Exablate Neuro

Exablate 4000
Checklists Handbook

For Type 1.1 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 & 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** release of the Exablate 4000 Type 1.1 Handbook for SW version 7.33, applicable GE 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 page are all **Revision 2.0** with the corresponding chapters of the manual:

Chapter #	Chapter Name	Chapter Revision, Date	# of Pages in Chapter
Chapter 1	System Setup Checklist	2.0, 04/22	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 on the bottom of this Checklist and select the option most suitable to your workflow and preferences.
> If turning on the System prior to connecting the Helmet System cables to the Front End Unit, 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.*

Connecting the Helmet System Cables to the Front End Unit

☐ *Unlock the Storage and Transfer Cart (STC) wheels, and position it near the Front End Unit (FE)*
☐ *Connect the Water Cable and the two, uniquely labeled, Quick Coupler Cables to 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, as indicated by a 'Click' sound.

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 disclaimer popup window will open; click "OK" to continue.*

Preparing the Water System

☐ *Unload the Water Reservoir from The Water Reservoir Compartment in the Front End Unit and disconnect it via the Quick Release Cable.*
☐ *Fill the Reservoir up to the marking, Connect and return it to its designated compartment*
  Use fresh Reverse Osmosis water for DQA and cleaning, Type 2medical grade water for treatments
☐ *Set the water system to "Preparation" either from the Workstation "Utilities" menu (🛠) or from the Water System Control Touchscreen*
☐ *Degassing will start. The status of the Water System and Dissolved Oxygen (DO) levels [in PPM]) are indicated on the status bar on the bottom of the Workstation screen and the screen in the FE Unit.*

> **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

Preparing the MR Table

- ☐ *Bring the MR cradle all the way out of the MRI bore.*
- ☐ *Remove any imaging coils or MRI Baseplates currently connected to the MRI Table*
- ☐ *Place the Exablate MR Baseplate on the MR Table and ensure it is fully coupled*

Positioning the Helmet System on the MR Table

- ☐ *Unlock the STC wheels and roll it towards the MR Table while releasing the cables*
- ☐ *Place the STC perpendicularly to the MR Table, so that the markings are aligned*
- ☐ *Release and lower the Coupling Bridge. Ensure full connection between Coupling bridge and MR table.*
- ☐ *Lock the STC's wheels in place*

> **CAUTION:**
>
> To avoid damage to the system components, ensure there is a clear path between the Helmet System and its designated position on the MR Adapter Baseplate.

- ☐ *Place your hands on the Auxiliary and Main Handles. While pressing the "Transducer Release Button", slowly and firmly slide the Helmet System into place. A 'Clicking' sound denotes full coupling.*
- ☐ *Lower the Main Lock to secure the Helmet System in place*
- ☐ *Connect Tracking and Head coil Connector/s to the MRI Table*
- ☐ *Connect the Patient Stop Sonication Button cord to the socket on the MRI Table.*
- ☐ *Place and\or align Landmark Labels*
- ☐ *Close the STC Bridge, unlock the STC wheels and roll it away from the MR table. it will not be needed until after the treatment*

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.*
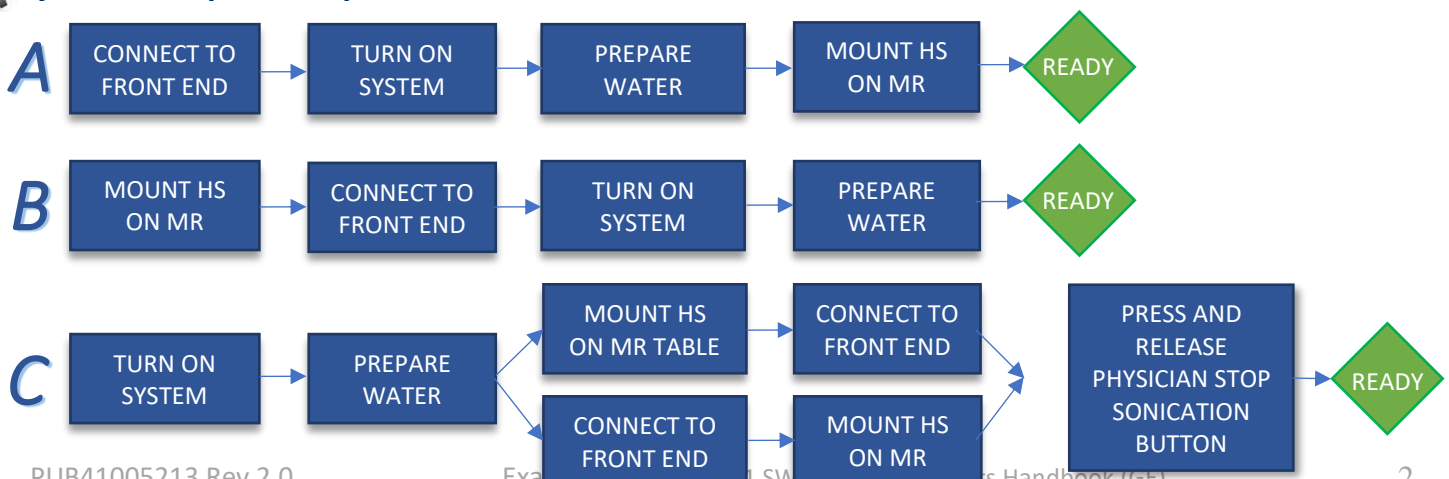
> **WARNING:**
> Visually inspect the Exablate System to:
> - Verify the integrity of the Transducer, Front End and MR Table
> - Confirm that the connectors are properly fastened
> - Confirm that the Exablate MR Baseplate and Helmet System are properly docked
>
> Failure to follow these instructions may result in improper system function.

System Setup Flow Option Charts

A   CONNECT TO FRONT END → TURN ON SYSTEM → PREPARE WATER → MOUNT HS ON MR → READY

B   MOUNT HS ON MR → CONNECT TO FRONT END → TURN ON SYSTEM → PREPARE WATER → READY

C   TURN ON SYSTEM → PREPARE WATER → [MOUNT HS ON MR TABLE → CONNECT TO FRONT END] / [CONNECT TO FRONT END → MOUNT HS ON MR] → PRESS AND RELEASE PHYSICIAN STOP SONICATION BUTTON → READY

Preparation Checklist
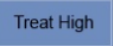
⚙ *System Set-Up for DQA*

- ☐ *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 connector (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 scanner console: Open New Exam*
- ☐ *In MR room: Set Landmark and Advance Cradle to scan position*
- ☐ *Start a* **New Treatment** [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 scan** [icon]
  - ⬚ *On 3T MR:* **skip** *TG calibration (select "Cancel")*
  - ⬚ *Perform an MRI central frequency scan (optional)* [icon]
- ☐ *Open the* **Image Retrieval Dialog** [icon]**,** *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** [icon]
- ☐ *Set the* **Treatment Protocol** [icon] *to* **Brain-DQA**
- ☐ *Press* **Stop Sonication Button** *and proceed to* **Treatment Stage** [Treatment]
- ☐ *Set Treatment level to* **Treat High** [Treat High]

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

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

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

  Use the **next sonication button** [icon] *to switch between the predefined spots.*
  - ⬚ *Review results and* **Adjust Spot Location** [icon] *if it is not in place (>0.5$_{mm}$ from target)*
  - ⬚ *Repeat sonications as needed (after adjust, if images are with artifacts, unclear thermal rise etc.)*

Spot #	Orientation	Frequency Direction	Power	Duration	Goal [Expected Temperature]	Spot Confirmation
☐ 1	Axial	AP	20 w	13 Sec	Geometric alignment	Spot is **clearly visible, aligned in RL**
☐ 2	Sagittal	AP	20 w	13 Sec	Geometric alignment	Spot is **clearly visible, aligned in SI**
☐ 3	Axial	RL	30 w	13 Sec	Geometric alignment Temperature increase	Spot is **clearly visible, aligned in AP**
☐ 4	Axial	RL	30 w	13 Sec	Steering verification	**Steered** focus to the correct side
☐ 5	Axial	RL	250w	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		
☐ DQA setup Holder	☐ Patient Membrane	☐ Head Frame Set
☐ Treatment Kit, including Patient Membrane, DQA Gel, and Head fixation screws		

PATIENT MANAGEMENT			
☐ Surgical Marker	☐ Razor/shaving tools	☐ Warming Blankets	☐ Ear Plugs
☐ IV Line	☐ Compression Stockings	☐ Blood Pressure/pulse Oxy	☐ 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: screw/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*

☐ *Ensure the transducer is placed in the "**Home**" position (as defined by label on HS)*

☐ *Bring the patient into the MR suite. Assist patient on **Table***

☐ *Attach **Frame** to **Baseplate** and **Membrane** to **Transducer***

　☐ *Plug the **Head Coil** into its dedicated connector (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*
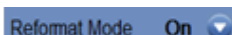
The patient and the Exablate system are now ready for treatment…

Treatment Checklist – Planning Stage ⚙️

☐ *on MR scanner console: Register Patient, In MR Room: Set Landmark-center according to labels*

☐ *on MR scanner console: Prescribe and run a 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 an 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*** 🔲 *(**Note**: The Step last edited will be the one scanned)*

⬚ *Wait for automatic **Movement Detection Reference** images acquisition to finish*

☐ *Choose an image acquisition method and proceed accordingly:*

⚙️ ***Reformat Mode***	⚙️ ***Scan by AC-PC***
☐ *Locate and place the **AC*** 🔲 *and **PC*** 🔲	☐ *Locate and place the **AC*** 🔲 *and **PC*** 🔲
☐ *Define the **Mid-Line*** 🔲	☐ *Define the **Mid-Line*** 🔲
*(**Parallel** to anatomical midline)*	*(**Parallel** to anatomical midline)*
☐ *Turn **Reformat Mode** ON* 🔲 Reformat Mode **On**	☐ *Scan remaining orientations*
☐ *Press* 🔲 *to create volume*	🔲 🔲 🔲
☐ *Fine-tune orientations.*	⬚ *User may perform targeting during scans*
☐ *press* ✅ *to create series*	

☐ *Alternative Method: acquire images via scan prepared series* 🔲 *or from **Archive*** 👤

⬚ *If No **Movement Detection Images** have been acquired, press* 🔲 *to acquire*

☐ *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*

☐ *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

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 ≥ 200cm²*
  - ❗ *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<19ºC*
- ☐ *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*	☐
	AP	*Sagittal(SI) **OR** Axial(RL)*	*Confirmed A\P*	☐
	SI	*Coronal(RL) **OR** Sagittal(AP)*	*Confirmed S\I*	☐

⬚ *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 ~50ºC*
- ☐ *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 Procedures*

- ☐ ***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 **Cleaning Procedure Checklist**, move transducer **as superiorly as possible.***
- ☐ ***Release** Head Frame from the Baseplate, take the patient **off the Table** and **Remove the Head frame.***
- ☐ *Transfer Helmet System to the Cart. 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*** *- 50 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 **Cleaning Procedure Checklist***

☐ *Ensure Transducer is empty and all water used during the procedure has been discarded of*

☐ *Fill the Water System Reservoir (Tank) with ~13 liters of fresh fresh Reverse Osmosis water, as marked on the Tank*

☐ *Pour **Water Tank Disinfectant** in the Tank and re-connect it*

☐ *On the Water System home screen (Figure 1A), press the "Clean" option* 🧴
   The system will switch to Clean Mode (Figure 1B)

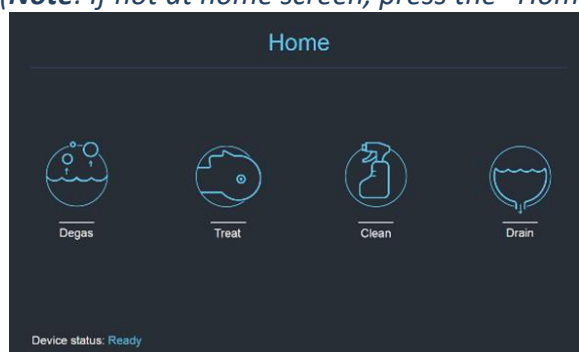☐ *(**Note**: If not at home screen, press the "Home" button* ⌂ *)*

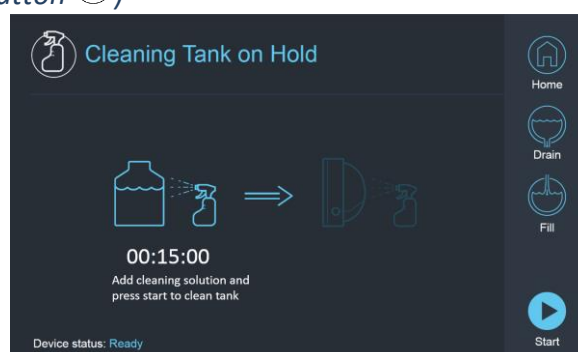**Fig. 1A:** *Water System Touchscreen "Home" Menu*

Fig. 2B: *Water System "Clean" Menu – on Hold*

☐ *Press "Start"* ▶ *button to start the cleaning operation (Figure 2A). A countdown timer on the WS status bar and water system screen displays the remaining cleaning time of the Tank*
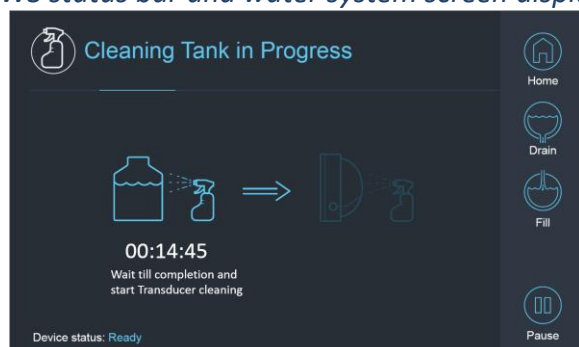

Fig. 2A: *"Tank Cleaning in Progress" Screen*

Fig. 2B: *– "Cleaning Tank Completed" Screen*

☐ *Mount Patient Membrane on the DQA holder setup (without a DQA phantom)*

☐ *Attach the DQA holder setup to the HS and seal the Transducer*

☐ *A "Cleaning Tank Completed" message (Figure 2B) will appear when the timer reaches zero. The system is now ready for stage two of the cleaning cycle – Transducer cleaning.*

☐ *Verify that the Transducer is connected to the water system connector at the Front-End*

☐ *Fill the Transducer by pressing the "Fill" button* 🖱 *on the Screen or on the Water System Remote Controller. 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 fill and drain times for the transducer cleaning procedure)*

☐ *Start the "Cleaning Transducer" timer by pressing the "Start" button* ▶ *on the Screen (Figure 3A) or on the Water System Remote Controller*
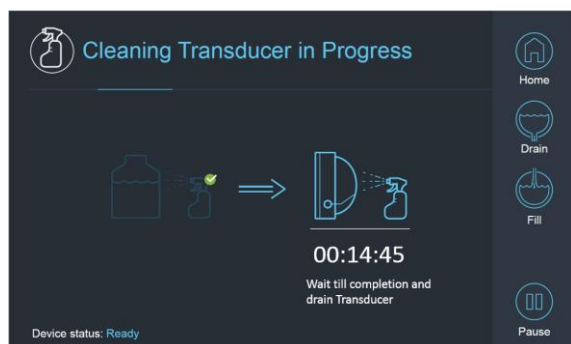

Fig. 3A: *"Cleaning Transducer in Progress" Screen* **Fig. 3B:** *"Cleaning Transducer Complete" Screen*

☐ *When timer is over, the Transducer cleaning is completed (Figure 3B)*

☐ *Set the Release Valve to air*

☐ *Drain the water from the Transducer by pressing the "Drain" button* ⟲ *on the Screen or on the Water System Remote Controller*

☐ *Dispose the water from the Water Tank according to the site and/or local regulations.*

☐ *Leave the Tank open to air (without the cap)*

☐ *Replace the phantom holder interface membrane with the protective transducer cover*

☐ *Turn off the Exablate® Workstation if no more treatments are scheduled for the day*

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).*

Wiping the Transducer

☐ *Before and after each cleaning cycle, clean the internal surface of the Transducer with the cleaning & disinfection wipes. **Do not apply force on the Transducer surface**.*
* **Visually inspect Transducer surface for soil/ 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

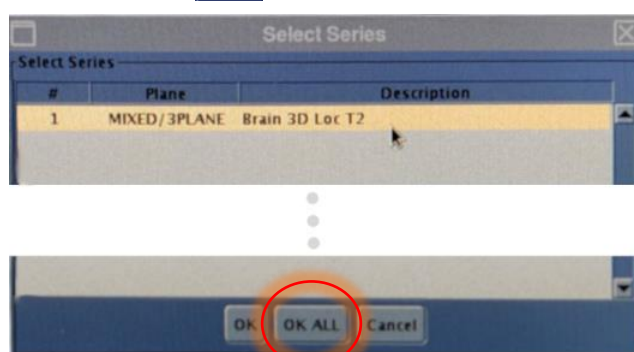*Perform once per treatment (after 3D localizer) in order to improve image quality.*

☐ *Once scanned,* ***Duplicate & Edit*** *the* ***3D localizer*** *scan on the MR console screen*

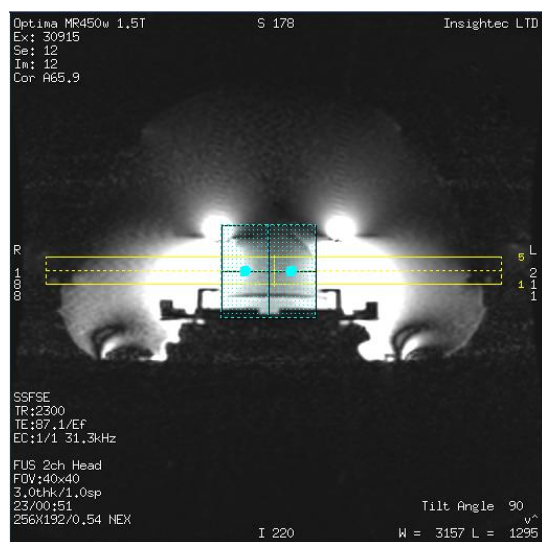☐ *Press the* ***GRx*** *button* GRx *to bring up the* ***Graphic Rx toolbar****:*

☐ *Make sure the 3D localizer is displayed on the MR screen as planning background*

⬚ *If not - Press* [icon] *, 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* [Save Rx] *and proceed with the treatment flow on the* ***FUS Workstation***