaction period and while making color comparisons.

5. After 2 minutes, use the color comparator to determine the level of dissolved oxygen in the sample.

6. The comparator should be trans-illuminated with a strong white light. The filled sample ampoule should be placed between the color standards for viewing. It is very important that the ampoule be compared by placing it on both sides of the standard tube before concluding that it is darker, lighter or equal to the standard. (Figure 49)

---

**CAUTION**

Ablation with the *Sonablate* requires degassed water (≤ 3 ppm dissolved O₂ content).

DO NOT proceed with the ablation procedure until this has been achieved.

---

**NOTICE**

If the dissolved O₂ content is > 3 ppm after having followed the previous preparation steps, the degassing ability of the system may have been compromised.
If the dissolved O\textsubscript{2} content is $> 3$ ppm after having followed the previous preparation steps, verify the following:

- All connections are air-tight, and all tubing is correctly attached (tighten as needed);
- The vacuum pump produces a vacuum when the Sonachill pump is activated between –22” and –30” of Hg.
- The water is circulating properly through the water-path.

Take appropriate action to remedy the problem, and repeat the above steps. If the problem persists, the user should contact the Authorized Service Provider for assistance.

### CAUTION

Vacuum levels between 0 and –22” of Hg. are not sufficient to correctly degas the water in the probe water-path and are indicative of a degassing system malfunction. Should this occur, re-tighten all connections, inspect the tubing lines and filter cartridge for leaks, and replace as needed. Lower vacuum levels can also be indicative of water being present in the vacuum pump itself. Service personnel will be able to service unit and resolve any issues with the vacuum pump and/or associated tubing should this be the case.

DO NOT proceed with the ablation until a proper vacuum level has been measured, and the dissolved oxygen content of the water in the probe water-path is $\leq 3$ ppm.

### Inline Degasser Usage

### CAUTION

The presence and accumulation of air bubbles anywhere in the water path during operation indicate an air leak, poor tubing connection, or component failure/tubing rupture. Depress the EMERGENCY STOP button and correct the problem prior to continuing.
Once the inline degassing system is prepared as described above, the probe is ready to be used with the system. During the procedure, the system will not only chill the water in the water-path, but continuously degas it as well.

**CAUTION**

Do not use the probe until ALL air bubbles have been removed from the probe tip (either manually or by the inline degasser), and from the reservoir bottle (either manually or by the inline degasser).

- During the procedure, it is possible to add small amounts (less than 60cc) of non-degassed water to the water-path for probe positioning and bolus inflation purposes.
- The vacuum function of the Sonachill unit required for correct inline degasser operation may be compromised if water is allowed to enter into the vacuum line. This may occur accidentally or during filter cartridge rupture. Should this occur, depress the EMERGENCY STOP button, and contact the Authorized Service Provider.
- At the end of each procedure, discard the used Water Path Kit in accordance with the infectious waste control procedures of the facility, and clean the system as described in Chapter 16.
CHAPTER 6: PREPARE SYSTEM

The Prepare System section shows procedures that are performed prior to patient ablation.

Opening Sonablate Software

Double click on Sonablate desktop icon to open the application software. Perform the Test Safety Circuit procedure as previously detailed in System Setup section. After the Test Safety Circuit is completed and closed, the following screen can be access (Figure 50):

*Figure 50. Start-up screen with flowchart*

- Select Prepare System button (Figure 51)

*Figure 51. Flow chart close-up*
Entering Ablation Information

The following screen (Figure 52) will appear:

![Image](image_url)

**Figure 52. Opening screen for Prepare System section with checklist**

1. Prepare System
   - 1. Enter procedure information
     - 1. Enter or confirm site name
     - 2. Enter doctor name
     - 3. Enter patient ID
     - 4. Choose procedure type

![Image](image_url)

**Figure 53. Checklist: Enter procedure information**

Complete the procedure information steps in the checklist by entering demographic information into appropriate fields in the upper left hand screen (Figure 53), then check box to verify completion.

The Doctor’s name and preferences can be saved by the selecting the button. On the next application start, select previously stored preferences by clicking the button on the right side of the field. The type of checklist and workflow can be saved as a part of preferences.
Choosing the Type of case from Primary or Salvage will determine the duty cycle of the HIFU procedure. A Primary case corresponds to a 3on-3on-3off duty cycle while the Salvage case corresponds to a 3on-6off duty cycle. Note that if a Salvage type of case is selected all the zones including the anterior are utilize the 3on-6off duty cycle in the Treat a Zone tab and cannot be changed during HIFU ablation.

A user can decide whether or not to utilize the Checklist. An Active checklist selection will require the user to physically check off tasks in order to proceed to the next screen. An Inactive checklist will not require the user to check off tasks, but will be available with the checklist steps for reference.

Choose the Use Workflow Chart option to automatically bring up the workflow chart after completing the checklist steps for the screen; the user will have to click on the next step in the workflow to proceed to the next screen. Using the Automatically advance option will automatically navigate to the next tab in the software after completing the checklist tasks. Note: If the Inactive checklist and Automatically Advance options are selected, the user will have to click button on top right region of application to proceed.

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<tr>
<th>NOTICE</th>
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<tbody>
<tr>
<td>⚠️</td>
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<tr>
<td>All checklists must be completed in order to proceed to subsequent steps.</td>
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<th>NOTICE</th>
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<tr>
<td>⚠️</td>
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<tr>
<td>Enter information according to facility privacy/confidentiality guidelines regarding patient identification.</td>
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</table>

**Initialize Probe**

1. Plug in probe
2. Observe home sequence

*Figure 54. Checklist: Initialize probe*
Complete the steps to initialize the probe, then check box to verify completion (Figure 54). To prevent the use of a probe which contains cracks, transducer delamination, or other defects, probes and transducers should be visually inspected prior to use. If any defects are observed, the probe should not be used; contact service for repair.

After inspection, plug probe connector into console and observe homing sequence.

<table>
<thead>
<tr>
<th>CAUTION</th>
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<tbody>
<tr>
<td>Imaging and Ablation verification procedures should be performed on a periodic basis by the Authorized Service Provider on each probe to confirm and document the functionality of the probe.</td>
</tr>
</tbody>
</table>

Each probe is uniquely identified with a probe assembly serial number located on its label (Figure 55). In the software, a PPF (Probe Property File) Number is configured to recognize each probe individually by its serial number and is displayed on the screen when connected.

**Dressing the Probe**

Complete the following steps to dress the probe, then check box to verify completion (Figure 56).

- **3. Dress probe**
  - 1. Probe sheath
  - 2. O-rings
CAUTION

The probe must be dressed with an alternate, latex-free sheath for patients with a history of latex sensitivity (see Appendix D, Sonablate System Components and Accessories).

Materials Needed

- One Sonablate Disposable Kit, which contains one disposable Sonablate Probe Tip Kit and one disposable Water Path Kit.
  - The Probe Tip Kit contains the following items:
    - Three latex sheaths
    - Six O-rings
    - One O-ring applicator
    - Two packages of Ultrasound gel
  - The Water Path Kit contains the following items:
    - Plastic reservoir
    - Tubing, fittings, and stopcocks
    - Degassing filter
    - Heat Exchanger
- 1 liter of degassed water

Dressing the Probe

1. Open Sonablate Probe Tip Kit
2. Unroll the sheath onto the probe tip using care not to damage or puncture the sheath.
3. Place the O-ring onto the narrow end of the applicator.
4. Roll the O-ring to a point near the opposite end (wide end) of the applicator.
5. Carefully slide the applicator over the tip of the probe until the button-tip touches the inside of the tapered end of the applicator.
6. Remove wrinkles in the sheath away from the transducer window by pulling it tautly toward the probe neck. Roll the O-ring onto the groove in the proximal region of the probe tip.
7. Carefully remove the O-ring applicator.
8. Manually apply a second O-ring over the distal end of the probe, i.e. button-tip.
9. Place the probe in the probe arm cuff and secure the probe.
Initialize Water Path for Sonachill and Probe

Complete the steps to initialize the water path, then check box  to verify completion (Figure 57).

- **4. Initialize water path - Sonachill**
  1. Attach tubing set to the Sonachill
  2. Open valves
  3. Turn pump on
  4. Fill water reservoir
  5. Fill water syringe
  6. Turn pump off

- **5. Initialize water path – Probe**
  1. Attach tubing set to the probe
  2. Turn pump on
  3. Use syringe to adjust water level of the sheath to neutral
  4. NOTE: You will remove air bubbles from the probe tip, water reservoir and tubing on the next screen

- **6. Preparation complete**

*Figure 57. Checklist: Initialize water path – Sonachill*

1. Connect Sonachill unit via the connector cable to the back of Sonasource console.

2. Ensure that the Sonachill tubing is connected as shown on the tubing diagram on the back of the Sonachill unit.

3. Set up Water Path Kit per instructions in Chapter 5 of this manual.

4. To fill the Water Path Kit, follow these instructions:
   
a. Disconnect fitting in chiller loop at yellow fittings (see arrow in Figure 44) and place both ends into basin or bottle filled with water.

b. Turn pump on and allow loop to fill completely, allowing most of the air bubbles to escape from this loop.

   
c. Turn pump off.

   
d. Reconnect yellow fittings.
e. Place the probe end of the water path tubing (red and blue fittings) into the water in the basin or bottle. Make sure that the ends of the tubing are submerged deep enough in the basin such that no air will be pulled into the water path during this process.

f. Flip reservoir upside down so tubing connections are on top and stopcocks are on the bottom. Turn pump on and allow loop and reservoir to fill completely, allowing most of the air bubbles to escape from the loop. Turn pump off. Return reservoir to original position.

g. Locate small baggie containing probe tubing adapter. Connect this fitting to the blue, luer fitting at the end of the water path tubing.

h. Connect both ends of the probe tubing (y-fitting on one side and blue fitting with probe tubing adapter on the other) to the Sonablate probe.

i. Dress probe as described in Section 6 of this document.

j. Pre-fill a syringe with 30cc of distilled or sterile water, attach it to the top of the reservoir, and add this water to the water-path and probe, completely emptying the syringe. This additional water (30cc) will over-inflate the bolus. Close the reservoir stopcocks.

5. Activate the pump of the Sonachill unit by clicking on the “Pump ON” button on the “Prepare System” screen. This will also activate the degassing function at the same time.

6. Verify that the vacuum gauge shows a vacuum level between –22” and –30” of Hg.

7. Leave the pump running/activated for at least 15 minutes to allow the system to degas the water in the water-path prior to using the probe. (The chiller may activate at this time automatically, depending on the chiller set-point temperature; to cool the water).

8. After a time lapse of 15 minutes deactivate the pump by clicking on the “Pump OFF” button on the “Prepare System” Screen.

9. Open the syringe stopcock, and remove approximately 25cc of water from the water-path, and close the stopcock.

10. Use this water volume to verify that the water in the water-path is now degassed to \( \leq 3 \) ppm dissolved \( O_2 \). If value is >3ppm add 25cc back to the system and repeat step 7 after a lapse of 10 minutes. If Sonachill still fails to properly degas, contact service.
11. Re-activate the pump to continue to degas the water in the water-path prior to probe usage. Verify that the vacuum gauge shows a vacuum level between −22” and −30” of Hg.

12. Click on pump icon to activate pump and chiller (Figure 58).

![Pump and Chiller Status](image1)

**Figure 58.** Pump ON and OFF Buttons and Pump Status Indicator

![Both tubes inside water bottle](image2)

**Figure 59.** Both tubes inside water bottle

![Reservoir in original position](image3)

**Figure 60.** Reservoir in original position
WARNING

The Sonachill pump/chiller must be running during the procedure to ensure proper cooling during ablation.

CAUTION

Keep the reservoir bottle completely filled. Do NOT use with air in the bottle.
WARNING

A water drop may indicate water is leaking out of the system, typically due to a broken sheath. If this occurs during ablation, use the emergency stop button to discontinue operation immediately and follow procedure for removing the probe from patient.

Figure 61. Recirculation tubing with luers

Preparation Complete

Check Preparation complete box and continue to next step: Preplan Zone.
SECTION II

Introduction

The purpose of the following physician instructions is to provide detailed procedures for a standardized, best-practice approach to using the Sonablate. All the procedures required to deliver HIFU for whole prostate gland ablation and key concepts instrumental in delivering the most effective Sonablate HIFU ablation are provided.

Also included are specific approaches for patient care before and after HIFU, the use of anesthesia and potential adverse events. These approaches are designed for physicians to consider in their own HIFU cases and have been compiled from actual cases performed by experienced HIFU physicians.

This section of the Sonablate User Manual may be used independently for training purposes.

**KEY CONCEPT**

**Ultrasound as an energy source**

Think of the HIFU pulse or beam as an acoustic scalpel, understanding that Sonablate HIFU is a dynamic and interactive process that requires an attentive HIFU physician to continuously monitor and modulate energy during the procedure.
CHAPTER 7: PREPLAN ZONES

After Preparation Complete, has been checked the Preplan a Zone screen will appear (Figure 62):

![Preplan a Zone screen](image1)

**Figure 62. Preplan a Zone screen**

Select Preplan Zones button (Figure 63).

![Flowchart close-up](image2)

**Figure 63. Flowchart close-up**

The following screen (Figure 64) will appear:
Remove Air Bubbles

Complete the following steps to remove air bubbles and prepare the patient, then check boxes to verify completion (Figure 65).

Remove air bubbles from the probe tip, water reservoir and tubing by manipulating probe, tapping probe body firmly in various positions, and activating transducer motion in both planes while occasionally flipping the transducer back and forth between A-Side and B-side.

2. Preplan Zones
   - □ 1. Remove air bubbles from the probe tip, water reservoir and tubing
   - ▼ 2. Prepare patient
     - □ 1. Patient enters the room
     - □ 2. Introduce appropriate sedation or anesthesia
     - □ 3. Position patient in modified lithotomy position

Prepare Patient

The patient is positioned supine on the table and sedated with anesthesia. During HIFU, the patient must remain immobilized during the procedure (approximately 2-4 hours). After appropriate induction of anesthesia, the urologist inserts a Foley catheter and/or a suprapubic
catheter. Place the patient in a modified lithotomy position to keep the pelvis level and parallel to the floor, which enables the probe to be parallel to the rectal wall.

**Prepare Probe**

Complete the following steps to prepare the probe, then check boxes to verify completion (Figure 66).

- ▶ 3. Prepare probe
  - 1. Secure the stepper to the table rail
  - 2. Secure the probe arm to the stepper
  - 3. Insert the probe into the patient
  - 4. Secure the probe to the probe arm

![Figure 66. Checklist: Prepare Probe](image)

**Multi-Axis Stepper Set-up**

1. Only surgical tables with a dropping leg section with attached surgical rails can be used with the stepper assembly.

2. Adjust the vertical, horizontal and depth displacements of the stepper to a neutral position.

3. After the patient is positioned in a modified lithotomy position, lower the leg section to 90°.

4. Starting from the bottom of the table’s left side; slide the surgical rail socket (Figure 67) of the multi axis stepper to the top of the leg section. Note: there may not be enough room below the leg section to slide the stepper onto the rail. If this occurs, raise the leg section to allow for enough room to slide the stepper onto the rail. Then return the leg section to 90°.

![Figure 67. Surgical rail socket](image)
5. Latch the top of the stepper assembly to the top of the leg section surgical rail (Figure 67).

6. At this point, the stepper is secure from sliding down the rail. Tighten the two securing screws (Figure 68) against the surgical rail (Figure 67) to avoid any unnecessary movement of the stepper.

![Figure 68. Securing Screws](image1)
![Figure 69. Stepper and probe arm attached to table rail with lockout safety device](image2)

**Probe Arm Set-up**

1. Mount the rail clamp of the probe arm to the surgical rail of the stepper and tighten the rail clamp knob. Then tighten the central locking knob of the probe arm with it positioned away from the patient.

2. Cover the rail clamp knob with the lockout safety device (Figure 69).

3. Insert the probe through the probe arm collar. Lock the collar to secure the probe (Figure 69).

**Securing the probe in the articulating arm**

Adjust the probe position such that the transducer window will be facing anterior and the reference mark is at zero degrees as shown in (Figure 70). Lock the probe arm cuff knob to secure the probe in this position.
NOTICE

Anoscopy or proctoscopy may be performed prior to HIFU at the physician’s discretion.

Probe Insertion into Patient

1. Using a small amount of ultrasound gel, dilate the patient’s rectum using gloved index and middle fingers (two finger dilation is essential before introducing the probe). Only use lubricating gel that is compatible with ultrasound.

2. Perform a limited digital rectal examination to check for retained stool. If stool is present, the rectum should be irrigated with water until clear. The rectal vault should be free of feces, as this could impede accurate ultrasound imaging.

3. Ensure that any excess gas and water introduced during irrigation are released.

4. Carefully apply a thin layer of ultrasound gel to the sheath covering the probe tip. Check for air bubbles that may be trapped in the gel and, if necessary, eliminate them by smoothing the gel with a gloved index finger.

5. While holding the probe in the right hand, loosen the central knob on the probe arm.

6. Place the left index finger at six o’clock in the patient’s rectum, apply pressure slightly downward and carefully insert the probe until the entire balloon is inserted into the
rectum. Insert the probe so that approximately 1/3 to 1/2 of the probe neck is past the anal sphincter. Do not pass the maximum insertion point as depicted in Figure 71.

7. If the probe tip insertion is difficult, reduce water bolus volume using the syringe on the Sonachill unit and try again.

---

**WARNING**

DO NOT FORCE the probe insertion.

If there is bleeding from the rectum, stop the probe insertion and do not treat until the source of bleeding has been identified.

IT IS IMPERATIVE to ensure that there is no preexisting rectal disease such as proctitis, ulcerative colitis, trauma, stricture or stenosis.

---

**View Live Images**

Once the probe is properly placed, position the prostate image within the acoustic window by following these steps (Figure 72):

- 4. To view live sector images, do one of the following:
  - Choose the sector image button in the Scan box
  - Move the slider above the linear image to the sector position you wish to view
  - Select a button below the live sector image to change the image position

- 5. To view live linear images, do one of the following
  - Choose the linear image button in the Scan box
- **Move the slider above the sector image to the linear position you wish to view**
- **Select a button below the live linear image to change the image position**

**Figure 72. Checklist: Sector/Linear imaging**

In the bottom right hand corner of the active window (Figure 73), select the sector scan button (red arrow) and fully extend the transducer until the Foley catheter balloon in the bladder can be visualized utilizing the arrow button or dragging the indicated slide pod (white arrows).

Once the probe has been positioned accurately and satisfactory preprocedure imaging has been achieved; securely lock the central knob on the probe arm.

**Figure 73. Transverse scan to find bladder/Foley catheter**
**KEY CONCEPT**

**Position Patient for Optimal Imaging**

The patient and the probe should be positioned to ensure the rectal wall will be as parallel to the solid green line as possible when imaged in the longitudinal window. Typically, the probe is placed nearly horizontal and parallel to the floor.

---

**Probe Positioning and Orientation**

Complete the steps for probe positioning, and then check the boxes shown in Figure 74.

**Imaging Procedure**

Imaging is done in the transverse (sector) and the sagittal (linear or longitudinal) planes, which are illustrated in Figure 75 to help display the orientation of the probe and the planes.

When scanning in the transverse plane, the image plane is controlled with the arrow buttons (white arrows) or with the slider (yellow arrow) (Figure 76). Utilizing these features, the transverse image may be moved incrementally toward the prostate base (head image) or toward the prostate apex (foot image). Each .05 cm arrow click moves the transducer 0.5 mm, while the arrow with red dot moves the transducer to the next ablation site (3.0 mm in between ablation sites). Each slider bar click moves the transducer to the next ablation site. Selecting the “H” symbol (red arrow) places the transducer in the middle of the transverse scan field. The green border around the frame indicates active scanning in transverse plane.

Use the slider or arrow buttons to scan through the transverse images; the entire gland should be visible from base to apex. Any prostate tissue left outside of the imaging window will not receive ablation during this ablation session.

- ▮ 6. Alternating between live sector and linear images, adjust the probe position and orientation, the stepper and the DGC sliders such that:
  - The entire prostate is visible from base to apex
  - The urethra is visible in the midline linear view
  - The prostate is centered in the sector views
  - The rectal wall is parallel to the probe
  - The rectal wall indicators are between 1.0 cm to 2.0 cm away from the transducer face to avoid alert messages and forced duty cycle
7. Verify

- The prostate is fully visible within all sector views
- The prostate’s base-apex dimension is fully visible within all linear views

Figure 74. Checklist: Probe/Stepper position and Depth Gain Compensation (DGC) settings

Figure 75. Orientation of probe tip and imaging planes

NOTICE

The green border around the frame indicates active scanning.
Once adequate transverse positioning is achieved, activate the sagittal (linear) scan (white arrow, Figure 77).

When scanning in the linear plane, the image plane is controlled with the arrow buttons (white arrows) or with the slider (yellow arrow) (Figure 78. Utilizing these features, the linear image may be moved incrementally toward the patient’s right (“R” image) or toward the patient’ left (“L” image). Each 0.5° arrow click moves the transducer 0.5°, while the arrow with red dot moves the transducer to the next ablation site (3.0° in between ablation sites). Each slider bar click moves the transducer to the next ablation site. Selecting the “H” symbol (red arrow) places the transducer in the middle of the linear scan field (typically prostatic midline). The green border around the linear screen indicates active scanning in the linear plane.
If the Foley catheter is not seen at the midline, make sure the probe is aligned to the longitudinal axis of the prostate by loosening the cuff knob of the probe arm and rotating the probe. Once the urethra is visible at midline, lock the cuff knob. The prostate gland should be centered on the screen when imaged transversely.

**KEY CONCEPT**

**Optimize the image quality:**

An optimized image will allow for the most appropriate measurement of the gland and planning of HIFU ablation. When imaging, use the master gain slider and the individual depth gain compensation (DGC) sliders, and dynamic range (Figure 80) to get an image that contains grayscale levels with contrast and brightness. The prostate, seminal vesicles, bladder, rectal wall, and location of Denonvilliers’ fascia should be clearly identified.

To optimize gray scale image; close the Checklist by clicking the red X (if enabled) to access the **DGC- Depth Gain Compensation** tool (Figure 79).

**NOTICE**

The rectal wall image must be set to the appropriate gray scale level in order for the chevrons to properly track the rectal wall.
Adjust the vertical Master Gain slider to change the gray scale of the overall image (Figure 80. Depth Gain Compensation (DGC) box).

Adjust the eight horizontal DGC sliders to adjust the gray scale at corresponding image depths.

Adjust the vertical Dynamic Range slider to adjust overall image contrast (see Dynamic Range section).

The DGC for each band, Master Gain and Dynamic Range can be controlled by arrow keys on the keyboard for more fine control.

**NOTICE**

Planning with a Foley catheter aids in the initial probe positioning and assists with the identification of the bladder neck and the apex. The catheter must be removed before the final review of the ablation plan.
In the longitudinal image, it is important that the rectal wall is parallel to the solid green line. The slope should be as close to zero as possible, which is accomplished by tilting the probe up or down.

**SUMMARY**

The probe is positioned properly when these conditions are met:

- The entire prostate from base to apex is visible in the longitudinal image.
- The lateral edges are visible and clearly defined.
- The Foley catheter is visible at the midline.
- The rectal wall is parallel to the solid green line.
- The DGCs are set so that the prostate, seminal vesicles, bladder, rectal wall and Denonvilliers’ fascia can be clearly identified.

**Measuring Procedure**

Once a well-defined image of the gland is obtained and the prostate is properly positioned, the physician should measure the gland.

Complete the following steps to measure the prostate, and then check the boxes shown in Figure 81.

- Locate and display the sector image with the largest vertical.
Select live linear imaging
Slide the horizontal slider above the linear image to the tallest point of the prostate

9. Measure the prostate on the sector image with the largest vertical extent
Choose Use Mouse in the Prostate Dimensions and Volume box (if necessary)
Use the mouse to click on the Anterior and Posterior of the prostate
Use the mouse to click on the Right and Left of the prostate
Use the mouse to click on the Base and Apex of the prostate
Verify that the prostate’s AP dimension is less than or equal to 4 cm
After measurements are complete, click on the Lock button in the Prostate Dimensions and Volume box

Figure 81. Checklist: Identify largest vertical extent and measure volume

<table>
<thead>
<tr>
<th>NOTICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take all measurements before adding additional water to the sheath. Adding additional water can compress the prostate and make measurements inaccurate.</td>
</tr>
</tbody>
</table>

How to measure:

Measurements will be achieved in this screen in Preplan Zones (Figure 82).
Figure 82. Prostate volume measurement screen

Use Mouse, in the Prostate Dimension is the default and preferred measurement method (Figure 83).

Figure 83. Prostate Dimension and Volume box

Image in transverse plane; move the transducer from apex to base until the largest AP prostate dimension is obtained. (Figure 84).

On the linear image, the yellow vertical marker (see yellow arrow) at the top of the image is now positioned in line with the highest area of the prostate (green arrow).
Click on the most anterior boundary of the prostate and then on the most posterior boundary of the prostate (yellow arrows) to measure the AP diameter (**Figure 85**).

Using the same transverse image, click from the right boundary of the prostate to the left boundary of the prostate (red arrows) to measure the width of the gland (**Figure 85**).

On the longitudinal image (positioned at midline) measure the length by clicking at the base and the apex of the prostate (green arrows) (**Figure 85**).

The measurements will be entered in the appropriate parameters and the volume will be calculated automatically (**Figure 86**). Click the Lock button to save the measurements. Once complete, check all the boxes in checklist items (**Figure 81**).

**NOTICE**

Prostate volume is automatically calculated and displayed in the Prostate and Dimensions and Volume box. The first three measurements on the transverse and longitudinal images are automatically stored into the appropriate parameters. The volume (V) is calculated \( V = D_1 \times D_2 \times D_3 \times 0.52 \) and the readings saved. To re-measure, click again on the transverse or longitudinal images. If the Lock button has been pressed, select Use Mouse to re-initialize measuring the prostate.
Figure 85. Gland measurement (height, width and length)

Figure 86. Measurements displayed and locked

**NOTICE**

Measure the gland and define the number of ablation zones based on the AP distance. The maximum prostatic height, consisting of the sum of the rectal wall thickness and AP diameter, should be less than 3.7 cm in order to treat the anterior prostatic tissue.
Fine Adjustment

Complete the following steps to adjust positioning, and then check all the boxes in checklist items (Figure 87).

- 10. Use syringe to add water in order to compress the prostate (if applicable)
- ▼ 11. Readjust the probe position and orientation, the stepper and the DGC sliders (if needed) such that:
  - *The entire prostate is visible from base to apex*
  - *The urethra is visible in the midline linear view*
  - *The prostate is centered in the sector views*
  - *The rectal wall is parallel to the probe*
  - *The rectal wall indicators are between 1.0 cm to 2.0 cm away from the transducer face to avoid alert messages and forced duty cycle*
  - *The prostate is fully visible within all sector views*
  - *The prostate's base-apex dimension is fully visible within all linear views*

Figure 87. Checklist: Add water if needed. Re-evaluate probe/stepper position. Adjust DGC.

After the measurements have been made, add up to 60 ml of degassed water to the Sonachill water reservoir using a 60 ml luer lock syringe. This is to ensure good acoustic coupling between the sheath along the rectal wall and to help compress the gland. Re-adjust the master gain and depth gain compensation (DGC) sliders (in Tools drop-down list) as needed to obtain optimal images that clearly identify the prostate, seminal vesicles, bladder, and rectal wall.

Once the water has been added, rescan in both planes to recheck the prostate assuring all the parameters listed in checklist are verified. When completed, check the corresponding check boxes.

NOTICE

The Master Gain and DGC sliders should be adjusted to obtain an optimal image and clear rectal wall delineation. The Master Gain and DGC sliders are located in the Tools drop-down menu. The eight horizontal sliders control the gain for different corresponding levels of tissue depth (DGC) while the single vertical slider controls the overall image gain.
Establishing Ablation Zone

Ablating tissue with HIFU irreversibly changes the physical properties of the targeted tissue and ultrasound propagation may be impeded by these physical changes. When ablating tissue with HIFU, users must progress the ablation systematically from the farthest ablation point to the closest (anterior to posterior). Targeting tissue beyond a region that has been ablated might be ineffective.

When ablating, the first zone ablated is always along the anterior portion of the prostate. The subsequent zones to be ablated are then placed towards the rectal wall (posterior portion) to ensure that all parts of the prostate are ablated.

Follow instructions in checklist to preplan ablation zones in Figure 88.

Locate and display the sector image with the largest vertical extent by moving the slider to the point in the linear image where the prostate has the largest vertical extent.

Image in sector plane, moving the transducer from apex to base until the largest AP dimension is obtained.

On the linear image, the yellow vertical marker (see yellow arrow) at the top of the image is now positioned in line with the highest area of the prostate (green arrow) (Figure 89).
12. Preplan treatment zones on the sector image with the largest vertical extent
   - Locate and display the sector image with the largest vertical extent
   - Use the mouse to mark the outline of the prostate
     - Single mouse clicks add points to the outline
     - Click-and-drag near a point moves the point
     - Click-and-drag near a segment adds a point
     - Double-click near a point deletes the point
     - Clicking on the start point closes the outline
     - Double-clicking away from a point or segment adds a point and closes the outline
     - Upon closing the outline, the software suggests the number and position of treatment zones
   - After closing the outline, confirm or change the suggested treatment zones
13. Zone preplanning complete

Figure 88. Checklist: Preplan treatment zones

![Figure 88](image)

Figure 89. Identifying largest vertical gland height

For the following steps the Undo and Redo buttons are useful to return incrementally to previous steps (Figure 90).
Use the mouse to mark the outline of the prostate in the sector image:

- Single mouse clicks add points to the prostate outline (Figure 91).
- Click-and-drag near a point marked with "x" moves the point.
- Click-and-drag near a segment adds a point.
- Double-click near a point deletes the point.
- Clicking on the start point closes the outline.
- Double-clicking away from a point or segment adds a point and closes the outline.

Upon closing the outline, the software suggests the number and position of ablation zones (Figure 91).

After closing the outline tracing, confirm or change the suggested ablation zones in the Preplan Zones box (Figure 90).

The number of zones can be changed by opening the drop-down menu in the Automatic tab. The position of zones may be moved by selecting the zone to be adjusted, then use the up or down arrows to adjust zone position (Figure 90).

When the steps are completed, check all the boxes shown in Figure 88.
CHAPTER 8: POSITION PROBE

When “Zone preplanning complete” box has been checked, the following screen will appear (Figure 92). Click on Position Probe to continue with ablation planning.

Figure 92. Position Probe flowchart selection

Ablation Planning Considerations

The goal of HIFU for a prostate ablation procedure is to ablate the entire gland. Ablating tissue with HIFU irreversibly changes the physical properties of the targeted tissue and ultrasound propagation may be impeded by these physical changes. Therefore, when ablating tissue with HIFU, users must progress the ablation procedure systematically from the farthest point to be ablated to the closest with respect to the transducer or anterior to posterior. Targeting tissue located beyond a region that has been ablated will be ineffective.

When ablating, the first zone ablated is always along the anterior portion of the prostate with the subsequent zones to treat placed towards the rectal wall (posterior portion), ensuring that all parts of the prostate are ablated (Figure 93). The A-side transducer (4.0 cm focal length) creates an ablation lesion that is 1.2cm x 0.3cm x 0.3 cm. The B-Side transducer (3.0 cm focal length) creates an ablation lesion that is 1.0cm x 0.3cm x 0.3 cm.
Figure 93. Ablation zones

NOTICE

PLAN ZONES TO MINIMIZE POSTERIOR OVERLAP:

The AP diameter determines how many zones are necessary to treat the gland. Before planning any ablation, make sure to note the AP diameter and determine in how many zones to treat and where the overlap will be.

The following information is a guide only. The number of zones can vary due to tissue density and the degree of prostate compression. Most glands are ablated in three zones. If the AP measurement is less than 2.5 cm, the gland may be ablated in two zones. Anything greater than 2.5 cm will usually be ablated in three or more zones.

If the gland requires 3 or more zones, strive to have overlap of ablation in the anterior zone, versus the posterior zone to prevent overheating of the posterior zone/rectal wall.

Use the 4.0 cm transducer to treat the anterior (top row); the screen displays this zone with teal lines. Use the 4.0 cm transducer to treat the center of the prostate (center row) unless the rectal wall is more than 2.0 cm from the transducer. If the rectal wall is more than 2.0 cm from the transducer, use the 3.0 cm transducer, as indicated with dark blue lines. Finally, treat along the posterior zone of the prostate using the 3.0 cm transducer.
An example of three ablation zones is shown in Figure 94. The image on the left shows the highlighted anterior zone (top row), the second image shows the highlighted middle zone (center row), and the image on the right shows the highlighted posterior zone (bottom row).

![Figure 94. Anterior, middle and posterior zones during ablation](image)

**CAUTION**

When flipping the transducer, the sheath needs to be inflated by adding water beyond the level of the GREEN line on the longitudinal image. Failure to do this may result in an error during transducer flipping.

The first zone ablated must include the anterior portion of the prostate and the anterior margin, but should exclude the pubic bone and dorsal vein complex. Use a combination of stepper movements and water volume adjustments to position the prostate so the targeted tissue is within the ablation zone of the chosen transducer (Figure 95).

Modifying the vertical position of the prostate in relation to the transducer can be done by stepper adjustments, water level changes, or a combination of both.

- Adjusting the stepper up effectively lowers the position of the prostate with respect to the ablation zone. Moving the stepper down effectively raises the position of the prostate with respect to the ablation zone.
- Increasing or decreasing the water volume assists in positioning as well, but also may affect compression and acoustic coupling along the rectal wall.

Tissue in a zone must be ablated completely before repositioning the probe to treat tissue closer to the rectal wall.
Confirm Probe Position

- Complete the following steps to position the probe, and then check all the boxes in the checklist (Figure 96).

4. **Position Probe**
   - ▼ 1. Locate and display the sector image with the largest vertical extent
     - □ Select live linear imaging
     - □ Slide the horizontal slider above the linear image to the tallest point of the prostate
   - □ 2. Observe that the prostate outline created in the Preplan Zones workflow step is displayed on the sector image
   - ▼ 3. Adjust the probe position
     - □ Select live sector imaging
     - Use the stepper to adjust the probe up/down and left/right to center the image prostate in the outline. Use one of the following guidelines depending upon which treatment zone you are positioning
       - If you are positioning the probe for the first (most anterior) treatment zone, center the prostate left/right and match the top of the prostate with the top of the outline
       - If you are positioning the probe for the middle zone(s), if any, center the prostate left/right and up/down in the outline
       - If you are positioning the probe for the last (most posterior) treatment zone, center the prostate left/right and match the bottom of the prostate with the bottom of the outline
   - □ 4. Probe positioning complete

Figure 96. Checklist: Confirm probe position


**Prostate Height**

Locate and display the sector image with the largest vertical extent by moving the slider to the point in the linear image the prostate has the largest vertical extent:

- Select live linear image
- Slide the horizontal slider above the linear image to the tallest point of the prostate (yellow arrow) (Figure 97).
- Observe that the yellow prostate outline created in the Preplan Zones workflow step is displayed in the sector image (Figure 97).

![Figure 97. Identifying largest vertical gland height](image)

**Adjust the probe position**

Select the live sector image. Adjust the stepper, as necessary, up/down and left/right in order to center the prostate image in the outline, then use one of the following guidelines depending upon which ablation zone you are positioning:

- **First ablation zone** (most anterior): center the prostate left/right and match the top part of the prostate with the top of the outline.
- **Middle zone(s), if any**: center the prostate left/right and up/down in the outline.
- **Last ablation zone** (most posterior): center the prostate left/right and match the bottom of the outline.
- Upon completion, check all boxes in Figure 96.
CHAPTER 9: PLAN A ZONE

When all the boxes have been checked in Probe Position the following screen will appear (Figure 98).

![Figure 98. Plan a Zone flowchart](image)

- Select Plan a Zone. The following screen will appear (Figure 99).

![Figure 99. Volume stack confirmation box](image)

**Update Volume Stack and Identify Critical Structures**

- Select “Yes” in the dialogue box to acquire updated images (Figure 99).
• Complete Steps in Figure 100 then check all boxes. Note: “Identify neurovascular bundles,” step is typically accomplished only in the posterior zone (see Neurovascular Bundle (NVB), section for details).

5. Plan a zone

☐ 1. Update the volume stack
   • You are prompted to update the volume stack upon entry to this screen
   • To update the volume stack later, choose the volume stack button in the Stack/Live box and then the volume scan button in the Scan box

☐ 2. Visually identify nearby critical structures by moving through the sector and linear stack images
   • Identify bladder neck
   • Identify rectal wall
   • Identify pubic bone

☐ 3. Identify neurovascular bundles (if applicable)
   • Open the NVB - Doppler for Neurovascular Bundle Detection tool
   • Enable Doppler and choose live sector imaging
   • Move the Doppler gate to identify the NVB on as many sector images as possible

Figure 100. Checklist: Update volume stack. Identify critical structures and NVB’s (if applicable)

Outline and plan the prostate

Complete steps to outline the plan as in Figure 101 below, and then check all the corresponding check boxes.

• Choose the polygon button (yellow arrow) in the Planning Method box (Figure 102).

• Use the mouse to mark the outline of the prostate in the coronal image (Figure 103) utilizing the steps detailed in Figure 101. The outline may be accomplished by dragging-to-draw or by clicking dot-to-dot.

☐ ▼ 4. Outline and plan the prostate on the R-Mode image
   ☐ Choose the polygon button in the Planning Method box (if it is not already chosen)
   ☐ ▼ Use the mouse to mark the outline of the prostate
      • Single mouse clicks add points to the outline
      • Click-and-drag near a point marked with "x" moves the point
      • Click-and-drag near a segment adds a point
      • Double-click near a point deletes the point
      • Clicking on the start point closes the outline
      • Double-clicking away from a point or segment adds a point and
- Upon closing the outline, the software suggests the number and position of treatment zones
  
  - Click the "+" button in the Add or Remove Treatment Shots box to add shots

Figure 101. Checklist: Outline prostate in R Mode image

Figure 102. Choose polygon
Figure 103. Outline prostate in coronal plane

- The *Undo* and *Redo* buttons are helpful for making necessary corrections to outlining (Figure 104)

![Add or Remove Treatment Shots](image)

**Figure 104.** Undo and Redo options

- Once the outlining of the prostate in the coronal plane is complete and the circle is closed (Figure 105), choose the red plus sign in the *Add or Remove Treatment Shots* box (Figure 106).
Figure 105. Prostate outline complete

Figure 106. Choose plus (+) sign to fill outline with ablation skittles

- The outline will be filled with red ablation skittles (red dots) (Figure 107)

Figure 107. Outlined area filled with ablation skittles
Refine the Treatment Plan

To refine the treatment plan, follow steps below in Figure 108 utilizing Method 1 or Method 2. Check the boxes when completed.

5. Refine the treatment plan
   - Move through the sector and linear stack images to review the treatment plan
   - ▼ To add or remove treatment shots, method 1
     - Choose the "+/-" button in the Planning Method box
     - Click or click-and-drag, starting on a filled space to remove treatment shots
     - Click or click-and-drag, starting on an empty space to add treatment shots
   - ▼ To add or remove treatment shots, method 2
     - Choose the draw button (the right hand button) in the Planning Method box
     - Click and drag to draw an arctangle or rectangle on a sector, linear or rmode image
     - Click the "+" button in the Add or Remove Treatment Shots box to add shots
     - Click the "-" button in the Add or Remove Treatment Shots box to remove shots
   - ▼ Add or remove treatment sites to cover the desired portion of the treatment zone while avoiding critical structures
     - Avoid bladder neck
     - Avoid rectal wall
     - Avoid pubic bone
     - Avoid neurovascular bundles

Figure 108. Checklist: Refine treatment plan

- For either refinement method, utilize the arrow navigation buttons with red dots to sequentially address each sector and linear ablation plane (yellow arrows, Figure 109).
NOTICE

Regardless of which refinement method is used it is recommended to start ablation refinement at the extreme patient right in the linear image window and progress one plane at a time toward the patient’s left until all linear planes have been addressed, adding or subtracting ablation lesions as needed. After the linear ablation images are refined, move the sector images to the extreme base and proceed to refine the sector planes one frame at a time toward the prostatic apex, adding or subtracting ablation lesions as needed.

Method 1:

- Choose the “+/−” button in the Planning Method box (yellow arrow, Figure 110).
- Click or click and drag, starting on a filled space to remove ablation shots.
- Click or click and drag, starting on an empty space to add ablation shots.

Method 2:

- Choose the draw button (red arrow, Figure 110) in the Planning Method box.
- Click and drag to draw an arctangle or rectangle on a sector, linear or rmode image.
- Click the "+" button in the Add or Remove Ablation Shots box to add shots.
- Click the "-" button in the Add or Remove Ablation Shots box to remove shots.
WARNING

Be careful not to treat beyond or above the apex, as this may increase the risk of urinary incontinence, urethral strictures or osteitis pubis.

M418

WARNING

Due to the geometric shape of the prostate, in order to treat all of the prostatic tissue it may be necessary to allow energy to be placed beyond the capsule of the prostate. This is especially true in the anterior and posterior ablation zones when ablating laterally and distally. Be aware that if more than 1/3 of the lesion is outside of the prostate, you are placing a significant amount of energy outside of the gland. In this case, evaluate what structures outside of the gland are being exposed to HIFU energy and avoid placing energy into the vital structures, namely the pubic bone, external urinary sphincter, rectal wall and bladder neck. If these structures are being exposed to HIFU energy, replan to avoid potential serious complications due to damage to these structures.

M419

NOTICE

Confining HIFU to the Gland:

With HIFU, physician must find a balance between applying too much energy outside the gland and under-ablating tissue inside the gland.
Adjustments

If prostate is larger than prescribed ablation zone

If the ablation zone at the chosen depth does not include the entire width of the prostate, there is tissue outside of the acoustic window, use the following guidelines to make adjustments:

- Being careful to maintain the probe arm and probe tip water volume, loosen the collar to rotate the probe until the unabluted region at this height can be covered by the next ablation region.
- Verify this position allows for some overlap with the previously ablated region by using the grid and landmarks of the prostate.
- Tighten the probe arm collar and proceed to plan this new region.
- Continue until the entire width has been ablated at this height and linear position with respect to the base and apex.

Similarly, if the full length of the prostate from base to apex cannot fit within the ablation zone, treat the tissue in multiple steps in order to treat all tissue from the apex to base. Treat the apex first and then adjust to treat the base so any overlap is at the base of the prostate (versus apex).

Adjust RF Signal Quality

To adjust the RF signal quality, follow steps in the checklist to adjust RF signal quality (Figure 111). NOTE: RF signal quality must be adjusted within prescribed ranges to optimize Tissue Change Monitoring (TCM) feature. (See Tissue Change Monitoring (TCM), section for details.)

- Open the DGC - Depth Gain Compensation tool
- Choose live sector imaging
- Adjust the Head and Foot limits in the RF Signal Quality Box to the boundaries of the treatment region
- Adjust the DGC and Master Gain sliders until both Amplitude and Saturation are in the green regions

6. Adjust the RF Signal Quality

7. Zone treatment plan complete

Figure 111. Checklist: Adjust RF signal quality

Click on Tools (yellow arrow), then pick DGC-Depth Gain Compensation (red arrow) from drop-down menu (Figure 112).
Activate the linear screen (Figure 113) by clicking the live scan button (yellow arrow), followed by clicking the linear image button (red arrow).

Adjust the Head/Foot limits in the *RF Signal Quality* box (Figure 114) utilizing the two sliders. Set each limit (vertical dotted lines) to the end boundaries of the ablation box (red arrows) utilizing the Head/Foot sliders (yellow arrows).
Next adjust the **Master Gain** (vertical slider) and/or **DGC** (eight horizontal sliders) to get the **Amplitude** and **Saturation** scales within the green zones (yellow arrows, Figure 115). Optimal amplitude is ≥ 200. Optimal saturation is ≤ 300.

NOTE: Optimal RF signal quality readings are generally achieved in the mid-sagittal plane of the gland. In the presence of midline calcifications or Foley catheter the user may image slightly off midline.

---

**Figure 114.** Set head/foot limits (red arrows) utilizing head foot sliders (yellow arrows)

**Figure 115.** Amplitude and Saturation scales
Warning

The rectal wall distance (RWD) measurements are VERY dependent on the DCG setting. Poor image quality in the near field results in inaccurate rectal wall distance (RWD) measurements. It is imperative to verify that the green chevrons are aligned along the entire length of the rectal wall.

Once the RF signal quality is optimized, check remaining boxes in the Plan a Zone checklist. The following screen will appear (Figure 116).

![Figure 116. Treat a Zone flowchart](image)
CHAPTER 10: TREAT A ZONE

Clicking the Treat a Zone button opens a new screen and checklist.

**Probe Temperature**

Click on the highlighted Treat a Zone button to proceed with ablation (yellow arrow, Figure 117).

![Figure 117. Choose Treat a Zone](image)

The screen appears as shown in Figure 118. Verify the chiller temperature button (yellow arrow) is in green zone.

![Figure 118. Verify chiller temperature button is green](image)
Follow the steps in the checklist to confirm the probe temperature is in the correct range (Figure 119).

6. Treat a zone
   □ 1. Confirm probe temperature is in range
   □ ▼ 2. Start HIFU delivery
      - Choose the "play" button in the HIFU Power box
      - You may be prompted to update the reference images
      - To manually update the reference images later, choose the volume stack button in the Stack/Live box and then the volume scan button in the Scan box
      - When reference imaging is complete, you may be prompted to set the treatment power if you have not already done so
      - When reference imaging is complete and treatment power is set, you will be prompted to start HIFU
      - To interrupt HIFU delivery at any time, choose the Pause button in the HIFU Power box or press E-Stop (the red physical button on Sonasource console)

   Figure 119. Checklist: Start HIFU delivery

Start HIFU Delivery

Choose the play button in the HIFU Power box (green arrow, Figure 118). The following dialogue box will appear (Figure 120)

![Figure 120. Choose Yes to acquire reference images](image)

Click Yes to update reference images (Figure 120). Updated sector and linear images will be acquired and automatically displayed; the following dialogue box will appear (Figure 121). Click OK.

![Figure 121. Choose OK](image)
Adjusting HIFU ablation power

The default power setting is zero. The user MUST set the initial ablation power.

Suggested ablation dosage is based on average rectal wall distance (RWD). The average rectal wall distance (indicated by teal number) is used to determine the initial dosage set by the physician based on the guidelines contained in Table 1, below, for the 4.0 cm and 3.0 cm focal lengths, respectively. If the rectal wall is not flat, there will be significant difference between the average (teal) and actual (white) rectal wall distance numbers. It is recommended to use the actual numbers to determine power settings in this situation.

Once the initial dosage is determined from the reference images, manually adjust the power accordingly.

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<th>3.0 cm-fl</th>
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NOTICE

Energy Modulation (Adjusting the Power Dosage):

HIFU is a dynamic procedure that requires adjustment of energy within the prostate gland. Very close continuous comparison of the ablation and reference images is essential to ensuring the energy is always being applied as it was planned.

The amount of power applied during HIFU is determined by a relationship between two factors: Rectal wall distance and Tissue response. Therefore, it is important to monitor both rectal wall distance and tissue responses.

Adjust power according to the guidelines in the power table to select an appropriate power dosage for the corresponding rectal wall distance.

The suggested and current powers are displayed in the gray boxes (yellow arrows, Figure 122). Suggested power is based on Rectal Wall Distance (RWD). The suggested power is achieved by sliding the vertical pod button to the center of the blue box; (red arrow, Figure 122). The power pod can be adjusted utilizing one of three methods:

1. In the HIFU Power box hold a right or left mouse click on the vertical power pod button, then move mouse up or down to set the power.

2. In the HIFU Power box mouse click on the vertical up/down black arrows located on the left side of the HIFU Power box to move the power up or down in one watt increments.

3. A third alternative for adjusting power is pressing the F12 key on the keyboard and then using the up/down arrows. The power will be either increased by one watt (up arrow) or decreased by one watt (down arrow). When this feature is activated, a message will appear in the Status window at the bottom of the screen: TAP change via function key ON. To deactivate this feature, press the F12 key again. The Status window will display: TAP change via function keys OFF.

Once initial power is set, user may begin HIFU ablation, click on the play button.

Note that once the HIFU delivery starts, changing of tools display from top right region is disabled and is re-enabled when HIFU delivery is paused.

A dialogue box will appear. Click Yes to start HIFU ablation (Figure 123).
Upon starting ablation, immediately observe the suggested power setting box and the current power setting box in the HIFU Power box; adjust power as necessary throughout ablation (yellow arrows, Figure 122).

Choose the desired HIFU Duty Cycle (2 options):

1. The default ablation cycle, or duty cycle, of Sonablate is 9 seconds; 3 seconds ON /6 seconds OFF (red arrow Figure 124). This choice allows more cooling time. Extra cooling may be helpful to slow down ablation time if near-field heat changes increase. (See HIFU Cycle Alternative section for details).

2. The 3 seconds ON, 3 seconds ON, 3 seconds OFF (yellow arrow Figure 124) is selected for quicker zone ablation times, generally, in the anterior and middle ablation zones. When ablating with the 4 cm transducer (Side A) in the anterior and middle zones, this duty cycle will accelerate the ablation time.

Monitor Ablation
Delivery of HIFU ablation will begin immediately after the button is clicked. During HIFU ablation, the user MUST monitor the items in Checklist (Figure 125), updating parameters as needed and pausing as necessary to make required adjustments.

3. Monitor the treatment while HIFU power is on
   - **Monitor these items**
     - Patient movement
     - Prostate movement: shifting and/or swelling
     - Tissue reaction
     - Echogenicity near the rectal wall
     - Other near field changes
     - Rectal wall distance (RWD) on live versus reference image
     - Reflectivity index (RIM)
     - RIM box position
     - TCM display
     - Probe temperature
     - Interface between transducer and sheath
   - **When necessary:**
     - Adjust power level
     - Pause the treatment
     - Adjust the treatment plan
     - Halt the treatment

**Figure 125. Checklist: Monitored items**

During HIFU ablation, the top two images shown on the screen are real-time images that display updates during HIFU. The lower part of the screen displays the pre-procedure reference images at the corresponding location. As the ablation pulses are delivered, the ablated areas are shaded in red on the upper two images on the screen (Figure 126), unless Tissue Change Monitoring (TCM) is turned on, then the linear images will have the corresponding TCM color. (Figure 127)

Detailed explanations of each monitored parameter follows.
Figure 126. Live sector/linear images at top; reference sector/linear images at bottom.

Figure 127. Live sector/linear images with TCM turned on

WARNING
Pause or stop ablation if the patient moves; realignment of the rectal wall is needed.
CAUTION

If for any reason, there is an urgent need to pause the procedure, depress the Emergency Stop button on the console immediately (Figure 128).

Patient or Prostate Movement

HIFU is a dynamic procedure that requires adjustment of energy within the prostate gland. Continuous comparison of the real-time images and the reference images is essential to ensuring that the ablation is always being applied as it was planned. In the event of prostate movement or swelling, the live image will differ from the reference image below it. When changes are observed, pause or stop ablation and click on Edit Treatment Plan in the HIFU Power box (see yellow arrow Figure 129). Review the images prior to restarting the HIFU. Repositioning the probe after zone completion may be necessary if complete coverage from apex to base cannot be achieved.
The grid button is activated by selecting *Image Options* from the drop-down menu in the *Tools* feature (upper right-hand corner), and then select *Grid*. A one-centimeter grid will appear in all live and reference images and may be utilized in comparing screens and aid in identifying gland movement (*Figure 130*, inset magnified for detail).

---

**NOTICE**

If the patient moves, pause ablation and use the stack tool to verify energy is still being delivered to the desired areas.

The *Grid* button is a tool useful in monitoring prostate movement. Press the *Grid* button to activate a 1 cm grid across all transverse and longitudinal images. Press the *Grid* button again to toggle off. (*Figure 130*).
Tissue Reaction

“Popcorn” are echogenic changes caused by HIFU ablation indicating cavitation (also reported as “Uchida” grades). “Popcorn” is separated into three grades as follows:

**Grade 1:** small, non-overlapping hyperechoic regions contained within the ablation zone

**Grade 2:** contiguous hyperechoic regions (connecting to adjacent ablation sites) within the ablation zone (Figure 131).

**Grade 3:** large hyperechoic regions or micro bubble clouds appearing outside the ablation zone.

The dosage levels or energy should be adjusted to achieve regular “popcorn” Grades 1 and 2 within the target ablation area every two-three HIFU pulses.

If more than two consecutive HIFU pulses produce Grade 2 popcorn, decrease power by 1-2 W.
If Grade 3 popcorn appears, pause ablation until the “popcorn” grade 3 is no longer apparent in the image Figure 132).

**Near Field Changes**

It may be necessary to modulate energy due to near field changes.
The near field is any tissue between the transducer and the ablation zone/target tissue. Near field changes are defined as any hyperechoic changes on the ultrasound images seen in this near field zone.

These types of changes can cause a deterioration of image quality in the ablation zone (Figure 133). In order for tissue to be ablated with HIFU, it must be well visualized in the ultrasonic image.

![Figure 133. Near field change](image)

**WARNING**

Near field changes distort image quality and impair ablation:

Near field changes suggest there is excessive energy absorption between the transducer and the ablation zone; this can result in unintentional heating of the rectal wall. It may also mean energy is absorbed in the near field and does not get transmitted to the target tissue.

What should be done about near field changes?

- If near field changes are observed during HIFU ablation, decrease power in 1 watt increments.
• If the changes persist, press the Pause HIFU button and activate longitudinal imaging by clicking the sagittal scan button. Monitor images until the near field changes have resolved; pause a minimum of 2 minutes.
• Do not take new reference images or adjust/modify the stack while near field changes are present as this will distort the extent of the changes.

Power Dosage

Power must be adjusted based on tissue response and rectal wall distance. The ablation dosage delivered during HIFU ablation should be guided by image feedback. During the procedure, the user must adjust power to correspond to the rectal wall distance, since it will vary within an ablation zone. Setting up the initial probe placement so that the rectal wall is flat with minimal slope will minimize this variation and the need to adjust power.

Rectal Wall Distance during ablation

The average RWD of the live and reference images should be monitored during ablation (Figure 134).

If the difference in average rectal wall distances of the live image versus the reference image in the sagittal window exceeds 0.2 cm:

• Press Pause HIFU button.
• Activate longitudinal imaging by clicking the sagittal scan button for real-time visualization.
• Adjust the stepper up or down to match the rectal wall distances or add or subtract water to sheath bolus.
• Once completed, select play button to resume ablation.
The rectal wall distance (RWD) is the distance from the transducer to the rectal wall (rectum). In order to get an accurate measurement which is calculated from the longitudinal image, adjust the DCG gains to clearly depict the rectal wall.

Physicians should verify that the chevrons are located along the rectal wall-sheath boundary. If these markers are not along the boundaries, adjust the DGC settings and master gain until the markers track the rectal wall.

The RWD display on the longitudinal image includes several important items, labeled in Figure 136, and discussed below.

At each of the 15 longitudinal ablation locations (every 0.3 cm), the distance to the rectal wall is calculated in centimeters. A chevron is drawn on top of the longitudinal cross section for each measurement. Together, the 15 indicators represent the position of the rectal wall.
WARNING

The rectal wall distance (RWD) measurements are VERY dependent on the DGC setting. Poor image quality in the near field results in inaccurate RWD measurements. It is imperative to verify that the green chevrons are aligned along the entire length of the rectal wall.

The teal number displays the average RWD in centimeters. If the average rectal wall distance is greater than or equal to 1.25 cm, then a green lighted dot is displayed to indicate there is enough room to flip the transducer. If the red lighted dot is displayed, the transducer may not be able to flip (Figure 136) and should not be attempted as this may cause a rectal wall injury. A solid green line is displayed on the screen at 1.0 cm.

One of the 15 chevrons is displayed in white (the other 14 are green). The white chevron indicates the rectal wall distance at the next location that will receive the next HIFU ablation shot. The white number is the rectal wall distance that corresponds to the white chevron indicator on the longitudinal image (Figure 136).

NOTICE

Rectal Wall Distance:

To treat the RWD should be greater than or equal to 0.8 cm. If the distance between the rectal wall and the transducer is close to its upper limit (2.0 cm for the 4.0 cm transducer or 2.3 cm for the 3.0 cm transducer), a dashed yellow warning line appears on the image. If the RWD exceeds its upper limit, a dashed red line appears on the image and an alert message will pause ablation (Figure 137).
The physician should monitor the entire ablation procedure and should not leave the room during the procedure.
WARNING

The user must monitor the screen display during the entire procedure to watch for any evidence of patient movement or any echogenicity developing near the rectal wall or the near field on the updated images or high RIM™ value.

If the patient moves during the procedure, click on the “Pause HIFU” button to pause the ablation. Re-image the prostate, and verify the ablation plan before restarting the HIFU procedure.

RIM (Reflexivity Index Monitor)

The RIM box measures the pixel brightness level of the image as seen in the yellow rectangular RIM box in both the live and reference sagittal images (Figure 138). The software compares the image in the RIM box between the ablation and reference images. The software displays a numerical RIM value as the pixel brightness level within the yellow box changes.

In order for the RIM to be accurate, the average rectal wall distances between the ablation and reference images must be within 0.2 cm.
**WARNING**

A rising RIM value suggests that the region within the box in the ablation image is potentially accumulating heat which could damage the rectal wall.

The RIM status will display an indicator in green, yellow, or red zone(yellow arrow, Figure 138). Green indicates normal values. If the RIM value reaches yellow ("caution" level), evaluate for the cause. Check the RWD and correct as necessary.

Red indicates out of tolerance and the software will automatically halt ablation. This condition requires the user to investigate and remedy cause. Note: User may choose the “RIM, RWD, and RVB display option from the drop-down “Tools” menu and observe various monitored parameters including RIM value (red arrow, **Figure 138**)

**NOTICE**

If rectal walls are mismatched (not within 0.2 cm tolerance), the RIM number may be falsely elevated. It may be necessary to adjust the stepper or water in the probe tip to match the rectal wall distance in the ablation and the reference images while scanning live in the sagittal plane.

**DO NOT DO THIS WHILE ABLATING.**

**WARNING**

Pause ablation, select image scanning and confirm that both reference and actual image displayed on the screen are from the same location before making any adjustment .

If the RIM value remains elevated after matching the rectal wall distance, this may be an indication of heat buildup. Ablation should remain paused until the tissue returns to a baseline level and the condition is resolved. **Figure 139** illustrates correctly positioned RIM boxes.
Figure 139. Correct positioning of RIM box with the rectal wall/sheath interface near the bottom of the box.

WARNING

It is not appropriate to adjust the master gain slider or the individual DGC sliders to artificially decrease RIM value.

CAUTION

DGC sliders should not be adjusted after the start of the HIFU ablation. This could change the rectal wall baseline of the reference images and impair the RIM from working properly.
RIM Box Adjustment

The RIM box adjustment feature allows the user to define the size of the RIM Box. Adjust the size of the box by activating linear imaging after one shot of HIFU.

TCM

For details on tissue change monitoring software, please see Chapter 12.

Probe temperature

Continuously monitor the probe temperature to protect the rectal wall.

Interface between transducer and sheath

Reverberations

Reverberation, caused by sound bouncing between the rectal wall/sheath boundary and the transducer, indicates a blockage of ultrasound transmission. Ablation will not be effective if reverberation is present. Should reverberation occur, as indicated by a series of white marks across the image (Figure 141), immediately pause the procedure and remove the obstruction before resuming ablation. If a reverberation is present in the ablation zone, the software will detect it, turn the RVB indicator red, and display an alert message. The user will need to take appropriate action to resolve the cause of the reverb. Since reverb is generally created secondary to an interface at the rectal wall sheath boundary due to stool, mucous, gel, air, etc., the user will need to pause ablation and clear the obstructive interface before restarting ablation.
Figure 141. Reverberations result from sound bouncing between the rectal wall/sheath boundary and the transducer.

**WARNING**

NEVER ablate in the presence of reverberation. The ultrasound will be blocked at the rectal/sheath boundary and the ablation will be ineffective.

**Calcifications**

Patients with calcifications (hyperechoic structures which produce a shadow) should be ablated carefully. Depending on the size and density of the calcification(s), the HIFU beam could be obstructed resulting in tissue that is not ablated.
**WARNING**

Calcifications that measure greater than 1.0 cm may block ultrasound waves from reaching ablation areas resulting in tissue that is not ablated. Calcifications within 1.0 cm of the rectal wall are especially of concern since deflection of ultrasound may cause rectal wall heating.

---

**Pausing, Adjusting and Stopping Ablation**

The user may choose to pause ablation because of a shift in the gland position secondary to swelling or patient movement causing planned ablation sites that are no longer within the gland.

To pause HIFU ablation, click on the pause button located at the bottom middle of the screen in the HIFU Power box (Figure 142).

The user may then make necessary adjustments in the appropriate menus before resuming ablation.

---

![Figure 142. Start and Pause HIFU buttons](image)
Resuming a Paused Ablation

To resume the HIFU ablation, click on the Start HIFU button located at the bottom middle of the screen in the HIFU Power box (Figure 142). A dialogue box for confirming start of HIFU ablation will appear on the screen; click “YES” to continue.

Emergency Stop Procedure

In case of an emergency, press the red emergency stop button (E-Stop) situated on the monitor arm (Figure 143). The ablation power supply is turned off, HIFU ablation is suspended, and the Sonachill is stopped. The emergency stop button status is indicated on the screen by a small icon situated in the lower right-hand corner of the ablation screen (Figure 144).

![Emergency Stop Button](image)

**Figure 143. Emergency stop button**

![Emergency Stop Icon and Stop Button Icon](image)

Emergency Stop icon is black and gray when button is not depressed  
Stop button icon is red when button is depressed  

**Figure 144. Emergency stop button icon indications**

To resume ablation, turn the red emergency stop button clockwise. Restart the Sonachill unit by choosing “Pump and Chiller Status” from the drop-down menu in the Tools list. Click the Start HIFU button in the HIFU Power box. A dialogue box for confirming start of HIFU ablation will appear on the screen; click “YES” to continue. Do not run HIFU with the Sonachill unit turned off.
**System Error/Alerts**

If during HIFU ablation or during ablation planning any alert condition is detected, *Sonablate* software will automatically pause ablation and the alert icon situated in the lower left-hand corner of the screen will start flashing and a “List of Alarms” dialogue box will display the list of alert messages (**Figure 145**). When displayed, follow instructions on the screen.

![Figure 145. Display of alert messages](image)

Once corrective steps have been taken, the error message can be erased by clicking on the clear button in the lower part of the message box. The ablation can be resumed by clicking the Start HIFU button. *Sonablate* software will not resume ablation until the error has been cleared.

**Treatment Zone review**

Ablation stops automatically when a zone is complete. The following screen appears (**Figure 146**):

![Figure 146. Treatment zone complete](image)

Due to small unnoticeable movements and swelling during HIFU, ablation should be reviewed and revised after every zone. This must be done before proceeding to the next zone. To review and revise select *Edit Treatment Plan* in the HIFU Power box (**Figure 147**).
A dialogue box will appear; choose “Yes” to change to stack mode (Figure 148).

The following dialogue box will appear (Figure 149). Choose “Yes” to update volume stack before reviewing and revising.

**Add ablation shots (if necessary)**

Images will update (Figure 150) and the user can review ablation, re-ablate any area not properly ablated and add additional ablation as necessary utilizing the same methods used
during initial ablation planning (see Plan a Zone Section: Refine Treatment Step). After review and addition of ablation (if necessary), click on Edit Treatment Plan (Figure 151) located in Layout box to return to Treat a Zone screen. Next, select the Start HIFU button if ablation has been added and HIFU ablation will resume. If upon review no ablation was added, finish the check list to continue to the next zone.

Figure 150. Updated images for ablation review and edit

Figure 151. Choose Edit Treatment plan to return to Treat a Zone screen

Once ablation is finished within a zone, complete the checklist (Figure 152).
4. Using live imaging, review the results of the zone treatment
5. If needed, add treatment shots and repeat from step 1
6. Zone treatment complete
   - If more treatment zones remain, go to the Position Probe workflow step
   - If this was the last treatment zone, go to the Finish Treatment workflow step

Figure 152. Checklist: End of zone checklist

Upon completing checklist, the current zone will be erased and the software will move to Position Probe screen to position probe for the next zone (Figure 153).

If additional ablation zones are required, plan the next ablation zone by repositioning the probe as needed and follow checklist steps for the new ablation zone. If it is necessary to overlap ablation zones, ensure that the majority overlap of re-ablated tissue is between the anterior or middle zone of the prostate.

Figure 153. Select Position Probe from flowchart

Ablating the Posterior Zone

WARNING

When ablating the posterior zone of the prostate, it is important that the rectal wall, as well as the Denonvilliers’ fascia, is not included within the ablation zone.

If the shape of the prostate does not allow ablation of the entire zone in one pass without ablating portions of the rectal wall or Denonvilliers’ fascia, it may be necessary to incrementally
treat the posterior zone in order to adjust for different rectal wall heights. At the apex, the rectal wall tends to “tent upwards” and away from the transducer. It is important to position the ablation so as to always maintain ablation anterior to the Denonvilliers’ fascia in this anatomic area.

NOTICE

Conforming HIFU to posterior zone:

The rectal wall distance may be shorter in the center of the gland than it is laterally, which means that the posterior zone may need to be ablated in more than one step to adjust for the different rectal wall distances. Splitting up the posterior zone ablation prevents placing HIFU lesions below Denonvilliers’ fascia laterally, and at the same time prevents applying excessive HIFU to tissue outside the gland.

How to treat the posterior zone in multiple zones:

- First, the prostate should be positioned for the posterior zone.
- Plan the first portion of the ablation to cover as much of the gland as possible without exposing the rectal wall or Denonvilliers’ fascia to ablation.
- After this zone is complete, adjust the rectal wall height using the stepper or water in probe tip so that the unablated tissue is within the ablation zone without any exposure to the rectal wall or Denonvilliers’ fascia.
- Repeat these steps until all prostatic tissue in the posterior zone has been ablated.
Figure 154. All ablation is anterior to Denonvilliers’ fascia

WARNING

When positioning for the posterior zone, all ablation must be anterior to Denonvilliers’ fascial plane. Never direct ablation below the Denonvilliers’ fascia into the rectal wall (Figure 154).
CHAPTER 11: FINISH TREATMENT

CAUTION

Deflate the original volume of water from the sheath before removing the probe tip from the patient’s rectum.

After the final zone is ablated, ablation stops automatically. The following screen will appear (Figure 155). Select the highlighted Finish Treatment button from the flow chart.

![Flow Chart for Treatment](image)

Figure 155. Select Finish Treatment

The following treatment summary and final checklist screen will appear (Figure 156).
Follow checklist instructions, checking-off boxes as each step is completed (Figure 157).

**6. Finish treatment**
- 1. Turn pump off
- 2. Deflate the sheath by withdrawing water
- 3. Disconnect the probe connector from the console
- 4. Remove the probe from patient
- 5. Remove the probe from the probe arm
- 6. Clean and disinfect the probe
- 7. Remove the probe arm from the table
- 8. Exit the Sonablate software

**Figure 157. Final treatment checklist**

**Turn Pump Off**

Turn off the pump by selecting *Turn Pump Off* in *Pump and Chiller Status* box.

**Deflate the Sheath by Withdrawing Water**

Deflate the probe sheath (while still in the patient) by withdrawing water utilizing the syringe attached to the reservoir. NOTE: All the water that was injected since the insertion of the probe should be removed.
**Disconnect the Probe Connector from the Console**

Disconnect the probe connector from the console prior to removal of the probe tip from the patient’s rectum. This will put the transducer in a free state so motors are disengaged.

**Remove the Probe from Patient and Probe Arm**

Remove the probe from the patient, then remove the probe from the probe arm collar.

**Clean and disinfect or sterilize the probe**

Refer to Cleaning and Disinfection and Sterilization procedures in Chapter 16 for further steps.

**Remove the probe arm from the table**

The probe must be held securely while a technician removes the articulating arm and Stepper from the table.

**Exit the Sonablate software**

Once the cleaning and disinfection procedure is complete and any necessary administrative tasks are finished, complete the checklist by checking box # 8 to exit Sonablate software. The following screen will appear (Figure 158). Click on “Exit” circle.

![Figure 158. Exit flowchart](image)

The following dialogue box will appear. Choose “Yes” to exit (Figure 159).
Select the Windows shutdown procedure from the Start button in the lower left corner of the screen (Figure 160). Select the Shutdown action from the dialogue box.

The monitor will turn black and the status LED on the monitor will turn from green to yellow. At this time, turn the power off by flipping the switch located on the back panel of the console. (Figure 161)
NOTICE

To reboot the console computer after powering OFF the Sonasource console, it is necessary to wait at least one minute prior to powering the console back ON. Failure to wait can result in the computer not rebooting after switching ON the console.
Tissue Change Monitoring (TCM)

Introduction

Tissue Change Monitoring (TCM) is a tool used to assist the physician in monitoring and recording changes which occur real-time during HIFU.

Sonablate ultrasound images are created from echoes of high frequency sound waves from tissue inside the body. These signals are also known as radio frequency (RF) signals. The RF signal is converted to the B-mode ultrasound image by Sonablate hardware and software.

The tissue change monitoring tool measures change from the focal zone of the HIFU transducer pre-HIFU and post-HIFU.

TCM results are mapped into different colors overlaid on Sonablate live linear ablation screen. The colors represent the relative amount of the tissue change shown in the pre-HIFU vs. post-HIFU RF signals. The color overlay appears on Sonablate in real-time following each HIFU exposure.

TCM readings are available at all times during Sonablate HIFU procedure, and are displayed on both the 2D and 3D images.

The RF signal quality is important to the TCM calculations. Depth Gain Compensation (DGC) and Master Gain must be properly adjusted to optimize effectiveness of TCM. See: Plan a Zone section: Adjust RF Signal Quality

TCM Displays and Controls

TCM color is displayed by selecting “Image Options” from the “Tools” drop-down menu (Figure 162 A) Next, click on “TCM” to display TCM color overlays (Figure 162 B) instead of default red ablation overlays (Figure 162 C)
**Figure 162.** A: TCM display button. B: TCM overlay. C: Default red overlay

**TCM color coding:**

Grey indicates no TCM calculation was made because *(Figure 163)*:

- Poor RF signal will show as grey, indicating no TCM calculations are possible at the site.
- The RF signal was either too low (image too dark) at this site to make the TCM calculation
- HIFU ablation was paused after the site was ablated but before the TCM calculation could be accomplished

Green indicates TCM did not see enough change in the RF signal pre-HIFU vs. post-HIFU because *(Figure 163)*:

- The site may not have been adequately ablated
- The site may have been already ablated so no additional change in RF signal occurred
- Some tissue properties at this site prevented a change in RF signal (for example: near field blockage of the ultrasound or a calcium deposit)

Yellow indicates a moderate change in RF signal *(Figure 163)*:

- The site appears to be adequately ablated

Orange indicates TCM saw a greater change in RF signal *(Figure 163)*:

- The site appears to be ablated
The transparency level of TCM color overlay can be adjusted to various levels depending on user preference. Utilize the “Zone Brightness” slider (yellow arrow) in the “Image Options” tool box to adjust the transparency level. More transparent (Figure 164). Less transparent (Figure 165)
TCM statistics and RF signal quality values can be displayed by selecting “TCM – Tissue Change Monitoring Calculations” from the drop-down Tool menu. The display will show total HIFU ablation cycles and cumulative values for each color (Grey, Orange, Yellow, Green) expressed as percentages and raw cycle numbers for the current zone (Figure 166). The numbers will reset to zero at the beginning of a new zone. The RF Signal Quality is also displayed.

**NOTICE**

Due to rounding, the total of the Green, Yellow, Orange and Grey percentages may be different to 100.

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**Neuro-Vascular Bundle (NVB) Detection**

**Introduction**

This is a group of nerves and blood vessels surrounding the prostate. Preserving the NVB is considered important for preventing the potential adverse effect of impotence.
The NVB detector uses a pulse-wave Doppler technique to locate blood vessels around the prostate, allowing the physician to spare the blood vessels in the ablation zone.

**NOTICE**

**Disclaimer:** Use the NVB detector for HIFU ablation planning purposes ONLY.

If quantitative blood flow measurements for diagnosis are desired, do not use Sonablate.

This device may not be used as a diagnostic-imaging device.

The NVB detector uses the same imaging transducer as regular Sonablate ultrasound imaging mode. After the pre-planning imaging, NVB detection (if desired) is accomplished in the “Plan a Zone” mode. The display of the blood flow area is overlapped on the B-mode images in transverse (sector) and longitudinal (linear) planes. The indication of the flow is displayed in different colors presenting the flow directions and intensity of the estimated mean velocity.

According to the NVB indications on the images, the physician can plan the HIFU lesions avoiding these areas at his/her discretion. NVB is typically utilized when planning ablation in the posterior zone since the neurovascular bundles are typically located at the gland’s posterior-lateral margins. However the feature may be utilized in any zone to aid in the detection of blood flow. See sample NVB screen in Figure 167.

![NVB Screen](image)

**Figure 167. NVB Screen**
NVB Detection Controls

NVB detection is accomplished while in the Plan a Zone screen before planning ablation sites. To start detection choose NVB – Doppler for Neurovascular Bundle Detection from the Tool drop-down menu. Three Doppler tool boxes will appear (Figure 168)

![NVB tool box]

Figure 168. NVB tool box

The following controls are available for interaction with the NVB detector. Any controls shown on these screens without explanation are not directly NVB related, and behave as described in their respective parts of this manual.

Note: During NVB detection live ultrasound imaging is not available. You must first select the imaging plane before starting NVB detection. NVB detection is typically accomplished in the transverse image plane; however detection may also be accomplished in the longitudinal image planes.

Acquire an image plane to sample with NVB. Select the button on the right in the Stack/Live box (Figure 169), and then choose sector or linear plane in the Imaging box (Figure 169). Again, NVB detection is generally sampled in the sector plane.

![Stack/Live and Imaging]

Figure 169. Live sector scanning selections

Once an image plane is chosen, select NVB Doppler from the Doppler Gate box (Figure 170)
Utilize the slider at the top of the selected image pane to place the Doppler sampling gate at the desired sampling site (**Figure 171**, yellow arrows). The four arrow controls may be used to fine tune Doppler gate position to find blood flow (**Figure 172**). Detected vascular flow within the Doppler gate (magnified inset **Figure 173**) will fill with color: reds, oranges, yellows or blues, depending on direction and velocity.
Numerous Doppler samples should be taken bilaterally at various sector (or linear) planes in order to accurately portray the vascular course. Once the vascular anatomy has been mapped the user may continue with planning ablation sites in the Plan a Zone (See Plan a Zone section). The Doppler mapping will allow the user to avoid NVB’s during the refining of ablation (Figure 174).

**NVB Peak vs. Live Display**

There are two view selections for the NVB detected readings and displays. One shows “live” readings and the other shows “peak” readings.
Peak readings hold the largest reading found at this location. Peak readings are useful for holding the readings on the screen when you scan multiple gates.

Live readings change many times each second with the flow readings. Live readings are useful for listening to the varying (pulsing) signal at one location.

Peak readings are active when the View Peak button is green (on). Live readings are active when the View Peak button is gray (off) (Figure 175).

![Figure 175. View Peak on (left); View Peak off (right)](image)

**Doppler Audio**

Doppler audio volume can be adjusted utilizing the slide pod in the Doppler Audio box or muted by clicking the mute button (Figure 176). An audio file may be recorded by clicking on the Record button. A raw sound graph can be displayed by selecting the Show Graph button (Figure 176).

![Figure 176. Doppler Audio](image)

**Doppler Parameters**

Several low-level adjustments/controls are available in the Doppler Parameters box (Figure 177).
There are four sliders for Doppler settings: two gain sliders for display and ultrasound echo, a noise threshold slider, and a Doppler pulse repetition rate (PRF) slider. Those controls can be adjusted to optimize the received Doppler signal and NVB readings and display.

In general, higher noise threshold settings (Threshold) help to avoid false readings on the display. The higher ultrasound echo gain (E Gain) and color gain (S Gain) can increase the amplitude in the received Doppler signal and enhance the color brightness to the highest NVB readings. Adjust the PRF slider (PRF(KHz)) to reduce some strong reflected noise in certain situations. To restore all the sliders to their saved values, press the default button.

![Doppler Parameters settings](image)

**Figure 177. Doppler Parameters settings**

**HIFU Cycle Alternatives**

**Introduction**

Sonablate has two ablation duty cycles that can be utilized during delivery of HIFU ablation. Both ablation duty cycles are 9 seconds long but each has different ablation on/off times:

- the default cycle (3 seconds on / 6 seconds off), and
- the alternative cycle (3 seconds on, 3 seconds on, 3 seconds off).

**NOTICE**

While the 3on/6off duty cycle is always available, the 3on/3on/3off duty cycle’s availability is configured by the software license in use.

Use of the 3on/3on/3off duty cycle outside of recommended clinical parameters requires modified licensing.

**Default Ablation Duty Cycle 3on/6off**

The default Sonablate HIFU duty cycle for both 4.0 cm and 3.0 cm focal length transducers is 3 seconds of HIFU “on time” followed by 6 seconds of HIFU “off time” (**Figure 178**). This cycle
allows added cooling time in the posterior zone; and can be used in the presence of near field heat in other zones.

During the HIFU “off time” the following occurs:

- Live transverse image is refreshed
- Live longitudinal image is refreshed
- RIM® is calculated from the longitudinal images
- Rectal wall distance (RWD) measurements are made
- Reverberation detection and testing is performed

![Figure 178. Default HIFU Cycle 3 On/ 6 Off](image)

**Alternate Duty Cycle 3on/3on/3off**

The alternate duty cycle treats two adjacent ablation sites before the HIFU “off time” and is available only for the 4.0 cm focal length transducer. For this purpose, Sonablate software briefly turns the power off to the amplifier, while the transducer is moved to the next ablation site in the ablation plan.

This alternate pulse cycle is 3 seconds of HIFU “on time” followed by 0.5 seconds of HIFU “off time” (for repositioning) followed by 3 seconds of HIFU “on time” followed by 3 seconds of HIFU “off time”. Two sites are ablated for each 3on/3on/3off HIFU cycle (Figure 179).

During the HIFU “off time” the following occurs:

- Live longitudinal image is refreshed
- RIM™ is calculated from the longitudinal images
- Rectal wall distance (RWD) tests are made
- Reverberation detection and testing is performed

![NOTICE]

The transverse image is refreshed only when the transverse (angle) position changes.
Figure 179: Alternative HIFU Cycle 3 on/3 on/3 off

NOTICE
The 3on/3on/3off alternate HIFU cycle provides fewer image updates during the HIFU ablation as compared to the default HIFU cycle.

Choosing the “3on / 6off” option in the HIFU Power box causes the software to obtain a longitudinal and a transverse image update after each HIFU “on time”.

Imaging Comparison Between HIFU Cycles

Sonablate ablation order may be described as a “longitudinal first” order. This means all the longitudinal sites for a given transverse (angle) position are ablated in order starting at the apex of the prostate and proceeding towards the bladder neck. Sonablate then moves to the next transverse (angle) position and repeats this process.

The 3on/3on/3off HIFU cycle eliminates the transverse image update during HIFU “off time”. This does not diminish the data available to the users for evaluating ablation safety and efficacy.

The 3on/3on/3off HIFU cycle does decrease the time available for studying the longitudinal image before subsequent HIFU lesions are created. Two design controls help mitigate this potential risk:

- During Sonablate certification, physicians are initially trained using the standard pulse series (3on/6off).
- Choosing the default 3on/6off slows the HIFU process providing for better observations.
CHAPTER 13: ADDITIONAL SCREENS/FUNCTIONS/INDICATORS

Included below are various features that were not detailed in the instructional text secondary to keeping instructions concise and as brief as possible.

**Pump and Chiller Status Box**

The *Pump and Chiller Status* box ([Figure 180](#)) is default displayed in the *Prepare System* screen. The Pump and Chiller Status box may be displayed optionally in the *Treat a Zone* screen by selecting the feature from the drop-down *Tools* menu.

When the chiller power cord is connected to *Sonablate* the *Connected* indicator button will be green. When the *Turn Pump On* button is activated the *Pump* indicator button will be green. The temperature indicator light will remain yellow or red until the water is chilled to a predetermined range. Ablation will not start if the temperature range is in the yellow or red status.

![Figure 180. Pump Chiller Status box: Off (left), On (right)](image)

**Probe Information Box**

The *Probe Information* box ([Figure 181](#)) is default displayed in the *Prepare Systems* screen. When the probe connector is attached to *Sonablate*, the Probe indicator turns green and the
four digit probe serial number is displayed. The cumulative transducer run time is shown in minutes. The run time is the actual amount of HIFU on time (“firing”).

![Probe Information](image)

**Figure 181. Probe Information status**

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas sterilization other than the Ethylene Oxide sterilization cycle described in <a href="#">Chapter 16</a>, ultraviolet sterilization, heat sterilization, autoclaving and chlorine bleach may damage the <strong>Sonablate</strong> probe.</td>
</tr>
<tr>
<td>The entire probe is not watertight and must not be submerged in water or any other liquid.</td>
</tr>
<tr>
<td>After each patient procedure and before disinfecting the probe, treat the sheath, gloves, and any waste materials as infectious.</td>
</tr>
<tr>
<td>Dispose of the waste material in accordance with infectious waste control procedures of the facility.</td>
</tr>
<tr>
<td>Reference the Cleaning and Disinfection section of this manual <a href="#">Chapter 16</a> for additional information.</td>
</tr>
</tbody>
</table>

---

**Screen Layout Options In Preplan Zones Section**

The default screen in the **Preplan Zones** section is displayed in **Figure 182**. Note the left hand button in the **Layout** box is selected (green).
To select the optional display select the right hand button in the Layout box (Figure 183). The user may zoom alternate images into the large window by selecting the Zoom button next to the desired image (yellow arrows).
Preplan Zones Box

The user may utilize options in the *Preplan Zone* box to override the default automatic number of zones selected and/or to override the default zone positions. The software automatically chooses the number of ablation zones and zone overlap based on gland height. The user may override this by selecting the drop-down list in the *Zone Count* menu (yellow arrow, Figure 184). The user may now choose the desired number of ablation zones. The ablation zone color overlays in the images will automatically update.

![Figure 184. Zone Count choices in Preplan Zones drop-down menu](image)

The user may also override default ablation zone positions and overlap by utilizing the up/down arrows of any or all ablation zones (Figure 185). Appropriate transducer and zone names may also be chosen. Note: In most ablation scenarios, the default settings will suffice.

![Figure 185. Preplan Zone adjustments. User may adjust zone position (up/down arrows), transducer side (A/B), and zone description (Anterior, Mid-gland, Posterior)](image)
Transducer Box

The transducer may be flipped by selecting either Side A (4 cm) or Side B (3 cm) in the Transducer box (Figure 186). This function should be utilized during the probe tip debubbling process as well as choosing the appropriate transducer for a given ablation zone.

Drop-down Menu Options in Preplan a Zone Tools

Five options are available to the user in the Preplan a Zone section Tools drop-down menu (Figure 187). The Prostate Dimensions and Volume box is default to open in the Preplan a Zone section.

Checklist will display the section’s user checklist to aid in procedural steps.

DGC and NVB have been detailed in previous sections.

PID Settings should only be utilized by qualified service personnel.

Image Options contains numerous features to aid the user in the process of delivering ablation. Note: Image Options box is also available in Position Probe, Plan a Zone, and Treat a Zone sections.
Figure 188. Image Options box allows many feature manipulations

Select/deselect Grid to add/remove the 1 cm grid overlay on all four images to aid in detection of gland movement or swelling (note grid in magnified insert Figure 189).

Figure 189. Grid “on”. Note grid matrix (insert magnified for detail)

In Image Options box:

- Select/deselect NVB button to activate/deactivate display of NVB markings on image.
- Select/deselect Skittles button to activate/deactivate display of red “skittle” ablation dots.
- Select/deselect Rwd button to activate/deactivate display of 15 rectal wall tracking chevrons.
• Select/deselect Focus button to activate/deactivate display of the alternative ablation focal zone. If activated, user will see both focal zones (4.0 cm teal and 3.0 cm blue) simultaneously on all image screens. If deactivated, user will see only active ablation focal zone.

• Select/deselect TCM button to activate/deactivate display of TCM color overlay (orange, yellow, green, gray). If deselected, only red ablation lesions will be displayed.

• Select/deselect Tick Marks button to activate/deactivate display of millimeter/centimeter scales surrounding all image borders.

• Select Measurement Tool to obtain up to two measurements in each image screen. User may utilize to measure cysts, calcifications, various distances, etc. If desired, choose floppy disc icon (save) at bottom of screen to store image of measurements.

• Select Temporal Filter to filter out noise from the ultrasound image. Turn the Temporal Filter off while moving the probe. This will increase the image response and is advised if the organ being scanned is moving to reduce motion blur. Note: On a newer Sonablate system with the Motor Filter Assembly installed, the Temporal Filter button might have no effect. In this situation, keep the Temporal Filter button off.

• The Zone Brightness slider will adjust the brightness level of the ablation overlay box whether TCM colors or red ablation lesions (toward left for greater translucency; toward right for greater opacity).

• The RWD Brightness slider will adjust the brightness of the 15 chevrons tracking the rectal wall (toward left for greater translucency; toward right for greater opacity).

• Select Clear to erase gland images and measurements. The Clear button will NOT erase planned or ablated ablation zones or NVB markings.

**Drop-down Menu Options in Position Probe and Plan a Zone Tools**

Six drop-down menu options are available in Position Probe and Plan a Zone sections (Figure 190). These all have been detailed in previous sections. Each section defaults with the user checklist displayed to aid in procedural steps.
Screen Layout Options in Plan a Zone section

The default screen in the Plan a Zone section is displayed in Figure 191. Note the top button (default) in the Layout box is selected (green). Ablation can be planned and refined on any of these three options.

To select the second optional display choose the middle button in the Layout box (Figure 192). The user may zoom alternate images into the large viewing window by selecting the Zoom button next to the desired image (yellow arrows).
To select the third optional display choose the bottom button in the *Layout* box (Figure 193). The user may display four, nine, or sixteen images by selecting the 2x2, 3x3, or 4x4 respectively (see zoom inset Figure 193). The user can navigate through the images at various intervals utilizing the forward/reverse arrows in the bottom left hand corner (yellow arrow).
Drop-down Menu Options in Treat a Zone Tools

There are seven additional menu items in this drop-down menu (Figure 194) which were not available options in other sections. Five of these have not been previously described:

- Treatment Time
- RIM, RWD and RVB
- HIFU Amplifier Status
- HIFU Energy Calculations and
- RIM Box Adjustment.

![Figure 194. Drop-down Tools menu options in Treat a Zone section](image)

*Treatment Time* box displays three key ablation time components (Figure 195). The Therapy remaining in current zone and the Therapy completed in current zone are reset to zero at the end of each treatment zone. The first box displays total time projected to deliver treatment to the current zone. This will change if any ablations are added or deleted during the ablation of this zone. The second box displays the time of total treatment delivered thus far during the current zone. The third box displays the time of therapy completed over all zones. These times are not based on actual clock time, but on procedure ablation cycles (ablation on/ablation off cycles) and does not include pauses or delays during ablation.
**RIM, RWD and RVB box (Figure 196):**

*Reflectivity Index* provides status by displaying green, yellow, or red buttons and a raw ratio number. If the status button turns red the software will display an alert message, suspend ablation and a dialogue box will appear. The user must take corrective action (see previous *RIM* section).

*Average Rectal Wall Distance* provides status by displaying green, yellow, or red buttons and the average rectal wall distance in cm at a given linear sector. If the status button turns red the software will display an alert message, suspend ablation and a dialogue box will appear. The user must take corrective action (see previous *RWD* section).

*Rectal Wall Distance* provides status by displaying green, yellow, or red buttons and the rectal wall distance at the current point of ablation in cm at a given linear sector. If the status button turns red the software will display an alert message, suspend ablation and a dialogue box will appear. The user must take corrective action (see previous *RWD* section).

*No Reverberation Detected* displays green or red status. If reverberation is detected the status button will turn red. The software will display an alert message and suspend ablation. A dialogue box will appear. The user must take corrective action (see previous *Reverberation* section).

*HIFU Amplifier Status Box (Figure 197)*
For the default ablation cycle, the RF amplifier sends the ablation pulse for 3 seconds and then stops sending the ablation pulse for 6 seconds. This is also termed as “3 On and 6 Off”. During HIFU ablation, this is represented on the screen by a small indicator which flashes purple during the ablation on cycle. The power delivered is displayed in the watts box. There is a Countdown Timer, which shows the remaining time for the “On” and “Off” cycles.

**HIFU Energy Calculations Box (Figure 198)**

The first box displays the joules at the last single ablation delivery site. The second box displays the number of total ablation cycles. The total energy displays the cumulative ablation energy delivered. The fourth box displays the Energy density calculated by dividing the total energy by the prostate volume (if the prostate volume has not been calculated, then the energy density cannot be calculated).

**Treatment Progress box (Figure 199)** demonstrates the ablated and unablated sites during the ablation of the current zone. The example demonstrates a completed ablation.
Dynamic Range Setting

*Dynamic Range* is the vertical slider located at the right-hand side of the *DGC-Depth Gain Compensation* box (Figure 200) and is an aesthetic setting based on user preference. An image plane must be active (live scan) to make an image adjustment.
The user may choose overall high contrast (more distinct black/white tones) at the low-end of the numbered scale (see image on left set at “2” (Figure 201). Or the user may choose overall low contrast (more shades of gray) at the high-end of the numbered scale (see image on right set at “5”, Figure 201). Dynamic range adjustments will not affect the RF signal quality.

Figure 201. Dynamic Range: high contrast left (more blacks/whites); low contrast right (more shades of gray)

Ablation History Review

The ablation history review feature is useful for review during any part of the ablation. Ablation history review is activated by selecting the “H” icon at the bottom of the screen (Figure 202, magnified inset). A separate screen will open.

Figure 202. Ablation history review icon (magnified inset)

The history review feature saves the following screenshots:
- On entry and exit from each screen (Prepare, Position, Plan, etc.)
- When a screen’s checklist is completed
- Whenever there is an alert
- After any operation that changes the prostate dimensions and volume.
- After any operation that changes the positions or transducer settings on the Preplan a Zone screen
- For every HIFU shot (or pair of shots in 3/3/6) after TCM is computed
- At the end of a zone’s delivery to record TCM and ENERGY stats
- The user may also add screen shots at any time with the Save icon in the status bar at the bottom of the screen (disk icon)

The ablation history review default opens to the first saved screen. The user may choose one of four screen display options from the four icons at the bottom left screen (Figure 203, inset magnified): 1 to 1, Fit, Fit Width or Fit Height.

![Figure 203. Four screen display options (magnified inset, bottom left hand corner)](image)

To navigate through screen shots the user may utilize the horizontal slide pod (yellow arrow) or the forward/reverse arrows (red arrows) shown in Figure 204. If the image number is known the user may insert the image number in the white box (green arrow) and press keyboard enter to go directly to image.
The user may utilize the checklist guide in the right hand column (Figure 205) to identify what step the image was captured in. The step will be highlighted green. The numbers in parentheses shows the number of screenshots obtained in that step. The user may click on any step in the column to navigate directly to the first image in that step.

When viewing any image captured in the Treat a Zone section, a vertical gray summary column will display between the ablation screen and the checklist steps (Figure 205, highlighted by yellow box). There are four summaries that with cumulative data up to that point in ablation (Exception: RF Signal Quality is a data snapshot of the RF data for that ablation site). The summaries are: Treatment Time, TCM, RF Signal Quality and HIFU Energy Calculations.

To close the ablation history review display, select Close icon in bottom right hand corner, as shown below (highlighted yellow box).
Figure 206. Close ablation history review
CHAPTER 14: ABLATION CHECKLIST

This is a convenient, at-a-glance collection of an example of the checklist steps displayed throughout the user software interface.

Prepare System

1. Prepare System
   - 1. Enter procedure information
     - 1. Enter or confirm site name
     - 2. Enter doctor name
     - 3. Enter patient ID
     - 4. Choose procedure type
   - 2. Initialize probe
     - 1. Plug in probe
     - 2. Observe home sequence
   - 3. Dress probe
     - 1. Probe sheath
     - 2. O-rings
   - 4. Initialize water path - Sonachill
     - 1. Attach tubing set to the Sonachill
     - 2. Open valves
     - 3. Turn pump on
     - 4. Fill water reservoir
     - 5. Fill water syringe
     - 6. Turn pump off
   - 5. Initialize water path - Probe
     - Attach tubing set to the probe
     - Turn pump on
     - Use syringe to adjust water level of the sheath to neutral
     - NOTE: You will remove air bubbles from the probe tip, water reservoir and tubing on the next screen
   - 6. Preparation complete

Preplan Zones

2. Preplan Zones
   - 1. Remove air bubbles from the probe tip, water reservoir and tubing
   - 2. Prepare patient
     - 1. Patient enters the room
     - 2. Introduce appropriate sedation or anesthesia
     - 3. Position patient in modified lithotomy position
3. Prepare probe
   - Secure the stepper to the table rail
   - Secure the probe arm to the stepper
   - Insert the probe into the patient
   - Secure the probe to the probe arm

4. To view live sector images, do one of the following:
   - Choose the sector image button in the Scan box
   - Move the slider above the linear image to the sector position you wish to view
   - Select a button below the live sector image to change the image position

5. To view live linear images, do one of the following:
   - Choose the linear image button in the Scan box
   - Move the slider above the sector image to the linear position you wish to view
   - Select a button below the live linear image to change the image position

6. Alternating between live sector and linear images adjust the probe position and orientation, the stepper and the DGC sliders such that:
   - The entire prostate is visible from base to apex
   - The urethra is visible in the midline linear view
   - The prostate is centered in the sector views
   - The rectal wall is parallel to the probe
   - The rectal wall indicators are between 1.0 cm to 2.0 cm away from the transducer face to avoid alert messages and forced duty cycle

7. Verify
   - The prostate is fully visible within all sector views
   - The prostate's base-apex dimension is fully visible within all linear views

8. Locate and display the sector image with the largest vertical extent
   - Select live linear imaging
   - Slide the horizontal slider above the linear image to the tallest point of the prostate

9. Measure the prostate on the sector image with the largest vertical extent
   - Choose Use Mouse in the Prostate Dimensions and Volume box (if necessary)
   - Use the mouse to click on the Anterior and Posterior of the prostate
   - Use the mouse to click on the Right and Left of the prostate
   - Use the mouse to click on the Base and Apex of the prostate
   - Verify that the prostate's AP dimension is less than or equal to 4 cm
   - After measurements are complete, click on the Lock button in the Prostate Dimensions and Volume box
10. Use syringe to add water in order to compress the prostate (if applicable)

11. Readjust the probe position and orientation, the stepper and the DGC sliders (if needed) such that:
   - The entire prostate is visible from base to apex
   - The urethra is visible in the midline linear view
   - The prostate is centered in the sector views
   - The rectal wall is parallel to the probe
   - The rectal wall indicators are between 1.0 cm to 2.0 cm away from the transducer face to avoid alert messages and forced duty cycle
   - The prostate is fully visible within all sector views
   - The prostate's base-apex dimension is fully visible within all linear views

12. Preplan ablation zones on the sector image with the largest vertical extent
   - Locate and display the sector image with the largest vertical extent
   - Use the mouse to mark the outline of the prostate
     - Single mouse clicks add points to the outline
     - Click-and-drag near a point moves the point
     - Click-and-drag near a segment adds a point
     - Double-click near a point deletes the point
     - Clicking on the start point closes the outline
     - Double-clicking away from a point or segment adds a point and closes the outline
     - Upon closing the outline, the software suggests the number and position of treatment zones
   - After closing the outline, confirm or change the suggested treatment zones

13. Zone preplanning complete

**Position Probe**

3. **Position Probe**
   - 1. Locate and display the sector image with the largest vertical extent
      - Select live linear imaging
      - Slide the horizontal slider above the linear image to the tallest point of the prostate
   - 2. Observe that the prostate outline created in the Preplan Zones workflow step is displayed on the sector image
   - 3. Adjust the probe position
      - Select live sector imaging
Use the stepper to adjust the probe up/down and left/right to center the image prostate in the outline. Use one of the following guidelines depending upon which treatment zone you are positioning:

- If you are positioning the probe for the first (most anterior) treatment zone, center the prostate left/right and match the top of the prostate with the top of the outline.
- If you are positioning the probe for the middle zone(s), if any, center the prostate left/right and up/down in the outline.
- If you are positioning the probe for the last (most posterior) treatment zone, center the prostate left/right and match the bottom of the prostate with the bottom of the outline.

4. Probe positioning complete

Plan a Zone

4. Plan a zone
   1. Update the volume stack
      - You are prompted to update the volume stack upon entry to this screen
      - To update the volume stack later, choose the volume stack button in the Stack/Live box and then the volume scan button in the Scan box
   2. Visually identify nearby critical structures by moving through the sector and linear stack images
      - Identify bladder neck
      - Identify rectal wall
      - Identify pubic bone
   3. Identify neurovascular bundles (if applicable)
      - Open the NVB - Doppler for Neurovascular Bundle Detection tool
      - Enable Doppler and choose live sector imaging
      - Move the Doppler gate to identify the NVB on as many sector images as possible
   4. Outline and plan the prostate on the R-Mode image
      - Choose the polygon button in the Planning Method box (if it is not already chosen)
      - Use the mouse to mark the outline of the prostate
        - Single mouse clicks add points to the outline
        - Click-and-drag near a point marked with "x" moves the point
        - Click-and-drag near a segment adds a point
        - Double-click near a point deletes the point
        - Clicking on the start point closes the outline
        - Double-clicking away from a point or segment adds a point and closes the outline
        - Upon closing the outline, the software suggests the number and position of treatment zones
Click the "+" button in the Add or Remove Treatment Shots box to add shots

5. Refine the treatment plan
   • Move through the sector and linear stack images to review the treatment plan
   • ▼ To add or remove treatment shots, method 1
     • Choose the "+/-" button in the Planning Method box
     • Click or click-and-drag, starting on a filled space to remove treatment shots
     • Click or click-and-drag, starting on an empty space to add treatment shots
   • ▼ To add or remove treatment shots, method 2
     • Choose the draw button (the right hand button) in the Planning Method box
     • Click and drag to draw an arctangle or rectangle on a sector, linear or rmode image
     • Click the "+" button in the Add or Remove Treatment Shots box to add shots
     • Click the "-" button in the Add or Remove Treatment Shots box to remove shots
   • ▼ Add or remove treatment sites to cover the desired portion of the treatment zone while avoiding critical structures
     • Avoid bladder neck
     • Avoid rectal wall
     • Avoid pubic bone
     • Avoid neurovascular bundles

▼ 6. Adjust the RF Signal Quality
   • Open the DGC - Depth Gain Compensation tool
   • Choose live sector imaging
   • Adjust the Head and Foot limits in the RF Signal Quality Box to the boundaries of the treatment region
   • Adjust the DGC and Master Gain sliders until both Amplitude and Saturation are in the green regions

7. Zone treatment plan complete

Treat a Zone

5. Treat a zone
   □ 1. Confirm probe temperature is in range
   □ 2. Start HIFU delivery
      • Choose the "play" button in the HIFU Power box
      • You may be prompted to update the reference images
To manually update the reference images later, choose the volume stack button in the Stack/Live box and then the volume scan button in the Scan box.

When reference imaging is complete, you may be prompted to set the treatment power if you have not already done so.

When reference imaging is complete and treatment power is set, you will be prompted to start HIFU.

To interrupt HIFU delivery at any time, choose the Pause button in the HIFU Power box or press E-Stop (the red physical button on Sonasource console).

3. Monitor the treatment while HIFU power is on
   - Monitor these items
     - Patient movement
     - Prostate movement: shifting and/or swelling
     - Tissue reaction
     - Echogenicity near the rectal wall
     - Other near field changes
     - Rectal wall distance (RWD) on live versus reference image
     - Reflectivity index (RIM)
     - RIM box position
     - TCM display
     - Probe temperature
     - Interface between transducer and sheath
   - When necessary:
     - Adjust power level
     - Pause the treatment
     - Adjust the treatment plan
     - Halt the treatment

4. Using live imaging, review the results of the zone treatment

5. If needed, add treatment shots and repeat from step 1

6. Zone treatment complete
   - If more treatment zones remain, go to the Position Probe workflow step
   - If this was the last treatment zone, go to the Finish Treatment workflow step

Finish Treatment

6. Finish treatment
   - 1. Turn pump off
   - 2. Deflate the sheath by withdrawing water
   - 3. Disconnect the probe connector from the console
   - 4. Remove the probe from patient
   - 5. Remove the probe from the probe arm
6. Clean and disinfect the probe
7. Remove the probe arm from the table
8. Exit the SB software
CHAPTER 15: PATIENT CARE

This section is devoted to recommendations based on cumulative feedback from physicians experienced in delivering Sonablate HIFU.

These recommendations are provided in four categories:

- Pre-HIFU Patient Care and Medications
- Post-HIFU Patient Instructions
- Anesthesia Care during HIFU Ablation
- Post-HIFU Care of Adverse Events

NOTICE

This is a recommendation based on cumulative feedback from HIFU physicians. Pre-HIFU and Post-HIFU patient care is technically outside the scope of the operating manual for Sonablate device; however it is being provided here for guidance to Sonablate users.

Pre-HIFU Patient Care and Medications

These recommendations are based on cumulative feedback from physicians experienced in delivering Sonablate HIFU. They are intended to be used as a guide only for your patients who will undergo HIFU ablation.

Pre-HIFU Patient Care

- Clear liquids starting in the morning the day before the procedure
- NPO for eight hours before procedure
- Antibiotic the morning of procedure with sip of water
- TED Hose or other compression stockings in the pre-op area
- Two enemas administered two hours before procedure (consider more vigorous preparation in cases of chronic constipation)
- Catheter care review with patient prior to procedure

Medication Guidance

(Medication guidance is based on physician preference; examples of some common medicines used noted in parentheses)

- Antibiotic (such as Levaquin or Ciprofloxacin)
  - Day of and 24 hours post-op
The continued use of suppressive antibiotics is left to the physician’s discretion.

- Stool softener, fiber replacement, high fiber diet
- Bladder antispasmodic (such as Detrol LA or Vesicare)
  - To decrease bladder spasm symptoms early post-treatment
- Penile rehabilitation (such as Cialis)
  - Oral medication or vacuum device
  - Some physicians have initiated medicines once catheter is removed while others have begun one day post-HIFU.
- NSAIDS of choice (prn)
- Alpha-adrenoceptor antagonist (such as Flomax)
  - Until voiding well

**Anesthesia Care during HIFU Ablation**

These recommendations are based on cumulative feedback from physicians experienced in Sonablate HIFU. They are intended to be used as a guide only for anesthesiologists involved in Sonablate HIFU procedures.

The following items must be addressed for patient safety and optimal outcomes:

- **Anesthesia**
  - Used to ensure no patient movement during the procedure
  - Spinal/epidural and conscious sedation or general anesthesia
- **Deep venous thrombosis prophylaxis**
  - TED hose while inactive for 72 hours following HIFU
  - Sequential compression devices (SCD) during HIFU
- **Infection control and prevention**
  - Good hand hygiene
  - Antibiotics – intro-op (such as Gentamycin)
- **Vital sign monitoring**
  - Including surveillance for hypothermia
- **Hydration and urine output**
WARNING

Use of Nitrous Oxide (N2O) during a HIFU procedure increases the generation of echogenic changes in the prostatic tissue below the intended ablation zone, ranging from micro bubble cloud formation to total blockage of the ultrasound (the image appears black behind the cloud).

Use of Nitrous oxide (N2O) during HIFU should be avoided.

Please inform the anesthesia staff in advance of the procedure.

POST-HIFU CARE

NOTICE

This is a recommendation based on cumulative feedback from HIFU physicians. Pre-HIFU and Post-HIFU patient care is technically outside the scope of the operating manual for Sonablate device; it is being provided here only as guidance to Sonablate users.

Follow the physician’s instructions for patient care and the manufacturer’s instructions of any related products used.

Patients should be educated about how to care for their catheter, as well as other important information, to prepare them for recovery specific to the procedure. Patients should be provided with urinary drainage bags, a small leg bag and a large bag for overnight use.

Patient Education Topics:

1. Passage of tissue and small amounts of blood mixed with urine is completely normal.
2. It is very important that you wash your hands with soap and warm water before and after catheter care when working with your catheter connections and insertion site.
3. You should clean the insertion site and change the dressing over the site at least once a day or when the dressing becomes soiled.
4. Before inserting anything into the suprapubic catheter (i.e. catheter bag tip or plug), clean with alcohol wipes or soap and warm water. Also, clean all caps daily with alcohol wipes or soap and warm water.
5. Signs and symptoms of infection include (but are not limited to): fever, increasing redness/warmth at the insertion site, cloudy drainage and/or swelling at the insertion site.
6. Avoid constipation by increasing your fiber intake and/or using a stool softener.
7. Do not push or strain when urinating.
8. Do not insert anything into the rectum for up to six months after HIFU to allow for appropriate healing.
9. Do not immerse catheter insertion site in baths, swimming pools or hot tubs until well healed.
10. Do not attempt sexual intercourse until the suprapubic catheter has been removed and your physician has cleared you for this activity.

Instructions to give to patient:

Patient Procedure – Day 1 (post HIFU):

1. Drink plenty of fluids. Drink at least eight tall glasses of fluid daily (total 64 oz.). Sodas and alcohol do not count as fluid.
2. Take medications as instructed.
3. Make certain urine is draining into drainage bag.
4. Change dressing (bandage) as necessary. Before and after changing the dressing, wash hands with soap and warm water.
5. Wear anti-embolic hose during first 72 hours, when inactive.
6. Ambulate and resume all normal, non-strenuous activities.
7. Empty urine bag when full. The small leg bag will need to be emptied every 1-2 hours and the large night bag should last through the night.
8. Change to the large bag at bedtime and ensure urine is draining before you go to sleep.

Patient Procedure - Days 2 – 4:

Before showering:

1. Remove the dressing
2. Close the clamp
3. Disconnect the leg bag
4. Plug the catheter
5. Cleanse the incision site
6. Rinse thoroughly
7. Pat dry
8. Replace dressing
9. Remove plug
10. Connect the bag
11. Open the clamp
12. Ensure urine flow into the leg bag
13. Empty bag when full

Patient Procedure - Days 5 through catheter removal (Voiding Trial: There are 3 phases):

Phase 1: Start Voiding Trial as described below during the daytime. Continue to connect to your overnight bag at night.

- Most patients need to repeat this for several days before they are successful. Repeat Steps 1–5 at least 3 times per day until you can urinate normally. Bloody fluid may drain from your penis; this should be a small amount and is temporary. If it does not resolve on its own within a couple of days or there is a lot of volume, notify your doctor.

  1. Empty the drainage bag.
  2. CLOSE the catheter clamp. Your bladder will now begin to fill with urine.
  3. Wait until you feel the need to void. This will usually be 1 to 2 hours.
  4. Try to empty your bladder by urinating normally into the toilet. DO NOT PUSH or STRAIN. If you feel pain STOP.
  5. Open the clamp at least every 2 hours or anytime your bladder feels full and you CANNOT urinate.

- Once successful in voiding, open the clamp every 2 hours (after you have voided) and allow any urine remaining in the bladder to drain into a measuring cup. The amount of urine that is retained or left behind is called residual urine. Measure and record these amounts each day. You will now progress to Phase 2.
Phase 2: You will keep the catheter clamped for progressively longer periods of time and continue to measure the residual urine. You will continue to connect to your overnight bag. You will no longer need to use your leg bag at this point. Simply coil up your catheter inside of your underwear when the clamp is closed.

1. The first step in Phase 2 is to close the clamp for 4 to 6 hours at a time. Empty your bladder normally whenever needed. Open the clamp if, at any time you feel the need to urinate and cannot. Open the clamp about every 4 to 6 hours (after voiding) and allow remaining urine to drain into a measuring cup. Measure the residual urine and record these amounts each day.

2. When the residual urine is less than ½ cup (100 cc or 100 ml), keep the catheter clamp closed for 8 hours and measure and record your residual urine.

3. When residual urine is less than ½ cup (100 cc or 100 ml) increase the time the catheter is clamped closed to 12 hours and measure and record residual urine.

4. When residual urine is less than ½ cup (100 cc or 100 ml) progress to Phase 3.

Phase 3: You will keep the catheter clamp closed (24 hours a day) and no longer use the overnight bag until the catheter is removed. Urinate in the morning, open the clamp, and record the residual urine. Contact your HIFU physician for further and instructions or if you have questions.

- Catheter removal criteria: voiding with a good stream with the residual volume is less than ½ cup (100 cc or 100 ml) after the clamp has been closed for 24 hours.
Post-HIFU Care Of Adverse Events (for healthcare professionals)

NOTICE

This is a recommendation based on cumulative feedback from HIFU physicians. Pre-HIFU and Post-HIFU patient care is technically outside the scope of the operating manual for Sonablate device; it is being provided here only as guidance to Sonablate users.

Follow the physician’s instructions for patient care and the manufacturer’s instructions of any related products used.

The following information is designed to assist healthcare professionals in addressing adverse events should they arise following HIFU. It is not intended for HIFU-trained physicians only, but may be helpful should patients visit other physicians regarding these events.

These recommendations are based on cumulative feedback from physicians experienced in delivering Sonablate HIFU. They are intended to be used as a guide only for patients who have undergone HIFU ablation.

Potential problems and complications after a HIFU procedure are similar to those seen with other procedures for prostate tissue ablation procedures or other urological procedures. However, the etiology and management of such potential complications are slightly different than if they occurred independently of HIFU.

Ablation Procedure Background for Non-HIFU Healthcare Professionals

Sonablate HIFU is a minimally invasive ultrasound-based thermal ablation technique used for ablation of the prostate, including the prostatic urethra, resulting in coagulative necrosis of the prostatic tissue. Patients who receive HIFU have a suprapubic catheter (SP tube) placed to assist in emptying the bladder during the healing period, which is usually 2-4 weeks. Debris may pass through the SP tube initially and through the penis during voiding. Debris may continue to pass for a period of 4-6 weeks post-HIFU (and longer in some cases). Timing for the removal of the SP tube is critical to the HIFU recovery process. It is very important for patients to follow the voiding protocol in order to avoid having their SP tube removed prematurely.

The following is a summary of how to help HIFU patients with recovery during the weeks following HIFU. It also includes a synopsis of potential problems and complications that may occur with HIFU patients, as well as a review of the etiology and management of such complications.

Potential problems and complications after a HIFU procedure are similar to those seen with other procedures for prostate tissue ablation procedures or other urological procedures.
However, the etiology and management of such potential complications are slightly different than if they occurred independently of HIFU.

**Catheter Removal**

When the patient successfully completes the voiding trials, the SP catheter is ready to be removed. Patients should make an appointment for catheter removal. Ideally, a urine culture should be obtained 48-72 hours prior to catheter removal to ensure there is no evidence of infection.

If a urine culture has not been obtained prior to removal, it is a good idea to obtain it upon removal and treat appropriately if positive. Use caution because the urethra and bladder walls tend to be quite soft, which increases the risk of perforation.

A dressing should be placed over the insertion site when the catheter is removed. The patient may experience some leakage from the site within the first 24-48 hours. The patient will have to replace this dressing on a regular basis during this time; a wet dressing should never be left in place. The bladder will normally close within 48-72 hours.

**Urinary Retention Immediately Post-HIFU**

Urinary retention is expected for 7-10 days following the procedure, but may also extend for several weeks as a result of edema caused from the thermal effect of the HIFU procedure. Patients will have an SP tube with a clamp that they can manually open or close. The SP tube is secured within the bladder via a balloon which is inflated inside the bladder and a suture to the skin on the outside. In some occasions, a patient may have a standard Foley catheter instead of an SP tube.

**Inadvertent Dislodgement and Reinsertion of Catheter**

Inadvertent dislodgement of the SP catheter may result in urinary retention that requires the placement of a well-lubricated Coude tip Foley catheter or a second SP tube. Re-catheterization in this early post-HIFU period may be difficult due to swelling. In the event that a Foley catheter cannot be inserted, it may be prudent to abandon any further attempts as this may cause additional urethral trauma, stricture/scar formation or even rectal injury. It is important to be conservative, allow the urethra to heal and not remove the SP catheter prematurely.

**Urinary Retention after the Catheter Removal**

Urinary retention may continue after the catheter has been removed because of mucus/tissue plugs, scar tissue or a urethral stricture formation. Patients should void prior to leaving the doctor’s office to ensure they are no longer experiencing urinary retention and so their urinary stream may be assessed.
To help avoid additional complications due to sloughing tissue obstructions, patients should be encouraged to drink plenty of water. A mucus or tissue plug may pass on its own; if it does not, however, a temporary Foley or Coude catheter may be placed for 2-3 days to relieve the retention and dislodge the tissue plug.

An obstruction may occur on more than one occasion as necrotic tissue continues to be eliminated after the procedure, an occurrence which can last up to several months. Obstructions that occur 2-6 weeks post-HIFU are due typically to sloughing tissue present in the urethra. It is recommended that you attempt three conservative interventions, such as inserting a Foley drainage catheter or an SP drainage catheter, to dislodge or clear the tissue plug before considering a transurethral resection of the prostate (TURP). During this early period after HIFU, the anatomic landmarks of the prostate (i.e., bladder neck, verumontanum) may be difficult to identify, making it more difficult to avoid injuring these structures during an invasive or aggressive procedure performed to clear the obstruction.

Urethral Stricture

A urethral stricture may be the result of trauma to the urethral mucosa. With HIFU, a stricture is most likely to occur at the apical region of the prostate during the first 1-6 months post-HIFU. The physician’s goal should be to follow patients carefully so a stricture is identified before urinary retention occurs. It is important to monitor the patient carefully. Careful monitoring will assist in detecting urethral obstructions early before acute retention and blind instrumentation become necessary.

Strictures are identified by the usual symptoms: slow stream (most common), incomplete emptying of the bladder and recurrent UTI or urinary retention. Urethral strictures may occur also with the passing of a urinary catheter.

If a stricture is believed to be present, perform a flexible cystoscopy to confirm its presence and proceed with the least aggressive intervention possible:

- **Dilation** - Pass a guide wire through the stricture or maneuver a filiform through the stricture under cystoscopic guidance. Avoid blind dilation.
- **Direct vision urethrotomy** - This should be performed in an OR along with placement of a well-lubricated Coude tip Foley catheter.
- **Holmium laser visual urethrotomy** - This should be performed in an OR along with placement of a well-lubricated Coude tip Foley catheter.
- **Balloon dilation** - This should be performed in an OR only and include use of a well-lubricated Coude tip Foley catheter.

Strictures are managed most often by initial dilation. Subsequent or intermittent self-catheterization (ISC) may be necessary for a short period of time. An open primary urethrotomy may be necessary, but rarely required. The use of ISC is recommended over a prolonged use of an indwelling catheter and is less likely to aggravate or cause further stricture formation.
When an indwelling catheter is required, typically 2-3 days are sufficient. A urine culture and antibiotic suppression are recommended.

**Bladder Neck Contractures**

Bladder neck contractures are less common than prostatic apical stricture, but when they occur, it is typically around three months post-HIFU. They are best managed in the OR with incision or resection of the bladder neck. Special care and extra consideration should be given when using a Green Light laser and vaporization as there may be very little vascularity in the tissue after HIFU, which causes poor vaporization.

**Urinary Tract Infection/Epididymitis/Orchitis**

A urinary tract infection may occur when there is an indwelling catheter/suprapubic tube still in place. Immediately after the HIFU procedure, patients are maintained on suppressive antibiotic therapy. Ideally, a urine culture should be obtained 48-72 hours prior to catheter removal to ensure there is no evidence of infection. If a urine culture has not been obtained prior to removal, however, it is a good idea to obtain one upon removal and treat appropriately, if positive. Keep in mind that the sensitivity involved with a positive culture may mandate a different antibiotic.

Infections occurring after the drainage catheter has been removed should be treated in the same way as other urinary infections. A post-void residual should be performed to determine if urinary retention may be causing the infection or if the infection is resistant to antibiotic therapy.

The etiology of epididymo-orchitis is an underlying urinary tract infection and should be treated with the standard broad spectrum antibiotic and anti-inflammatory therapy.

**Rectal Injury**

A five-year experience study performed outside the U.S. shows that the incidence of rectal injury after HIFU is 1%\(^1\). The etiology of rectal injury is secondary to thermal injury to the rectum. Minor rectal mucosal burning or irritation can be managed by local therapy, such as a warm sitz bath and local Proctofoam ointment application, similar to the treatment of hemorrhoids or a rectal fissure. Although rare, there is a risk of a rectal-urethral fistula. A small

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fistula may be managed conservatively with urinary (Foley or SP tube) diversion as well as a non-constipating diet, hydration and stool softener until healing is demonstrated. A larger or non-healing fistula may require a temporary colostomy and surgical correction.

Erectile Dysfunction

The etiology of erectile dysfunction post-HIFU is similar to that of other therapies for localized prostate tissue ablation. Penile rehabilitation is encouraged to help preserve potency and decrease the incidence of penile atrophy. Typically, a post-HIFU patient is given a penile rehabilitation drug, such as Cialis 20mg QOD, upon removal of the drainage catheter or as early as one day post-HIFU, as is common with some physicians. The use of a vacuum therapy system is another option physicians may offer. Restoration of blood flow is essential for erectile functionality to return after the HIFU procedure. Other therapeutic choices include Muse, Caverject or Trimix.

Urinary Incontinence

The etiology of urinary incontinence post-HIFU is similar to that of other therapies for localized prostate tissue ablation and may result from inadvertent injury to the external urinary sphincter. The first step in evaluating urinary incontinence in a post-HIFU patient is rule out urinary retention or overflow incontinence as determined by a post-void residual ultrasound of the bladder. Any infection causing irritative symptoms, urgency and urge incontinence should be treated with antibiotics.

The treatment for stress urinary incontinence should be conservative in the first 12 months following HIFU, after which surgical intervention could be considered.

Elevated PSA

Since HIFU ablates prostate tissue, whole-gland ablation will be expected to decrease the prostate specific antigen (PSA). Following ablation PSA levels may be managed according to previously published urology standards, such as the American Urology Association.
CHAPTER 16: CLEANING, DISINFECTION AND STERILIZATION

The Sonablate probe is considered a semi-critical device since the probe comes in contact with mucous membrane in the rectum. The probe should be cleaned and then either high level disinfected or Ethylene Oxide sterilized after each use. Additionally, the potential for cross-contamination of the probe arm and stepper exists. As a result, the probe arm and stepper should be cleaned and steam sterilized or low level disinfected before each use. Cleaning and sterilization (or high level disinfection) of the Sonablate probe and cleaning and sterilization or low level disinfection of the stepper and probe arm and cleaning of the console and Sonachill unit surfaces are required for reuse of the system.

After procedure, the probe condom/sheath, O-rings, water, used cleaning materials, used Water Path Kit, and any other used disposables (e.g. surgical tape) must be discarded in marked hazardous material containers and handled using applicable personal protective equipment according to the policies of the medical facility.

- Console: cleaning
- Sonachill: cleaning
- Probe: cleaning, and either high level disinfection or Ethylene Oxide sterilization
- Probe arm: cleaning and sterilization or low level disinfection
- Stepper: cleaning and sterilization or low level disinfection

Individuals handling cleaning and disinfecting agents must follow the instructions of the agent manufacturer, including instructions for personal protective equipment.

<table>
<thead>
<tr>
<th>CAUTION</th>
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<tbody>
<tr>
<td>The probe is constructed of delicate components, which may be damaged if dropped, and should be considered unsafe under these circumstances. If connected to the system, the probe should be disconnected immediately. Any probe which has been dropped should be returned to the repair center for inspection and repair.</td>
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<table>
<thead>
<tr>
<th>CAUTION</th>
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<tbody>
<tr>
<td>If the probe or Sonachill becomes contaminated during use on a patient with Creutzfeld-Jacob disease, the probe and Sonachill should be destroyed as these components may not be disinfected adequately.</td>
</tr>
</tbody>
</table>

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Cleaning the Console and Sonachill Unit

CAUTION

Always replace the water reservoir and connecting tubes.

1. Wipe the exterior surfaces of Sonasource console, Sonachill unit, and water path tubing using surface with disinfectant cloths (e.g. CaviWipes, or equivalent), as described below. Ensure that all surfaces remain visibly wet for 3 minutes. Use additional wipes if necessary.
   
   a. Use one wipe to wipe the left side and panel of the console for 3 minutes.
   
   b. Use one wipe to wipe the right side and panel of the console for 3 minutes.
   
   c. Use one wipe to wipe the top of the console, the monitor arm, and the back and edges of the monitor for 3 minutes.
   
   d. Use one wipe to wipe the front of the console and keyboard for 3 minutes.
   
   e. Use one wipe to wipe the back side and panel of the console and power cord for 3 minutes.
   
   f. Use one wipe to wipe the Sonachill housing for 3 minutes.
   
   g. Use one wipe to wipe the Sonachill power cord for 3 minutes.
   
   h. Use one wipe to wipe the water path tubing for 3 minutes. Make sure to wipe each tube individually and over the clips and the outside of the luers.
   
2. Allow all surfaces to air dry for 3 minutes.

3. Wipe the monitor screen with an LCD wipe.

4. Visually inspect all surfaces and repeat cleaning as needed.
Cleaning the Probe

CAUTION

Gas sterilization other than the Ethylene Oxide sterilization cycle described in Chapter 16, ultraviolet sterilization, heat sterilization, autoclaving and chlorine bleach may damage the Sonablate probe.

After each patient procedure and before disinfecting the probe, treat the sheath, gloves, and any waste materials as infectious.

Dispose of the waste material in accordance with infectious waste control procedures of the facility.

Reference the Cleaning and Disinfection section of this manual Chapter 16 for additional information.

The entire Sonablate probe should not be submerged under water as water leakage into the body of the probe or cable connector will damage probe parts.

During normal use or testing, do not submerge the probe in water beyond the probe tip level.

During the cleaning and disinfection processes described in this chapter, cover the cable connector to ensure fluid does not get into the connector end.

Material Needed for Manual Cleaning of Sonablate Probe

i. Enzol® Enzymatic Detergent

ii. Spray bottle

iii. Nylon bristle brush and 50cc Syringe

iv. Lint free cloth

v. Decontamination trays (provided by SonaCare Medical or equivalent)

Note: Both the Sonablate probe cleaning steps and the high level disinfection or EO sterilization steps should occur (i) prior to first use, and (ii) after each use.
Additionally, the high level disinfected probes should be stored in a location and manner that promotes continued drying until the next procedure.

Sonablate probe should be cleaned immediately after use without allowing the probe to air dry beyond 20-30 minutes.

1. Detergent Preparation
   a) Prepare Enzol per the manufacturer’s recommendations (1 oz/gal using lukewarm tap water). Transfer the prepared detergent into a spray bottle.

2. Pre-Rinse with Water
   a) Place the probe in a perforated tray over a sink.
   b) Using a gentle sprayer, rinse the entire probe with warm running tap water (<45°C) for 5 minutes. Move the transducer to ensure all sides of the transducer and shaft are rinsed. Extend the transducer shaft to its maximum length while rinsing.
   c) While rinsing, use nylon bristle brush to scrub all distal portions of the probe (i.e., probe tip, transducer, and transducer shaft). Use soft towel to scrub the entire probe (end-to-end) twice.
   d) Flush each lumen 3 times by injecting 50 ml of water with a syringe.

3. Manual Cleaning with Detergent
   a) Spray detergent over the entire probe surface to get all surfaces sufficiently wet with the detergent.
   b) Slowly inject 50 mL of detergent into each lumen and continue alternating between lumens for 5 minutes.
   c) Spray detergent over the entire probe surface while cleaning with a soft towel soaked in detergent for 5 minutes. Periodically use nylon bristle brush to clean all distal portions of the probe (i.e., probe tip, transducer, and transducer shaft) while spraying with detergent.

4. Post-Rinse with Water
   a) Rinse the entire probe with warm running tap water (<45°C) for 5 minutes. Move the transducer to ensure all sides of the transducer and shaft are rinsed. Extend the transducer shaft to its maximum length while rinsing. While rinsing;
   b) Use nylon bristle brush to scrub all distal portions of the probe (i.e., probe tip, transducer, and transducer shaft). Use soft towel to scrub the entire probe (end-to-end) twice.
c) Flush each lumen 5 times by injecting 50 ml of water with a syringe

5. Visual Inspection and Drying

a) Visually inspect the entire probe for visible soil and repeat cleaning steps if necessary.

b) Inject air 5 times through the narrow lumens using 50 mL syringe or until no more water is seen coming out of the outlet.

c) If medical grade compressed air is available then spray forced air over the entire probe including the connector.

d) Dry the entire probe with a lint free cloth if the probe will be sterilized. The probe does not have to be dried if it will be high-level disinfected immediately following Cleaning.

6. Thoroughly examine all surfaces that have been cleaned and visually inspect the entire probe to make sure there is no visible soil remaining.

**Sterilization of the Probe**

Once the probe has had ample time to dry, wrap the probe in two applications of 1-ply polypropylene wrap.

Use Ethylene Oxide (EO) gas sterilization to sterilize the probe. Follow manufacturer’s recommendations listed below to assure a proper sterile product.

The required EO sterilization cycle parameters are as follows:

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<tr>
<th>In Chamber Conditioning:</th>
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<tbody>
<tr>
<td>Temperature</td>
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<tr>
<td>Relative Humidity (minimum)</td>
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<tr>
<td>Vacuum Set Point</td>
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<tr>
<td>Conditioning Time</td>
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<tr>
<th>Exposure:</th>
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<tbody>
<tr>
<td>Temperature</td>
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<tr>
<td>Relative Humidity</td>
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<tr>
<td>EO Concentration (minimum)</td>
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<tr>
<td>Gas Exposure Time (full cycle)</td>
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<td>Gas Type</td>
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<tr>
<th>Aeration:</th>
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<tr>
<td>Aeration Time</td>
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<td>Aeration Temperature</td>
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</table>

CAUTION

Do not use a sterilization process and parameters for Sonablate probe that is different from the Ethylene Oxide sterilization process listed in this section.

Do not use a sterilization process that requires temperature to exceed 55°C while sterilizing Sonablate probe.

High Level Disinfection of the Probe

WARNING

Only use high level disinfection if the fitting shown below is present on the probe. Executing this process without shown fitting, will result in permanent damage to the probe.

Materials Needed for High Level Disinfection of Sonablate Probe

i. Revital-Ox™ Resert® High Level Disinfectant
ii. Cavicide disinfectant
iii. Purified Water
iv. Trigger Sprayer
v. 50cc Syringe
vi. Lint free cloth
vii. Decontamination trays (provided by SonaCare Medical or equivalent)

1. Ensure the minimum recommended concentration of the Resert (high level disinfectant – HLC) using the Resert test strips. Fill a spray bottle with the Resert.
2. **Pre-Rinse with Water: Perform this step if the probe was stored in a storage area following cleaning.**
   
   a. Place the probe in a perforated (rinsing) disinfection tray placed over a sink.
   
   b. Rinse probe with 2L purified water (PURW). Lift and rotate the probe as necessary to rinse all surfaces.
   
   c. Inject four times 50 cc of purified water with a syringe into the lumen attached to the probe. Repeat the same on the other lumen.

3. **Soak in Disinfectant (Resert XL):**
   
   a. Pour two bottles (4 Liter each) of the disinfectant into the (soaking) disinfection tray;
      
      i. Attach the stop-cocks to the two lumens of the probe and turn them into open position.
      
      ii. Fill a 50 cc syringe with the disinfectant and remove all air from the syringe. Slowly inject 50 cc of disinfectant ascertaining that air bubbles are not created in the lumens. Close the stop-cock and detach the syringe.
      
      iii. Do the same to the other lumen.
      
      iv. Place the probe in the disinfection tray. Spray and wipe the entire probe surface (end-to-end twice) with disinfectant to ascertain the surfaces are completely soaked with the disinfectant.
      
      v. Cover the exposed surfaces of the probe with lint-free cloths soaked in Resert®. Spray disinfectant on the lint-free cloth again to soak them further with detergent.
   
   b. Cover the lid of the disinfection tray and wait for 12 minutes for the probe to soak in the disinfectant.
   
   c. After 12 minutes open the lid of the disinfection tray;
      
      i. Open the stop-cocks attached to the lumens and let the disinfectant drain out of the lumens into the tub.
      
      ii. Turn the probe over to soak the opposing surface of the probe housing and probe cable.
iii. Fill a 50 cc syringe with the disinfectant and remove all air from the syringe. Slowly inject 50 cc of disinfectant ascertaining that air bubbles are not created in the lumens. Close the stop-cock and detach the syringe.

iv. Do the same to the other lumen.

v. Spray and wipe the entire probe surface (end-to-end twice) with disinfectant to ascertain the surfaces are completely soaked with the disinfectant.

vi. Cover the exposed surfaces of the probe with lint-free cloths soaked in Resert®. Spray disinfectant on the lint-free cloth again to soak them further with detergent.

d. Cover the lid of the disinfection tray and wait for 12 minutes for the probe to soak in the disinfectant.

4. **Post-Rinse with Water:** Open the lid of the disinfection tray;

a. Open the ports of the stop-cock attached to the lumens and let the disinfectant drain out of the lumens into the tub.

b. Place the probe in a perforated (rinsing) disinfection tray placed over a sink. Rinse probe with 2L purified water (PURW). Lift and rotate the probe as necessary to rinse all surfaces.

c. Inject 50 cc of purified water with a syringe into the lumen attached to the probe. Repeat this step 5 times.

d. Repeat the same to rinse the other lumen.

5. **Disinfectant (Cavicide) Spray and Wipe Down:**

a. Fill a 50 cc syringe with the Cavicide and remove all air from the syringe. Slowly inject 50 cc of disinfectant ascertaining that air bubbles are not created in the lumens. Close the stop-cock and detach the syringe.

b. Do the same to the other lumen.

c. Spray Cavicide over the entire probe to wet all surfaces. Lift and rotate the probe as needed and continue spraying to keep all surfaces wet for 5 minutes.

d. Wipe the entire probe with Cavicide wipes for 5 minutes.

e. Open the stop cock and let the Cavicide drain out of the lumens.
f. Inject air several times through each lumen to ascertain Cavicide has been completely drained out of the lumens.

6. Let the probe air dry for 5 minutes and dry the probe with a lint free cloth or gauze if necessary.

7. The high level disinfected probes should be stored in a location and manner that promotes continued drying until the next procedure.

Cleaning and Sterilization of the Probe Arm

<table>
<thead>
<tr>
<th>CAUTION</th>
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<tbody>
<tr>
<td>Do not immerse the arm in liquid. This may result in retention of water within the joints of the arm and subsequent corrosion. Corroded joints may result in failure of the articulated probe arm.</td>
</tr>
</tbody>
</table>

Probe Arm Cleaning:

Materials needed for cleaning:
- CaviWipes disinfectant towelettes
- Chux pad (or lint free cloth)
- Cavicide spray
- Soft bristled brush

1. Lock the articulating probe arm so that the arm is bent to less than a 45 degree angle using the central knob.

2. Wipe the surface of the probe arm using enzymatic agent soaked cloths (e.g. CaviWipes™, or equivalent).
   a. Use one wipe to wipe the inside and outside of the collar for 30 seconds.
   b. Use one wipe to wipe the central knob, shafts, and rail lock and knob for 30 seconds.

3. Ensure that all surfaces remain visibly wet for 3 minutes by gently spraying with additional Cavicide (if needed). Rewet surfaces with additional sprays if necessary. Use soft bristled brush to brush crevices during 3 minutes.
4. Allow the Probe arm to air dry for 3 minutes.

5. Visually inspect the entire test article for visible soil. If soil remains, repeat the manual cleaning above for that area.

**Probe Arm Sterilization parameters:**

1. Wrap the probe arm in two layers of 1-ply polypropylene wrap.

<table>
<thead>
<tr>
<th>Sterilizer Type</th>
<th>Pre-Vacuum</th>
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</thead>
<tbody>
<tr>
<td>Preconditioning Pulses</td>
<td>3</td>
</tr>
<tr>
<td>Temperature</td>
<td>132°C</td>
</tr>
<tr>
<td>Cycle Time</td>
<td>4 Minutes</td>
</tr>
</tbody>
</table>

2. Allow to dry for 60 minutes.

**Cleaning and Disinfection of the Probe Arm**

- **CAUTION**

  Do not immerse the arm in liquid. This may result in retention of water within the joints of the arm and subsequent corrosion. Corroded joints may result in failure of the articulated probe arm.

  M442

1. Lock the articulating probe arm so that the arm is bent to less than a 45 degree angle using the central knob.

2. Wipe the surface of the probe arm using enzymatic agent soaked cloths (e.g. CaviWipes™, or equivalent). Ensure that all surfaces remain visibly wet for 3 minutes.
   
   a. Use one wipe to wipe the inside and outside of the collar for 30 seconds.

   b. Use one wipe to wipe the central knob, shafts, and rail lock and knob for 30 seconds.

3. Lay the probe arm on a clean cloth (e.g. chux pad). Lean the arm against a clean, vertical surface with the central knob pointed up and resting on the collar and the rail lock. Tie disinfectant cloths over the top of the cuff joint and the rail locking joint as indicated in the image below. These disinfectant cloths will help prevent excess fluid from entering the arm joints.
4. Spray the entire surface of the probe arm with CaviCide™ surface disinfectant liquid (or equivalent cleaning agent) as described below. Spray enough so that the liquid is visible on the surfaces of the arm but not so much that the disinfectant is dripping off of it.

   a. Spray the inside and outside of the collar.

   b. Spray all sides of the shafts.

   c. Spray the central knob and the back side of the center pivot point.

   d. Spray the rail lock and knob.

   e. Spray the joint sockets. Take caution to avoid spraying so much that the disinfectant is dripping into the joint.

   f. Avoid moving the arm after spraying so that the liquid does not drip into the joint sockets.

5. Ensure that all surfaces of the probe arm are visibly wet for 10 minutes. Spray the surface again if necessary.

6. Allow the probe arm to air dry until completely dry.

7. Wipe the probe arm with a clean cloth soaked with water. Do not allow water to drip in any joints.

Dry the arm with a clean cloth.

Cleaning and Sterilization of the Stepper

Materials needed for cleaning:
- CaviWipes disinfectant towelettes
- Chux pad (or lint free cloth)
- Cavicide spray
- Soft bristled brush

**Stepper Cleaning**

1. Wipe the surface of the stepper using surface disinfectant cloths (e.g. CaviWipes™, or equivalent). Ensure that all surfaces remain visibly wet for 3 minutes. Rewet surfaces with additional wipes if necessary.
   
a. Use one wipe to wipe each of the knobs for 30 seconds.

   b. Use one wipe to wipe the latch, the rail, the ruler, and the entire length of the screws and rods for a total time of 30 seconds.

   c. Use one wipe to wipe the sides and the bottom, all remaining flat surfaces, for a total of 30 seconds.

**Sterilization**

1. Sterilize the stepper at the following conditions with the stepper wrapped twice in 1-ply polypropylene wrap:

<table>
<thead>
<tr>
<th>Sterilizer Type</th>
<th>Pre-Vacuum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preconditioning Pulses</td>
<td>3</td>
</tr>
<tr>
<td>Temperature</td>
<td>132°C</td>
</tr>
<tr>
<td>Cycle Time</td>
<td>4 Minutes</td>
</tr>
</tbody>
</table>

2. Allow to dry for 60 minutes.

**Cleaning and Disinfection of the Stepper**

1. Wipe the surface of the stepper using surface disinfectant cloths (e.g. CaviWipes™, or equivalent). Ensure that all surfaces remain visibly wet for 3 minutes. Rewet surfaces with additional wipes if necessary.

   a. Use one wipe to wipe each of the knobs for 30 seconds.

   b. Use one wipe to wipe the latch, the rail, the ruler, and the entire length of the screws and rods for a total time of 30 seconds.

   c. Use one wipe to wipe the sides and the bottom, all remaining flat surfaces, for a total of 30 seconds.
2. Spray the entire surface of the stepper with CaviCide™ surface disinfectant liquid (or equivalent cleaning agent) concentrating on crevices that are not easily reached with disinfectant cloths.
   
a. Spray enough that the liquid is visible on the surfaces of the stepper but not so much that the disinfectant is dripping off of it.
   
b. Spray the plate behind the rail and allow for the disinfectant to wet behind the plate as well.
   
c. Spray the crevices of the screws for each of the knobs.
   
d. Spray the flat surfaces.
   
3. Ensure that all surfaces of the stepper are visibly wet for 10 minutes. Spray the surface again if necessary.
   
4. Allow the stepper to air dry until completely dry.
   
5. Wipe the stepper with a clean cloth soaked with water.
   
6. Dry the stepper with a clean cloth.
Chapter 17: Clinical Studies

SonaCare Medical has been granted FDA regulatory authorization for the use of Sonablate in the ablation of prostate tissue. The safety and effectiveness of the Sonablate in other clinical usages and patient populations have not been established. The effectiveness of Sonablate in the treatment of any specific disease of the prostate is unknown.

Whole Gland, Salvage Ablation Trial:

A study conducted in the US included 117 subjects at 20 centers, ranging in age from 53 to 83, who had previously undergone external beam radiation therapy to the prostate and who underwent whole gland salvage focused ultrasound ablation of their prostate following recurrence of their disease as evidenced by prostate biopsy. Ablation effectiveness was evaluated by analyzing changes in prostate volume and biopsy results (assessed at baseline and 12 months post-ablation), and through changes in PSA levels (assessed at baseline and throughout the 12-month follow-up period). Safety evaluations were conducted using patient completed questionnaires and investigator reported adverse events through 12 months post-ablation.

The following results demonstrate that the Sonablate effectively ablates targeted prostatic tissue:

- Among the 73 patients who had prostate volumes determined both pre- and post-ablation, the mean reduction in volume was 11.8 cm\(^3\) (95% confidence limits = 9.7, 14.0). This change represents a mean reduction of 46% from the baseline volume. Of the 44 patients who did not have volumes calculated post-ablation, there was only a single case of a positive biopsy.

- Eighty-three percent (82.9%) of the total cohort of 117 patients had a reduction in PSA post-ablation (95% confidence limits = 74.6, 89.0). For this analysis, missing data was treated using the last value carried forward method.

- Sixty-one percent (60.6%) of the total cohort of 117 patients had a negative post-ablation biopsy (95% confidence limits = 51.2, 69.5). For this analysis, 30 patients who did not have a 12-month biopsy were considered "positive."
The safety profile for Whole Gland, Salvage Ablation, as reported in this clinical trial, is summarized below:

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Percentage of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erectile Dysfunction</td>
<td>71%</td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>50%</td>
</tr>
<tr>
<td>Urinary Incontinence (leak)</td>
<td>47%</td>
</tr>
<tr>
<td>Hematuria</td>
<td>43%</td>
</tr>
<tr>
<td>Urinary Retention</td>
<td>43%</td>
</tr>
<tr>
<td>Urinary Frequency</td>
<td>35%</td>
</tr>
<tr>
<td>Urinary Incontinence (pads)</td>
<td>32%</td>
</tr>
<tr>
<td>Urinary Urgency</td>
<td>29%</td>
</tr>
<tr>
<td>Urinary Tract Obstruction</td>
<td>20%</td>
</tr>
<tr>
<td>Dysuria</td>
<td>18%</td>
</tr>
<tr>
<td>Urethral Stricture</td>
<td>15%</td>
</tr>
<tr>
<td>Epididymitis/Orchitis</td>
<td>8%</td>
</tr>
<tr>
<td>Bladder Neck Contracture</td>
<td>5%</td>
</tr>
<tr>
<td>Rectal Fistula</td>
<td>4%</td>
</tr>
<tr>
<td>Urinary Fistula</td>
<td>2.6%</td>
</tr>
<tr>
<td>Osteomyelitis</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

Twenty-seven device/procedure related serious adverse events (SAEs) were reported in 21 subjects (18%), all of which resolved.
## APPENDIX A: LABELING SYMBOLS

<table>
<thead>
<tr>
<th>Description</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applied Part, Type B</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Part Number</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Serial Number</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Lot Number</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Do Not Reuse</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>WEEE (Waste in Electrical and Electronic Equipment)</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Consult Instructions for Use</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Contains Natural Rubber Latex</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Does Not Contain Natural Rubber Latex</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Use By Date</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Temperature Limits</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Keep away from Sunlight</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Date of Manufacture</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Manufacturer</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Caution</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>CE Mark</td>
<td><img src="image" alt="Symbol" /></td>
</tr>
<tr>
<td>Notified Body CE Mark</td>
<td><img src="image" alt="CE Mark" /></td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Authorized Representative</td>
<td><img src="image" alt="Authorized Representative" /></td>
</tr>
<tr>
<td>“ON” (power)</td>
<td><img src="image" alt="“ON” (power)" /></td>
</tr>
<tr>
<td>“OFF” (power)</td>
<td><img src="image" alt="“OFF” (power)" /></td>
</tr>
<tr>
<td>Equipotentiality</td>
<td><img src="image" alt="Equipotentiality" /></td>
</tr>
<tr>
<td>Do Not Use if Package is Damaged</td>
<td><img src="image" alt="Do Not Use if Package is Damaged" /></td>
</tr>
<tr>
<td>Do Not Sterilize Twice</td>
<td><img src="image" alt="Do Not Sterilize Twice" /></td>
</tr>
<tr>
<td>Product is Sterile by Irradiation</td>
<td><img src="image" alt="Product is Sterile by Irradiation" /></td>
</tr>
</tbody>
</table>
APPENDIX B: LICENSE AND SOFTWARE ACTIVATION

This appendix provides general information for the authorized use and operation of the user interface to Sonablate software. Sonablate platforms are delivered and installed with either locked or unlocked license software according to the order agreement. Platforms with locked license software require activation codes for authorization of use. Activation codes are intended only for use by the physician user and authorized technical/service personnel. If your order agreement provided an unlocked license, you may disregard the information presented in this appendix. Please consult your authorized distributor for more information regarding license and authorization of use.

Background

Activation codes provide controlled access to Sonablate HIFU Prostate Ablation software module. For previous users please note this most recent authorization software revision has undergone a dramatic alteration.

The role of the activation software is to provide a mechanism for controlling access to Sonablate ablation software. Authorized SonaCare Medical distributors may utilize authorization software to create required activation codes for licensed controlled Sonablate units in their regions. Each activation code is a unique, one-time use code which allows a predetermined usage time in hour increments. The amount of time allotted per activation code is determined by the order agreement.

Software Activation with Locked License

After the user starts the ablation software by activating Sonablate HIFU Prostate Therapy icon on the desktop, the following dialogue box will appear (Figure 208):

![Figure 208. Enter activation code](image)

Next the user must enter the 26 character activation code (Figure 209) provided by their authorized distributor to gain access to Sonablate HIFU Prostate Therapy software. Note: The activation code is NOT case sensitive and no numeric 0’s (zeroes) are utilized in the code. Dashes are optional but are presented in the supplied activation code for ease of use.
Upon entering the activation code and clicking OK, the Use Activation Code? dialogue box (Figure 210) is displayed denoting the amount of clock time allowed for the inputed activation code. Click “Yes” to start Sonablate ablation software. Note: The prescribed clock time will start upon clicking the yes. If user is not ready, select “No”.

If the activation code was previously used and the allotted time was exhausted the following box will be displayed (Figure 211):

If the activation code is entered incorrectly the following box will be displayed (Figure 212):

License Required

In rare circumstances after Sonablate software startup, a License Required dialogue box may be displayed (Figure 213). If so, the user must call their authorized distributor for a valid license file. Please have the code displayed in the box available if asked.
Figure 213. License required
### APPENDIX C: SYSTEM REQUIREMENTS, SPECIFICATIONS, AND SERVICE

#### Power Requirements, Operating Conditions, and AC Power On/Off Sequence

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power requirement</td>
<td>The console is configured by manufacturing per device produced and shipped according to its intended destination. The configuration is indicated by the rating label on the rear of the console. (Figure 215) The indicated voltage and current capacity is required to power Sonasource console:</td>
</tr>
<tr>
<td></td>
<td>100 Volts AC, 50/60 Hz, 10 Amperes (e.g. Japan)</td>
</tr>
<tr>
<td></td>
<td>110-120 Volts AC, 50/60 Hz, 9 Amperes (e.g. Americas)</td>
</tr>
<tr>
<td></td>
<td>220 Volts AC, 50/60 Hz, 6 Amperes (e.g. China, Russia)</td>
</tr>
<tr>
<td></td>
<td>230-240 Volts AC, 50/60 Hz, 5 Amperes (e.g. EU)</td>
</tr>
<tr>
<td></td>
<td>Sonablate is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td></td>
<td>Mains power quality should be that of a typical commercial or hospital environment. It is recommended that the facility provide an uninterrupted power supply for continued operation.</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>+10 (50°F) to 32 (89.60°C)</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>30 to 75% (non-condensing)</td>
</tr>
<tr>
<td>Operating atmospheric</td>
<td>70.0 kPa to 106.0 kPa</td>
</tr>
<tr>
<td>pressure</td>
<td></td>
</tr>
</tbody>
</table>
### Power-Up sequence
- Toggle switch on the console rear to the “OFF” position.
- Toggle circuit breaker to the “OFF” position.
- Insert provided AC power cord into inlet of rear console.
- Connect AC power cord to hospital grade receptacle supplying rated power requirement. (Figure 214)
- Toggle circuit breaker to the “ON” position.
- Toggle switch on the console rear to the “ON” position.

### Power-Down sequence
- Shutdown Computer (Windows “Shutdown”):
  - Select “Start” then “Shutdown”
  - Wait approximately 30 seconds for the computer to power off.
  - The monitor will power off into standby mode when the computer is off.
- Toggle switch on the console rear to the “OFF” position.
- Toggle circuit breaker to the “OFF” position.
- Disconnect the AC power cord from the receptacle.

### CAUTION
The console hardware is configured by manufacturing and labeled for the proper power requirement. (Figure 215) Only connect the power requirement specified by the label using the supplied power cord.
WARNING

Grounded reliability can only be achieved when this equipment is connected to a receptacle marked “hospital grade” and with the supplied “hospital grade” main power cord.

Classification

Sonablate is classified as follows:

- According to the classification criteria of Medical Device Directive 93/42/EEC Annex IX, the device classification for the Sonablate system has been listed as CLASS IIb equipment. An examination of the full quality assurance system of Focus Surgery, Inc. has been carried out by notified body issuing EC Certification.
• The Sonablate system has been designed and tested to comply with the requirements as defined by IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (3rd edition)
• According to the type and degree of protection against electric shock, as described by the classification criteria in IEC 60601-1, the Sonablate has been evaluated as CLASS I Equipment for continuous operation.
• According to the type and degree of protection against electric shock, as described by the classification criteria in IEC 60601-1, the Sonablate probe has been evaluated as a Type B Applied Part

Figure 217. Label: Type B Applied Part (located on probe)

• Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529: IPX0, ordinary equipment
• The equipment is not suitable for use in the presence of uncontrolled or excessive levels of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

System Specifications

Storage Recommendation

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
</table>
| Temperature | +18 to +33 \degree C  
(+65 to +92 \degree F) |
| Humidity | 30 to 40% non-condensing |
**Console Specifications**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>39 in (99 cm) to console top</td>
</tr>
<tr>
<td></td>
<td>54 in (137 cm) stowed for transport</td>
</tr>
<tr>
<td>Width</td>
<td>20.5 in (53 cm)</td>
</tr>
<tr>
<td>Depth</td>
<td>34 in (86 cm)</td>
</tr>
<tr>
<td>Weight</td>
<td>300lbs (90.72kg)</td>
</tr>
<tr>
<td>User interface</td>
<td>Keyboard, Mouse, Emergency Stop Button</td>
</tr>
<tr>
<td>Monitor</td>
<td>Flat-panel monitor</td>
</tr>
<tr>
<td>Functions</td>
<td>Custom – point and click</td>
</tr>
<tr>
<td>Page printer</td>
<td>Digital, black and white, thermal printer</td>
</tr>
</tbody>
</table>

**Probe Specifications**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probe Type</td>
<td>Longitudinal (linear) &amp; transverse (sector) mechanical probe with custom ultrasound imaging and ultrasound ablation functions</td>
</tr>
<tr>
<td>Plastic Components Material</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Water delivery system</td>
<td>Closed-loop, self-contained, active cooling via water inlet/outlet tubing</td>
</tr>
<tr>
<td>Patient interface</td>
<td>Synthetic Latex or Latex Sheath</td>
</tr>
<tr>
<td>Coupling medium</td>
<td>Ultrasound coupling gel</td>
</tr>
<tr>
<td>Imaging angle</td>
<td>90°</td>
</tr>
<tr>
<td>Ablation angle</td>
<td>90°</td>
</tr>
<tr>
<td>Parameter</td>
<td>Specification</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Imaging linear extent</td>
<td>4.5 cm</td>
</tr>
<tr>
<td>Probe Tip diameter</td>
<td>3.45 cm</td>
</tr>
<tr>
<td>Probe Tip neck diameter</td>
<td>1.75 cm</td>
</tr>
<tr>
<td>Transducer focal lengths</td>
<td>3.0 cm, 4.0 cm</td>
</tr>
<tr>
<td>Imaging frequency</td>
<td>6.5MHz nominal (3.5-8MHz range)</td>
</tr>
<tr>
<td>Ablation frequency</td>
<td>4.0 MHz</td>
</tr>
<tr>
<td>Duty Cycle (variable)</td>
<td>• 3 seconds “ON” and 6 seconds “OFF” (default)</td>
</tr>
<tr>
<td></td>
<td>• 3 seconds “ON”, 3 seconds “ON”, 3 seconds “OFF” (fast mode, 4.0 cm focal length transducer only, covers 2 ablation sites)</td>
</tr>
<tr>
<td>Longitudinal lesion spacing</td>
<td>3.0 mm</td>
</tr>
<tr>
<td>Transverse lesion spacing</td>
<td>3˚</td>
</tr>
<tr>
<td>Temperature monitoring</td>
<td>Via built-in thermistor located in the probe tip</td>
</tr>
<tr>
<td>Attachment method</td>
<td>To stepper rail using a custom probe arm with probe cuff</td>
</tr>
<tr>
<td>Weight</td>
<td>3 kg (7lbs)</td>
</tr>
<tr>
<td>HIFU Total Acoustic Power</td>
<td>0-28W, 24W typical (3.0 cm Focal Length Transducer)</td>
</tr>
<tr>
<td></td>
<td>0-40W, 37W typical (4.0 cm Focal Length Transducer)</td>
</tr>
<tr>
<td>Imaging acoustic output</td>
<td>4.4 µW (fixed - 3.0 cm Focal Length Transducer)</td>
</tr>
<tr>
<td></td>
<td>4.6 µW (fixed - 4.0 cm Focal Length Transducer)</td>
</tr>
<tr>
<td></td>
<td>SOFT TISSUE THERMAL INDEX &lt; 1.0</td>
</tr>
<tr>
<td></td>
<td>MECHANICAL INDEX &lt; 1.0</td>
</tr>
<tr>
<td>Parameter</td>
<td>Specification</td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Sector driver</td>
<td>In-line rotary motor</td>
</tr>
<tr>
<td>Linear driver</td>
<td>Linear actuator</td>
</tr>
<tr>
<td>Longitudinal imaging Frame Rate (typical)</td>
<td>2 FPS</td>
</tr>
<tr>
<td>Transverse imaging Frame Rate (typical)</td>
<td>3 FPS</td>
</tr>
<tr>
<td>Field of view</td>
<td>4.5 x 6.25cm</td>
</tr>
<tr>
<td>Probe length</td>
<td>58.7cm</td>
</tr>
<tr>
<td>Maximum Sector sweep angle</td>
<td>112 degrees</td>
</tr>
</tbody>
</table>
Service

Sonablate contains no user-serviceable parts. All repairs or requests for circuit diagrams, parts list, calibration instructions or other technical information should be directed to the following location for evaluation and necessary action.

Service Tel: 1-704-332-4439

Main Office:

SonaCare Medical, LLC
Focus Surgery, Inc.
4000 Pendleton Way
Indianapolis, IN 46226, USA
Tel: 1-317-541-1580
Fax: 1-317-755-1352
E-mail: service@sonacaremedical.com

Alert/Error Messages

During operation of Sonablate, the software may detect an alert condition or an error may be detected which may cause the system to operate improperly or become inoperable. In case of an alert condition or error, the alert icon will turn red. When this happens, click on the alert icon. This will bring up the “List of Alarms” message box, which will show the alert message on the screen (Figure 218).

For some alert messages a simple corrective action is advised. However for others, the procedure will have to be stopped, until a service engineer inspects the unit and clears it for use.

![List of Alarms](image)

Figure 218. Display of alert messages
For details about the screen display of errors / alerts, see HIFU Ablation Procedure section of this manual.

**Sonablate System Components & Accessories**

The part numbers listed below represent the Sonablate system and standard accessories used during procedures and testing. A complete list of replacement components is available to service personnel and distributors.

<table>
<thead>
<tr>
<th><strong>Sonablate Main System Components</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>102-17000-0009</td>
<td><em>Sonasource</em> Console</td>
</tr>
<tr>
<td>102-17000-0007</td>
<td>Sonachill™</td>
</tr>
<tr>
<td>202-17000-0012</td>
<td><em>Sonablate</em>® Probe HF 30/40 3G</td>
</tr>
<tr>
<td>302-17000-0001</td>
<td><em>Sonablate</em>® Probe Arm</td>
</tr>
<tr>
<td>308-17000-0002</td>
<td><em>Sonablate</em>® Multi-Axis Stepper Kit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Ablation Consumables</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>404-13500-0001</td>
</tr>
<tr>
<td>403-17000-0001</td>
</tr>
<tr>
<td>E01017AST61</td>
</tr>
<tr>
<td>302-08275-1001</td>
</tr>
<tr>
<td>Ablation Preparation and Reusable Components</td>
</tr>
<tr>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>101-04412-0143</td>
</tr>
<tr>
<td>302-17000-0009</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preventative Maintenance and Testing: Equipment, Fixtures and Consumables</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>302-08275-0005</td>
<td>Water CHEMets Test Kit</td>
</tr>
<tr>
<td>302-18115-0002</td>
<td>Verification Unit Assembly</td>
</tr>
<tr>
<td>302-18119-0006</td>
<td>Acrylic Verification Shell Holder Assembly</td>
</tr>
<tr>
<td>302-08115-0004</td>
<td>Acrylic Block Holder</td>
</tr>
<tr>
<td>302-18275-0003</td>
<td>Gray-Scale Phantom Assembly</td>
</tr>
<tr>
<td>302-08115-0006</td>
<td>Acrylic Verification Shell</td>
</tr>
<tr>
<td>302-08275-0007</td>
<td>Acrylic Verification Blocks</td>
</tr>
<tr>
<td>208-17000-0001</td>
<td>Decontamination Kit</td>
</tr>
<tr>
<td>302-08275-0012</td>
<td>Water Chemets Test Kit Refills</td>
</tr>
<tr>
<td>302-08275-0026</td>
<td>CHEMets Comparator</td>
</tr>
<tr>
<td>301-14325-0001</td>
<td>TAP Meter Assembly</td>
</tr>
</tbody>
</table>
APPENDIX D: SONABLATE IMAGE FUSION

Introduction

Fusion of Ultrasound and Magnetic Resonance Imaging (MRI) integrates radiology annotations onto the Sonablate®’s transrectal ultrasound scan for focal ablations.

NOTE: Image fusion and the ability to plan a zone with image fusion are optional features that may or may not be enabled on a particular Sonablate device; refer to your Sonacare Medical representative for details.

Importing MRI data:

Have the patient’s MRI image file available either on a CD or USB drive. Ensure the file is in Digital Imaging and Communications in Medicine (DICOM) format.

Accessing the 3rd party fusion software:

1. The fusion software can be accessed in the “Preplan Zones”, the “Plan a Zone”, and the “Treat a Zone” phases. The post-fusion ablation planning functions are not available in the “Preplan Zones” phase.
2. When prompted by the Checklist click the “Tools” dropdown box in the upper-right corner of the screen and select “Image Fusion” from the list (Figure 219). The Image fusion box will appear (Figure 220).

Figure 219. Image fusion display button
3. Click “Import Study” and select the desired MRI data to import from the CD or USB drive. Choose “import” to import it into Sonablate.

<table>
<thead>
<tr>
<th>CAUTION</th>
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<tbody>
<tr>
<td>Verify all patient information prior to importing MRI data to avoid a potential mismatch of patient data.</td>
</tr>
</tbody>
</table>

4. Select “Scan for Fusion” to update the volume stack of ultrasound images. The Perform Fusion button will be greyed out until scanning has completed.

5. Select “Perform Fusion” to open the 3rd party fusion software program and fuse the MR images with the volume stack.

*Please refer to the manual of your fusion software on how to perform image fusion. Once fusion is complete in your 3rd party program, the data will be imported into the Sonablate software.*
6. Confirm that the selected study is the correct data for the current patient.
7. Back in the Sonablate program, regions of interest from the MRI data are now visible in the ultrasound image stacks. Each region is outlined in a different color with corresponding labels and options in the Image Fusion box (Figure 221).

![Figure 221. Image Fusion - regions of interest](image)

8. To remove the fusion data and start over click “Erase Results”.
9. To move all contours use the “Adjust Position” arrows (Figure 222):
   a. “Up” and “Down” arrows move the outlines towards anterior and posterior.
   b. “Left” and “Right” arrows move the outlines laterally.
   c. “Diagonal Up Left” and “Diagonal Down Right” move the outlines proximally and distally.
   d. The button with the square in the center reverts the outlines back to their original positions.
10. When in the Preplan Zones workflow tab, click the  (volume planning) button under preplan zones pane to enable moving the fusion structures. Click on the  (polygon outline planning) button to select the outline drawing. Note after entering dimensions of prostate in preplan zones, lock the dimensions to avoid changing dimensions instead of dragging fusion image or marking an outline.

![Image](image.png)

**Figure 222.** "Adjust Position" arrows.

11. The prostate capsule contour and regions of interest can be toggled visible or hidden with the check box next to their label in the “Show” column (**Figure 223**).

12. A margin can be added to a region of interest by changing the value of the Margin (mm) field. Enter positive or negative numbers to create a dotted line inside or outside any of the contours (**Figure 223**).

![Image](image.png)

**Figure 223.** Image fusion box: visibility and margins

If you are in the Pre-Plan Zones phase, return to the checklist now and continue following onscreen prompts. The following steps are only available in the Plan A Zone phase.
Plan a Zone with Image Fusion:

13. When prompted by the Checklist click the “Tools” dropdown box in the upper-right corner of the screen and select “Image Fusion” from the list.

14. Select “Image Fusion Planning Mode” in the Planning Method box (Figure 224).

Figure 224. Planning Method box

15. In the Image Fusion box the “Type of Structure” and “Strength of the Effect of The Structure Type” options are now activated. The “Type” drop down menu offers the following ablation planning options for each region of interest (Figure 225):

Figure 225. Image fusion box - types of structures

a. Neutral – this region of interest will be disregarded in ablation planning
b. Target – this region will be targeted with HIFU
c. Avoid – this region will be avoided when ablating
d. Restrict – planned HIFU lesions will be restricted to the inside of this outline (e.g., the prostate capsule)

16. Use the “Strength” adjustment to fine tune how strictly the planning software should adhere to the set Types of Structure. Ablation site suggestions will automatically be added to the prostate ultrasound images according to your selections (Figure 226).
17. To accept the suggested ablation plan and add the proposed treatment sites to targeted regions, press the “+” button at the bottom of the screen. To remove treatment sites in avoided or outside of restricted regions press the “-” button (Figure 227). The targets now have solid red circles (Figure 228 Figure 229).
Figure 228. Ablation plan example after fusion

Figure 229. Suggested ablation plan sites (left) vs. accepted ablation plan sites (right).

18. To return to the checklist click the “Checklist” button at the top right of the screen and continue refining the ablation plan using the methods outlined in Chapter 9 of the user manual.
CAUTION

The regions of interest indicated on [the ablation screen] are based on the fusion of MRI images (including annotations if applicable) with real-time ultrasound images. The regions of interest indicated do not represent medical advice or an ablation plan. It is the user’s responsibility to determine the appropriate ablation plan based on the regions of interest and other information deemed relevant by the user.
APPENDIX E: SONALINK

Introduction

Sonalink is a telemonitoring/video conferencing tool powered by VSee video chat that enables a physician to connect to a physician or technician (remote user) that can provide instruction and/or guidance while using the Sonablate software. The physician can interact via video chat and or share the application screen to enable a remote user to view and/or take remote control over the Sonablate software.

NOTE: Online tutorials are available from the VSee Support Center (vsee.zendesk.com) Additional account support can be reached via email at support@vsee.com.

Starting VSee:

VSee should be configured to start and login when Windows starts. To start manually, double click on the VSee icon. Log in with the username and password assigned to the console; refer to your Sonacare Medical representative for details.

Using VSee:

1. To initiate a call, find the desired user in the contact list. If the user is not already in the contact list, type in the user’s email address in the search bar and add them to the contact list.

![Figure 230. VSee Contact list.](image-url)
2. Click on the contact to open a chat window. Messages can be sent to the remote user by typing in the text box.

![Figure 231. VSee Chat Window.](image)

3. Click the Call button (video camera) to initiate the video call. A status window will appear at the bottom of the screen showing the status of the call.

![Figure 232. VSee Call Status.](image)

4. Have the remote user accept the call to connect. Accepting the call will automatically bring each user’s video feed. As long as the video feed window is open, the call is connected.
5. To mute the microphone or to disable the camera, click the On buttons next to the microphone and camera icons on the video feed. Muting the microphone or disabling the camera will show a red line through the respective icons.

6. Check the audio quality and internet quality of each user at the bottom of each video feed; green is strong quality, orange is weak quality, and red is poor quality. Adjust settings as needed to achieve the best call quality possible. If any user is temporarily disconnected due to a weak internet connection, VSee will automatically attempt to reestablish the connection. The user will notice that a message, “Recovering lost connection” is displayed on the video feed during attempts to reestablish a connection.
<table>
<thead>
<tr>
<th><strong>WARNING</strong></th>
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<tbody>
<tr>
<td>Intermittent loss of connectivity resulting in delays or broken communication between the physician and remote user can lead to patient hazards. Therefore, Sonalink is only to be used by a trained HIFU physician for the purpose to receive supplemental guidance from a remote user or to provide demonstration. While HIFU is firing, pause HIFU before any attempt to establish a remote session or resolve a connection issue. Do not cause undue delay to the ablation procedure and discontinue the use of Sonalink if there are connectivity issues.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CAUTION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication errors can lead to device failures if serviced remotely. Therefore, Sonalink is not to be used for service, such as repair or maintenance activities.</td>
</tr>
</tbody>
</table>
7. To share the Desktop, click on the Tools button and click the Share Desktop button.

![Figure 236. Sharing the Desktop.](image)

8. To share a specific application, choose the Share Application button. Applications can also be shared by clicking the Share button at the top of each application.

Note: The Sonablate software application display utilizes the entire screen. The video feed will not appear on top of the Sonablate software while HIFU is firing.

9. Once the Desktop or Application is shared with the remote user, a tool panel will appear.

![Figure 237. VSee Contact list.](image)

10. The remote user can enable remote control by clicking the Take Remote Control. An orange border will appear around the button to indicate that it is enabled.

![Figure 238. Remote control is active (remote user display).](image)

11. To disable the ability for the remote user to have control, the local user can click the Disallow Remote button. The remote user will see that the Take Remote Control button has been disabled.
12. The local or remote user can use the Pen tool to draw on the screen.

13. Change the pen color by clicking on the Color button.

14. To type a message on the screen, click the Text button and begin typing in the text box.

15. Clicking the Erase button will remove all Pen markings and Text boxes on the screen.

16. While the Sonablate software is running, all other windows will be hidden. To access the VSee window, press the keys Alt+Tab to switch to the desired window.
17. To end the call, click the End call button at the top of the remote user’s video feed. A message will appear on the video feed that the user has hung up. If the remote user ends the call during a screen share, the orange box surrounding the screen share window will disappear.

Figure 243. Ending the session.
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