Exablate Prime

Checklists Handbook

For Exablate 4000 Type 1.1 Systems with Software Version 9.0

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 Prime (4000 Type 1.1 SW9.0) Operator Manual

InSightec, Ltd.

5 Nachum Heth St. PO Box 2059
Tirat Carmel 39120 Israel
www.insightec.com

CE 0344

EC REP Obelis s.a.
Bd. General Wahis 53,
1030 Brussels, Belgium

Exablate 4000 Type 1.1 transcranial MR guided focused ultrasound system **(**'Exablate Prime'), Software version 9.0 processing software, and its related documentation are the confidential proprietary property of INSIGHTEC. Only licensees of INSIGHTEC (“INSIGHTEC”) have the right to use the information contained herein. Only licensees specifically granted copy and/or transfer rights have the right to copy and/or transfer this information. Any unauthorized use, disclosure, assignment, transfer or reproduction of this confidential information will be prosecuted to the full extent of the law.

INSIGHTEC shall not be liable nor obliged in any manner in respect to any bodily injury and/or property damage arising from the use of this software if such use is not in strict compliance with the instructions and safety precautions contained in the relevant operating manuals, including all supplements thereto, in all product labels and according to the terms of warranty and sale of this software, nor if any changes unauthorized by INSIGHTEC are made to the software contained herein.

User-provided programs or protocols are not validated nor warranted by INSIGHTEC. The use of data obtained with such user provided software or protocols are the sole responsibility of the user.

Users should be aware of the risk of transmission of computer viruses by exchanging files and CDs.

Trademarks of third-party proprietors are the sole property of those proprietors.

Specifications are subject to change without notice and following applicable regulation and laws.

One or more parts of the product may incorporate or be distributed with open source software. Refer to the Copyright Notice button in the Utilities Screen.

For Technical Support contact INSIGHTEC at +44-808-189-0427 or at Service_EMEA@insightec.com

INSIGHTEC website: http://www.insightec.com/

REVISION INFORMATION

This is the **Revision 1** release of the Exablate 4000 Type 1.1 Handbook for SW version 9.0.
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 1.0** with the corresponding chapters of the manual:

Chapter #	*Chapter Name*	*Chapter Revision, Date*	*# of Pages in Chapter*
Chapter 1	System Setup Checklist	1.0, 10/23	2
Chapter 2	Preparation and DQA Checklist	1.0, 10/23	2
Chapter 3	Treatment Checklist	1.0, 10/23	2
Chapter 4	Cleaning Procedure Checklist	1.0, 10/23	2

System Set Up Checklist

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.

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.

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

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

- ☐ *Wake the system up by moving the mouse.*
- ☐ *Login with your Username and Password provided*
  *(**Note:** Windows® login parameters are case sensitive)*
- ☐ *Select the **appropriate** Application option (commercial, legacy viewer, planning mode…).*
- ☐ *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. Treatments require purified water complying with ISO3696 (1987) Grade 2, or ASTM (D1193-91) Type II, or NCCLS (1988) Type II for (Fresh Reverse Osmosis water can be used for DQA and cleaning).*
- ☐ *Set the water system to “Prepare Water” either from the Workstation “System Settings” 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.*

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 wheels.*

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.

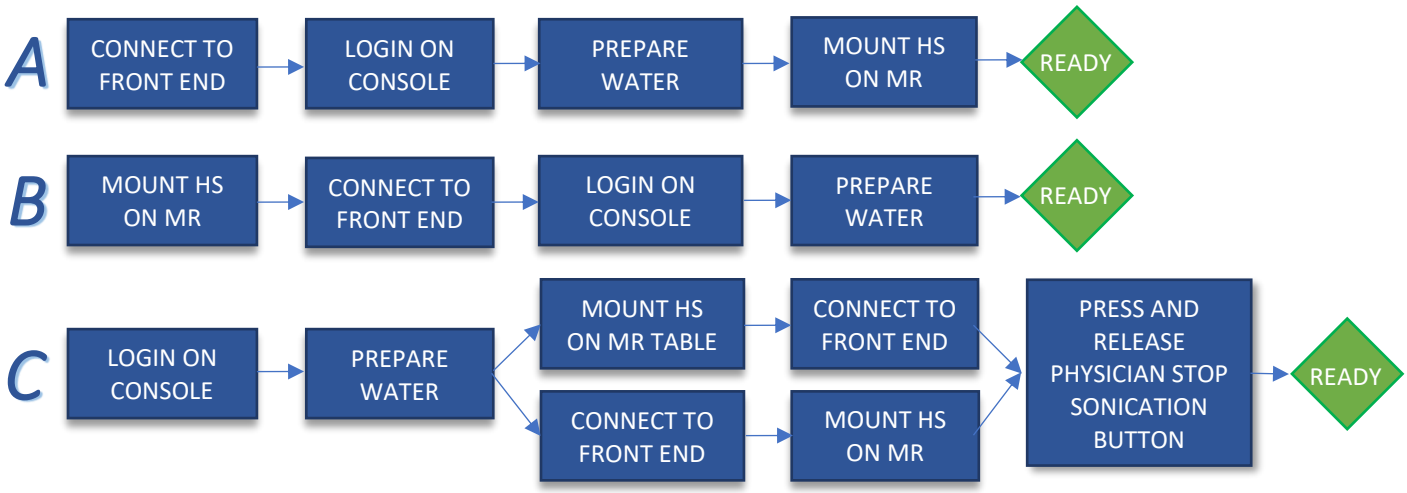
Note some systems require undocking\angling MR table for proper docking

- ☐ *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.*
- ☐ *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 MR console was rebooted at the beginning of the day. If not, reboot it.*
- ☐ *Confirm that the System and MR status fields are "Ready" on Workstation screen, and the FUS and Host Power Indicators on the operator console are illuminated.*
- ☐ ***GE:** on SW version DV26 and up you may need to press the 'External Host' button on the MR WS:*  *select 'Exablate' from the drop down menu in order to enable communications.*
- ☐ ***SIEMENS: Ensure "remote connection" icon on bottom of the MR workstation screen is enabled:***  ***If Disabled (***  ***) click on it to enable communication.***

System Setup Flow Option Charts



Preparation Checklist

Screening - SDR Calculation *(can be performed ahead of the treatment day)*

- ☐ *From the main screen, select **SCREENING.*** Calculate SDR
- ☐ *Import **CT images** via the image retrieval dialog* +
- ☐ *Select intended target side and location (or adjust transducer location manually)*
- ☐ *Press* Calculate *to observe estimated SDR value and additional treatment parameters*
- ☐ *To keep calculation results in Database for reference, press* Save Results

Pre-Planning Session (optional, can be performed ahead of the treatment day)

- ☐ *From the main screen, select **PRE-PLANNING.** Define username, indication and target.* Start Pre-Planning
- ☐ ***REGISTRATION**: Load, register and approve registration for images of interest.* +
- ☐ ***AC-PC Plane**: Review, adjust as needed, and approve AC and PC location as well as midline alignment.*
- ☐ ***NPR REVIEW:** Review, augment, and approve non-pass regions on CT and MR images as needed.*
- ☐ ***TARGET** & SAVE: Set a target. Patient SDR and other parameters are available.*
- ☐ *TARGET & **SAVE**: **Save** the preparation session to disk for future reference and use.*

DQA - Daily Quality Assurance (perform at the start of each treatment day)

System Set-Up for DQA

- ☐ *Perform one of the System Setup flow options as defined by the **System Set Up Checklist.***
- ☐ *Affix the Patient Membrane intended for the treatment into the **DQA Holder Setup.***
- ☐ *Place a **DQA Phantom** into **DQA Holder Setup**, and mount it onto the 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 DQA** from the **DQA** tab in the main menu of the Exablate application software.*
- ☐ ***PLAN screen:** Locate Transducer, Find Central Frequency, and Acquire Planning Scan.*
- ☐ ***In MR Room:** Press Patient Stop Sonication Button. A prompt will appear on the WS screen.*
- ☐ *Advance to the **SONICATE** stage and press the **SONICATE** button. A DQA sonication will commence. Review the results:*
  - ⬚ *Two thermal spots, each centered around a target (green dot)*
  - ⬚ *The peak temperature at the center of each spot is at least 46°C*
  - ⬚ *The sonication concluded with a cavitation halt.*
- ☐ *Perform at least two DQA sonications using different scan orientations (e.g. Axial, Sagittal).*
- ☐ *QUIT*

Following the DQA procedure

- ☐ *Drain water from transducer and set water system to **Degassing mode.***
- ☐ ***Wipe** and **Dry** the **DQA Setup** and **Membrane**, stow the DQA holder setup away.*
- ☐ *Make sure the Transducer is set as **Superiorly as possible** to accommodate **patient** placement.*
- ☐ *Discard DQA Phantom.*

Patient preparation and positioning

Required accessories

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

INSIGHTEC PATIENT AND TREATMENT ACCESSORIES		
☐ Head Frame Set	☐ Patient Membrane	☐ Patient Fixation Kit

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).

Patient Preparation

☐ *Prepare MR table for patient arrival: mattresses (cover with blankets), cushions, warm blankets,*
☐ *Confirm patient is **shaved** and the **scalp** is **cleaned** with alcohol.*
☐ *Ensure **IV line** is in place.*
☐ *Fit the patient with **Compression Stockings** [recommended].*
☐ *Affix the **Head Frame**, as inferiorly as possible above the eyebrows.*
☐ *Place the **Patient Membrane** on the patient's head, as low as possible. Ensure the Head Coil connectors are in the right location according to the coil socket position next to the transducer*

Patient Positioning

☐ *Bring the patient into the MR suite. Assist patient on **Table.***
☐ *Attach **Frame** to **Frame holders***
☐ *Move **Transducer** to estimated clinical position**. Ensure clearance between patient and Transducer.***
☐ *Latch the **Membrane** to the **Transducer** (ensuring all latches are fastened).*
⬚ *Plug the Head Coil into its dedicated connector (if applicable).*
☐ *Fit **earplugs**, 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.*
☐ ***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.*

On MR Scanner Console and in MR Room

☐ *Register Patient\Open exam.*
☐ *Set **landmark** center according to labels.*

Entrance Screen TREATMENT Tab

☐ *Define username, indication and target, and select desired Defaults Profile.*
☐ *Verify active exam on MR belongs to the intended patient.*
☐ *Select the applicable Patient Membrane code OR press*  *to register a new Membrane.*
☐ Start Treatment

Treatment Checklist

PLAN Stage

CALIBRATION Substage:

- ☐ *Press* Auto-Calibrate *to perform automatic calibration sequence.*
- ! *Pre-operative images and NPR can be reviewed during calibration.*
- ! *Individual calibration scans can be prescribed from the "Manual Calibration" expandable menu.*
- ☐ *Load a CT scan and (optional) Pre-op MR images* + *, or a ready planning session* Load Pre-Treatment Plan ...

SCAN Substage

- ☐ *Define desired scan type, protocol, and location. Press* Scan *to acquire images.*
  Acquire at least one volumetric scan or three planar slabs using protocol of choice.
  Note: *You may press* Scan from MR *to acquire scans as manually defined on MR console.*

NPR REVIEW Substage

- ☐ *Review, augment, and* Approve *NPR markings on CT and MR images.*
- ! *Removal and recalculation options are available from the "More" menu.*

REGISTRATION Substage

- ☐ *Review, adjust, and* Approve Set *for any image set to be used in Treatment.*
- ! *The approve button is available only once all 3 image windows are populated.*
- ! *Thumbnails marks: – Auto-registration awaiting. – Approved. – Reference series.*
- ! *Advanced options are available by clicking the right mouse button over the thumbnails.*

AC-PC PLANE Substage: *Review, adjust, and* Approve AC-PC Plane

- ! *Upon entry, auto-calculated AC-PC locations are presented for review.*
- ! *AC-PC markers from loaded pre-planning session have their own dedicated markers.*

TARGETING Substage

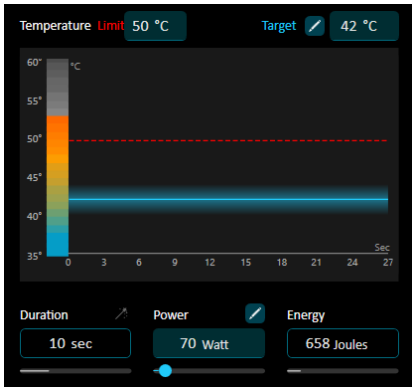
- ☐ *Place target at suitable anatomic location*
- ☐ *Inspect distance to focal point, adjust transducer location if needed and* Update Transducer Location
  Note: required adjustment values are also displayed on the front-end screen.
- ☐ *Instruct Patient to press Stop Sonication Button*
- ☐ *Ensure compliance with local inclusion criteria and labeling*
- ☐ Finalize Treatment Plan *and proceed to THERAPY.*

CAUTION:
Automatic registration and AC-PC location are meant to serve as a base for user review. Automatic NPR calculation is not expected to detect all abnormalities, please review carefully and augment as needed.

THERAPY Stage

DEFINE Substage

- ☐ *Define Sonication Parameters: Target **Temperature**, sonication **Duration** and **Power:***



- *Two of the parameters are set manually while the third is automatically calculated to reach Target Temperature.*
- *Press*  *to toggle Manual\Auto.*
- *The Target Temperature (when manual) can also be adjusted by dragging the teal temperature line.*
- *No suitable parameters exist for gray temperatures on the temperature bar (for a set Power\Duration value).*
- *Prediction results change adaptively during treatment.*

- ☐ *Set the Temperature Safety Limit, according to the selected mode (see Sonication Pref. Tab):*
  1) *By Prediction: Aligned to Target Temperature.*
  2) *By Levels: Set between four predefined values, marked by dashed red line.*
  3) *Manual: Set temperature limit manually. marked by draggable dashed red line.*
- ☐ *Set thermal scan parameters: **Orientation**, **Frequency** direction, and **number of slices**.*
- ☐ *Review target coordinates. Unlock and adjust as needed.*
  ***Note**: The SONICATE button is disabled while coordinates are unlocked (or if the spot is invalid).*
- ☐ *Press **SONICATE** to initiate sonication.*
- ☐ *Gradually increase parameters to achieve clinical effect & permanent lesioning temperatures.*

SONICATE Substage

- ! *Observe and monitor thermal map for unintended heating.*
- ! *Observe CT to anatomy image alignment to account for patient movement.*
- ! *You may stop the sonication at any time by pressing* 

*or the physical **STOP SONICATION** button on the Exablate Console (which will also terminate scan on MR).*

REVIEW Substage

- ☐ *Evaluate spot and dose location and size, and check for heating outside of treatment area.*
- ☐ *Make sure spot is aligned along all orientations before proceeding to lesional temperatures.*
- ☐ *Evaluate Patient before & between sonications and drive sonication according to clinical feedback*
- ! *Refer to the* 

and 

to evaluate previous sonications.
- ! *The "Tools" tab includes controls for updating peak temperature, spot alignment correction, Background Elimination state Patient movement detection image review.*
- ! *The "Evaluation" tab includes additional relevant information, and a space for comments*
- ☐ *Press* 

to proceed to the next sonication.
  In case of partial or corrupted data: 

Post-Treatment Procedures

- ☐ *Open the Air Release Valve on top of the Transducer and Drain the water from the Transducer.*
- ☐ *Move transducer as superiorly as possible. Disconnect Head Coil (if applicable).*
- ☐ *Release the Membrane and assist the patient off the table.*
- ☐ *Perform cleaning as defined below and stow away system components until the next treatment.*

Cleaning Procedure Checklist

Basic Water System Cleaning Procedure

Basic Cleaning should be performed between patients

- ! *Requires **Cleaning & Disinfection Wipes** - 0.2 - 0.4% of benzalkonium chloride (CAS # 8001-54-5)*
- ☐ *After the transducer has been fully drained, perform a front-End drain as well.*
- ☐ *Discard all water used during the procedure.*
- ☐ *Wipe the Transducer gently with dedicated cleaning & disinfection wipes. Do not apply force!*

Full Water System Cleaning Procedure

Full Cleaning should be performed once a week of after 5 cases (the earlier)

- ! *Requires **Water Tank Disinfectant** - 50 ml Sodium Hypochlorite (CAS # 7681-52-9) 4.00% - 4.99%*
- ! *Requires **Cleaning & Disinfection Wipes** - 0.2 - 0.4% of benzalkonium chloride (CAS # 8001-54-5)*
- ☐ *Drain Transducer and discard of water in Water System Reservoir ("Water Tank").*
- ☐ *Attach Cleaning Cover\ DQA holder to the Transducer.*
- ☐ *Fill the water tank with 14 liters (3.7 US gallons) of fresh Reverse Osmosis water.*
- ☐ *Pour **Water Tank Disinfectant** in the Tank and re-connect it to the Front-End.*
- ☐ *On the Water System home screen (Figure A), press the "Clean" option .*
- ☐ *Ensure all prerequisites have been fulfilled and press "START" ▷ (Figure B).*

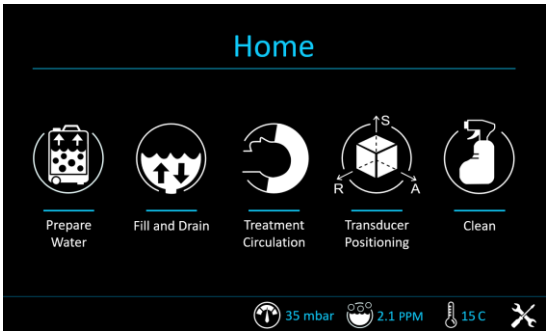


Fig. A: *Water System Touchscreen "Home" Menu*

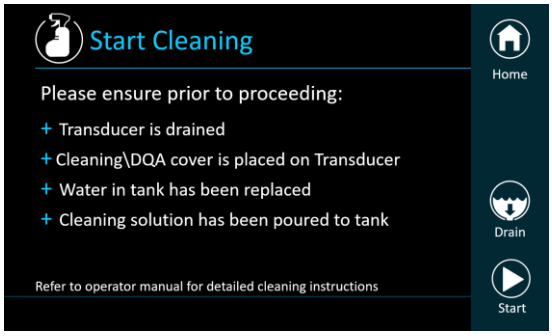


Fig. B: *Water System "Clean" Menu – on Hold*

- ☐ *A countdown timer displays the remaining cleaning time of the Tank (Figure C).*
- ☐ *Tank cleaning is complete (Figure D). Fill Transducer by pressing the "Fill" button on the Screen or Water System Remote Controller. Close Valve once the Transducer is full. "Proceed" ▷*

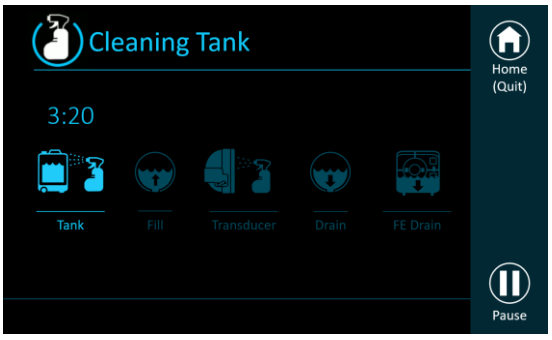


Fig. C: *"Tank Cleaning in Progress"*

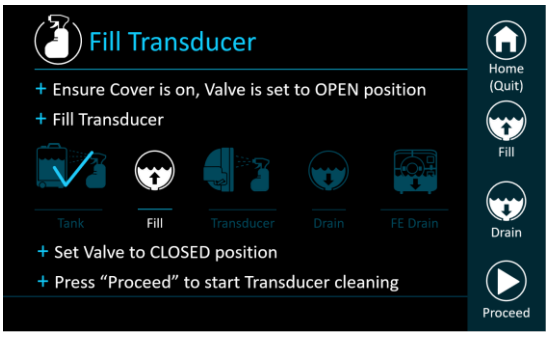


Fig. D: *"Cleaning Tank Completed"*

- ☐ *A countdown timer displays the remaining cleaning time of the Tank (Figure E).*
- ☐ *When timer is over, open valve to air and drain the water from the Transducer by pressing the "Drain" button on the Screen or on the Water System Remote Controller (Figure F). "Proceed" ▷*

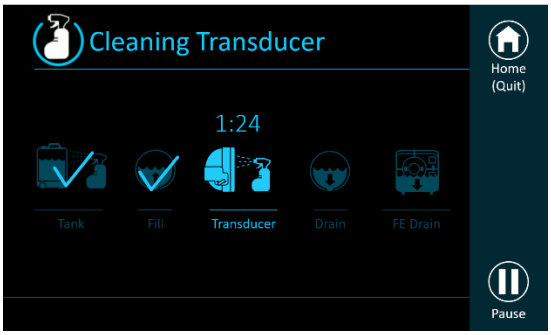


Fig. E: "Cleaning Transducer in Progress"

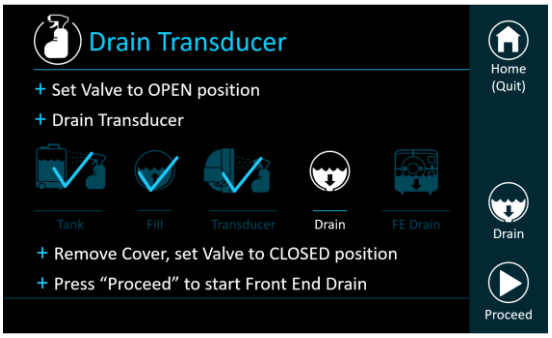


Fig. F: "Cleaning Transducer Complete"

- ☐ *A countdown timer displays remaining Front-End draining time (Figure G).*
- ☐ *Cleaning is now complete (Figure H). Dispose of water according to site and/or local regulations.*

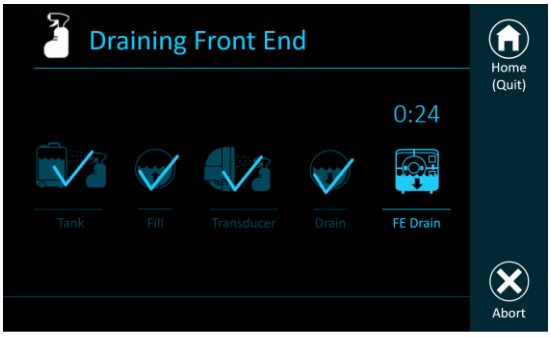


***Fig. G:** "Draining Front-End"*

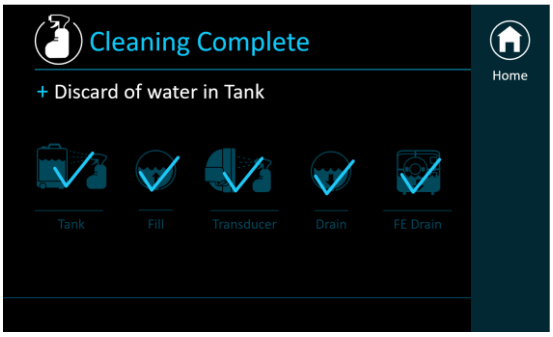


***Fig.H:** "Cleaning Complete"*

- ☐ *Leave the Tank open to air (without the cap).*
- ☐ *Wipe the Transducer gently with dedicated cleaning & disinfection wipes. Do not apply force!*
- ☐ *Place protective transducer cover on transducer*

✓ Accessory Handling

General instructions

- ☐ *It is recommended to wear personal protective equipment (i.e. gloves).*
- ☐ *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.*

Head Frame Cleaning Procedure

- ! *Requires **IPA 70%** (**"rubbing alcohol"**) - (isopropyl alcohol 70% in water)*
- ! *Requires **Purified water** (ISO3696 (1987) Grade 2, **or** Type II (ASTM (D1193-91) **or** NCCLS (1988))*
- ! *Requires **Lint Free Cloths***
- ☐ *Immediately after use, wipe components with de-ionized distilled water to remove any residue of Betadine and blood or other debris*
- ☐ *Dry thoroughly the components with paper*
- ☐ *In case of persistent stains see operator manual for instructions*