

Exablate Neuro

Exablate 4000 Operator's Manual

For Type 1.0 and 1.1 Systems Running Software Version 7.33

Caution: Federal law restricts this device to sale by or on the order of a physician

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REVISION INFORMATION

Manual Catalog Number: **PUB41005064**

Revision Release Date: **May 2023**

This is the **Revision 2** release of the Exablate 4000 Operator's Manual for System Software Version 7.33, applicable for Mid-Frequency Exablate 4000 systems installed within 1.5 and 3.0 Tesla MRI Systems.

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



WARNING:

W107

Ensure that this document conforms to your installed Exablate product, system configuration and Workstation (WS) software (SW) version. To verify your installed Exablate WS SW version, see information in the Utilities screen.

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1. SYSTEM OVERVIEW

1.1. Introduction

The **Exablate® Model 4000 Type 1.0 & Type 1.1** (“Exablate”, “Exablate Neuro” or “the system”) is a transcranial, magnetic resonance, image-guided focused ultrasound (MRgFUS) system that is designed for non-invasive ablation of brain tissue.

Focused ultrasound energy is repeatedly transmitted to the target region, gradually heating the tissue at the focal spot of the ultrasound beam until the target tissue is ablated and the desired outcome is achieved, while nearby tissue remains unaffected.

Targeting is accomplished using magnetic resonance (MR) images taken during the treatment. The treatment process is constantly monitored by real-time closed-loop thermal feedback under full control of the treating physician. Once the treatment is complete, the treatment outcome is confirmed with immediate post treatment MR imaging sequences.

Exablate Model 4000 encompasses two cradle types (Type 1.0 – Dedicated MRgFUS Treatments Table, and Type 1.1 – Detachable Transducer System that is mounted on general purpose MR Table)

The system is designed to interface with GE and Siemens MR systems (1.5T and 3T Scanners, with various types of magnets, software and hardware interfaces) **For detailed Intended Use/Indications for Use refer to the Information for Prescribers (IFP) document provided with this Operator’s Manual.**

1.2. Intended Users

The system may only be operated by licensed Neurosurgeons that have successfully completed the INSIGHTEC Exablate training program.

1.3. Document Conventions

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



NOTE:

Notes provide information to aid in obtaining optimum equipment performance.



CAUTION:









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

















WARNING:








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









1.3.1. Symbols Glossary:




Symbol	Symbol Title	Description	Standard Reference
	CE mark	Designates that the product labeled is authorized for sale in EU.	93/42/EEC 2017/745
	Authorized representative in the European Community	This symbol shall be accompanied by the name and address of the authorized representative in the European Community.	ISO 15223-1: 2016, clause 5.1.2
	Prescription devices	Caution: Federal law restricts this device to sale by or on the order of a physician / special practitioner.	21 CFR 801.109 21 CFR 801.15(c)(1)(i)F
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1: 2016, clause 5.1.1
	Date of manufacture	This symbol shall be accompanied by a date to indicate the date of manufacture.	ISO 15223-1: 2016, clause 5.1.3
	Use-by date	This symbol shall be accompanied by a date to indicate the expiration date.	ISO 15223-1: 2016, clause 5.1.4
	Batch code	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.	ISO 15223-1: 2016, clause 5.15
	Serial number	This symbol shall be accompanied by the manufacturer's serial number.	ISO 15223-1: 2016, clause 5.1.7

Symbol	Symbol Title	Description	Standard Reference
	Catalogue number	The manufacturer's catalogue number shall be adjacent to the symbol.	ISO 15223-1: 2016, clause 5.1.6
Model	Model/ designation Type	The name and/or number used to represent one medical device, or a family of medical devices to group many variations that have shared characteristics.	IMDRF/RPS WG/N 19:2016
	Keep away from sunlight/ Keep away from heat	Indicates a medical device that needs protection from light sources.	ISO 15223-1: 2016, clause 5.3.2
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1: 2016, clause 5.3.4
	Lower limit of temperature	The lower limit of temperature shall be indicated adjacent to the lower horizontal line.	ISO 15223-1: 2016, clause 5.3.5
	Temperature limit	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1: 2016, clause 5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1: 2016, clause 5.3.8
	This way up	This way up	ISO 7000-0623

Symbol	Symbol Title	Description	Standard Reference
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1: 2016, clause 5.4.2 IEC 60601-1 Ed 3.1 Table D1 (28)
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself	ISO 15223-1: 2016, clause 5.4.4 IEC 60601-1 Ed 3.1 Table D.1 (10)
	General Warning (There is a certain danger)	To be placed together with a supplementary symbol or text.	IEC 60601-1 Ed 3.1 Table D.2 (2)
	General mandatory action	To be placed together with a supplementary symbol or text	IEC 60601-Ed 3.1 Table D.2 (9)
	Follow instructions for use	Refer to instruction manual/ booklet	IEC 60601-Ed 3.1 Corrigendum 1 Table D.2 (10)
	Warning, electricity	Dangerous voltage	IEC 60601-1 Ed3.1 Table D.2 (3)
	WEEE- waste of electrical and electronic equipment	Discard the electrical and electronic equipment according to local regulation policy	Directive 2012/19/EU

Symbol	Symbol Title	Description	Standard Reference
	Type BF applied part	Degree of Protection against electric shock (Type BF)	IEC 60601-1 3.1Ed Table D.1 (20)
	Type B Applied Part	Type B Applied Part	IEC 60601-1 3.1Ed Table D.1 (19)
	Body weight	To identify the control or the indicator to enter or call up the body weight of a person	IEC 60417-5665
	Safe working load	Safe working load	IEC 60417
	Alternating current	Indicating the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	IEC 60601-1 3.1Ed Table D.1 (1)
	Three-phase alternating current	Indicating the rating plate that the equipment is suitable for three phases alternating current only; to identify relevant terminals.	IEC 60601-1 3.1Ed Table D.1 (2)
	Three-phase alternating current with neutral conductor	Indicating the rating plate that the equipment is suitable for three phases alternating current with neutral conductor only; to identify relevant terminals.	IEC 60601-1 3.1Ed Table D.1 (3)

Symbol	Symbol Title	Description	Standard Reference
	Protective earth (ground)	Identifying any terminal, intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.	IEC 60601-1 3.1Ed Table D.1 (6)
	Input; entrance	Indicating an entrance (e.g. hydraulic pump).	ISO 7000-0794
	Output; exit	Indicating an exit (e.g. hydraulic pump).	ISO 7000-0795
	Method of sterilization	Method of sterilization using ethylene oxide.	ISO 15223-1: 2016, clause 5.2.3
	MR Safe	Indicates that the device is safe- it poses no risks in any MR environment.	FDA guidelines for testing and labeling of medical devices in MR environment
	Medical device	Indicates the item is a medical device	ISO 15223-1:, clause 5.7.7
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1: , clause 5.2.8
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:, clause 5.4.3

Symbol	Symbol Title	Description	Standard Reference
	MR Conditional medical devices	Indicates that the device is MR conditional - A medical device with demonstrated safety in the MR environment within defined conditions	FDA guidelines for testing and labeling of medical devices in MR environment
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.	ISO 15223-1, clause 5.2.6
	Model number	Indicates the model number or type number of a product	ISO 15223-1:, clause 5.1.10

1.4. Scope of This Manual

This operator's manual covers the Exablate system for the following configurations:

- Trade name: Exablate
- Model: 4000
- Cradle Type: 1.1 / 1.0
- Software version: 7.33
- MRI magnetic field strength: 1.5T / 3.0T

1.5. System Characteristics

1.5.1. Specifications

- Tissue destruction mechanism: Thermal coagulation necrosis
- Planning: Treatment planned in multiple MR Images either by multiple acquisitions (i.e. along Coronal, Axial and Sagittal planes) or by reformatting of a single volumetric scan.
- Area measurement: The system allows the operator to measure an area on an image, and indicates the STD & mean within that area.
- Movement monitoring: Movements above 2mm (per axis, compared to reference image acquired during Planning) cause a safety halt.
- Reflection monitoring: None (data collection only)
- Cavitation monitoring: Passive cavitation detection, real time display; Sonication automatically halted if excessive cavitation is detected.

SPECIFICATION	NOMINAL MODE
Transducer	<i>1024 elements annular sector phase array</i>
Transducer aperture (diameter)	<i>300mm</i>
Transducer radius of curvature	<i>150mm</i>
Focal distance	<i>135 – 165 mm (achieved by electronic focusing)</i>
Frequencies	<i>620 – 720 kHz</i>
Frequency control	<i>Accuracy of +/-1kHz</i>
Energy range	<i>40 kJ</i>
Effective radiating area (ERA)	<i>1400cm²</i>
Focal region size	<i>~1.5 x 1.5 x 3 mm</i>
Focal control	<i>Electronic</i>
Imaging during treatment	<ul style="list-style-type: none"> • <i>PRF MR Images at 5 seconds interval or less</i> • <i>Spatial in-plane precision of 1.1 mm or less</i> <i>Anatomical image (Magnitude) SNR are >7</i>
Water Temperature measurement	<i>Active head cooling by cooled water (15°C default) circulation monitored with +/-1°C accuracy</i>

Thermal Imaging/Targeting accuracy	<i>Detection of the thermal spot center with 1mm accuracy</i>
Tissue Temperature measurement	<i>Proton Resonance Frequency (PRF) MR thermometry accuracy <2°C in all scan orientations</i>
Movement monitoring	<i>Accuracy of ~1mm</i>
Energy density in target (trans-skull)	<i>400~800 W/cm²</i>
Ultrasound output	<i>~1500W</i>
Effective strength	<i>~1 W/cm²</i>
Amplitude control	<i>Accuracy of +/-1Vrms or +/-15%</i>
Phase control	<i>Accuracy of +/-30°</i>
Calibrated power	<i>Accuracy of +/-30%</i>
Area measurement	<i>Accuracy of 0.1mm</i>
Max. output pulse width	<i>~60 sec</i>
Sonication duration	<i>9 - 60 sec</i>
Duty cycle	<i>1</i>
Cooling time	<i>20 ~ 400 sec (<1min/kJ transmitted)</i>

1.5.2. Treatment Outcome Monitoring Method:

Treatment outcome monitoring are provided by three different methods:

- Using real time thermometry, the operator gets real time feedback on treatment outcome, as temperature is correlated to tissue viability.
- Independent assessment using standard MR imaging sequences is performed during and after treatment to assess ablation size and location.
- Neurological evaluation during and after the treatment provides a clinical assessment.

1.5.3. System Electrical Specifications:

- Rated power voltages: 380V/400V/480V
- Number of phases: 3 phases
- Rated power frequency: 50/60Hz
- Rated power input: ~30Kva
- Protection against electric shock: Applied Part Type B



WARNING:

Deviation from compliance with the guidelines and methods detailed in this document and official INSIGHTEC documentation may cause serious injury to operator and/or patient and compromise treatment efficacy. All equipment must be operated by professionals trained by INSIGHTEC.

W001

1.5.4. System and Kits Environmental Conditions

■ System Operating Conditions:

	Equipment Room	Magnet Room	Operator Room
Temperature range	15-32°C	10-22°C	15-32°C
Relative humidity	≤ 80%	≤ 75%	≤ 75%

- Atmospheric pressure: 700 to 1060 hPa
- Altitude: -30 m (-100 ft.) to +3000 m (+9800 ft.)

■ System Storage & Transportation Conditions:

- Temperature range: 5 to 50°C
- Relative humidity: ≤ 90%
- Atmospheric pressure: 700 to 1060 hPa

■ Kit Transportation Conditions:

- Temperature range: 5 to 50°C
- Relative humidity: 15%-90%
- Atmospheric pressure: 700 to 1060 hPa

■ Kit Storage Conditions:

- Temperature range: 15 to 25°C
- Relative humidity: 40%-80%
- Atmospheric pressure: 700 to 1060 hPa

1.5.5. Effects of the System acoustic output levels on living tissue

- This equipment is used to cause tissue coagulative necrosis by heating using focused ultrasound.
- Low output level is used for targeting, without reaching coagulative necrosis.
- Dose level output generates coagulative necrosis of the targeted tissue, at the prescribed size.
- Excess output level will cause a larger than planned spot size and are prevented by the system's safety mechanisms.

1.6. System Components

1.6.1. Overview

The Exablate Neuro system consists of the following integrated components:



WARNING:

W002

The use of accessories, transducers and cables other than those specified or provided by INSIGHTEC of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

In the Operator Room:

- Operator Console (WS – Workstation)

Inside the MRI Suite:

■ **For Systems with Type 1.0 Cradle:**

- Exablate MRI Table, including:
 - Transducer
 - Mechanical Positioner
 - Frame Fixation Posts
 - MR Tracking and Head Coil Connector/s
 - Water System Remote Controller
- Front End Unit (FE), including:
 - Power and Water Cables
 - Patient Stop Sonication Button
 - Nurse Stop Sonication Button

■ **For Systems with Type 1.1 Cradle**

- Front End Unit (FE)
- Helmet System (HS):
 - Transducer
 - Mechanical Positioner
 - Frame Fixation Posts
 - Power and Water Cables
 - MR Tracking and Head Coil Connector/s
 - Patient Stop Sonication Button
- Storage and Transfer Cart (STC)
- Exablate MRI Table Adapter Baseplate
- Water System:
 - Water System Control Touchscreen (within FE)
 - Water Reservoir (within FE)
 - Water System Remote Controller (attached to FE).

In the Equipment Room:**■ For Systems with Type 1.0 Cradle**

- Equipment Cabinet
- Water System Components:
 - Water Chiller
 - Water System Control screen
 - Water Reservoir

■ For Systems with Type 1.1 Cradle

- Equipment Cabinet
- Water System Components:
 - Water Chiller

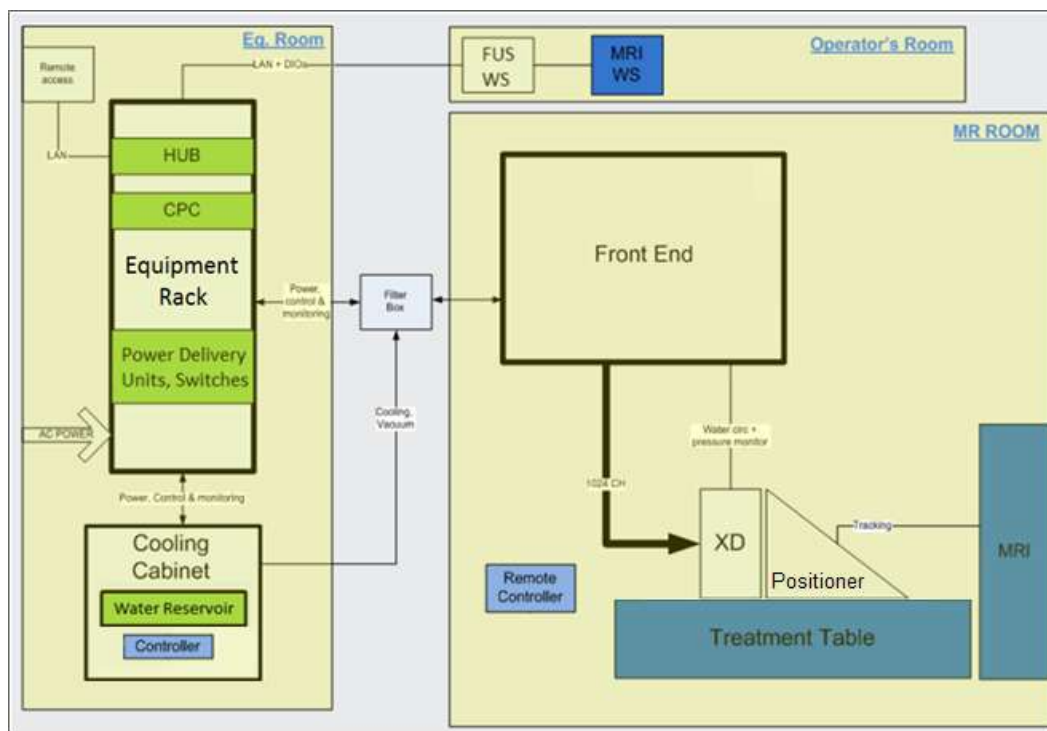


Figure 1-1: Schematic Representing Layout of Type 1.0 System Components In-Site

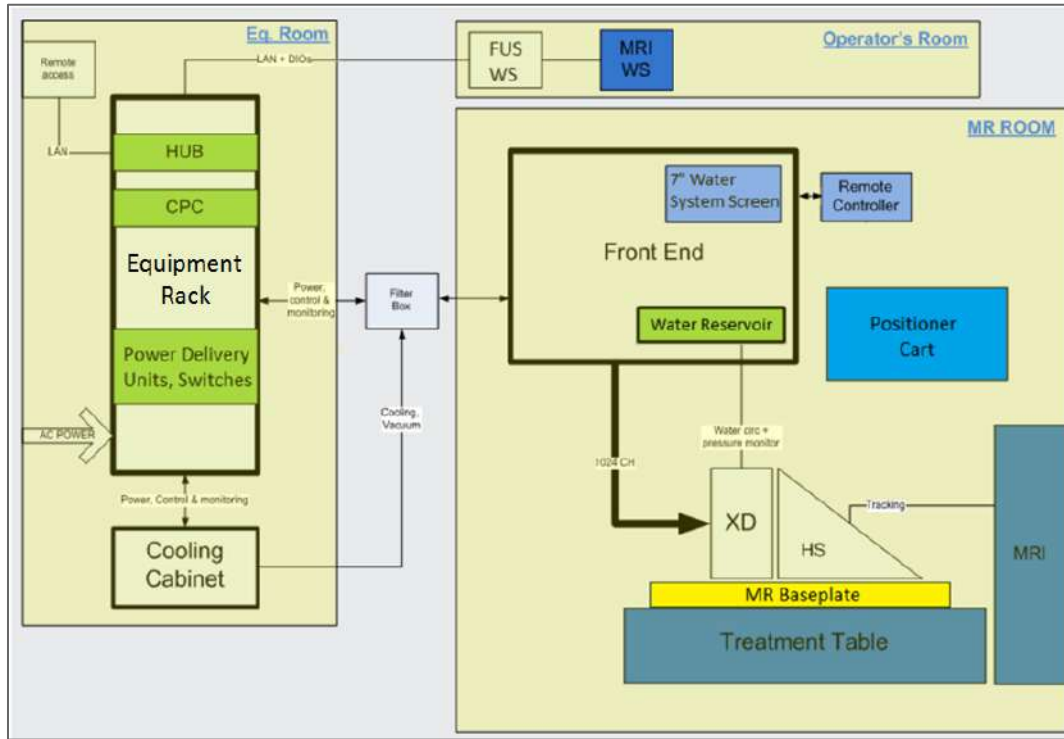


Figure 1-2: Schematic Representing Layout of Type 1.1 System Components In-Site

1.6.2. Operator Console Workstation

The Exablate Neuro Operator Console allows the operator to control and monitor both the system and the treatment. It is positioned alongside the MRI Workstation in the control room. The Exablate software is controlled by a standard mouse and keyboard combination. The Operator Console is fitted with a green Power Button, a blue Water System Control Button and state indicator, and a red Operator Stop Sonication Button. It is fitted with USB ports and a CD drive for importing and exporting images and technical data.



Figure 1-3: Exablate Neuro Operator Console Workstation

1.6.3. Front End Unit

The Front End (FE) Unit incorporates the electronic systems that drive the ultrasonic transducer.

It is located in the magnet room and is connected to the Equipment Cabinet.

The unit can be moved around the room, within a limited area.

The Type 1.1 FE is equipped with a connector panel holder to store the Detachable Cable Connector Panel for easier cable management.

FE Harnesses - When the Front-End Unit is stored away from the MRI Suite, the harness connectors may be disconnected by the site personnel after being trained to do so (see **Figure 1-4**).



Figure 1-4: Type 1.0 (L) and Type 1.1 (R) Front-End Units

1.6.4. Exablate Type 1.0 Treatment Table

The Exablate 4000 Type 1.0 Treatment Table incorporates the focused ultrasound transducer along with the mechanical positioning unit that moves and locks the transducer in place (See section 3.3.4). Treatments are conducted with the patient lying on the patient table inside the MR scanner (see **Figure 1-5**). The Exablate patient table is docked to the MR Scanner prior to an Exablate procedure and is later detached to facilitate regular operation of the MR scanner.



Figure 1-5: Type 1.0 Treatment Table

1.6.5. Exablate Type 1.1 Treatment table components

MRI Table Adapter Baseplate

The Exablate MRI Table Adapter Baseplate facilitates connecting the Exablate Transducer along with its Mechanical Positioning and Frame Fixation Unit. It contains a basin that retains spilt water in the case of an emergency patient evacuation (see **Section 2.2.3**). Different MR scanner models and makes may have different Baseplates adapted for them.



Figure 1-6: MRI Table Adapter Baseplate (for illustration purposes only)

Helmet System

The Helmet System (HS) is fixed onto the MR Table Baseplate during the treatment and incorporates the focused ultrasound Transducer, the Mechanical Positioning System that allows manipulation of the transducers positioning and pitch in place, and the Frame Fixation Posts that keep the patient's head immobilized during treatment. The Helmet System connects to the Front-End Unit via the Power and Water Cable.



Figure 1-7: Helmet System

1.6.6. Patient Stop Sonication Button (Type 1.0)

The **Patient Stop Sonication button** is connected to the Front-End. The button is intended for the patient during the treatment. Pressing the button immediately interrupts the treatment.



Figure 1-8: Patient stop sonication button (Type 1.0)

1.6.7. Patient Stop Sonication Button (Type 1.1)

The **Patient Stop Sonication button** stop sonication button is connected to the helmet system via a blue & white cable. Connect the stop sonication cable to the MR table after transferring the HS. The button is intended for the patient during the treatment. Pressing the button immediately interrupts the treatment.



Figure 1-9: Patient Stop Sonication Button (Type 1.1)

When not in use, bend the cable around the Frame Holder and put the sonication button in its dedicated holder.

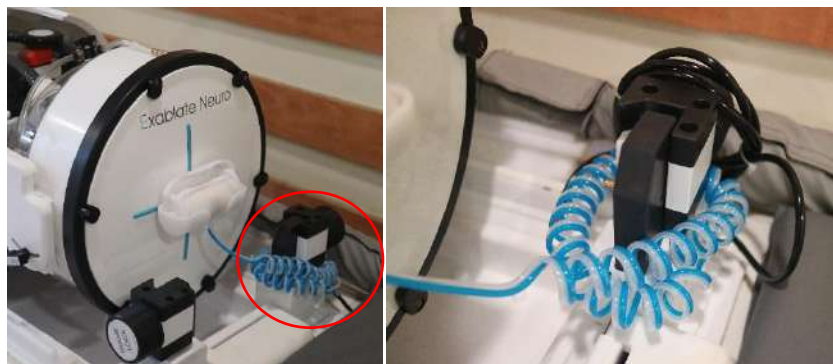


Figure 1-10: Stop sonication cable (Right) and Button (Left) storage, Type 1.1

**CAUTION:**

C001

Failing to stow the Type 1.1 Patient Stop Sonication-Button as described above may lead to damage when transferring the Helmet System to or from the STC

1.6.8. Storage and Transfer Cart (STC) with Detachable cable connector panel (Exablate Type 1.1 Only)

The STC houses the Helmet System when it is not in use. It is fitted with wheels and can be locked in place and may be stored inside or outside the MRI Suite. It includes a coupling mechanism for latching onto the MRI Table and transferring the Helmet System onto the MRI Baseplate.

The Detachable cable connector panel is mounted on the Connector panel holder on the front of the STC and is meant to assist in the process of connecting the cables to the Front End, as well as keeping the connectors protected when the system is not in use. The cable connector panel can be used to carry the cables over to the front end, where it can be held in another Connector Panel Holder.



Figure 1-11: STC Cart Without (Left) and with (Right) Helmet System

1.6.9. Exablate Type 1.1 Water System

- During an Exablate Neuro treatment, the part of the patient's skull transversed by the ultrasound beams is immersed in water to facilitate ultrasound transmission and ferry heat away from the skull.
- The water system offers a semi-closed water circulation loop, enabling filling and draining of the transducer water interface, preparing and circulating the water during treatment (while keeping it cooled and degassed) and performing a cleaning procedure following the treatment.
- The portable water reservoir holds up to 13 liters (3.45 US gallons) of water and is housed inside the designated Water Reservoir Compartment in the Front-End Unit.
- During treatment, when the MR is not scanning, this water is circulated and degassed by the Water Chiller, located in the equipment room.
- The various modes, states, and parameters of the Water System (see **Section 3.5.**) can be controlled via the Workstation Software, or by the dedicated **Water System Control** touch-screen located on the FE.
- Water system states can also be controlled via the Water System Remote Controller or the blue Water System Control Button on the Operator Console.
- For further details regarding the water system interface, refer to **Section 3.5.**
- For further details regarding water system maintenance and the cleaning procedure, see **Chapter 12**

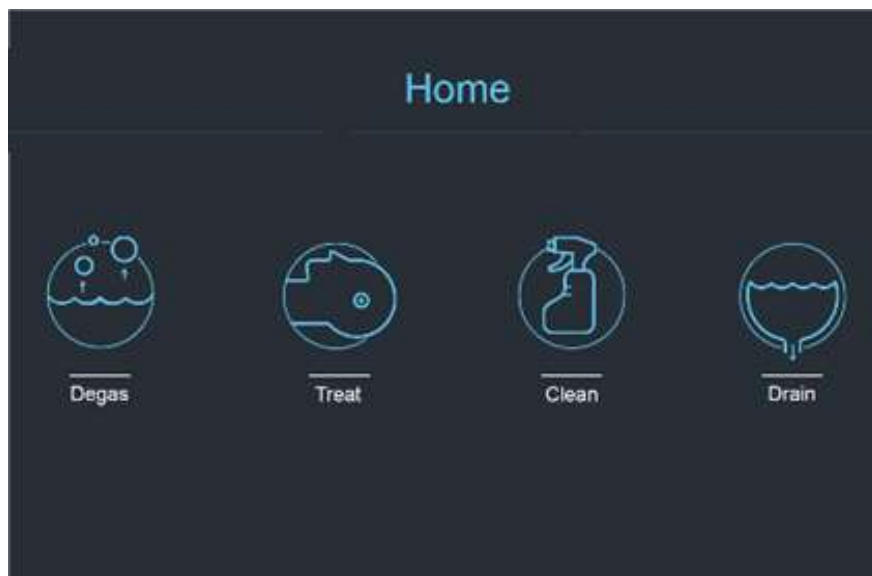


Figure 1-12: Water System Control 'Home' Screen (L) and Chiller (R)

1.6.10. Exablate Type 1.0 Water System

The water system offers a semi-closed water circulation loop, designed to provide for several requirements for the trans-cranial procedure:

- Filling and draining the transducer's water interface during procedure preparations.
- Circulating the water during procedure to keep interface water cooled and degassed.
- The water system is usually located in the MRI equipment room. Review the **System Cleaning and Disinfection Procedure (Chapter 12)** for more information.
- Perform the cleaning procedure in between procedures.
- The cleaning procedure requires the use of the **Cleaning and disinfection materials**, for further details regarding the Cleaning and Disinfection Procedure see **chapter 12**.



Figure 1-13: Exablate Neuro Type 1.0 Water Chiller with integrated control screen

1.6.11. Equipment Cabinet

The Equipment Cabinet incorporates the electrical components of the Exablate Neuro system and the main power switch. This unit is usually located in the MRI equipment room.

Do not interact with the equipment cabinet. Only authorized INSIGHTEC service personnel are qualified to move, disconnect or service this unit.



Figure 1-14: Exablate Neuro Equipment Cabinet (illustration)



NOTE:

N001

The red Emergency Power-Down Button on the bottom of the equipment cabinet is to be pressed in case of emergency for complete power down (e.g. in event of a fire or electrical short-circuit).

1.6.12. Key Exablate 4000 Treatment Components

For each treatment, ensure the following components are available:

- 1 x Exablate Neuro Patient Membrane
- 1 x Exablate Neuro DQA Phantom Gel
- 1 x Exablate Neuro Treatment Accessories Kit
- 4 x Disposable Head Frame Screws (Compatible with Frame Type DHRS or Type PFK)
 - For frame type PFK only: a set of Head Frame Screw Adapters (See section 1.8)
- One Neuro Head Frame set is supplied with the system, see detailed components description in the relevant Head Frame section

The treatment components are provided compatible with your exact system configuration (Exablate 4000 model, MR type & field strength).

For applicable part numbers please refer to the Part Numbers file provided with the system or available on demand.



WARNING:

W005

Treatment kit and accessory compatibility may vary per MRI and system type.

Please contact the Insightec representative to ensure system compatibility with the relevant components. Discard single use accessories following treatment.



WARNING:

W003

Do not use accessories which are incompatible with your exact system configuration (Exablate 4000 model, MR type & field strength).



WARNING:

W004

Inspect treatment kit components before use. If a component is damaged, do not use it and discard according to local regulation.







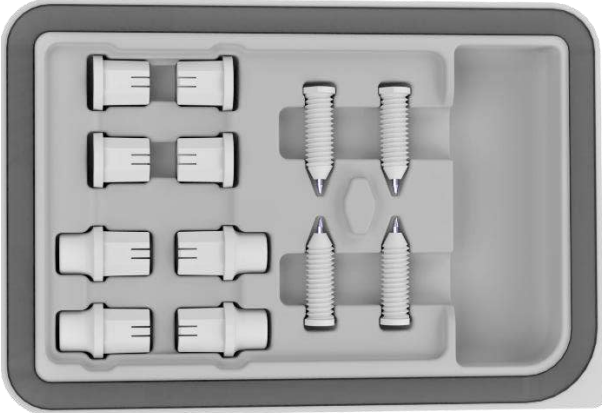
1.6.13. General Accessories for Exablate 4000 Type 1.0 & Type 1.1

List of accessories supplied with the system (as per specific system configuration).

DESCRIPTION	CONTENT DESCRIPTION
Hose with adapter: threaded tap	For easier filling of the water tank
Hose with adapter: flexible tap	For easier filling of the water tank
Manual Drain Kit	Used to manually drain water from transducer in the event of mains power loss during procedure.
Landmark Labels	Landmark Label Sticker
DQA Setup Kit for Type 1.1 or 1.0 Systems	Case including DQA Phantom Gel holder head frame adapters fit for the Type 1.1 or 1.0 Exablate system
DQA Setup Membrane mounting Jig	For assembly of Head Coil on DQA setup, to allow QA for specific Head coil. For use with DQA Setup Kit for Type 1.1/1.0 Systems
Hose with funnel for Water tank	For easier filling of the water tank

1.6.14. Head Frame Types

There are different types of Head Frames, refer to the relevant section according to the frame in use.

Exablate Head Frame Base	UCHRA Head Frame Base
Type DHRS: Posts for use with Head Ring Screws (DHRS)	
 <p>Refer to Section 1.7</p> 	 <p>Refer to Appendix A</p> 
Type PFK: Posts for use with the Patient Fixation Kit (PFK)	
 <p>Refer to Section 1.8</p>	 <p>Refer to Appendix B</p> 

1.7. Exablate Head Frame Type DHRS Instructions for Use

**WARNING:**

W117D

Determine applicable configuration as described in 1.6.14 and refer to relevant documentation only.

1.7.1. Exablate Head Frame

This section describes how to properly assemble, use, handle and maintain the Exablate Neuro Head Frame. Read and become familiar with these instructions before using INSIGHTEC's Head Frame.

Exablate Neuro Head Frame is a head frame used for the fixation of patient's head during treatment with Exablate 4000 System. The Exablate Head Frame is MR Conditional. Always inspect Exablate Neuro Head Frame prior to use. Do not use if damaged.

**WARNING:**

W006

The Exablate Neuro Head Frame is intended for use only for Exablate Neuro treatments.

**WARNING:**

W007

Perform a visual inspection prior to using the frame, and ensure all screws are fully tightened. Contact Insightec in case the frame is dropped, or any damage is detected. Do not use if damaged!

**WARNING:**

W008D

The Disposable Head Frame Screws (Long or Short) are provided **STERILE** using Ethylene Oxide.

- Visually inspect screw package before use to verify the integrity of sealing. Discard of screws in case of tears, punctures or other visual damage to package or components.
- Disposable Head Frame Screws are intended for single-use only. Do not re-use or re-sterilize. Re- use may result in cross contamination, and in dullness of the screw, leading to potential patient movement. Dispose of the screws according to hospital and local laws.

**WARNING:**

W009

The Head Frame is to be used within an MR device. It should not contact the patient. Maintain a gap between the Head Frame and the patient's skin to avoid RF burns.



NOTE:

N002D

Be sure to gather the small miscellaneous parts (such as screws, wrenches and accessories) following use to prevent loss.



NOTE:

N003

For Instructions of the UCHR based Headframe previously supplied with Exablate systems, see appendix A

1.7.2. Exablate Neuro Head Frame Set



NOTE:

N004

The Exablate Neuro Head Frame is already attached in its case to the Head Frame Anterior bar and the two posterior Head Frame Posts.

In case of small head, see below instructions for the Anterior bar replacement.



NOTE:

N005

Post position can be adjusted according to patient's anatomy.



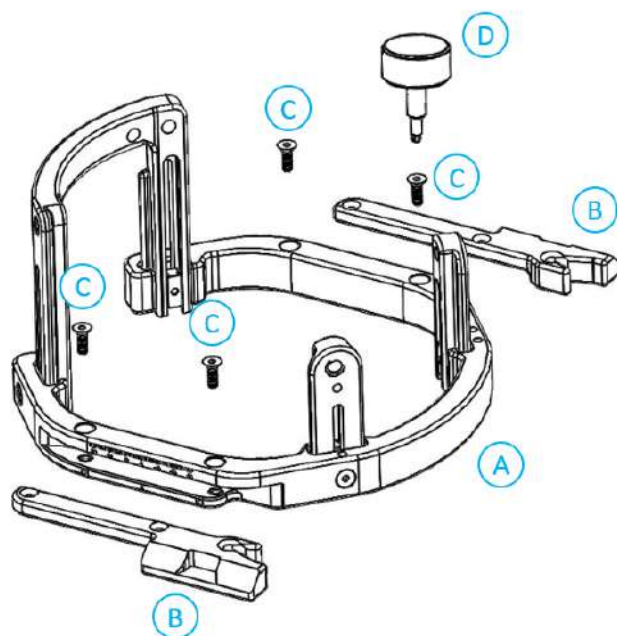
Part Name	Qty.	Part Name	Qty.	Part Name	Qty.
A Headframe Base	1	E Side Holder Fixation Screws	4	I Long Side Holders (Type 1.1 Only)	4
B Posterior Posts	2	F Post Fixation Screws	4	J Patient Fixation Wrench	2
C Anterior Bar	1	G Frame Placement Strap	1	K Frame Assembly Wrench	2
D Side Holders	2	H Anterior Bar for Small Heads	1		

Figure 1-15 The Exablate Frame Type DHRS Set (illustration)

1.7.3. Replacing the Side Holders

The Exablate Type DHRS Head Frame set includes two sets of side holders.

The Low Side Holders allow extending the reach of the transducer along the A-P direction and are especially relevant if aiming for an anteriorly located target in a 60cm MR bore. An informed choice of side holders may also help maximize patient comfort.



	Part Name	Qty.
A	Headframe Base	1
B	Side Holders	2
C	Side Holder Fixation Screws	4
D	Head Frame Assembly Wrench	1

Figure 1-16: Connecting Side Holders to the Headframe (for illustration purposes only)



A	Frame Assembly Wrench
B	Patient Fixation Wrench
C	Side Holder Fixation Screw
D	Post Fixation Screw

Figure 1-17: Head Frame Screws and Wrenches

1.7.4. Fastening the posts, and replacing the Head Frame Anterior Bar (Optional)

In case of a patient with a small head, the User can replace the Anterior bar with the Anterior Bar for Small Heads. Using this component enables to bring the screws up to 19mm closer to the patient's head.

1. Detach the Head Anterior Bar from the Head frame using the Head Frame Assembly Wrench to untighten the attachment screws.
2. Attach the Anterior Bar for Small Heads onto the anterior socket of the head Frame, use the Head Frame Assembly Wrench to tighten the attachment screws.

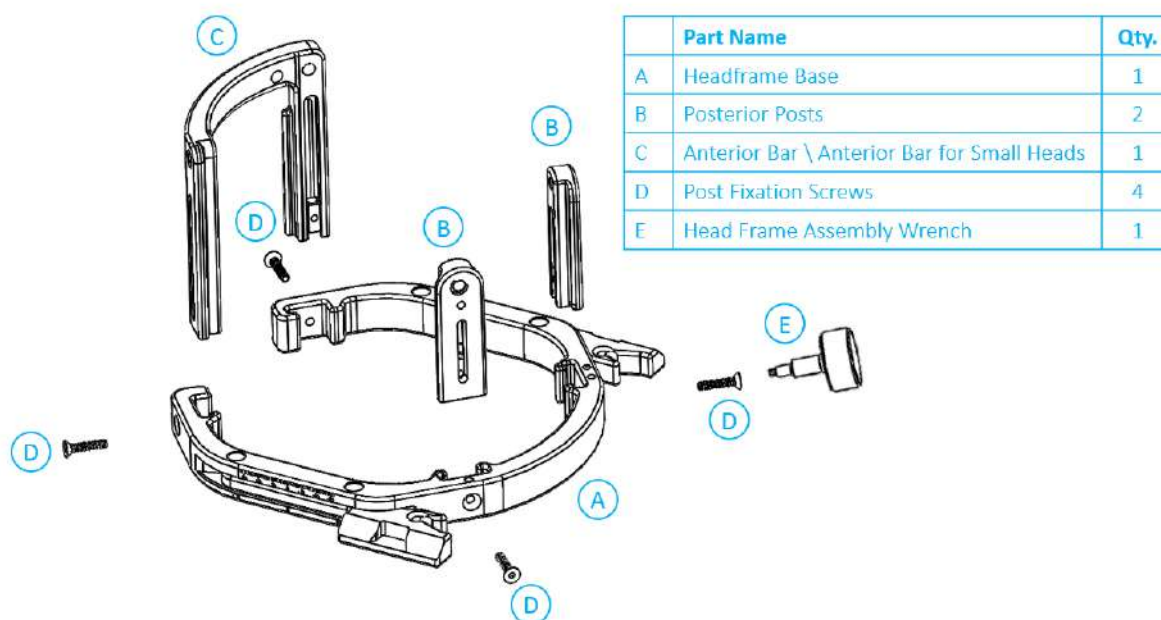


Figure 1-18: Connecting Posts and Bars to the Headframe (for illustration purposes only)



NOTE:

N102D

It is possible to slide the posts up and down to optimize the headframe's fit to the patient.



WARNING:

W010

Ensure each post is thoroughly fastened.

1.7.5. Positioning the Frame on the Patient

**WARNING:**

W109D

Headframe fixation may only be performed by a licensed Neurosurgeon with stereotactic experience.

- Shave the patient's scalp thoroughly, then wipe it clean with a "rubbing alcohol" soaked gauze or pad.
- Ensure that the posts are tightly fastened.
- Insert the Disposable Head Frame Screws to their predisposed fixation holes on the posts and Bar from the internal side of the frame (See **Figure 1-21**) to avoid screws' pin contamination.

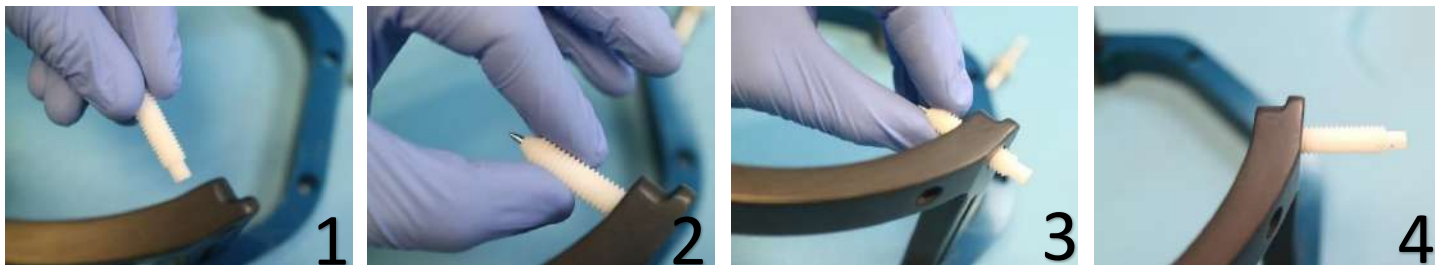


Figure 1-19: Internal Screw insertion

**WARNING:**

W011

Select the appropriate anterior bar so that the screws protrude at least 13 mm from the outside surface of the Head posts and Anterior bar.

**WARNING**

W115D

It is recommended to use an antibacterial ointment on the tips of the screws. Disinfect and bandage the screw insertion sites after removing the headframe

- (Optional) Use head Frame Positioning Straps to place and adjust the vertical height of the Head Frame (**Figure 1-20**).



Figure 1-20: Headframe placement straps

- Place the Frame as inferiorly as possible to enable optimal coverage for the Exablate treatment.
- Mark with a marking pen the projected screw entry sites and the superior temporal line (optional)



NOTE:

N006

Using the Head Frame Positioning Straps helps support the weight of the Head Frame Assembly during placement on the patient. Head Frame Post and Bars are height adjustable



NOTE:

N007D

Use all four (4) Disposable Head Frame Screws to attach the Frame to the Patient

- Only use the Head Frame components and tools provided by INSIGHTEC
- Placing the Head Frame assembly is easier if two people perform the procedure.



CAUTION:

C003

Four anterior Head Frame Bar fixation holes are available for the Disposable Head Frame Screws' insertion. The medial access points can be utilized to avoid damaging the patient's temporalis muscle.

- Apply local anesthesia through the post fixation holes or on marked screws insertion sites. With or without temporarily moving the frame.
- Allow the local anesthetic to take effect.
- Use the Patient Fixation Wrench provided by INSIGHTEC to drive the Disposable Head Frame Screws into the patient's skull.

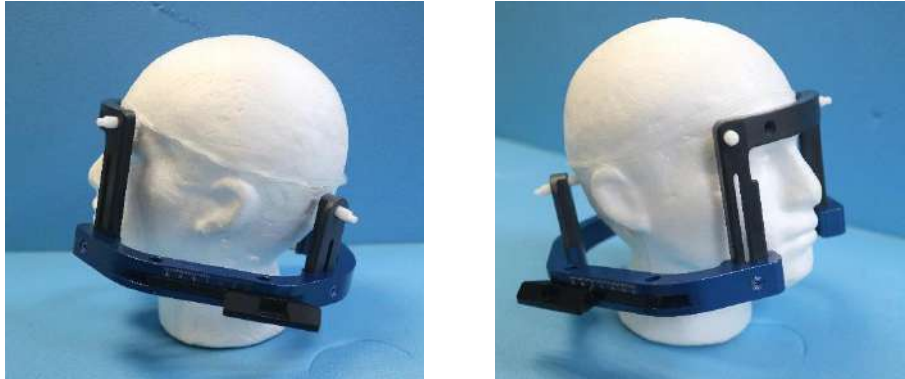


Figure 1-21: Typical Headframe Placement

- Keep a distance between the skin and the outer aspect of the bar at each screw site
- Tighten the screws: two diagonally opposed screws at a time, alternatively and equally
- Apply moderate force to ensure the Frame is securely tightened to the patient's skull.



CAUTION:

Overtightening of the Disposable Head Frame Screw can cause premature failure of the head Frame posts and/or the Disposable Head Frame Screw. C004D

Be sure that the spine of the posts does not press against the skin for patient comfort.



WARNING:

Overtightening of the Disposable Head Frame Screws may cause skull injury: W012D

- Prior to frame application, the surgeon should review details of the patient's CT
- Avoid applying an extra strength during screw insertion on the skull

- Remove the Head Frame Positioning Straps.
- Attach a silicone cap to the end of each Disposable Head Frame Screws.



Figure 1-22 Membrane protective silicone caps on screw's extremity

- The Patient is now ready for **Patient Membrane** placement.

1.7.6. Head Frame maintenance

Use the following guidelines to maintain Head Frame components after each treatment:

1. Immediately after use, wipe components with de-ionized distilled water to remove any residue of Betadine and blood or other debris
2. Dry thoroughly the components with paper
3. For persistent stains, wipe relevant areas with Isopropyl Alcohol 100% (IPA)



CAUTION:

C005D

Do not use saline. Saline may cause damage to the metal surface.
Do not use corrosive agents, such as Clorox® or Cidex®.
Do not use alcohol or hydrogen peroxide on any black composite materials.



NOTE:

N008D

The use of Betadine® or similar solution containing iodine may stain the surface of the Head Frame.

To minimize discoloration, wipe off any traces of Betadine® or similar solutions as soon as a possible during or following the procedure.



NOTE:

N009D

If instruments are exposed to highly caustic solutions such as bleach solutions, immediately rinse the instruments with de-ionized distilled water to prevent corrosive damage to surfaces and moving parts.



CAUTION:

C006

Headframe expected life cycle is 10 years. Contact your Insightec representative regarding replacement Frame, discard following said period and in case of any visual signs of damage/ corrosion.

**NOTE:**

N010

Headframe components are Autoclave compatible.

Recommended Autoclave Parameters:

1. The Head Frame should be disassembled prior to autoclave process.
2. Place the components in adequate autoclave bag, i.e., *Sterilization Pouches*
3. The following table provides the recommended autoclave parameters for the Exablate head frame components:

<u>Steam Autoclave</u>		
	Option 1	Option 2
Temperature	250°F / 121°C	270°F / 132°C
Exposure Time	20 minutes	10 minutes
Dry Time	20 minutes	10 minutes

1.8. Exablate Head Frame Type PFK Instructions for Use

**WARNING:**

W117D

Determine applicable configuration as described in 1.6.14 and refer to relevant documentation only.

1.8.1. Exablate Head Frame Type B

This section describes how to properly assemble, use, handle and maintain the Exablate Neuro Head Frame type B. Read and become familiar with these instructions before using INSIGHTEC's Head Frame.

The Exablate Neuro Head Frame is used for the fixation of the patient's head to the treatment table during treatments with the Exablate 4000 System. The Exablate Head Frame is MR Conditional. Always inspect Exablate Neuro Head Frame prior to use. Do not use if damaged.

**WARNING:**

W006

The Exablate Neuro Head Frame is intended for use only for Exablate Neuro treatments.

**WARNING:**

W007

Perform a visual inspection prior to using the frame, and ensure all screws are fully tightened. Contact Insightec in case the frame is dropped, or any damage is detected. Do not use if damaged!

**WARNING:**

W118D

The Disposable Head Frame Screws and adapters are provided STERILE using Ethylene Oxide.

- Visually inspect screw package before use to verify the integrity of sealing. Discard of screws in case of tears, punctures or other visual damage to package or components.
- Head Frame Screws and Adapters are intended for single-use only. Do not re-use or re-sterilize. Re-use may result in cross contamination, and in dullness of the screw, leading to potential patient movement.
- Dispose the screws and all 8 adapters according to hospital and local laws.

**WARNING:**

W009

The Head Frame is to be used within an MR device. It should not contact the patient. Maintain a gap between the Head Frame and the patient's skin to avoid RF burns.

**NOTE:**

N002D

Be sure to gather the small miscellaneous parts (such as screws, wrenches and accessories) following use to prevent loss.

**NOTE:**

N003

For Instructions of the UCHR based Headframe previously supplied with Exablate systems, see appendix A

1.8.2. Exablate Neuro Head Type PFK Frame Set**CAUTION:**

C042

The Exablate Neuro Head Frame is already assembled in its case to the Head Frame posts. Make sure they are strongly tightened to the head frame base.

**NOTE:**

N005

Post position can be adjusted according to patient's anatomy.

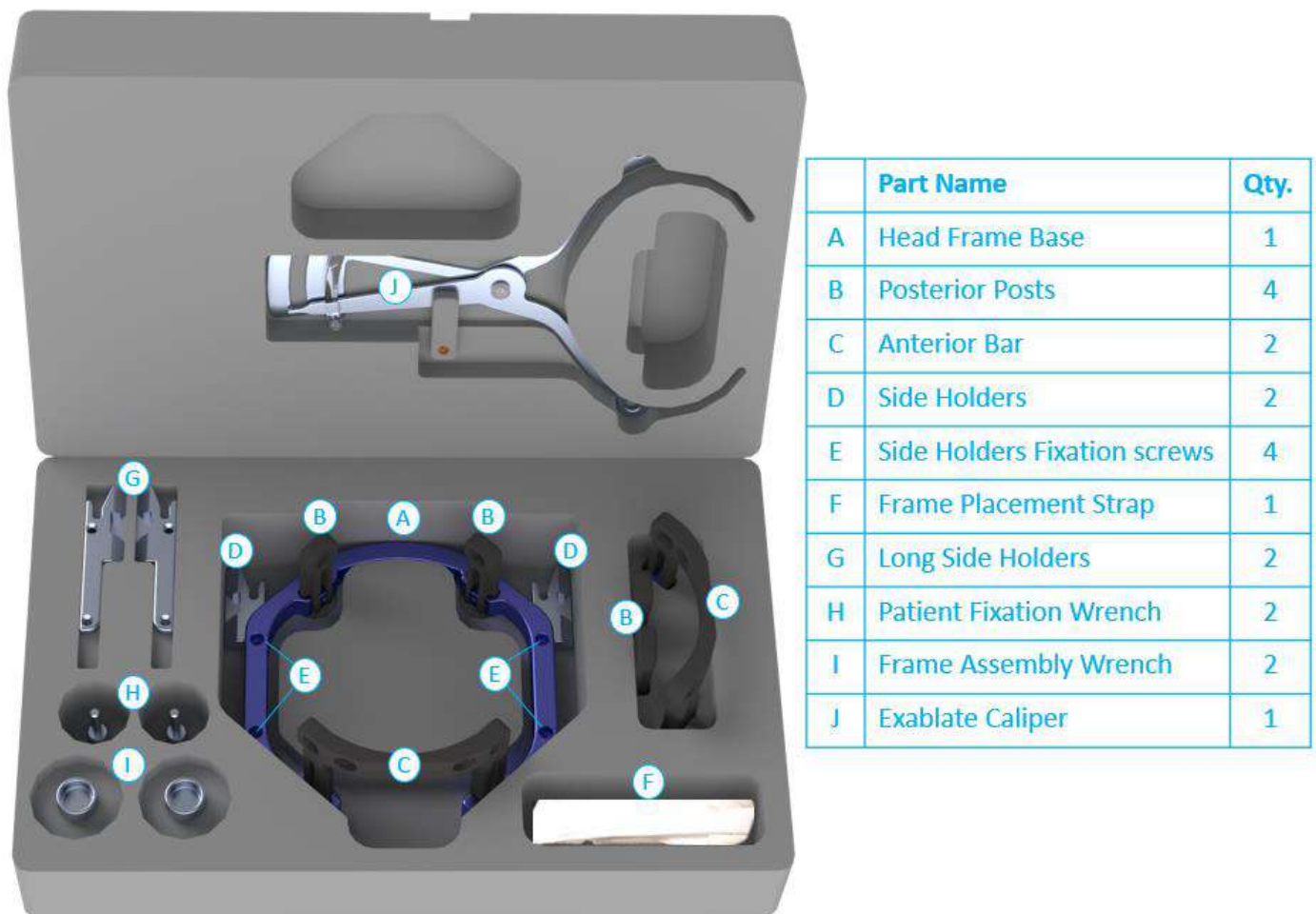


Figure 1-23 The Exablate Frame Set (For illustration purposes only)

1.8.3. Exablate Neuro Patient Fixation Kit (PFK)

The PFK (Patient Fixation Kit) is composed of 4 Patient Fixation Screws, 4 Short Adapters and 4 Long Adapters (Figure below). The adapters offer a sterile interface for the screws and provide compatibility with a wide range of head sizes. As shown in the figure below, the Screws and Adapters are assembled onto the posts of the Exablate Head Frame via dedicated fixation holes.

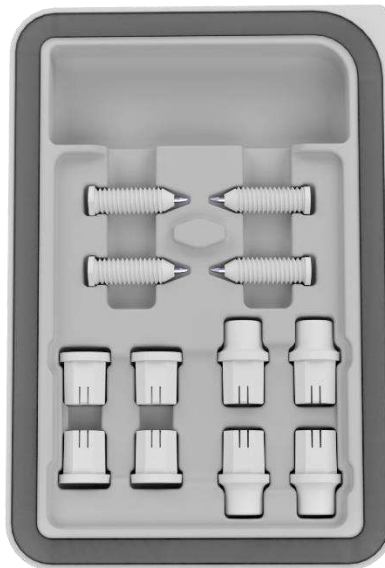


Figure 1-24: Exablate Neuro Patient Fixation Kit (PFK)

1.8.4. Exablate Caliper

The Exablate Caliper enables to determine what is the patient's optimal adapters combination to use (Section 1.9.4) by measuring the patient's head diagonal (See **picture 1-27** - from front pin insertion location to its contralateral posterior pin insertion location on patient's head).

The Caliper has a range of three different intervals for 3 types of head size: SS, SL, LL (Section 1.9.4).

In order to choose the right combination of adapters to insert in the frame fixation holes, use the caliper provided in the Head Frame Set (Section 1.9.3) on a shaved patient's head.

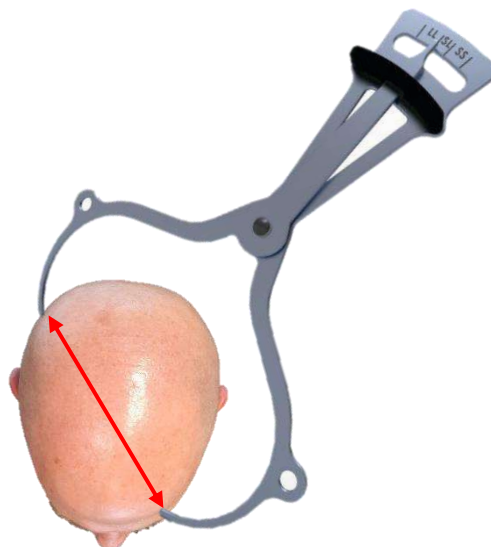


Figure 1-25 - Exablate Caliper for Head diagonal measurement and combination estimation

1.8.5. Different Adapter Combinations

The Exablate Caliper enables to determine what is the optimal adapter combination to use for each patient, by measuring the patient's head diagonal (Section 1.8.5)

Using the provided Caliper (**Section 1.8.5**), measure the distance between contra-lateral pin insertion points (e.g. the distance between the left posterior and right anterior intended fixation locations).

Based on this measurement, select the appropriate combination of adapters (see below).

Note that in case of abnormal or asymmetric patient anatomy, a different combination may be optimal for each pair.

Caliper reading: SS	Caliper reading: SL	Caliper reading: LL
Short Adapters	Mixed Adapters	Long Adapters
		

1.8.6. Replacing the Side Holders

In some configurations, the Exablate Type PFK Head Frame set includes two sets of side holders.

The Low Side Holders allow extending the reach of the transducer along the A-P direction and are especially relevant if aiming for an anteriorly located target in a 60cm MR bore. An informed choice of side holders may also help maximize patient comfort.

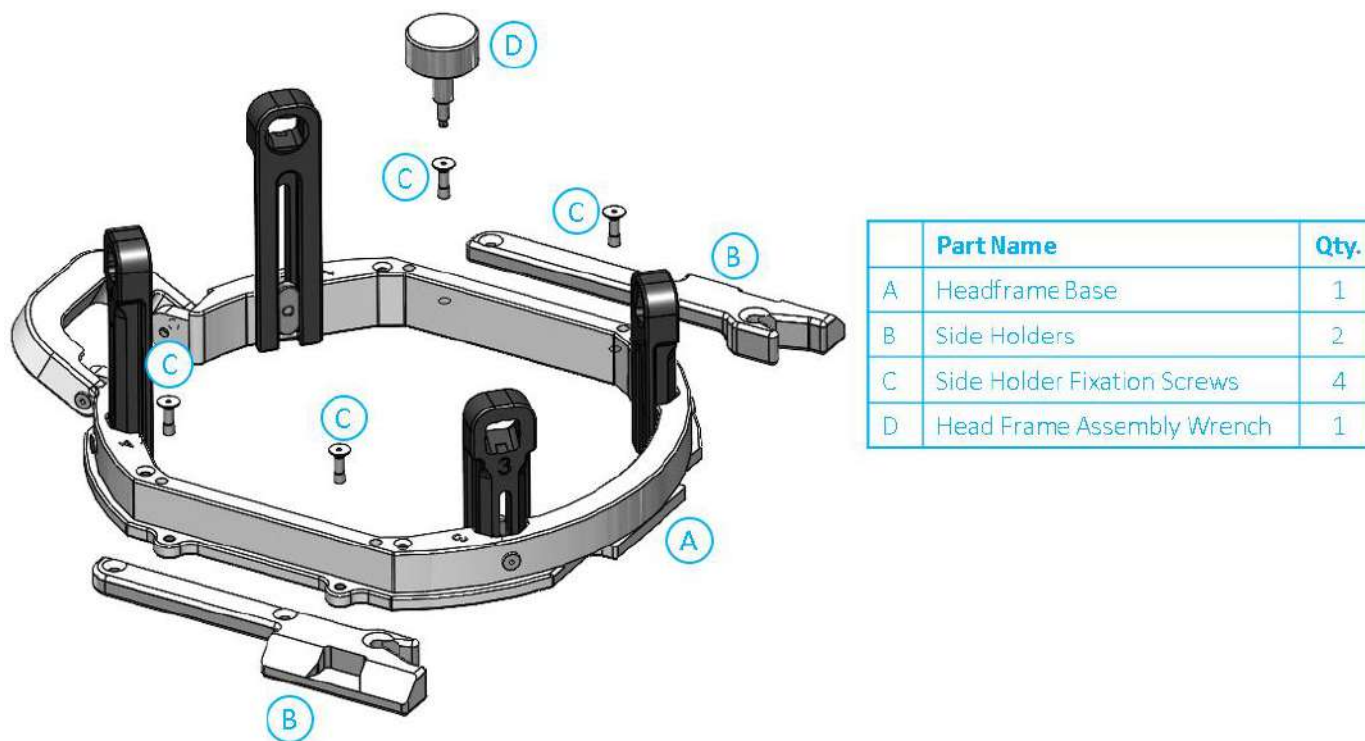


Figure 1-26: Connecting Side Holders to the Headframe (for illustration purposes only)

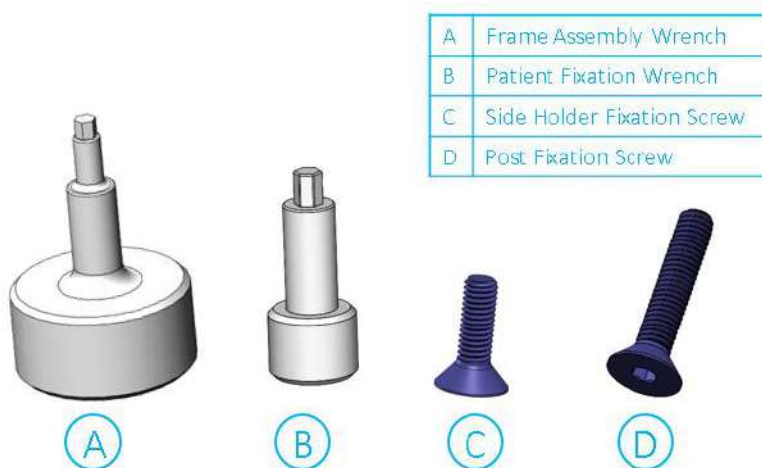


Figure 1-27: Head Frame Screws and Wrenches

1.8.7. Preparing the Head Frame for patient's head

According to patient's head size anatomy, chose the right adapters' combination from the PFK to insert to the Head Frame posts and bar using the caliper on a shaved head (see section 1.9.2 and 1.9.5).

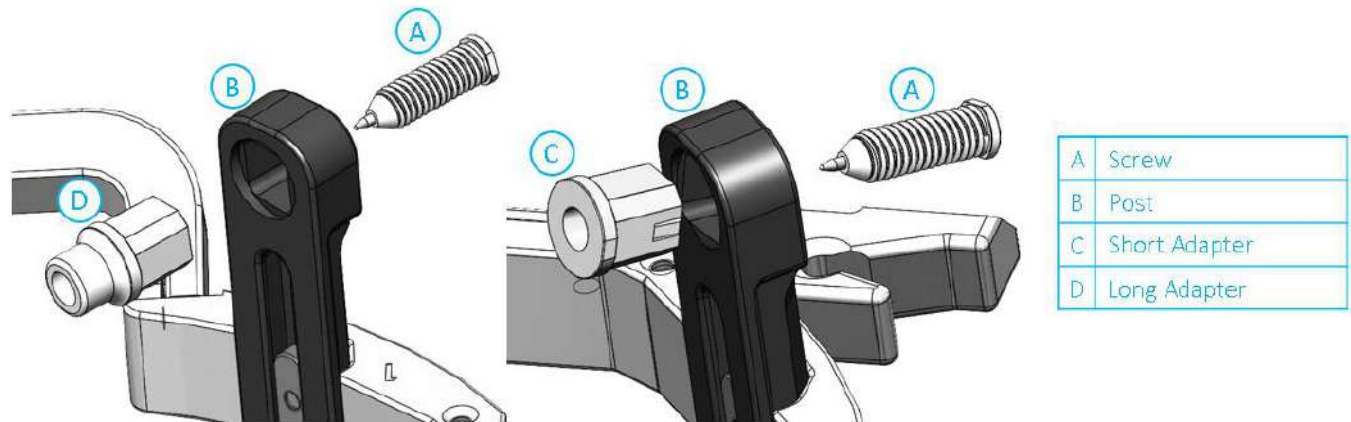


Figure 1-28: Internal Adapter insertion to posts

Insert the 4 adapters to their dedicated fixation holes on the Head Frame posts from the internal side of the posts (See **Figure 1-28**). Make sure the adapter is strongly attached to the head frame posts.



WARNING:
Ensure each post is thoroughly fastened.

W010

If necessary, use the Head Frame Assembly Wrenches (**Figure 1-27**) to tighten the posts.

1.8.8. Positioning the Frame on the Patient



WARNING:
Headframe fixation may only be performed by licensed Neurosurgeon with stereotactic experience.

W109D

- Shave the patient's scalp thoroughly, then wipe it clean with a "rubbing alcohol" soaked gauze or pad.
- Ensure that the posts are tightly fastened.
- Choose the right 4 Adapters according to the guidelines provided in section 1.9.5.
- Insert the Adapters to their predisposed fixation holes on the posts and Bar from the internal side of the frame (See **Figure 1-28**)
- (Optional) Use head Frame Positioning Straps to place and adjust the vertical height of the Head Frame.
- Place the Frame as inferiorly as possible to enable optimal coverage for the Exablate treatment.

**NOTE:**

N006

Using the Head Frame Positioning Straps helps support the weight of the Head Frame Assembly during placement on the patient.

- Mark with a marking pen the projected screw entry sites and the superior temporal line (optional)
- Apply local anesthesia through the fixation holes in the posts or on marked screws insertion sites, with or without temporarily moving the frame.
- Allow the local anesthetic to take effect.
- Insert the Disposable Head Frame Screws to their predisposed fixation holes in the adapters.

**WARNING:**

W115D

It is recommended to use an antibacterial ointment on the tips of the screws. Disinfect and bandage the screw insertion sites after removing the headframe

**CAUTION:**

C003

Four fixation holes in the anterior Head Frame Bar are available for the Disposable Head Frame Screws' and Adapters insertion. To avoid, if applicable, placement of the screws into the temporalis muscle, use the two medial access points.

- Use the Patient Fixation Wrench provided by INSIGHTEC to drive the Disposable Head Frame Screws into the patient's skull.

**NOTE:**

N007D

Use all four (4) Disposable Head Frame Screws to attach the Frame to the Patient

- Only use the Head Frame components and tools provided by INSIGHTEC
- Placing the Head Frame assembly is easier if two people perform the procedure.
- Keep a distance between the skin and the outer aspect of the bar at each screw site.
- Tighten the screws: two diagonally opposed screws at a time, alternatively and equally.
- Apply moderate force to ensure the Frame is securely tightened to the patient's skull.

**CAUTION:**

C004D

Overtightening of the Disposable Head Frame Screw can cause premature failure of the head Frame posts and/or the Disposable Head Frame Screw.

Be sure that the spine of the posts does not press against the skin for patient comfort.

**WARNING:**

W012D

Overtightening of the Disposable Head Frame Screws may cause skull injury:

- Prior to frame application, the surgeon should review details of the patient's CT
 - Avoid applying an extra strength during screw insertion on the skull
-
- Remove the Head Frame Positioning Straps.
 - The Patient is now ready for **Patient Membrane** placement.

1.8.9. Head Frame maintenance

Use the following guidelines to maintain Head Frame components after each treatment:

1. Immediately after use, wipe components with de-ionized distilled water to remove any residue of Betadine and blood or other debris
2. Dry thoroughly the components with paper
3. For persistent stains, wipe relevant areas with Isopropyl Alcohol 100% (IPA)



CAUTION:

C005D

Do not use saline. Saline may cause damage to the metal surface.
Do not use corrosive agents, such as Clorox® or Cidex®.
Do not use alcohol or hydrogen peroxide on any black composite materials.



NOTE:

N008D

The use of Betadine® or similar solution containing iodine may stain the surface of the Head Frame.

To minimize discoloration, wipe off any traces of Betadine® or similar solutions as soon as a possible during or following the procedure.



NOTE:

N009D

If instruments are exposed to highly caustic solutions such as bleach solutions, immediately rinse the instruments with de-ionized distilled water to prevent corrosive damage to surfaces and moving parts.



CAUTION:

C006

Headframe expected life cycle is 10 years. Contact your Insightec representative regarding replacement Frame, discard according to local regulations following said period and in case of any visual signs of damage/ corrosion.



NOTE:

N010

Headframe components are Autoclave compatible.

Recommended Autoclave Parameters:

4. The Head Frame should be disassembled prior to autoclave process.
5. Place the components in adequate autoclave bag, i.e., *Sterilization Pouches*
6. The following table provides the recommended autoclave parameters for the Exablate head frame components:

<u>Steam Autoclave</u>		
	Option 1	Option 2
Temperature	250°F / 121°C	270°F / 132°C
Exposure Time	20 minutes	10 minutes
Dry Time	20 minutes	10 minutes

1.9. Head Coil Specifications

For full Safety precautions, refer to **2.4 section**.

1.9.1. Coil Description

The Exablate 4000 system supports Patient Membranes with integrated 2 channel Head Coils (**Tc MRgFUS Head Coil**) to improve image quality. Each coil type's connector plug is specifically encoded for compatibility with its designated Exablate type and coil connector socket. To plug the coil, make sure the connector plug is aligned with the socket.

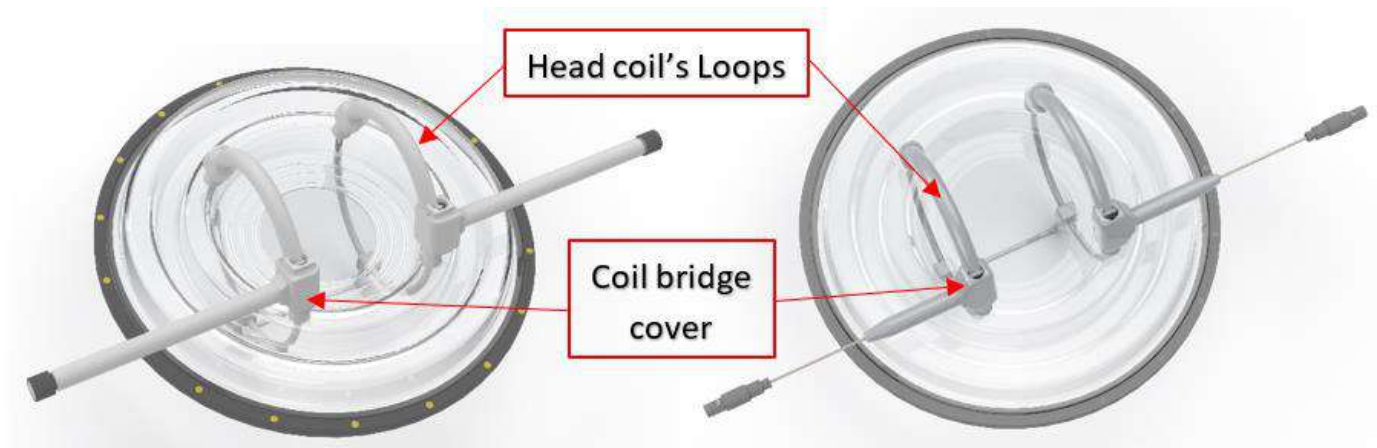


Figure 1-29: Examples of Tc MRgFUS Head Coil



NOTE:

N103

The actual appearance of the MRgFUS Head coil and socket depends on the system type and the treatment kit delivered with the system.

Each coil is comprised of 2 physical loops that are integrated into the Patient Treatment Membrane and are dressed on the patient's head and then connected to Exablate Positioner via a Low Noise Amplifier (LNA) unit that connects to a control unit. All Head Coils are configured with Coil Bridge Cover.

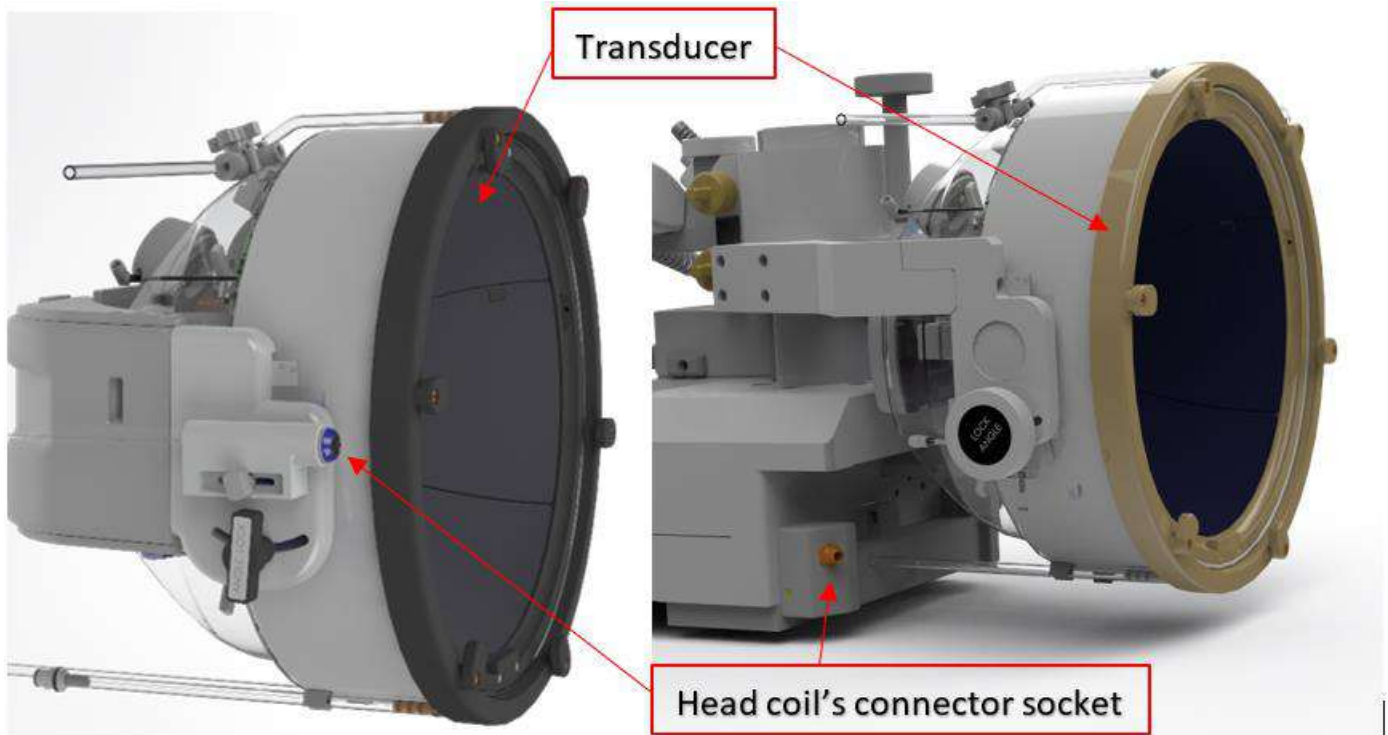


Figure 1-30: Examples of Tc MRgFUS Head Coil Sockets (For illustration only)

1.9.2. Head Coil Connector Socket - Mechanical Adjustment



NOTE:

N011

This section applies to all Tc MRgFUS Head Coil connectors that are mounted on the transducer holder.

The Head Coil Connector socket's position can be adjusted by loosening the coil connector adjustment screw and sliding the socket along the S-I direction. Tighten the screw back to set the sockets position. This can help mitigate pressure applied on the coil or patient.

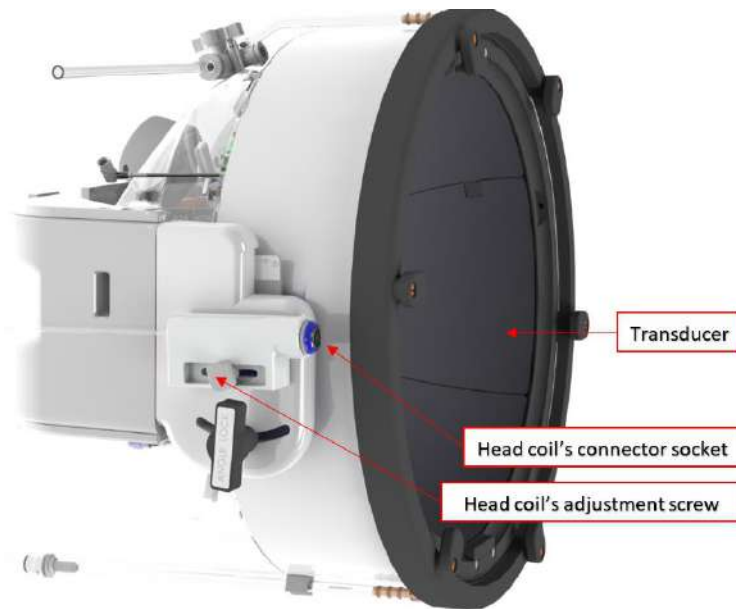


Figure 1-31:Head Coil connector socket (for all coils types except for Type 1.0 1.5T GE).



Figure 1-32: Coil Connector Plug connecting to the Coil Connector Socket (For illustration only).



NOTE:

The actual appearance of the coil connector depends on system configuration

N105

1.9.3. Coil Classification



Type BF applied part

Class I equipment.

Ordinary equipment.

Suitable for continuous operation.

1.9.4. Troubleshooting

Problem #1: The system does not recognize the coil connection to the system when selected in the software.

Symptoms	Suggested Actions	Resolution
The coil MR connector has become disconnected from the system interface.	Check to make sure the coil MR connector is fully engaged.	Engage connector and try the scan again.

Problem #2: The MR system fails to pre-scan or scan, showing the error: 'The Driver Module Has Detected a Fault'

Symptoms	Suggested Actions	Resolution
One or both of the coil connectors is disconnected.	Check to make sure the coil connectors are connected.	Engage connector and try the scan again.

Problem #3: The coil exhibits poor image quality on patient scans.

Symptoms	Suggested Actions	Resolution
The coil has a high noise level.	Check coil shape, it should be close to a circle. Any significant distortion of the shape might cause significant signal loss or detuning of the coil.	If the coil is defective, return the coil for service.
The coil has low signal.		
Dark bands are observed in the images.		

1.9.5. Head Coil Configurations


1.5T Systems are configured to work only with the head coil configuration.

3T Systems supporting head coils are configured to work in different possible coil configurations; ‘HEAD’, ‘BODY (Head Connected)’ (if applicable) and ‘BODY’ (see **section 11.2.3**). Different scenarios are described below.



Figure 1-33: Examples of MR connectors

Scenario #1: The default configuration when scanning with the membrane’s head coils.

System Type	Membrane Type	Imaging	Suggested actions
For all systems supporting Head coils	Exablate Neuro Patient Membrane with Coil 3.0T/1.5T	Scan with Insightec’s Head Coils	<ol style="list-style-type: none"> 1. Make sure the MR connector(s) are connected to the MR 2. Make sure the membrane’s head coils connectors are connected to their dedicated socket 3. The default coil configuration in ‘Utils’ on the workstation is ‘HEAD’ 
GE Type 1.0			4.a. With GE Type 1.0 MRI systems (If applicable): Make sure the silver cable is connected to the MR connector
GE Type 1.1			4.b. With GE Type 1.1 MRI systems: Make sure the switch on the MR connector is ON (Blue led indicator ON)

Scenario #2: When Head coil is on patient's head, and for some reason a scan with the Body coil is required.

NOTE: Scanning without the head coil may reduce image quality.

System Type	Membrane Type	Imaging	Suggested actions
For 3T systems only	Exablate Neuro Patient Membrane with Coil 3.0T	Scan with the MR integrated Body Coil	<ol style="list-style-type: none"> 1. Keep MR connector connected the to the MR 2. Keep the membrane's head coils connectors connected to their dedicated socket 3. Switch coil configuration in 'Utils' on the workstation to 'Body (Head Connected)'
3T GE Type 1.0			4.a. With GE Type 1.0 MRI systems: Keep the silver cable connected to the MR connector
3T GE Type 1.1			4.b. With GE Type 1.1 MRI systems: Keep the switch on the MR connector ON (Blue led indicator ON)



Scenario #3: When treating with a patient membrane without an integrated head coil - Body coil will be used during the treatment.

System Type	Membrane Type	Imaging	Suggested actions
For 3T systems only	Exablate Neuro Patient Membrane without Coil	Scan with the MR integrated Body Coil	<ol style="list-style-type: none"> 1. Connect the MR connector(s) to the MR 2. Switch coil configuration in 'Utils' on the workstation to 'BODY'
3T GE Type 1.0			3.a. With GE Type 1.0 MRI systems: Disconnect the silver cable from the MR connector
3T GE Type 1.1			3.b. With GE Type 1.1 MRI systems: Switch the Blue led indicator on the MR Connector to OFF



Scenario #4 (troubleshooting): When the treatment started and encountered malfunction related to the head coil, an Error is shown on the workstation. The user need to change and work with MR integrated Body coil.

NOTE: In the case of scenario #4, there is a risk of image artifact from the unused membrane's head coils. Perform only as troubleshooting if the head coils don't work toward treatment's end.

System Type	Membrane Type	Imaging	Suggested actions
For 3T systems only	Exablate Neuro Patient Membrane with Coil 3.0T	Scan with the MR integrated Body Coil	<ol style="list-style-type: none"> 1. Keep MR connector connected the to the MR 2. Keep the membrane's head coils connectors connected to their dedicated socket 3. Switch coil configuration in 'Utils' on the workstation to 'BODY'
3T GE Type 1.0			4.a. With GE Type 1.0 MRI systems: Disconnect the silver cable from the MR connector
3T GE Type 1.1			4.b. With GE Type 1.1 MRI systems: Switch the Blue led indicator on the MR Connector to OFF



2. SAFETY

2.1. Exablate General Safety Considerations

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

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

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

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

Unauthorized personnel should not be allowed access to the system.

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

As of July-22-2014, the Exablate Neuro System is designed to meet the Directive 2011/65/EU (Restrictions of Hazardous Substances (RoHS)).

Disposable Head Frame Screws are provided STERILE –Do not re-use or re-sterilize. Do not use if package is open or damaged.

System expected usable lifetime is 10 years. Upon lifetime elapsing please consult INSIGHTEC for further instructions.



NOTE:

Any serious incident that has occurred in relation to the device should be reported to INSIGHTEC and the competent authority of the Member State in which the user and/or patient is established.

N012

Use of Exablate System within MRI Environment



The Exablate 4000 Type 1.0 Treatment Table is MR Safe



The Exablate 4000 Type 1.1 Helmet System is MR Safe



WARNING:

W013

Do not attempt to use components other than the Exablate hardware, software, and system accessories, and the specified MR imaging system with the device.



WARNING (Type 1.1 Only):

W014

The Exablate Helmet System Storage and Transfer Cart is meant to be operated within an MR environment. To avoid the risk of inadvertently bringing in magnetic articles into the MR room, Only the Exablate Neuro Helmet System may be placed on the cart. Do NOT use the cart to bring any other items (magnetic or otherwise) into the MR suite.



WARNING:

W015

Operating heavy equipment may cause in risks of injury, operate heavy equipment with care.

WARNING:

W016



- The Exablate Front End cabinet contains ferro-magnetic components and may not be moved too close to MR bore.
- Type 1.1 (1.5 & 3T) Only: The Front-End Unit must be tethered or fixated at all times, at a minimal distance defined by INSIGHTEC Service during installation.

2.1.1. Use of MR Equipment

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

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

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

**WARNING:**

W017

Auxiliary equipment (such as gating equipment, vital signs monitoring systems and RF coils) that has not been specifically tested and approved for use in the MR environment may result in burns or other injuries to the patient, as well as degraded image quality.

2.1.2. System Service

The Exablate system should be installed, maintained and serviced by INSIGHTEC personnel, or other qualified personnel certified by INSIGHTEC.

Periodic maintenance should be performed according to INSIGHTEC's service standards by INSIGHTEC or by INSIGHTEC certified personnel.

**WARNING:**

W018

Cybersecurity and software updates are done as part of service periodical maintenance. If the System is NOT appropriately serviced and maintained, cybersecurity risks may increase over time and the System should not be used for clinical treatments.

**WARNING:**

W019

Updates should only be implemented by authorized Insightec technicians/personnel. Operators of Exablate should not accept or implement any updates.

**WARNING:**

W020

If the System is NOT appropriately serviced and maintained, it should not be used for clinical treatments.

**WARNING:**

W021

Do not attempt to repair the Exablate System in the event of system failure, malfunction or any evidence of damage to the components

**CAUTION:**

C007

The system should be discarded of according to local regulations.

2.1.3. Safety Instructions**WARNING:**

W022

Before using the Exablate Neuro system:

- Read and understand each of the following safety warnings.
- Refer to the safety information supplied with the MRI System.
- The Exablate Neuro system is Type B applied part.
- The system is properly grounded by design and by the installation process.

- It is important for the safety of the patient and operator to maintain proper system grounding. Connect the system as instructed, and do not disconnect any of the system's connection.

**WARNING:**

W023

Inspect all cables on Treatment Table (Type 1.0), Helmet System (Type 1.1) and Front End to ensure proper coupling and verify no tears or other visible damage is present.

2.1.4. System Setup

When setting up the system for treatment, make sure you adhere to the following cautions:

- Ensure that the wheels of the FE and STC (Type 1.1 only) are locked when they are not being moved.
- Use the designated handles only when maneuvering the FE or STC.

**WARNING:**

W024

Make sure all cables are laid out on the floor in a way that does not constitute a tripping hazard.

**WARNING:**

W025

In case of a mechanical shock on the transducer, as the following:

- Heavy object falling on the transducer surface (e.g. DQA Set Up Holder)
- Collision during Transducer positioner movement (e.g. Transducer internal surface pressed against the frame screw)
- Type 1.0: Violent collision of the MR table with a wall during movement.
- Type 1.1: Violent collision of the HS during STC movement.

Do not operate and contact INSIGHTEC for a conformity check.

**WARNING:**

W026

The Front-End Unit should only be moved by two persons.

Type 1.1. Only:

- Make sure that the Transducer is positioned on the HS according to the **Home Position** label (Type 1.1 only).
- To avoid the risk of pinching – hold both HS handles firmly when transferring the HS back and forth to the MRI Table.

**CAUTION:**

C008

Place extra care while handling/transferring the transducer. Rough handling may damage the transducer and affect its characteristics adversely.

- When lifting the MRI Exablate Adapter Baseplate, and loading the Water Reservoir into the FE, practice proper lifting technique.
- When handling the Main Cable, make use of the STC and/or the Detachable cable connector panel Plate to enable easier handling.



CAUTION

C009

Careless handling of the Detachable cable connector panel may result in injury. Please assure firm grip before use. Slide carefully into Connector panel holder and ensure it is firmly in place. Ensure cables are locked to connector panel before letting go. Carry carefully to avoid accidental release of cables.

2.1.5. System Stability

The Exablate system complies with Council EU MDR 2017/745, Annex I and 2006/42/EC Machinery standard regarding stability requirements.

Standard MR table operations and procedures are unchanged by the Exablate setup. Operations like **Table Up/Down**, **Cradle In/Out**, and **Patient Positioning** should be performed according to MR Manufacturer manual.

The system operator is obliged to meet and follow instructions addressing the stability of the system and safety precautions in a prompt and timely manner, as well as reducing the risks of collision of parts, falls, slipping and tripping.

2.2. Operator and Patient precautions

2.2.1. Operator Precautions

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

Review and follow all operator instructions included with the console.

The patient, operator and nurse must each be able to freely activate a stop-sonication button at any time during the procedure. Pressing the stop-sonication button immediately ceases the sonication. Releasing the button enables the treatment to resume.

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

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

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

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

Changes to and modifications of this equipment by unauthorized personnel is NOT allowed.



WARNING

W108

For your safety and for protecting the patient, be aware that the Exablate Neuro system may contain **Natural Rubber Latex**, which may cause allergic reactions.

Make sure that both the site's staff and the patient who may be in direct contact with the system parts are not allergic to natural rubber latex products, prior to every system use.

2.2.2. Patient Protection and precautions

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

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

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



WARNING:

W027

- Refer to safety guidelines issued by the MRI safety procedures and restrictions that may apply to the specific site.
- Do not leave a patient unattended in the magnet room.

The **Stop-Sonation button** must be given to all patients. Pressing the button immediately interrupts treatment. Three stop-sonication buttons are available on the system:

- One is on the operator's console.
- One is given to the patient.
- One is located on the Front End Unit, to be controlled by a staff member in the treatment room.

Instruct the patient to stop sonication when feeling pain or heat.

Supply the patient with hearing protection.

The patient is not always in view of the console operator. Be sure that medical personnel are in the magnet room during the procedure or that the patient is constantly in view and equipped with means to communicate distress.



WARNING:

W028

Cradle movement may cause patient injury. Verify that the patient's fingers and clothing (hospital gowns) are not in danger of being caught in the equipment during positioning or cradle motion.

Cover the mattresses on the MR table with sheets.

Type 1.1 only: Position the leg holder on the mattress.

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

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

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

The Exablate system creates heat in the target, which may cause thermal ablation based on temperature rise levels and duration. Thermal ablation prediction (referred to as thermal dose) is estimated using two dose levels of 17 and 240 cumulative equivalent minutes (CEM) at 43°C. Based on correlation with tissue damage seen on MR images, the two dose levels represent worst case scenario and size (i.e. low and high probability for) of thermal damage, respectively.

For each sonication, a spot overlay of those two dose levels (17 and 240 CEM) is presented on the WS screen. This overlay represents the location and bounding area of the spot and contributes to spot size estimation.



WARNING:

W029

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



WARNING:

W030

In case of abnormal system behavior, unexpected thermal maps, unexpected temperature rise, or inability to see or understand thermal maps, abort sonication and treatment immediately.

Cavitation refers to formation and collapse of bubbles (created from dissolved gas), which fills cavities that are created in low pressure regions. As a result, bio-effects may occur due to these bubbles and are dependent on the extent and type of cavitation. The Exablate has a built-in cavitation detector and a mechanism to automatically stop or adjust the power levels to avoid cavitation, which may cause unintended tissue damage (see **Section 11.2.10**).



WARNING:

W031

Prolonged immobilization may lead to increased risk of deep venous thrombosis (DVT) or pulmonary embolism (PE). In order to avoid this, the patient should be wearing **Thromboembolic Stockings (TEDs)**, also referred to as '**anti-embolism**' stockings through the entire procedure time in the MRI.



WARNING:

W032

Ensure that the patient has the Stop Sonication button and that he is able to operate it before initiating treatment. In the event of pain or patient motion, failure to do so may result in serious injury.

**WARNING:**

W033

The attending team must monitor the patient continuously during the procedure, taking into account the patient's medical history. Ensure monitoring means are available (e.g. patient monitor, audio\visual systems, pulse oximeter, Nurse in MR room etc.) Evaluate the patient's wellbeing after each sonication, and perform a full assessment at the end of the procedure, providing additional care accordingly.

**WARNING:**

W114

Due to the fixation of the head, the risk for asphyxiation in case of vomiting while the head is fixated to the treatment table, is increased.

Please ensure there is an available suction device primed and ready, and consider administering anti-emetic medication as needed.

**WARNING:**

W034

To avoid contamination of the water, verify fine shaving and no open cuts or lacerations on the area of the scalp above the Patient membrane.

**WARNING:**

W035

Failure to monitor the MR thermal maps during the procedure may result in unintended heating of non-targeted tissues, which may cause permanent injury. Operator must cancel/abort the procedure if MR thermometry data are not available.

**WARNING:**

W036

Ensure that only degassed water is used in the circulating area between the transducer and the Patients' skull to avoid air bubbles in the system which might result in skin burn.

**WARNING:**

W037

Prior to the delivery of each sonication throughout the treatment, the beam path should be evaluated to avoid scars or other irregularities in the skin which can cause pain or skin burns.

**WARNING:**

W038

Inadequate cooling time between sonications could lead to thermal build-up that may cause serious damage to normal tissues outside the targeted volume. The cooling time between sonications is automatically scaled according to the actual energy applied and sonication parameters, and should not be decreased.

**WARNING:**

W039D

For type 1.1: Due to shift compensation (section 4.2.4) a mismatch between RAS coordinates on Exablate workstation and MR Workstation may occur. During treatment, always refer to the Exablate workstation coordinates.

**WARNING:**

W040

If the skull bone is heated significantly, tissue adjacent to the skull can also absorb heat and may be damaged. To prevent damage to this tissue, heating of the skull should be minimized – this is achieved both by circulating chilled water across the outer surface of the skull (avoid heating of outer skull-skin interface) and choosing target regions at a depth in the brain at least 2.5 cm from the skull (avoid heating of internal skull-tissue interface).

**WARNING:**

W041

Please note that the head average and local SAR displayed on the MR console are not accurate for the Exablate 4000 setup, due to the water and FUS transducer. Actual values can be as high as a factor of 4.

While the active cooling of the head compensates for higher average and local RF induced heating (a.k.a SAR), so that SAR limitation applied by the MR system are sufficient, apply extreme caution when using custom scan types to minimize risk of tissue heating

2.2.3. Patient Emergencies

Each Exablate Neuro site must develop appropriate patient emergency procedures.

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

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

1. Press the **Physician Stop Sonication** button on the workstation or the Front End unit to shut down the MR and the Exablate Neuro system. This will immediately stop any energy deposition and halt active MR scans.
2. If necessary, notify emergency personnel.
3. Bring the cradle outside of the bore, either by using the MRI scanners interface or if needed (e.g. in case of power loss) via the manual emergency release procedure as defined by the respective MR/IA diagnostic cradle manufacturer's emergency release procedures.
4. In emergency situations, it may become necessary to remove the patient from the room:

■ **For MRI Scanners with Fixed Tables:**

- Drain the water from the transducer and release the patient. Controlled water draining takes up to five minutes, but if necessary the patient can be released in ~20 seconds without performing a drain, as most of the water will be contained in the designated basin below the transducer.
- In case of power loss with no urgency, Use the manual drain kit to drain water (See **Appendix C**) (the Manual Drain procedure takes up to 15 minutes [see NOTE on next page]).
- To bring the patient out of the MRI Suite, keep a non-magnetic gurney inside the magnet room or a regular gurney outside of the magnet.

- Take the transducer as superiorly as possible and release the patient from the transducer interface as expediently as possible.
 - **For MRI Scanners with Detachable Tables:**
 - Drain the water from the transducer and release the patient. Controlled water draining takes up to five minutes, but if necessary the patient can be released in ~20 seconds without performing a drain, as most of the water will be contained in the designated basin below the HS.
 - If time allows – Release the patient from the frame holder and transfer the Helmet System to the Storage and Transfer Cart. Otherwise detach the quick-coupler cables from the Front end and place on MR Table in a manner that will not inhibit table movement. Proceed to remove the patient table from the magnet room.
 - Since the patient table is not very maneuverable, consider keeping a non-magnetic gurney inside the magnet room or a regular gurney outside of the magnet.
5. Attend to the patient, following established hospital emergency protocols.

**NOTE:**

N013

The water system is drained and filled by the Water System Remote Controller or Water System Control Touchscreen. In case of complete power loss, or other malfunction of the automated water system, Emergency Drain Kit can be used to drain water from the transducer. Draining water from transducer may take up to 5 minutes. Review the **Manual Drain Kit Use instructions (Appendix C)**

In case of emergency, the patient can be released from the transducer without draining the water, in less than a minute. Most of the released water (up to 10 liters/2.65 US gallons) will be contained within the MR Baseplate, but a risks of water spillage and a slippery floor exist.

**WARNING:**

W042

Water spillage may cause risks of MR damage, electrocution and slipping on wet floor.

**WARNING:**

W043

Life-support, resuscitation or any other equipment based on ferromagnetic components are not allowed in the magnet room (e.g. scissors, sharp tools near patient).

2.3. Water System Precautions

The water system is used to keep the skull cool during treatment. The water temperature is monitored by the system and is displayed on the Workstation screen and for Type 1.1 systems on the Water System Touchscreen as well.

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

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

An improper seal between the patient's head and the Patient Membrane could result in a water leak in the MR bore. During water filling or draining (see **Section 3.5**), confirm the following:

- The air ventilation tap is open.
- The operator must be next to the patient.
- Monitor any water leaks from the transducer.
- Watch for any excessive pressure in the Patient Membrane.

Prior to moving the cradle into the MR bore, always confirm:

- Confirm that the water drain below the transducer is empty and dry.
- Confirm that the air ventilation pore has been locked.

There are two (2) elements on the left side of the operating console (see **Figure 2-1**):

- The blue button is the **Circulation Controller**.
- The green LED is the **Power ON Indicator**.



Figure 2-1: Circulation Controller

2.3.1. Water System Indicator & Circulation Controller

The blue **Circulation Controller** on the operator console illuminates continuously when the water circulation in the transducer's interface is active. The system will automatically cease circulation in case a system error is detected (e.g. excessive pressure, cable disconnected) or the temperature in the water interface is higher than the desired set point, when this happens, the Circulation Controller will flash, and prompts will be displayed:

- A simple message in the lower left corner of the Workstation screen
- Type 1.0: A simple error description on the water system screen
- Type 1.1: A detailed error description with mitigation steps will be displayed on the Water System Control Touchscreen.



WARNING:

W044

The water in the transducer's interface may start getting warm because of a prolonged sonication sequence. Monitor the water temperature displayed on the workstation and water system control screens.



NOTE:

N014

The blue **Circulation Controller** is also used to pause the circulation. Press it once to pause water circulation (controller indicator will be OFF), press it again to resume water circulation (controller indicator will illuminate).

Follow the instructions displayed on the **Water System Control** screen to resolve the relevant error.

Make sure you first take the patient cradle out of the bore to confirm:

- No water leaks are visible.
- Water level in the transducer interface is nominal.
- Water pressure is nominal.
- No air is present in the transducer interface.
- Water hoses are not tangled or obstructed.
- Air ventilation pore is closed.

After resolving the issue and ensuring the Transducer interface is properly filled with water, RESET circulation by pressing the blue Circulation Controller, the RESET icon on the Water System Control Screen, or the RESET button on the Water System Remote Controller.

If the problem persists, contact your INSIGHTEC Service representative for troubleshooting.

2.4. Head Coil Precautions

For full specifications pertaining to the use of Tc MRgFUS Head Coils **see Section 1.9**

Compatibility



WARNING:

W045

Insightec MRgFUS Coils are intended for use with INSIGHTEC Exablate 4000 Systems only! No modification of the coil is allowed!



WARNING:

W046

Each Coil is compatible only with its designated and approved Exablate System Type and MR Scanner Models. Each Coil's labels and packaging define its compatibility. Verify coil compatibility before connection. Never connect a coil that is not properly labeled! A coil tuned for different magnet strength may cause burns

Coil Operating Safety

The MRgFUS Coil cannot be serviced on site. In case of coil fault or fault suspicion, replace the Patient Membrane with the Coil and contact your INSIGHTEC Service Representative for service and maintenance needs. Personnel should observe all warnings and cautions that appear in this manual.



WARNING:

W047

No modification of the coil is allowed!

Patient Safety



WARNING:

W048

Perform scans only when the coil is fully submerged in water (from the transducer side). Failure to comply may result in degraded image quality and patient burns.



WARNING:

W049

Monitor the patient periodically. Stop the scan immediately if the patient reports any heating, burning or tingling sensations.

Patient safety and comfort should be the primary concern during the scanning procedure. Always follow proper safety, operating and maintenance procedures to ensure that the patient is not exposed to electrical or mechanical hazards that may potentially cause injury.

Equipment Safety

Personnel using the Coil must have appropriate training for proper connection, operation and handling of the Coil.

**WARNING:**

W050

Auxiliary equipment (such as gating equipment, vital signs monitoring systems and RF coils) that has not been specifically tested and approved for use in the MR environment may interfere with the proper operation of the Coil and degrade image quality

**CAUTION:**

C011

Prevent cables from forming loops. Looping will degrade scan performance of the Coil through RF coupling. Keep the length of the cable in the bore to a minimum. Avoid bending the cable 180 degrees. Route the cable connecting to the MRI directly out of the bore, keeping it as straight as possible

Electrical and Mechanical Safety**WARNING:**

W051

Before using the Coil:

- Visually check to ensure there is no external damage. Do not use the Coil if the housing or cable is broken.
- Verify that the Coil is properly connected. Electric shock may result if the coil is attached to the system during cleaning or when it is wet.

**CAUTION:**

C013

If the coil is found to be defective, replace coil. If attempting to replace the coil without displacing patient from table after planning images have been obtained, verify thoroughly that no patient movement has occurred and perform a full re-plan if necessary.

**WARNING:**

W052

3T MRI Only: It is also possible to switch from the Head Coil to the MRI's built in body coil by pressing the 'Switch MR Coil' button in the 'Utils' menu (See **1.9.5**)

If so - do not disconnect the Head Coil **OR** replace the membrane with a membrane without an integrated Head Coil.



2.5. Electromagnetic Compatibility (EMC) Precautions



CAUTION:

C015

- The Exablate Neuro system should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.
- The Exablate Neuro system requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in **section 2.5.2**.
- Be aware that portable and mobile RF communication equipment can affect the Exablate Neuro system.
- The Exablate Neuro should not be used adjacent to Portable RF readers. If use of adjacent RFID readers is necessary, Insightec service must be informed to verify normal operation in the configuration in which it will be used.



WARNING:

W053

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Exablate 4000 System including cables specified by Insightec. Otherwise, degradation of the performance of this equipment could result.



NOTE:

N015

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment, this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.



WARNING:

W116

In case of system power loss due to AC inputs mains Voltage interruption, the system will shut down. Wait for a stable return of the AC power and restart the system to repeat the planning stage and resume the treatment. If the return of power is delayed, and you decide to abort the treatment, empty the water from the transducer using the Manual Drain Kit.

2.5.1. Statement of the Exablate Neuro System Essential Performance:

The essential performances of the Exablate Neuro are:

■ Safety Monitoring:

- Monitors and verifies that sonication is executed as planned.
- Verifies that monitoring is running continuously.
- If failure of any of the above does NOT stop the sonication/halts the CSA (Control System Application), the system is NOT safe.

■ Spectrum Monitoring:

- Monitors the spectral signal that exists during the sonication.
- It may also be used to control the transducer's power output.
- Continuously verifies that the spectrum signal is below the allowed maximum.
- If the spectrum monitoring fails to control the signal to below the set limit, or to stop the sonication/halt the CSA if that it is above the limit, the system is NOT safe.

2.5.2. List of cables for type 1.0 and 1.1

ExAblate 4000 type 1.0 Cables list		
No.	Name	Location From- to
1.	380-400 / 480 VAC 3 phase	Equipment room Power-PCDU
2.	MRI present	PCDU-MRI
3.	Chiller mains	EC to Chiller
4.	WS CPC comm	CPC-WS
5.	WS MRI comm	WS- MRI
6.	W2214	LPS –Filter Box
7.	W4214	LPS –Filter Box
8.	W2215	HPS –Filter Box
9.	W4215-1	HPS –Filter
10.	W4215-2	HPS -Filter
11.	W2216	EDU - Filter Box
12.	W4216	EDU - Filter Box
13.	W2218	EDU - Filter Box
14.	W2317	Filter Box - FE
15.	W4317-2	Filter Box - FE
16.	W4317-3	+15v Filter - FE
17.	W4317-4	-15v Filter - FE
18.	Lx Trigg	EDU-MRI
19.	Rcv unblank	EDU-MRI
20.	W-2278	EDU-Chiller
21.	W-2277	CPC-Chiller
22.	W-2201	Chiller-Pen Panel
23.	W-2326	Pen Panel-Table

ExAblate 4000 Type 1.1 - Connector / Cables list		
No.	Name	Location From- to
1.	380-400 / 480 VAC 3 phase	Equipment room Power-PCDU
2.	MRI present	PCDU-MRI
3.	Chiller mains	EC to Chiller
4.	WS CPC comm	CPC-WS
5.	WS MRI comm	WS- MRI
6.	CBL14215	+15V HPS –Filter
7.	CBL 24215	-15V HPS –Filter
8.	CBL 34317	+15V Filter – FE
9.	CBL 44317	-15V Filter - FE
10.	W 2220	EDU - Filter Box
11.	W 2219	Rack I/O Unit - Filter Box
12.	W 2317	Filter Box – FE
13.	Rcv unblank	EDU-MRI
14.	W-2298AA	Rack I/O Unit Chiller

2.5.3. Summary of EMC Test Results

IEC 60601-1-2 Edition 4.0 (2014).

Environment of intended uses:

Professional Healthcare Facility Environment

Test	Standard	Class/ Severity level	Test result
Emission (IEC/EN 60601-1-2 sections 7.1- 7.2)			
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11 / EN 55011	Group 1 Class A on AC mains 3 phases	Complies
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11 / EN 55011	Group 1 Class A	Complies
Immunity (IEC/EN 60601-1-2 sections 8.9-8.10)			
Immunity from Electrostatic discharge (ESD)	IEC/EN 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC/EN 61000-4-3	3.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC/EN 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC/EN 61000-4-4	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Surge	IEC/EN 61000-4-5	± 2 kV on AC main 3ph, DC, AC 1ph; ± 1 kV on signal cables Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0 & 6.0 VRMS 0.15÷80 MHz, 80% AM, 1 kHz on AC mains 3 ph, AC mains 1 ph & signal cables	Complies
Immunity from power frequency magnetic field	IEC/EN 61000-4-8	30 A/m @ 50 Hz & 60 Hz	Complies
Immunity from voltage dips, short interruptions and voltage variations	IEC/EN 61000-4-11	AC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

3. GETTING STARTED

3.1. System Set-Up – Type 1.0



WARNING:

W054D

The water system will reach its optimal operating conditions after approximately one hour. Take this into consideration and turn on the system as early as possible before the procedure, to avoid downtime when the patient arrives.



NOTE:

N016

It is suggested to keep the *Exablate 4000 Type1.1 [or Type 1.0] Handbook for SW7.33* accessible near the system for handy step by step checklists of setup and treatment procedures.

3.1.1. Docking and connecting the Table

Start up the system in the following sequence:

1. Confirm that the MR console was rebooted at the beginning of the day. If not, reboot it.
2. Undock the imaging table and dock the Exablate Neuro Treatments table to the MR scanner.
3. Ensure that all Front-End cables are properly connected
4. Attach the two quick-coupler cables, each uniquely labeled, to the patient table (see **Figure 3-1**).
Align the cable with the connector and slide it gently inside.
Lock the quick-coupler's connector.
5. Attach the water system cable to the patient table (see **Figure 3-1**).



CAUTION:

C016D

- Make sure that the quick coupler connectors are connected each to its intended labeled connection port.
 - The connectors must be gently aligned into place before locking.
 - Ensure the water cable is locked all the way.
6. Connect the MR **Tracking and Head Coil connector/s** into the MR Coil Socket on the MRI Table. (see **Figure 3-1**).
 7. **If applicable:** connect the TcMRgFUS Head Coil to the MR Coil connection port.
 8. Cover the table with mattresses and sheet



WARNING:

W055

Ensure that the cables are securely attached to the patient table before turning on the main power switch. Do not disconnect the cables once the main power has been turned on except in an emergency.

**NOTE:**

N017

The FE cables may also be attached to the table after **System power ON** (see 3.2.2) and **Water System Preparation** (see 3.2.3). In that case, press and release the Operator's Stop Sonication button to reset connections following cable connection.

**WARNING:**

W056

Visually inspect the Exablate Neuro system to:

- Verify the integrity of the Transducer, Front-End and MR Table.
- Confirm that the connectors are properly fastened.
- Confirm that the table is properly docked.

Failure to follow these instructions may result in degraded system functionality.

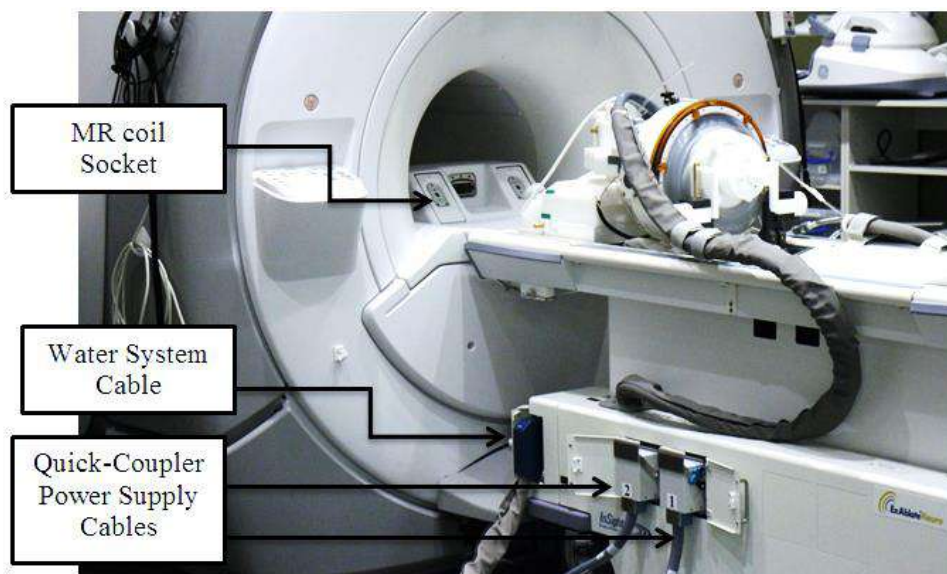


Figure 3-1: Patient Table Connections

3.1.2. System Power ON

**NOTE:**

N018

System power ON may also be performed prior to Cable connection (see 3.1.1). In that case, press and release the Operator's Stop Sonication button to reset connections following Helmet System connection.

1. Remove all external media drives and/or CD's from the console computer.
2. Turn ON the system by pressing the green Power ON switch located on the operator's console; the **Begin Logon** notice appears.
3. Press **Ctrl+Alt+Del** to access the logon information dialog box.

- Log in to FUS with your INSIGHTEC provided Username and Password (Windows® logon parameters are case sensitive); click OK to continue.

**CAUTION:**

C017D

ExAblate Workstation username & password should not be printed or shared with anyone.


- Select 'Brain Mid-Frequency' from the application selection screen.
- The Exablate Neuro disclaimer popup window opens; click OK to continue.

3.1.3. Prepare the Water System

- Disconnect and unload the Water Reservoir from its Compartment in the Cooling Unit.
- Fill the reservoir with 5.25 gal. (20 liters) of water, return it to its place, and attach the water connectors. Use fresh Reverse Osmosis water (or Type 2 medical grade water) for DQA and cleaning, Type 2 medical grade water for treatments.
- Start water degassing according to the following procedure:



Figure 3-2: Water System Control Panel

- Set the water system state to **Preparation** from the Workstation screen's Utilities menu (water system state button: ) or do **Degas** from the Water System Controller screen (see **Figure 3-2**).
- Press the Blue button on the console or the circulate button on the water system remote to commence degas circulation.
- The degassing process will start, and a system's status indication will appear on the bottom of the screen in the **Device Status** as **Degassing**, **Temperature** or **Dissolved Oxy**. Wait for the PPM level to reach < 2.0 before proceeding.

**CAUTION:**

C018

If the blue **Cooling Indicator** on the Workstation Console (or the green light on the remote) start flashing, there is a malfunction in the system. See **Chapter 2.3** (Water System Precautions) for more details.

**NOTE:**

N019

You may prepare the water even when the Exablate table is disconnected.

3.1.4. Verify System is Ready for Treatment

Confirm that the **device** and **MRI** status indicator are 'ready' (green), and that the blue water system indicator on the operator console is illuminated (indicating active circulation. If not, press it to initiate circulation).

NOTE:

N020D



For some GE scanners with newer SW versions (DV26 and up) you may need to press the 'External Host' button on the MR console and select 'ExAblate' from the drop down menu in order to enable communication between the Exablate workstation and the MR scanner.



Figure 3-3 : Selecting 'Exablate' as external host (GE MR Interface)



Figure 3-4 : System Ready

3.2. System Set-Up – Type 1.1

**WARNING:**

W054D

The water system will reach its optimal operating conditions after approximately one hour. Take this into consideration and turn ON the system as early as possible before the treatment, to avoid downtime when the patient arrives.

**NOTE:**

N021

It is suggested to keep the *Exablate 4000 Type1.1 [or Type 1.0] Handbook for SW7.33* accessible near the system for handy step by step checklists of setup and treatment procedures.

3.2.1. Connect the Helmet System to the Front End

1. Unlock the STC wheels, and position it near the Front-End Unit.

In case of difficulty accessing the FE with the STC, it is possible to carry the cables using the Detachable Cable Connector Panel and place it in the Connector Panel Holder on the FE.

2. Connect the Water Cable and the two, uniquely labeled, Quick Coupler Cables to the Front End

**CAUTION:**

C016D

Make sure that the quick coupler connectors are connected each to its intended labeled connection port.

- The connectors must be gently aligned into place before locking.
- Ensure the water cable is locked all the way.

**NOTE:**

N022

Helmet System connection may also be performed after **System power ON** (see 3.2.2) and **Water System Preparation** (see 3.2.3). In that case, press and release the Operator's Stop Sonication button to reset connections following Helmet System connection.

3.2.2. System Power ON

1. Confirm that the MR console was rebooted at the beginning of the day. If not, reboot it.
2. Turn ON the system by pressing the green Power ON switch located on the operator's console; the **Begin Logon** notice appears.
3. Remove all external media drives and/or CD's from the console computer.
4. Press **Ctrl+Alt+Del** to access the logon information dialog box.
5. Log in to FUS with your INSIGHTEC provided Username and Password (Windows® logon parameters are case sensitive); click **OK** to continue.



**CAUTION:**

C017D

ExAblate Workstation username & password should not be printed or shared with anyone.

6. Select 'Brain Mid-Frequency' from the application selection screen.
7. The Exablate Neuro disclaimer popup window opens; click **OK** to continue.

3.2.3. Prepare the Water System

1. Unload the Water Reservoir from The Water Reservoir Compartment in the Front-End Unit and disconnect it via the quick release cable.
2. Fill the reservoir with 13 liters (3.45 US gallons) of water (Type 2 medical grade  water for the procedure, fresh Reverse Osmosis water (or Type 2 medical grade water) for Cleaning \DQA). Connect and return it to its designated compartment.
3. Set the water system state to **Preparation** from the Workstation screen's Utilities menu (water system state button ) or to **Degas** from the Water System Control Touchscreen.
4. Press the blue button on the workstation console, or the **circulate** button on the water system remote controller or the 'play' symbol on the touchscreen to commence degas circulation
5. Degassing will start and indications on the Water System's status will appear on the bottom of the screen in the **Device Status** [(**Degassing**, **Temperature** (°C), and **Dissolved Oxygen** (DO) levels [in PPM]] as well as on the Water System Control Touchscreen.



NOTE:

You may proceed with System Set Up while water preparation is ongoing Preparing the MR Table.

N023

3.2.4. Preparing the MR table

1. Bring the MR cradle all the way out of the MRI bore.
2. Remove any imaging coils or MRI Baseplates currently connected to the MRI Table.
3. Place the Exablate MR Baseplate on the MR Table and lock it in place (if applicable).
4. Ensure the Transducer is positioned in the Helmet System according to the **Home Position** label.
5. For DV GE MRI, Undock the table and remove it 20cm away from the MR or rotate the table 30° to enable access of the STC. Lock the table in place.
6. Unlock the STC and roll it towards the MR Bore while releasing the cable.
7. Place the STC perpendicularly to the MR Table, so that the blue markings are aligned.

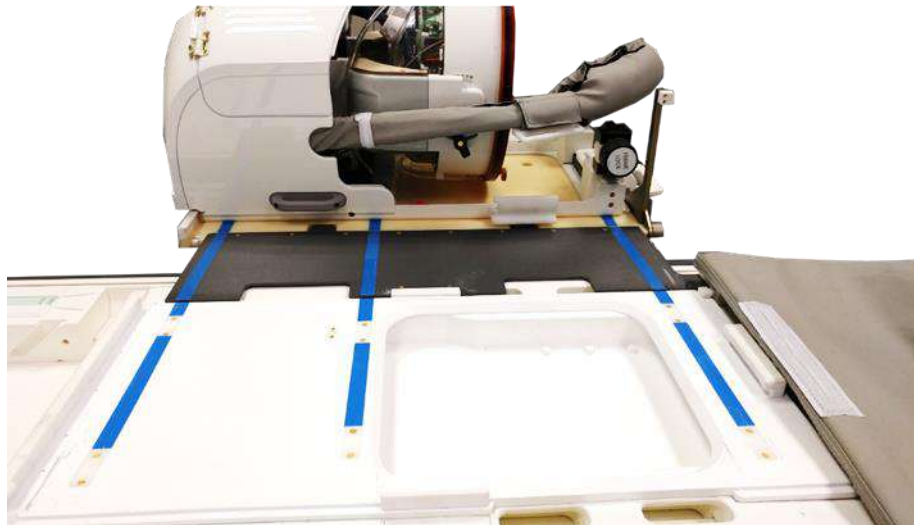


Figure 3-5: STC Bridge Coupled with MR Table for HS Transfer

8. Lock the STC's wheels in place
9. Release and lower the Coupling Bridge. Ensure connection. Ensure the main latch is folded back to avoid collisions with the frame posts.



CAUTION:

C019

To avoid damage to system components, make sure no cables are obstructing the path of the Helmet System to its position on the MR Table

10. Place one hand on the auxiliary handle and the other on the main handle, with your thumb against the 'lock' button, and while pressing the **Transducer Release Button** slowly and firmly slide the Helmet System into place; a 'Clicking' sound denotes full coupling.



Figure 3-6: Transferring the HS to the MR Table

11. Lower the **Main Lock** to secure the Helmet System in place.
12. Connect the **MR Tracking and Head coil connector/s** into the MR Coil Socket on the MRI Table.
13. Connect the **Patient Stop Sonication Button** to its socket on the MR Table
14. Unlock the STC and roll it into a location where it will not interfere with the treatment or potentially obstruct emergency procedures.
15. For DV GE MRI, Dock the table back to the MRI.
16. Place mattresses and head **cushion** (optional) on the table, and cover with sheet

3.2.5. Verify System is Ready for Treatment

Confirm that the **device** and **MRI** status indicator are 'ready' (green), and that the blue water system indicator on the operator console is illuminated (indicating active circulation. If not, press it to initiate circulation).



NOTE:

For some **GE** scanners with newer SW versions (DV26 and up) you may need to press the 'External Host' button on the MR console and select 'ExAblate' from the drop down menu in order to enable communication between the Exablate workstation and the MR scanner.

N020D





Figure 3-7 : Selecting 'Exablate' as external host (GE MR Interface)



Figure 3-8 : System Ready




NOTE:

N024

For **SIEMENS** systems, ensure "remote connection" icon on the bottom of the MR workstation screen is in its enabled state:



If Disabled () click on it to enable communications.



WARNING:

W057

Visually inspect the Exablate Neuro system to:

- Verify the integrity of the Transducer, Front-End, Helmet System and MR Table.
- Confirm that the connectors are properly fastened
- Confirm that the Exablate MR Baseplate and Helmet System are properly docked

Failure to follow these instructions may result in improper system function

3.3. Patient Positioning and Release

3.3.1. Accessories Required for frame fixation

- Head Frame – head frame which allows fixing of the patient's head to the bed.
For recommended use operating guidelines, cleaning, and maintenance procedures of the Head Frame see **1.7 and 1.8. Head Frame Instructions for Use.**
- Disposable Head Frame Screws for affixing the headframe to the patient's skull.
- If applicable: Place protective Frame Pin Caps over the Disposable Head Frame Screws' extremity to protect the elastic Patient Membrane and a sachet of silicon sealant to ensure sealing between the membrane and transducer, if necessary.
- Head Frame Positioning Straps is available to assist in frame placement.

3.3.2. Frame and Patient Membrane fixation

1. Ensure that the patient's scalp is shaved well, and that any scars or scalp lesions (i.e., eczema or psoriasis) are marked for avoidance in the treatment beam path to minimize heating/burning at the scalp.
2. Apply local anesthesia\numbing agents according to local protocol\regulation
3. Affix the frame to the patient, as low as possible, while maintaining clear airway access.
4. Place the **Patient Membrane** (an elastic membrane which seals the transducer and enables acoustic interface between the transducer and the patient's head) on the patient's head on top of the Head Frame (See Section 1.8), as low as possible, in the right orientation:
Membrane without Head Coil: screws\plastic side down (towards patient's feet).
Membrane with an integrated Head Coil: Ensure the Head Coil connectors are in the right location according to the coil socket position next to the transducer (See **Figure 3-9** and **Figure 3-10**).



NOTE:

Patient Membranes are “one size fits most” .

Some cutting may be required for abnormally large heads or sensitive patients.

N025

5. Confirm the tightness of the membrane to avoid discomfort or harm to the patient.

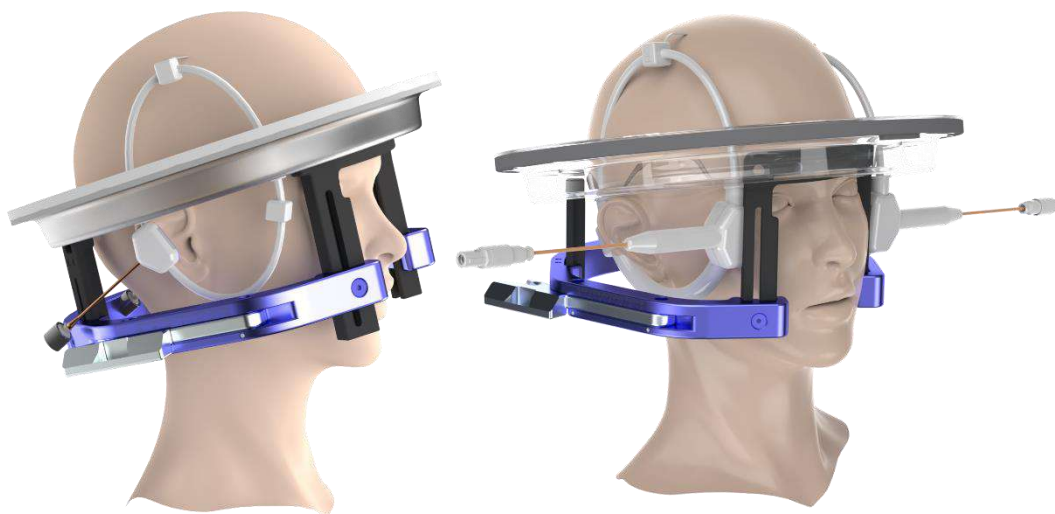


Figure 3-9: Examples of Patient Membrane dispositions

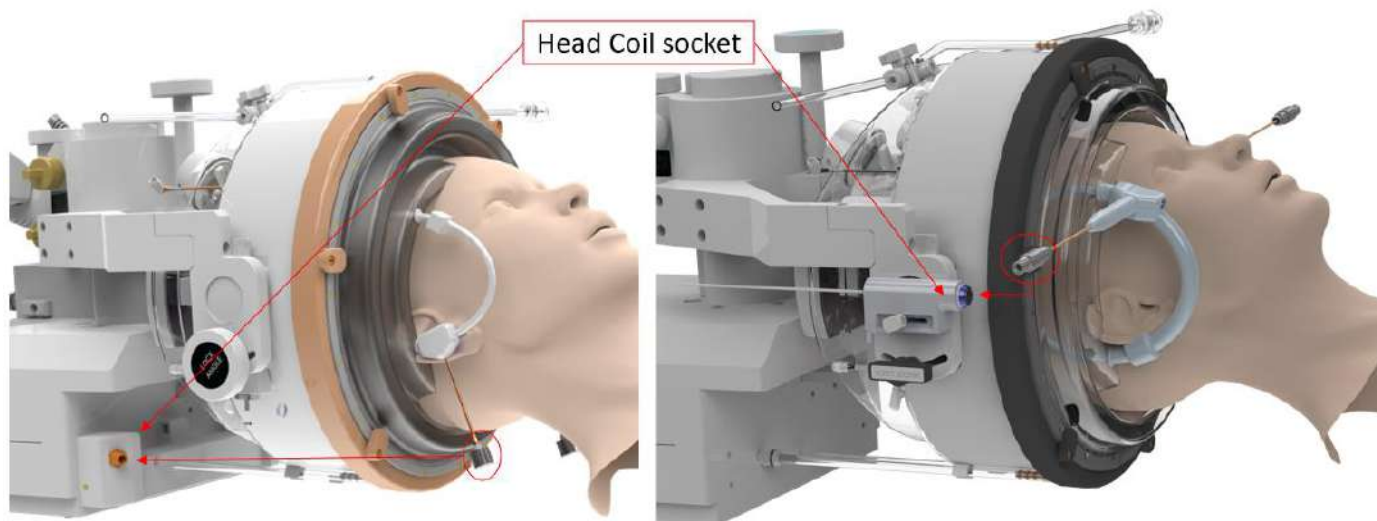


Figure 3-10: Examples of Patient Membranes disposition according to their Head Coil socket position.

3.3.3. Getting on the treatment Table



WARNING:

W058

Make sure that the transducer is positioned as superiorly as possible to avoid patient injury when positioning on table. And maintain eye contact when moving the transducer towards the patient to ensure clearance between the patient's head and the transducer.



NOTE:

N026

Maximal allowed patient weight:

- Type 1.0 systems: 300 lbs. (135 kg)
- Type 1.1 systems: 440 lbs. (200 kg)

1. Assist the patient on the table, lower the MR table and use stools if need be.
2. Instruct patient to lie down and guide the Head Frame into the **Base Plate Attachment**; lock it in place.
3. Use **Cushion** or **Patient Leg Holder** (Type 1.1 only) on the MR table as needed to improve patient comfort (optional).
4. Ensure that the transducer's front-ring seal (O-ring) is secured tightly in place. If loose, replace with spare O-ring and contact your Insightec representatives to order new replacement.
5. Move the transducer to the treatment position. **Maintain eye contact with the Patient's head and the transducer to avoid hitting the patient with the transducer.**

**CAUTION:**

C041

When moving the transducer, always ensure the patient's head or headframe pins do not touch the transducer. In case you feel irregular resistance while moving the transducer, immediately stop and examine the set-up

6. Couple the **Patient Membrane** with the transducer. Confirm that all latches are fastened in place and that the patient does not feel any pain or discomfort.
7. If applicable: connect Head Coil (see **image 3-9**)

**NOTE:**

N027

Head Coil Connectors of all Head coils except for Type 1.5T GE (1.0) are adjustable in the S-I direction. See **section 1.10** for further explanation.

8. Strap the patient to the treatment table.
9. Fit the patient with earplugs.
10. Fill the transducer with water:
 - Open the Transducer Ventilation Tap.
 - Press and hold down the **Fill** button on the Water System Remote Control or on the **Water System Control** screen (type 1.1 only) (see **Figure 1-9**).
 - Watch for any water leaks and press the **Fill** button until the transducer is full. The membrane should feel tight, and there should be no areas where the membrane is concave past the transducer's rim.
 - Close the Transducer Ventilation Tap.
 - Press the red **Pressure Release Valve** to release excess air from tubing, and then press Fill to reset. Press fill to add more water if needed (without opening the ventilation tap).

**WARNING:**

W059

The transducer interface must be filled completely with water without air bubbles to provide adequate acoustic coupling. Pay strict attention that no air has entered the transducer interface and that it is filled with water continuously during the treatment. Incorrect coupling may cause reduced focal zone temperatures, defocusing and misalignment of the focal spot, and/or severe damage to system components

After the patient is lying comfortably on the patient table, insulate the patient from the MR scanner with appropriate thermal-resistant pads to prevent potential RF burns. Place the pads along the patient's sides to insulate the patient from the scanner walls. Patients in danger of touching the scanner ceiling require thermal-resistant pads for the back and buttocks.

Verify that an open space of more than 0.5' (1.25 cm) exists between all system components and the patient to the sides and top of the scanner.

**WARNING:**

W060

Pay strict attention to the top part of the transducer and ensure proper clearance from the top of the magnet bore. When moving transducer towards the patient maintain eye contact at all times to ensure clearance between patient and transducer.

Ensure that the patient's gown does not hinder the movement of the table mechanism as it goes in and out of the scanner.

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



Figure 3-11: Subject Positioned on Type 1.1 System, with Leg Holder (for illustration purposes only)

3.3.4. Mechanical Positioning of the Transducer



Figure 3-12 Type 1.1 Mechanical Positioning Unit, Levers (L), Locks (R)

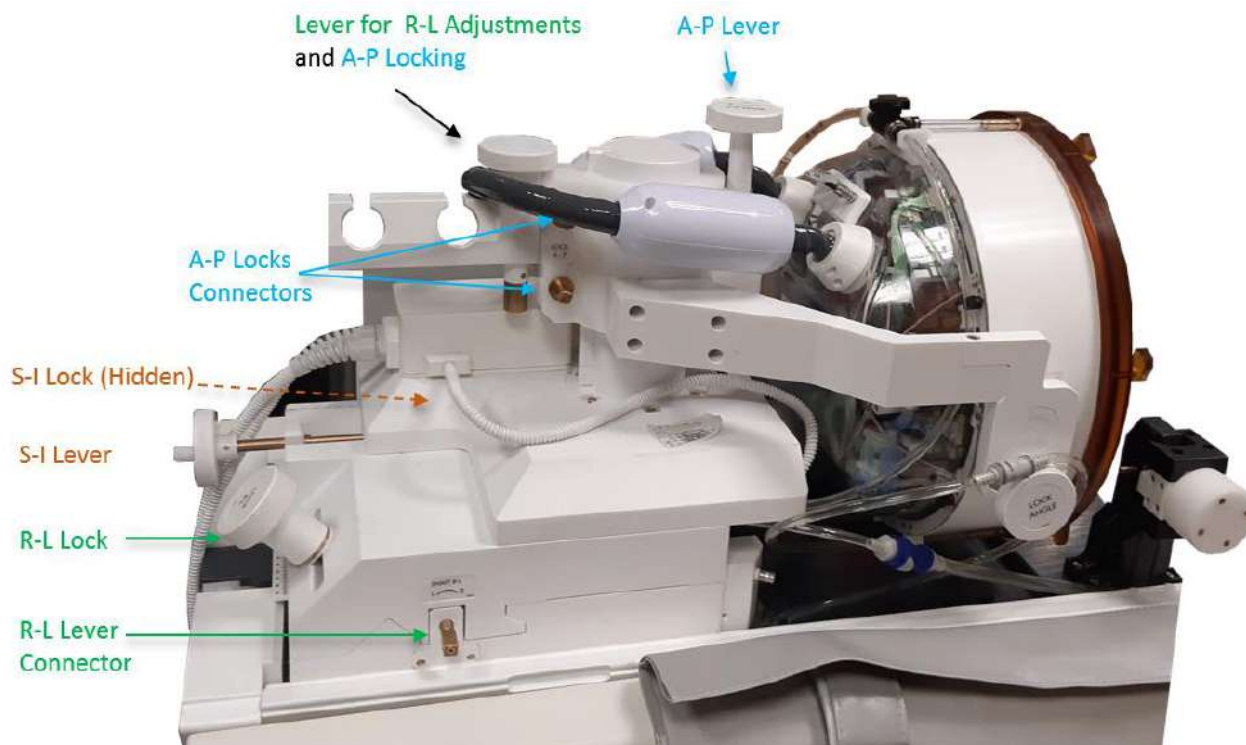


Figure 3-13: Type 1.0 Mechanical Positioning Unit

The transducer's location is set by a mechanical positioning unit, manually adjusted by the operator. This allows moving the transducer to enable easier patient placement and then to bring the transducer's Natural Focal Point (Transducer Focus) to the anatomical target.

The transducer's location can be adjusted along all three main MR axes:

Right-Left, Anterior-Posterior, and Superior-Inferior. It can also be rotated around the R-L axis.

Note the convention: R+, L- A+, P S+, I-.

To move the transducer on a specific axis turn the Axis lock counter clockwise to open the slider on the relevant axis and use the dedicated levers to turn the relevant positioner in the desired direction, as indicated by the value on the positioner (Type 1.1) or on the rulers (Type 1.0).



Figure 3-14: Type 1.1 A-P Positioner Lever

Once the transducer reaches the desired location on each one of the axes, turn the lock clockwise to eliminate transducer movements along the sliders during the treatment.

To adjust the angle, unlock the angle lock, adjust the angle manually, and re-lock.

3.3.5. Patient Release

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

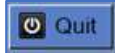

1. Bring the cradle out of the MR bore.
2. Drain the water from the transducer:
 - Open the **Transducer Ventilation Tap**.
 - Press and hold down the **Drain** button in the **Water System Remote Control** or Water system screen (Type 1.1 only) until the transducer is completely empty.
3. Unfasten the latches and disconnect the **Patient Membrane** from the transducer
4. Move the transducer **Superiorly**, as far away from the patient as possible.
5. Release the **Head Frame** from the **Base Plate Attachment**.
6. Instruct and guide the patient to sit up.
7. Remove the **Patient Membrane** from the patient's head.



Figure 3-15: 1.5T (Type 1.0) TcMRgFUS Head Coil Connector Plug and socket (For illustration only).

3.4. Shutdown

To shut the system down, proceed as follows:

1. Press this button on the system toolbar to transition to the **Startup** screen.
2. Press this button; the system responds with the **Shutdown Confirmation** message.  
3. Press **Yes** to continue; the automatic shutdown procedure is initiated. This takes several minutes.
4. Disconnect the coupler cables from the Front-End Unit **only** when the console has automatically powered down, and the power-ON light has extinguished:
 - Unlock the quick-coupler lever and gently slide the cable's quick-coupler out.
 - Pull the white handle towards you and slide the hose cable's quick-coupler out.
5. To prevent damage to the transducer at the end of the working day, verify that the transducer is empty and dry, and attach the transducer cover.



CAUTION:

Do not leave the transducer filled with water unattended or for an extended period of time. Make sure you discard of the water following a treatment day.

C020

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

3.5. Operating the Water System

The water system is a semi-closed water circulation loop used for filling and draining of the transducer water interface and preparing and circulating cool degassed water during treatment.

Various modes, states, and parameters of the Water System can be controlled either through the Workstation or by using a dedicated Water System Control screen located either on the chiller in the equipment room (Type 1.0) or on the Front-End Unit (Type 1.1). The Water System states can also be controlled using the blue Water System Control Button located on the Operator Console.

For details regarding the Water System cleaning and maintenance, review **Chapter 12**.



Figure 3-16: Type 1.1 Water System Remote Controller

3.5.1. Water System Remote Controller

The Water System Remote Controller is connected to the Front-End Unit via a flexible cord. The Remote allows the user to perform the following operation: drain water, fill water, pause\resume & reset.

Type 1.0: When circulating, the little green button in the top right corner is lit.

Type 1.1: When circulating, the RESET\CIRC button is lit (see **Figure 3-16**).



Figure 3-17: Type 1.1 Water System Remote Controller States
Idle (Left) and While Circulation Is Active (Right)

The green (Type 1.0) or blue (Type 1.1) LED on the top of the Remote Controller mirrors the state of the water system LED on the Operator Console i.e., when the water system is online, the LED is lit. The LED will start blinking if there is a Water System error.

3.5.2. Water System Touchscreen Icons (Type 1.1 Only)



Home

Return to **Home** screen.



Drain

While the button is pressed, the system will drain water from the Transducer to the Reservoir. The **Drain** function is available at all times, from all of the Water System Control Touchscreen's screens.



Fill

While the button is pressed, the system will fill water from the Reservoir to the Transducer. Filling is available from the various mode screens.



Circulate

Starts water circulation in Reservoir or Transducer (**NOTE:** Depending on selected mode).



Pause Circulation

Halt water circulation.



Reset

Reset Water System Error (**NOTE:** Does not automatically restart circulation).

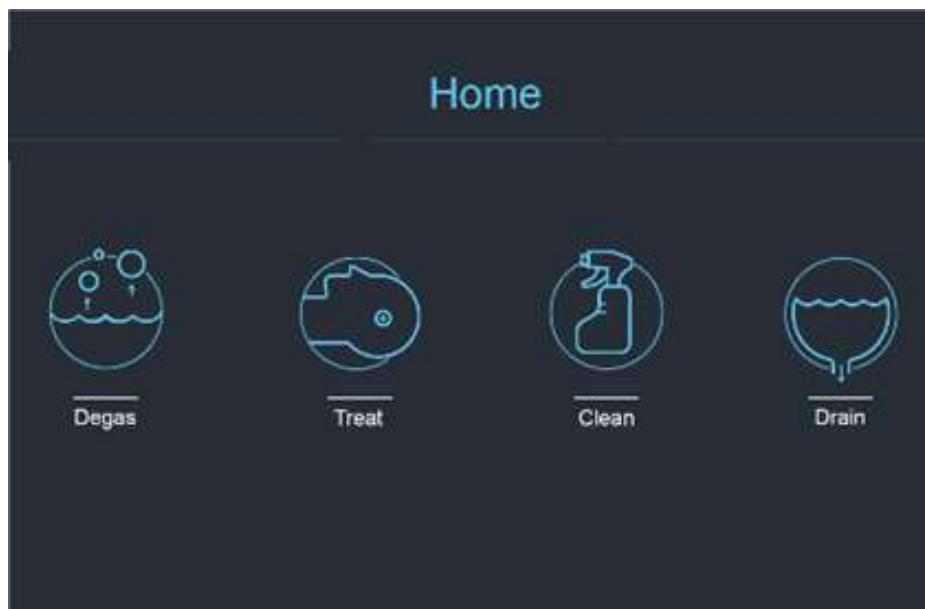


Figure 3-18: Water System Operating Modes

The Exablate 4000 Water System has three main operation modes: **Degas**, **Treat** and **Clean**.

The user can cycle between the operating modes via the **Water System Control** screen (see **Figure 3-19**) or from the **Utilities Menu** on the Operator Console (see **Figure 3-19**).

3.5.2.1. *Degas Mode (Preparation)*

The water within the Water Reservoir is cooled down and air bubbles are filtered out.

Preparing the water from 25°C to 15°C and from a PPM level of 5.0 PPM to 1.0 PPM takes up to 30 minutes.



Figure 3-19: Type 1.1 Degas Mode Screens



CAUTION:

To avoid introducing large amounts of air into the system, only perform degassing when the reservoir is filled with water (up to the green marking on the Water Reservoir).

C021

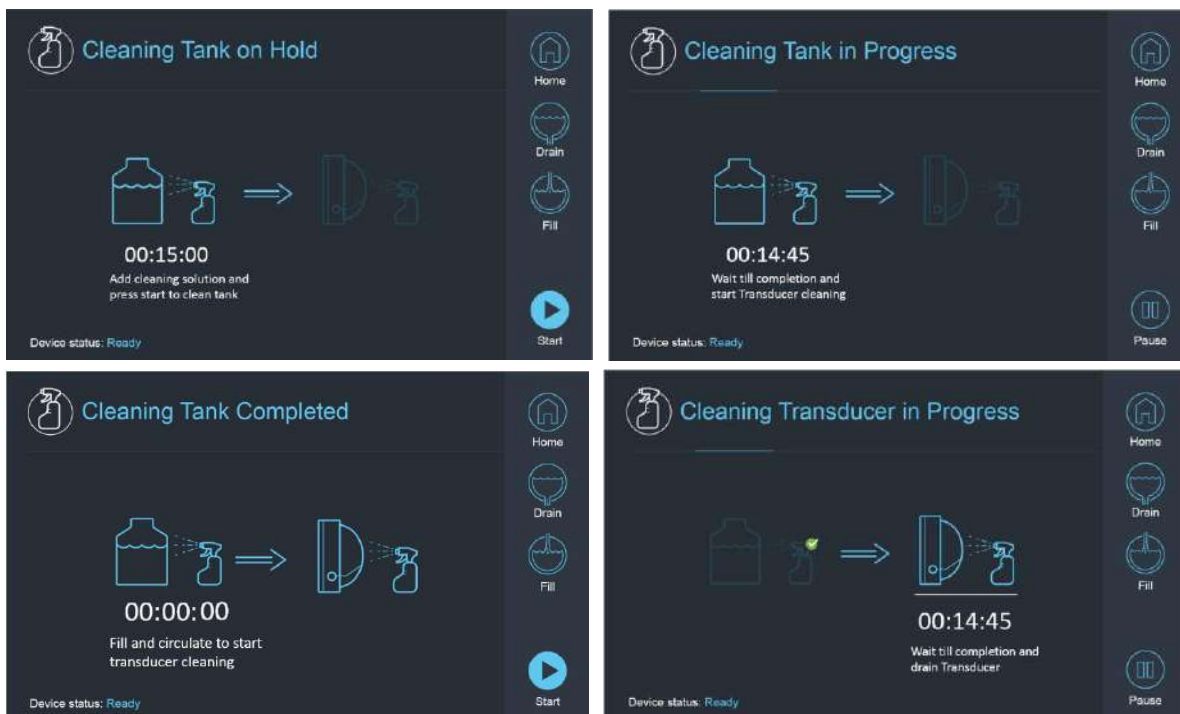
3.5.2.2. Treat Mode (Treatment Circulation)

- To be used when the transducer is sealed and filled with water (e.g., during treatment or a DQA).
- Water is circulated around the patient's skull in order to facilitate and expedite cooling of the skull after performing treatment sonications.
- Treatment circulation also maintains water temperature and degassing levels for the water volume contained in the transducer.

3.5.2.3. Clean Mode (Post Treatment)

After every treatment, once the Helmet System has been transferred from the MR table to the cart, a cleaning procedure is to be performed to clean and disinfect the Transducer as well as the entire Water System Piping and Reservoir.

To achieve that two 15-minute circulation cycles are to be carried out, circulating fresh water with an added cleaning solution through the system piping and reservoir (akin to degassing circulation) and then through the Transducer (similar to treatment circulation). After the Transducer cleaning circulation cycle has concluded the operator can drain the water and proceed to **System Shutdown**.



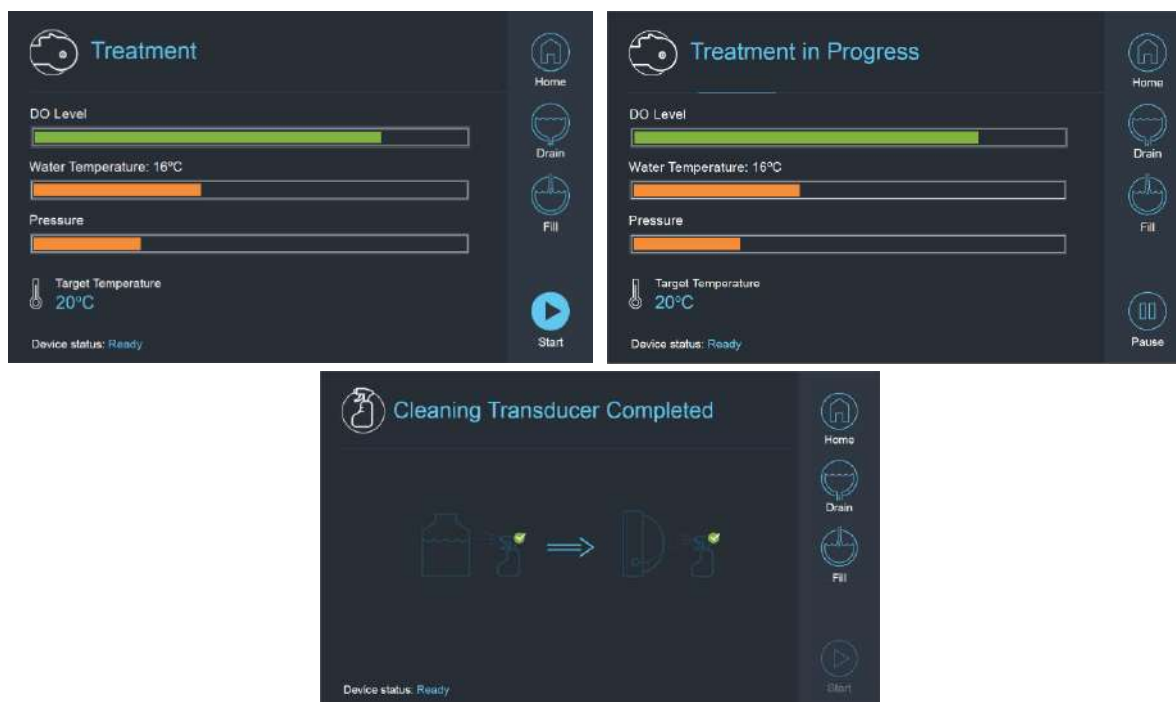


Figure 3-20: Clean Mode Screen Sequence on Type 1.1 system

3.5.3. Operating the Water System from the Operator Console

The Utilities (**Utils**) menu on the Operator Console can be accessed from the **Main** menu or during treatment.



It contains a section that allows the user to set the Water System stage to Preparation (Degassing)\ Treatment Circulation or Cleaning, define the target temperature of the chiller, and turn the water cooling ON/OFF.

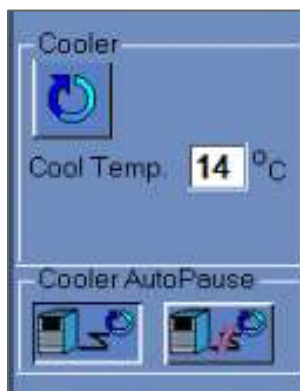


Figure 3-21: Water System Controls in Utilities Screen



After setting the system state, the Operator can press the Blue button on the Operator Console to turn circulation ON/OFF.

3.5.4. Water System Error Handling

Water System Errors are indicated by the following:

- The blue water system control button on the Operator Console flashes
- The blue Led on the Water System Remote Controller flashes
- The Device status message on the bottom left of the WS screen states Error within the brackets.
- A detailed error description with mitigation steps is displayed on the Water System Control Touchscreen

The system will automatically cease circulation in case a system error is detected (e.g. excessive pressure, cable disconnected) or the temperature in the water interface is higher than the desired set point. Some errors (e.g. low water pressure) enable sonication while others (e.g. water temperature exceeds defined limit) will lead to a prompt before sonicating.

In any event of an Error, the user must perform actions to mitigate the error.

Follow the instructions displayed on the Water System Control Screen to resolve the relevant error.

Make sure you first take the patient cradle out of the bore to confirm:

- No water leaks are visible
- Water level in the transducer interface is nominal
- Water pressure is nominal
- No air is present in the transducer interface
- Water hoses are not tangled or obstructed
- Air ventilation pore is closed

After resolving the issue and ensuring the Transducer interface is properly filled with water, reset circulation by pressing the blue **Circulation** Controller, the **RESET** icon on the **Water System Control** screen, or the **RESET** button on the Water System Remote Controller.

If the problem persists, contact INSIGHTEC Service representative for troubleshooting

3.5.5. Water leak mitigation

Rarely, the Treatment membrane may be accidentally punctured, resulting in a water leak.

Note that if the puncture is minor and its location poses no harm to the patient, it may be possible to proceed with the treatment. In case of a moderate leakage, use the supplied Leak Mitigation Clamp to pinch the membrane and stop the leak (See **Figure 3-22**).



NOTE:

For treatment kit configurations where no leak mitigation clamp is supplied (identifiable by opaque whitish membranes), use the provided gel sealant sachet for temporary mitigation of minor leaks and punctures. Do not apply this material on clear membranes.

N076

In case of a significant tear, discard the membrane and restart the treatment using a new membrane.



CAUTION:

C010

If a membrane has been damaged, discard of it following the treatment.



WARNING:

W111

The Leak Mitigation Clamp supplied as part of Exablate treatment kits is verified for MR use.

The use of unauthorized clamps may result in injury or imaging artifacts.



Figure 3-22: Example of Leak Mitigation Clamp usage

3.6. Workstation Start-Up Screen

Ensure that the Exablate Neuro system is turned ON and logged into.

Optional: The Exablate application selection window will appear, for Exablate systems with more than one application capability, Click the **Treat** button of the desired application, in order to enter the **Startup** screen and start the treatment.

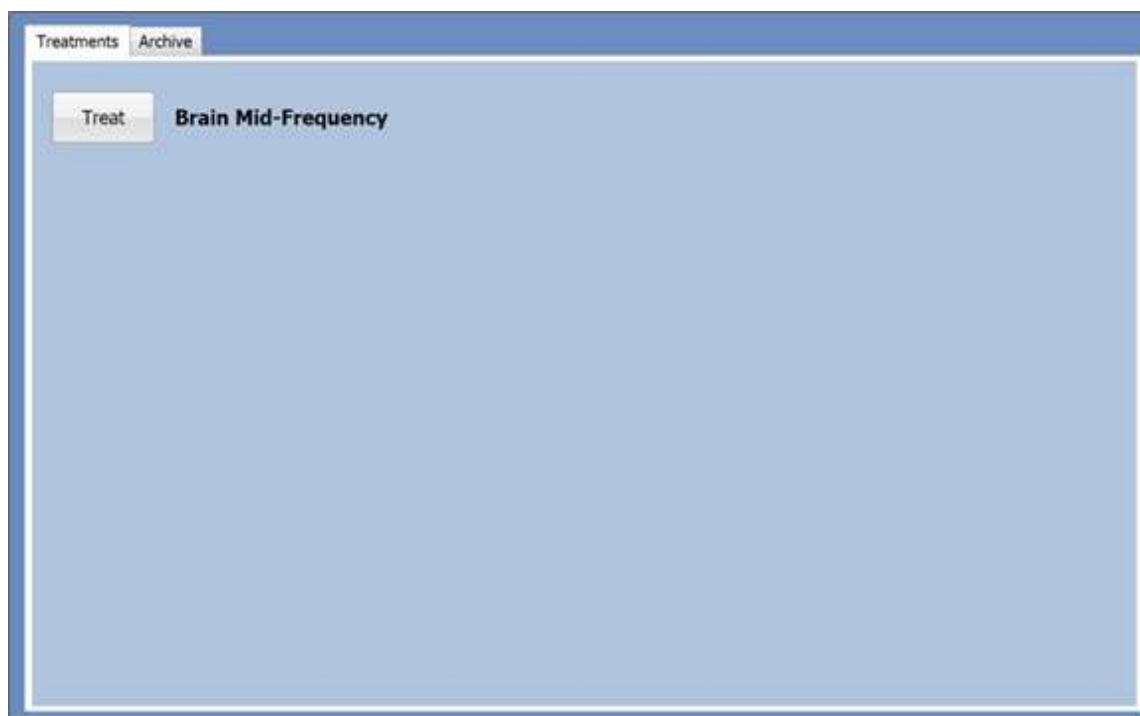


Figure 3-23: Select Application Screen



NOTE:

To review previous treatments, press on the **Archive** tab, then press on the **Archive** button of the desired application.

N028

After selecting the application, the **Start-Up** screen will appear:

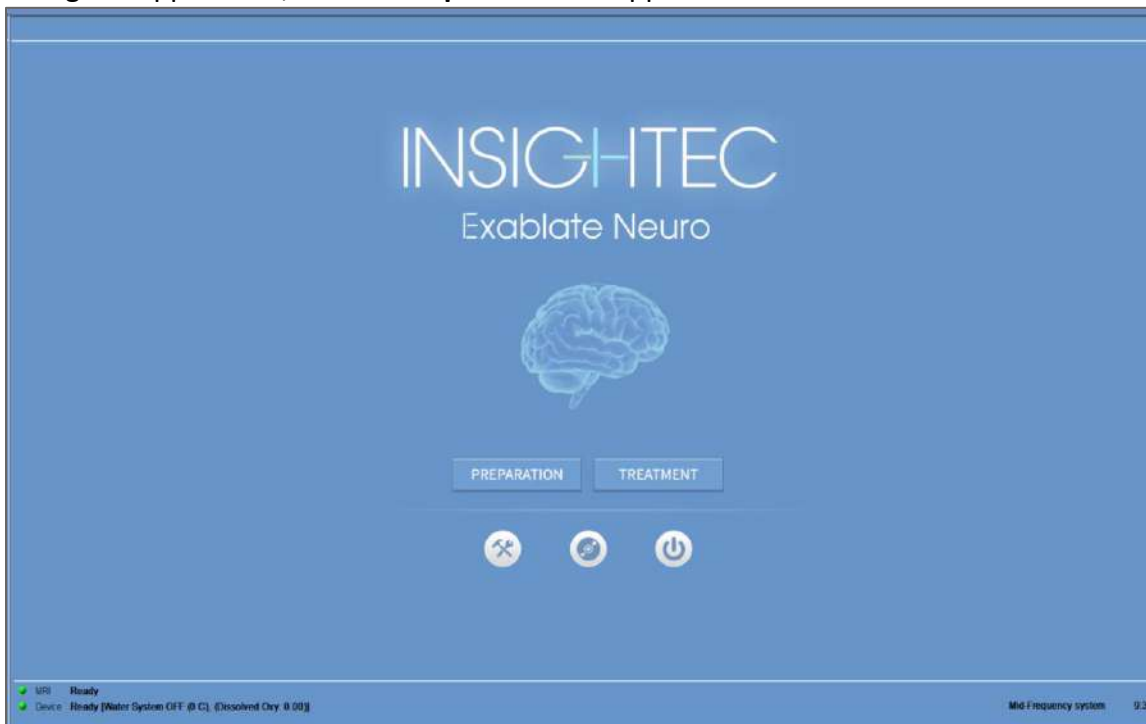


Figure 3-24: Start-Up Screen

The **Start-Up** screen displays the **Pre-Treatment Session** button, **Treatment Start** button, three (3) **Command** buttons and a **Status Bar**.

3.6.1. Treatment Start

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

PREPARATION

**Prepare a
Planning Session**

Press this button to begin the **Pre-Treatment Plan** session or to open an existing session that was saved (see **Chapter 6**).

TREATMENT

Start Treatment

Press this button to begin a treatment session\DQA.

3.6.2. Command Buttons

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

**Utilities**

Press this button to access the **Utilities** mode (see **Chapter 9**).

**Data Management**

Press this button to access **Data Management** operations (see **Chapter 13**).

**Shutdown**

Press this button to shut down the Exablate Neuro system.

3.6.3. Status Bar

The status bar displays the operational status of the Exablate Neuro and the water system (**Device**), and the status of the MRI (**MR**).




Figure 3-25: Device and MR Status Bar

Verify that the buttons in the Status Bar are green and proceed to patient positioning. When the buttons are red, follow the system's on-screen instructions.

3.7. Begin Treatment

After turning ON power to the system and positioning the patient, the treatment procedure is initiated from the console:

1. Press  on the **Start-Up** screen; the **Treatment Data Dialog Box** appears.
2. Type the physician's name in the Physician Name text box. This step is required, and the system will respond with an error message if you attempt to advance to the next stage without a name in this text box. The physician name consists of letters only (no numbers or symbols).

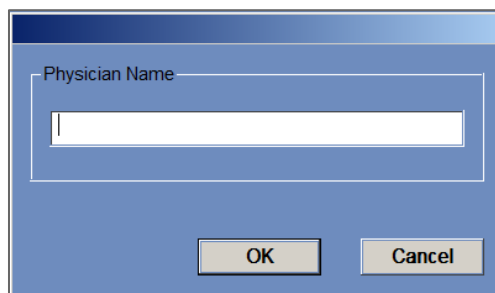


Figure 3-26: Treatment Data Dialog Box

4. TOOLS & OVERLAYS

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

4.1. Treatment Screen - Overview

Along the left side of the **Treatment** screen, several tools are displayed to help plan and conduct the treatment. Different tools are available to the operator depending on the stage of the treatment. The tools are described in each of the following sections and the descriptions refer to the general tools, and the Specific tools for the 'planning' and 'Treatment' Stages.

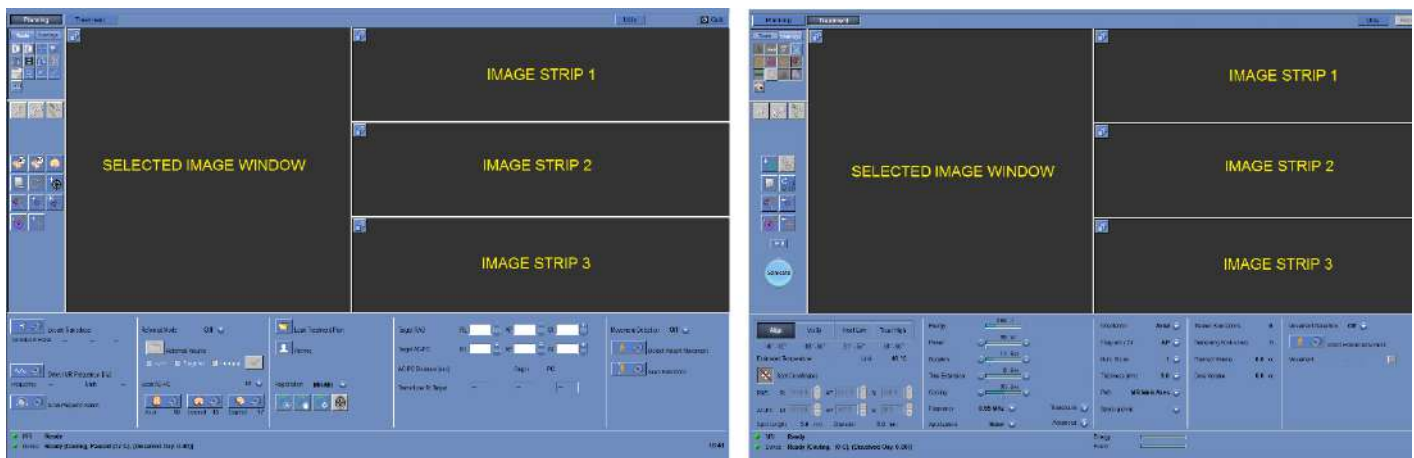


Figure 4-1: Treatment Stage Screens

4.1.1. Exablate Main Toolbar

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



Figure 4-2: Exablate Main Toolbar

4.1.2. Treatment Stages

Exablate Neuro treatment are divided into two stages the **Planning Stage** is dedicated to acquisition of planning MR images, delineation of non-pass regions and target determination, while the **Treatment** stage is where the actual treatment sonications are performed and reviewed.

4.1.3. Information Area

In this area warning messages and treatment/progress status information is displayed to the operator.

4.1.4. Utilities

Utils – provides access to the **Utilities** menu (See **Chapter 11**)

Replay – views and analyzes the results of previous sonications (See **Chapter 10**)

Exit – aborts the treatment and transitions to the **Startup** screen.

4.1.5. Image Strips

Three rows of image strips appear on the screen. Any content that has been loaded into the system can be displayed, using the navigation tools next to each strip (see **Figure 4-1**).

4.1.6. Selected Image Window

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



NOTE:

N029

All user editing and interaction with graphic objects is performed in the selected image window **only**.

4.1.7. Image Strip Selection

Image	Name	Description
	Image Strip Selection	Press this button to select the images in one of three image strip windows to be displayed from the pull-down menu. Options may vary between stages depending on the data available.

4.2. Image Overlays

4.2.1. Image Annotations

The image annotations consist of the orientations, patient details, scan parameters, scaling bar and image type. MR magnitude images (anatomy) consist of slice location, and temperature maps consist of the acquisition time.

4.2.2. Shadow Cursor

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

4.2.3. Cursor Coordinates (Type 1.0 & 1.1)

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

There are multiple coordinate systems displayed in the cursor coordinate area throughout the treatment:

- **Treatment MR Coordinates** – RAS Coordinates of the treated patient, relative to MRI Exam landmark, these are the 'real world' coordinates of a treatments, and are used to place spot on targeted anatomy and to keep all image sets aligned .
 - **Appear without annotation** – on Intra-Operative MR image, Thermometry images, Movement Detection images.
 - **Appear annotated as 'Tx MR'** – on Pre-Operative CT and MR (**following registration only**)
- **AC-PC Coordinates** – a coordinate system set on an axis aligned to the AC-PC Plane (defined by the orientation of oblique the intra-operative images. (0,0,0) is at the PC).
 - These require placing AC, PC and midline on the intra-operative image.
 - **Appear annotated as 'AC-PC'**– on Intra-Operative MR image, Thermometry images, Movement Detection images, Pre-Operative CT and MR (**following registration only**)
- **CT Coordinates** – The native RAS coordinates of the pre-operative CT images.
 - Appear only on the CT scan, without annotation
- **Pre-Operative MR Coordinates** – The native RAS coordinates of the pre-operative MR images.
 - Appear only on the Pre-Operative MR images, without annotation.



WARNING:

A discrepancy in the RAS coordinates between different Pre-Operative series may indicate patient movement during image acquisition – deeming the exam unfit for planning. If such a discrepancy is detected during Pre-planning (by comparing anatomy or during MR-CT registration) consider discarding the exam or the problematic orientation.

W061

4.2.4. Additional Cursor Coordinates (Type 1.1 Only)

For Type 1.1 Systems only, the MR Treatment table contains an additional set of trackers which enable localization of the transducer relative to the MR table. These enable the system to account for cases where the patient and transducer move together slightly, due to some freedom in the table's range of movement. Such a movement (as opposed to a patient movement) does not pose a risk and can be accounted for by:

- **(Shifted) Treatment MR Coordinates** – RAS Coordinates of the treated patient, relative to the Helmet System. These replace the original (unshifted) coordinates to serve as the 'real world' coordinates of a treatments, used to place spot on targeted anatomy and to keep all image sets aligned. They behave exactly as the Type 1.0 Treatment MR coordinates (see above).
- **Treatment unshifted MR Coordinates** – If a cradle movement (**not** patient movement) within acceptable limits has been detected, as mentioned above, the Tx MR coordinates will be shifted to compensate for the shift. The unshifted (original) coordinates will be displayed in parentheses, to act as a reference point if necessary. (see **Figure 4-3**)
 - **Appear within parentheses** – on images acquired intra-operatively (thermometry, anatomy, planning, movement detection)

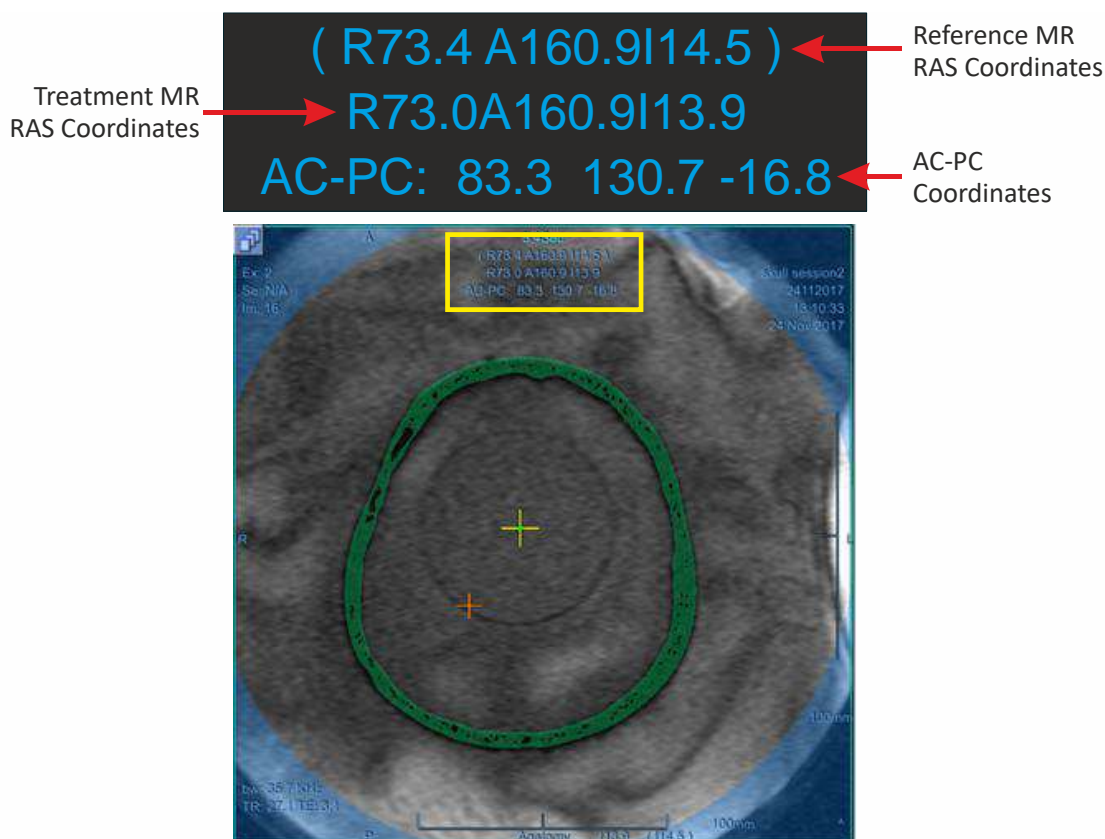


Figure 4-3: Type 1.1 Cursor Coordinates

(in this example the entire cradle (Inc. Helmet System and 'patient') are shifted Superiorly by 0.6mm)

**WARNING:**

W039D

For type 1.1: Due to shift compensation (section 4.2.4) a difference between RAS coordinates on Exablate workstation and MR Workstation may occur. During treatment, always refer to the Exablate workstation coordinates.






4.3. General Tools

The Tools menu includes various tools for manipulating image display (Pan\Zoom\Window\center), Adding measurements (Line, Area, Angles), as well as special display modes (Flicker\animation\3D view). There are also tools for copying markings from image to image (within the same series) and for saving snapshots of the screen.



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



4.3.1. Image Manipulation Tools

Image	Name	Description
	Zoom	<ul style="list-style-type: none"> To see a close-up of an image, press this button. To zoom in, drag the mouse up. To zoom out, drag the mouse down. Any change in one image is automatically reflected in all the other images on the same type of strip. Alternatively, press the left mouse button and drag the mouse as above to change the zoom.
	Pan	<ul style="list-style-type: none"> To navigate around a zoomed image, press this button and then move the cursor to the image you wish to navigate to. Drag to pan the image. Alternatively, right press and drag to pan the image. Any change is automatically reflected in all the other images on the same type of strip.
	Modify Contrast & Brightness	<ul style="list-style-type: none"> Press this button to change the image windowing (brightness or contrast). Drag the mouse up to brighten and down to darken the image. Drag the mouse left to increase the contrast and right to decrease the contrast. The change is automatically reflected in all the other images on the same type of strip. Alternatively, press the middle mouse button and move the mouse as above to change the brightness or contrast.
	Reset	<ul style="list-style-type: none"> Press this button to restore all images to default zoom, pan, contrast, and brightness settings. Reset applies to the entire image slice in all strips simultaneously.
	Center	<ul style="list-style-type: none"> Press this button and then select a location in any image. By pressing on it, the images with this point will appear at the center of the strips.

4.3.2. Measurement Tools

Image	Name	Description
	Measure Distance	<ul style="list-style-type: none"> Press this button to measure the actual distance between two points. This function is applicable only to the selected image window. To measure distance: <ol style="list-style-type: none"> Press an image from the image strips to view in the selected image window. Press on the first point to measure. Move to the second point and press again. Double press to complete the Measure command. If needed, edit the measurement line by moving its tip. Exablate calculates and displays the distance between the two points. Distance Measurements and their labels can be moved and adjusted by clicking and dragging the points at the ends of the line.
	Measure Angle	<p>Press this button to measure an angle, or to place a right angle on the image. This function is applicable only to the selected image window.</p> <ul style="list-style-type: none"> To measure an angle: <ol style="list-style-type: none"> Select Angle from the menu. Press on the first point of the angle to be measured. Move to the second and third points and press again. Double-press to complete the Measure command. <p>The system will calculate and display the angle.</p> To place a right angle: <ol style="list-style-type: none"> Select Right Angle from the menu. Press on screen to add the right-angle figure. To place an AC-PC Measurement (requires AC and PC markings): <p>This tool will place a right angle, with one ray on the midline starting from the PC point with a length of '25% x [AC-PC distance]' and the second ray with a length of 14 mm.</p> <ol style="list-style-type: none"> Select AC-PC Target from the menu. The angle will be placed automatically. Angles and their labels can be moved and adjusted by clicking and dragging the points at the ends of the line.

	Measure Area	<p>Press this button to measure the attributes of a drawn polygon. This function is applicable only to the selected image window.</p> <ul style="list-style-type: none"> To measure an area, draw a polygon: <ol style="list-style-type: none"> Press on the first point of the polygon to be measured. Continue to draw the outline of the polygon with single presses. Close the polygon by pressing again on the first point. The polygon's average pixel value, the standard deviation of pixel values within the polygon and its area are calculated and displayed. Label can be moved if needed. NOTE: on a temperature map, the pixel value is the temperature value. The average temperature within a polygon is displayed in the temperature graph (see Section 8.2.6). Area measurement and their labels can be moved by clicking and dragging the polygon outline
--	---------------------	--

4.3.3. Additional Tools





Image	Name	Description
	Screen Snapshot	Press this button to take a snapshot of the screen and save it with the treatment database. When the specific treatment is exported, the screen dumps associated with it are copied to the CD.
	Copy Selected Figure	Select a graphic object in the main window. Press this button and then press on the image that the object needs to be copied to.
	Animation	Press this button to display the selected series as a cine.
	3D View	<ul style="list-style-type: none"> Press this button to show the treatment data in three dimensions, to clinically assess the treatment plan. The overlays include the skull, calcifications, region of treatment, sonications and treatment progress.
	Image Flickering	Press on the Image Flickering button to iteratively pass between the reference and current movement detection images in the selected image window.

4.4. Overlays

The overlay controls toggle the display of various elements on the screen. This section describes the overlay tools which toggle the graphic overlays onto the MR images.








Image	Name	Description
	Treatment Envelope	Press this button to display a green circle that defines the Treatable Area (as governed by the extents of the transducer).
	Text Overlay	Press this button to show or hide the text Overlays on the images.
	Measure	Press this button to show or hide the Measurement graphic overlays on the images.
	Transducer Template	Press this button to show or hide the Transducer's Template on the MR images.
	Thermal Scan Planes	Press this button to display the locations of the MR thermal slices on the selected image window and on the image strips. The lines display the intersection between the planned images and the thermal scan images for selected sonication spots.
	ROT	Press this button to show or hide the contours of the Region of Treatment (ROT)
	Boney Tissue Contour	Press this button to show or hide the Boney Tissue Contours .
	Sonication Spots	Press this button to select the Sonication Spots display (show/hide all spots).
	Accumulated Dose	Press this button to show or hide the accumulated dose. The accumulated dose appears as a blue overlay on the image. In the Thermal Evaluation screen, the dose from the last sonication is displayed in green.
	Target	Press this button to show or hide the Target Marker Overlay .
	AC PC	Press this button to show or hide the AC, PC, and Midline Marker overlays.
	No Pass Regions (NPR)	Press this button to show or hide the contours of the No Pass Regions (NPR) .


Image	Name	Description
	Energy Pass Zone	<p>After calculating the transducer elements map of a sonication spot, you can view the rays from the transducer elements to the spot. A ray defines the acoustic path from a single element to the sonication spot.</p> <p>Select a spot and press this button to select the rays display option from the pop-up menu:</p> <ul style="list-style-type: none">• Show All – displays all the rays from the transducer elements to the selected spot. Rays are colored according to their status• Elements ON – displays only the rays of the transmitting elements.• Elements OFF – displays only the rays of the non-transmitting elements.• Selected Elements – displays only the rays of the selected elements in the transducer elements map. <p>Hide All – Hide all rays.</p>
	Fiducials	Press this button to show or hide the Fiducial Markers .
	Temperature Monitoring Volume	Press this button to show or hide the Temperature Monitoring Volume .
	From-To	Press this button to show or hide the From-To Lines overlay.

4.5. Planning Stage Tools





4.5.1. General Action Tools

Image	Name	Description
	Delete Selected Object	Press this button to remove the selected object. Applies to all types of measurements and NPR markings.
	Delete All Objects	Press this button to remove all objects of the same type as the selected object. Applies to all types of measurements and NPR markings.
	Treatment Protocol	Press this button to access the treatment protocol dialog box.
	Add Fiducial Marker	Press this button and then point and press in the Selected Image window to place a Fiducial Marker on the screen. Fiducials are displayed in the same RAS location for all images which have 'Treatment MR' coordinates, and are particularly useful for comparison anatomical feature locations on Pre-op and Intra-op imaging, and for monitoring patient movement during a treatment session (in conjunction with the Image Flickering Tool).
	Temperature Monitoring Volume	Use this feature to add a region in which the temperature rise will be monitored during the sonication: <ul style="list-style-type: none">● Press on this button.● Draw a closed contour region on the MR image.● Re-press the Temperature Monitoring Volume button. The average temperature in the delineated area will be shown as a purple graph.



4.5.2. Targeting Tools

Image	Name	Description
	Place Target	Press this button to place your target. Target may only be placed on Intra-Operative images. RAS and AC-PC* (relative to PC) coordinates of the target will be displayed on the bottom right section of the main screen * - Only if AC and PC have been marked




4.5.3. No Pass Region Marking Tools

Image	Name	Description
	Draw Polygon No Pass Regions (NPR)	<p>Define NPR (No Pass Regions) as follows:</p> <ol style="list-style-type: none"> 1. Press on the image to display it in the Selected Image window. 2. Press on the Draw No Pass Regions button; draw NPR contours around the sensitive tissues. 3. If required, continue to define the NPR on additional slices (interpolate if necessary). 4. Move the NPR by pressing it and dragging. Delete the NPR by pressing it and then pressing the Delete button.
	Draw Spherical No Pass Regions (NPR)	Press this button to define a spherical NPR with a specific radius from the drop-down menu.
	Automatic Sinus & Calcification Detection	<p>Press this button to automatically detect and mark sinuses and calcifications on the pre-operative CT with NPRs.</p> <p>NOTE: Requires CT-MR registration to be performed</p> <p>NOTE: The marked area is in relation to the location\Placement of the Transducer relative to the CT.</p> <p>NOTE: All markings must be reviewed</p>
	Interpolate	<p>Use this feature to interpolate graphic elements that were drawn on non-adjacent slices:</p> <ul style="list-style-type: none"> • Press on the graphic element you want to interpolate. <p>Press the Interpolate button; the drawn element is interpolated into a continuous surface or a 3D volume.</p>



4.5.4. Movement Detection

Image	Name	Description
	Scan and detect patient movement	Press this button to start a new movement detection scan and determine if patient movement has occurred.
	Scan patient movement reference images	The system is taking reference images automatically. If reference images need to be taken again, press this button to start a new movement detection reference scan.






4.5.5. Anatomical Alignment Tools

Image	Name	Description
	Anterior Commissure Marker	<p>Press this button to mark the Anterior Commissure on the MR images, to enable the system to align all planning images with the AC-PC plane.</p> <p>To use this marking tool:</p> <ul style="list-style-type: none">• Press on the AC Marker button.• Navigate through the images to find the exact location of the Anterior Commissure. <p>Place the marker on the MR image where the center of the Anterior Commissure is clearly seen.</p>
	Posterior Commissure Marker	<p>Press this button to mark the Posterior Commissure upon the MR images, to enable the system to align all planning image with the AC-PC plane.</p> <p>To use this marking tool:</p> <ul style="list-style-type: none">• Press on the PC Marker button• Navigate through the images to find the exact location of the Posterior Commissure. <p>Place the marker on the MR image where the center of the Posterior Commissure is clearly seen.</p>
	Define Midline	<p>Press this button to define the brain Midline angle. This is done to fully define the AC-PC plane aligned coordinate system for Planning image acquisition and/or reformatting of planning images.</p>











4.5.6. Calibration

Image	Name	Description
	Automatic Transducer Tracking	<p>Press this button to perform a scan on the MR that will automatically track the transducer's current location and update its focal coordinates on-screen.</p> <p>For certain MR configuration, TG calibration will be initiated upon the 1st time this button is pressed.</p>
	Scan and Detect MRI Frequency	<p>Press this button to scan on the MR to automatically detect the corrected MR Central Frequency values, to minimize imaging frequency shifts.</p>

4.5.7. Registration Tools

Image	Name	Description
	Perform Automatic Image Registration	Press this button to perform Automatic Image Registration . Press again to stop the registration process.
	Manual Editing of Registration Mask	Use this button to edit the CT segmentation mask location: <ul style="list-style-type: none"> • Select a MR image and press Manual Registration; the segmentation mask and a registration box will appear on the image. • Drag and/or rotate the registration box to move and/or rotate the segmentation mask. • Overlap the segmentation mask and the anatomical boney structures on the MR images.
	Registration Type	The tag displays the image registration type. Press this menu button and select one of the following: <ul style="list-style-type: none"> • CT-MR - to register the MR coordinates system of the planning MR images with that of the loaded CT images. • MR-MR - if a Treatment Plan was loaded, MR coordinates system should be registered with the pre-treatment loaded MR images.
	Registration Options	Press this button to access the Registration Options dialog box. (See 7.10.3)
	Adjust Segmentation	Press this button to adjust the CT image segmentation, based on bone and air thresholds: <ul style="list-style-type: none"> • Select the CT image to display it in the selected image window. • Press this button to change the thresholds of bone and air: <ul style="list-style-type: none"> ❖ Drag the mouse up to increase and down to decrease the bone threshold. ❖ Drag the mouse left to increase and right to decrease the air threshold. • The change is automatically reflected in all the CT images (bone is colored in green and air in blue).

4.5.8. Image Acquisition

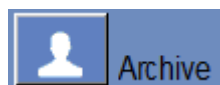
Image	Name	Description
	Scan Prepared Series	<p>Press this button to run the planning images scan, after preparing it on the MR.</p> <ul style="list-style-type: none"> GE: Press the Auto Pre-Scan button on the MR workstation. Wait until the MR completes the pre-scan. SIEMENS: Adjust the series Press the Scan Prepared Series button on the Exablate Neuro workstation; the planned scan will start to run on the MR. <p>When the scan ends, the new scanned MR series will appear in one of the Exablate Neuro workstation image strips.</p> <p>NOTE: This button enables running of scans in a more generic use for all different scan orientations.</p>
	Planning Scan Protocol	Select protocol to be acquired via the Axial\Coronal\Sagittal scan buttons
	Scan Axial	Press this button to run the Axial series from the Exablate Neuro workstation, based on the AC-PC, Midline and scanning range inputs.
	Scan Coronal	Press this button to run the Coronal series from the Exablate Neuro workstation, based on the AC-PC, Midline and scanning range inputs.
	Scan Sagittal	Press this button to run the Sagittal series from the Exablate Neuro workstation, based on the AC-PC, Midline and scanning range inputs.
	Reformat Volume	After turning reformat mode on (), press this button to create three reformatted series from the series in the Selected Image Window.
	Create Reformatted Series	After aligning the reformatted strips by adjusting AC, PC, and Midline position. Select desired orientations (<input checked="" type="checkbox"/> Axial <input checked="" type="checkbox"/> Sagittal <input checked="" type="checkbox"/> Coronal) and press this button to produce the final image strips.
	Open Image Retrieval Dialog	Open dialog which allows importing Pre-Operative and Intra-Operative (MR\CT) images from a variety of sources. See 4.6 - The Image Retrieval Dialog for instructions
	Load Treatment Plan	Load Pre-Planning session (if available) which includes Pre-Operative Images and markings

4.6. The Image Retrieval Dialog

Figure 4-4: Image Retrieval Dialog Menu

The Image retrieval dialog is used during a treatment's planning stage (and for the preparation of a Pre-treatment Planning Session). It allows the user to import CT and MR images into the treatment from the hospital system or directly from a CD or external storage device (e.g. a USB thumb drive).

To access the menu, press the 'Archive' button on the 'planning' stage screen:



Press 'Search' to populate the exam list with all exams from the selected source or narrow down the selection by filling in the various data-fields (Patient ID, Last Name, First Name, Exam Number or Age). Wildcards are accepted (e.g. 'Patient ID:12*' will return all exams whose ID begins with '12').

Highlight the desired exam by clicking on it with the mouse cursor and press 'Select Exam' to populate the Series Selection list in the box below. Only one exam may be selected at a time.

During a treatment the active exam parameters are automatically entered into the 'Search' Dialog, and once a series from it has been imported it is highlighted in the Exam selection list.

Proceed to select series (multi select with ctrl\shift is supported) and press 'Retrieve Selected Series'. The selected series are then auto-sorted by type (CT\MR) and orientation and then slotted into place.

**NOTE:**

N030

Only series belonging to the active exam on the MR will be recognized as 'Planning' images. Other MR image exams will be classified as 'Pre-Operative' (During a pre-planning session all images are considered Pre-Operative).

Edit the image range if needed (up to 250 CT or 150 MR images per series are supported):

Planning Exam:	8775	Patient ID:	MR_Pre				
Exam Date:	2018/03/15	Patient Name:	BR007-123-123123				
Series:	4	Orientation:	OSAG	Images:	75	<input type="text" value="1"/> - <input type="text" value="75"/>	<input type="button" value="x"/>
Series:	11	Orientation:	OAX	Images:	126	<input type="text" value="35"/> - <input type="text" value="120"/>	<input type="button" value="x"/>

Figure 4-5: Editing Image Range

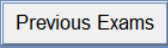
To replace a chosen series, select and retrieve another series of the same type and orientation.

**NOTE:**

N031

All 'Pre-Operative' images in use must belong to the same exam.

To remove a series simply press the little  icon next to the image range.

To re-access exams from an external source previously loaded during a session, Press  button.

**WARNING:**

W062

Ensure that you select a range of CT images covering from one slice above the head apex and down below the brain, to enable the system to use adequate parameters of aberration correction of the acoustic beam (automatically) throughout the treatment, based on the specific skull characteristics.

**NOTE:**

N032D

Due to system technical storage limitations, no more than 250 CT images can be loaded. The system will alert the user if more than 250 CT images were selected for loading. Confirm the entire acoustic interface is represented in the selected CT series

4.7. Treatment Stage Tools


4.7.1. General Action Tools

Image	Name	Description
	Delete Selected Object	Press this button to remove the selected object. Applies to all types of measurements and NPR markings.
	Delete All Objects	Press this button to remove all objects of the same type as the selected object. Applies to all types of measurements and NPR markings.
	Treatment Protocol	Press this button to access the treatment protocol dialog box.
	Add Fiducial Marker	Places a Fiducial Marker on the screen. Fiducials are displayed in the same RAS location for all images which have 'Treatment MR' coordinates, and are particularly useful for comparison anatomical feature locations on Pre-op and Intra-op imaging, and for monitoring patient movement during a treatment session (in conjunction with the Image Flickering Tool).
	Temperature Monitoring Volume	Use this feature to add a region in which the temperature rise will be monitored during the sonication: <ul style="list-style-type: none"> Press on this button. Draw a closed contour region on the MR image. Re-press the Temperature Monitoring Volume button.
	Transducer Elements Window	Select a sonication spot and press this button to view the Transducer Elements window.
	Advanced Option Mode	If Advanced Option Mode is enabled on the system, and if required, press to open the Advanced Option dialog box (See Chapter 9).






4.7.2. Targeting Tools

Image	Name	Description
	Unlock\Lock Target coordinates	Press this button to unlock and change target coordinates. Coordinates should be locked when not undergoing editing.




4.7.3. Movement Detection

Image	Name	Description
	Scan and detect patient movement	Press this button to start a new movement detection scan and determine if patient movement has occurred.

4.7.4. Sonication and Spot Control Tools

Image	Name	Description
	Add Sonication Spot	Use this button to add a sonication spot; the spot is added to the location selected on the MR image or to the selected ROT group.
	Re-Plan ROT	Press this button to create a new plan for the selected ROT . It will be set according to the ROT parameter settings and the selected spot parameters. NOTE: changes to treatment protocols or preparing a new ROT Plan will cause all previous changes manually introduced in the current plan to be lost.
	Set Spot as Current Spot	Press this button to set the selected spot as the Current Spot to be treated.
	Move to next Spot	Press this button to automatically select the next planned spot to be treated. NOTE: This option is available only when selecting the Brain DQA Protocol from the Treatment Protocol dialog box (see Chapter 5)
	Start Sonication	Press this button to perform a sonication. This command is enabled only after a sonication spot is defined in the Treatment Stage and both the MR and device lights in the status bar are green.

4.7.5. No Pass Region Marking Tools

Image	Name	Description
	Draw Polygon No Pass Regions (NPR)	Define NPR (No Pass Regions) as follows: <ol style="list-style-type: none">1. Press on the image to display it in the Selected Image window.2. Press on the Draw No Pass Regions button; draw NPR contours around the sensitive tissues.3. If required, continue to define the NPR on additional slices (interpolate if necessary).4. Move the NPR by pressing it and dragging. Delete the NPR by pressing it and then pressing the Delete button.
	Draw Spherical No Pass Regions (NPR)	Press this button to place spherical NPRs on the image . Choose desired sphere volume from the drop-down menu.
	Interpolate	This allows interpolation of graphic elements between non-adjacent slices: <ul style="list-style-type: none">• Press on the (polygonal) graphic element you want to interpolate.• Press the Interpolate button Elements are interpolated into a continuous surface or a 3D volume.

5. DAILY QUALITY ASSURANCE (DQA)

This chapter details Daily Quality Assurance (DQA) procedure.

The DQA procedure should be conducted at the start of each day, prior to each treatment, using the membrane intended for the treatment, to verify proper operation of the Exablate Neuro system.

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

Accessories required for the DQA procedure (refer to accessory table for P\Ns):

- DQA Phantom Gel– Semi -solid, water based, crossed-linked gel mimicking brain tissue.
- DQA Phantom Gel Set Up holder– holds the gel and seals the transducer during the DQA procedure (See 5.1).



WARNING:

W063

Violation of the DQA Phantom Gel handling policy defined in Handling Instructions of DQA Phantom Gel' (section 5.3) may lead to false/unreliable DQA results



WARNING:

W064

Visually inspect kit before use.

In case of signs of visual damage or if freeze indicator is activated (see picture below), contact your INSIGHTEC representative.



5.1. DQA Set Up Procedure



NOTE:

N033

- It is suggested to keep the *Exablate 4000 Type1.1 [or Type 1.0] Handbook for SW7.33* accessible near the system for a handy step by step checklist of the DQA procedure flow.
- Follow the instructions to ensure that the system is functioning properly and verify DQA results.

Prior to starting the DQA, confirm the following:

1. Reboot the MR system if it has not been rebooted that day.
2. Power on the system.
3. Visually check the integrity of the transducer:
 - For loose fittings or cracks.
 - For any loose or damaged connectors or water lines on the patient table.
4. Ensure that the patient table and HS are completely set up and ready (as detailed in **Chapter 3**).
5. Place the DQA phantom gel and holder onto the transducer and seal it.



CAUTION:

C044

Be careful not to drop the DQA phantom gel or set up on the transducer.

6. Move the transducer to the DQA position according to the labels.
7. Fill the transducer with water.
8. Apply Landmark according to the Landmark Labels that were placed on the cradle and table. Ensure that both labels are accurately aligned before performing the landmark (see Figure 5-1).

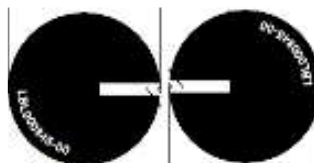


Figure 5-1: Aligned Landmark Labels

9. Ensure that the cables are free to travel with the patient table.
10. Send the Exablate cradle to the center of the MR bore and define your landmark\iso-center at the center of the transducers rim.
11. Open a new exam on the MR console and run the **Localizer** scan
12. Enter the Exablate workstation and select the **Brain DQA** protocol from the **Treatment Protocol** dialog box.

13. Scan the images in all three orientations from the predefined protocol saved on the MR and upload them to the Exablate workstation and verify coil performance.
14. Perform a short treatment flow, following the order of planned spots. Check that the system operates properly, that the spot is within 3 mm of the target location and that the dose threshold level has been achieved.
15. Verify that the system halts or modulates power for the specific sonication which intentionally creates cavitation.

**CAUTION:**

C022

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

**NOTE:**

N034

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

5.2. DQA Set Up Holder

Note: The DQA Set Up Holder description below is relevant for all types of membranes.

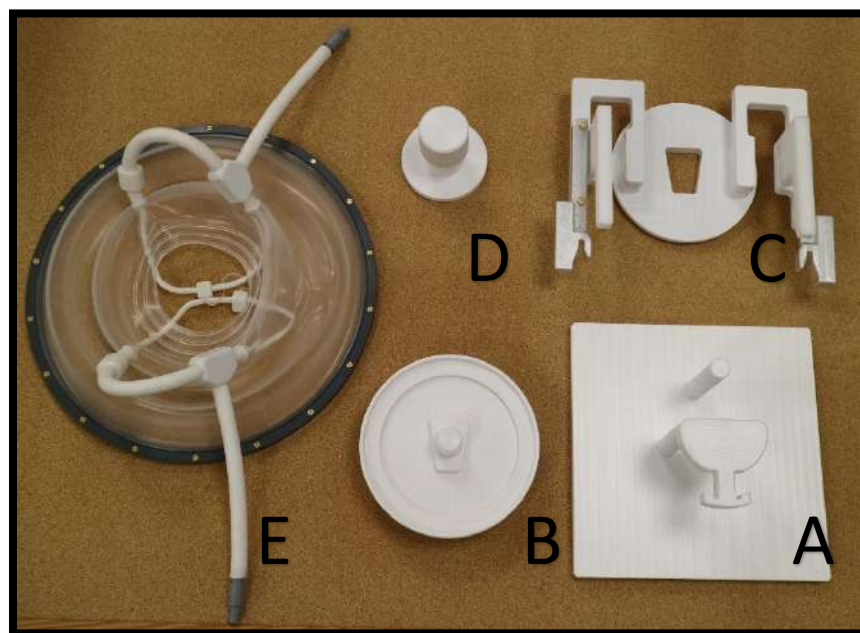


Figure 5-2: DQA Set Up Holder Components. Mounting Jig (A), Phantom Gel Holder (B), Base (C), Lock (D), Patient Membrane - for illustration only (E).

Components required for the DQA Set Up Holder (as shown in **Figure 5-2**):

- A- Mounting Jig: Plate support helping to build the Set Up, it is not part of the final product.
- B- Phantom Gel Holder: Holds the DQA phantom Gel and seal the membrane to the base.
- C- Set Up Base: Holds the Membrane and connects the Set Up to the Frame holder on the table/HS.
- D- Set Up Lock: Lock the Part B with Part C.
- E- Patient Membrane (with or without coil).

Step 1 (A, B): Bring the Holder on to the Mounting Jig. Interlock the two pieces together as shown in **Figure 5-3**.



Figure 5-3: DQA Holder and Mounting Jig Assembly

Step 2 (A, B, E): Pose the membrane on the assembly from Step 1.

If applicable, put the Head Coil Plug Connectors from either side of the 'Cable Side' engraving on the Phantom Gel Holder, as shown in **Figure 5-4**.



Figure 5-4: Membrane, Superior and Inferior Head Coils disposition.

Step 3 (A,B,C,E): Pose the DQA Set Up Base on the assembly from step 2. Interlock the Base with the Phantom Gel Holder (**Figure 5-5**).

Step 4 (A, B, C, D, E): Screw the Lock to the Holder screw to maintain the pieces together.



Figure 5-5: DQA Set Up Holder Assembly

To Prepare DQA phantom Gel for use:

1. Open bag and retrieve the DQA phantom Gel.
2. Insert the DQA phantom Gel to its dedicated slot in 'DQA phantom Gel holder'.

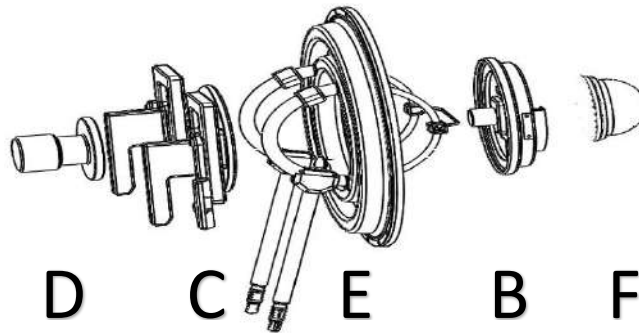


Figure 5-6: 3D break down of DQA Set Up Holder Assembly. Mounting Jig (A), Phantom Gel Holder (B), Base (C), Lock (D), Patient Membrane - for illustration only (E), Phantom Gel (F)

5.3. Handling Instructions of DQA Phantom Gel

The DQA phantom gel is a solid, water-based, cross-linked gel, delivered in a sealed aluminum bag.

To Prepare DQA phantom for use and set up the DQA Holder, see **section 5.1**.



CAUTION:

The DQA phantom gel is meant for single use. Following a DQA procedure, dispose of the DQA Phantom Gel according to local regulations .

C023

6. PRE-TREATMENT PLANNING SESSION

**WARNING:**

W110

Regardless of Planning session, always review treatment candidate's pre-operative MR and CT images prior to scheduling a treatment to assess patient suitability

6.1. Overview

A pre-treatment Planning Session can be performed prior to the treatment (on treatment day or at an earlier date):

1. creating a **Treatment Plan** by loading or scanning high-quality (head coil) images for treatment planning and reference during treatment. This **Treatment Plan** can be saved and then loaded for reference during the actual treatment.

This also allows the user to pre-emptively perform tasks to make the treatment timeline more efficient. Typically, these tasks include:

- Loading CT images.

**WARNING:**

W065

Review CT images for clips, scars, unclosed sutures or anything that may affect the treatment plan.

- Loading of high-quality MR contrast images.
 - NPR drawings.
 - Target delineation, assessment of patient and transducer positioning.
2. Calculating the skull score (SDR) for the patient, which may serve as a treatment inclusion\exclusion criteria.
 3. Analyzing and considering the techno-clinical parameters of the specific case.

To create **Treatment Plan** in advance, press the **PREPARATION** button on the main entrance screen. It can also be used to review and adjust previously prepared treatment plan files.

**NOTE:**

N035

The **Pre-Treatment Plan** session roughly consists of the same stages as in a treatment and does not contain any specific extra functionality beyond the benefits described above.

**NOTE:**

N036

During the **Preparation** session, there is no need for water filling in the interface or connecting the Exablate Device to the MR in any way. Therefore, the Device status is not relevant to a planning session, and the MR may be used as usual while a Planning session is in progress.

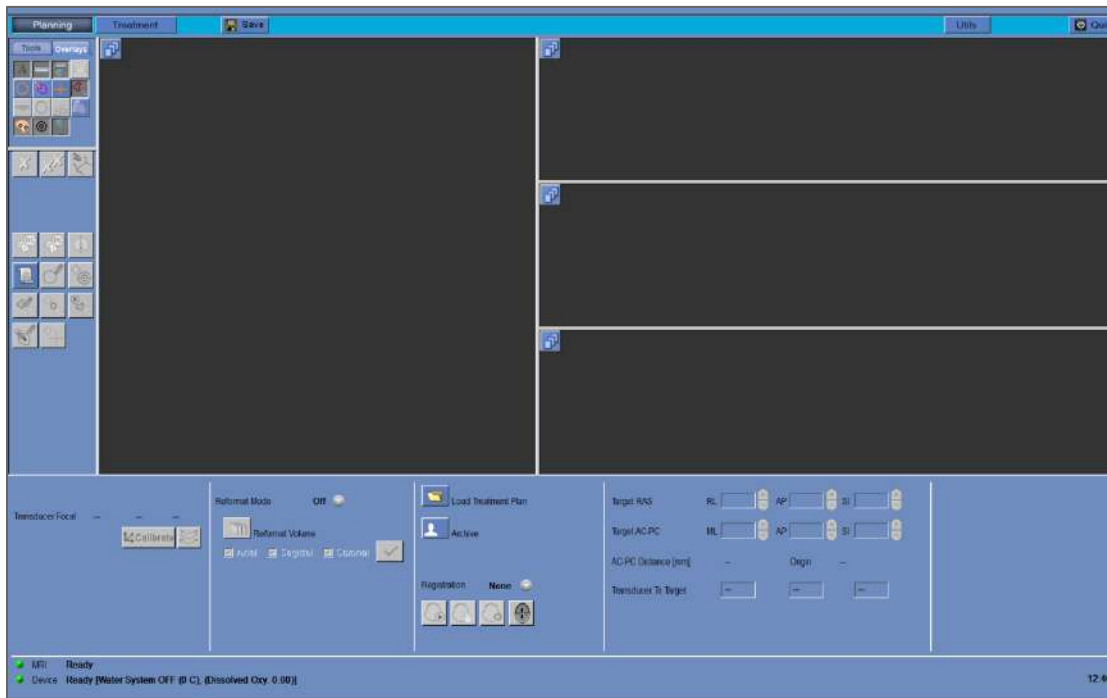


Figure 6-1: Preparation Screen

6.2. Pre-Operative Image Guidelines

6.2.1. Guidelines for Pre-Operative CT

Performing an Exablate treatment requires a CT scan of the patient's skull, which must conform to the following Insightec imaging guidelines:

- CT images should be reconstructed to be aligned with the AC-PC plane and orthogonal to the brain's mid-plane
- The range of axial images must cover the entire head from few slices above the calvarium down to the skull-base, inclusive
- CT should be acquired with inter-slice resolution of 1mm (ST=1mm, Spacing=0)
- If the CT machine generation you are using does not allow the images to be acquired at thickness of 1mm, use higher resolution (E.g. 0.625mm) and then reformat the images into 1mm cuts

- CT must be post-processed using one of the following **specific** types of 'Bone' kernels, validated for standardized SDR calculation:
 - For 'GE' CT scanner – 'BONEPLUS'
 - For 'Siemens' CT scanner – 'H60s', 'Hr60s', 'H60f', 'Hr60f', 'Hr56f'
 - For 'Philips' CT scanner – 'C'
 - For 'Toshiba' or 'Canon Medical Systems' CT scanner – 'FC30' (UE0 disabled)
- Use symmetric matrix size of 512 X 512
- CT scans should be acquired with no contrast agents injected

**CAUTION:**

C024

The accuracy of SDR calculations for CT scans obtained using non-standard kernels is not validated and it cannot be reliably used to estimate patient suitability for treatment.

In addition to the CT, it is recommended (but not mandatory) to upload Pre-Operative MR images of the patient to provide high-quality anatomic reference images. These may be loaded as part of a pre-treatment planning session or brought in via the image retrieval dialog. (for guidelines regarding Pre-operative image acquisition see **section 4.5.8**)

6.2.2. Pre-Operative MR imaging recommendations

Preoperative MR imaging is optional (as opposed to the Mandatory CT), but highly recommended, in order to prepare a detailed pre-treatment plan which includes high quality anatomical imaging. Pre-Operative scans should be scanned with a head coil, and can be T1 or T2 weighted, as per the user's preference. Images overlaid with additional information (e.g. tracts) can also be used provided they are formatted as regular DICOM images.

Images can be acquired as:

- Three orientational (Axial\Sagittal\Coronal) series, already aligned along the relevant anatomy planes. Zero spacing is required, and it is recommended that these images have a slice thickness of 2.0mm and a resolution of 512x512.
- As a single volumetric series to be reformatted on the treatment workstation.
The single volumetric series should span the entire skull (from calvarium to base) with a slice thickness of 1-1.3mm and zero spacing to allow satisfactory quality. It is reformatted to three series (Sag\Ax\Cor) on the treatment workstation, with special attention given to the axial series along the AC-PC line. The end result should be 3 orientational series – Sagittal, Axial and Coronal series aligned with the relevant anatomical plane (e.g. AC-PC) on which the target area and relevant anatomy are clearly visible.

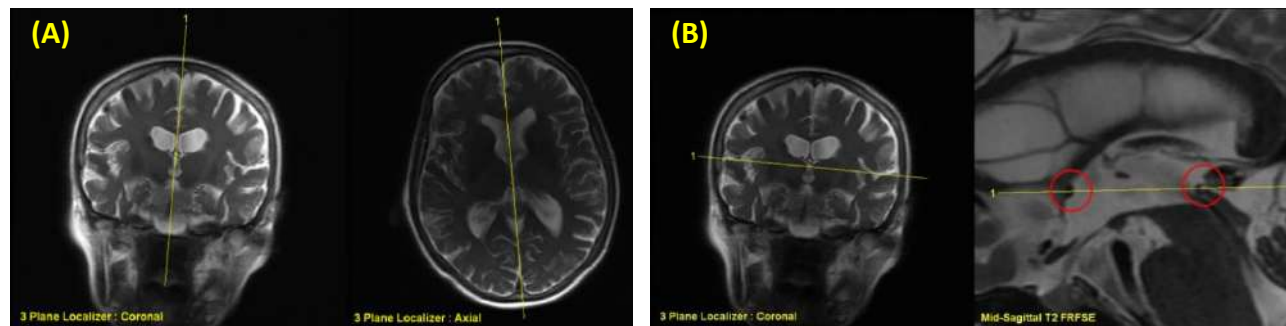


Figure 6-2: Planning Image Prescription Guidelines


(A) Prescription guidelines for Sagittal scan: Through AC-PC and midline

(B) Prescription guidelines for Axial scan: Through AC-PC and balanced on Coronal

PREPARATION

6.3. Planning Session Procedure – With Pre-Operative MR Images

6.3.1. Planning Session Flow

1. Turn ON the system.
2. Ensure that the pre-operative data is located in the MR or on CD/USB.
3. Press this button on the **Start-Up** screen and enter **PREPARATION** stage
4. Press the **Image retrieval** button  and retrieve Patient's Pre-Op CT and MR [optional] images. Select three MR Planning Image orientations (Sag\Ax\Cor), or in case the desired Pre-Op MR series is volumetric, select that series and then follow the reformat procedure flow (see **7.8.2**) to create three Planning Image orientations.



NOTE:

Due to system technical storage limitations, no more than 250 CT images can be loaded. The system will alert the user if more than 250 CT images were selected for loading. Confirm the entire acoustic interface is represented in the selected CT series



N032D




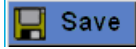


WARNING:

Make sure you select the range of CT images to cover one slice above the head apex and down, to enable the system to use adequate parameters of aberration correction of the acoustic beam (automatically), throughout the treatment, based on the specific skull characteristics.

W066D

5. Perform an CT-MR registration using the Automatic  and Manual  registration controls
6. If the MR planning series is volumetric - follow the Reformat procedure as described in Section **7.8.2** to produce three image MR orientations
7. [optional] Ensure AC-PC and midline markers are in place.



8. Position the transducer on the relevant target by pressing this button: 
9. Adjust the Transducer templates position and tilt in all orientations.
press the **Calibrate** button to set the transducer's **Home** position. 
10. Press the **Automatic Sinus and Calcification Detection** button to mark the sinuses and calcifications.
11. Review the CT and MR Images and add relevant NPRs if necessary, described in **Section 7.14.2**. 
12. [optional] Place fiducial in points of interest.
13. Switch to **Treatment Stage**. Calculate the spot's technical parameters through the **Transducer Elements Map** including the **Skull Score (SDR)**, as described in **Section 8.1.9.3**.
14. Press the **Save** button to save the **Pre-Treatment Plan** session. 
15. **Quit**

6.3.2. Pre-Treatment Session Data

The following data, which was drawn during the **Preparation** session, will be saved and loaded to the **Treatment Stage**:



- No-Pass Regions (**NPRs**) – Manual, Auto-CT, Auto-Sinus
- Fiducials
- Temperature monitoring volumes
- AC, PC points – will be marked as Azure 'Pre-markers' in **Treatment Stage**.
- CT-MR registration
- Measurements – lines, angles, areas.

6.4. Loading a Pre-Treatment Session

To upload a previously saved **Pre-Treatment Plan** session (e.g. during a treatment), click the  button on the  screen, and select the relevant session.

6.5. SDR Calculation without Pre-Operative MR Images

In case no Pre-Operative images are available, or only SDR calculation is needed, it is possible to estimate a patient's SDR without using Pre-Operative MR images

1. Turn ON the system.
2. Ensure that the Pre-Operative data is located in the MR or on CD/USB.
3. Press this button on the **Start-Up** screen and enter **PREPARATION** stage 
4. Press the **Image retrieval** button  and retrieve Patient's Pre-Operative CT Scan



NOTE:

N032D

Due to system technical storage limitations, no more than 250 CT images can be loaded. The system will alert the user if more than 250 CT images were selected for loading. Confirm the entire acoustic interface is represented in the selected CT series



WARNING:

W066D

Make sure you select the range of CT images to cover one slice above the head apex and down, to enable the system to use adequate parameters of aberration correction of the acoustic beam (automatically), throughout the treatment, based on the specific skull characteristics.




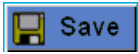
5. Follow the Reformat procedure as described in **Section 7.8.2** to produce three 'planning-MR' image series from the CT.



CAUTION:

C025

- Reformatted CT images should NOT be used as planning images during a treatment
- Draw only on the original CT series, since 'Fake' planning images need to be deleted before saving the session, therefore any drawing on these series will not be saved.

6. Place the AC-PC and midline markers, as described in **Section 7.7.3**, roughly in place.
7. Position the transducer on the relevant target by pressing this button: 
8. Adjust the Transducer templates position and tilt in all orientations. press the **Calibrate** button to set the transducer's **Home** position. 
9. (Optional) Press the **Automatic Sinus and Calcification Detection** button to mark the sinuses and calcifications. This will provide a more accurate SDR estimation. 
10. Switch to **Treatment Stage**. Calculate the spot's technical parameters through the **Transducer Elements Map** including the **Skull Score**, as described in **Section 8.1.9.3**.
11. If a marked CT is meant for use during a treatment, open the **Image Retrieval Dialog** and **delete** any 'Fake' MR Pre-Operative planning images Prior to saving the **Pre-Treatment Plan**
12. (Optional) Press the **Save** button to save the **Pre-Treatment Plan** session. 

13. **Quit**

7. TREATMENT: PLANNING STAGE

This chapter describes the planning stage of an Exablate treatment and describes in detail its different stages and tools. The chapters are roughly ordered in a chronological order of a typical treatment.

7.1. Overview

The **Planning Stage** is the first stage of an Exablate Neuro treatment procedure. This stage provides the system with necessary data related to imaging and treatment planning.



NOTE:

N037

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



NOTE:

N038

It is suggested to keep the appropriate *Exablate 4000 Type1.1 [or Type 1.0] Handbook for SW7.33* accessible near the system for a handy step by step checklist of a treatment's planning stage flow.

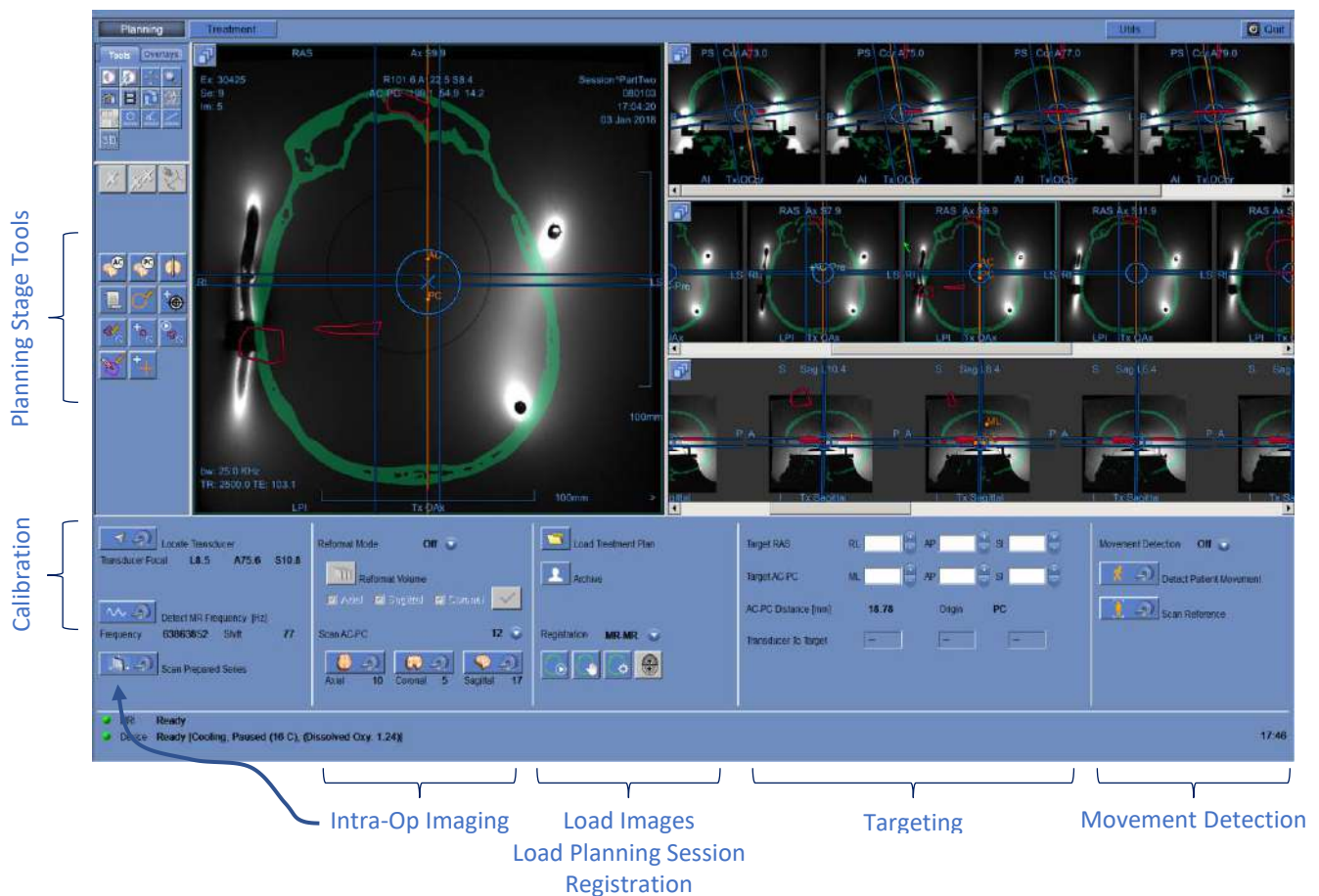


Figure 7-1: Planning Screen

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

1. **On the MR Console:** Register Patient (**SIEMENS**) or open a new Exam (**GE**).
2. Send the Exablate cradle to the center of the MR bore (**GE**: Landmark, **SIEMENS**: Iso-Center). The MR cradle location indicator should show '0mm' on screen while the second label which was placed upon the cradle should be aligned with the one upon the table.
3. Press 'TREATMENT' on the main screen to enter the treatment's PLANNING stage.
4. Define the required Treatment Protocol according to the specific target characteristics.
5. Upload the Pre-Treatment Plan (if one exists) into the Exablate Neuro system (optional - see **Chapter 12**). Otherwise load only Pre-Tx CT (mandatory)
6. **On the MR Console:** Perform a 3D Localizer scan
7. **(Optional) On SIEMENS 3T MRI systems only:** Perform a **B1 calibration procedure**, as detailed in the *Exablate 4000 Type1.1 Handbook for SW7.33 Running on SIEMENS MRIs* (also see **7.5.1**)
8. **(Optional) On 3T GE Systems with an MR version of DV26 or higher only:** Perform a **TG calibration procedure**, as detailed in the *Exablate 4000 Type1.1 [or Type 1.0] Handbook for SW7.33 Running on GE MRIs* (also see **7.5.2**)
9. **Automatically track** and determine the transducer's home position and orientation relative to the patient's anatomy.
10. Determine and fix the **Central Frequency**, that will be used in the MR images throughout the treatment (to minimize imaging and thermal shifts).
11. Plan and acquire **MR planning images** (or alternatively scan planning images on the MR and retrieve the relevant series to the Exablate workstation).
If volumetric – Reformat the planning images.
12. If unmarked - Run the **Automatic Sinus and Calcification Detection** algorithm based on the CT image values.
13. Review image to define/add sensitive areas that will limit or eliminate the acoustic energy from passing through it, by drawing **No Pass Region Contours** upon the CT or MR images
14. Automatically and/or manually **Register** between the different sets of images that were retrieved to the Exablate workstation. This process matches between the coordinates of different sets of images using a controlled registration:
 - CT to MR live (from the day of treatment) images
 - MR Pre-Operative to MR Live images
15. Determine the desirable **Target location** and adjust the location of the transducer accordingly to match between its natural focus and the target.

16. Examine the **Movement Detection Reference** images that were taken automatically during the Planning stage.

The rest of the tasks and features are considered as **optional**:

17. **Optional**: Add **Fiducial Markers** to utilize them if a patient movement occurred.



18. **Optional**: Define a Temperature Monitoring Volume that enables the operator to monitor the rise of temperature within a pre-defined region, during the actions of a sonication.

19. **Optional**: Define the **Region of Treatment (ROT)** for larger treatment portions.

7.2. Selecting a Treatment Protocol

Selecting a **Treatment Protocol** is necessary to enable the system to adjust parameters according to the treatment-specific target characteristics, or while performing Daily Quality Assurance (**DQA**).

To select or update the **Treatment Protocol**, use the following element:

Image	Name	Description
	Treatment Protocol	Press this button to access the treatment protocol dialog box. 

1. Press this button to open the **Treatment Protocol Dialog** box:

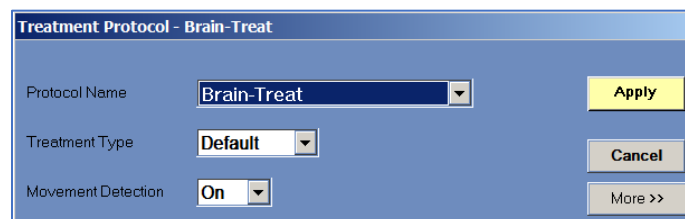


Figure 7-2: Treatment Protocol Dialog Box

- From the **Protocol Name** drop-down list, select the **Treatment** or **DQA** protocol, per the specific procedure you would like to perform; the default parameters for the selected protocol appear in the sonication parameters frame.
- To change the status (ON/OFF) of the **Automatic Movement Detection** feature, select the specific option from the drop-down list.

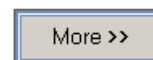


WARNING:

Movement detection is ON by default and turning it off in a clinical setting is strongly discouraged.

W067

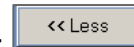
4. Press this button to change the sonication spot parameters (Advanced Mode):



- Use the typing **Remarks** area to keep your notes per Treatment Protocol.

- **Max Energy** (in Joules): this is the energy for planning the treatment.
- **Cooling Duration** (in seconds): this is the default required cooling period for a sonication energy pulse of the default value displayed. Actual cooling for each spot will be scaled automatically according to the actual energy applied.
- **Sonication Duration** (in seconds): this is the length of time the ultrasound energy is applied to the target tissue in each nominal sonication.
- **Sonication Grid Density**: this determines the degree of planned spot overlap of adjacent sonications. There are three available settings: **Low**, **Medium** and **High**. The spot overlap is an important consideration, particularly in determining the overall length of a treatment session and completeness of ablation.
- **Spot Size**: this determines the dimensions of the spot along the propagation direction:
 - ❖ **Nominal**: the energy is delivered continuously.
- **Apodization**: this determines the effective transmitting area of the transducer.
- **Body Temperature**: the default is normal body baseline temperature. Change this value to the temperature of the organ treated.
- **Spot Geometry Parameters**: enables you to manually control the size of the predicted spot (**Height** and **Diameter**)

5. Press this button to close this advanced mode of the **Treatment Protocol**:



NOTE:

N039

The selected sonication parameters are used for all treatment spots in the selected **ROT**.

6. Close the **Treatment Protocol** dialog box:

- If no changes were made to the protocol, press **Apply**.
- If changes were made to the protocol, press **Save As** to access the **Save Protocol** dialog box.

7. Type in the name of the new **Treatment Protocol**.

8. Press **Delete** to delete current user-defined protocol.

9. Press **Cancel** to discard the new information and transition to the **Main** screen.



NOTE:

N040

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

7.3. Loading Pre-Operative Data

Performing an Exablate treatment requires a CT scan of the patient's skull (see guidelines in **6.2.1**). In addition to the CT, it is recommended (but not mandatory) to upload Pre-Operative MR images of the patient to provide high-quality anatomic reference images (see recommendations in **6.2.2**). These may be loaded as part of a pre-treatment planning session or brought in via the image retrieval dialog. (for guidelines regarding Pre-operative image acquisition see **section 4.5.8**).

7.3.1. Load Pre-planning session

A pre-treatment plan can improve treatment time management by allowing the user to perform various tasks ahead of the treatment, as well as provide high-quality reference pre-operative imaging.

Elements carried over from a pre-planning session into treatment include: NPRs (sinuses, calcifications), CT-MR registration, line and area measurements, AC&PC markings (marked in teal, to distinguish from intra-op AC&PC).



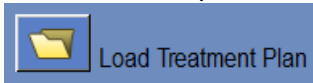
NOTE:

The target marking will NOT carry over from a pre-plan to the treatment.

N041

For instruction on how to prepare a **Treatment Plan** prior to treatment, refer to **Chapter 10**.

1. To Load a ready-made Planning Session Press the 'Load Treatment Plan' button:



2. Select the **Treatment Plan** you wish to upload from the opened dialog box. Ensure that the date, time and name of the selected **Treatment Plan** is the correct one.



NOTE:

If a **Treatment Plan** was loaded, its planning images and CT images appear in the **Pre-Operative Exam** section and the **CT Exam** section, of the **Image Retrieval Menu**.

N042




NOTE:

The loaded images will not be aligned to Intra-Operative images until MR-MR registration has been performed

N043

7.3.2. Load Pre-operative images during a treatment

To load Pre-operative images during a treatment, open the Image Retrieval Dialog  and retrieve the wanted images from the hospital network or external storage.



NOTE:

All MR images belonging exams\patients which are not the active exam will be recognized as Pre-operative.


N044

7.4. 3D Localizer Scan

Prescribe and acquire a **3D Localizer** scan on the MR workstation. This serves as the base for planning image alignment and is also used for B1\TG calibration where applicable. Any scan may be used, but the recommendation for SIEMENS MR systems is to use the pre-installed shimming+T1_loc sequence.

7.5. Transducer Location Tracking and TG\B1 Calibration

The following elements are used for the **Transducer Location Tracking** and **Calibration** procedures:

Image	Name	Description
	Automatic Transducer Tracking (Tracker Scan)	Press this button to perform a scan on the MR that will automatically track the transducer's current location and update its focal coordinates on-screen.



NOTE:

N045

- Pressing the Transducer Tracking button updates the transducer location, eliminating the ability to return to the previous calibration, or to display the previous Transducer Focal coordinates.
- In case of non-clinical research configurations, the transducer calibration can be set to **Manual Mode** in **Utilities** stage to allow a wider coverage of the imaging, and to avoid tracking coils-based calibration (see 7.5.5)

7.5.1. B1 Calibration (Type 1.1 – SIEMENS MR Systems)

After pressing the tracker scan button for the 1st time in a treatment, the user is prompted to perform a B1 calibration procedure. This requires performing a tfl_Bmap scan protocol (included in the pre-installed Insightec protocols) on the MR console (following the Localizer scan).

A region of interest (ROI) is marked on the resulting flip angle (FA) map (around the intended target area, eschewing artifacts). The Amplitude measured value is multiplied by 800 and divided by the FA mean value measured.

$$\text{Amplitude (New)} = \frac{(\text{Amplitude (sys)}) * 800}{\text{Mean Measured Flip Angle}}$$

This manipulation is done in order to calibrate the Transmit Amplitude leading to a flip angle of 80 at the target.

The calibration is finalized by setting the 'Amplitude (temp)' value in the Adjustments menu's 'Transmitter' tab to the new Amplitude calculated. The next step must then be opened on the MR console to set the change.

**NOTE:**

N046

This flow is presented as a step by step checklist in the *Exablate 4000 Type1.1 [or Type 1.0] Handbook for SW7.33 Running on SIEMENS MRIs*

7.5.2. Local TG Calibration (Only for 3T GE MR Systems with DV26 or higher installed)

For 3T GE MRIs which have the DV26 interface (or higher) installed, Exablate 4000 supports local TG calculation per scan. This further optimizes image quality.

When pressing the tracker scan button for the 1st time in a treatment, the user is asked if they wish to enable or skip local TG calibration:

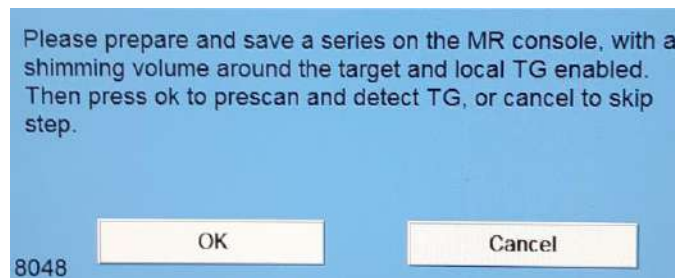


Figure 7-3: Local TG prompt

**NOTE:**

N047

- Local TG calibration must be set-up prior to pressing “OK”, otherwise the process will fail.
- Choosing "Cancel" means that a Local TG calibration will not be performed. Once a successful TG calibration has been performed, or the user has selected to skip it (by pressing "Cancel"), the user will not be able to repeat this calibration during a treatment/session.
- Local TG calibration adds ~10 seconds to every pre-scan sequence.

To prepare for Local TG calibration ensure a 3D localizer has been acquired. Then, duplicate and edit the series, placing a volume from the 'Shim' tab of the 'GRx' menu on the MR console. This volume should be centered around the intended target area and its limits should be within the patient's brain tissue. 'Local TG' Must be enabled on the 'Shim' tab as well:

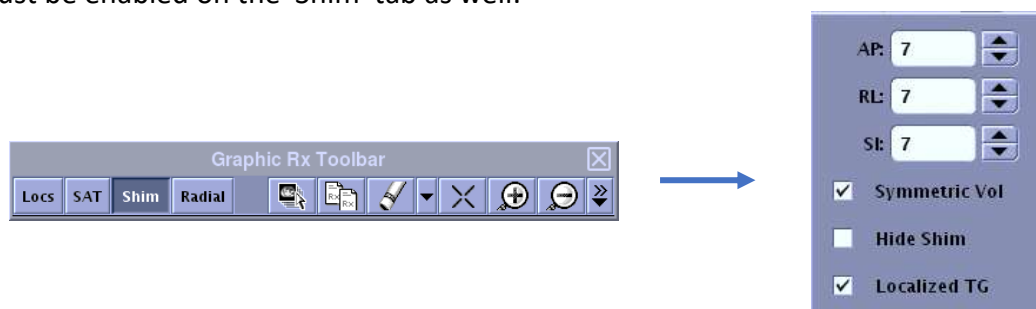


Figure 7-4: GE DV26 GRx and Shim menus

Save the series, and only then dismiss the message on the Exablate workstation by selecting 'OK'.

**NOTE:**

N048

This flow is presented as a step by step checklist in the *Exablate 4000 Type1.1 [or Type 1.0] Handbook for SW7.33 Running SIEMENS MRIs* and the *Exablate 4000 Type1.1 [or Type 1.0] Handbook for SW7.33 Running on GE MRIs*

7.5.3. Max TG\TA protection

The following safety mechanism exists for all Exablate 4000 systems with SW 7.33, regardless of B1 or local TG calibration: If a calculated TG\TA value during a pre-scan exceeds a pre-defined safety limit the user is prompted with a message suggesting auto-setting the TG\TA to a lower value, or ignoring the warning.

**WARNING:**

W068

Excessive TG\TA values may lead to RF induced burns. It is strongly advised to accept the 'Auto-set' option when presented with a warning message specifying that the detected value is above the maximal value.

7.5.4. Transducer Location Scan (Tracker Scan)

1. Once TG\TA calibration has been performed (if applicable), the user is prompted to confirm the exam parameters, as they appear in the pop-up message on the operating console screen. The MR then performs tracking scans to automatically detect the transducer's location (For type 1.1 systems this scan also locates the cradle).

Once the tracking procedure has ended, the **Transducer Focal** coordinates are updated to the section under the **Scans** tab (see **Figure 7-5**).

Transducer Focal R19.6 A48.2 S2.7



Figure 7-5: Transducer Focal Coordinates

2. Pressing the button again repeats the tracker scan, without prompting TG\B1 calibrations




7.5.5. Manual Transducer Calibration (Research Optional)

If it becomes necessary to perform calibration without relying on tracking information, the calibration can be set to **Manual** mode in **Utilities** stage (see **Chapter 11**).

Image	Name	Description
	Calibrate	Press this button to set the transducer's home position and orientation.

	Disable/Enable Trackers	Press this button to enable/disable the use of trackers to locate transducer's location. Default option is ON .
	Transducer Template	Press this button and press again on the image to position the transducer template.

Follow these steps to perform **Manual Transducer Calibration**:

1. Disable Trackers from the 'Utils' menu.
2. Press this button and confirm the patient's name and position, as they appear in the pop-up message on the operating console screen. 
3. The MR then performs three scans (sagittal, coronal and axial), visualizing the transducer's home position. These images appear in the image strips. The Transducer Template is displayed as a yellow overlay.
4. Move the template until it is in the right location or press this button and press on the image to position the transducer template in the desired location. 
5. Press the **Calibrate** button. 



NOTE:

Perform calibration correctly, with special attention to **Roll** and **Pitch** corrections. Inaccuracies in the transducer tilt will result misallocation of the spot.

N049

7.6. Scan and Detect MRI Frequency

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

This feature enables you to scan and detect the MRI Central Frequency. This procedure will be performed automatically by the system.

Click the **Scan and Detect MRI Frequency** button to scan and detect the value of the central frequency to be used for the scans throughout the treatment. The results will appear on screen (see **Figure 7-6**).



Frequency **63861124 Hz** Shift **44**

Figure 7-6: Detected MRI Frequency Frame



WARNING:

Monitoring anatomy images during sonications and switching sonication frequency directions enable monitoring and management of frequency related shift

W112

7.7. Intra-Op Image Acquisition: Anatomically Aligned MR Planning Images (Based on AC-PC)

This feature enables you to plan and acquire the MR Planning images from the Exablate Neuro workstation, while enabling the operator to:

- Ensure that one of the Axial/Sagittal planning images will intersect with the Anterior and Posterior Commissures line.
- Ensure that all images that will be acquired are aligned with the AC-PC plane.
- The series of Axial images will be produced perpendicular to the Midline (in coronal view), so all planning images will be acquired perpendicular to each other.
- The treatment region of interest around the target will be covered by planning images of all three orientations.

7.7.1. Guidelines for initial series planning

The first series (recommended: sagittal) should be prescribed directly on the MR workstation, based on a '3 plane localizer' scan, and aligned to the relevant anatomical orientation (e.g. the AC-PC plane). To that end – starting by acquiring the sagittal view (based on axial and coronal '3 plane localizer' images) and then using that sagittal series to better align the axial one is recommended.

In any case, care must be taken to prescribe a precise mid-orientation slice, allowing for detailed visualization of the relevant anatomy (e.g. AC and PC). For a sagittal slice, the mid-sagittal slice must pass in the middle of the third ventricle with the proper angle (**Figure 7-7, Right**). The tilt of this plane has to be checked on the coronal 3 plane localizer image (**Figure 7-7, Left**), adjusting also here the angle to be strictly mid-sagittal.

While it is recommended to base the scan on the MR on the pre-built protocols, the user may employ other protocols and parameters (while keeping a slice thickness of 2.0mm or less, zero spacing, and 512x512 matrix).



NOTE:
Not all scan types are supported.

N050D

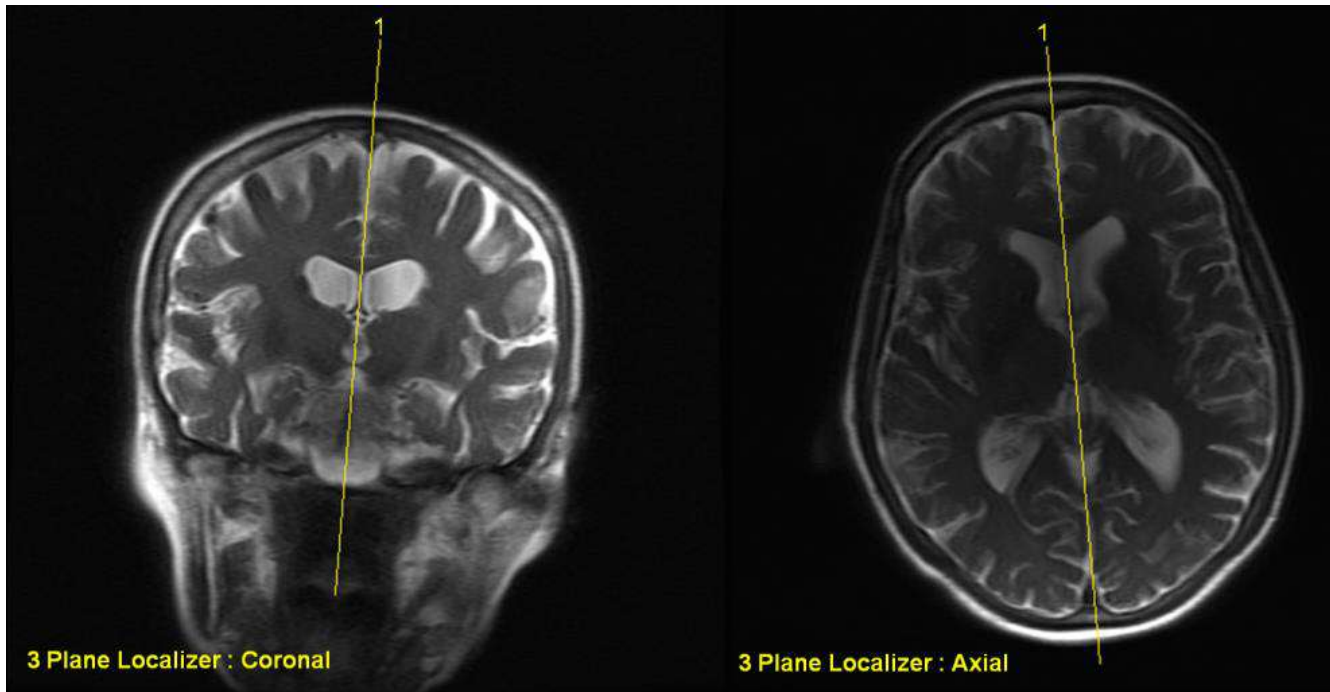



Figure 7-7: Prescription guidelines for Sagittal scan: Through AC-PC and midline

7.7.2. Image Acquisition Flow

1. On the MR console: Prepare a MR imaging series for Sagittal/Axial scan on the MR:
 - Select sequences that clearly show the region of treatment and include the entire skull anatomy.
 - Ensure that the range of images covers the desired region of treatment
 - Ensure at least one image intersects both the AC and PC anatomical structures.
 - If needed, adjust scan parameters such as slice thickness and FOV, to optimize the imaging quality.
2. Run an **Auto Pre-Scan** (GE) or **Adjust** (SIEMENS) the wanted series from the MR workstation and wait until the MR is ready to scan, as indicated by the **Scan Prepared Series** button becoming active.
3. Press **Scan Prepared Series** button  to acquire the prepared series using the optimal **Central Frequency** value that was previously found.
4. When the MR has completed scanning this series, the set of images will be retrieved automatically and displayed on one of the **Image Strips** of the Exablate Neuro workstation.
5. Review the images to confirm that:
 - The patient is correctly positioned so that the target is in a treatable position.
 - Carefully check each image to verify that the patient has not moved during imaging.
 - Verify that both Anterior and Posterior Commissures clearly appear on the images.

**NOTE:**

N051

Sequentially to the first series scanned by the 'scan prepared series' option, an additional scan will start running on the MR.

- This scan is the **Movement Detection Reference Scan** (see **Section 4.5.4**).




**CAUTION:**

C026D

Re-acquire images if at any point the quality or alignment of the planning images are not satisfactory.

7.7.3. Place the AC-PC and Midline Markers

Look for the image where you can clearly see the anatomical structures of the AC and PC.

1. Use this tool to mark the Anterior Commissure (**AC**). 
2. Use this tool to mark the Posterior Commissure (**PC**). 
3. Press Midline button 
 - If no coronal series is loaded to the system, the system uses the scanned planning images to reconstruct a temporary coronal series on the Exablate Neuro workstation producing a new, reformatted coronal series that will appear on the main image window (see **Figure 7-8**).
 - If there are already coronal images in the system, it will present them in the main image window to place the midline.
4. Place the **Midline point** on one of the Coronal MR images, where you can clearly see the brain's midline. This is done to fully define the AC-PC plane aligned coordinate system for Planning image acquisition, thus the midline **does not have to run through anatomical midline, but parallel to it**. The Midline plane will automatically intersect with both the AC and PC markers and will be drawn as an average line between the midpoints.
5. To rotate or change the midline plane, move the **Midline point** to better represent the midline or place a new Midline.
6. Navigate through the coronal reconstructed images to ensure that the **Midline Graphic Object** is aligned with the anatomical brain midline structure on the MR images.

**NOTE:**

N052

To return to the display of the reconstructed coronal series, either press on the **Midline Marker** button or select the series from the **Image Strip Selection** drop-down menu.

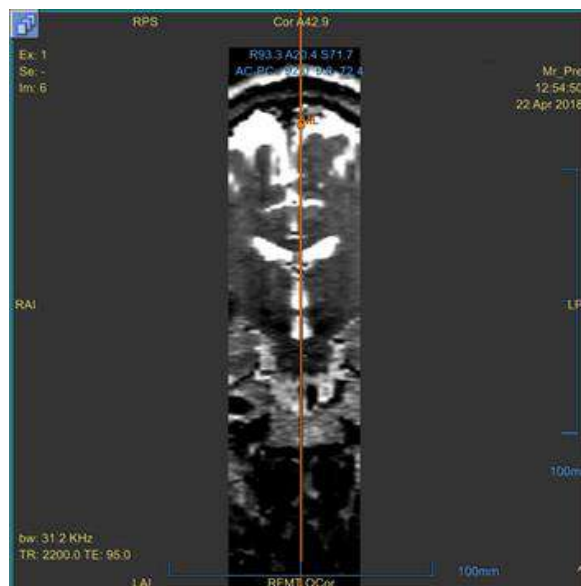


Figure 7-8: Reconstructed Coronal Image

The reconstructed image showing the Midline graphic object – Orange vertical line and the midpoint.



NOTE:

You can see the distance between the AC and PC markers (placed on the images) in the **Target Determination** area.

N053

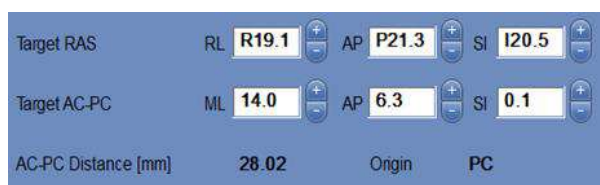


Figure 7-9: AC-PC distance display

7.7.4. Define Planning Scans Protocol

Planning images that are scanned from the Exablate Neuro workstation through the **Scan by AC-PC** mechanism may be scanned with different protocol sequences, depending on site installation. Set sequence from the drop down menu located above the 'Scan Sagittal Series' button.

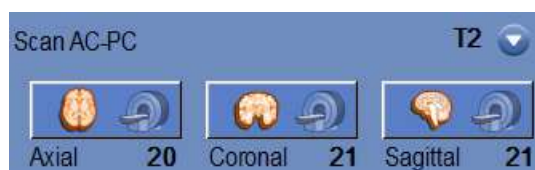


Figure 7-10: AC-PC Aligned Image Acquisition Controls

7.7.5. Define the Scanning Range

The blue lines that appear on screen represent the **Scanning Range** (From-To) of images which are about to be acquired by the Exablate Neuro workstation. The number of images for each orientation can be seen below their respective acquisition icons.

Display of the scan-lines is controlled by the following Overlay button:



1. To customize the **Scanning Range**, the operator can drag the graphic line object to the sides to enlarge or reduce the coverage area.



NOTE:

N054

It is recommended to select the minimal number of slices required to fulfill the clinical needs, to minimize the expected scanning duration.

2. When the **Scanning Range** has been defined, press on the Respective **Scan by AC-PC** button for each orientation to run the scan on the MR:



NOTE:

N055

Re-scanning the orientation already acquired via the **Scan Prepared Series** button is recommended only if the angle of the relevant orientation has been altered.

3. When all series have been retrieved and uploaded to the Exablate Neuro workstation, review the images to confirm that:
 - The target to be treated is clearly identifiable.
 - The patient is correctly positioned so that the target is in a treatable position.
 - Carefully check each image to verify that the patient has not moved during imaging.
 - Verify that the actual **Scanning Range** meets the expected one.



NOTE:

N056

- The range of planning images must cover both the AC and PC markers.
- Inspect the Sagittal images to ensure the Axial scanning range covers folds in the membrane (indicated by dark pockets [on FIESTA\T2] outside of the skull)
- The **Slices No.** will appear with a minus sign ('-') when the superior line is dragged below the inferior line or when the anterior one is dragged more posteriorly than the posterior line. In such a case, it is not possible to perform the scans using this feature.

7.8. Intra-Op Image Acquisition: Volumetric (Reformat) Series

This provides an alternative method for intra-operative image acquisition. It allows for precise finetuning of the AC-PC plane to produce the three intra-operative planning image series by reformatting another series scanned on the MR.

- Produces a planning image series that will be aligned with the AC-PC plane.
- Ensures one of the Axial planning images will intersect with the Anterior and Posterior Commissures line.
- The series of Axial images will be perpendicular to the Midline (in coronal view), so all planning images will be perpendicular to each other.
- The treatment region of interest around the target will be covered by planning images of all three orientations.



Figure 7-11: The Reformat Controls

7.8.1. Acquire the Volumetric Series

1. Acquire a **3D Localizer** scan on the MR workstation.
2. Prepare a volumetric protocol scan on the MR (e.g. 3D Bravo).
3. Ensure that the range of images covers the entire skull anatomy. If required adjust the scan parameters, such as slice thickness and **FOV**, to optimize the imaging quality.
4. Run an **Auto Pre-Scan** (GE) or **adjust the series** (SIEMENS) series from the MR workstation and wait until the MR is ready to scan.
5. Press this button to perform the scan with the optimal **Central Frequency** value that has been previously found (see Section 7.6).
6. When the MR has completed scanning this series, the set of images will be retrieved automatically and displayed on one of the **Image Strips** of the Exablate Neuro workstation.
7. Review the images to confirm:
 - That the patient is correctly positioned so that the target is in a treatable position.

- Carefully check each image to verify that the patient has not moved during imaging.
- Verify that both Anterior and Posterior Commissures clearly appear on the images

**NOTE:**

N057

Following the Volumetric Series acquisition via the **Scan Prepared Series** button, an additional scan will start running on the MR. This scan is the **Movement Detection Reference Scan** (see **Section 4.5.4**).

7.8.2. Operate Reformat Mode

1. Set the **Reformat** mode to **ON** by selecting it from the mode menu.
2. Press this button to define **the series on the main image** as a volume series.
3. The system creates three perpendicular series with 2 mm spacing between the images in default reformatting; 19 images are shown in each series.
4. Placing the AC-PC and midline markers as described in **Section 7.7.3** will change the reformatted series on the screen to produce anatomically aligned images. Each movement of one of the markers will simultaneously change the image.
5. Select the series required for planning by checking or un-checking the series.



6. Press this button to accept the checked reformatted series as planning images.

**NOTE:**

N058

Changing the Reformat mode to OFF without pressing the **Accept** button will close the mode and disregard the reformatted series.

- If the AC-PC and midline markers are placed on the original volume series before entering Reformat mode, the initial three series created when the mode is turned ON are AC-PC aligned images.

**CAUTION:**

C026D

Re-acquire images if at any point the quality or alignment of the planning images are not satisfactory.

7.9. Intra-Op Image Acquisition: Manual Acquisition (Based on MR User Interface)

The following options are alternatives to acquiring the planning images from the Exablate workstation based on the AC-PC and Midline markers:

7.9.1. Option A: Acquire all images from MR workstation via 'Scan Prepared'

Plan all planning image sequences using the MR workstation and acquire them from the Exablate workstation via the **Scan Prepared Series** button. This will ensure the use of the same MRI Central Frequency as for all other the scans throughout the treatment, while retaining active Cradle Tracking data, and allowing the use of planning image protocols not integrated into the WS.

1. Prepare a planning series on the MR. While it is recommended to base the scan on the MR on the pre-built protocols, the user may employ other protocols and parameters (while keeping a slice thickness of 2.0mm or less, and zero spacing, and 512x512 matrix).



NOTE:


Not all scan types are supported.

N050D

When prescribing the series:

- Select sequences that clearly show the region of treatment and include the entire skull anatomy.
- Ensure that the range of images covers the desired region of treatment
- Ensure at least one image intersects both the AC and PC anatomical structures.
- If needed, adjust scan parameters such as slice thickness and FOV, to optimize image quality.

For an example of image alignment see **section 6.3.1**.

2. When the scan is ready to be scanned, press the **Auto Pre-Scan** (GE) button on the MR workstation or Adjust the series (SIEMENS).
3. Then press the **Scan Prepared Series** Button:

4. Pre-determined MR Central Frequency values will be used automatically.
5. As each of the scan series completes, it will automatically be retrieved to the Exablate Neuro workstation and displayed on one of the **Image Strips**.
6. After acquiring each scan, confirm that:
 - The target to be treated is clearly identifiable.
 - The patient is correctly positioned so that the lesion is in a treatable position.
 - Closely examine each image and verify that there are no air gaps visible along the entire acoustic path from the transducer to the lesion.
 - Carefully check each image to verify that the patient has not moved during imaging.

7.9.2. Option B: Load intra-op images from the Image Retrieval Menu

Loading the planning images using via the Image Retrieval dialog may be useful in case a series is mistakenly deleted or in a non-human research setting.




WARNING:

W069

For Type 1.1 Systems: This Option is **not recommended** in a clinical setting, as Cradle Tracking will NOT be performed.

1. Press the **Archive** button to access the Image Retrieval Dialog:



2. Locate the active exam (you may search by name\date\exam number or simply press search to retrieve all available exams)
3. The newly acquired scan series will appear on the **Exam Selection List**.
4. Click on each one of the selected series you would like to upload as Planning Images (ctrl and Shift button functionality is supported). And press **Retrieve Selected Series**
5. Selected series will be slotted into the relevant slot (sorted by orientation and modality. MR Series from non-active exams may only be loaded as pre-operative images).
6. To select only part of the series, edit the Image range next to its name.
7. To change the selection, click  and select different set of images. These images will replace the previously selected ones.
8. Press **OK** to upload the images. (See 4.6 for more instructions on using the Image Retrieval Dialog)
9. After loading the images, confirm that:
 - The target to be treated is clearly identifiable.
 - The patient is correctly positioned so that the lesion is in a treatable position.
 - Closely examine each image and verify that there are no air gaps visible along the entire acoustic path from the transducer to the lesion.
 - Carefully check each image to verify that the patient has not moved during imaging.



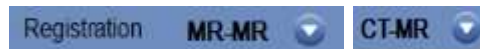
NOTE:

N059

For Type 1.1 Systems: You may overwrite previously loaded series, but Cradle Tracking is not supported for series loaded via the Archive menu.

7.10. Registration Procedure

7.10.1. Registration Types



To enable the system to profile boney tissue, register the MR coordinates system with that of a loaded CT image. The **CT-MR** registration aligns between:

- Pre-operative CT to Pre-operative MR (In planning stage or in a pre-planning session)
- Pre-operative CT to intra-operative MR.

The **MR-MR** registration aligns between the Pre-operative and Intra-operative images, but it requires a **CT-MR** registration as a basis.

In a nominal flow, the Registration Type is automatically set.

Before the registration process, verify that the CT images segmentation is valid.

7.10.2. Performing a Registration

1. Press this button to initiate an automatic registration process; the registration is performed automatically. An estimate of the time left to complete the registration progress is presented in the **Information Area** of the main toolbar.



Registration remaining time: 0:00:44

Figure 7-12: Registration Status



NOTE:

If the registration results are satisfactory even before the registration process is completed, it is possible to stop the process using this button.

N060



2. If required, use this tool to manually match the registration mask with the boney tissue on the MR images. Adjust iteratively on all three MR orientations until the CT segmentation mask fully corresponds to the anatomy on the MR images. Select the green square to move the CT frame, and the lever to rotate it
3. If needed, press this button to **Save** or **Load** the registration. It is possible to modify the registration parameters in the **Registration Options Dialog** box (see **Section 7.10.3**).
4. For CT image segmentation, the **Air** and **Bone Thresholds** appear on the bottom left corner of the main image when the CT image is selected. The thresholds can be changed using this button.



7.10.3. Edit Registration Options

If required, edit the registration options as follows:

1. Press this button to open the **Registration Options Dialog** box (see **Figure 7-13**).

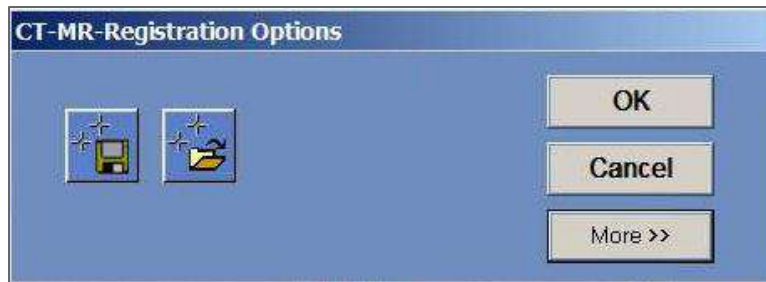


Figure 7-13: Registration Options Dialog

2. **Save:** Press this to save the last image registration that was performed
3. **Load:** Press button and select the required registration file from the displayed browser file.
4. Press the **More>>** button to change the registration parameters:
 - **Initial Solution** – defines the initialization of the registration.
 - **MR Strip Orientation** – defines the orientation of the created volume during the registration process. Select the required orientation from the drop-down list.
 - **Run Time** – defines the registration process time. For setting the run time, change the timing bar.
 - **Search Range** – defines the search space for the registration. For setting the search range, change the range bar.
5. Close the **Registration Options** dialog box:
 - If no changes were made to the registration, press **Cancel**.
 - If changes were made to the registration parameters, press **OK**.



WARNING:

W070

Inaccuracy in the registration may generate sub-optimal computation of focusing correction and skull heating temperatures. Verify that the registration results accurately match between CT and MR images.

7.11. Target Determination

To determine the target, the user may perform measurements on the anatomical images of the patient, or type in coordinates relative to the RAS coordinate system or the location of the PC marker.

The **Measure Angle** and **Measure Distance** tools can assist in this. The **AC-PC Angle** is particularly useful for VIM targeting as it will align a 90° angle along the AC-PC line, 25% anteriorly and 14.0mm to the right, targeting the patients left hemisphere.

7.11.1. Placing the Target Manually

Press the **Place Target** button and then place the marker (🎯) by pressing the left mouse button on top of the requested anatomical location in the main image window.



N061

**NOTE:**

The target may only be placed on intra-op MR planning images.

7.11.2. Typing Target Coordinates

The **Target Section** of the Treatment Stage screen enables the user to type in the target location in two different coordinate systems:

- **Target RAS:** these are coordinates relative to the coordinate system of the MR.
(**R-L:** Right-Left, **A-P:** Anterior-Posterior, **S-I:** Superior-Inferior)
- **Target AC-PC:** these are coordinates relative to coordinate system defined by the placement of the AC, PC, and midline markers. Its origin (0,0,0) is at the PC.
(**M-L:** Medio(+)-Lateral(-), **A-P:** Anterior(+)-Posterior(-), **S-I:** Superior(+)-Inferior(-))

Every points RAS and AC-PC coordinates can be seen when hovering above it in the main image window. Once coordinates have been entered in one system, the other will be automatically updated, and a target will appear on screen (if AC-PC has not been placed, the AC-PC coordinate set is unavailable).

Target RAS	RL	R19.3	AP	A48.2	SI	S2.5
Target AC-PC	ML	15.2	AP	6.3	SI	-0.1
AC-PC Distance [mm]	24.97		Origin	PC		
Transducer To Target	L0.3		P0.0		I0.2	

Figure 7-14: Target Coordinates Section

7.11.3. Adjusting the Target

Regardless of the target placement method, the target may be updated either by dragging it with the mouse or by adjusting the coordinates (the other coordinate set will be automatically adjusted). Remember that since the RAS and AC-PC axes are orientated differently a 1mm adjustment in one may not translate to 1mm in the other.

Placing a new target will overwrite the previous target.

7.12. Aligning the Transducer Focal Location to Target

While the **Target Center** is the center of the exact anatomical location of the desired region to be treated, the geometrical center of the transducer (**Transducer Focus**) is the optimal location for energy delivery. Therefore, to ensure optimal energy delivery efficiency, the **Target Center** and **Transducer Focus** should be in the same location. This means that the Transducer location should be adjusted using the positioning slider mechanism.

The Target Section (see **Figure 7-14**) include the **Transducer to Target** translation vector. It specifies the direction and required distance [in mm] the transducer needs to be moved to, to have the **Transducer Focus** aligned with the desired **Target Center** location.

Adjust the transducer location as indicated by the vector (For specific instructions on Mechanical Transducer adjustment see **3.3.4.**), and run a Transducer Tracking Scan to ensure that the distance between the Transducer Focus and Target is satisfactory.



NOTE:

Make sure you write down the initial sliders' values before moving the transducer.

N062



WARNING:

The **Automatic Tracking** procedure must be repeated after any change of the mechanical positioning unit location by pressing this button.

W071



7.13. Define a Region of Treatment (ROT)

Drawing the Region of Treatment (**ROT**) can be used to define a large treatment volume (multiple adjacent target spots).

1. Press on an image to display it in the selected image window.
2. Press this button and trace the **Region of Treatment (ROT)** on the selected image.
3. Toggle this overlay button to display the treatment limits and verify that the **ROT** is within the effective treatment area of the transducer. If this situation cannot be reached in the desired transducer tilt settings, reposition the transducer mechanically and return to the **Calibrate Stage** to locate the transducer by calibrating the system again.
4. Repeat on additional slices if necessary, press on the **ROT** and press this button to interpolate.

The system will automatically pack the **ROT** with treatment spots while entering the (**Treatment Stage**).



**WARNING:**

W072

Carefully examine the **ROT** and spots within the volume, on all relevant images to ensure a safe treatment plan before applying each one of the sonications.

7.14. No Pass Region Marking

7.14.1. Automatic Calcification and Sinus Detection

To enable the system to compute and automatically detect the sinus cavities, you may run the **Automatic Sinuses and Calcifications Detection** feature.



This feature will identify (based on the CT image characteristics):

- **Sinuses** - Air cavities in the skull, in the area that is inside the transducer volume.
- **Calcifications** – Areas of bright tissue within the brain, typically calcifications. These are also only marked in the area that is inside the transducer volume.

The system will automatically mark the detected regions by NPRs. Calcifications and Sinuses are treated as different entities, meaning that selecting 'Delete All' will only delete the selected entities' type. After running the algorithm make sure to Review the results to verify correct marking of the sinuses and manually complete the NPR contours for full coverage, if required.

When loading a **Pre-Planning Session** the CT and Sinus markings are carried over. Re-running the automatic Calcification and Sinus Detection algorithm will overwrite the previous auto-markings.

**NOTE:**

N063

Since detection limits are dependent on transducer location, the automatic sinuses detection should be performed after the transducer location has been determined (see **Section 7.5**) and CT and MR-live images are loaded and registered.

- Calcification markings can be individually or completely deleted independent of Sinus markings

**WARNING:**

W073

The **Automatic** algorithm can only **assist** the operator in marking the sinuses and calcifications. Therefore, after running this feature pay strict attention and review all the CT images to ensure that:

- All sinuses were identified and marked correctly.
- No regions were marked unnecessarily.
- After each running of this feature, you must review the computation results.

7.14.2. Drawing No Pass Regions (NPRs) Contours

When there is a need to prevent the beam path from passing through sensitive regions, **NPR (No Pass Regions)** contours should be drawn on all relevant images.

After drawing these contours, the system will automatically update the beam path to each sonication spot and will prevent the beam from passing through the NPR contours.



WARNING:

W074

Ensure that you are using both the MR and CT images to carefully identify sensitive regions and mark them with **NPRs**. Particularly gaps and air folds in the beam path (e.g. calcifications, sinuses, and air cavities)



WARNING:

W075

Drawing **NPR** contours may be used to prevent injury to the patient during treatment. The treating physician should identify and draw the regions where the beam should not pass through.






WARNING:

W076

Make sure to evaluate spot shape and alignment when modifying NPRs substantially

Examine the sensitive anatomical structures on the images, and draw their **NPR** contours as follows:

1. Select an imaging strip where the regions that the beam should not pass through are best identified.
2. Press this button to draw polygonal NPR contours around the sensitive tissues, where they appear in the images. 
3. Use this button to interpolate between polygonal NPR contours to define the volume of the NPR. 
4. Press this button for drawing spherical NPRs around round sensitive areas, Spheres can be chosen with 2, 4 and 8mm diameters. 



NOTE:

N064

The larger spheres will normally cover multiple MR image slices.



WARNING:

W077

If Interpolation was used on the **NPRs**, manually check the interpolation results in all slices. If the interpolation action failed to achieve the desired results, delete the interpolated contours, and manually draw additional NPR contours in the necessary locations.

7.15. Automatic Movement Detection

The **Automatic Movement Detection** feature can assist you in detecting patient movement during the treatment.

Reference Movement Detection images are automatically acquired by the system during the Planning Image acquisition process.



WARNING:

W078

Ensure that you monitor patient movements during sonications using the real-time anatomy images to confirm no movement; use the **Automatic Movement Detection** feature as an additional advisory element.



WARNING:


W079

Monitoring patient movement is important to assure accurate sonication targeting.

- Monitor the fiducial markers during the treatment to facilitate the detection of patient movement.

7.15.1. Initiate Manual Movement Detection (Optional)

At any stage during the treatment, movement detection can be done to verify a patient's positioning

1. Press this button to start a new movement detection scan. 
2. The system will calculate the movement and inform you if a significant movement was detected.


7.15.2. Tracking Movements Manually

At any stage during the treatment, patient positioning (detect movements) can be performed based on the **Anatomy Real-Time** images (during the delivery of sonications).

To assist in manually tracking the patient's positioning, fiducial markers can be added on the anatomical distinct edges as reference markers that will appear on the real-time images (should be intersected with the thermal map plane).

Monitor the fiducial markers during the treatment to facilitate the detection of patient movement.

To add these fiducial markers:

1. Select a relevant Planning Image or Movement Detection Reference image in the Main Image window.
2. Press this button to add new fiducials. 
3. Point and press in the Selected Main Image window to create a marker on the anatomical edges of the relevant organs.

4. Press again at another location to add as many fiducial markers as required.
5. Repeat in all image orientations. If required, move or delete the fiducials.

7.16. Advancing to Treatment Stage

Before advancing to **Treatment Stage**, confirm that both the patient and the nurse have been instructed in the use of the **Stop Sonication** button, and that the patient is holding it and understands how to operate it.



WARNING:

The patient, nurse and operator should be instructed to stop the sonication if the patient feels pain, heat or any unexpected sensation and/or if operator recognizes patient's distress, wrong spot location or shape or undesired temperature behavior.

Treatment

W080

Also, the operator's console **Stop Sonication** button needs to be checked to ensure that it is working properly.

Press the **Treatment** button on the main toolbar to advance to the next stage in the treatment.



NOTE:

N065

- The system will not proceed to **Treatment Stage** without testing the **Patient Stop Sonication** button.
- If no registration was performed, a message is displayed inquiring whether proceeding without registration is desired. At this point consider performing registration or proceed on to **Treatment Stage**.
- When a **Reference Movement Detection** scan is not yet produced when entering **Treatment Stage**, the system will display this message: **Press Scan to Start Movement Detection Reference Scan**. Press **Scan** to take reference MR images for the **Movement Detection** feature. Do not interact with the MRI during the reference scan acquisition.

8. TREATMENT: TREATMENT STAGE

8.1. Overview

Treatment Stage is the stage where the actual treatment is performed. If required, you may change the plan and the sonication parameters anytime during the treatment.

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

1. **Treatment Stage Main** screen: this screen (see **Figure 8-1**) enables you to conduct the **Pre-Sonication** phase and provides the means to prepare and plan the spot prior to the actual delivery of energy.
2. **Thermal Evaluation** screen: this screen (see **Figure 8-8**) enables the user to perform the **Sonication & Post Sonication Phases**. During the sonication time, the system displays the temperature maps and the magnitude images acquired in real-time. When the act of applying the energy has been completed, the system provides a set of tools to perform retrospective analysis and adjustments as necessary.

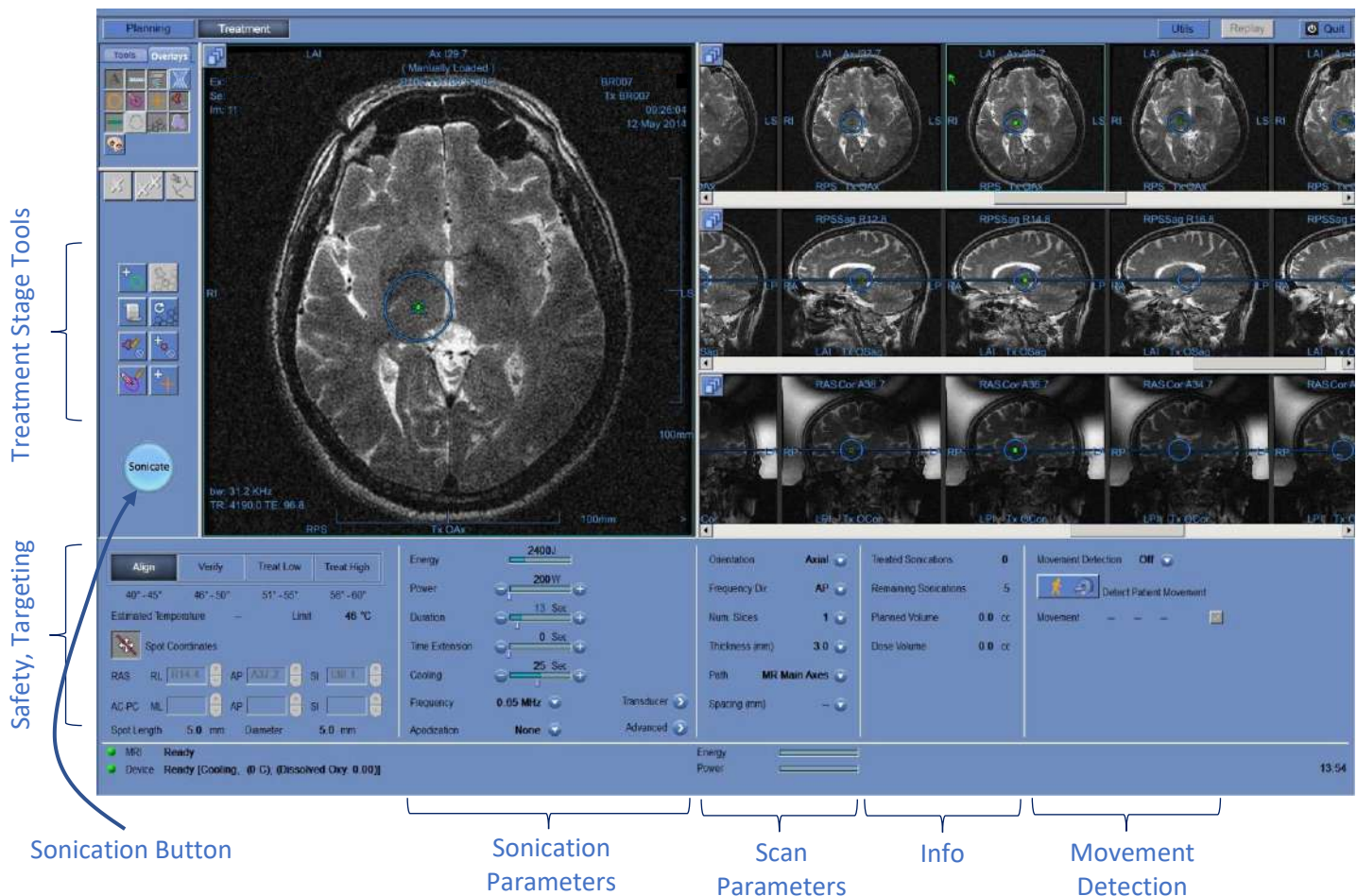


Figure 8-1: Treatment Stage Screen

8.1.1. Treatment Level (Temperature Estimator)

This feature enables you to obtain an initial suggestion of the required sonication parameters in four treatment levels:

- **Align:** Where the hot-spot center location is being evaluated and adjusted.
- **Verify:** Where tissue response and physiological feedbacks are expected prior to a permanent lesioning temperature.
- **Treat Low:** First step of therapeutic energy delivered to tissues that require low temperatures.
- **Treat High:** Where the system aims to reach an adequate level of temperatures within the target that will ensure permanent controllable lesioning of the anatomical structure.

Align	Verify	Treat Low	Treat High
40° - 45°	46° - 50°	51° - 55°	56° - 60°
Estimated Temp.	42 °C	Temp. limit	46 °C

Figure 8-2: Treatment Levels and Estimated Temperature

1. To generate an initial suggestion of the next sonication parameters, press the desired treatment level.
2. The sonication parameters will be updated according to the predicted desired treatment levels.
3. The **Estimated Temperature** field of the next spot (using the selected parameters) will be updated.



WARNING:

W101

Always select your treatment level according to your desired sonication outcome. Note that the sonication halt based on temperature limit will always lag approximately half a phase behind energy emission, thus the final temperature may be several degrees above the threshold.



NOTE:

N066

Changing the spot parameters manually does not affect the treatment Levels. To refresh the suggested sonication parameters, switch to a new treatment level and return to the current treatment level.

**WARNING:**

W081

- When switching between treatment levels, confirm a moderate, gradual increase in energy with respect to the previously observed peak temperature in the target.
- Do not change the treatment level to increase the energy, unless you are certain that the heated area is within the expected target (anatomical structure).

8.1.2. Temperature Limit

The **Temperature Limit** is an additional safety tool designed to monitor the thermal rise in real-time and prevent excessive heating of the target area.

During sonications, the temperature in the target area is being monitored based on real-time thermal imaging. If temperatures exceed the maximal defined temperature value, the system will automatically cease energy transmission, while the MR scan will continue as prescribed.

The maximal temperature value can be defined as:

- Limit based on current treatment level (Default, Recommended).
- Limit based on the temperature estimation from the Temperature Estimator.

The value of the temperature limit is presented on screen as seen in **Figure 8-2**.

This feature is operated from the Utilities (**Utils**) screen (see **Section 11.2.12**) where the following menu is available:

- OFF - to disable this feature
- By level
- By estimation

**WARNING:**

W082

Disabling the temperature limit algorithm should only be done under specific circumstances and for non-ablative energies. Use extra care when disabling the temperature limit algorithm.

8.1.3. Spot Information Frame

This frame displays the current spot coordinates and dimensions that are calculated from Spot Plan: **Length**, **Diameter**, and **Coordinates**.

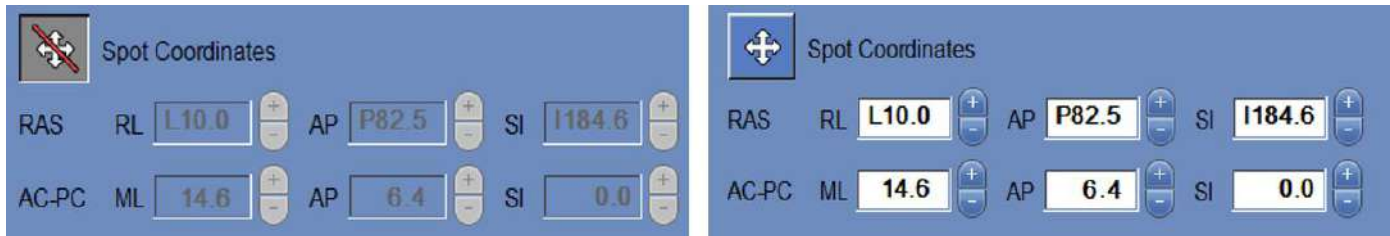


Figure 8-3: Spot Information Frame
(R) Locked (L) Unlocked

Press this button to lock all the planned spots. **Lock** state is eliminating spot location editing during the procedure.

Re-pressing this button will enable editing of the spot location.



To change the selected spot's coordinates, you may either drag the spot to the desired location in the MR images, or alternatively insert the required spot coordinates.



NOTE:

Pay attention to signs while inserting the spot coordinates (i.e., L/R, A/P and S/I).

N067



CAUTION:

Make sure you confirm the spot's location with the MR images after manually inserting a set of coordinates.

C027

8.1.4. Real-time Power Control

This feature enables you to perform sonications within a closed loop for the power levels, keeping the acoustic signal within predefined thresholds and below the cavitation safety threshold.















This feature is operated from the **Utils** screen (see **Section 11.2.10**) where the following menu is available:

- **Stop Sonication** – system will automatically stop energy transmission if the acoustic signal crosses the predefined thresholds
- **Modulate Power** – as described above, but additionally, the system modifies output power in real-time, based on live acoustic feedback. The system attempts to deliver the requested power but reduces power when required to avoid exceeding the cavitation safety threshold.

8.1.5. Sonication Parameters Frame

If necessary, change the parameters as described below. All changes to the spot parameters affect all sonication spots in the selected **ROT**.

Confirm the changes by pressing the **Apply** button, or the **Cancel** button to retrieve previous parameters.

Image	Description
	<p>The Acoustic Energy required for the next sonication.</p> <p>The displayed value is equal to $\text{Power} \times (\text{Duration} - 1)$. The subtracted second is to account for ramping of power. The energy field can not be edited manually.</p>
	<p>Set the maximal Power to be applied during the sonication.</p> <p>Change the value by pressing the  or  buttons.</p>
	<p>change Sonication Duration by pressing the  or  buttons.</p> <p>Duration should be set to the maximum time allowed duration for the sonication. When Acoustic Mode is set to Stop Sonication, Duration values are set by the quotient of Energy/Power and cannot be edited.</p>
	<p>When Acoustic Mode is set to Modulate Power, the system will lower the power in response to detected cavitation signals and extend the sonication using the Time Extension value in order to deliver the prescribed energy.</p>
	<p>Change the Cooling Duration by pressing the  or  buttons.</p>
	<p>Select a Frequency from the pull-down menu.</p>
	<p>Select an Apodization Percentage to determine the effective transmitting area of the transducer out of the total active elements.</p>
	<p>The Focusing method use during sonications is based on the CT scans.</p>



CAUTION:

C028

Verify the desired sonication parameters before performing sonication. Unintended sonication parameters may result in ablation of unintended tissue. Check temperature estimation (see **Section 8.1.1**) and confirm spot location before each sonication.

If the sonication parameters prescribed by the user have exceeded the system's performance or safety limits, updated parameters will be presented before sonication starts.

8.1.6. Thermal Scan Parameters Frame

This section controls the parameters of the thermal scan to be taken during the next planned sonication.

Orientation	Axial
Frequency Dir.	AP
Num. Slices	1
Thickness (mm)	3.0
Path	MR Main Axes
Spacing (mm)	—

Figure 8-4: Thermal Scan Parameters Frame

- **Orientation:** Select one of the following for scan orientation:
 - In case of MR Main Axes: one of the three main orientations (Axial, Coronal or Sagittal).
 - In case of Planning images: one of the three main orientations (Axial, Coronal or Sagittal), or if planning images were taken as oblique - one of three oblique orientations (OCor, OAx, OSag).
- **Frequency Direction:** Select the frequency direction from one of three settings: **RL**, **AP**, or **SI**. The chosen frequency direction for a thermal scan is indicated by a small arrow mark ('>' or '^') on the bottom right corner of the main image window. Remember that the frequency direction is more sensitive to thermal image shifts.



WARNING:

W113

Switching between scan orientations and frequency directions is important in order to obtain an optimal estimation of heating position, shape, and size.

- **Thickness:** select the slice thickness from one of these settings:
 - **Single-slice** – 3, 5, 7 or 10 mm
- **Number of Slices:** Select number of slices for single-slice or multi-slice (when available) thermal imaging:
 - 1 (Single-Slice) uses protocols of thermal imaging intersecting with the center of the planned spot.
 - 3 or 5 (Multi-Slices) use protocols for volumetric thermal imaging. A few parallel scan slices will be taken while the center slice will intersect with the center of the planned spot.
 - **Multi-slice** slice thickness– 3 or 5 mm
 - **Spacing** (for multi-slice thermal imaging): select the spacing between the slices
- **Path:** select one of the following options:
 - **MR Main Axes** – scan direction will be defined by the MR main axes.
 - **Planning Images** – scan direction will be defined by the Planning images direction.

**NOTE:**

N068

For each selected sonication, the thermal scan grid lines (blue color line/s) are automatically displayed on the screen, according to the thermal scan parameters.

8.1.7. General Information Frame

Treated Sonications	8
Remaining Sonications	4
Planned Volume	0.0 cc
Dose Volume	0.0 cc
Adjustments:	
Prior	L2.1 A1.0 S0.0

Figure 8-5: General Information Frame**■ Treated Sonications:**

The system automatically indicates the number of sonications already conducted.

■ Remaining Sonications:

The system automatically indicates the number of remaining sonications in the treatment plan.

■ Planned Volume:

The system automatically calculates the planned volume based on the pre-defined **ROT** volume.

■ Dose Volume:

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

Thermal dose is an automatically calculated volume that reached 54°C for 3 seconds (or thermally equivalent), based on real-time thermal imaging. This volume is considered to be ablated, based on physical models.

■ Adjustments:

The system indicates the adjustments that were done during the treatment by showing the adjustment vector in all three directions on-screen:

- **Prior:** the adjustment vector with which sonication was performed (in the **Thermal Evaluation** screen and **Replay Mode**).
- **Current:** the adjustment vector calculated based on current sonication evaluation (Only in **Replay Mode**).

8.1.8. Movement Detection Frame

When the **Movement Detection** option is turned ON, the system will automatically perform movement detection imaging ('current image') and analysis of every sonication, and will alert if the movement larger than 1.5 mm.

If a movement is detected, the evaluated direction of movement will be displayed (point in three axes represents the direction vector). If estimated movement is above one mm, check movement detection images to verify the movement.

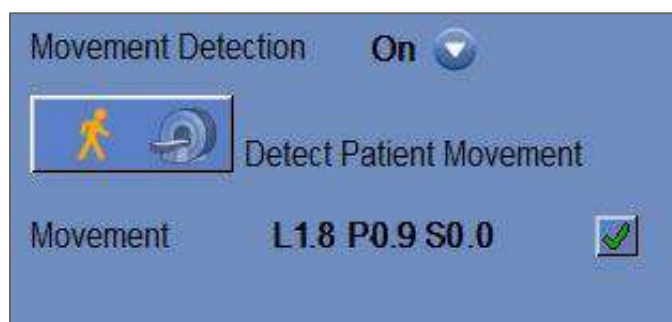


Figure 8-6: Movement Detection Frame



WARNING:

W083

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

8.1.9. Transducer Elements Window

The transducer elements screen displays the **Transducer Elements Map** and the **Transducer Elements Parameters** for the sonication spot. The rays from the transducer elements to the sonication spot can be seen on the images (a ray defines the acoustic path from a single element to the sonication spot).

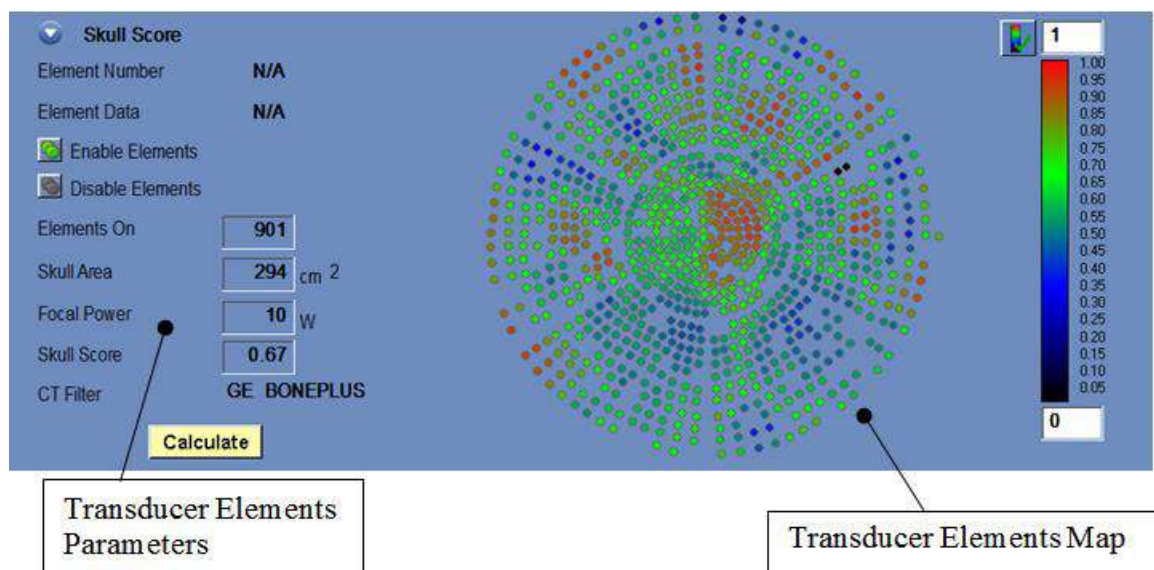
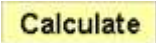





Figure 8-7: Transducer Elements Window

8.1.9.1. Action Tools

Image	Name	Description
	Calculate Elements	Press this button to calculate the transducer elements map and parameters for a selected sonication spot.
	Set Map Range	Press this button to apply the scaling range of the transducer map.
 Enable Elements  Disable Elements	Enable/Disable Elements	Press these buttons to turn selected element(s) ON or OFF : Select element(s) from the Transducer Elements Map by pressing on it. Press Enable Elements to turn ON or Disable Elements to turn OFF.

8.1.9.2. Transducer Elements Map

For each sonication spot, it is possible to view its derived **Transducer Elements Map**.

Each of the following profiles can be displayed on the map:

- The **Average Power** (in Watts) transmitted from each element.
- The **Phase Correction** (in degrees) applied for skull aberration correction of each element.
- The **Thickness** (in mm) of the skull that the ray passes through.
- The **External Angle** (in degrees) between the ray and the skull surface at the intersection area.
- The **Air in Skull** (in mm) along the ray path.
- The **Internal Temperature** (in Celsius) estimation of the brain tissue temperature at the inner surface of the skull.
- The **External Temperature** (in Celsius) estimation of the temperature at the skin adjacent to the skull.
- The **Ray Shift** (in mm) as a measure of ray refraction.
- The **Skull Average Intensity** (in Watts/cm²) shows the average acoustic energy density on the surface of the skull.
- The **Manual Disabled** displays the elements that were manually turned OFF by the operator.
- The **Skull Score** calculation for each element.

8.1.9.3. Transducer Elements Parameters

1. Press on a transducer element to view its parameters in the **Transducer Elements Parameters** frame. Each parameter value is displayed next to the corresponding profile.
2. General parameters of the selected spot are displayed:
 - The **Elements ON** displays the total number of transmitting elements.
 - The **Skull Area** (in cm²) displays the total area of the skull that the rays pass through.
 - The **Focal Power** (in Watts) displays the estimated peak power that reaches the target location after traversing through the skull and brain tissue.
 - The **Skull Score** reflects the variability in the bone density of the entire skull.
 - The **CT Filter** type displays the filter that CT images were reconstructed with.



NOTE:

A minimum of 700 elements ON is advised for an effective treatment.

- The skull area must exceed 200 cm².

N069D

8.1.10. Spot and Ray Colors

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

8.1.10.1. *Sonication Spot Colors*

- **Green** – Untreated spots, which are valid and may be treated.
- **Green Highlighted** – Next spot to be sonicated.
- **Yellow** – Warns you that energy density in the skull is above the threshold and if focusing optimization process was performed in a distant location.
- **Red** – non-treatable spots (spot parameters are not valid).



NOTE:

N070

When the untreated spot is yellow or red, the reason will be displayed in the information box by pressing on the spot.

8.1.10.2. *Ray Colors*

The rays are colored to provide additional feedback about their status:

- **Green** – Transmitting elements
- **Red** – Non-transmitting elements



NOTE:

N071

- For non-transmitting element, the reason will be displayed in the information box by selecting the ray.
- Selected sonication spots or rays are highlighted.

8.2. Thermal Evaluation Screen

After the sonication energy is applied, the system displays the **Thermal Evaluation** screen (see **Figure 8-8**).

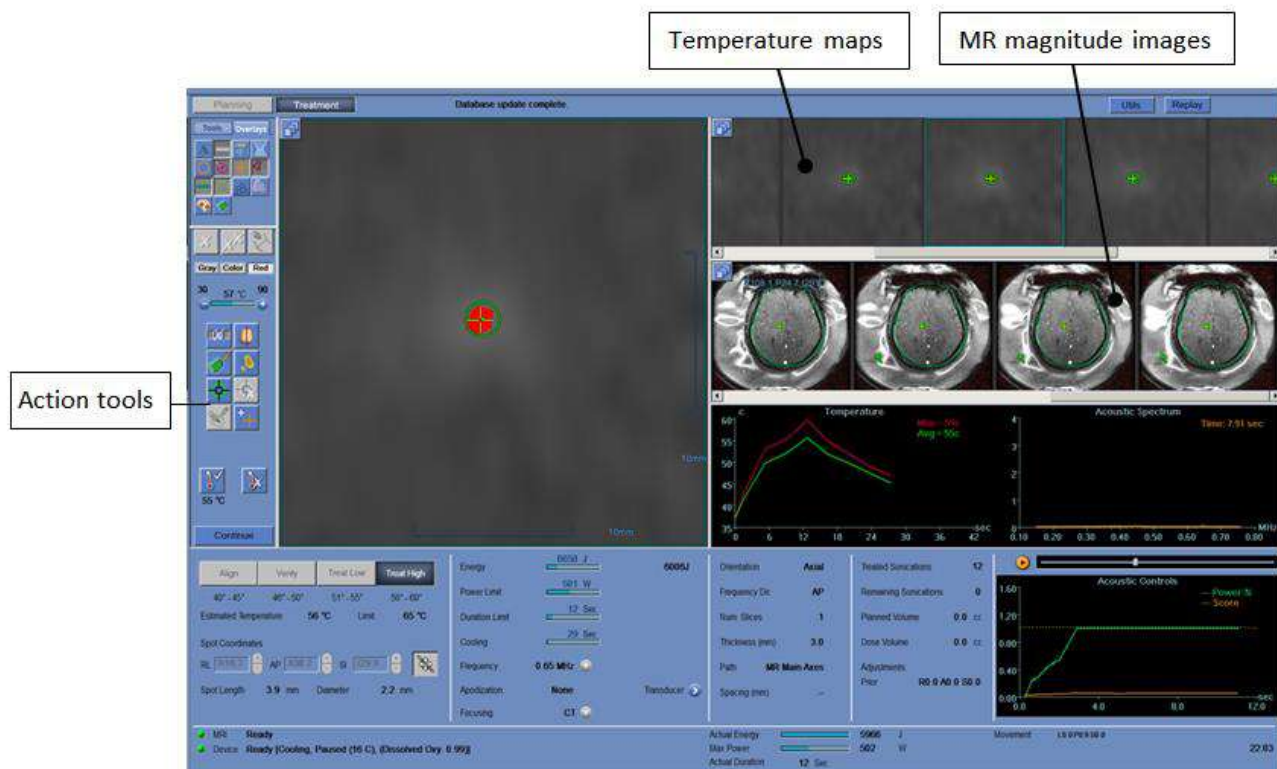


Figure 8-8: Thermal Evaluation Screen Elements

8.2.1. Image Strips

- The top image strip shows the temperature maps acquired during the sonication.
- The bottom strip displays the set of MR magnitude images taken during the sonication. The **Image Strip** selection menu button may be used to manually change this default setting.
- The **Selected Image** window shows the MR image acquired closest to the end of the sonication. The calculated thermal dose contour is superimposed on the post-sonication temperature maps.
- To navigate through the MR images along time, use the keyboard **Right** and **Left** arrows or alternatively press on the desired image.



NOTE:

for multi-slice thermal scans, the central slice is displayed, and pressing the **Up** and **Down** arrows allows navigating between the different slices of the temperature maps. An annotation on the bottom of the selected main image indicates the scan location along the perpendicular axis

N072

8.2.2. Thermal Evaluation Action Tools








Image	Name	Description
	Background Temperature Correction	<ul style="list-style-type: none"> If the background temperature changes due to various imaging artifacts, background temperature can be corrected. Press this button to perform background temperature correction, according to the Background Mask which covers as large an area as possible on the temperature map of brain tissue, while avoiding skull area and air cavities displayed (mask is transparent). The temperature maps and graphs are updated. Background correction is set to ON by default <p>NOTE: If you selected the Background Temperature option, that button will remain pressed for the next sonication.</p>
	Spot Location Adjustment	To perform spot location adjustment, select the temperature map with the hottest spot to the Selected Image window.
	Reset Adjustment	Press this button to reset all accumulated adjustments to the treatment.
	Heat Estimation	<ul style="list-style-type: none"> Press this button to provide an automatic evaluation by the system of heated regions, and mask out erroneous regions in the temperature maps. <p>NOTE:</p> <ul style="list-style-type: none"> This overlay provides only a suggestion for heated regions. Do not solely rely on the algorithm and carefully examine the entire thermal map to detect real heated regions. If you selected the Heat Estimation option, that button will remain pressed for the next sonication.
	Draw Dose Polygon	<p>If erroneous thermal dose regions (caused by artifacts), mark the thermal dose on the temperature map as follows:</p> <ol style="list-style-type: none"> Press on a temperature map with thermal dose to display it in the selected image window. Press the Draw Dose Polygons button; draw polygons around the correct thermal dose regions. Continue to define the Dose Polygons on additional slices (interpolate if necessary). If it becomes necessary to refine or redefine the drawn polygon, move it by pressing it and dragging, or delete by pressing it and then pressing the Delete button. <p>When pressing this button, only the thermal dose inside the</p> <div>Continue</div> <p>dose polygons will be accumulated.</p>

Image	Name	Description
	Remove Noisy Image	<p>To avoid an erroneous dose, it is possible to ignore entire noisy thermal images in temperature calculations:</p> <ol style="list-style-type: none"> 1. Press on the noisy thermal image to display in the selected image window. 2. Press the Remove Noisy Image button (the noisy temperature map is replaced by an interpolated map and thermal dose calculations are updated accordingly). 3. To cancel the selection, press again.
	Add Fiducial Marker	<ul style="list-style-type: none"> • Use this feature to add fiducials on anatomical features as reference markers. These fiducials will be seen on planning images as well. • Press this button and then point and press in the Selected Image window to create a marker.

8.2.3. Continue Treatment Tools





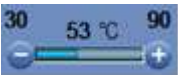


Image	Name	Description
	Continue to Main Treatment Screen	<p>Press this button to continue to the Treatment screen.</p> <p>NOTE: By pressing this button you accept the following Thermal Outcomes from this sonication:</p> <ul style="list-style-type: none"> • Measured Thermal Dose accumulation. • Accepted Peak Temperature. <p>These parameters may affect the Treatment Levels (Temperature Estimator) and the Accumulated Measured Thermal Dose. Carefully examine the sonication outcomes before pressing the Continue button.</p>
	Update Accepted Peak Temperature	<p>Press this button to update the Accepted Average Peak Temperature as the outcome of this sonication. This temperature will be selected as the inputs for the Treatment Levels (Temperature Estimator).</p> <p>As a default, the system will accept the average peak temperature calculated automatically by the system at the end of the sonication (where the Temperature Cursor was located by the system).</p> <p>To update the Accepted Temperature:</p> <ol style="list-style-type: none"> 1. Drag the Temperature Cursor to where peak temperature was reached, on the Thermal Maps. 2. Make sure this location is indeed the center of the real thermal spot. 3. Press this button; the temperature will be updated to the Accepted Temperature Field.

Image	Name	Description
	Reject Thermal Outcomes	Press this button (toggle) to Reject All Thermal Outcomes from last sonication. Hold this button down before pressing the Continue button, to reject the thermal outcomes.

8.2.4. Temperature Scaling Tools

Image	Name	Description
	Temperature Scale Viewing	Press on different tabs for different scaling: <ul style="list-style-type: none"> Gray displays temperature maps in grayscale. Color displays temperature maps in color. Red displays a red overlay on the grayscale image. The red overlay displays all the areas where the temperature is above a pre-determined threshold.
	Temperature Threshold	To view the desired temperature scale, set the temperature threshold by pressing the  or  buttons; the selected value appears on the scale.

8.2.5. Measured Sonication Parameters Indicators

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

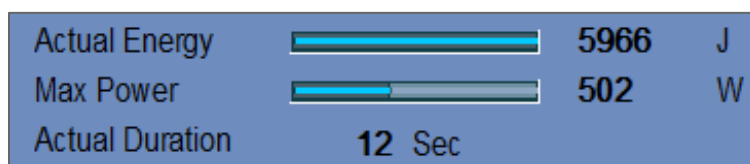


Figure 8-9: Measured Sonication Parameter Indicators

8.2.6. Temperature Graph

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

The graph displays:

- **Red Line** – evolution of the temperature at the cursor's location, during and after sonication.
- **Green Line** – average temperature around that cursor.
- **Azure Line** – average temperature within a measurement polygon.
- **Magenta Line** - average temperature within the Temperature Monitoring Volume

The highest temperature reached by each graph line is displayed on the upper-right corner of the frame.

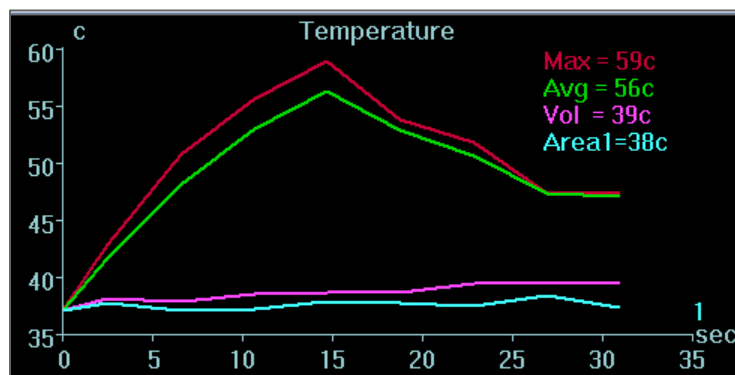


Figure 8-10: Temperature Graph



NOTE:

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

N073

8.2.7. Acoustic Spectrum and Acoustic Controls

Three additional graphs are displayed during the sonication; they are displayed as soon as sonication begins:

- **Acoustic Spectrum Data** – presents the spectrum of frequencies that are transmitted back to the transducer.
- **Acoustic Controls (Levels)** – present two graphs:
 - **Spectral Energy Score** – displays the intensity of the spectrum frequencies at each time point (orange/yellow line).
 - **Power Percentage** – displays the normalized actual transmitted power for each time point throughout the sonication (green line).

The **Acoustic Spectrum** and the **Spectral Energy Score** display graphs which assist in detecting the creation of micro-bubbles associated with cavitation effects.

Acoustic Spectrum with high values in the range of half the transmitting frequency; indicates the possibility of cavitation effects and will result in a **Spectral Energy Score** above the dashed horizontal line. If this occurs during sonication, the system will automatically react depending on the current Acoustic mode:

- If system is in **Stop Sonication** mode, it will cease energy transmission, while the MR scan will continue as prescribed.
- If system is in **Modulate Power** mode, power will be reduced automatically until the **Spectral Energy Score** will be below the threshold. The system then will try to increase the power again while keeping the spectral energy below the threshold.

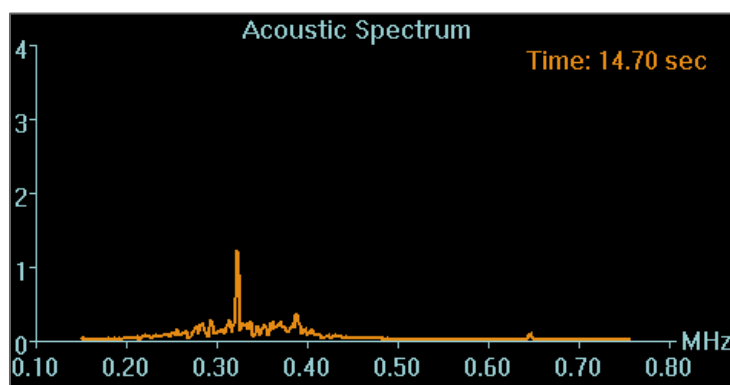


Figure 8-11: Acoustic Spectrum Graph

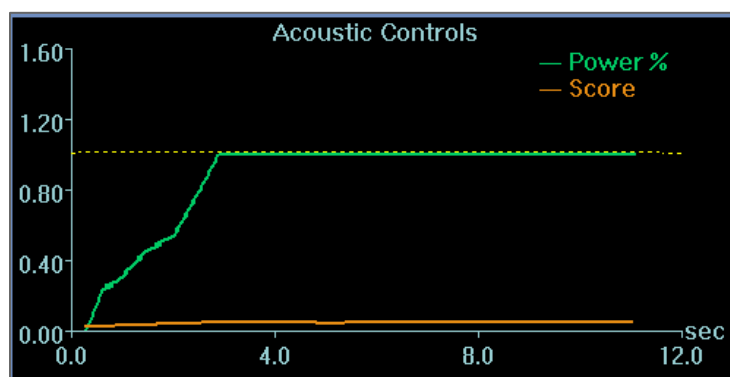


Figure 8-12: Acoustic Controls (Levels) Graph

All graphs are captured during sonications and can be reviewed in the thermal evaluation stage by pressing this button; the data is displayed as cine color.



At the end of each sonication, graphs present the time of the highest Acoustic Spectrum Signal.

8.3. Treatment Procedure

8.3.1. General Sonication Flow

1. Verify that the patient is comfortable.
2. Examine the next spot to be sonicated:
 - When highlighted in green, the spot is valid and may be treated.
 - When highlighted in yellow, the spot is above the threshold on one of the **NPR's**, or it crosses the threshold of energy density on the skull. Cautiously try to optimize the location and/or the orientation. Check the parameters and assess if the clinical situation allows this sonication.

**NOTE:**

N074

When the untreated spot is not green, the reason is displayed in the information box at the top-right corner of the screen when you press on the spot.

3. Based on the examination of the actual dose, previous sonication performance, and patient feedback - determine the sonication plan:
 - Adjust sonication parameters: **Energy, Duration, Frequency, Time Extension**.
 - Confirm that the estimated external and internal temperatures are adequate.
 - Change thermal scan parameters (MR protocol, scan orientation, frequency direction).
 - Add/remove spots.

**WARNING:**

W084

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

- There are no water leaks from the transducer by visually inspecting the transducer area.
- The blue **Circulation Controller** on the operator's console is illuminated continuously. A flashing indicator means that the water temperature or pressure is exceeding limits.
- Degassing level is nominal and PPM value is less than 2.0.

**WARNING:**

W093

- Remind the patient to stop sonication when feeling pain or heat.
- if any undesired signs appear, the **Stop Sonication** button must be pressed immediately.

**WARNING:**

W092

In case of an unanticipated system action or patient reaction, the operator, the nurse or the patient can immediately stop the system with the **Stop Sonication** button.

4. Press the **Sonicate** button to apply the ultrasound energy.

**CAUTION:**

C029

If the sonication parameters prescribed by the user have exceeded the system's performance or safety limits, updated parameters will be presented before sonication starts.

5. Right before energy delivery, **Tracking** and **Movement Detection** scans are performed, and the system automatically detects if patient or transducer movement has occurred.



WARNING:

W085

In case of patient movement or repositioning, you must return to the **Planning Stage**, scan new planning images, and create a new plan based on these new images.

6. During sonications, the following factors should be monitored:

- Patient discomfort or abnormal reactions.
- Energy transmission, as displayed by the energy bar.
- Spectrum signal during the transmission of acoustic energy.
- Patient motion, by observing the fiducial markers or the CT mask on the updated MR anatomical images.
- The evolving temperature rises during sonication.
- The real-time images to ensure coupling.



WARNING:

W088

Confirm a moderate, gradual increase in energy with respect to current treatment level energy (**Align, verify, treat low** or **treat high** mode) in which a hot-spot was observed.










WARNING:

W087

The measured temperature assumes a background temperature of 37°C, in case of a different true baseline temperature, please adjust the baseline temperature (see **9.2.3**)

7. After sonication, the **Thermal Evaluation** screen will appear with the actual thermal dose contour overlaid on the image (see **Figure 8-8**). Review the results:

- Drag the cursor around the image and evaluate the temperature graphs. Press this button to change the accepted peak temperature to the one currently shown. 
- Analyze the thermal results near the skull and the thermal dose in the sonication area. If required, press this button to draw Measurement Polygons near the surface of the skull to evaluate the temperature rise 
- To remove a specific noisy thermal image from the temperature calculations, use this button. 
- Toggle Background Temperature Correction OFF\ON to evaluate the image quality. 
- If required, press this button to draw a dose polygon and estimate the heated regions on the temperature maps. 
- If the temperature map still contains an erroneous thermal dose (caused by residual artifacts), use this button to define which regions should be considered as dosed regions 
- If the resulting temperature map is deemed unreliable, press this button to reject the measured thermal dose and accepted peak temperature, and then press the Continue button. 

**WARNING:**

W086

In case of abnormal system behavior, unexpected thermal maps, rise and inability to see or understand thermal maps, abort sonication and treatment immediately.

- Before sonication:
 - If there is a need to increase treatment energy, do so in gradual steps and monitor any thermal rise after each sonication.
- During sonication:
 - Monitor the temperature maps during sonication. If an unexpected thermal rise is found outside the target location, stop the sonication.
 - If there is a need to stop the sonication process, press the Stop Sonication button.
- After sonication:
 - Carefully examine the thermal images and the thermal dose contours after each sonication to avoid possible damage to unintended tissues.
 - Monitor the thermal rise at the target location, and at the relevant pass zone with special attention to the interface with the skull and other sensitive regions.

8. Press the **Continue** button to continue to the next sonication.

**NOTE:**

N075


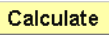
After continuing to the next sonication, you will not be able to edit the **Accumulated Measured Dose** of previous sonications or the **Accepted Peak Temperature** for the **Treatment Levels (Temperature Estimator)**.

9. Repeat the procedure until all planned sonications have been performed, or alternatively repeat the selected spot until you have reached the desired clinical outcome (for a single target). Changes to the treatment plan are possible at any stage during treatment

10. If required, press Replay to view the results of previous sonications

8.3.2. View Transducer Elements

The transducer elements map and the parameters of each element can be viewed for each sonication spot

1. Press the  button to view the Transducer Elements Map, according to the selected profile
2. Select a sonication spot (single spot or in the center of the ROT) from the Selected Image window.
3. Press the  button to view the Transducer Elements Map, according to the selected spot.
4. Select the Elements-ON option from the Pass Zone Overlay menu to verify that the rays do not pass through sensitive tissues.
5. If required, press an element in the transducer map or on a ray in the selected image window, to view the element's profiles

**NOTE:**

N069D

- A minimum of 700 elements ON is advised for an effective treatment.
- The Skull area must exceed 200 cm²

8.3.3. Adding a New Sonication Spot (Multi spot treatments only)

1. Press this button and add a reference sonication spot in the **Selected Image** window.
2. Verify that the sonication test spot is located within the **ROT**.
3. Verify that the position of the sonication spot is exactly within the desired target location.
4. The system will warn you if the spot is technically invalid (e.g. spot is outside the treatment limits).



8.3.4. Confirm Treatment Plan (Multi spot treatments only)

After examining the treatment plan in all orientations, verify that the sonication spots cover the target tissue (including the margins as required by clinical considerations).

If required, edit the plan as follows:

1. Select the desired sonication spot to edit by pressing on the spot.
2. Change the **ROT** parameters or selected spot parameters.
3. To update the grid density according to the new parameters, you should prepare a new ROT plan, using this button.
4. Add, move or delete a sonication spot/fiducial marker as required.



Align

8.3.5. Geometric Verification ('Align' Level)



WARNING:

W091D

Always adhere to the sonication safety instruction as defined in the start of **section 8.3.1**.

Failure to do so may result in patient injury

Geometric Verification is used to confirm that the thermal spot can be identified and is located at the intended location. The **Adjust** function corrects the transducer's electronic position according to the offset between the sonication location, as defined by the user, and the planned spot's location.

To ensure proper tissue targeting and to avoid injury to non-targeted tissue, geometrical verification must be performed prior to ablative sonications. treatment with to ensure proper alignment before beginning treatment

Treatment parameters should be set at levels that are estimated to deliver a temperature of 40-45°C at the target.



WARNING:

W090

Accurate calibration of the alignment of the transducer at the start of the treatment is critical



NOTE:

N077

- The targeting accuracy is in accordance with the thermal imaging quality allowing the detection of the thermal spot center with 1mm accuracy from the actual lesion location in the brain.
- The target accuracy is affected by the CT of the skull and the targeted tissue.

1. Sonication parameters should be examined in the **Sonication Parameters** and the **Thermal Scan Parameters General Information** and **Treatment Options** frames.




NOTE:

N078

- The default scan orientation will be axial.
 - Initial parameters for first sonication are constant (100 W, 10 sec, 1000 J)
2. Confirm that the sonication parameters are adequate to assure that the thermal rise will be below dose threshold.
 3. Verify that the patient is comfortable, and notify the patient that verification is about to begin.
 4. Sonicate, as described in **section 8.3.1**
 5. When the thermal imaging is complete after sonication, and the **Thermal Evaluation** screen appears, begin by evaluating the thermal spot as described in **section 8.3.1**, but do not press continue prior to performing the additional Geometric alignment evaluation as described hereby:

8.3.5.1. Geometric Adjustment

1. Every sonication has a pre-set frequency direction, along one of the plane's main axes. If a hot spot can be adequately identified, verify that it is within 1.0 mm of the planned location along the phase direction. If it is, continue with verifying location on other orientations.
2. If the hot-spot is over the 1.0 mm margin, press this button, then press on the hot-spot center in the Selected Image window, to adjust to the correct position. 
3. A pop-up message will display the required adjustment in spot's location (see **Figure 8-13**). The shift along the frequency direction is ignored by default to avoid erroneous corrections. If required, the tick mark can be un-checked.

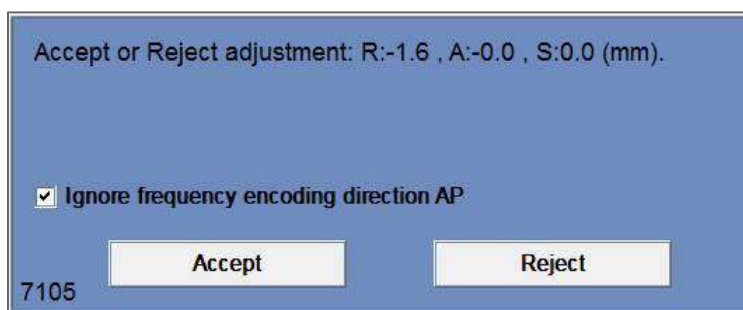


Figure 8-13: Adjustment Message

4. Press Accept or Reject adjustment and then press the Continue button to move to the next sonication.



- The performed adjustment appears on screen in the **General Information** frame. The vector represents the real adjustment that was calculated, based on the decision if to ignore- or not to ignore the shift in the frequency direction.
- For each sonication the adjustment that was performed previously will appear as a '**Prior**' adjustment. In **Replay Mode**, additional vectors appear as '**Current**' indicating that the adjustment was done based on the current sonication's thermal evaluation.

**WARNING:**

W094

Take extreme caution before performing an adjustment:

- If adjustment is required, it must be performed. However, do not perform an adjustment unless you can clearly see the entire hot-spot and be certain that the adjustment is necessary.
- If the adjustment is over 2 mm, before performing it apply another sonication with a different orientation (that shows the same direction), to confirm the necessity of the adjustment.
- Failure to do so may increase the risk of unintentionally treating non-targeted tissue.

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

- Confirm that no air has entered the transducer interface and that it is filled with water.
- Verify that the energy accumulated in the last sonication, displayed in the **Sonication Measured Parameters Indicators** (see **Figure 8-9**), is the same as the energy requested.
- Repeat the sonication while modifying scan parameters to different orientations.
- Increase the sonication energy level in small increments, repeating the geometric verification sonication until a hot-spot is observed. Perform an additional MR scan to evaluate the patient's movements or changes.
- Perform an additional MR scan to evaluate patient's movements or changes.

6. After the spot is aligned in the axial orientation, press this button and repeat the **Geometric Verification Procedure** in all orientations (change the scan orientation in the **Thermal Scan Parameters General Information** frame).

6. After the Geometric Verification Procedure is successfully completed, advance to the Thermal Spot Verification Stage.

**WARNING:**

W095

Do not continue with the treatment if a hot-spot is not adequately visible and confirmed to be well-aligned with the planned target, in all three dimensions.

**WARNING:**

W096

This is effectively the beginning of the treatment; select the spot parameters as though you are beginning a treatment.

**NOTE:**

N079

If the spot appears red, it is invalid and cannot be sonicated.

- If the spot appears yellow, be cautious. Try to optimize the location and/or the orientation.

**WARNING:**

W089

The geometric verification procedure must be repeated if one or more of the following incidents occur during treatment:

- Repositioning of the transducer or updating **Planning Stage** parameters.
- Modifying CT/MR registration.
- Patient movement is detected, and new planning images are loaded.
- No **Pass Region** polygons have been modified.
- Thermal hot-spot is not noticed on thermal imaging sequence during treatment.
- Spot placed in new target location.

Verify

8.3.6. Thermal Spot Verification ('Verify' Level)

**WARNING:**

W091D

Always adhere to the sonication safety instruction as defined in the start of **section 8.3.1**.

Failure to do so may result in patient injury

Thermal Spot Verification is used to confirm the tissue response and physiological feedbacks are as expected prior to permanent lesioning temperature.

Switch to the **Verify Treatment Level** frame, to calculate an initial prediction of the required sonication parameters (Power, Duration and Energy) that will theoretically increase the level of the peak temperature to be within 46 to 50°C.

1. Sonicate and evaluate the sonication as described in **Section 8.1.3**

Monitor the sonication for:

- Patient discomfort or abnormal reactions
- Spectrum signal during the transmission of the acoustic energy
- Patient motion by observing the fiducial markers and the CT mask on the MR anatomical images
- The evolving temperature rise during sonication

2. Check whether there has been patient motion by observing the location of the fiducials and the CT mask location on the Anatomical images from the sonication.
3. Analyze the results and compare the size of the obtained spot with the planned spot:
 - If they match, accept the Thermal outcome and transition to the **Treatment** screen.
 - If they don't match, change the sonication parameters and repeat the **Geometric Verification**

**NOTE:**

In case of artefacts, see NOTE at the start of **Section 8.3**

N080D

4. Once suitable parameters for treatment have been set and an acceptable spot size is achieved, switch to **Treat Low** Treatment mode.

Treat Low**8.3.7. Target Stimulation ('Treat Low' Level)****WARNING:**

Always adhere to the sonication safety instruction as defined in the start of **Section 8.3.1**.
Failure to do so may result in patient injury

W091D

Target Stimulation is used to deliver therapeutic energy to tissues that require low temperatures. Switching to **Target Stimulation** level will generate an initial prediction of the spot parameters that will theoretically increase the level of the peak temperature to be within 51 to 55°C.

1. Sonicate and evaluate the sonication as described in **Section 8.1.3**

Monitor the sonication for:

- Patient discomfort or abnormal reactions
 - Spectrum signal during the transmission of the acoustic energy
 - Patient motion by observing the fiducial markers and the CT mask on the MR anatomical images
 - The evolving temperature rise during sonication
2. Check whether there has been patient motion by observing the location of the fiducials and the CT mask location on the Anatomical images from the sonication.
 3. Analyze the results and assess the clinical feedback from the patient to ensure an accurate targeting of the desired anatomical structure.
 - If they don't match, change the sonication parameters and repeat the sonication.
 - If the spot seems misaligned, consider repeating the Geometric Verification
 - Adjust the target location according to clinical feedback
 4. If the clinical assessment meets the expectations of targeting this anatomical structure, press the Continue button to accept the Thermal outcome and transition to the Treatment screen. Proceed to **"Treat High"** once the desired clinical effect is seen, without any side effects.

**NOTE:**

N080D

In case of artefacts, see NOTE at the start of **Section 8.3**

**WARNING:**

W097

Once suitable parameters for treatment have been set and an acceptable spot size is achieved, switch to **Target Ablation** mode

**8.3.8. Target Ablation ('Treat High' Level)****WARNING:**

W091D

Always adhere to the sonication safety instruction as defined in the start of **Section 8.3.1**.

Failure to do so may result in patient injury

Target Ablation is used to deliver therapeutic energy to tissues that require high temperatures.

Switching to **Target Ablation** treatment level will generate an initial prediction of the spot parameters that will theoretically increase the level of the peak temperature to be within 55 to 60°C.

1. Sonicate and evaluate the sonication as described in Section 8.1.3

Monitor the sonication for:

- Patient discomfort or abnormal reactions
 - Spectrum signal during the transmission of the acoustic energy
 - Patient motion by observing the fiducial markers and the CT mask on the MR anatomical images
 - The evolving temperature rise during sonication
- 2.** Check whether there has been patient motion by observing the location of the fiducials and the CT mask location on the Anatomical images from the sonication.
- 3.** Analyze the results and assess the clinical feedback from the patient to ensure an accurate targeting of the desired anatomical structure.
- If they don't match, change the sonication parameters and repeat the sonication.
 - If the spot seems misaligned, consider repeating the Geometric Verification
 - Adjust the target location according to clinical feedback
- 4.** If the clinical assessment meets the expectations of targeting this anatomical structure, press Continue to accept the Thermal Outcome. Repeat as deemed clinically necessary to obtain a durable clinical effect

**NOTE:**

N080D

In case of artefacts, see NOTE at the start of **Section 8.3**

8.4. Conclusion of the Treatment Session

After the treatment session, the patient may be released from the treatment table. Verify that:

1. The cradle is pulled out of the MR bore.
2. Water is drained from the transducer and Transducer is moved superiorly.
3. Patient is released from the frame holder and membrane.
4. Head frame removed.
5. Patient examined in recovery room.



CAUTION:

Exit (and shutdown) workstation at the end of the last session of the day.

C030



WARNING:

Adhere to handling, and cleaning instructions for coils and membranes as detailed in the 'Patient Membrane and Coil Handling Procedure' (**Section 12.2**). Failing to comply with the above may result in reduced imaging quality, water leakage, cross-contamination, burns and electrocution risk.

W098

9. ADVANCED OPTION MODE

9.1. Overview

**WARNING:**

W099

Improper use of **Advanced Option Mode** may degrade the quality of treatment and may even result in personal injury. Do not alter these settings without consulting your INSIGHTEC representative.

Advanced Option Mode enables you to override the automatically generated treatment plan, and manually set the treatment parameters. This includes:

- Sonication parameters.
- MR scan protocol parameters.
- Adjusting advanced sonication parameters.
- Adjusting acoustic correction parameters (ACT).

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

To change a parameter:

1. Press the button next to the parameter to be changed or adjusted; the parameter's value text box appears.
2. Type in or select the required value.
3. Press on:
 - **OK** to accept the changes.
 - **Cancel** to reject all changes and close the dialog box.
 - **Reset Values** to reset all changes.

To return the parameter to system default:

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

**NOTE:**

N081

Manual changes made to parameters from the **Advanced Options** dialog box appear in the **Sonication Parameters** frame and the **Progress Parameters** frame in blue text.

9.2. Adjusting Sonication Parameters

Press the **Sonication** tab to adjust the **Sonication Parameter** options

The screenshot shows the 'Advanced Options' dialog box with the 'Sonication' tab selected. The dialog has four tabs: 'Sonication', 'MR Scan', 'Advanced', and 'ACT'. The 'Sonication' tab is active, displaying two main sections: 'Sonication Parameters' and 'Thermal Dosimetry Parameters'. The 'Sonication Parameters' section includes four settings, each with a checkbox and a control: 'Acoustic Power' (100 W), 'Sonication Duration' (10 Sec.), 'Spot Type' (Mode0), and 'Frequency' (0.650 MHz). The 'Thermal Dosimetry Parameters' section includes 'Body Temperature' (37 °C). Below these sections is the 'Sonication Type' section with a 'Type' dropdown menu set to 'Combined Modulated'. At the bottom of the dialog are three buttons: 'OK', 'Reset Values', and 'Cancel'.

Parameter	Value	Unit
Acoustic Power	100	W
Sonication Duration	10	Sec.
Spot Type	Mode0	
Frequency	0.650	MHz
Body Temperature	37	°C
Sonication Type	Combined Modulated	

Figure 9-1: Sonication Parameters Dialog Box

9.2.1. 'Sonication Parameter' frame

It is possible to change the following sonication parameters by unlocking them in the menu and typing\selecting a new value:

- **Acoustic power:** The Power to be transmitted in the upcoming sonication. Up to 1500W requested (Actual delivered power maybe lower).
- **Sonication Duration:** The sonication duration for the upcoming sonication, up to 60 seconds.
- **Spot type:** Should be left at '0' in a clinical setting.
- **Frequency:** It is possible to slightly change the Exablate transducer's transmission frequency. Since every Exablate installation is already calibrated per site, this is not recommended.

All parameters remain set until adjusted again or starting a new treatment from the main menu. If either one of the 'Acoustic Power' or 'Sonication Duration' parameters has been set from the 'Advanced Options' menu, both settings can no longer be adjusted from the main 'Treatment Stage' screen until they are locked in the menu the again.

9.2.2. 'Sonication Type' frame

It is also possible to switch between different predefined sonication types:

- **Combined Modulated:** The Default Regular sonication
- **Sham Sonication:** Zero energy sonication, if required (e.g. for Sham treatment in blinded double arm study).
- **DQA Self Test:** Low power sonication for verification of the cavitation detection mechanism in a DQA setup.
- **Treatment Self Test:** Low power sonication for verification of the cavitation detection mechanism during a treatment.



WARNING:

Before pressing 'Sonicate' for a Sham sonication, ensure that the planned sonication power displayed on screen does not exceeds 1 Watt.

W100

9.2.3. 'Thermal Dosimetry Parameters' frame

The measured temperature for sonications consists of the sum of a predefined baseline 'Body Temperature' and the measured temperature delta. The default baseline value is 37°C, but it may be changed by unlocking the 'Body Temperature' field and typing another value.

9.3. Adjusting MRI Scanning Protocol Parameters

Press the **MR Scan** tab to access the **MR Scan protocol** options.



NOTE:

N082

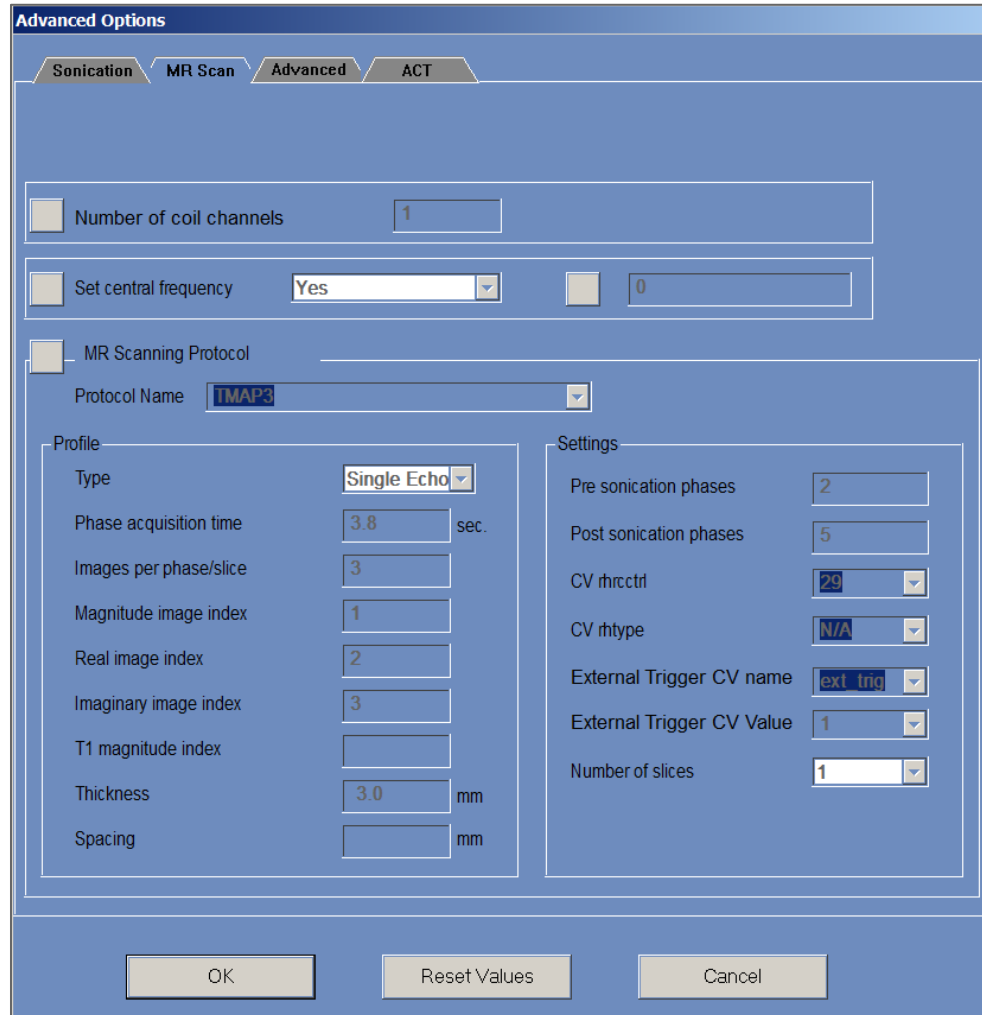
The "MR Scan" Tab settings are **for advanced research only**. Do not alter these settings without consulting your INSIGHTEC representative. The settings in the "MR Scan" tab work for certain Exablate 4000 configurations only.

9.3.1. Changing MR Parameters

- **Number of Coil Channels:** define number of coil channels when sonication with a non-nominal coil
- **Set Central Frequency:** Press the button to manually input a central frequency for thermal scans

9.3.2. Select MR Scanning Protocol

This feature and its settings are not fully supported across all Exablate 4000 WS SW7.33 configurations. Do not alter these settings without consulting your INSIGHTEC representative.



The dialog box is titled "Advanced Options" and has four tabs: "Sonication", "MR Scan", "Advanced", and "ACT". The "MR Scan" tab is selected. It contains several sections:

- Number of coil channels:** A text box with the value "1".
- Set central frequency:** A checkbox (checked), a dropdown menu with "Yes", and a text box with "0".
- MR Scanning Protocol:** A checkbox (checked) and a dropdown menu with "TMAP3".
- Profile:**
 - Type:** A dropdown menu with "Single Echo".
 - Phase acquisition time:** A text box with "3.8" and "sec.".
 - Images per phase/slice:** A text box with "3".
 - Magnitude image index:** A text box with "1".
 - Real image index:** A text box with "2".
 - Imaginary image index:** A text box with "3".
 - T1 magnitude index:** An empty text box.
 - Thickness:** A text box with "3.0" and "mm".
 - Spacing:** An empty text box and "mm".
- Settings:**
 - Pre sonication phases:** A text box with "2".
 - Post sonication phases:** A text box with "5".
 - CV rhrcctrl:** A dropdown menu with "29".
 - CV rhtype:** A dropdown menu with "N/A".
 - External Trigger CV name:** A dropdown menu with "ext_trig".
 - External Trigger CV Value:** A dropdown menu with "1".
 - Number of slices:** A dropdown menu with "1".

At the bottom are three buttons: "OK", "Reset Values", and "Cancel".

Figure 9-2: MR Scan Parameters Dialog Box

9.4. Adjusting Advanced Sonication Parameters

Press the **Advanced** tab to access the **Advanced** option dialog box.

9.4.1. Sonication Parameters

This defines the sonication focal point in RAS Coordinates. Press the button next to **Sonication Focal Coordinates**, and then **RAS** or **XYZ** to change the focal spot location in the selected coordinates.

9.4.2. Changing Thermal Dosimetry Parameters

- **Tissue Coefficient:** this defines the coefficient of the tissue for temperature map calculations. For soft tissue, use a value of **0.00909**.
- **Nominal Dose Threshold:** this defines the time in minutes to achieve a thermal dose at 43°C. The nominal threshold value is **240** minutes (see **Section 2.2.2**).

Advanced Options

Sonication **MR Scan** **Advanced** **ACT**

Sonication Parameters

☐ Sonication Focal Coordinates

RAS R A S

XYZ X Y Z

Thermal Scan Shift

☐ Axial mm

☐ Coronal mm

☐ Sagittal mm

Thermal Dosimetry Parameters

☐ Tissue Coefficient

☐ Nominal Dose Threshold

OK Reset Values Cancel

Figure 9-3: Advanced Sonication Parameters Dialog Box

9.5. Adjusting Acoustic Correction Parameters (ACT)

Press the **ACT** tab to access the **ACT** dialog box.

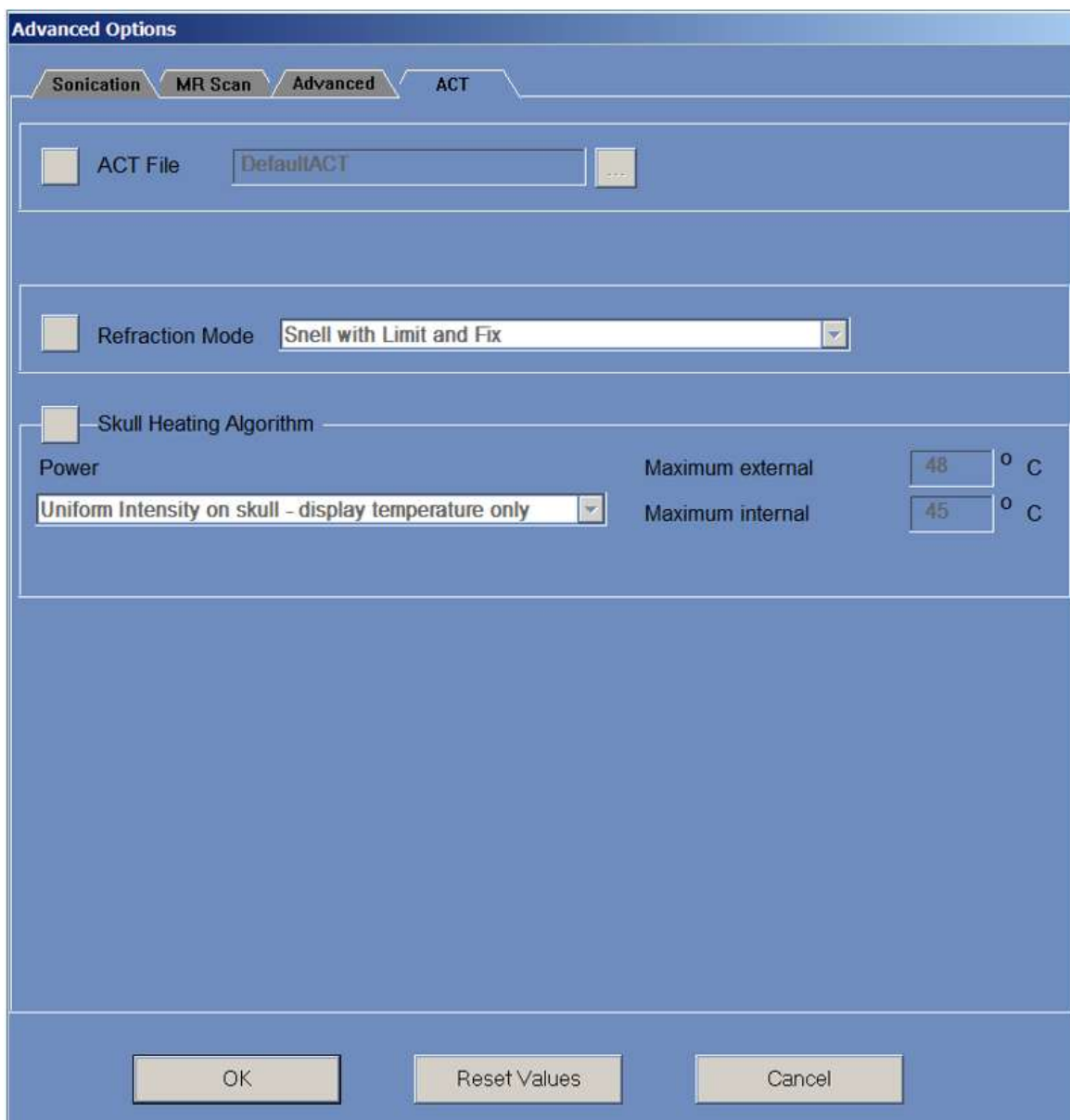



Figure 9-4: Acoustic Correction Parameters Dialog Box

9.5.1. Changing ACT

The **ACT** file determines the amplitudes and the phases of the transducer elements. Press the  button next to **ACT File** to load new **ACT** file. Press this button to open the file browser and select the required **ACT** file.

9.5.2. Changing Refraction Mode

The refraction modes are used for acoustic calculations. Press the button next to **Refraction Mode** to change the correction calculation. The options are:

- Snell with Limit and Fix (default)
- Snell Refraction
- Prediction Refraction

9.5.3. Changing the Skull-Heating Algorithm

Skull heating is an algorithm for temperature calculations near the skull during sonication. The skull-heating algorithm determines the power distribution of the transducer elements. Press the button next to **Skull Heating Algorithm** to select one of the following options:

- **Disable Skull Heating** – for not using this algorithm.
- **Uniform Intensity - display temperature only** – for uniform power distribution of the elements. The temperatures near the skull will be displayed and won't affect the power.
- **Uniform Intensity - modify sonication power** – for uniform power distribution of the elements. If the temperatures near the skull are above pre-defined thresholds, the power is cut off.
- **Distributed Intensity - display temperature only** – for non-uniform power distribution of the elements depending on the temperatures near the skull.
- **Distributed Intensity - modify sonication power** – for non-uniform power distribution of the elements depending on the temperatures near the skull. If the temperatures near the skull are above pre-defined thresholds, the power is cut off.
- **Uniform Intensity on the skull - display temperature only** – for power distribution of the elements depends on uniform intensity on the skull.

If required, change the following thermal parameters that are part of the skull-heating algorithm:

- **Maximum External** – defines the external temperature threshold.
- **Maximum Internal** – defines the internal temperature threshold.

10. REPLAY STAGE

10.1. Overview

Replay mode enables you to analyze the results of previous sonications. **Replay** can also be activated from **Data Management** (see **Chapter 13**) to view past treatments.

Press the **Replay** button in the main toolbar to access the **Replay** screen. This screen is similar to the **Thermal Evaluation** screen displaying the results of the last performed sonication (see **Section 8.2**). This way the operator can observe the acquired temperature maps and the temperature graph of all previous sonications.

Replay

If you access **Replay** from **Data Management**, the **Replay** screen displays the first sonication in the treatment.

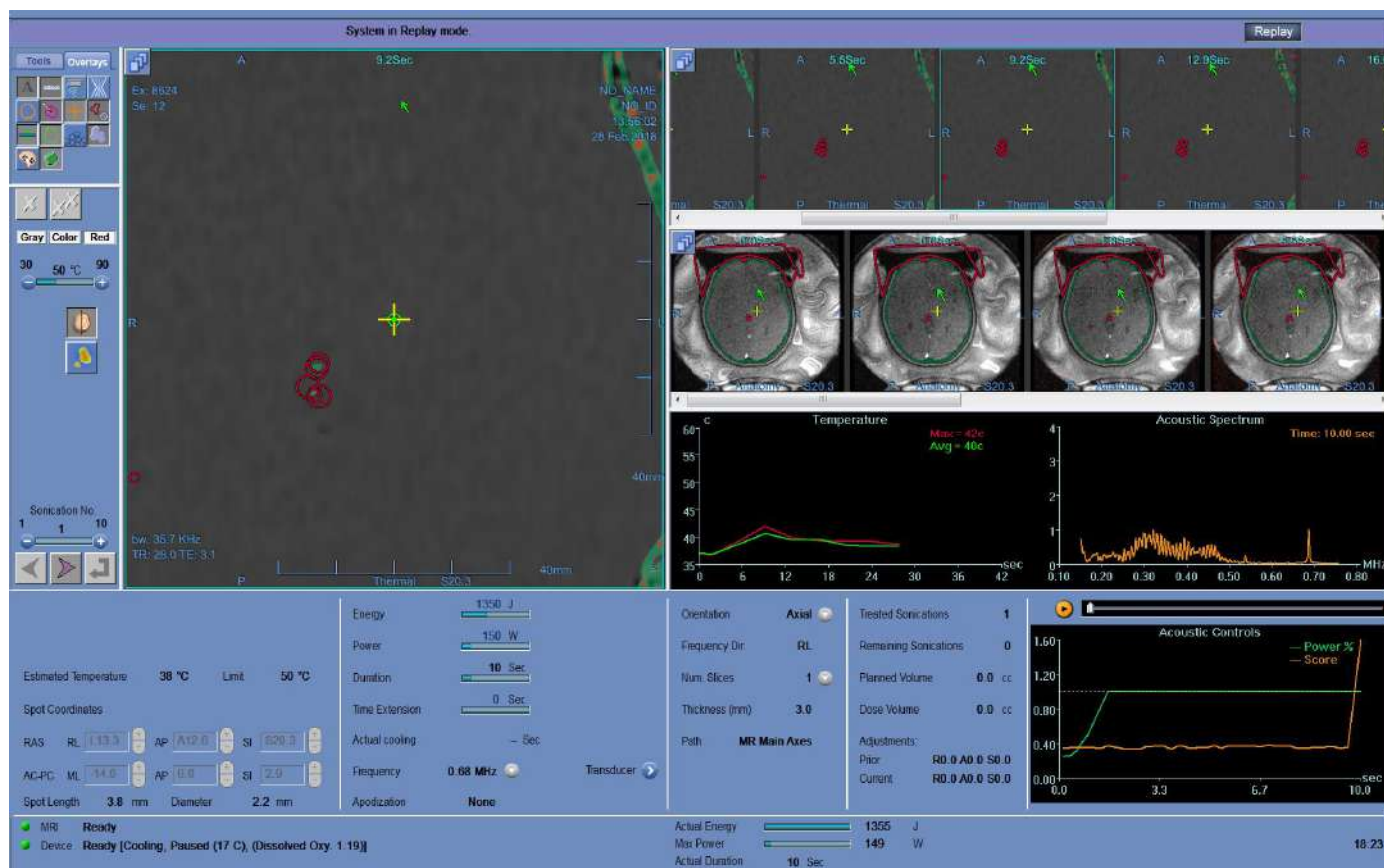


Figure 10-1: Replay Mode Screen

10.2. Sonication parameters

When a treatment conducted with a previous Exablate WS version (e.g. WS7.0) is loaded into the WS7.33 Replay mode, the sonication parameter display will not show the prescribed energy, the energy delivered can still be seen at the bottom of the screen (See **Figure 10-2**).

Note that "time extension" will always be displayed as zero since it is contained in the regular sonication duration for WS7.0 (See **Figure 10-2, Bottom**).



Figure 10-2: WS7.0 Treatment's sonication parameters displayed on WS 7.0 (Top) versus on WS 7.33 (Bottom)

10.3. Replay Action Tools





Next or Previous Sonication

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



Sonication No. Bar

Use the  and  buttons in the **Sonication No. Bar** to choose to view a certain sonication and press this button.



10.4. Exit Replay

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



11. UTILITIES

11.1. Overview

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

These means include MR operations, turning device ON/OFF, operate water system, connection to the site network, **Trackers** use, and changing **Calibration** mode, **Acoustic** mode, **Temperature** limit definition and **Tissue** type.

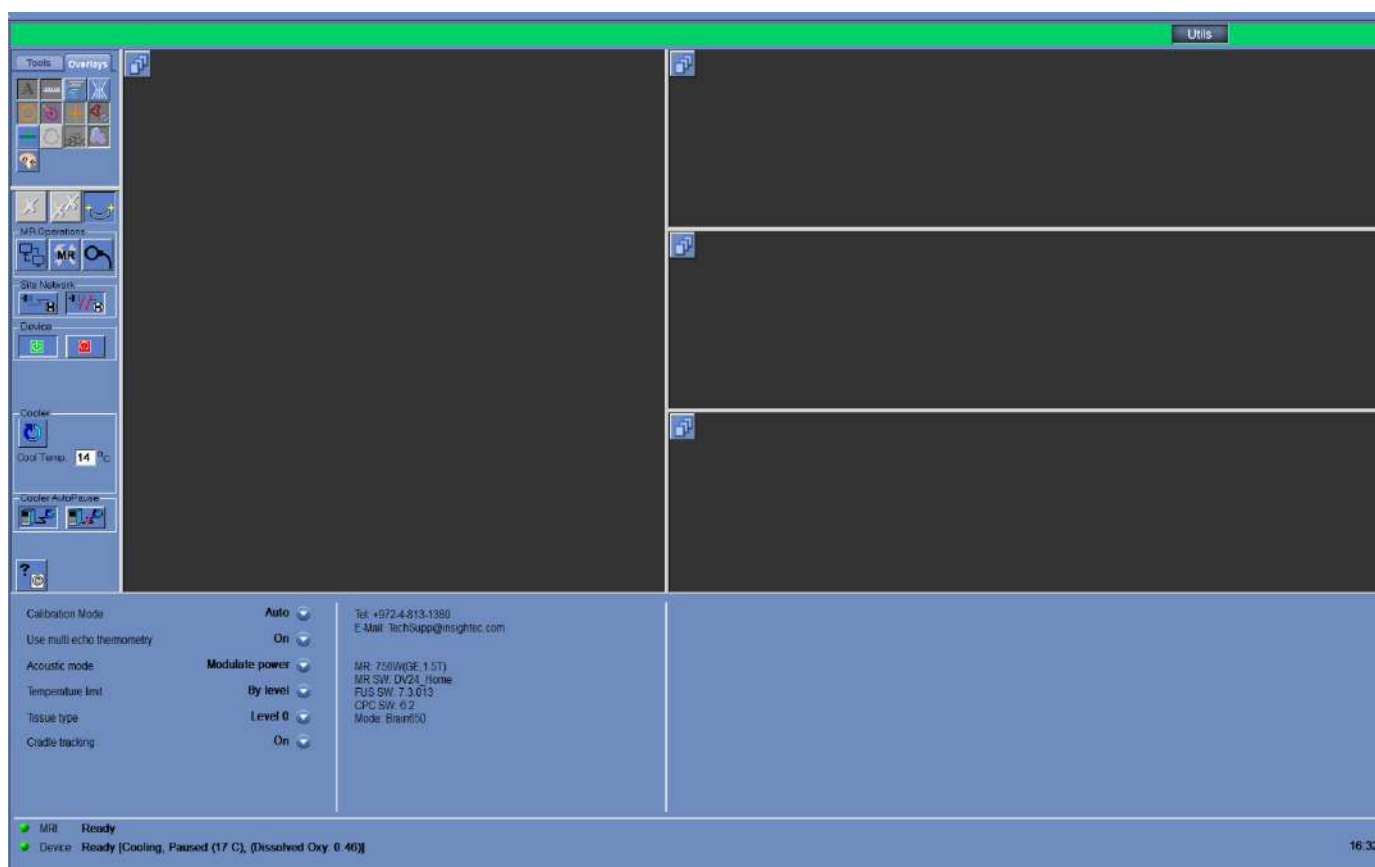











Figure 11-1: Utilities Screen

11.1.1. Utilities Action Tools

The **Utilities** tools are (refer to **Figure 11-1**):

Image	Name	Description
	Reset MRI Communications (GE Only)	Reset MRI Communications
	Setup MRI	Press the Setup MRI button to manually reset the connection to the MRI and/or the MR protocols in the MR system (if they were changed or removed).
	Switch MR Coil	Press the Switch MR Coil button to define the MR coil used for the treatment scans as the alternative coil.
	Disable/Enable Trackers	<ul style="list-style-type: none"> Press this button to enable/disable the use of trackers to locate transducer's location. Default option is ON.
	Turn Device ON/OFF	<ul style="list-style-type: none"> Press red button to turn the device OFF. Once Shutdown completes (see Device Status bar) press the green button to turn device back ON.
	Connect/Disconnect to the Site network (GE Only)	<ul style="list-style-type: none"> Press this button to connect the MR system to the hospital network. Press this button to disconnect from the hospital network.
	Operate Water System options	<p>Press this button to:</p> <ul style="list-style-type: none"> Turn Cooler ON/OFF. Set Transducer temperature. Set Preparation Stage – transferring the system to degassing mode. Set Clean stage. Set Treat stage – this stage comes automatically ON when treatment begins.
	Enable/Disable Water System Auto-Pause	<p>Press this button to manually control water circulation.</p> <p>Press this button to automatically pause the water circulation whenever MR scan is performed.</p>
	Copyright Notice	Press this button to review the list of open source software that components of the product may incorporate or be distributed with.

11.2. Utilities – MR Tools

11.2.1. Reset MR Communications

Press the **Reset MR Communications** button to refresh the connection between the FUS WS and the MRI.



11.2.2. Setup MR Protocols

Press the **Setup MRI** to manually reset MR settings and restore the connection between the Exablate system and the MRI.



11.2.3. Switch MR Coil (Optional where Applicable, i.e. sites using the Insightec Head Coils)

For each site, a default and an alternative coil are defined during the installation process.

The **Switch MR Coil** procedure is performed when there is a need to use the alternative coil instead of the default coil (e.g. Scan with the MRs integrated body coil instead of the Insightec Head Coil).

- Press this button and select the coil you want to use from the existing coils; the system will automatically define the MR coil in use as the alternative coil. From this point on, all scans will be performed using the alternative coil.
- To return to the default coil definitions, press the same button again and select the correct coil or exit the treatment.



11.2.4. Disable/Enable Trackers

This procedure is to be used when there is a tracker scan failure, or the trackers results are wrong and consequently the system interprets it as transducer movement.

The default option is ON, therefore **Calibrate** stage will be performed with trackers and a trackers scan will be performed before each sonication.

Press the same button to change it to **OFF**.



11.2.5. Turn System Hardware ON/OFF

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

Press this button to turn OFF the Exablate Neuro system.

When the device shutdown is complete, the **Device Status** (in the status bar) appears as **Not connected**.



Press this button to turn ON the Exablate Neuro system; when the device is ON, the **Device Status** (in the status bar) appears as **Ready**.



11.2.6. Connect/Disconnect to the Site Network

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

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

**CAUTION:**

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

C031

11.2.7. Operate Water System

This procedure is used when the water system needs to be switched to degassing mode (before **Treatment** or **DQA**), needs to set to **Cleaning** stage or needs to be restarted in the middle of a treatment.

Press this button and select the preferred option:



1. Turn the water system ON/OFF; the status bar indicates when the shutdown is complete. Press again to turn ON the water system; the status bar indicates when the water system is active.
2. Set the **Preparation** stage – transferring the system to degassing mode before treatment or DQA.
3. Set the **Cleaning** stage – transferring the system to cleaning mode after treatment.

The option of **Set Treat Stage** is automatically selected when treatment begins.

In addition, you can set a preferred cooling temperature by entering the degrees into this field and pressing **Apply**.

Cool Temp. 14 °C

11.2.8. Enable/Disable Water System Auto-Pause

This procedure is used to control the water circulation. Disable **Water System Auto-Pause**, mainly when you acquire images through the MR (e.g. post-treatment imaging).

1. Press this button to manually control the water circulation.
2. Press this button to automatically pause the water circulation whenever MR scan is performed. This will be indicated in the status bar.



11.2.9. Change Calibration Mode

The calibration procedure is automatically performed by the system.

This procedure is used when there is a tracked scan failure, or there is a need for wide imaging coverage. When the narrow imaging coverage of the default scan is not enough, the calibration can be set to a manual mode by selecting it from the **Calibration Mode** list.



Figure 11-2: Calibration Mode List Header

11.2.10. Enable Multi-Echo

Set this button to ON to enable using a **Multi-Echo** scans for a single slice, or multi-slices where available.



Figure 11-3: Enable Multi-Echo Scan Type

11.2.11. Change Real-Time Power Control – Acoustic Mode

This feature enables you to perform sonications in a closed loop to control the power to keep the acoustic signal within predefined thresholds and below the cavitation safety threshold.

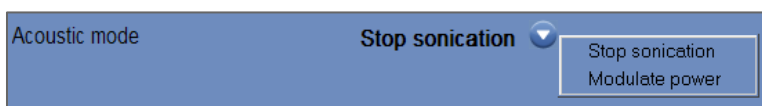


Figure 11-4: Acoustic Mode Options (in Clinical Setup)

During sonication, the acoustic spectrum is being monitored. Acoustic spectrum with high values in the range of half of the transmitting frequency indicates a possibility for cavitation effects. If this occurs during a sonication, the system will automatically react depending on the current **Acoustic** mode:

- **Stop Sonication** – the system will automatically stop energy transmission if the acoustic signal crosses the predefined thresholds.
- **Modulate Power** – the system will reduce power automatically until the acoustic signal falls below the threshold. The system then will try to increase power again while keeping the acoustic signal below the threshold.
- **OFF** (available only for pre-clinical use) - acoustic signal will not affect the sonication and it will be done as is.

11.2.12. Change Temperature Limit Configuration

Temperature limit is an additional feedback tool to monitor the thermal rise in real-time.



Figure 11-5: Change Temperature Limit

During sonication, the temperature in the sonication area is monitored based on real-time thermal imaging.

If the temperature exceeds the defined maximal temperature value, the system will automatically stop energy transmission, while the MR scan will continue as prescribed.

You can select from the following menu:

OFF - to disable this feature.

By level - limit is based on current treatment level (default value).

By estimation - limit is based on the estimation from the Temperature Estimator.

11.2.13. Change Tissue Type

There are two options for tissue type:

- **Mode 0 (Default)** – For use in alignment sonications and when treating complex tissue (boundary areas, near scars or for unknown or previously untreated tissue types, for example under clinical trials). In this mode, the system has lower thresholds for spectrum-based power modulation.
- **Mode 1** - Once alignment is complete (when treating approved indications, away from any anatomical anomalies) the user may switch to Level 1. Level 1 Tissue Type sonications allow for more variability in the acoustic signal prior to power modulation, and can therefore be used, for example, to overcome stutters in the power increase ramp.



NOTE:

The cavitation halt safety thresholds for both tissue types are identical.

N083

11.2.14. Disable Cradle Tracking (Type 1.1 Systems only)

In setups where cradle tracking is irrelevant, it may be disabled by setting **Cradle Tracking** to **OFF**. This means that a corrected HS relative coordinate system will no longer be displayed on the MR images, and any rigid change to the cradle's location will be ignored. **Patient** and **Transducer Movement Detection** algorithms will remain **Active**.



Figure 11-6: Cradle Tracking ON/OFF Settings



WARNING:

Disabling Cradle Movement Detection increases the risk for miss-targeting and is highly discouraged in a clinical setting

W102

11.3. System Configuration Information

Information regarding the system is displayed, including WS and CPC version, MRI type and SW, and FUS Mode. In Utility menu, this information is available only in treatment mode.

The software revision is defined by the first numbers (e.g. "7.33 ", not "7.33.54"):



NOTE:

N104

Information regarding the system can be found in Replay mode as well, on the bottom of the screen.

11.4. Copyright Notice

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

11.5. Exit Utilities

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

12. CLEANING AND DISINFECTION PROCEDURE

12.1 Cleaning/Disinfection Materials

CLEANING OF THE EXABLATE SYSTEM REQUIRES THE FOLLOWING:

■ Water Tank Disinfection

Sodium Hypochlorite (CAS # 7681-52-9) 4.00 - 4.99%, for disinfection and maintenance of the Exablate Water Tank, Water System and Transducer

For type 1.0 systems: 75mL (e.g. three 25ml bottles)

For type 1.1 systems: 50mL (e.g. two 25ml bottles)

The disinfection solution should include only Sodium Hypochlorite as the active material, without additional active ingredients (bleach, for example, is not suitable).



CAUTION:

Use of materials that deviated from the above instruction may result in system damage and reduced performance.

C043



NOTE:

Contact your INSIGHTEC representative for more information or if assistance is needed in acquiring the required cleaning materials.

N084

■ Surface cleaning & disinfection

One package of (at least five) Disinfecting wipes, containing 0.2 - 0.4% of benzalkonium chloride (CAS # 8001-54-5) for use in cleaning and disinfecting the Silicone Cover, Transducer and Exablate Accessories (see below).



NOTE:

The cleaning/disinfection procedure must be performed after completion of each patient treatment.

N085



CAUTION:

It is recommended to wear personal protective equipment (i.e. gloves) when handling the membrane and performing the cleaning procedure (handling system components, cleaning solution and wipes)

C032

12.2 Patient Membrane and Coil Handling Procedure

Patient membranes and Coils are provided non-sterile and are intended for single-use only. Discard of membranes, coils and their storage box after each use according to the local/site procedures.

12.3 Type 1.0 Exablate Table Cleaning Procedure

As the table falls within the confines of a non-sterile healthcare environment, INSIGHTEC expects the table to be covered with a cover with each subject.



NOTE:

The cover and table should be handled according to Institution requirements.

N086D

Use the dedicated surface cleaning and disinfection wipes (specified in **Section 12.1**) to thoroughly wipe all exposed surfaces of the procedure table.

12.4 Type 1.1 Exablate MRI Adapter baseplate, HS and Table Cleaning Procedure

As the MRI table falls within the confines of a non-sterile healthcare environment, INSIGHTEC expects the table to be covered with a cover for each patient.



NOTE:

N086D

The cover and table should be handled according to Institution requirements.

Step1. Prior to the cleaning process, transfer the Helmet System to the Storage and transfer cart

Step2. Use paper towels or a cloth to absorb soak up and wipe any excess water that may have accumulated in the baseplate basin and finish off by wiping the baseplate surface with a disinfecting wipe (specified in **Section 12.1**)

Step3. Disconnect and stow Adapter Baseplate

Step4. Use the dedicated surface cleaning and disinfection wipes specified in **Section 12.1** to thoroughly wipe all exposed surfaces of the Helmet System (Type 1.1), Frame and the Frame holding posts



NOTE:

N087

After removing the Helmet System from the MR Table, the MR may be used while the cleaning process is ongoing.

12.5 Transducer Cleaning Procedure

Clean the inner surface of the Transducer with dedicated surface cleaning and disinfection wipes (specified in Section 12.1). wipe all surfaces. See **Figure 12-1**. When cleaning the inner part of the Transducer, do so with extreme care to avoid scratching the elements.

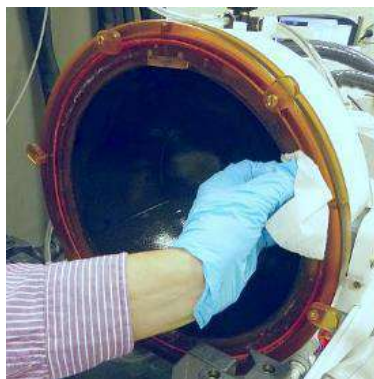


Figure 12-1



NOTE:
Wiped surfaces should be allowed to dry freely

N088

12.6 Type 1.0 Transducer and Water System Disinfection Procedure

- Step1. Turn on the Water System (refer to Exablate Neuro Operator's Manual for instructions).
- Step2. Verify that the Transducer is completely empty from water or soil. If not, drain it of water and/or clean visible soil with the provided cleaning and disinfection wipes (specified in **Section 12.1**).
- Step3. Open the compartment of the water tank in the water system by lifting the cover of the water tank cabinet. **See Figure 12-2.**



Figure 12-2



Figure 12-3

- Step4. Disconnect the pipes. See **Figure 12-2**.
- Step5. Open the cover of the water tank. See **Figure 12-3**.
- Step6. Dispose of the water in the tank by pouring it into a sink or water disposal vessel. Place tank upside down and make sure it is completely empty and verify visually.
- Step7. Using dedicated funnel, fill the tank (20 liters) with fresh Reverse Osmosis water (or Type 2 medical grade water) at room temperature (15-25°C). Use the fill line marking on the reservoir for water quantity of 20L.
- Step8. Pour 75ml of Sodium Hypochlorite (CAS # 7681-52-9) 4.00 - 4.99%, into the **Water Tank**.



NOTE:
Store and handle the cleaning solution according to manufacturer specifications.

N089D

- Step9. Re-connect the pipes to the tank.
- Step10. Make sure that the water system hose is connected to the procedure table. See **Figure 12-4**.

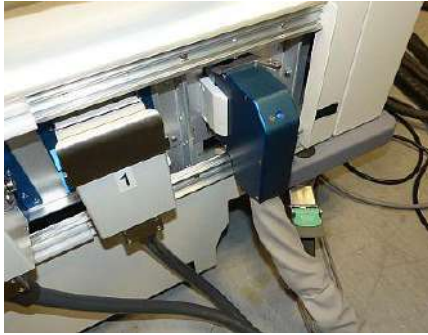


Figure 12-4



Figure 12-5

Step11. Press ESC on the Water System main screen. See **Figure 12-5**.

Step12. Press #3 for **Clean** option. See **Figure 12-6 (R)**.

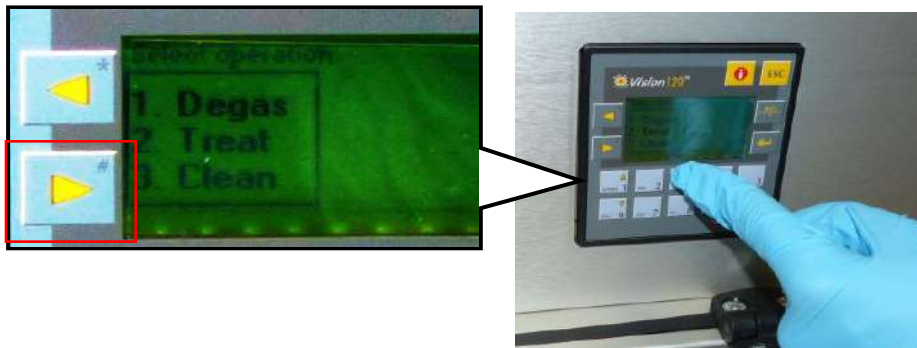


Figure 12-6


Step13. Press the **Circ** button on the **Clean** screen to start the cleaning operation (See **Figure 12-6 (L)**). Two timers will start working, one subsequent to the other. The first timer, 15 minutes in duration, shows the cleaning time of the water tank, and the second one shows the transducer cleaning time. During the first period the water tank is rinsed with the cleaning solution for disinfection. The water temperature during cleaning is controlled by the system and set to 20°C.



Figure 12-7



Figure 12-8

- Step14. If the pipes are not connected properly to the Tank, an error message **Low Xd Flow** will show-up. Rectify the problem and press **Enter** () to continue. See **Figure 12-8**
- Step15. Clean the Phantom Holder Interface Membrane with dedicated cleaning and disinfection wipes (specified in **Section 12.1**). Thoroughly wipe all surfaces, including the frame, to assure effective disinfection.
- Step16. Assemble the DQA Set Up Holder as described in section 5.1 and seal with it the Transducer (without the DQA Phantom Gel). See **Figure 12-9**.

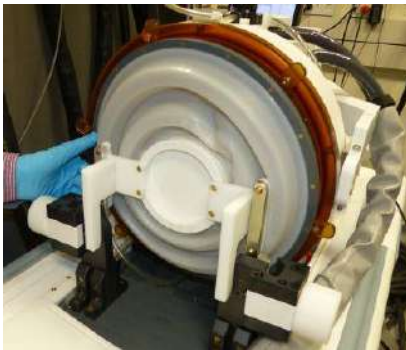


Figure 12-9



Figure 12-10

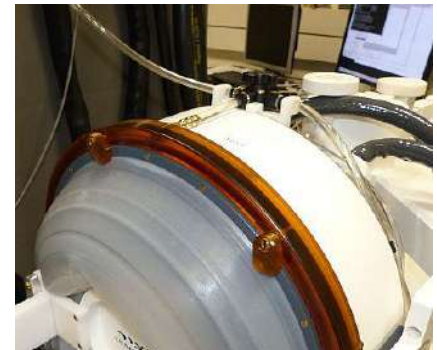


Figure 12-11

- Step17. Be sure to lock the Holder with all the clamps around the Transducer frame. **Figure 12-10**.
- Step18. Open the Valve on top of the Transducer to allow air to escape when the Transducer interface is filled with water. **Figure 12-11**.
- Step19. When first timer is done, press the Fill button on the Remote Controller (**Figure 12-12**) and fill the prepared water in the Transducer interface, until it overflows through the valve (**Figure 12-13**).

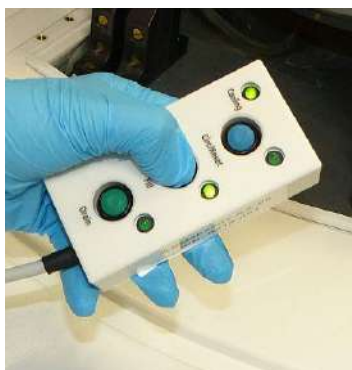


Figure 12-12

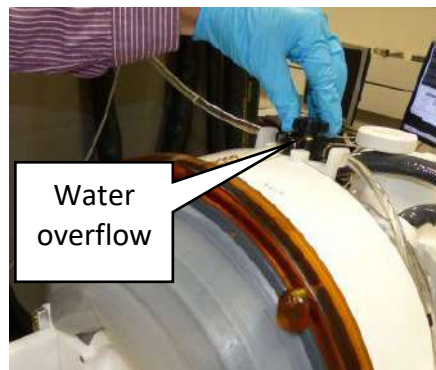


Figure 12-13



Figure 12-14

- Step20. Close the Valve. See **Figure 12-13**.
- Step21. Press the **Circ** button on the Remote Controller to start the **Clean Xd** timer (for 16 minutes). Verify that the circulation LED next to the **Circ** button is ON, indicating uninterrupted circulation. See **Figure 12-14**.

Step22. This stage takes 16min of rinsing the Transducer (Xd) and hoses with the cleaning solution for disinfection.

Step23. When the Clean Xd timer reaches 0, open the valve to allow drainage of the water.

Step24. Press the Drain button on the Remote Controller to drain the water from the Transducer (see **Figure 12-15**). Release the button once all the water has been evacuated.

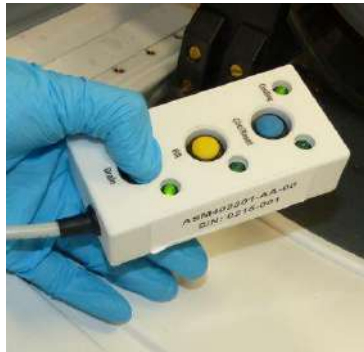


Figure 12-15

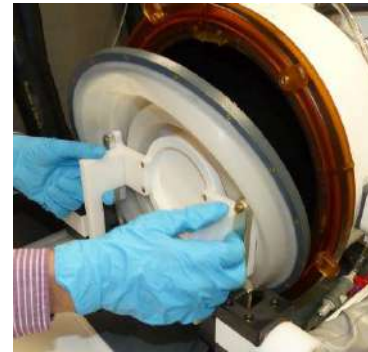


Figure 12-16

Step25. Release the clamps and remove the Phantom Holder Interface Membrane. See **Figure 12-16**.

Step26. Clean the Transducer internal surface with dedicated cleaning and disinfection wipes (specified in **Section 12.1**).

(see **Figure 12-17**) Use the wipes to clean and disinfect any other surfaces that may have been in contact with subject or staff.

Step27. Clean the Protective Cover with dedicated cleaning and disinfection wipes specified in Section 12.1 (see **Figure 12-18**).



Figure 12-17



Figure 12-18

Step28. Protect transducer surface using the protection cover (see **Figure 12-18**). Verify XD valve is still open, to avoid over pressure, and so that transducer can dry freely.

Step29. Dispose of the water from the 20 Liter water tank according to local regulations.

Step30. Leave the tank open and upside down for thorough drying



NOTE:

N090D

A residual water quantity of up to 5L may remain in hoses. This will be flushed out from system as part of the start-up cleaning/circulation prior to treatment set up

12.7 Type 1.1 Transducer and Water System Disinfection Procedure

Step1. If off - turn on the Water System (Refer to Exablate Neuro Operator's Manual for instructions).

Step2. Verify that the Transducer is completely empty from water or soil. If not, drain it of water and/or clean visible soil with the provided cleaning and disinfection wipes (specified in **Section 12.1**).

Step3. Open the compartment of the water tank in the water system by opening the water tank compartment door. **See Figure 12-19.**



Figure 12-19

Step4. Disconnect the pipes. see **Figure 12-20.**

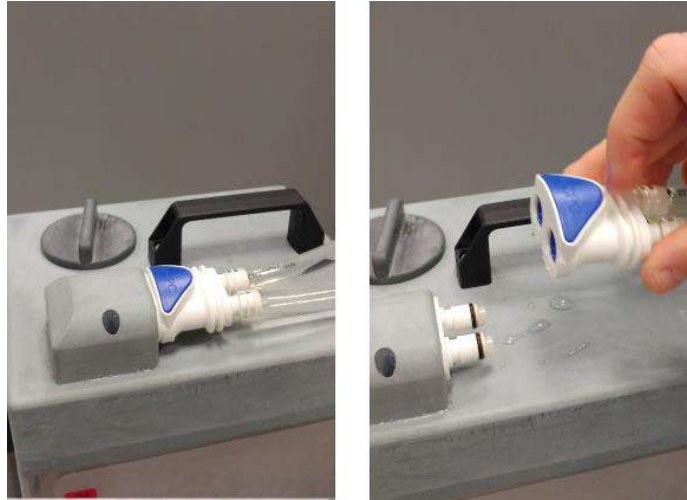


Figure 12-20

Step5. Open the cover of the water tank. see **Figure 12-21**.



Figure 12-21

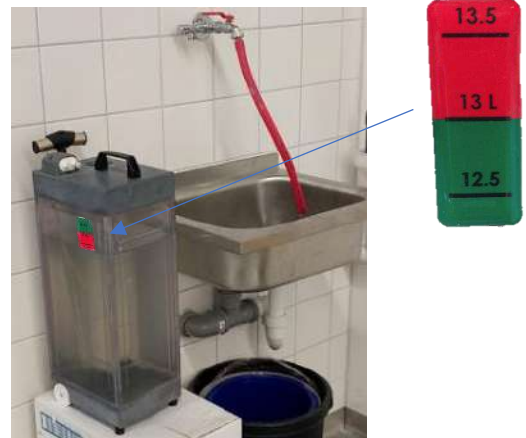


Figure 12-22

Step6. Dispose of the water in the tank by pouring it into a sink or water disposal vessel. Place tank upside down and make sure it is completely empty and verify visually.

Step7. Fill the tank with 13 liters of fresh Reverse Osmosis water (or Type 2 medical grade water) at room temperature (15-25°C). Use the fill line marking on the reservoir. See **Figure 12-22**.

Step8. Pour 50ml of Sodium Hypochlorite (CAS # 7681-52-9) 4.00 - 4.99%, into the **Water Tank**.



NOTE:

N089D


Store and handle the cleaning solution according to manufacturer specifications.

Step9. Re-connect the pipes to the tank and place in its compartment in the Front End.

Step10. Make sure that the water system hose is connected to the Front End. See **Figure 12-23**.



Figure 12-23

Step11. On the Water system main screen (**Figure 12-24**), press the 'Clean' option 

The system will switch to Clean Mode (**Figure 12-25**)


(NOTE: If not at home screen, press the 'Home' button )



Figure 12-24: 'Home' Menu



Figure 12-25: 'Clean' Menu – on Hold


Step12. Press 'Start'  button to start the cleaning operation (**Figure 12-26**). A countdown timer will appear, displaying the remaining Tank cleaning time



Figure 12-26: 'Tank Cleaning in Progress'



Figure 12-27: 'Cleaning Tank Completed' Screen

Step13. Once the timer reaches zero, a completion message appears (**Figure 12-27**) and the system is ready for stage two of the Cleaning cycle – Transducer cleaning.

Step14. Verify that the Transducer is connected to the water system connector at the Front-End

Step15. Clean the Phantom Holder Interface Membrane with dedicated cleaning and disinfection wipes (specified in **Section 12.1**). Thoroughly wipe all surfaces, including the frame, to assure effective disinfection. **Figure 12-28**.

Step16. Assemble the DQA Set Up Holder as described in section 5.1 and seal with it the Transducer (without the DQA Phantom Gel). See **Figure 12-29**.

Step17. Be sure to lock the Holder with all the clamps around the Transducer frame. See **Figure 12-30**.



Figure 12-28

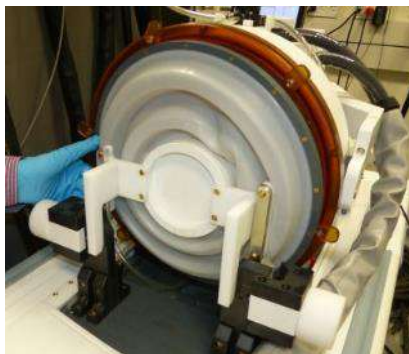


Figure 12-29




Figure 12-30

Step18. Open the Valve on top of the Transducer to allow air to escape when the Transducer interface is filled with water. See **Figure 12-31**




Figure 12-31: Air Release Valve (open)

Step 19. Fill the transducer via the Fill button  on the interface or the Water System Remote Controller so that the membrane is completely full. Close the Valve once the transducer is full.

(**Tip:** bringing the Transducer to an inferior position reduces the required volume for filling the Transducer interface, shortening filling time)

Step 20. Close the Valve once the transducer is full

Step 21. Press 'Start'  (on Screen (**Figure 12-32**) or Remote Controller (**Figure 12-33**)) to start 'Cleaning Transducer' timer

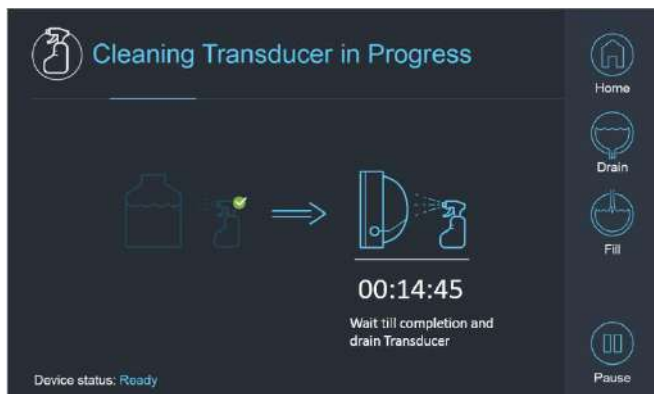


Figure 12-32: 'Cleaning Transducer in Progress'



Figure 12-33: Water System Remote Controller

Step 22. When timer is over, transducer cleaning is complete (**Figure 12-34**)



Figure 12-34: 'Cleaning Transducer Complete'

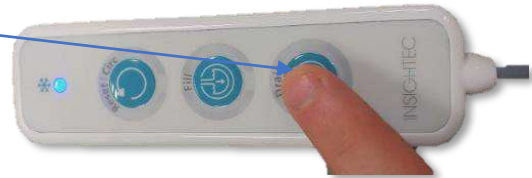



Figure 12-35: Drain

Step23. Set the Release valve to air

Step24. drain  the water from the transducer using the Screen or Remote, (**Figure 12-34**)

Step25. Dispose the water from the 13 Liter water tank according to local regulations, and leave the Tank open to air (Without valve)

Step25. Remove the sealing from the transducer-patient interface

Step26. Release and remove the Phantom Holder Interface Membrane (**Figure 12-36**).

Step27. Dry it using paper towels or a rag



Figure 12-37



Figure 12-36

Step28. Clean the Protective Cover (**Figure 12-37**) with dedicated cleaning and disinfection wipes (specified in **Section 12.1**).

Step29. Protect transducer surface using the protection cover (**Figure 12-37**). Verify XD valve is still open, to avoid over pressure, and so that transducer can dry freely.



NOTE:

a residual water quantity of up to 5L may remain in pipes. This will be flushed out from system as part of the start-up cleaning/circulation prior to treatment set up.

N090D

13. DATA MANAGEMENT

13.1. Overview

Data Management provides the following options:

- Store treatment records.
- Review treatment records.
- Export treatment records to a CD or USB flash drive.
- Import treatment records from a CD or USB flash drive.



NOTE:

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

N091

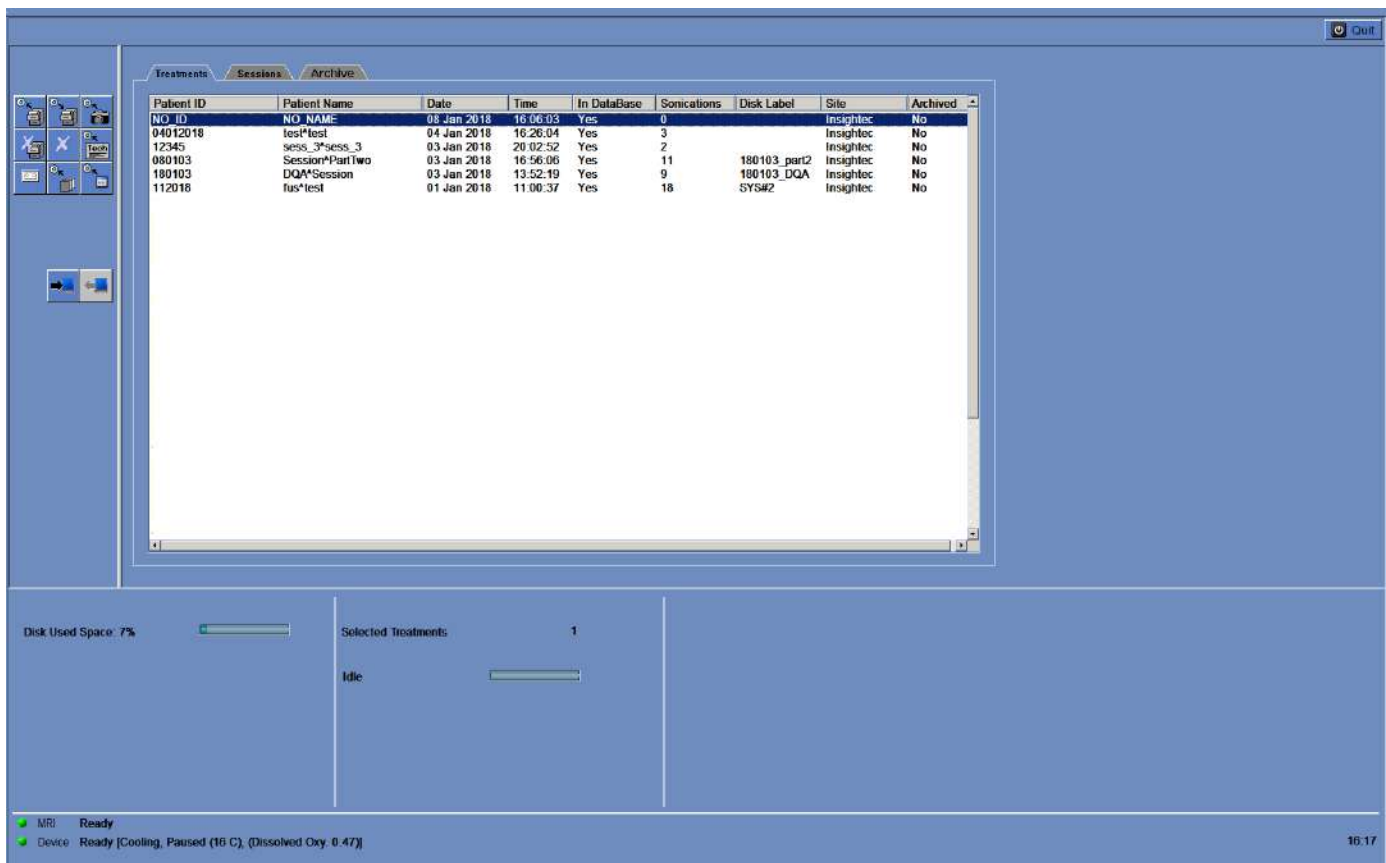


Figure 13-1: Data Management Screen

13.1.1. Cyber security

**CAUTION:**

C034

Only authorized personnel is allowed to physically access the ExAblate workstation.

**CAUTION:**

C035

Maintain physical access control to the MR control room and the Workstation

**CAUTION:**

C036

Maintain physical access restriction to the MR service area and the Equipment Cabinet.

**CAUTION:**

C017D

ExAblate Workstation username & password should not be printed or shared with anyone.

**NOTE:**

N092

It is recommended to contact your INSIGHTEC representative to modify the initial password and replace it with a strong password which fits your local password policy.

**CAUTION:**

C037

In case the WS and/or CPC hard drive/s physical security cannot be guaranteed in the MR control room or the Equipment Cabinet room, detach with the dedicated keys the WS and/or CPC hard drive/s when the system is not in use and store them in a safe and accessible controlled location.

**WARNING:**

W104

USB devices (such as Disk on Key) should be used on ExAblate workstation only by authorized personnel. USB devices require prior malware scan (by Anti Virus /Anti Malware).

Do not use the USB port to charge other equipment.

Do not insert into USB ports unauthorized devices including radiofrequency (RF) transmitters.

**NOTE:**

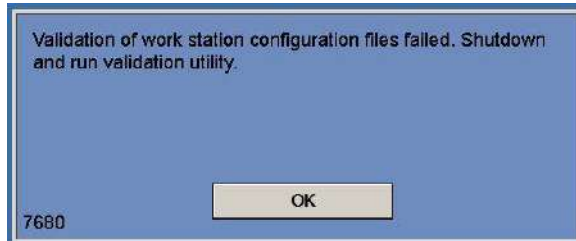
N093

It is recommended to use caution when transferring private patient information to portable media devices. The use encrypted USB devices is recommended.

**CAUTION:**

C038

In case of a security event resulted in an Ini-file modification, the following alert message will appear on the workstation screen:



Contact the local IT and Insightec service representative and do not proceed using the system until the issue is resolved.

Every Treatment export includes system login audit logs and Anti-Virus event logs.

- Login audit logs to the WS and the CPC can be found in a windows event viewer called 'WsSecurity.evt' and 'CpcSecurity.evt'.
- Anti-Virus event logs can be found in text files called 'OnAccessScanLog.txt', 'OndDemandScanLog.txt' and 'AccessProtectionLog.txt'.

**NOTE:**

N094

It is strongly recommended that local IT personnel evaluate periodically the system login audit logs and Anti-Virus event logs of treatment exports and estimate if there is any suspicion of cyber security events.

**CAUTION:**

C039

Shut down the system and disconnect the Workstation pc from the socket upon detection of a cybersecurity vulnerability or a security incident in the Exablate device. Report on security incidents and near misses, including those involving portable information assets, to your local IT Help/Service Desk and your Insightec representative

**WARNING:**

W105

Cybersecurity and software updates should only be implemented by authorized Insightec technicians/personnel.

Users should not accept or implement any updates on the Workstation or CPC (See section 2.1.3).

For security and compliance reasons, The Exablate 4000 workstation is not equipped with wireless capabilities.

**CAUTION:**

C040

It is forbidden to connect wireless adapters such as Wi-fi or Bluetooth adapters to the Exablate 4000 workstation pc.

13.1.2. Exablate System Minimum Network Requirements and Security Configurations









Requirement	WS	CPC	SBOX	Exablate LAN Switch	Customer Firewall	Customer network Switch
Network Switch				Layer 2 LAN Switch Min' 5 Ethernet 100/1000Mbps ports		
IP Address	1 fix IP address	1 fix IP address	1 fix IP address			
LAN network link speed	1Gbps	1Gbps	1Gbps	100/1000Mbps	100/1000Mbps	100/1000Mbps
WAN network link speed			100/1000Mbps		100/1000Mbps	100/1000Mbps
WAN bandwidth					Minimum 15Mbps	
Open TCP/IP ports	All (LAN)	All (LAN)	All (LAN) TCP (WAN) 3389,135,139,445,5800,5900,20,21 UDP(WAN) 137,138		<u>Terminal services:</u> TCP 3389 <u>Computer browsing</u> TCP 135, TCP 139, TCP 445, UDP 137, UDP 138 <u>VNC ports:</u> TCP 5800 TCP 5900 FTP: TCP 20,21 <u>HTTP/s:</u> TCP 80,443	
Site to Site Encryption					Encryption domain: IKEv1 Diffie-Hellman Group2 No PFS IKE security associations 1440 minutes Renegotiate IPsec security associations every 3600 seconds Phase 1: 3DES/SHA1 Phase 2: 3DES/SHA1	
LAN Latency	< 1Ms	< 1Ms	< 1Ms	< 1Ms		< 1Ms
WAN Latency			< 400Ms		< 400Ms	
Caballing	Minimum IEEE cat 5e					

13.2. Selecting a Patient

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

13.2.1. Action Tools

The following commands appear on the **Data Management** screen (see **Figure 13-1**):

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



NOTE:

N095

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

13.2.2. Export to CD or USB Flash Drive

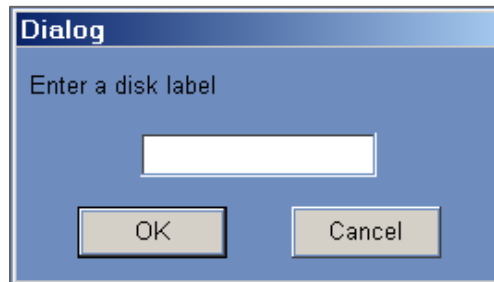


Figure 13-2: CD Disk Label Dialog Box

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

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



13.2.3. Import Treatment Records from CD or USB Flash Drive

To import one or more treatment records:

Place the CD with the treatment files in the CD drive or connect the appropriate USB device.

Press this button; select **From CD/DVD** or **From USB** from the drop-down menu; the imported treatments will be copied to the local drive and will be shown in the **Patient List** (see **Figure 13-3**).

13.2.4. Screen Dump to CD or USB Flash Drive

To store snapshots associated with the selected treatment:

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



13.2.5. Erase Selected Treatment



Use this button to erase selected treatment records from the database but leave the treatment's details in the **Patient List** (see **Figure 13-3**).

1. Select records to be erased from the patient list.
2. Press this button to erase treatment record. Records will be erased from the Database, but treatment details will remain on the patient list.



NOTE:

N096

- While Erased treatment information will still be displayed in the Patient List following deletion, the treatment data will no longer be accessible.
- The "Archived" column in the Database menu (see **Figure 13-3**) indicates if a treatment is available for playback
- Ensure that the treatment is exported prior to erasing it.

Patient ID	Patient Name	Date	Time	In DataBase	Sonications	Disk Label	Site	Archived
NO_ID	NO_NAME	08 Jan 2018	16:06:03	Yes	0		Insightec	No
04012018	test*test	04 Jan 2018	16:26:04	Yes	3		Insightec	No
12345	sess_3*sess_3	03 Jan 2018	20:02:52	Yes	2		Insightec	No
NO_ID	NO_NAME	28 Dec 2017	13:23:52	Yes	0		Insightec	No
NO_ID	NO_NAME	28 Dec 2017	10:13:24	Yes	0		Insightec	No
NO_ID	NO_NAME	28 Dec 2017	09:56:42	Yes	0		Insightec	No
NO_ID	NO_NAME	26 Dec 2017	16:44:06	Yes	0		Insightec	No
NO_ID	NO_NAME	21 Dec 2017	14:19:23	Yes	0		Insightec	No
20122017	test*test	20 Dec 2017	20:22:16	Yes	3		Insightec	No

Figure 13-3: Data Management Screen - Availability of Treatment in Database

13.2.6. Technical Export to CD or USB Flash Drive

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

1. Insert a blank CD into the CD-R drive or connect a USB flash drive.
2. Press this button; select To CD/DVD or To USB from the drop-down menu, and in the Technical Export dialog box select a date to locate log files, then press OK to start the export.





Figure 13-4: Technical Export Dialog Box

3. Type in a title for the disk/file and press **OK**.
4. Technical data will be exported to the CD or USB flash drive. The export progress can be viewed in the **Status Bar**.

13.2.7. Download MR Images

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

To export MR images (refer to **Figure 13-5**).

1. Press this button and select To CD/DVD or To USB from the drop-down menu; the download MR Images dialog box appears.
2. Select one exam from the Exam List. All relevant series will appear in Series List (this operation might take a while).
3. From the associated Series List select one or more series, using the Shift or Ctrl keys, or the Select All option button.
4. Type in a new patient name and treatment ID or use the system default (patient's initials).



Figure 13-5: Download MR Images Screen

1. Press the **Download** button to copy the images to the Exablate system; the images will be stored on the workstation and will appear in the **Data on WS** list.
2. Select the patients from **Data on WS** list and press the **Burn** button to export the images to a CD or to a USB flash drive. The export process can be viewed in the **Status Bar** (see **Figure 13-1**).
3. The CD is automatically ejected from the CD drive when the data export is complete.

Download

Burn



NOTE:

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

N097

13.2.8. Export Summary File

Use this button to export a summary file of a selected treatment to a CD or USB flash drive.

Select the treatment from the Patient List.



Press this button and select To CD/DVD or To USB from the drop-down menu, to create a treatment summary and export it.

13.3. External Database (Optional)

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

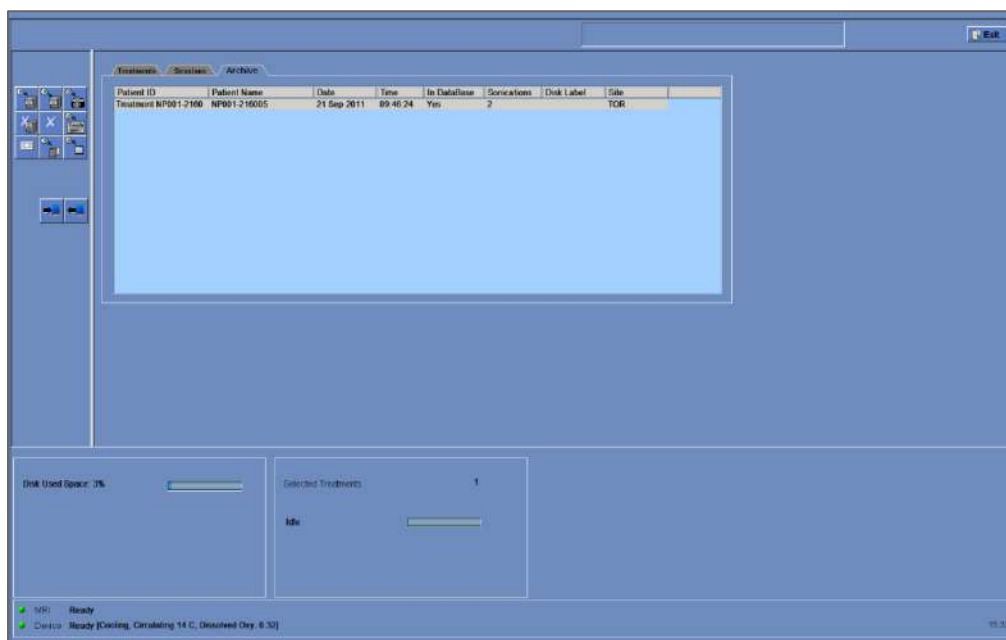





Figure 13-6: Data Management Screen – System with External Database

13.3.1. Action Tools

The following elements are added to the **Data Management** screen on systems with External Database (refer to **Figure 13-6**):

Image	Name	Description
	Select Database	Press a database tab to display the data on the Patient List .
	Erase Treatment and Record	Press this button to delete selected treatment records from the database and from the Patient List .
	Copy Records between Databases	<ul style="list-style-type: none"> Press this button to copy a treatment record from the Local database to the Archive database. Press this button to copy a treatment record from the Archive database to the Local database.

13.3.2. Select Database

There are two tabs to select the active database from.

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

13.3.3. Delete Complete Treatment Record

Use this button to delete selected treatment records from the database and from the **Patient List**.

1. Select records for deletion from **Patient List**.
2. Press this button to delete the selected records.



N098



NOTE:

- After deletion, no record of the treatment will be available.
- Ensure that the treatment was exported prior to deletion.

13.3.4. Records Management

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

- Press this button to copy a treatment record from the **Local** database to the **Archive** database.
- Press this button to copy a treatment record from the **Archive** database to the **Local** database.



The **Action Tools** presented in **Section 13.3.1** are available for use within the **Local** database.

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

13.4. Exit Data Management

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



A. UCHRA HEAD FRAME TYPE DHRS INSTRUCTIONS FOR USE



WARNING:

W117D

Determine applicable configuration as described in 1.6.14 and refer to relevant documentation only.

A.1. Exablate (UCHRA based) Head Frame

The Exablate (UCHRA based) Neuro Head Frame is a stereotactic head frame used for the fixation of patient's head during treatment with Exablate 4000 System.

This headframe is based upon the INTEGRA UCHRA headframe and is no longer supplied to new sites.

These instructions are intended for sites which still own one of these headframes.

Always inspect your Exablate Neuro Head (UCHRA BASED) Frame prior to use. Do not use if damaged.



WARNING:

W008D

The Disposable Head Frame Screws (Long or Short) are provided STERILE using Ethylene Oxide.

- Visually inspect screw package before use to verify the integrity of sealing. Discard of screws in case of tears, punctures or other visual damage to package or components.
- Disposable Head Frame Screws are intended for single-use only. Do not re-use or re-sterilize. Re- use may result in cross contamination, and in dullness of the screw, leading to potential patient movement. Dispose the screws according to hospital and local laws.



NOTE:

N002D

Be sure to gather the small miscellaneous parts (such as screws, wrenches and accessories) following use to prevent loss.

A.1.1. Exablate UCHRA Neuro Head Frame Set Contents

Part Description	Qty
HEAD SUPPORT HANDLE 70mm LEFT	1
HEAD SUPPORT HANDLE 70mm RIGHT	1
HEAD SUPPORT HANDLE 100mm LEFT	1
HEAD SUPPORT HANDLE 100mm RIGHT	1
LOW HEIGHT HEAD FRAME ASSY OR MEDIUM HEIGHT HEAD FRAME ASSY	1
STRAPS FOR HEAD FRAME POSITIONING	1
HEAD FRAME ASSEMBLING SCREW 20 MM	4 (and 6 already in frame)
HEAD RING WRENCH	2
CLEAR SILICONE CAPS 0.142X0.5	4



Figure A - 1: The Exablate UCHRA based Frame Set

A.1.2. Connecting\Replacing the Holders

The Exablate Head Frame set includes two sets of side holders.

The Low Side Holders allow extending the reach of the transducer along the A-P direction and are especially relevant if aiming for an anteriorly located target in a 60cm MR bore. An informed choice of side holders may also help maximize patient comfort.

Required Components	
Part Description	Qty
LOW HEIGHT HEAD FRAME ASSY OR MEDIUM HEIGHT HEAD FRAME ASSY	1
LOW SIDE HOLD RH/LH OR MEDIUM SIDE HOLD RH/LH	1
HEAD FRAME ASSEMBLING SCREW 20 MM	4
HEAD RING WRENCH	1

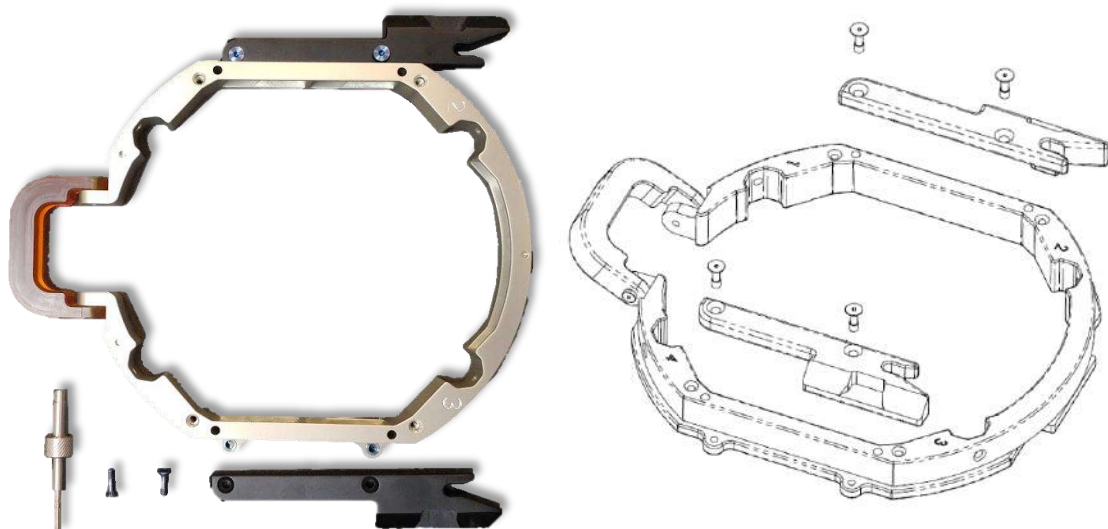


Figure A - 2: Connecting Side Holders to the Headframe (for illustration purposes only)

A.1.3. Attaching the Support Handles (Posts)

Required Components	
Part Description	Qty
LOW HEIGHT HEAD FRAME ASSY OR MEDIUM HEIGHT HEAD FRAME ASSY	1
HEAD FRAME ASSEMBLING SCREW 20mm	4
HEAD SUPPORT HANDLE 70mm LEFT	1
HEAD SUPPORT HANDLE 70mm RIGHT	1
HEAD SUPPORT HANDLE 100mm LEFT	1
HEAD SUPPORT HANDLE 100mm RIGHT	1
HEAD RING WRENCH	1



Figure A - 3: Connecting the frame Posts (for illustration purposes only)



CAUTION:

Note that the Posts are numbered, ensure each post is fastened in the slot marked with the corresponding number.

C002



NOTE:

It is possible to slide the posts up and down to optimize the headframe's fit to the patient.

N102D

A.1.4. Headframe Crossbar and Posts Set (Optional)

Frontal Bar Set for Use with Exablate Headframe
Part Description
Headframe Crossbar and Posts Set

The Headframe Crossbar and Posts Set is an optional accessory that can be acquired for use with the Exablate UCHRA Based Headframe, it consists of two angled frontal posts and a frontal crossbar that can be used for fixation of the headframe from access points that are more frontal than those of the default headframe set. To use the Frontal bar set:

1. Attach the frontal posts to the headframe ((A₁) to (A₂)) using the ordinary Headframe post attachment screws (1)).
2. Attach the frontal bar to the posts ((B₂) to (B₁)) using the supplied screws (2)).
3. The headframe screws are the same ones used with the default headframe, and they are screwed through pre-tapped fixation holes in the frontal bar (C).



Figure A - 4: Frontal Bar Set and Attachment

A.1.5. Positioning the Frame on the Patient

**WARNING:**

W109D

Headframe fixation may only be performed by licensed Neurosurgeon with stereotactic experience.

Disposable Head Ring Screws for Use with Exablate Headframe
Part Description
Long Disposable Head Frame Screws for Head frame fixation, also referred to as Disposable Head Ring Screws (DHRS)
Short Disposable Head Frame Screws for Head frame fixation, also referred to as Disposable Head Ring Screws (DHRS)
Straps for Headframe Positioning

- For unusual anatomy, consider using Crossbar and post set (see **A.1.4**) or short screws
- Shave the patient's scalp thoroughly, then wipe it clean with "rubbing alcohol" soaked gauze or pad.
- Ensure that the posts are tightly fastened.
- Ensure that the number on every post corresponds to the number on the Frame.
- (Optional) Use frame positioning straps to place the Head Frame.
- Place the Frame as inferiorly as possible to enable optimal coverage for the Exablate treatment.



Figure A - 5: Headframe placement straps

**NOTE:**

N007D

- Use all four (4) Disposable Head Frame Screws to attach the Frame to the Patient

- Only use the Head Frame components and tools provided by INSIGHTEC
- Placing the Head Frame assembly is easier if two people perform the procedure.
- Apply local anesthesia through the post fixation holes (or crossbar fixation holes, if applicable).
- Allow the local anesthetic to take effect.
- Use the head ring wrench provided by INSIGHTEC to drive the screws into the patient's skull.



WARNING

W115D

It is recommended to use an antibacterial ointment on the tips of the screws. Disinfect and bandage the screw insertion sites after removing the headframe

- Tighten the screws: two diagonally-opposed screws at a time, alternatively and equally
- Apply moderate force to ensure the Frame is securely tightened to the patient's skull

CAUTION:

C004D

Overtightening of the Disposable Head Frame Screws can cause premature failure of the head ring posts and/or the Disposable Head Frame Screws.

- Be sure that the spine of the posts does not press against the skin for patient comfort.



WARNING:

W012D

Overtightening of the Disposable Head Frame Screws may cause skull injury:

- Prior to frame application, the surgeon should review details of the patient's CT
- Avoid applying an extra strength during screw insertion on the skull
- Ensure the nose bridge is tightened and does not impede access to the patient's airways.
- Attach a silicone cap to the end of each Disposable Head Frame Screws.



CAUTION:

C012

Overtightening of the Disposable Head Frame Screws can cause premature failure of the head ring posts and/or the Disposable Head Frame Screws.

A.1.6. Cleaning and Maintenance

Use the following guidelines to clean Head Frame components after each treatment:

- Clean components with de-ionized distilled water.
- Thoroughly dry all components prior to storage.
- Discard the Disposable Head Frame Screws after each use.

**CAUTION:**

C005D

Do not use saline. Saline may cause damage to the metal surface.

Do not use corrosive agents, such as Clorox® or Cidex®.

Do not use alcohol or hydrogen peroxide on any black composite materials.

**NOTE:**

N008D

The use of Betadine® or similar solution containing iodine may stain the surface of the stereotactic system.

To minimize discoloration, wipe off any traces of Betadine® or similar solutions as soon as a possible during or following the procedure.

**NOTE:**

N009D

If instruments are exposed to highly caustic solutions such as bleach solutions, immediately rinse the instruments with de-ionized distilled water to prevent corrosive damage to surfaces and moving parts.

B. UCHRA HEAD FRAME TYPE PFK INSTRUCTIONS FOR USE

**WARNING:**

W117D

Determine applicable configuration as described in 1.6.14 and refer to relevant documentation only.

B.1 Exablate (UCHRA based) Head Frame Type PFK

The Exablate (UCHRA based) Neuro Head Frame Type PFK is a stereotactic head frame used for the fixation of patient's head during treatment with Exablate 4000 System.

This headframe is based upon the INTEGRA UCHRA headframe and is no longer supplied to new site.

These instructions are intended for sites which still own one of these headframes and received an additional set described in section B.1.1.

Always inspect your Exablate Neuro Head (UCHRA BASED) Frame prior to use. Do not use if damaged.

**WARNING:**

W118D

The Disposable Head Frame Screws and adapters are provided **STERILE** using Ethylene Oxide.

- Visually inspect screw package before use to verify the integrity of sealing. Discard of screws in case of tears, punctures or other visual damage to package or components.
- Head Frame Screws and Adapters are intended for single-use only. Do not re-use or re-sterilize. Re-use may result in cross contamination, and in dullness of the screw, leading to potential patient movement.
- Dispose the screws and all 8 adapters according to hospital and local laws.

**NOTE:**

N002D

Be sure to gather the small miscellaneous parts (such as screws, wrenches and accessories) following use to prevent loss.

B.2 Exablate UCHRA Neuro Head Frame Type PFK Set Contents

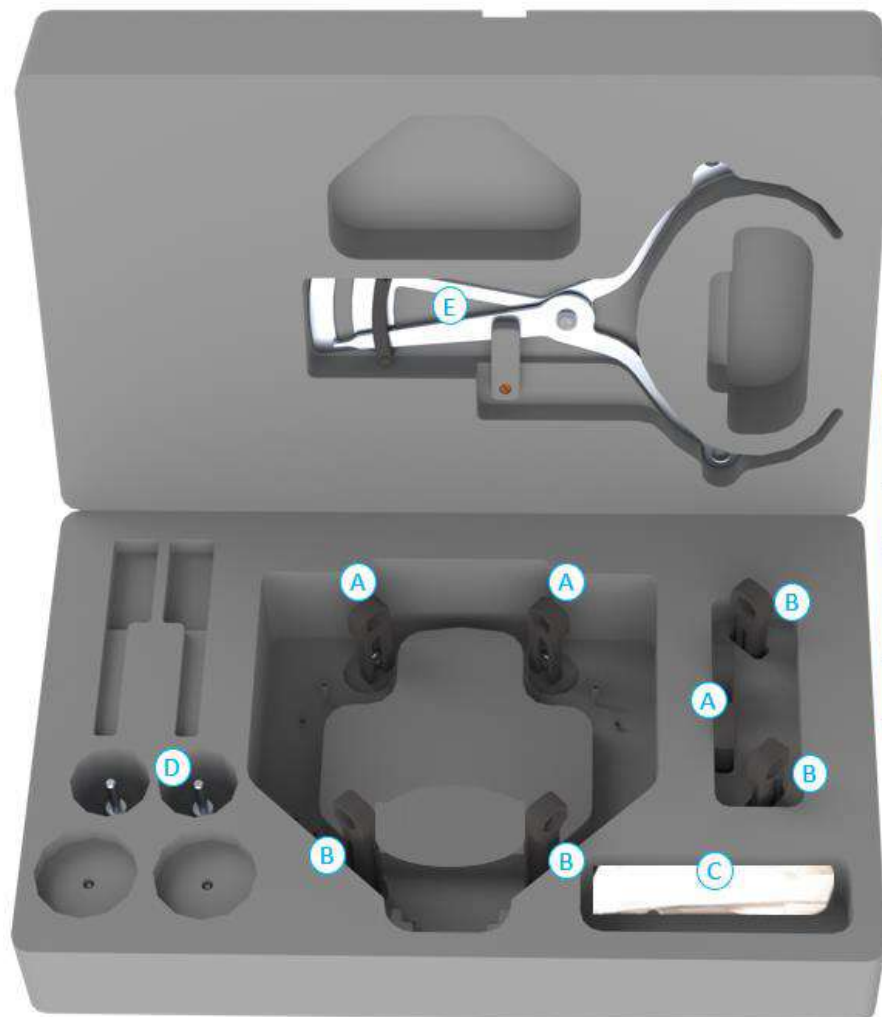
From Head Frame Set provided previously



Part Name	Qty.
Head Frame Base	1
Side Holders	2
Side Holders Fixation screws	4
Long Side Holders	2
Frame Assembly Wrench	2

Figure B - 6: The Exablate UCHRA based Frame Set

From New Head Frame Set provided by Insightec to be compatible with the PFK (For illustration purposes only):



	Part Name	Qty.
A	Posterior Posts	4
B	Anterior Posts	4
C	Frame Placement Strap	1
D	Patient Fixation Wrench	2
E	Exablate Caliper	1

B.3 Connecting\Replacing the Holders

The Exablate Head Frame set includes two sets of side holders.

The Low Side Holders allow extending the reach of the transducer along the A-P direction and are especially relevant if aiming for an anteriorly located target in a 60cm MR bore. An informed choice of side holders may also help maximize patient comfort.

Required Components	
Part Description	Qty
Low Height Head Frame Assy Or Medium Height Head Frame Assy	1
Low Side Hold RH/LH Or Medium Side Hold RH/LH	1
Head Frame Assembling Screw 20 Mm	4
Head Ring Wrench	1

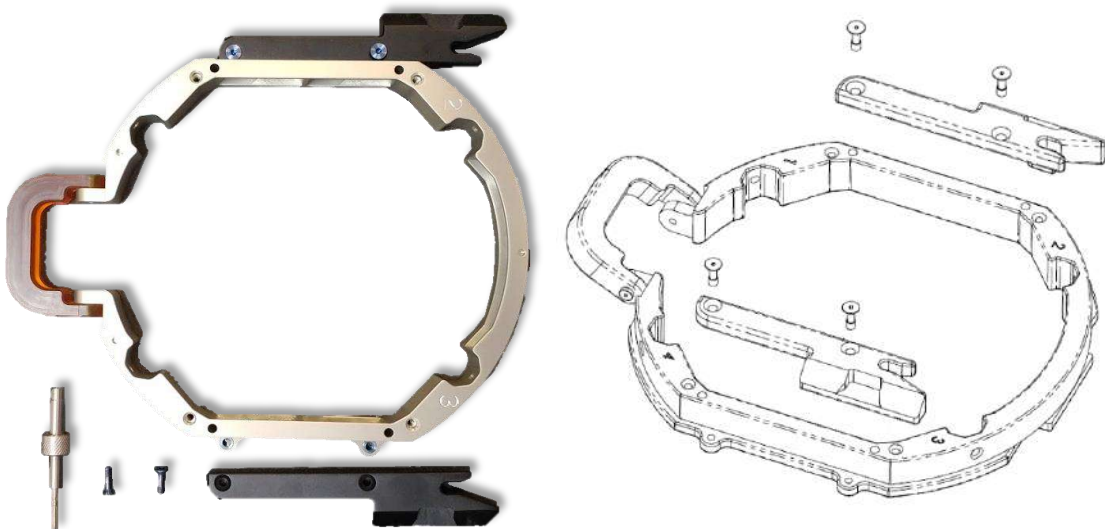


Figure B - 7: Connecting Side Holders to the Headframe (for illustration purposes only)

B.4 Attaching the Support Handles (Posts)

Required Components	
Part Description	Qty
Low Height Head Frame Assy Or Medium Height Head Frame Assy	1
Head Frame Assembling Screw 20mm	4
Anterior Posts	2
Posterior Posts	2
head Ring Wrench	1



Figure B - 8: Connecting the frame Posts (for illustration purposes only)



CAUTION:

Note that the Posts are numbered, ensure each post is fastened in the slot marked with the corresponding number.

C002



NOTE:

It is possible to slide the posts up and down to optimize the headframe's fit to the patient.

N102D

B.5 Exablate Neuro Patient Fixation Kit (PFK)

The PFK (Patient Fixation Kit) is composed of 4 Patient Fixation Screws, 4 Short Adapters and 4 Long Adapters (Figure below). The adapters offer a sterile interface for the screws and provide compatibility with a wide range of head sizes. As shown in the figure below, the Screws and Adapters are assembled onto the posts of the Exablate Head Frame via dedicated fixation holes.

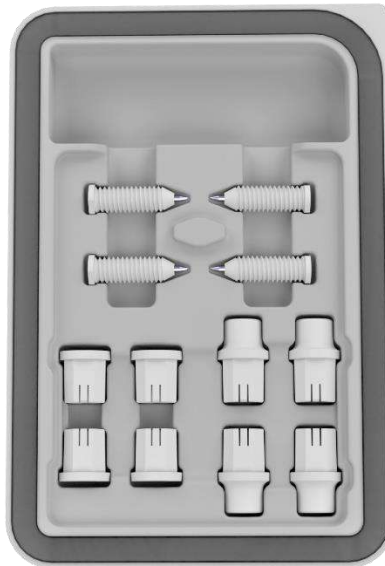


Figure 13-7: Exablate Neuro Patient Fixation Kit (PFK)

B.6 Exablate Caliper

The Exablate Caliper enables to determine what is the patient's optimal adapters combination to use (Section 1.9.4) by measuring the patient's head diagonal (See **picture 1-27** - from front pin insertion location to its contralateral posterior pin insertion location on patient's head).

The Caliper has a range of three different intervals for 3 types of head size: SS, SL, LL (Section 1.9.4).

In order to choose the right combination of adapters to insert in the frame fixation holes, use the caliper provided in the Head Frame Set (Section 1.9.3) on a shaved patient's head.

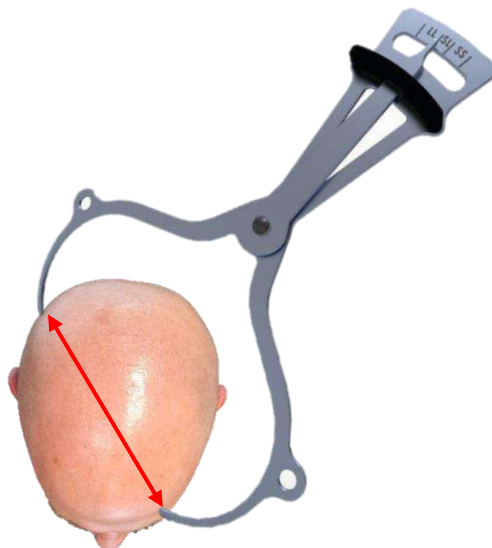


Figure 13-8 - Exablate Caliper for Head diagonal measurement and combination estimation

B.7 Different Adapter Combinations

The Exablate Caliper enables to determine what is the optimal adapter combination to use for each patient, by measuring the patient's head diagonal

Using the provided Caliper, measure the distance between contra-lateral pin insertion points (e.g. the distance between the left posterior and right anterior intended fixation locations).

Based on this measurement, select the appropriate combination of adapters (see below).

Note that in case of abnormal or asymmetric patient anatomy, a different combination may be optimal for each pair.

Caliper reading: SS	Caliper reading: SL	Caliper reading: LL
Short Adapters	Mixed Adapters	Long Adapters
		

B.8 Replacing the Side Holders

In some configurations, the Exablate Type PFK Head Frame set includes two sets of side holders.

The Low Side Holders allow extending the reach of the transducer along the A-P direction and are especially relevant if aiming for an anteriorly located target in a 60cm MR bore. An informed choice of side holders may also help maximize patient comfort.

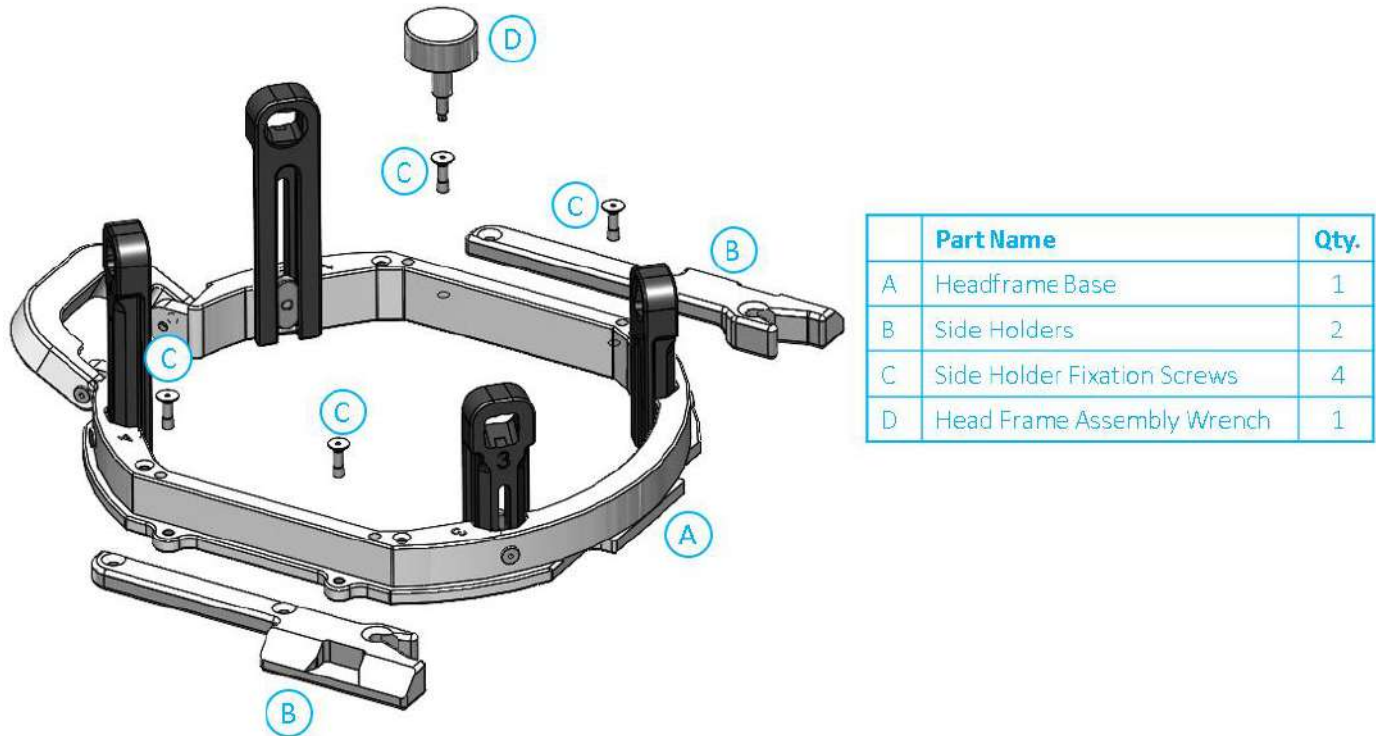


Figure 13-9: Connecting Side Holders to the Headframe (for illustration purposes only)

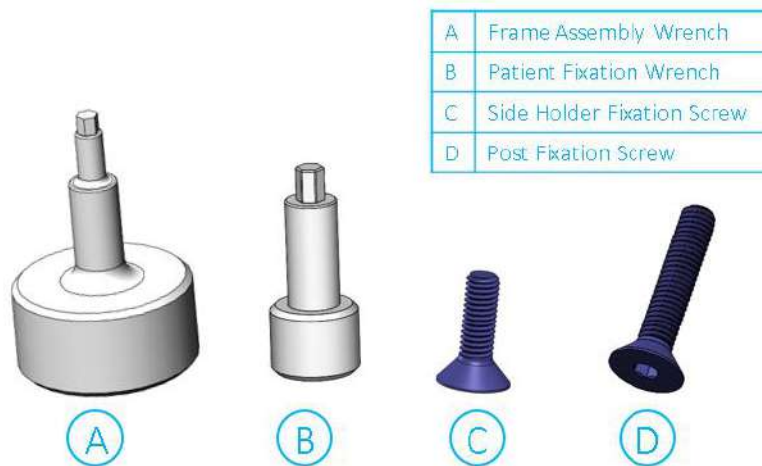


Figure 13-10: Head Frame Screws and Wrenches

B.9 Preparing the Head Frame for patient's head

According to patient's head size anatomy, chose the right adapters' combination from the PFK to insert to the Head Frame posts and bar using the caliper on a shaved head (see section 1.9.2 and 1.9.5).

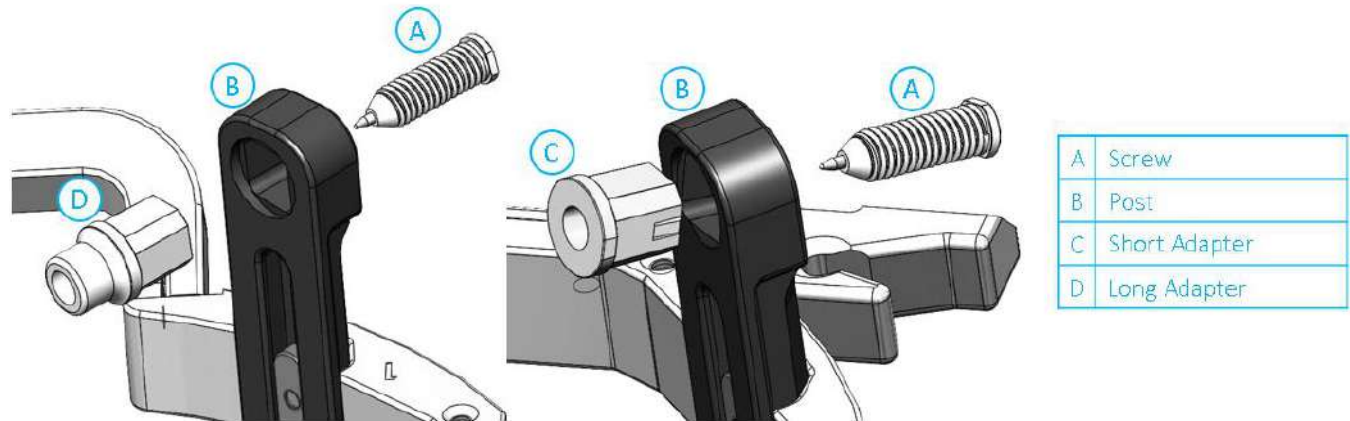


Figure 13-11: Internal Adapter insertion to posts

Insert the 4 adapters to their dedicated fixation holes on the Head Frame posts from the internal side of the posts (See **Figure 1-30**). Make sure the adapter is strongly attached to the head frame posts.



WARNING:
Ensure each post is thoroughly fastened.

W010

If necessary, use the Head Frame Assembly Wrenches (**Figure 1-29**) to fasten the posts.

B.10 Positioning the Frame on the Patient



WARNING:
Headframe fixation may only be performed by licensed Neurosurgeon with stereotactic experience.

W109D

- Shave the patient's scalp thoroughly, then wipe it clean with "rubbing alcohol" soaked gauze or pad.
- Ensure that the posts are tightly fastened.
- Choose the right 4 Adapters according to the guidelines provided in section 1.9.5.
- Insert the Adapters to their predisposed fixation holes on the posts and Bar from the internal side of the frame (See **Figure 1-6**)
- (Optional) Use head Frame Positioning Straps to place and adjust the vertical height of the Head Frame.
- Place the Frame as inferiorly as possible to enable optimal coverage for the Exablate treatment.

**NOTE:**

N006

Using the Head Frame Positioning Straps helps support the weight of the Head Frame Assembly during placement on the patient.

- Mark with a marking pen the projected screw entry sites and the superior temporal line (optional)
- Apply local anesthesia through the fixation holes in the posts or on marked screws insertion sites, with or without temporarily moving the frame.
- Allow the local anesthetic to take effect.
- Insert the Disposable Head Frame Screws to their predisposed fixation holes in the adapters.

**WARNING:**

W115D

It is recommended to use an antibacterial ointment on the tips of the screws. Disinfect and bandage the screw insertion sites after removing the headframe

**CAUTION:**

C003

Four fixation holes in the anterior Head Frame Bar are available for the Disposable Head Frame Screws' and Adapters insertion. To avoid, if applicable, placement of the screws into the temporalis muscle, use the two medial access points.

- Use the Patient Fixation Wrench provided by INSIGHTEC to drive the Disposable Head Frame Screws into the patient's skull.

NOTE:

N007D

Use all four (4) Disposable Head Frame Screws to attach the Frame to the Patient



- Only use the Head Frame components and tools provided by INSIGHTEC
- Placing the Head Frame assembly is easier if two people perform the procedure.

- Keep a distance between the skin and the outer aspect of the bar at each screw site.
- Tighten the screws: two diagonally opposed screws at a time, alternatively and equally.
- Apply moderate force to ensure the Frame is securely tightened to the patient's skull.

**CAUTION:**

C004D

Overtightening of the Disposable Head Frame Screw can cause premature failure of the head Frame posts and/or the Disposable Head Frame Screw.

Be sure that the spine of the posts does not press against the skin for patient comfort.



WARNING:

W012D

Overtightening of the Disposable Head Frame Screws may cause skull injury:

- Prior to frame application, the surgeon should review details of the patient's CT
- Avoid applying an extra strength during screw insertion on the skull

- Remove the Head Frame Positioning Strap

C. MANUAL DRAIN KIT USE INSTRUCTIONS



NOTE:

N099

Follow the Manual Drain Procedure when the water system is offline. The manual drain procedure takes considerably longer than draining the water nominally. In case of immediate emergency, release the patient from the patient interface without draining.

The Transducer Drain Kit (SET400174\SET400170) includes:

- 12-liter pouch
- Silicone tube with fittings

Manual Drain Procedure:

1. Disconnect blue water fitting below Transducer and fasten to the silicone tubing



Figure C - 1: Water fitting disconnection



Figure C - 2: (L) Water pouch and Silicone tube with fittings, (R) Air release Valve opening

2. Connect other end of the silicone tube to the water pouch
3. Verify Circulation tap on top of transducer is in Fill/Drain position
4. Place water pouch below transducer; wait ~10 minutes until drain completion
5. Reconnect blue water fitting below transducer

D. HARD DRIVE REPLACEMENT

D.1. Overview

- The Exablate clinical software is installed on the workstation (WS) PC and the Control PC (CPC).
- To support the research 'mode', both hard drives must be swapped by their corresponding research drives.
- At the conclusion of any research activity, the original (clinical) hard drives must be reinserted, and a DQA procedure performed with the clinical configuration.
- A cleaning procedure shall be performed before and after the DQA procedure.
- To enable the release of the hard drive, a dedicated key is required (see **Figure D-1**).



Figure D - 1: Research Hard Drive Set + Dedicated Key (in storage Case)

D.2. Hard Drive Replacement Steps

1. Verify that the WS PC is powered down.
2. Use a dedicated key to unlock the bay.
3. Rotate the key to the **Open** position (see **Figure D-2**).
4. Using the dedicated handle, remove the original (**Clinical**) hard drive from its bay.
 - Use the dedicated handle to release and insert drive from/to bay (see **Figure D-2**).
5. Gently insert the **Research** hard drive.
6. Rotate key to **Lock**.
7. Store the removed hard drive properly (safe, dry location, outside of MR room).
8. Repeat Steps 1 - 6 for the Control PC.
9. Store the dedicated key in a safe location.



Figure D - 2: PCs Hard Drive Bay (Note Keyhole with Open/Lock Position Designations)



WARNING:

W106

- Hard drives are not MR compatible.
- Hard drives must be stored outside of the MR room.



NOTE:

N100

A mismatch mode (where one PC has the 'research' hard drive and the other has the clinical hard drive or vice versa) will result in a start-up error. In this case, the system will not be operational.