

Exablate Neuro

Exablate 4000 Checklists Handbook

For Type 1.0 Systems
SW version 7.33 Running on GE MRIs

**WARNING:**

This document constitutes a shortened reference manual. It does not replace the Operator Manual.

Adhere to all warnings and precautions as detailed in the Exablate 4000 type 1.0 and 1.1 SW 7.33 Operator Manual.



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

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REVISION INFORMATION

This is the **Revision 2.0** release of the Exablate 4000 Type 1.0 Handbook for SW version 7.33, applicable MR systems. Please contact Insightec marketing support to determine if this is the most current release. Each chapter of this manual has a chapter revision level and date at the bottom. This indicates the release level & date for the individual chapters. Note that when the manual is updated, not all of the chapters are necessarily updated, so some chapters may have a revision level earlier than the release revision level . The cover page and this (copyright page, table of contents) pages are all **Revision 2.0** with the corresponding chapters of the manual:

| Chapter # | Chapter Name | Chapter Revision, Date | # of Pages in Chapter |
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| Chapter 1 | System Setup Checklist | 2.0, 05/23 | 2 |
| Chapter 2 | Preparation and DQA Checklist | 2.0, 04/22 | 2 |
| Chapter 3 | Treatment Checklist | 2.0, 04/22 | 2 |
| Chapter 4 | Cleaning Procedure Checklist | 2.0, 05/23 | 2* |
| Chapter 5 | TG Calibration Checklist | 1.0, 07/21 | 2* |

* - Including blank back pages

System Set Up Checklist



NOTE:

The water system will reach its optimal operating conditions within 30 minutes. Take this into consideration and turn on the system as early as possible before the treatment, to avoid downtime when the patient arrives.

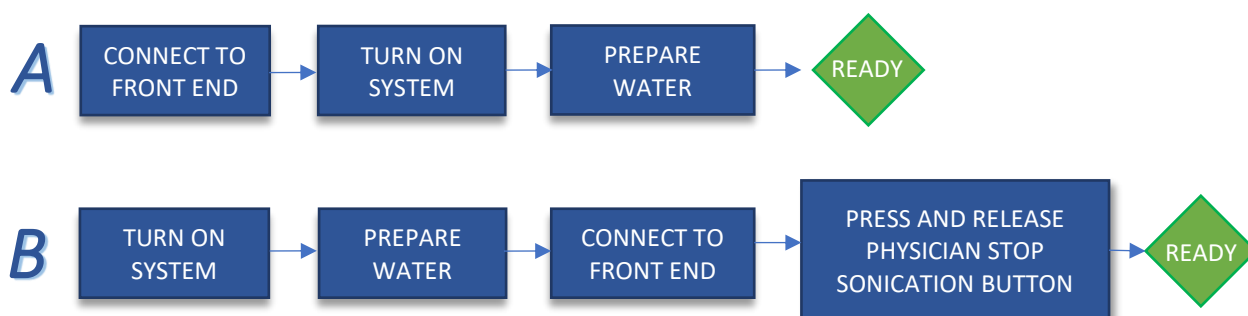


NOTE:

Multiple flows exist for System setup, consult the flowcharts and select the option most suitable to your workflow and preferences.
If turning on the System prior to connecting the Front End Cables to the Treatment Table, press the Operator Stop Sonication Button to re-initialize connections.

- ☐ Confirm that the MR console was rebooted at the beginning of the day. If not, reboot it.

System Setup Flow Option Charts



Connecting the Front End Unit and Water Cables to the Exablate Table

- ☐ Bring the Exablate Treatment Table to the MR Suite and Dock it to the MRI
- ☐ Connect Tracking and Head coil (If Applicable) Connector to the MRI Table
- ☐ Connect the Water Cable and the two, uniquely labeled, Quick Coupler Cables from the Front End



CAUTION:

Verify that each Quick Coupler connector is connected to its intended labeled position. The connectors must be gently aligned into place before locking. Ensure that the water cable is fully coupled.


System Power On

- ☐ Turn on the System by pressing the green Power On switch located on the operator's console.
The **Begin Logon** notice will appear.
- ☐ Remove all external media drives and/or CD's from the console computer.
- ☐ Press "Ctrl+Alt+Delete" to access the logon information dialog box.
- ☐ Login with the Username and Password provided to you by InSightec. Click "OK" to continue.
(Note: Windows® login parameters are case sensitive)
- ☐ Select "**Brain Mid-Frequency**" from the application selection screen.
- ☐ The Exablate Neuro disclaimer popup window will open; click "OK" to continue.





Preparing the Water System

- ☐ Disconnect and unload the Water Reservoir from the Chiller Unit in the equipment room.
- ☐ Fill the Reservoir with 20 liters of water and re-connect it in its designated compartment
Use fresh Reverse Osmosis water for DQA and cleaning, Type 2 medical grade water for treatments.
- ☐ Set water system to “Preparation” mode from Chiller screen or the Workstation “Utilities” menu () and commence circulation. Degassing will start. The status of the Water System is indicated on the status bar on the bottom of the Workstation screen.




NOTE:

You may proceed with System Set Up while water preparation is ongoing, Degassing will proceed (unless manually halted) until the operator fills the Transducer



Verify System is Ready for Treatment

- ☐ Confirm that the System and MR status fields are “Ready” on Workstation screen, and the green System Power Indicator on the operator console is illuminated.
- ☐ With GE SW version DV26 and up you may need to press the 'External Host' button on the MR WS and select 'ExAblate' from the drop down menu in order to enable communications. 



WARNING:

Visually inspect the Exablate System to:

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

Failure to follow these instructions may result in improper system function.



Patient Membrane and DQA Phantom Gel Handling



WARNING:

Failing to comply with Patient Membrane and DQA Phantom Gel Handling instructions may result in reduced imaging quality, water leakage, cross-contamination, burns, electrocution risk and false/unreliable DQA results

- ☐ It is recommended to wear personal protective equipment (i.e. gloves) when handling the accessories.
- ☐ Patient Membranes (with/without coil) and DQA Phantom are intended for single-use only.
- ☐ Discard of membrane and DQA Phantom Gel and their storage boxes following the conclusion of a treatment (according to the local/site procedures).







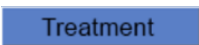
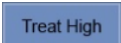
Preparation Checklist



System Set-Up for DQA

- ☐ Perform one of the System Setup flow options as defined by the **System Set Up Checklist**
- ☐ Ensure the Transducer is located in "**Home Position**", according to label on Positioner
- ☐ Affix the Patient Membrane intended for the treatment into the **DQA Holder Setup**
- ☐ Place a **DQA Phantom** into **DQA Holder Setup**, and lock it onto the Helmet System and Transducer
 - ☐ Plug the **Head Coil** into its dedicated connectors (if applicable)
- ☐ Make sure the transducer's **Air Release Valve** is **open**. **Fill transducer** with water until slightly convex.
- ☐ **Close Air Release Valve**. Release excess air from pipes via the **Red Excess Air Release button**.
- ☐ Perform short mandatory fill to replace lost water. Ensure no leaks. Begin water **Circulation**.

✓ DQA Procedure

- ☐ On MR console: **Open New Exam**
- ☐ In MR scanner room: **Set Landmark and Advance Cradle** to scan position
- ☐ Start a **New Treatment**  from the main menu of the Exablate application software
- ☐ on MR scanner console: Prescribe and run a 3-Plane Localizer scan
- ☐ on MR scanner console: Prescribe and run 3 orientations of DQA planning images (Sag, Ax and Cor)
- ☐ Run **Automatic Transducer Tracking** 
 - ☐ On 3T MR: **skip** TG calibration (See **TG-CALIB. Checklist**) (select "Cancel")
 - ☐ Perform an **MRI central frequency scan** (optional) 
- ☐ Open the **Image Retrieval Dialog** , **select and upload** the three **DQA planning series**
- ☐ Ensure the Transducer Focal Point is located at the **center** of the DQA phantom
 - ☐ If required: Reposition the transducer & Re-Run a **Transducer Tracking scan** 
- ☐ Set the **Treatment Protocol**  to **Brain-DQA**
- ☐ Press **Patient Stop Sonication Button** and proceed to **Treatment Stage** 
- ☐ Set Treatment level to **Treat High** 

NOTE: In the DQA procedure, there is NO need to use CT images or run Movement Detection scans

- ☐ **Sonicate**  the predefined set of **5 spots** using the parameters outlined in the following table

Press **Continue** to proceed to the next sonication 

Use the **next sonication button**  to switch between the predefined spots.

☐ Review results and **Adjust Spot Location**  if it is not in place (>0.5_{mm} from target)

☐ Repeat sonications as needed (after adjusting, in case of artifacts, unclear thermal rise etc.)

| Spot # | Orientation | Frequency Direction | Power | Duration | Goal [Expected Temperature] | Spot Confirmation |
|----------------------------|-------------|---------------------|------------------|-------------------|---|--|
| <input type="checkbox"/> 1 | Axial | AP | 20 _w | 13 _{sec} | Geometric alignment | Spot is clearly visible, aligned in RL |
| <input type="checkbox"/> 2 | Sagittal | AP | 20 _w | 13 _{sec} | Geometric alignment | Spot is clearly visible, aligned in SI |
| <input type="checkbox"/> 3 | Axial | RL | 30 _w | 13 _{sec} | Geometric alignment Temperature increase | Spot is clearly visible, aligned in AP |
| <input type="checkbox"/> 4 | Axial | RL | 30 _w | 13 _{sec} | Steering verification | Steered focus to the correct side |
| <input type="checkbox"/> 5 | Axial | RL | 250 _w | 3 _{sec} | Cavitation Control | Confirm Active Power Modulation / cavitation halt |

- ☐ **Quit** the treatment and return to entrance screen, drain water from transducer. Set to **Degassing**
- ☐ **Unplug and dry** the **Patient Membrane**, and stow the DQA Phantom holder setup away.
- ☐ **Inspect the transducer's surface** for visible soil or fractures.
- ☐ Handle accessories as described in **Patient Membrane and DQA Phantom Gel Handling** section.





Pre-Treatment Preparations

- ☐ Make sure all necessary INSIGHTEC accessories are available - For one treatment procedure:

INSIGHTEC PATIENT AND TREATMENT ACCESSORIES

| | | |
|---|---|---|
| <input type="checkbox"/> DQA setup Holder | <input type="checkbox"/> Patient Membrane | <input type="checkbox"/> Head Frame Set |
| <input type="checkbox"/> Treatment Kit, including Patient Membrane, DQA Gel, and Head fixation screws | | |

PATIENT MANAGEMENT

| | | | |
|--|--|---|--|
| <input type="checkbox"/> Surgical Marker | <input type="checkbox"/> Razor/shaving tools | <input type="checkbox"/> Warming Blankets | <input type="checkbox"/> Ear Plugs |
| <input type="checkbox"/> IV Line | <input type="checkbox"/> Compression Stockings | <input type="checkbox"/> Blood Pressure/pulse Oxy | <input type="checkbox"/> Pin Site Anesthesia |

- ☐ Ensure availability of a **CT scan** (mandatory) and **pre-treatment MR** (optional)
- ☐ Prepare **Pre-Treatment Plan** (with or without **pre-treatment MR** images)
- ☐ Perform **Daily Quality Assurance (DQA)** as outlined in this document
- ☐ Ensure **water system** is in **active degassing mode**, transducer is positioned as **superiorly** as possible.



Patient Preparation

- ☐ Confirm patient is **shaved** and the **scalp** is **cleaned** with alcohol.
- ☐ Ensure **IV line** is in place
- ☐ Fit the patient with **Compression Stockings** [recommended]
- ☐ Prepare the Head Frame to fit patient's head size anatomy using the provided accessories/kits
- ☐ Affix the **Head Frame**, as inferiorly as possible above the eyebrows
- ☐ Place the **Patient Membrane** on the patient's head, as low as possible, in the right orientation:
- ☐ Membrane without coil: screws/plastic side down (towards patient's feet)
 - ☐ Membrane with coil: Ensure the Head Coil connectors are in the right location according to the coil socket position next to the transducer
 - ☐ **Note:** in some cases membrane may require cutting to fit the patient









Patient Positioning

- ☐ Prepare table for patient arrival: mattresses (cover with blankets), cushions, warm blankets, etc.
- ☐ Make sure the transducer is placed superiorly and that it is roughly centered along the A-P direction
- ☐ Bring the patient into the MR suite. Assist patient on **Table**
- ☐ Attach **Frame** to **Table** and **Membrane** to **Transducer**
- ☐ Plug the **Head Coil** into its dedicated connectors (if applicable)
- ☐ Fit **earplugs** and **Mirrored Glasses** (optional), Cover patient with warming **Blankets**
- ☐ **Restrain** patient's feet and body with **straps** and use **patient Leg holder** if needed
- ☐ Equip patient with **Stop Sonication** button
- ☐ Move **Transducer** to estimated clinical position. **Ensure clearance between patient and Transducer**
- ☐ **Fill transducer** with water until slightly convex (via Water Control Screen or Remote Controller)
- ☐ **Close Air Release Valve**. Release excess air from pipes via the **Red Excess Air Release button**
- ☐ Fill additional water to replace lost water. Ensure no leaks. Begin **Treatment Circulation**
- ☐ **Minimize membrane air folds** within transducer's pass zone
- ☐ Ensure cables are free to move and **advance cradle to scan** position




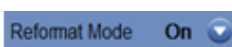


The patient and the Exablate system are now ready for treatment...

Treatment Checklist – Planning Stage

- ☐ on MR scanner console: Open New exam, Set Landmark according to labels
- ☐ on MR scanner console: Prescribe and run 3-Plane Localizer scan
- ☐ Run Automatic Transducer Tracking scan 
- ☐ On 3T DV26 (or higher) only: choose to **perform** or **skip** TG calibration (See **TG-CALIB. Checklist**)
- ☐ Perform an **MRI central frequency scan** 
- ☐ Select the appropriate **Treatment Protocol** 
- ☐ Load Pre-Plan  if available. Otherwise load CT scan  (Pre-op MR is optional)
- ☐ on MR scanner console: Plan the first orientation\ volumetric series on the MR Console
 - ☐ Select **2D** or **Volumetric** scan protocols, according to imaging preference
 - ☐ Take care to place your mid-slice along the AC-PC Plane
 - ☐ Up to 150 Axial\Sagittal\Coronal slices (Non-Volumetric)
- ☐ **Scan Prepared Series** . Once scanned, automatic Movement Detection acquisition occurs
- ☐ Choose an image acquisition method and proceed accordingly:


























Reformat Mode

- ☐ Locate and place the **AC**  and **PC** 
- ☐ Define the **Mid-Line** 
 - (**Parallel** to anatomical midline)
- ☐ Turn **Reformat Mode ON** 
- ☐ Press  to create volume
- ☐ Fine-tune orientations.
- ☐ press  to create series




Scan by AC-PC

- ☐ Locate and place the **AC**  and **PC** 
- ☐ Define the **Mid-Line** 
 - (**Parallel** to anatomical midline)
- ☐ Scan remaining orientations
 -   
 - ☐ User may perform targeting during scans

- ☐ Alternative Method: acquire images via scan prepared series  or from **Archive** 
- ☐ Run **Auto-Registration** 
- ☐ adjust manually  (If necessary) until satisfactory registration is obtained
- ☐ Determine target by measurements     OR by manual input of **AC-PC\RAS coordinates**
- ☐ Check distance between transducer focus and target
 - ☐ If necessary, adjust transducer location and re-run **Transducer Tracking scan** 
- ☐ If not already part of pre-plan, press the **Auto-Sinus & calcification Marking tool** 
- ☐ Review the CT images to evaluate sinus and calcification markings
 - ☐ If necessary, add markings using the **Polygonal**  and **Spherical NPR** tools
 - ☐ Use the **Interpolate** tool  to auto-draw **Polygons** between marked slices
- ☐ Mark **Membrane Folds** on Axial MR series with the **Polygonal NPR**  and **Interpolate**  tools
- ☐ Place **Fiducial Markers**  on Movement detection reference scans (optional)
 - ☐ If No **Movement Detection Images** have been acquired, press  to acquire
- ☐ Confirm **Water Temperature<19°C** and **PPM Level<2.0** (displayed on lower left corner of screen)
- ☐ Instruct Patient to press **Stop Sonication Button**. proceed to **Treatment Stage** 



Treatment Checklist – Treatment Stage

- ☐ Verify spot is **on target location** and **Locked**
- ☐ Press **Transducer**  to display **Transducer Element Map**. Press **Calculate** and confirm:
 - ! # Elements ON ≥ 700
 - ! Skull Area $\geq 200\text{cm}^2$
 - ! Skull Score ≥ 0.4 (or according to regional labeling)

Prior to Applying Sonication

- ☐ Set **Sonication Power, Duration and Time Extension**
- ☐ Set **Scan Orientation, Frequency Direction**
- ☐ Confirm Water Temperature $< 19^\circ\text{C}$
- ☐ Confirm **PPM Level** < 2.0

After Every Sonication

- ☐ Verify spot **alignment**
- ☐ Check for **Heating outside of treatment area**
- ☐ Update **Peak Temperature** if necessary 
- ☐ If **Background Temperature** is inconsistent, enable **Background Elimination** 

Align

- ☐ **Sonicate and check location of spot along phase direction, keeping sub-lesional target temp.**
- ☐ **Verify alignment for every direction. See table for reference:**

| Sonications # | Validating | Orientations (frequency directions) | Result |
|---------------|------------|-------------------------------------|--|
| | RL | Axial(AP) OR Coronal(SI) | Confirmed R\L <input type="checkbox"/> |
| | AP | Sagittal(SI) OR Axial(RL) | Confirmed A\P <input type="checkbox"/> |
| | SI | Coronal(RL) OR Sagittal(AP) | Confirmed S\I <input type="checkbox"/> |

-  If spot is misaligned, use the **Geo-Adjust Tool**  to pinpoint the center of the spot

! Continue to next level only after spot is clearly visible and aligned along **ALL** orientations

Verify

- ☐ Proceed to verify stage. Accumulated adjustments [mm]: RL: _____ AP: _____ SI: _____.
- ☐ Gradually increase energies by 10%-25% until reaching temperature of $\sim 50^\circ\text{C}$
- ☐ Evaluate Patient before proceeding to "Treat Low"

Treat Low

Treat High

- ☐ Gradually increase energies by 10%-25% until achieving effect & permanent lesioning temperatures
- ☐ If necessary, adjust Target Location



Post Treatment

- ☐ Open the **Air Release Valve** on top of the Transducer and **Drain** the water from the Transducer.
- ☐ **Disconnect Head Coil** (if applicable), **Release** and **handle the Membrane** as defined at the end of the **Set-Up Procedure Checklist**, move transducer **as superiorly as possible**.
- ☐ **Release** Head Frame from the table, take the patient **off the Table** and **Remove the Head frame**.
- ☐ Perform the cleaning as defined by **Cleaning Procedure Checklist**, or further detailed in the **Cleaning and Disinfection** Chapter of the Operator Manual.
- ☐ After the Cleaning, **drain** Transducer, **discard** drained water, and **Shut Down System**.
- ☐ **Check availability** of **DQA Phantom** and **Patient Membrane** for next treatment.

Cleaning Procedure Checklist

The Exablate Cleaning Procedure Requires:

- **Water Tank Disinfectant** - 75 ml Sodium Hypochlorite (CAS # 7681-52-9) 4.00% - 4.99%
- **Cleaning & Disinfection Wipes** - containing 0.2 - 0.4% of benzalkonium chloride (CAS # 8001-54-5)

Water System Cleaning Procedure

- ☐ Handle the Patient Membrane as defined at the end of the Set-Up Procedure Checklist
- ☐ Ensure Transducer is empty, and all water used during the procedure has been discarded of
- ☐ Fill the Water System Reservoir (Tank) with ~20 liters of fresh Reverse Osmosis water Pour **Water Tank Disinfectant** in the Tank and re-connect it
- ☐ On the Water system main screen, press #3 for Clean option (Figure 1A). Two timers will appear: First timer: cleaning time of the water tank; Second timer: Transducer (Xd) cleaning time.
- ☐ Press the "Circ" button on the Clean screen to start the Tank Cleaning operation (Figure 1B).



fig. 1A: Water System Screen: **Main Menu**

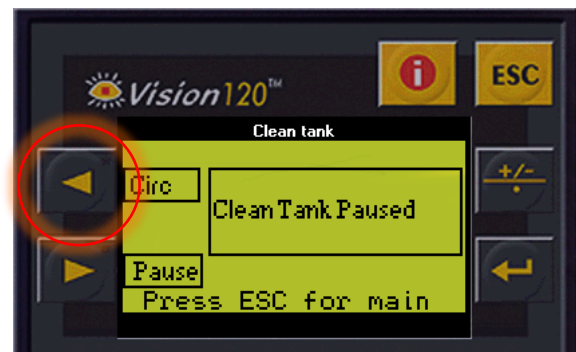


fig. 1B: Water System Screen: **"Clean" Menu**


- ☐ Allow 15 minutes for the first timer to run down, meanwhile verify that the treatment table is connected to the water system
- ☐ Mount Patient Membrane on the DQA holder setup (without a DQA phantom)
- ☐ Attach the DQA holder setup to the table and seal the Transducer
- ☐ When first timer is done (The WorkStation screen shows 00:00) fill the transducer interface with the prepared water. Press on "Circ" button again to start the "Clean Xd" timer.
- ☐ Allow 16 minutes for the transducer cleaning cycle.
- ☐ When Timers are over, drain the water from the transducer.
- ☐ Turn off the Exablate workstation.
- ☐ Dispose the water from the 20 Liter water tank according to local regulations.
- ☐ Leave the tank open and upside down for drying.
- ☐ Remove the DQA phantom holder interface membrane from the transducer-patient interface.
- ☐ Single use accessories: Discard according to local regulations.

Wiping the Transducer


- ☐ Before and after each cleaning cycle, clean the internal surface of the Transducer and the Patient membrane with the cleaning & disinfection wipes. **Do not apply force on the Transducer surface. Visually inspect the Transducer surface for soil or fractures.**
- ☐ Following treatment, place the protective cover to cover the Transducer surface

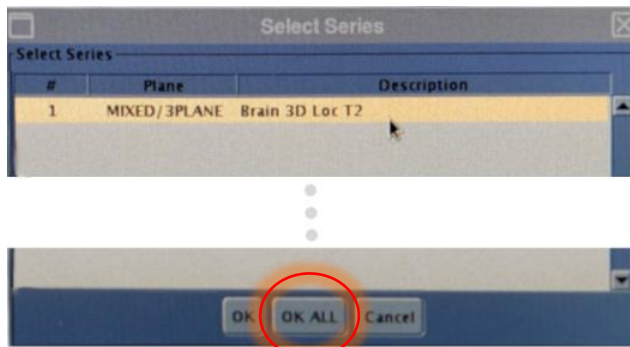
TG Calibration Checklist

Note: Applicable **Only** for 3T GE MR Scanners running DV26 or higher
Perform once per treatment (after 3D localizer) in order to improve image quality.

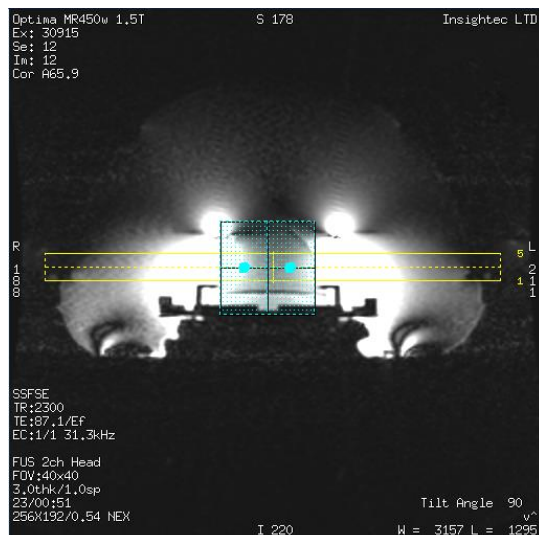
- ☐ Once scanned, **Duplicate & Edit** the **3D localizer** scan on the MR console screen
- ☐ Press the **GRx** button  to bring up the **Graphic Rx toolbar**:



- ☐ Make sure the 3D localizer is displayed on the MR screen as planning background
 - ☐ If not - Press , select the 3D Localizer series and press "OK ALL"




- ☐ Press **Shim** and click on one of the image windows to display the local Shim volume mesh:



Example of local Shim volume (in teal)



Shim menu

- ☐ In the **Shim** menu, enable Localized TG (mandatory)
- ☐ Drag the Shim Volume so it is centered roughly around the targeted area
- ☐ Set the volume size along each direction to 7-9. Ensure full volume is within brain tissue.
 - ☐ Enabling "Symmetric Vol" allows quicker changing of shim volume size
- ☐ Save the series  and proceed with the treatment flow on the **FUS Workstation**

