

TULSA-PRO[®]



TULSA-PRO[®] Transurethral
Ultrasound Ablation System

Operator's Manual

General Electric

PROFOUND



Publisher's Notice

TULSA-PRO® SYSTEM Model Number: PAD-105

Operator's Manual for General Electric

Document Number: 111229 REV C

Change Control Number: CO-05729

Published By:



Profound Medical Inc.

2400 Skymark Avenue, Unit 6
Mississauga ON L4W 5K5

Phone: 647-476-1350

Fax: 647-847-3739

<http://www.profoundmedical.com/>



EUROPEAN AUTHORIZED REPRESENTATIVE:

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Copyright © 2023 Mississauga, Canada.

All rights reserved. No part of this document may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from Profound Medical Inc.



Federal law restricts this device to sale by or on the order of a Physician.

Table of Contents

PUBLISHER'S NOTICE	2
TABLE OF CONTENTS	3
1. INTRODUCTION	8
2. ABBREVIATIONS	9
3. GENERAL INSTRUCTIONS	10
3.a Suggested Personnel.....	10
3.b Workflow Overview.....	10
3.c Operator, Personnel, and Patient Requirements.....	11
3.d TULSA-PRO® System Commissioning.....	11
4. PATIENT ADMISSION AND PREPARATION	13
5. EQUIPMENT SETUP	14
5.a Setup Inside the MRI Magnet Room.....	15
5.a.i Setting up the Base Plate, Patient Pad, and Straps.....	15
5.a.ii Preparing a Work Surface and Connecting the Positioning System (PS).....	16
5.b Preparing the System Cart Outside the MRI Magnet Room.....	16
5.b.i Cart Setup.....	17
5.b.ii Fluid Preparation.....	17
5.b.iii Tube Setup.....	17
5.c Connecting the System Electronics.....	19
5.d Register Patient on the MRI Console.....	19
5.e Preparing the Treatment Delivery Console (TDC).....	19
5.e.i TDC Computer Setup.....	19
5.e.ii Clock Synchronization.....	20
5.e.iii Treatment Delivery Console (TDC) Initialization.....	20
5.f Performing Pre-treatment Equipment Checks in the MRI Magnet Room.....	21
5.f.i UA and ECD Preparation.....	21
5.f.ii Pre-Treatment equipment checks.....	26
RF connectivity test.....	26
PS test.....	27
6. INITIAL PATIENT POSITIONING	30
7. DEVICE INSERTION	32
7.a Preparing the UA.....	32
7.b Inserting the UA.....	33
7.c Attaching the Ultrasound Applicator to the Positioning System.....	33

7.d Inserting the ECD	35
7.d.i To insert the ECD the first time:.....	35
8. MRI PATIENT POSITIONING	37
8.a Securing the Patient.....	37
8.b Device Check.....	40
8.c Entering Treatment Milestones	40
9. TREATMENT PLANNING	41
9.a Initial Imaging.....	41
9.a.i MRI sequence protocol and instructions	41
9.a.ii Moving the patient to landmark position	42
9.b Gross Positioning	42
9.b.i Reviewing initial device positioning	42
9.b.ii To adjust the ECD position or address bubbles lateral to the ECD:	44
9.b.iii If using an ECD with bubble removal channels:	44
9.b.iv Pushing planning images from the MRI to TDC.....	44
9.c Alignment	45
9.d Coarse Planning	47
9.e Detailed Planning.....	50
9.e.i Acquiring the treatment planning images for GE.....	50
9.e.ii How to draw prostate boundaries	53
9.e.iii Treatment planning guidelines.....	54
9.e.iv mpMRI Vision.....	55
9.e.v Contouring Assistant	56
10. DELIVERY.....	58
10.a Starting position and direction of rotation	59
10.b Treatment Initialization for GE	59
10.b.i Monitoring Treatment Delivery	60
10.c Toggling Power to One or More Treatment Elements.....	61
10.d Adjusting Beam Alignment during Treatment.....	62
10.e Delivery Paused.....	65
10.f Editing the Prostate Boundary during Treatment	66
10.g Creating a new Treatment Segment	68
10.h History Slider.....	68
10.i Thermal Boost.....	70
11. POST-TREATMENT IMAGING AND REPORTS	72

11.a Post-treatment Imaging.....	72
11.b Entering Treatment Milestones.....	72
11.c Treatment Reports.....	73
11.c.i Viewing treatment videos.....	74
11.c.ii Exporting reports and videos.....	75
11.d Post-treatment Session Export.....	76
12. DEVICE REMOVAL AND PATIENT RECOVERY.....	78
12.a Device Removal.....	78
12.b Patient Recovery.....	78
12.c Equipment dismantling.....	79
13. CLEANING AND DISPOSAL.....	80
13.a Disposables.....	80
13.a.i Ultrasound Applicator (UA).....	80
13.a.ii Endorectal Cooling Device (ECD).....	80
13.a.iii Fluid Tubing.....	80
13.b Reusable Equipment Cleaning & Disinfection.....	80
13.b.i General Cleaning and Disinfection.....	80
13.b.ii General Cleaning Reagents, Methods, and Tools.....	81
Cleaning Reagents.....	81
Cleaning Tools and Methods.....	81
Pre-cleaning Preparation.....	81
13.b.iii Performing Manual Cleaning and Disinfection.....	82
13.b.iv Positioning System – Cleaning and Disinfection Instructions.....	83
13.b.v Base Plate – Cleaning and Disinfection Instructions.....	84
14. SOFTWARE ALARMS.....	86
14.a Alarm Indicators.....	86
14.b Description of Alarm Conditions.....	87
14.c Multiple Alarm Conditions.....	88
14.d Alarm Condition Log.....	89
APPENDIX A. TULSA-PRO® MRI TROUBLESHOOTING TIPS.....	90
Patient motion concerns.....	90
Thermometry and temperature uncertainty.....	90
Access to User Documentation from TDC.....	91
APPENDIX B. TROUBLESHOOTING GUIDE.....	92
Alarm Signals.....	92

Fluid Cart.....	94
40-201: TDC lost a network connection to the System Cart.....	94
40-202: The cable between the System Cart and the System Electronics has been disconnected.....	96
40-206: The room temperature for the System Cart is too high.....	98
41-107: The Ultrasound Applicator fluid-circuit bag volume is too low.....	99
41-109: The Ultrasound Applicator fluid-circuit pump pressure is too low.....	101
41-110: The Ultrasound Applicator fluid-circuit pump pressure is too high.....	103
42-107: The ECD fluid-circuit bag volume is too low.....	104
42-109: The ECD fluid-circuit pump pressure is too low.....	106
42-110: The ECD fluid-circuit pump pressure is too high.....	108
Magnetic Resonance Imaging.....	110
50-201: The IP address or port for the MRI cartridge is wrong or in use.....	110
50-202: TDC lost network connection to the MRI.....	111
50-203: There is a delay in receiving the thermometry image.....	112
50-204: TDC has not received new thermometry images in the last 30 seconds.....	113
50-209: The thermometry images cannot be used.....	115
50-211: The thermometry scan does not match the prescribed image position or orientation.....	117
50-212: Someone changed the thermometry sequence parameters and they are out of range.....	119
50-213: The thermometry images cannot be used.....	120
50-214: The anatomy scan required for alignment is older than 2 hours.....	122
50-215: Check that the patient is in a head-first, supine position.....	123
Positioning System.....	124
10-102: TDC lost the network connection to the Positioning System Interface Box.....	124
20-102: The cable between the Positioning System (PS) and PS Interface Box is disconnected.....	126
20-201: There is a problem with the rotary motion.....	128
20-202: The TDC computer is busy and cannot process thermometry images fast enough.....	129
20-203: Something went wrong with the Positioning System communications.....	130
21-201: The Positioning System's linear axis moved unexpectedly.....	131
22-201: The Positioning System is not rotating the Ultrasound Applicator at the expected rate.....	132
22-202: The rotary home position has been lost.....	133
22-206: The Ultrasound Applicator (UA) has rotated too far in one direction.....	134

22-208: The Positioning System's rotary axis moved unexpectedly	135
Radio Frequency	136
30-201: Emergency switch button has been activated	136
30-202: The TDC computer is busy and cannot process thermometry images fast enough	137
31-201: The System Electronics amplifiers are overheating	138
31-202: The System Electronics amplifiers have turned off	139
32-102: TDC lost the network connection to the System Electronics	140
System.....	142
71-202: There is not enough hard-drive storage space to complete this session.....	142

1. Introduction

This guide contains operating instructions for setting up and operating the TULSA-PRO[®] Transurethral Ultrasound Ablation System, and for preparing and positioning patients with specific information for General Electric Magnetic Resonance Imaging (MRI) scanners.

You must use these instructions along with the *TULSA-PRO[®] Instructions For Use* for the TULSA-PRO[®] Transurethral Ultrasound Ablation System, which contains all regulatory information about the TULSA-PRO[®] system, including warnings and cautions that are essential for the safe and proper use of this medical device system.

If you need additional copies of the *TULSA-PRO[®] Instructions For Use* or *TULSA-PRO[®] Operator's Manual* for any MRI system, or have questions about this document's contents, please contact:



Profound Medical Inc.

2400 Skymark Avenue, Unit 6 Mississauga ON L4W
5K5

Phone: 647-476-1350

Fax: 647-847-3739

<http://www.profoundmedical.com/>



NOTE: On any TDC screen—except during Treatment Delivery—you can press F1 on your keyboard to open and review a PDF copy of the *TULSA-PRO[®] Operator's Manual*. Click **X** in the top corner of the PDF viewer to close the document window.

2. Abbreviations

This manual uses the following abbreviations:

ECD	Endorectal Cooling Device
MR	Magnetic Resonance
MRI	Magnetic Resonance Image/Imaging/Imager
PS	Positioning System
PSIB	Positioning System Interface Box
TDC	Treatment Delivery Console software
TULSA-PRO	Transurethral Ultrasound Ablation System
UA	Ultrasound Applicator

3. General Instructions

3.a Suggested Personnel

The following table describes the suggested roles and responsibilities required for a TULSA-PRO® procedure. At your site, some personnel might perform multiple roles. Instructions throughout this manual are color-coded by role based on the shading colors in the following table.

ROLE	TYPICAL ACTIVITIES WITHIN A TULSA-PRO® PROCEDURE
Urologist	<ul style="list-style-type: none"> • Patient inclusion and education (assess patient suitability, discuss risks and benefits of TULSA, visits, and follow-up care) • Patient preparation (catheter and guidewire insertion) • Device insertion (Ultrasound Applicator and Endorectal Cooling Device) • TULSA-PRO® Software operation (same as for <i>Radiologist</i>)
Radiologist	TULSA-PRO® Software operation: <ul style="list-style-type: none"> • Device positioning and alignment with anatomy • Treatment planning (contour prostate gland and prescribe control boundary) • Treatment delivery monitoring (watching for expected ablation and software alarms)
MRI Technologist	<ul style="list-style-type: none"> • Assessment of Magnetic Resonance Imaging (MRI) eligibility of patient and personnel required in MR environment • TULSA-PRO® equipment setup, dismantling, and storage • Patient and equipment positioning in MRI magnet room • Operation of MRI console for image acquisition
Anesthesiologist (with possible anesthesia assistants)	<ul style="list-style-type: none"> • Assessment of patient suitability for anesthetic • Sedation in the preparation area or MRI scanner room • Monitoring and adjusting sedation level during treatment planning and delivery • Patient recovery following ablation procedure and transfer to post-anesthesia care

3.b Workflow Overview

The following table summarizes the workflow of a TULSA-PRO® procedure. Detailed instructions for each step are described in subsequent sections of this document. Steps involving multiple personnel or

3. General Instructions

performed in parallel are listed on the same row. The primary role for each step is indicated in **bold**. Steps requiring Anesthesiologist support are labeled with an asterisk (*).

UROLOGIST	RADIOLOGIST	MRI TECHNOLOGIST
Patient Admission *		Patient MRI Screening
Patient Preparation *		Equipment Setup
		Initial Patient Positioning *
Device Insertion – UA		Device Insertion – UA
Device Insertion – ECD		Device Insertion – ECD
		MRI Patient Positioning *
	Initial Imaging	Initial Imaging
	Planning – Alignment	Planning – Alignment
	Planning – Coarse	Planning – Coarse
	Planning – Detailed *	Planning – Detailed *
Treatment Delivery *	Treatment Delivery *	Treatment Delivery *
	Post Treatment Imaging	Post Treatment Imaging
Patient Recovery *		Equipment Dismantling

3.c Operator, Personnel, and Patient Requirements

All personnel and operators who install and handle the TULSA-PRO® **must** receive training on equipment setup.

The patient and all operators entering the MRI magnet room must be screened by Radiology or MRI Personnel and must complete an MRI Screening Form.

Operators who set up equipment must be careful within the MR environment and must not enter the MR environment with any MR-Unsafe items in their pockets or on a tray or cart. The TULSA-PRO® equipment has been designed so that tools (such as screwdrivers and wrenches) are not required for setup.

3.d TULSA-PRO® System Commissioning

Before first using the TULSA-PRO® System at any MRI site, the system **must** undergo initial setup and acceptance testing by service personnel authorized by Profound Medical.

- Setup involves calibrating Fluid Circuit sensors and verifying the correct electrical connections.
- Acceptance testing verifies operation of equipment within the MRI environment.

3. General Instructions

- Service personnel will also configure the name and address of your site as it should appear in treatment reports (see *Exporting reports and videos*).

4. Patient Admission and Preparation

Patient admission and preparation is led by the **Urologist**, with assistance from the **Anesthesiologist** and the **MRI Technologist**.

After being admitted, the patient is taken to the MRI patient preparation area.

1. **MRI Technologist**: Screen the patient for MRI eligibility and obtain information needed to register the patient on the MRI computer.
2. **Anesthesiologist**: It is recommended you administer general anesthesia for patients undergoing this procedure.
3. **Urologist**: A supra-pubic catheter can be placed in the patient's bladder under cystoscope guidance to drain urine from the bladder and manage the urine flux during the procedure. If a supra-pubic catheter is not used, drain the bladder using a Foley catheter before inserting the guidewire.
4. **Urologist**: Under cystoscope guidance or using a Foley catheter, insert a maximum 0.96 mm (0.038 in) non-magnetic guidewire (such as Nitinol core) into the prostatic urethra and into the bladder.



Only use a guidewire that has been verified to be non-magnetic.

Do not acquire MR images while a guidewire is in the patient. Electric currents induced by the MRI in the guidewire could cause thermal injury to the patient or physician.

5. **Urologist**: Remove the cystoscope or Foley catheter and leave the guidewire in place. If this step is done outside the MRI magnet room, secure the guidewire to prevent it from falling out of the patient during transfer to the MRI bed.



Remove the cystoscope from the patient before entering MRI magnet room, or you can injure the patient.

5. Equipment Setup

MRI Technologist: Complete the equipment setup for the TULSA-PRO® by following these steps:

- inside the MRI magnet room:
 - set up the TULSA-PRO® base plate, patient pads, clips, and straps on the MRI bed
 - prepare a work surface and connect the Positioning System Interface Box to the Filter Box and Positioning System
- outside the MRI magnet room:
 - prepare the System Cart:
 - place the System Cart near the waveguide and raise the System Cart pole
 - prepare sterile water for the Ultrasound Applicator (UA) and doped sterile water for the Endorectal Cooling Device (ECD)
 - hang the UA tube set and ECD tube set (with capped ends) on the System Cart
 - pass the capped ends of tube sets through the waveguide to an assistant inside the MRI magnet room
 - connect the System Electronics to Treatment Delivery Console, Filter Box, and power outlet, and power on the System Electronics
 - register a new patient on the MRI console
 - initialize the Treatment Delivery Console (TDC) and turn on PSIB Display
- perform pre-treatment equipment checks inside the MRI magnet room:
 - connect the tube sets through waveguide to the UA and ECD on the MRI work surface
 - purge the UA and ECD and check for bubbles
 - if using an ECD with lubricant channels, prime the green and black channels of the ECD with lubricant
 - connect the UA and PSIB and perform RF Connectivity Test
 - perform a Positioning System (PS) Test

All electrical cables running into the MRI magnet room are connected through a filter box located on a penetration panel. All fluid lines running into the MRI magnet room are passed through a waveguide.

Figure 1 shows a schematic of the TULSA-PRO® equipment setup.



The TULSA-PRO® System must be used only within MRI systems that are tested and approved by Profound Medical. MRI systems that have not been tested might not produce desired treatment results. Refer to the 'Specification Sheet' in the *TULSA-PRO® Instructions For Use* and the site installation requirements for your supported MRI system.

5. Equipment Setup

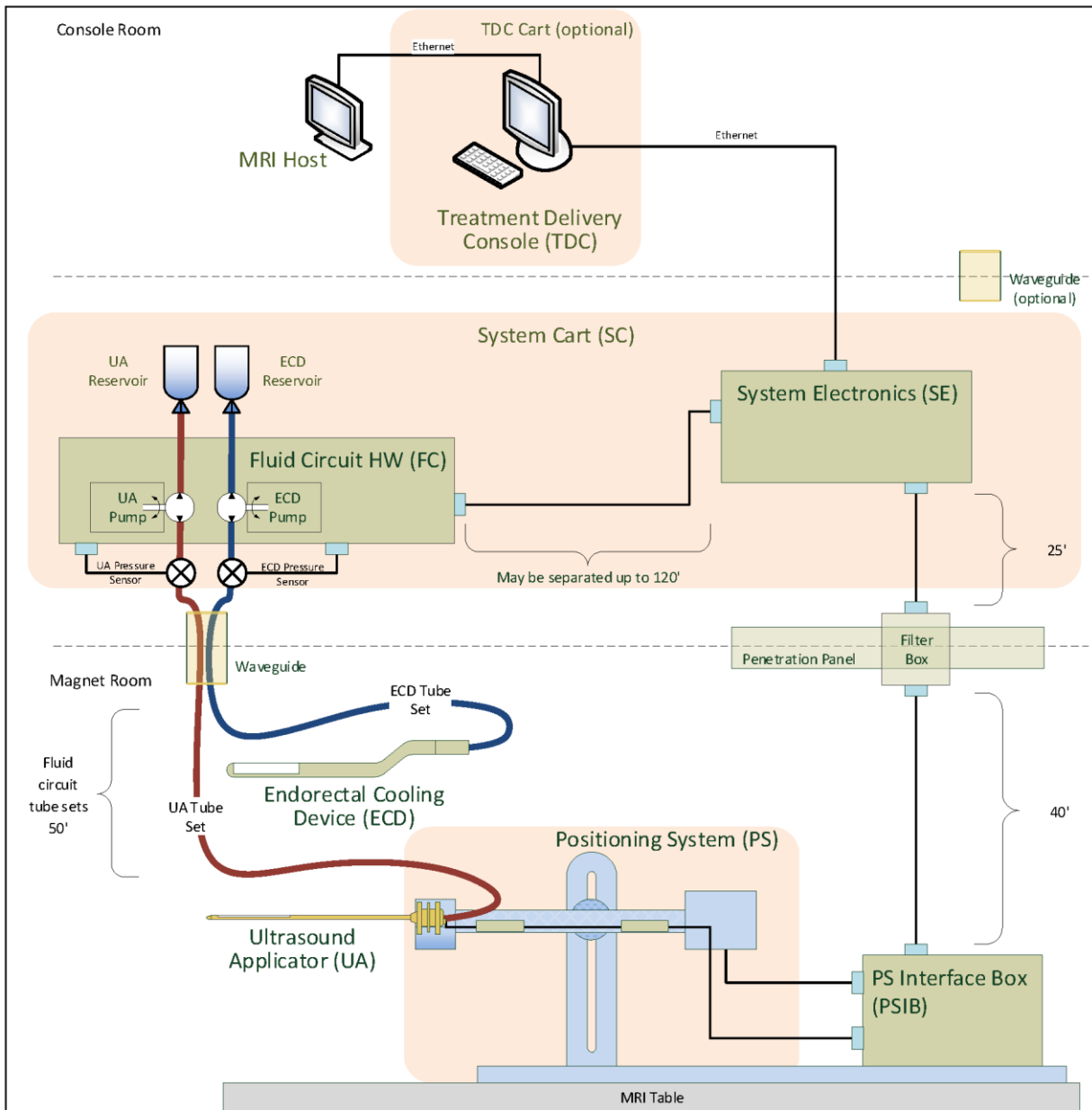


Figure 1: Schematic of TULSA-PRO® equipment setup

5.a Setup Inside the MRI Magnet Room

5.a.i Setting up the Base Plate, Patient Pad, and Straps

1. MRI Technologist Attach the base plate onto the foot end of the MRI table and secure using the four base plate straps (*Figure 2*, your configuration might not match exactly as shown). The feet of the base plate should fit in the rails of the MRI table and not move around when in position.

5. Equipment Setup

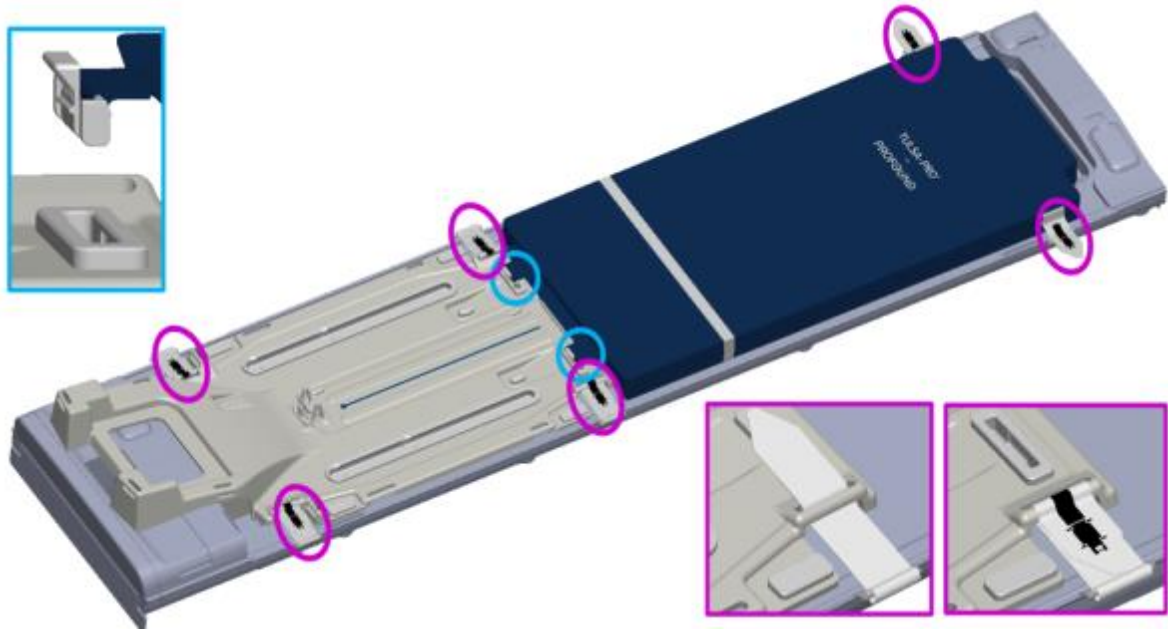


Figure 2: Securing the base plate and patient pad to the MRI bed

2. Place the patient pad on the MRI table and secure it using the provided straps shown in (Figure 2, your configuration might not match exactly as shown).
3. Drape the upper part of the patient pad with a sheet and place an absorbent pad at the end closest to the base plate.

5.a.ii Preparing a Work Surface and Connecting the Positioning System (PS)

1. **MRI Technologist:** Prepare a work surface on a countertop or cart in the MRI magnet room for performing quality assurance checks on the Ultrasound Applicator (UA), the Endorectal Cooling Device (ECD), and the Positioning System (PS).
2. Place the Positioning System and Positioning System Interface Box (PSIB) on the work surface. Manually move the PS backward as far as possible using the adjustment release. Adjust the PS manual vertical axis to near the top end of the range of travel, with the tilt angle horizontal or slightly tilting down.
3. Connect the PS cable between the PS and the PSIB. Connect the large white cable from the Filter Box (on the wall on the inside of the MRI magnet room) to the PSIB.



Be careful when installing the cable between the Filter Box and the PSIB. The cable pins must be carefully mated to the receptacle connector and not forced into place. Too much force will damage the cable pins.

5.b Preparing the System Cart Outside the MRI Magnet Room

MRI Technologist: The System Cart contains the fluid circuit hardware used to cool the Ultrasound Applicator (UA) and the Endorectal Cooling Device (ECD). Here is how to prepare the System Cart:

5. Equipment Setup

5.b.i Cart Setup

1. To provide access for the fluid tubes, position the System Cart near a waveguide in the equipment room. Ensure that airflow from the rear vent is not obstructed.
2. Lock the casters on the wheels to fix the System Cart in place.
3. While pressing the pole clamp release, raise the System Cart pole to its fully extended position.

5.b.ii Fluid Preparation



The ECD fluid supplements are not safe for drinking and should not come into skin contact. Use gloves when handling and do not ingest.

The fluid circuit tube sets have color-coded stickers and Luer fittings to distinguish them: red and white for the UA circuit, blue and yellow for the ECD circuit.

1. Prepare two 1000mL IV bags of sterile water. One will be treated with fluid supplements and used for the ECD fluid circuit, while the other will be used without supplements for the UA fluid circuit.
2. Designate one of the water-filled 1000mL IV bags as an ECD IV bag. Using a 30-60mL syringe with a 16G needle, extract 5mL of ECD Fluid Supplement – Manganese Chloride. Inject this solution into the syringe port of the ECD IV bag.
3. Withdraw 20mL of ECD Fluid Supplement – Span & Tween. Inject this solution into the syringe port of the ECD IV bag.



NOTE: The additives Manganese Chloride and Span & Tween eliminate MRI signal and help prevent bubbles in the fluid within the ECD and ECD fluid line. Do not refrigerate the sterile water or the ECD additives. When cold, the additives do not mix well and take longer to dissolve.

4. Shake the ECD IV bag for 30 seconds or until the solution is fully dissolved. The solution should look milky white, which will help you distinguish the ECD IV bag from the UA IV bag.
5. Set aside the other 1000 mL IV bag containing untreated, sterile water. This will be the UA IV bag.



Do not inject ECD fluid supplement into the UA fluid bag, because:

- **The ECD-fluid additives will eliminate the MRI signal shown from the water in the UA acoustic window, which is important during the *Alignment* phase of treatment planning. In other words, you might not properly identify the UA acoustic window and could misalign the UA.**
- **You increase the risk of infection if the treated fluid should leak out of the UA and into the urethra**

5.b.iii Tube Setup

1. Remove an ECD tube set (identified with a blue dot) from its packaging and install it on the System Cart:

5. Equipment Setup

- a. Lay the empty ECD reservoir bag on top of the Fluid Circuit tabletop.



NOTE: To avoid spills, ensure that the line clamps near the capped ends of the tube set are closed.

- b. Place the pump section of tube set into the ECD pump head and close it.

Avoid pinching the pump section of the tubing when installing it into the peristaltic pump head. Pay attention to both the top and bottom (inlet and outlet) of the pump head.



NOTE: If the tubing is pinched in the pump head, the tubing could fail in the middle of a treatment and cause a large water leak.

- c. Connect the ECD pressure sensor to the corresponding connection on the System Cart.
 - d. Insert the spike from the empty bag into the treated ECD IV bag and then open the line clamp by the spike port to allow the contents of the ECD IV bag to be transferred to the ECD tube set.
 - e. When all the contents from the ECD IV bag have been transferred to ECD reservoir bag, close the line clamp in between.
 - f. Hang the ECD reservoir bag on the blue weight sensor hook on the System Cart (*Figure 3*).
2. Repeat [Step 1](#). for the UA circuit using a UA tube set (identified with a red dot).
 3. With assistance from someone inside the MRI magnet room, pass the UA and ECD tube sets (capped ends) through the appropriate waveguide, into the MRI magnet room. Secure the tube sets near the MRI work surface.

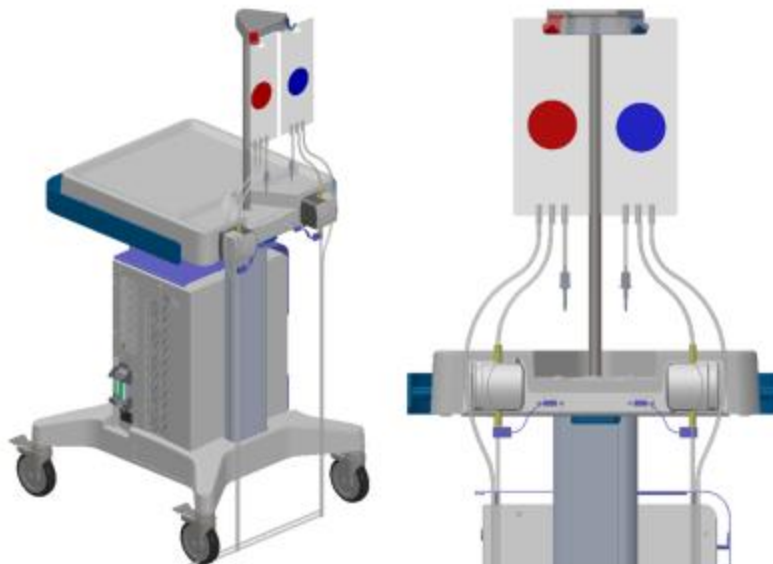


Figure 3: Preparing the system cart and fluid tube sets

5.c Connecting the System Electronics

The System Electronics enclosure is typically located in the MRI equipment room on the System Cart and close to the penetration panel holding the Filter Box. One large, black cable connects the Filter Box to the System Electronics. The System Electronics, Filter Box, and cable are installed by Profound Medical, and can remain connected when not in use.

To prepare the System Electronics for use, ensure the following connections are secure:



NOTE: If any cables are not connected, ensure they are free from damage before connecting.

1. The cable from the fluid circuit electronics, located under the cart tabletop, to the System Electronics enclosure.
2. The large black cable from the System Electronics enclosure to the Filter Box.
3. The Ethernet cable from the System Electronics enclosure to the Treatment Delivery Console (TDC) computer.
4. The System Electronics enclosure to a mains power outlet using a grounded, medical-grade power cord. Do **not** use extension cords.



NOTE: If you need to disconnect the System Electronics power cord, it is a latching connector and you must squeeze the two tabs together to remove the cord properly.

5. When all connections are established, turn the power switch on at the back of the System Electronics enclosure.

5.d Register Patient on the MRI Console

1. Register a new patient on the MRI console from the **Worklist Manager** tab using the information obtained at the time of admission. The patient orientation must be **Head First – Supine**. When prompted, select **Normal dB/dt** and **Normal SAR**.
2. Load the TULSA-PRO® MRI sequence protocol from the **Protocol Library**.



NOTE: The patient's last name, first name, ID, date of birth, and physician name registered on the MRI console will be used to populate the TULSA-PRO Treatment Report.

5.e Preparing the Treatment Delivery Console (TDC)


5.e.i TDC Computer Setup

1. Ensure the TDC computer is placed in the control room close to the MRI console and is connected to the System Electronics and the MRI Host via Ethernet cables.
2. Power on the TDC computer and monitor.

5. Equipment Setup

3. Log in to Windows on the TDC computer when it powers up. Profound Medical will provide the username and password after system training has been completed.



NOTE: To check that the TDC computer is connected to the MRI, click on the icon on the bottom right of the MRI console (), and ensure that TULSAPRO is selected.

5.e.ii Clock Synchronization

To correctly recognize and accept the most recent planning images, the clocks of the TDC computer and MRI host computer must be synchronized. If the TDC computer time-zone is different or the TDC computer time is more than 1 minute ahead or behind the MRI host, follow these steps to adjust the TDC system time:

1. On the TDC computer, right-click on the computer time in the bottom right of the screen and click **Adjust date/time** from the list.
2. In the **Date & Time** dialog, use the *Time Zone* drop-down list and *Daylight Saving* toggle switch to select the same Time Zone settings as the MRI host.
3. In the **Date & Time** dialog, click **Change** to manually adjust the time to match the MRI host to the nearest minute.
4. Close the **Date & Time** dialog.

5.e.iii Treatment Delivery Console (TDC) Initialization

1. Launch the TDC software from the desktop. The *Session Data Management* workspace will appear. Click **New Session** (*Figure 4*).

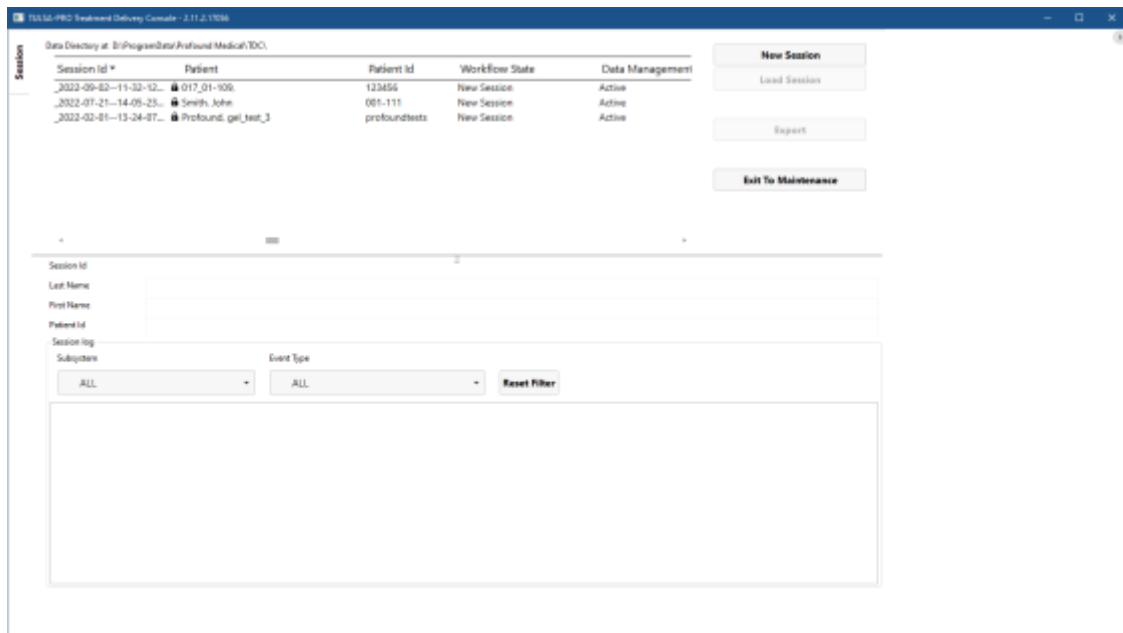


Figure 4: Session Data Management workspace of the TDC Main Menu

5. Equipment Setup

- After selecting **New Session**, you will enter the **Setup** Workspace (*Figure 5*) where you can ensure all equipment is functioning properly before proceeding. A green checkmark will appear in the MRI quadrant of the Setup Workspace if the TDC computer and MRI host can communicate with each other, and a patient is currently open with the TULSA-PRO® MRI sequence protocol on the MRI console.



NOTE: TDC automatically locks the session 12 hours after it was started and will not allow further changes to the session.

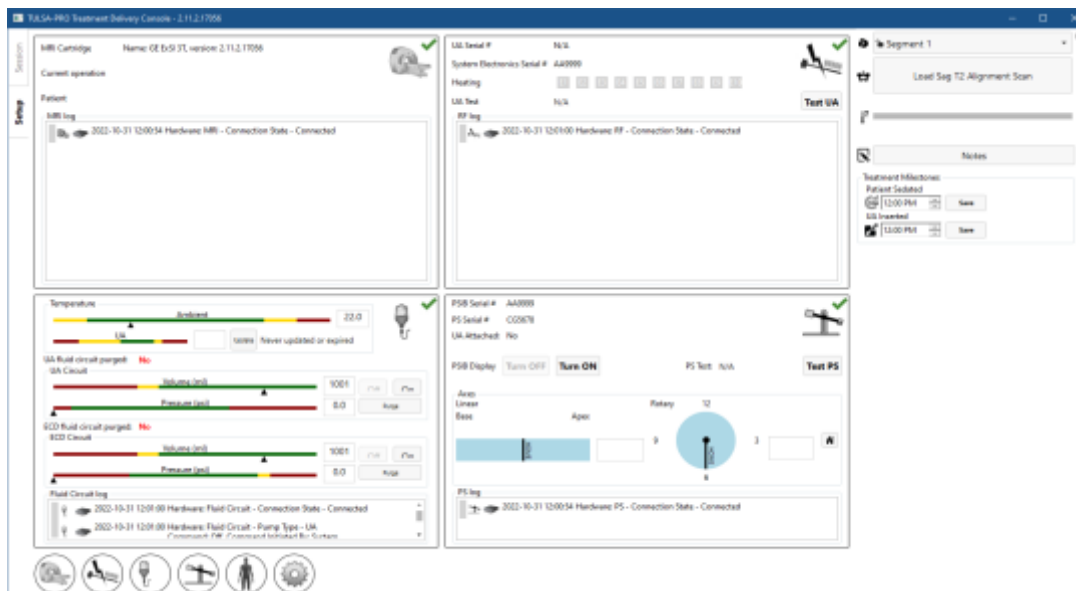


Figure 5: Setup workspace of the TDC software

- In the Positioning System (PS) quadrant of Setup, click **Turn ON** beside **PSIB Display**.



NOTE: On any TDC screen—except during Treatment Delivery—you can press F1 on your keyboard to open and review the *TULSA-PRO® Operator's Manual*. Click **X** in the top corner to close the document window.

5.f Performing Pre-treatment Equipment Checks in the MRI Magnet Room

5.f.i UA and ECD Preparation



The Ultrasound Applicator (UA) is fragile and should be handled with extreme care. If dropped or handled roughly, internal components could be damaged and not be obvious to the operator. Do not use a UA if you suspect any damage.



NOTE: MRI Technologist: The ECD is *not* sterile and can be handled accordingly. The UA and contents inside the UA packaging **are** sterile. *Figure 6* shows the UA inside its sealed and sterile package. There is another plastic cover that encloses the UA from its tip to the top of the handle that exposes the UA cable and guidewire inputs and fluid tubes. When you connect the fluid tubes and UA cable, the UA's sterile

5. Equipment Setup

barrier will have to be broken. Keep the internal plastic cover over the UA during preparation to limit contamination to only the top of the UA handle.

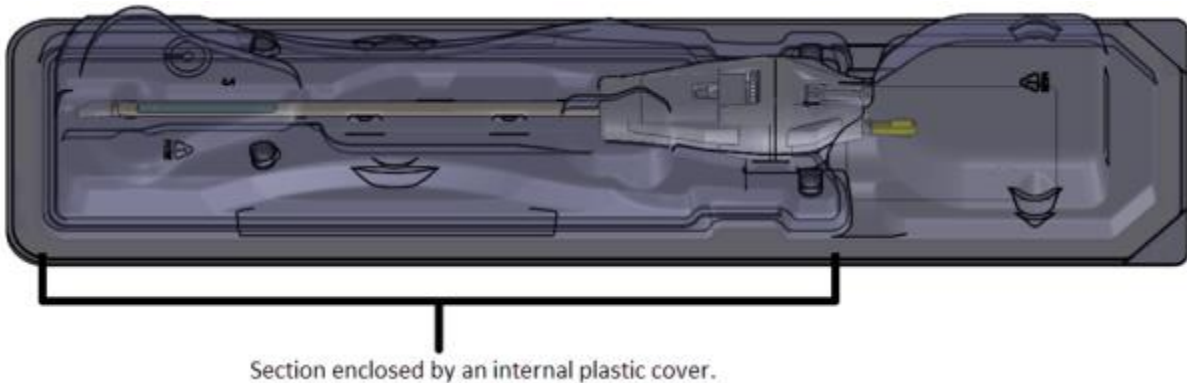


Figure 6: UA sealed inside a sterile package

Prepare the UA and ECD on a clean work surface and prime with fluid from the Fluid Circuit before inserting into a patient. Follow these instructions for priming the UA and ECD:

1. ECD: Open the ECD packaging and connect the ECD tube set to the ECD matching the color-coding of the fittings (blue to blue, yellow to yellow). Undo the line clamps near the fittings. The clear line (without any colour coding) will be used to inflate the ECD balloon after insertion into the patient's rectum. Do not connect any fluid tubing to the light blue line at this stage of ECD preparation.



NOTE: It is not necessary to handle the ECD with sterile gloves.

2. UA: Starting from the arrows on the bottom corners of the tray label, peel off the entire Tyvek cover. Do not remove the plastic package insert; keep the UA completely in its package.
3. UA: Remove the yellow cap from the back of the UA and keep for later use.



NOTE: MRI Technologist: Do not lose the yellow cap.

4. UA: Connect the UA tube set to the UA, matching the color-coding of the fittings (red to red, white to white). Undo the line clamps near the fittings.



NOTE: It is not necessary to handle the UA with sterile gloves.

5. On the PSIB display, choose the **Fluid Circuit** tab (*Figure 7*) and **Purge** the UA and ECD fluid circuits. You can also do this from the TDC by pressing **PURGE** beside the fluid circuit (FC) quadrant (*Figure 8*).

UA and ECD fluid circuit pressures (as shown on the TDC software interface) can fluctuate as air is purged from the UA and ECD lines. UA and ECD purging can occur concurrently. Purging lasts about two minutes.

5. Equipment Setup

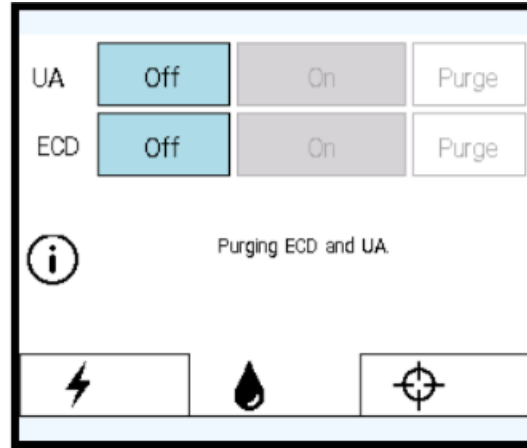


Figure 7: PSIB Display - Fluid Circuit tab

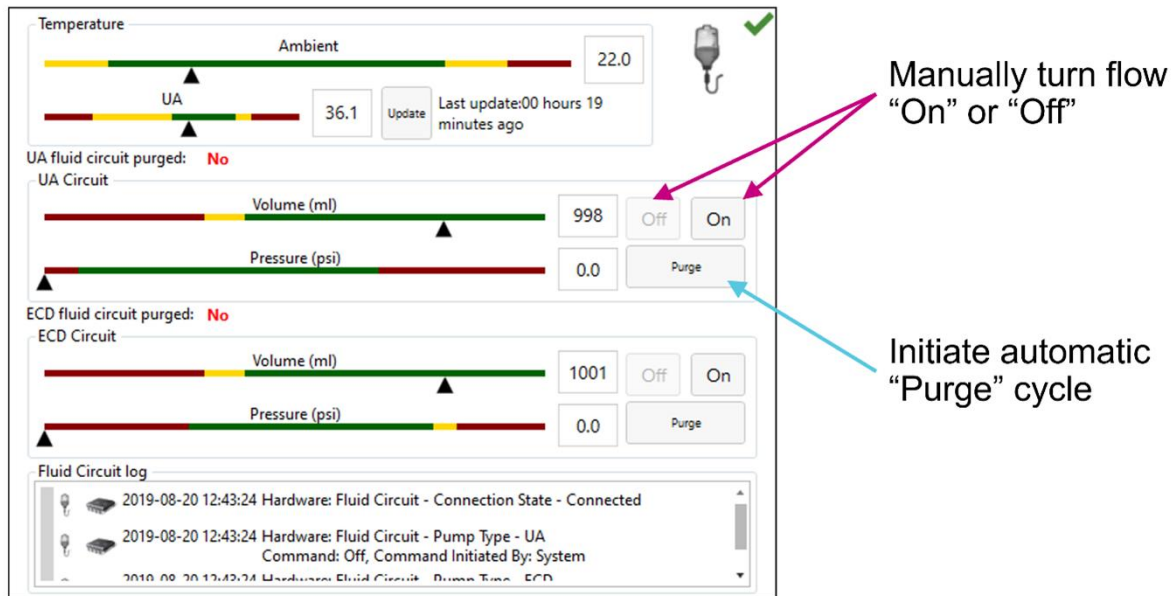


Figure 8: Fluid Circuit information box in TDC Setup workspace

5. During the two-minute device purging, check for leaks in the UA, ECD, and the entire UA and ECD tube sets.
6. Purge the ECD of all air bubbles
 - a. Holding the ECD inside its package, move it so that the cooling window faces up. Bubbles should dissipate in 90 seconds from the moment you clicked **Purge**. You can also lightly tap the package to dislodge any remaining bubbles. There should be no visible bubbles in the cooling window when purged correctly.
 - b. Inspect the entire ECD and ECD tube set for leaks. If you find a leak in the tubes, replace the tube set. If you find a leak in the ECD, replace the ECD. If you replace the tube set or ECD, return to [step 1](#) in this section and repeat the procedure.
 - c. Place and secure the ECD on the work surface until ready to be inserted into the patient.

5. Equipment Setup



If for any reason the ECD tube set is detached after initial fill and purge, you must purge the ECD of bubbles again.

7. Purge the UA of all air bubbles.
 - a. If the purging cycle ends before completing the steps in this process, return to the PSIB display (or TDC window) and manually turn the flow on by clicking **On**. The fluid pumps will remain on until you click **Off** (Figure 8).
 - b. While the purging operation is on, hold the UA in its package—be careful not to touch the UA handle to keep the UA sterile. Tip the package upwards in the 0° position, then tilt to approximately 45°, then 90°, and 135°. At each angle, slowly rotate the package approximately 360° (Figure 9).

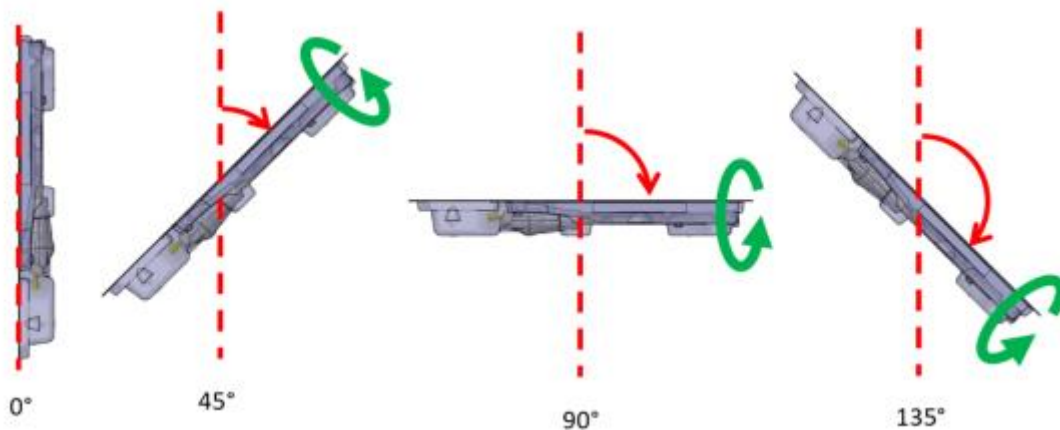


Figure 9: Recommended procedure for purging air from ultrasound applicator

- c. Rotate the UA package so that the flat side is facing down. Inspect the UA closely through the plastic package and ensure there are no signs of water in the package, which would indicate a leak. If you see any signs of water, the UA is defective and should not be used. Use a new UA package and repeat the UA preparation procedure.
 - d. Look through the package and carefully inspect the UA window for bubbles (Figure 10). There should be **no** bubbles of **any** size. If you see bubbles, gently tap the package-end close to the UA window against the work surface to dislodge them. If you still see bubbles, repeat the procedure, starting from [step “a”](#).



Figure 10: Examine the UA window for air bubbles

5. Equipment Setup

- e. Secure the UA package (flat side up) on a work surface. While avoiding contact with the UA handle, connect the UA cable from the PSIB to the UA by rotating the UA cable until the connector's keyed-slot lines up with the UA port.



If for any reason the UA tube set is detached after initial fill and purge, you must purge the UA of bubbles again.

8. If using an ECD with green and black lubricant channels, follow these steps to prime the channels with low-viscosity lubricant:



NOTE: Ensure that the ECD fluid circuit (blue and yellow channels) has been purged and checked for leaks ([Steps #5 and #6](#)) before priming the lubricant channels (green and black) for bubble removal.

- a. Connect the provided three-way stopcock and the syringe adapter to both the green and black-labeled channels (*Figure 11*).
- b. Connect the provided low-viscosity lubricant syringes to the syringe adapters by pressing the taper on the syringe into the syringe adapter tubing (*Figure 11*).



NOTE: To avoid creating air bubbles at the ECD surface, ensure there is no air in the lubricant syringe before connecting to the green and black channels. It is recommended you store lubricant syringes vertically with the tip pointing upwards to allow air to escape before the day of treatment. Remaining bubbles can be removed by rapidly swinging the syringe at arms-length from a tip-down to a tip-up orientation.

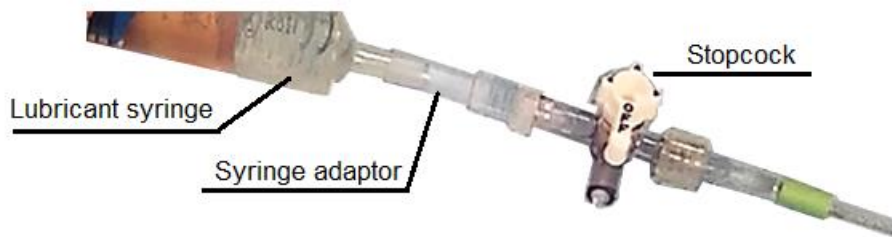


Figure 11: Lubricant syringe with adaptor and stopcock

- c. After attaching the syringe, remove air from the line by pushing or pulling a small amount of gel and any air out through the stopcock.
- d. Prime the lubricant injection and removal channels.
 - i. Slowly inject approximately 15-20 ml of low-viscosity lubricant into the green channel, which will later be used to extract air from the ECD surface. Gently press on the pores closest to the handle to allow lubricant to fill the small pores at the tip of the ECD. Use the stopcock to restrict and expel air when switching lubricant syringes. Ensure that lubricant emerges from all the small pores from the handle to the tip of the ECD.

5. Equipment Setup

- ii. Slowly inject approximately 8-10 ml of low-viscosity lubricant into the black channel, which will add lubricant to the ECD surface. Gently press on the pores closest to the handle to allow lubricant to fill the large pores at the tip of the ECD. Ensure that some lubricant emerges from all the large pores from the handle to the tip of the ECD (*Figure 12*).



Figure 12: Lubricant emerging from ECD pores

- iii. On the injection (black) channel, connect a new, full syringe of low-viscosity lubricant. The extraction (green) channel will be used for suction, so leave the empty syringe attached.



IMPORTANT: Only use the provided low-viscosity lubricant in the bubble removal channels. Other lubricants and ultrasound gel can cause additional air bubbles in the rectum.

Once the UA and ECD have been purged of all air bubbles and are ready for insertion in the patient, proceed to the next step.

5.f.ii Pre-Treatment equipment checks

The TDC software is designed to guide you through pre-treatment equipment checks before the patient arrives for treatment. These checks help to ensure that all equipment is set up correctly and functioning properly before starting patient treatment.

RF connectivity test

- a. Ensure the UA is connected to the UA tube set and purged of air (*see Purge the UA of all air bubbles.*).
- b. Without removing the UA from its package, ensure the UA cable is connected from the PSIB to the back of the UA. Care should be taken to avoid contaminating the UA handle.
- c. In the **RF** tab of the PSIB display (*Figure 13*), click **Test UA**.
The system will send a short burst of power to each of the ten UA elements to ensure continuity and functionality of all ten channels. This can also be done from the TDC Setup workspace from the RF information box in the top-right quadrant (*Figure 14*).

When the RF connectivity test is complete, the PSIB will display a short message (*Figure 13*). You can see detailed RF connectivity test results in the RF information box of the TDC software (*Figure 14*).

- d. Disconnect the UA cable from the PSIB to prepare for moving equipment to the MRI table.

5. Equipment Setup



NOTE: If you replace the UA after completing the RF connectivity test, the TDC software will detect the change in equipment. Before proceeding, you must **Unlock** the Setup stage and perform the test on the new UA.

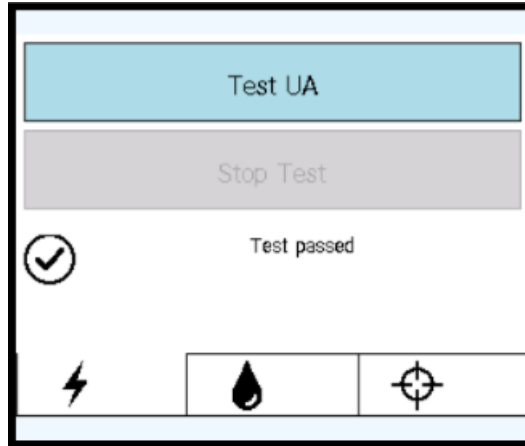


Figure 13: RF tab on PSIB display after successful RF connectivity test

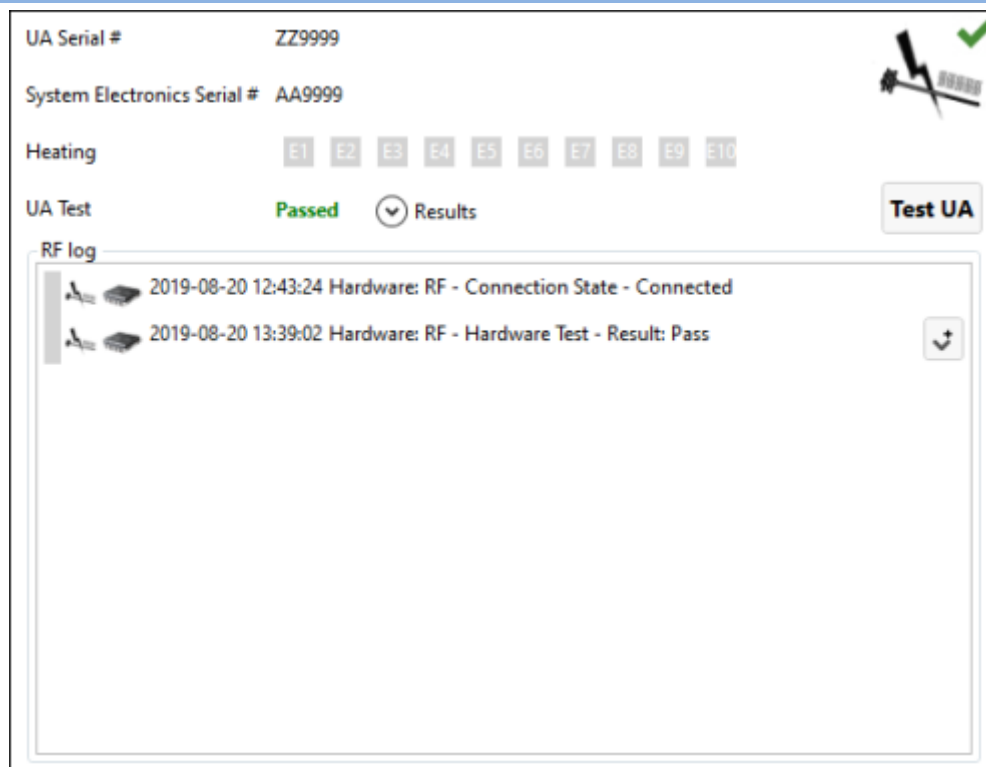


Figure 14: RF information box in Setup workspace after successful RF connectivity test

PS test

- a. Check that no UA is attached to the PS. Ensure that the cable between the PS and the PS Interface Box (PSIB) does not prevent the PS from moving along its translation axis.

5. Equipment Setup

- b. On the PSIB display, select the PS tab and click **Test PS** (*Figure 15*). The system will translate the PS forward and backward to test the continuity and functionality of the translation axis as well as home the PS in the translation axis. The system will also rotate the rotational axis clockwise and counter-clockwise to test the continuity and functionality of the rotational axis. (This can also be done from the TDC *Setup* workspace in the PS information box in the bottom-right quadrant *Figure 16*.)



NOTE: If you replace the PS after completing the PS Test, the TDC software will detect the change in equipment. Before proceeding, you must **Unlock** the Setup stage and perform the test on the new PS.

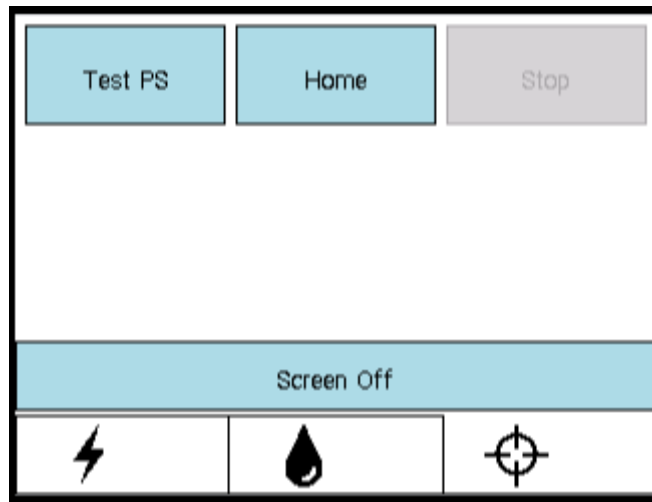


Figure 15: PSIB display - PS tab

5. Equipment Setup

PSIB Serial # 999999
PS Serial # CG5678
UA Attached: Yes

PSIB Display **Turn OFF** **Turn ON** PS Test: N/A **Test PS**

Linear Base
Apex

Rotary 12

9 3

HOME HOME

6

PS log
2015-09-15--11-11-08 Hardware: PS - Connection State - Connected

Figure 16: PS information box in Setup workspace

6. Initial Patient Positioning

Initial patient positioning involves transferring the patient to the already-prepared MRI table, positioning them correctly over the imaging coil, securing them using the leg rests and appropriate straps, and establishing MRI anesthesia and patient monitoring.

This step is led by the MRI Technologist, with specific assistance from the Anesthesiologist, and physical assistance in safely moving the patient from all members of the clinical team.

MRI Technologist:

1. Transfer the patient into the MRI magnet room using an MR-compatible gurney or by undocking the MRI bed.



When transporting the patient into the MRI magnet room, if the guidewire is already placed, make sure it is secured to the patient.

2. Position the patient on the MRI bed in a head-first supine position so that their sagittal midline is centered from left to right on the MRI table, and their prostate is (*Figure 17 [Your configuration might not match exactly as shown]*).

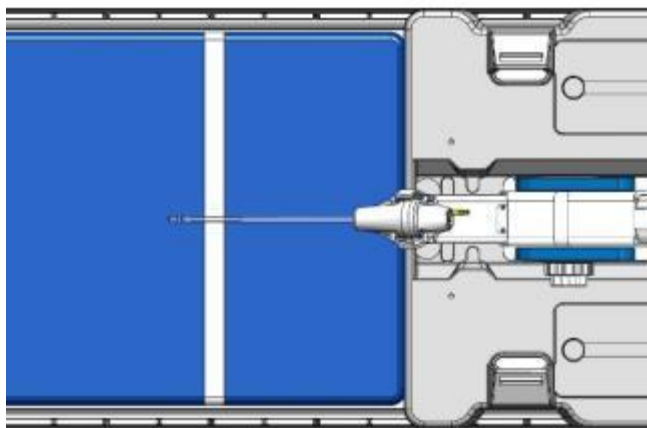


Figure 17: Centering and aligning the coils with the prostate

4. Have an assistant lift the patient's legs one at a time while you set up the leg supports (*Figure 18*):
 - a. Place the leg supports into the designated slots of the base plate.
 - b. Support the patient's legs and adjust the positions of the leg supports along the slots in the base plate.
 - c. Wrap the leg pad around the patient's leg, connect the buckle of the leg support strap, and pull the strap to tighten.
5. Provide the patient with ear protection to protect against MRI-related hearing injury, even though the patient might be under general anesthetic.

6. Initial Patient Positioning

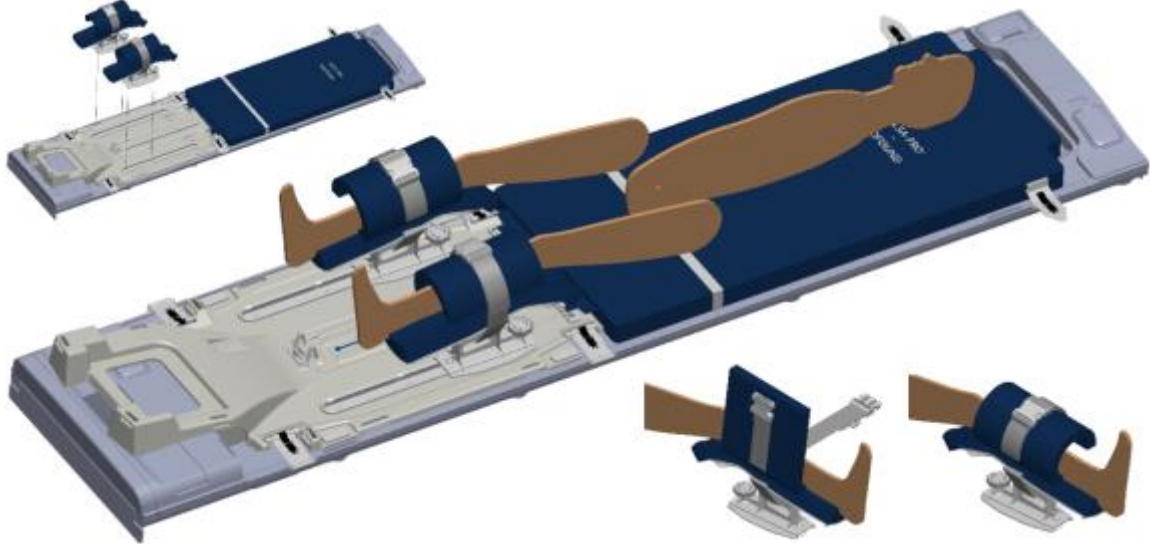


Figure 18: Initial patient positioning and attachment of leg supports

7. Device Insertion

The **Urologist** inserts the Ultrasound Applicator (UA) and the Endorectal Cooling Device (ECD) into the patient, with assistance from the **MRI Technologist**.

7.a Preparing the UA

Before inserting the Ultrasound Applicator (UA), perform a final test for bubbles or leaks.

1. **MRI Technologist:** Using the fluid circuit (**FC**) tab of the PSIB display (or the FC information box of the Setup workspace in TDC), flow water into the UA by clicking **ON**.
2. **MRI Technologist:** Ensure the UA cable is connected to the UA and disconnected from the PSIB.
3. **MRI Technologist:** Without touching the UA to maintain sterility, remove the plastic cover enclosing the UA in the package.
4. **MRI Technologist:** While holding the UA packaging tray by the long edges of its perimeter, flex the tray to release the UA from its snap features (*Figure 19*).
5. **Urologist:** Using one sterile, gloved hand, remove the UA from the package by gripping the end with the white plastic handle.

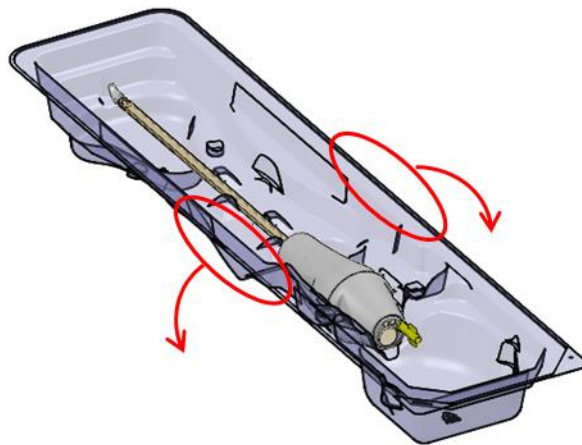


Figure 19: Releasing the UA from the packaging tray



To keep the UA sterile, *only* handle the packaging tray by its edges.

7. Device Insertion

7. **Urologist:** Closely inspect the UA along the length of the shaft for any water leakage, paying attention to the areas of interest shown in *Figure 20*. If you see water, the UA is defective and must not be used.

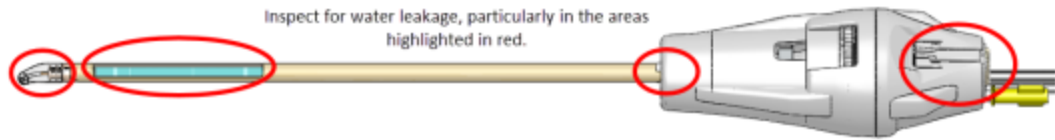


Figure 20: Areas to inspect for water leaks in the UA

8. **Urologist:** Closely inspect the UA window for bubbles of any size. If you see bubbles, using a sterile gloved finger, gently tap next to the UA window to dislodge the bubbles. Do not insert the device until you see no bubbles.

7.b Inserting the UA

1. **MRI Technologist:** Open sterile lubricant and present to the **Urologist**, as needed.
2. **Urologist:** Apply sterile lubricant directly into the urethra and onto the acoustic window of the UA, taking care to provide clear acoustic coupling by filling the urethra without creating bubbles.
3. **Urologist:** Wearing sterile gloves, thread the guidewire through the tip of the UA and insert the UA over the guidewire and into the prostate. Ensure the tip of the UA has entered the bladder.
4. **Urologist:** Remove the guidewire, leaving the UA in place.
5. **MRI Technologist:** Turn off UA flow at the PSIB.



Ensure the guidewire is removed before imaging the patient with the MRI. The guidewire has not been tested to ensure patient safety during MR imaging.

7.c Attaching the Ultrasound Applicator to the Positioning System



This procedure requires two operators: one to hold the UA at a natural angle and one to move the PS into place. Attempting this procedure with only one operator can physically injure the patient.

1. **Urologist:** Hold the UA handle with the UA positioned at a natural angle in the patient, while the **MRI Technologist** installs and adjusts the PS to capture the UA in the PS gripper.
2. **MRI Technologist:** Ensure that the slot for the PSIB is clear. Place the PS and PSIB in their respective slots on the base plate. Secure the Positioning System (PS) to its slot on the base plate between the patient's legs by closing the latch (*Figure 21*).

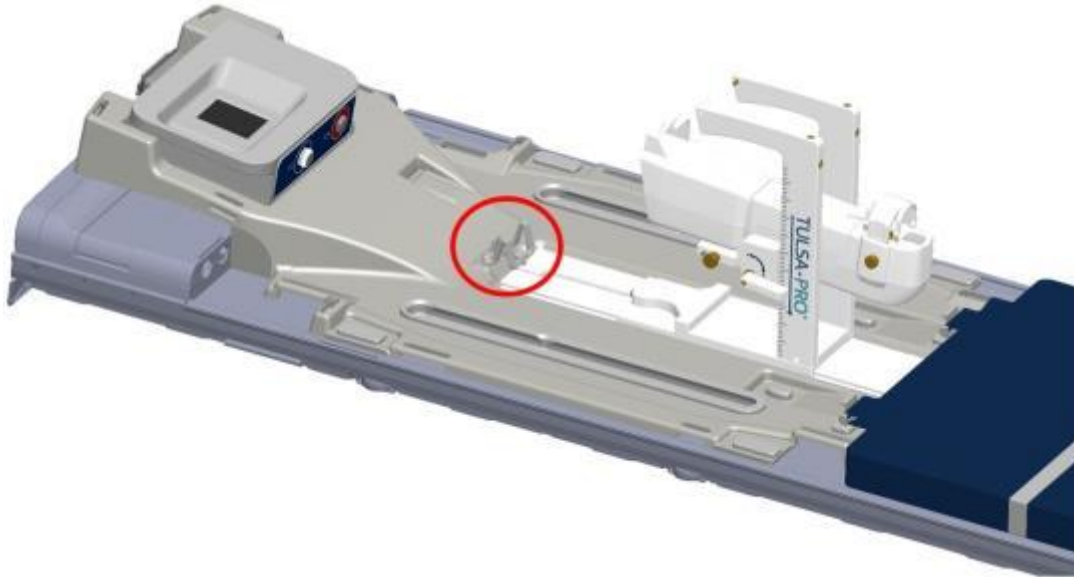


Figure 21: Secure the Positioning System using the latch on the base plate

3. MRI Technologist: Manually move the PS into position so that the UA gripper aligns with the natural angle of the UA in the patient. Manually adjust the base of the PS forward and backward and up and down, and tilt the linear axis of the PS up and down (*Figure 22*).

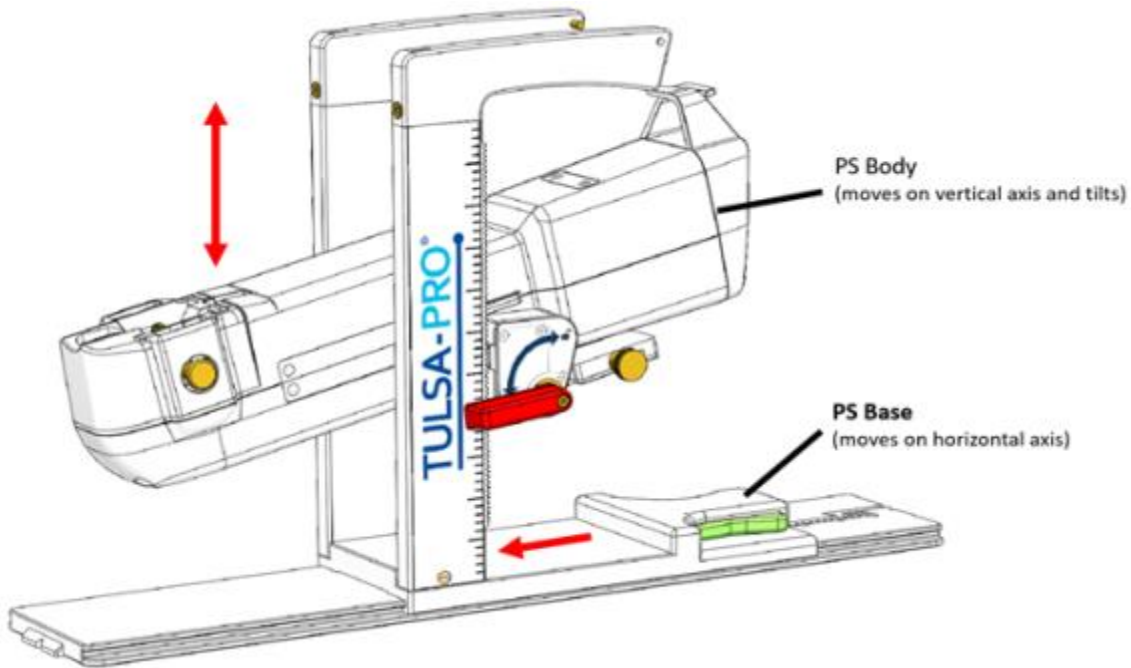


Figure 22: Adjusting the Positioning System



NOTE: The PS adjustment knobs and levers are not colored as in *Figure 22*, but are colored here to help with these instructions.

- a. Adjust the horizontal position of the PS base by pressing the lever (**green**) and slide the PS base into position. Release the lever to lock it in place.

7. Device Insertion

- b. Adjust both the vertical and tilt positions of the PS body by turning the outer lever (**red**) clockwise to unlock. Turn the outer lever (**red**) counter-clockwise to lock.
- c. Adjust the lateral movement of the PS body by turning the brass turn knobs located at the bottom rear of the PS (**gold**).



NOTE: Only adjust the forward and backward location of the PS at its base and ensure that the adjustment-release lock is fully disengaged before moving.

4. **MRI Technologist:** After locking the PS tilt and height, seat the UA in the PS nose and then secure it by pressing the UA clamp down over top of the UA until it is fully engaged with the PS nose. (Figure 23).



NOTE: You will hear an audible click when the clamp is fully inserted into the PS nose.



Figure 23: UA attachment to Positioning System

5. Ensure that the UA is not being 'forced' into position. If so, release the UA from the UA gripper and adjust the PS axes to achieve better alignment with the UA. Ensure the up-and-down and tilt-release knobs on the PS are locked before securing the UA in the gripper of the PS.
6. **MRI Technologist:** Thread the UA cable and UA tube set through the cable management arms on the top of the PS with minimal tangling or twisting of the cables. Connect the UA cable to the PSIB. The connector is keyed and will only fit in one orientation. If the UA cable has a large block along its length, place the block securely in its recess on the base plate near the PSIB. Ensure that the UA and PS cables do not prevent the PS from moving along its translation axis.
7. **MRI Technologist:** Replace the yellow cap on the hub of the guidewire channel at the back of the UA handle.

7.d Inserting the ECD

Urologist: Insert the Endorectal Cooling Device (ECD), with assistance from the **MRI Technologist** who passes the ECD, lubricant, and saline syringes to the **Urologist**.

7.d.i To insert the ECD the first time:

1. **Urologist:** Apply 5-10 ml of low-viscosity lubricant to your glove and wipe the anterior rectal surface.
2. **Urologist:** Apply 10-15 ml of the same lubricant to the ECD. Ensure lubrication covers the cooling window on the anterior surface of the ECD.

7. Device Insertion

3. **Urologist:** With fluid tubing attached, insert the ECD with a twisting motion, starting with the ECD window facing 9:00 and rotating clockwise to 12:00, while also applying upward pressure against the anterior rectal wall. Insert the ECD as far as possible until you feel resistance.
4. **Urologist:** Ensure the ECD cooling window is adjacent to and facing the prostate, with the handle-neck joint of the ECD at the anal verge and the raised, tactile ridge on the ECD handle facing anteriorly.
5. **Urologist:** After you confirm alignment, inflate the ECD balloon with 15-20 ml of saline to maintain upward pressure against the anterior rectal wall. Be prepared to fill the balloon up to a maximum capacity of 30ml, if needed, until the ECD is securely positioned in the rectum. It is important that the ECD remains stationary at the correct insertion depth during MR imaging and treatment.



Over-filling the balloon while inserted in the anal passage or rectum can cause stretching and possible trauma, especially if left overfilled for a long time. Also, over-filling the balloon to the point of breaking can cause trauma to the tissue.

If you under-fill the balloon, you risk having the ECD slide out during treatment, which would cause inadequate cooling of the rectal wall and lead to unintended thermal damage to the rectum and possibly to fistula.

8. MRI Patient Positioning

After transferring the patient to the MRI table and inserting the Ultrasound Applicator (UA) and Endorectal Cooling Device (ECD), the MRI Technologist secures the patient and imaging coils, and checks that the devices are ready for imaging. The Anesthesiologist does a final check.

8.a Securing the Patient

1. **MRI Technologist:** Place restraint straps around the patient to prevent motion of the pelvis during MR imaging and position the anterior coil.
2. **MRI Technologist:** Fasten one abdomen-arm strap tightly over the lower abdomen to minimize anterior-posterior breathing motion. Wrap the sheet over the abdomen and place the patient's hands on top. Fasten a second abdomen-arm strap over the arms to help fit the patient into the MRI bore (*Figure 24*, your configuration might not match exactly as shown).

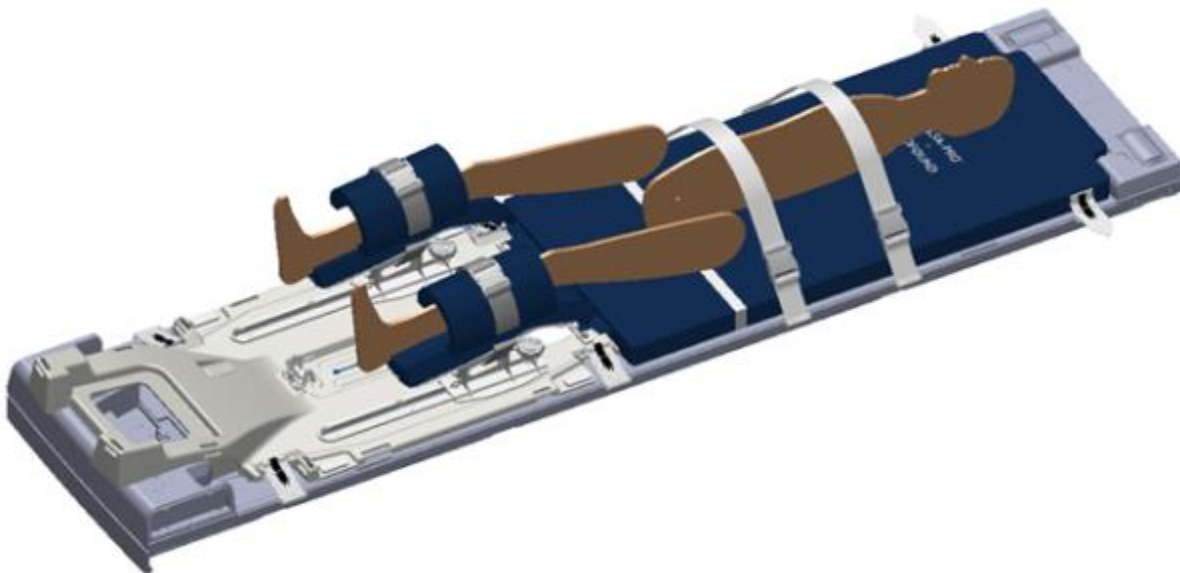


Figure 24: Securing the abdomen and arm straps

8. MRI Patient Positioning

2. MRI Technologist: Strap the anterior imaging coil over the patient's pelvis and arms. The coil should cover the prostate, without interfering with the travel of the Positioning System (*Figure 25*).

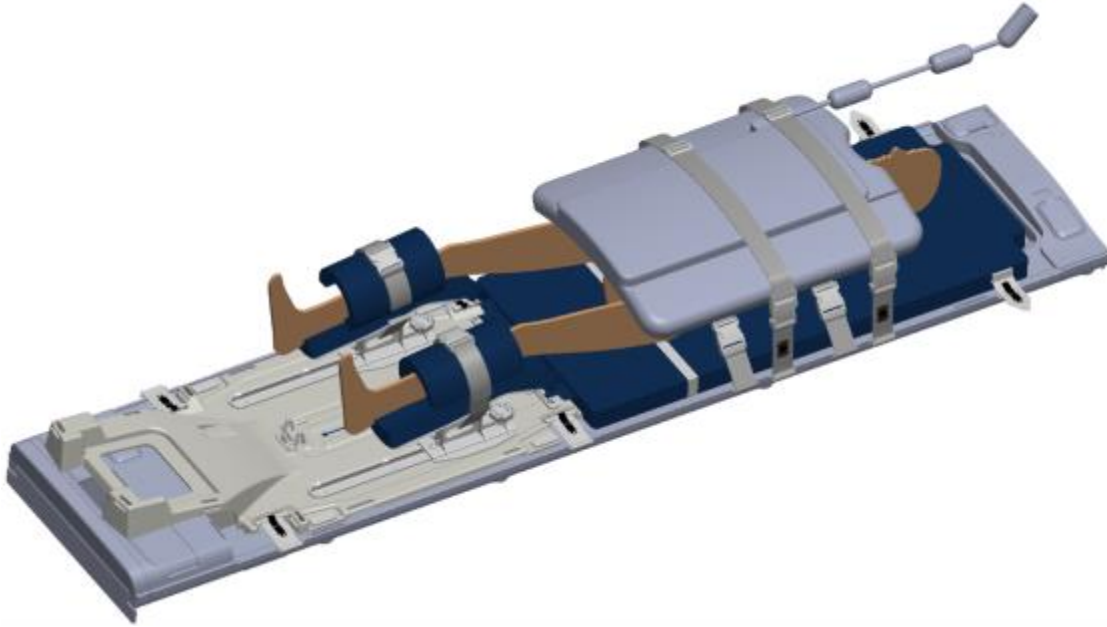


Figure 25: Placement of the anterior imaging coil

3. MRI Technologist: For the patient's comfort, use sheets to keep him warm and pads to avoid pressure points. Also, to avoid electrical burns, ensure that the patient's skin is not directly touching the coils or MRI bore.
4. MRI Technologist: Use tube-and-cable straps to manage fluid tubes and the white RF cable as shown in *Figure 26*. Leave some slack to allow the cables to slide freely and to reduce tripping hazards. Ensure no cables, tubing, or other materials can be caught while the MRI table is moving.

8. MRI Patient Positioning



Figure 26: Tube-and-cable straps of base plate: one for tube sets and one for RF cable

5. Anesthesiologist: Check that IV, gas, and monitoring lines are providing reliable readings and routed appropriately along the MRI table. Check that none of the straps are applying excessive pressure to the patient's skin or joints. If using a supra-pubic catheter, ensure that the urine collection bag is secured and unobstructed.

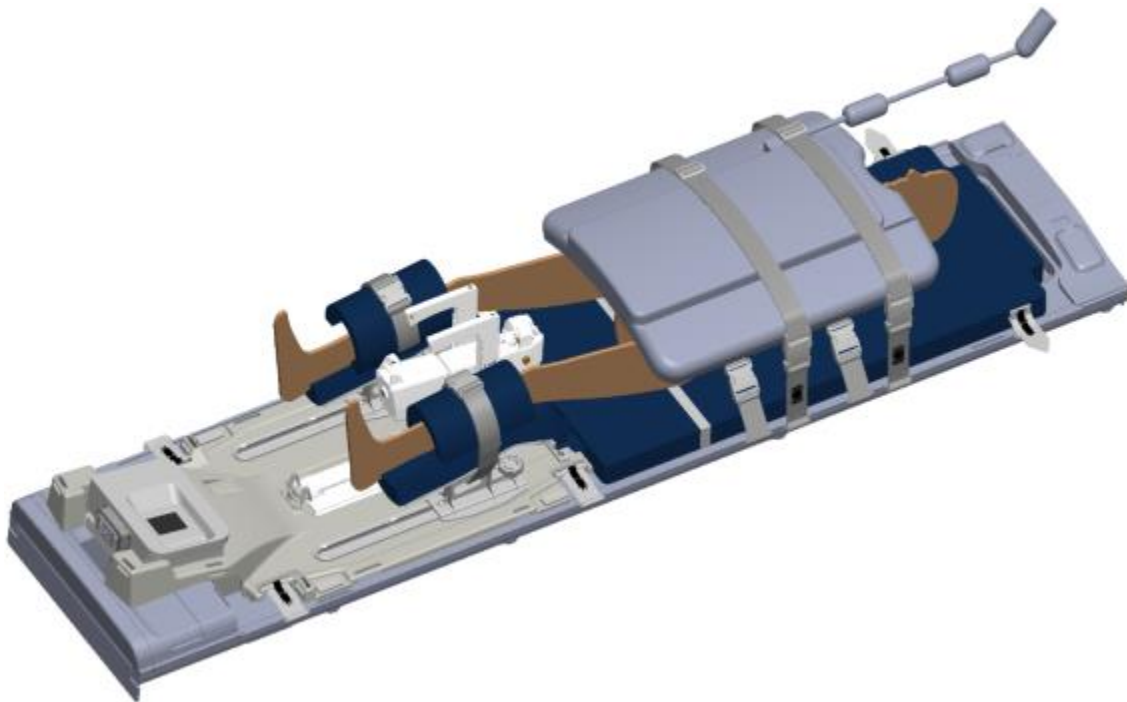




Figure 27: Patient positioning is complete

8.b Device Check

With the patient ready for imaging and treatment, the MRI Technologist homes the rotation of the ultrasound applicator, verifies that flow to the UA and ECD is off, and turns off the PSIB screen.

1. MRI Technologist: In the **PS** tab () of the PSIB display, click **Home** (). The system will rotate the UA clockwise and counter-clockwise to find the home position of the UA, so the UA window is facing downwards (6:00). Confirm that rotational homing completes successfully.
2. MRI Technologist: Use the PSIB display (or the Setup workspace of the TDC console) to ensure that the UA and ECD fluid flow is turned **OFF**.
3. MRI Technologist: Ensure that the PSIB screen is off by pressing and holding **Screen off** on the PSIB screen (or by clicking **Turn Off** beside the **PSIB Display** in the TDC software).

8.c Entering Treatment Milestones

MRI Technologist: After homing is complete, the icons in the Treatment Milestones section on the right side of the TDC *Setup* workspace will pulse to remind you to enter some data. Before moving to the Treatment Planning phase, enter the time when the Anesthesiologist finished sedating the patient and the time when the Urologist inserted the UA. Recording these times will allow for better estimates of total procedure and anesthesia duration.

To record these times in TDC:

1. In the TDC *Setup* Workspace, enter the sedation and UA insertion times under **Treatment Milestones** (*Figure 28*).
2. Click **Save**. The Treatment Milestones area will turn gray and the Save button will be replaced by **Edit**.

You can also enter these times after treatment is completed and the report is generated.

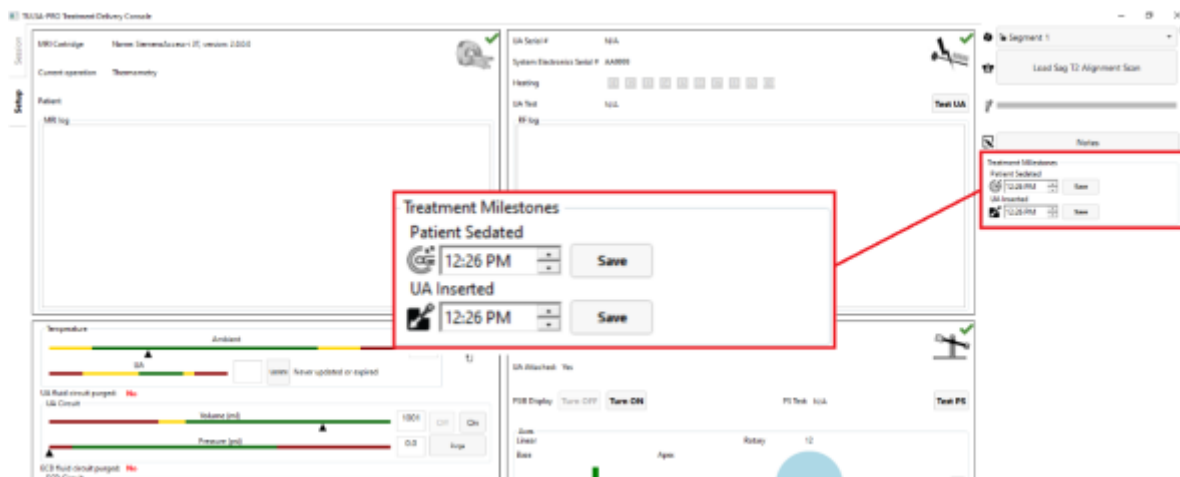


Figure 28: Entering Treatment Milestones in the TDC Setup Workspace


9. Treatment Planning

9.a Initial Imaging


With the patient positioned for imaging, the MRI Technologist can follow these instructions to set the landmark position and acquire localizer images using the TULSA-PRO® MRI sequence protocol.

9.a.i MRI sequence protocol and instructions

	SCAN NAME	PURPOSE	TDC STEP
1	Localizer	Initial scan used to confirm initial device positioning	Initial Imaging
2	SAG T2	Scan used for UA alignment and UA linear position adjustments	Alignment and Coarse Planning
3	SAG SWI	Susceptibility weighted imaging scan for calcification detection	Coarse Planning
4	AX THERM	Temperature uncertainty and Treatment Delivery	Detailed Planning and Delivery
5	AX T2	Anatomical T2-weighted scan for contouring the prostate	Detailed Planning
6	AX DWI	Diffusion weighted imaging scan for contouring the prostate	Detailed Planning
7	AX T1	Post-treatment scan acquired before and after administering IV contrast	Review

1. Align the landmark position on the MRI with the prostate and anterior MR imaging coil by pressing on the landmark strip, or by aligning the laser scope and pressing **Landmark**.
2. Slowly advance the MRI table for scanning, taking care to avoid pinching tubes and cables, pressure on the patient's skin, and direct contact of the patient's skin with the coils or MRI bore.
3. At the MRI console, click on the icon () to verify that the TDC computer is communicating with the MRI. If an ILT connection is not active, contact Profound Service for support.
4. Verify that the correct anterior and posterior coils are selected in the **Coil** tab ('GEM Body').
5. Run the Localizer scan. Double-click the **Localizer** scan, press **Save Rx**, and then press **Scan**. To view the **Localizer**, double-click on the next scan in the queue.

9.a.ii Moving the patient to landmark position

To maintain alignment of scan volumes, it is important to always return the patient to the same landmarked position in the MR bore. To accomplish this, with the MR bed outside the bore, press **Back to Landmark** () on the magnet control panel.

9.b Gross Positioning

The Radiologist determines the initial positions of the UA in the prostate and ECD in the rectum, using the Localizer images, and optional fast 2D sagittal T2-weighted or T1-weighted scans. Inserting the UA and ECD can significantly deform the shape of the urethra and prostate. If necessary, the Urologist, with help from the MRI Technologist, manually adjusts the device positions to eliminate air bubbles in or around the UA and ECD on the MR images.

9.b.i Reviewing initial device positioning

1. Radiologist: Check that the ultrasound applicator (UA) is inserted correctly:
 - a. The UA should pass within the prostatic urethra into the bladder and the active elements of the UA should be near enough to the intended treatment volume that the positioning system can be used for fine adjustment. Specifically, any required adjustment should be within the 39 mm maximum automated linear movement of the PS in either direction. If a larger adjustment is required, adjust the insertion depth of the UA manually.
 - b. The radius from the center of the UA to the edge of the prostate should be within the 30 mm maximum expected treatment depth of the center of the applicator. If the radius is beyond this depth, adjust the insertion angle of the UA manually.
2. If the UA positioning is incorrect, adjust the UA insertion depth or angle manually and then re-acquire another scan to confirm the correct positioning:
 - a. MRI Technologist: Move the MRI patient table out of the bore far enough for the Urologist to adjust the UA.
 - b. Urologist: With clean gloves, hold the UA handle as the MRI Technologist detaches the UA from the PS and unlocks the PS body.
 - c. Urologist: Adjust manually the UA insertion depth, angulation, or both.
 - d. MRI Technologist: Adjust the location and angulation of the PS body to match the desired UA positioning and captures the UA handle in the UA clamp of the PS.
 - e. MRI Technologist: Advance the MRI patient table and re-acquires a Localizer or fast 2D sagittal T2 or T1 sequence to verify the changes to device positioning.
3. Radiologist: To check for air bubbles in the rectum that can interfere with imaging or ultrasound delivery, scroll through all axial and sagittal images that intersect the UA window, paying special attention to the ECD notch region. There should be no bubbles within the ECD or between the ECD and the rectal wall adjacent to the prostate (in the ultrasound path). To confirm that the ECD is placed correctly:
 - a. The cooling window should cover the prostate and expected range of ultrasound energy from the UA, as confirmed on the sagittal MRI (*Figure 29*).

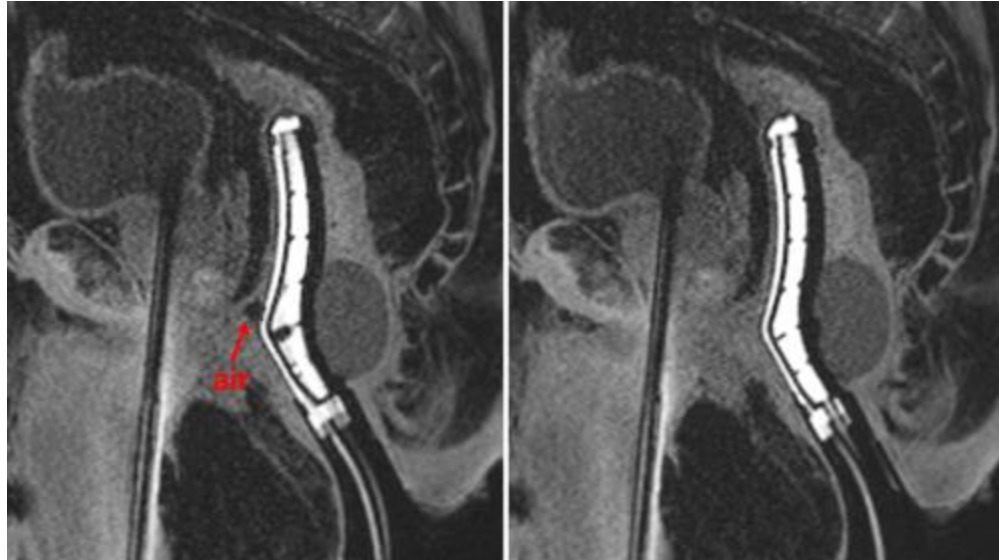


Figure 29: Sagittal images of ECD facing anteriorly towards the prostate, with air in the beam path (left) and correctly adjusted to eliminate air from the beam path (right)

- b. The orientation of the cooling window should face the prostate (anterior), as confirmed on the axial MRI (Figure 30).

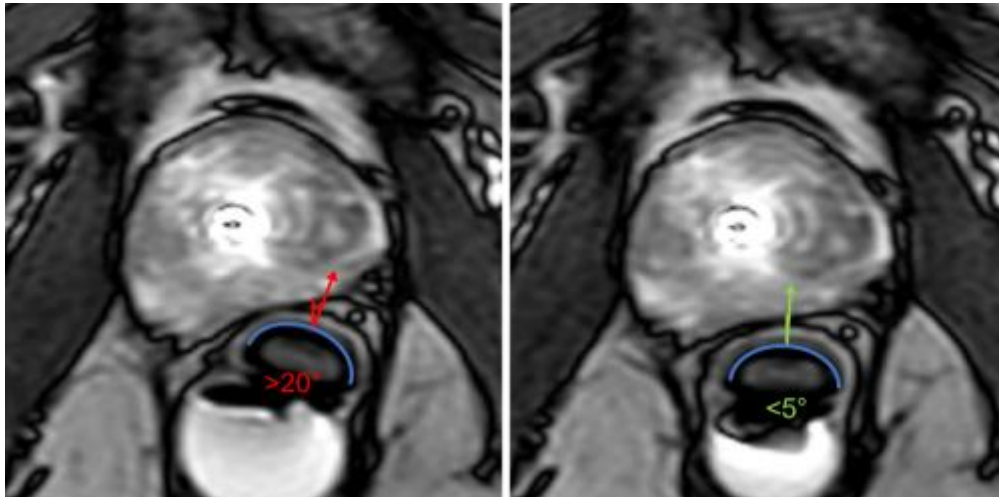


Figure 30: Axial images depicting ECD oriented incorrectly (left, rotated more than 20 degrees) and correctly (right, facing up towards the prostate)

- 5. If the ECD placement is not ideal or there are air bubbles in the rectum, manually adjust the ECD position in the rectum, use the ECD bubble removal channels, or both. Then re-scan to confirm ideal positioning:
 - a. **MRI Technologist:** Move the MRI patient table out of the bore far enough for the Urologist to adjust the ECD.
 - b. **Urologist:** Adjust the ECD position in the rectum manually so that the cooling window is facing and adjacent to the prostate and covers the expected range of ultrasound energy from the UA, and to eliminate air in the rectum lateral to the ECD.
To move the ECD closer to the prostate or move bubbles out of the ultrasound path,

9. Treatment Planning

inflate the ECD balloon with water or saline gradually in 5-10 mL increments, up to a maximum volume of 30 mL.

- c. **Urologist:** If using an ECD with green and black lubricant channels, remove small air bubbles from the lubricant anterior to the ECD by applying suction to the syringe on the extraction (green) channel, drawing air out from the ECD surface until all large bubbles (greater than 1 cm) are removed from the ECD tubing. Remove air gaps between the lubricant and the rectal wall by applying approximately 3 ml of low-viscosity lubricant into the injection (black) channel of the ECD tubing.
- d. **MRI Technologist:** Advance the MRI patient table and re-acquire a Localizer or fast 2D sagittal T2 or T1 sequence to verify changes to device positioning.



Whenever moving the patient back to the landmark position in the MR bore, follow the instructions in *Moving the patient to landmark position*.

6. Once the **Radiologist** is satisfied with the gross positioning of the ECD, the **MRI Technologist** acquires the SAG T2 sequence, and then pushes the images to the TDC computer using the instructions below.

9.b.ii To adjust the ECD position or address bubbles lateral to the ECD:

If the ECD is not positioned correctly or if there are air bubbles on gross positioning images **lateral** to the ECD within the rectum and not on the anterior surface, follow these steps:

1. **MRI Technologist:** Temporarily remove 5-10 ml from the ECD saline balloon.
2. **Urologist:** Rotate the ECD left and right while consistently applying upward force.
3. **MRI Technologist:** With the ECD cooling window correctly aligned, re-inflate the balloon with 10-15 ml (ideally, 5 ml more fluid than for the first insertion), ensuring that the ECD remains securely positioned in the rectum at the correct insertion depth.

9.b.iii If using an ECD with bubble removal channels:

If you see air on gross positioning images between the **anterior** surface of the ECD and the rectal wall, remove it by applying a combination of suction to the extraction (green) channel and additional lubricant through the injection (black) channel:

1. **Urologist:** If there are small bubbles in the lubricant anterior to the ECD, apply suction to the syringe on the extraction (green) channel, drawing air out from the ECD surface until you remove all large bubbles (greater than 1 cm) from the ECD tubing.
2. **Urologist:** If there is an air gap between the lubricant and the anterior rectal wall, apply approximately 3 ml of additional lubricant to the injection (black) channel.
3. Acquire another gross positioning image. If bubbles persist, repeat these steps.

9.b.iv Pushing planning images from the MRI to TDC

MRI Technologist: Follow these steps to push images (such as SAG T2, AX T2, and AX T1) to the TULSA-PRO® network node.

9. Treatment Planning



1. Open the **Image Management** work area on the MRI console () and select the image series you want to push to the Treatment Delivery Console (TDC).
2. In the **Destinations** list near the bottom of the screen, scroll horizontally and click on the **TULSAPRO** network node to send images to the TDC (*Figure 31*).



Figure 31: Pushing planning images from the MRI to TDC

3. In TDC, click **Load ... Scan** () to load the images into the TDC. Valid scans will show up in the list with the most recently acquired scan at the top; it might take a few seconds for the full list to show.
4. Double-click a scan from the list to load it into the TDC software.



Always check that you have selected the image sequence from the correct patient and that the sequence was taken after you last adjusted the patient's position. Note that it takes a few seconds for the newest scan to appear.

9.c Alignment

Radiologist: Use the Alignment workspace to define the location and angulation of the UA in the TDC software by aligning a graphical representation of the UA with the actual UA on the MRI image in three dimensions. Accurate alignment will be critical to safe and effective heat delivery within the intended tissue volume. See example below of the UA in MR images before (*Figure 32*) and after (*Figure 33*) Alignment.

1. Rotate the sagittal view to align the UA in the image with the gold UA overlay by clicking and dragging the light-blue circular overlay. Shift the sagittal view by clicking and dragging on the gold UA overlay. The length of the UA must overlap completely with the graphical UA overlay. In

9. Treatment Planning

particular, the superior horizontal edge of the UA window on the graphical overlay must match the edge of the actual UA window on the SAG T2 images, which will be visible as a light-to-dark transition (hyperintense signal within the acoustic window).

2. Similarly, rotate and shift the coronal view to align the actual UA with the graphical overlay.
3. Finally, shift the transverse view so that the circular graphical overlay overlaps completely with the cross-section of the actual UA. Transverse slices perpendicular to each transducer element are displayed on the left view of Alignment workspace (E1 to E10). The location of the center of each transducer element is represented by a pink dot on the UA graphical overlay and must be centered within the UA in all images along the length of the device.
4. When satisfied with the alignment of the graphical representation of the UA and the UA in the MRI image, click the **Register UA** button to advance to **Coarse Planning**.

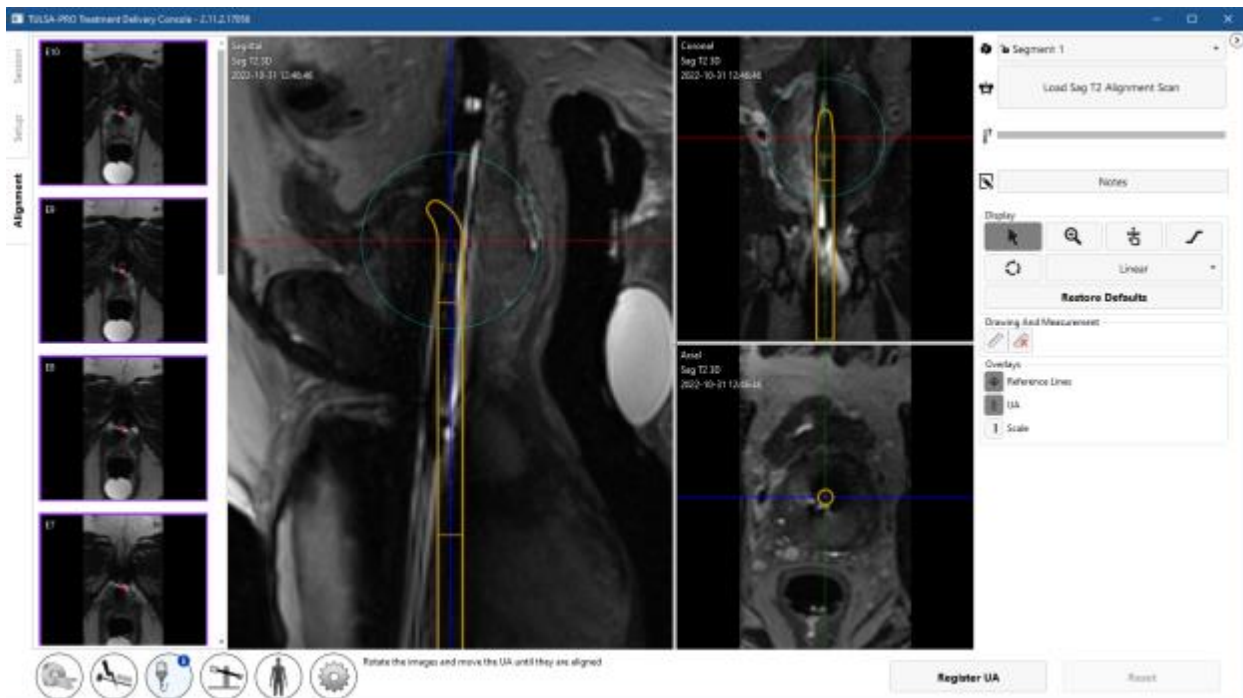


Figure 32: UA before alignment

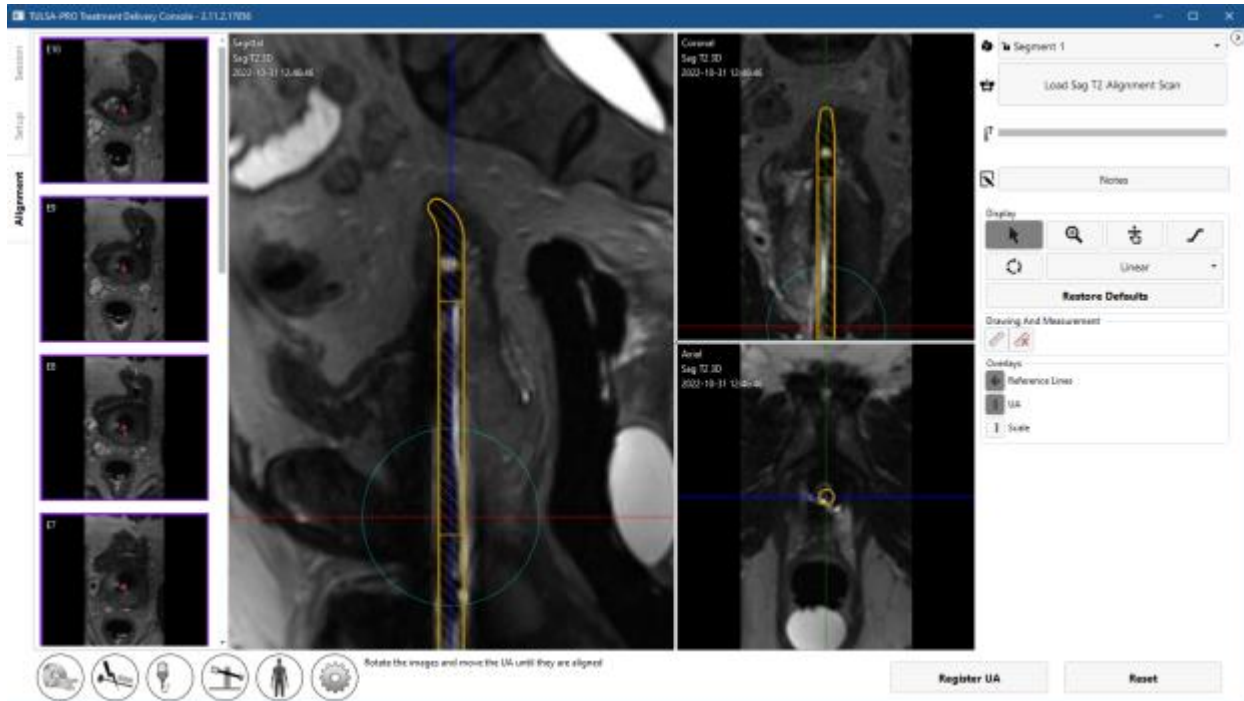


Figure 33: UA after alignment

9.d Coarse Planning

Radiologist: Define the treatable volume so that it covers the targeted tissue while sparing critical structures and minimizing the impact of small calcifications on the heating pattern, by adjusting the location of the UA inside the prostate and selecting which transducer elements should be enabled.

The treatment volume is displayed as a green rectangle on the sagittal and coronal views. Regions beyond a light blue line displayed 4 mm from the bottom and top edges of the green rectangle on the sagittal and coronal views are anatomical regions expected to be spared fully from thermal coagulation (*Figure 34*).

1. **Radiologist:** Move the UA overlay in and out of the gland to prescribe the intended UA location, placing the active transducer elements beside the intended ablation volume. Click-and-drag the UA overlay to move it within the prostate in a linear, head-to-foot direction. Click **Move** for the positioning system to advance the applicator to the prescribed location or click **Reset** to cancel the prescribed adjustment. If no change is needed, click **Reset** to cancel the adjustment rather than attempting to manually move the UA overlay back to its original position.



NOTE: When determining where to position the UA, identify the external urinary sphincter. If the external urinary sphincter cannot be identified, it should be considered immediately adjacent to the prostate apex. Place the light blue line below the first element on the external urinary sphincter (*Figure 34*).

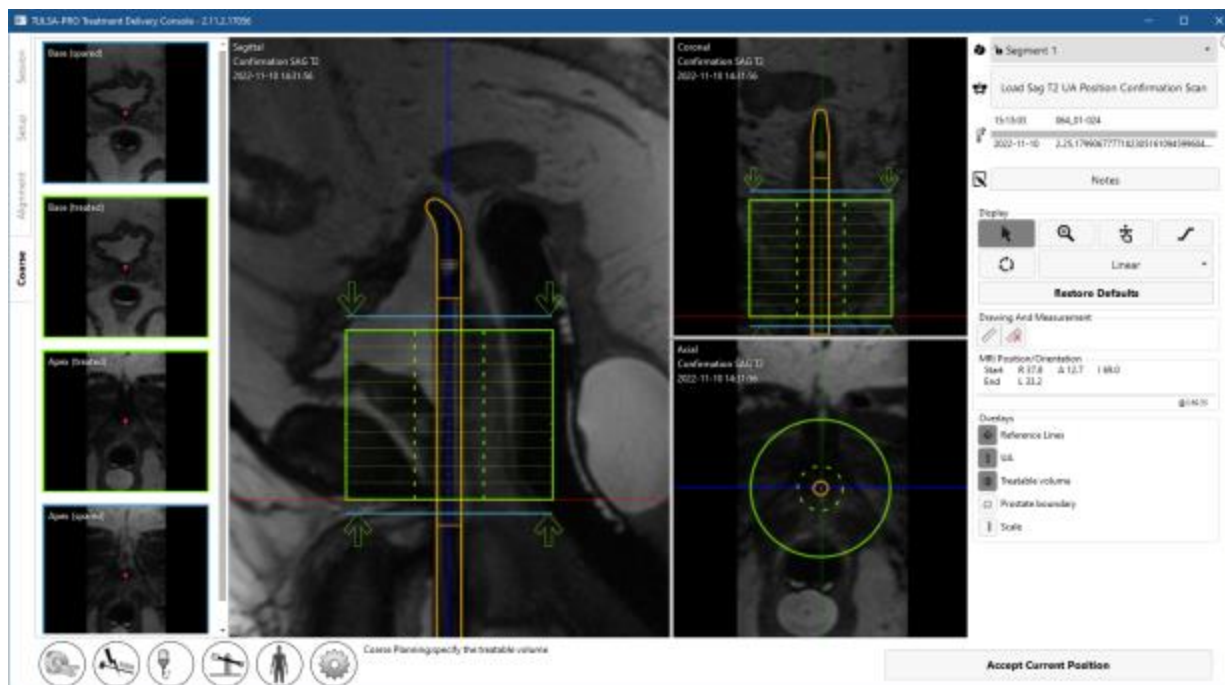


Figure 34: Coarse Planning workspace in TDC software

2. Radiologist: When adjusting the UA position, the presence of any small calcifications in the beam path should also be considered. Use the mpMRI Vision feature in Coarse Planning to load a set of sagittal susceptibility-weighted images (SWI), which highlight the magnetic field disturbances caused by intraprostatic calcifications. To reduce the shadowing effect of calcifications on ultrasound propagation and tissue heating, place the midline of the calcification between two adjacent ultrasound elements (instead of directly in front of an element) (*Figure 35*).
 - a. MRI technologist: Acquire a SAG SWI scan. Several output scans will be created automatically. Send this sagittal SWI output to TDC.
 - b. Radiologist: Click **Load ... Scan** and select the SAG SWI scan to import it. The SWI scan will replace the existing SAG T2 3D scan in all three imaging planes. Toggle between viewing the SAG SWI and SAG T2 scans in each pane by clicking the mpMRI button in the top right corner.



NOTE: The SWI scan must be acquired after the initial SAG T2 scan and before moving the UA in Coarse Planning. If the UA is moved after acquiring the SAG SWI scan and a confirmation SAG T2 scan is loaded with the UA in the new position, the old SWI image will no longer be available.

9. Treatment Planning

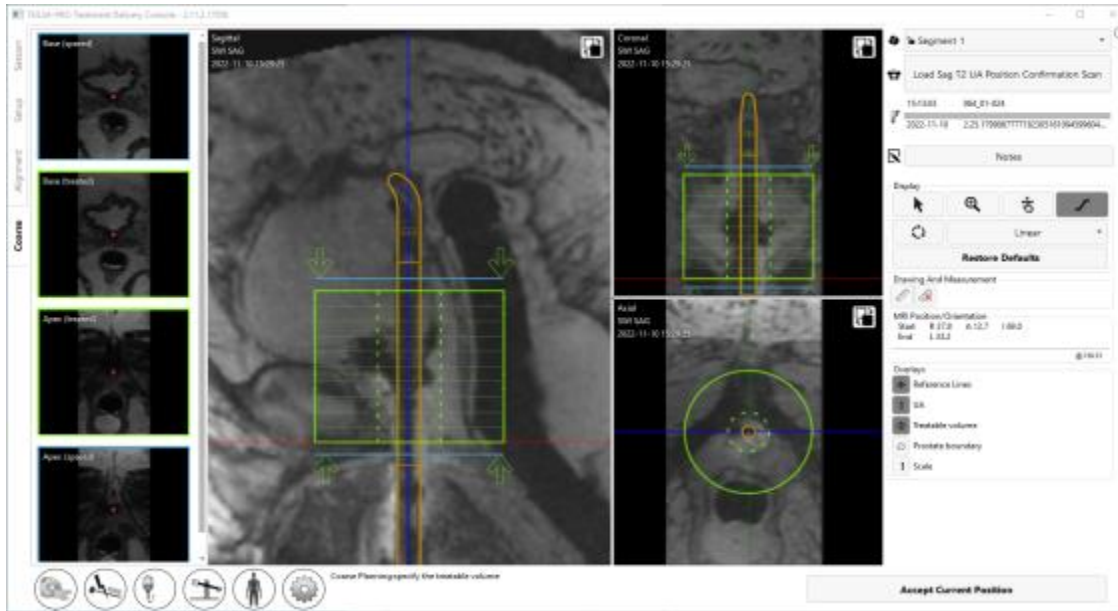


Figure 35: Using mpMRI Vision in Coarse Planning to visualize calcification on a SAG SWI scan and adjust the UA position to reduce the shadowing effect of the calcification on treatment

3. Radiologist: Adjust the treatment volume by enabling or disabling the treatment elements. Click and drag the green arrows above and below the green rectangle to disable elements beyond the apex and base.
4. To verify the position of the UA and maintain the same table position between planning and treatment, acquire an additional SAG T2 scan with the treatment volume at isocenter:
 - a. MRI Technologist: On the MRI console, right click on the SAG T2 scan and select **Duplicate & Setup**.
 - b. MRI Technologist: For the new SAG T2 scan, manually input the **Start / End Location** coordinates displayed in Coarse Planning on the TDC (Figure 36). Acquire the scan and send it to the TDC.
 - c. Radiologist: Click **Load ... Scan** to import the new scan and confirm that the UA is in the intended location.

9. Treatment Planning

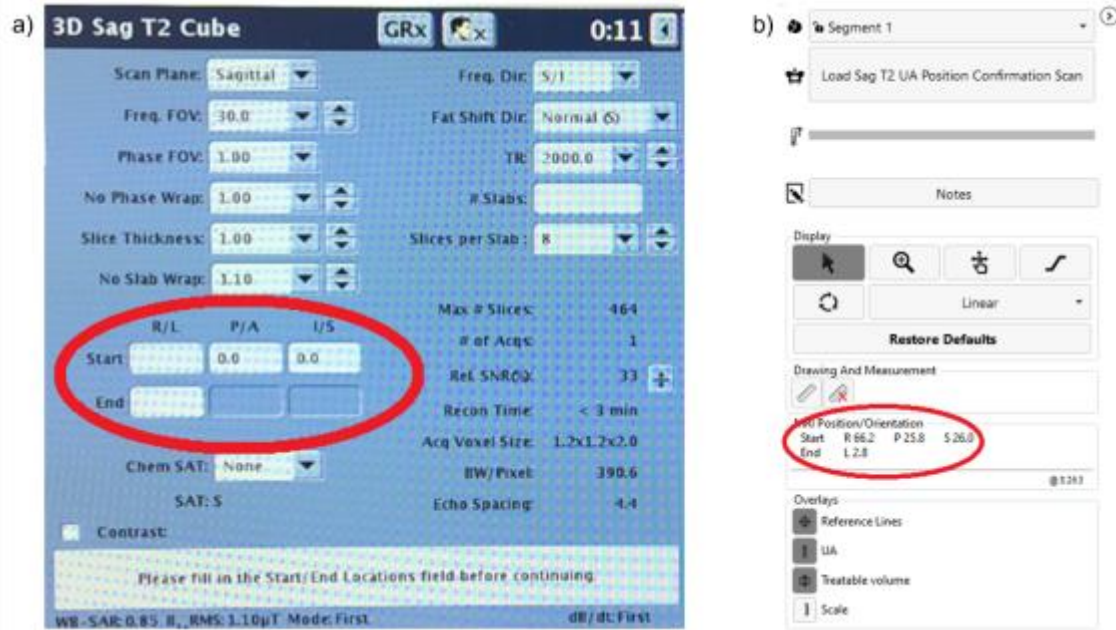


Figure 36: Manually prescribing Start/End Location coordinates for confirmatory SAG T2 scan

5. Radiologist: Once you are satisfied with the UA position and number of enabled elements, click **Accept Current Position** to proceed to Detailed Planning.

9.e Detailed Planning

Radiologist: After correctly positioning the UA in Coarse Planning, contour the prostate for each active ultrasound element with the help of a high-resolution device-axial T2 sequence (AX T2) and device-axial EPI thermometry images (AX THERM), acquired by the MRI Technologist. These images are acquired in twelve slices transverse to the UA: ten images centered on the individual ultrasound transducer elements, and two additional “monitoring” images near the prostate apex and base.

Anesthesiologist: Immediately before acquiring the treatment planning images and before treatment delivery, administer a GI anti-spasmodic drug to reduce GI peristalsis if directed by treating physician.

9.e.i Acquiring the treatment planning images for GE

MRI Technologist: On the MR Console, follow these instructions to acquire device-aligned AX T2 and AX THERM images. To prescribe AX THERM, you will need to modify additional scan control variables called Research CVs.

1. MRI Technologist: Open AX THERM, make sure the **Scan Plane** is set to ‘Oblique,’ and manually prescribe the **Start / End Location** coordinates given by TDC for the R/L, P/A, and I/S directions.



NOTE: Be careful not to click on the images or attempt to view the slices once the coordinates are entered, as this will change the slice location to wherever was clicked. If this happens, click **GRx**, and then press the erase button (🗑️).

2. MRI Technologist: With AX THERM open, navigate to the **Multi-Phase** tab and set **Total Phases** to 26.

9. Treatment Planning

3. Before acquiring AX THERM, modify any additional scan parameters called 'Research CVs.' Click **Save Rx** to apply your changes.
4. In the dropdown list next to the **Scan** button, select **Research > Download**(Figure 37).

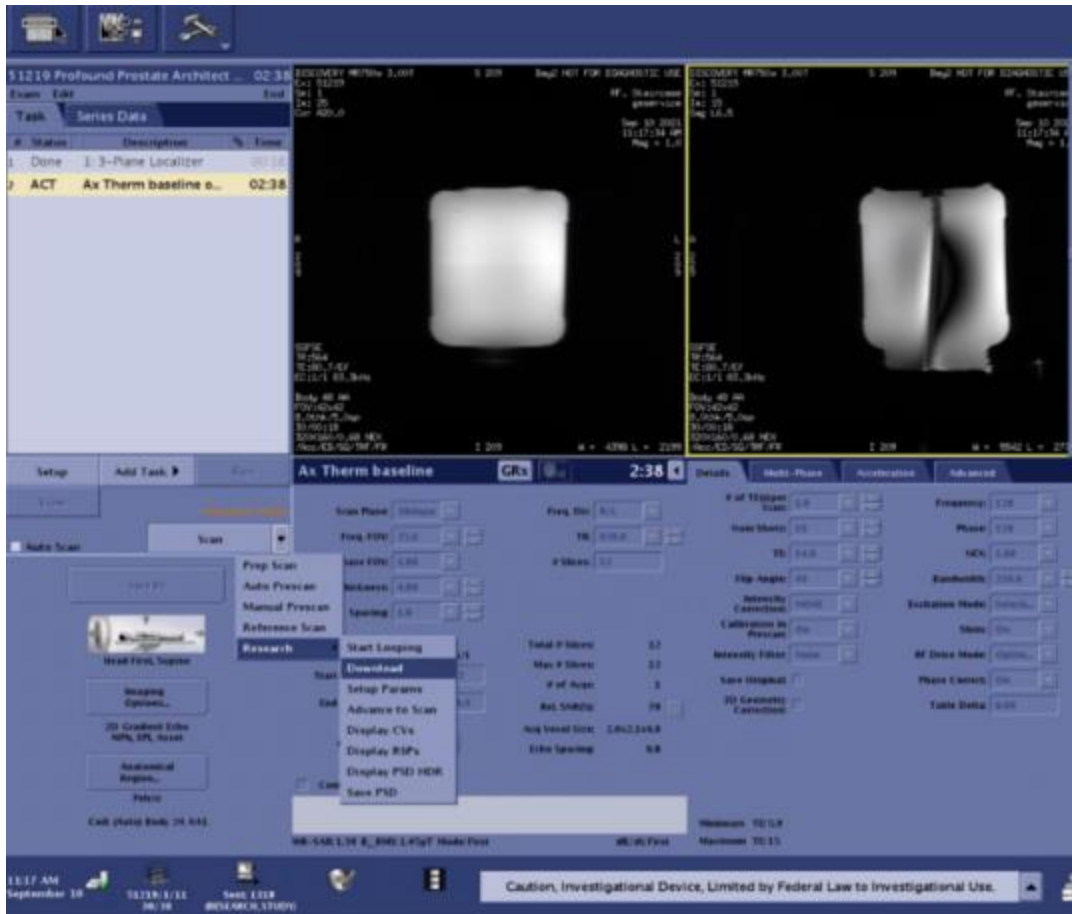


Figure 37: Downloading AX THERM scan parameters to the MRI

5. Wait a few seconds for the parameters to download to the MRI, and then instruct the physician to click **Update** in the *Detailed* workspace on the TDC console. TDC will take control of the MRI console to ensure that the imaging sequence parameters are correct.
6. On the MRI console, open the dropdown list next to the **Scan** button and select **Auto Prescan**.
7. On the MRI console, open the dropdown list next to the **Scan** button again and select **Research > Display CVs**.
8. In the new window that appears (Figure 38), type 'dda' (all lowercase) next to **CV Name**, set the **Current Value** to 0, and then click **Accept**.

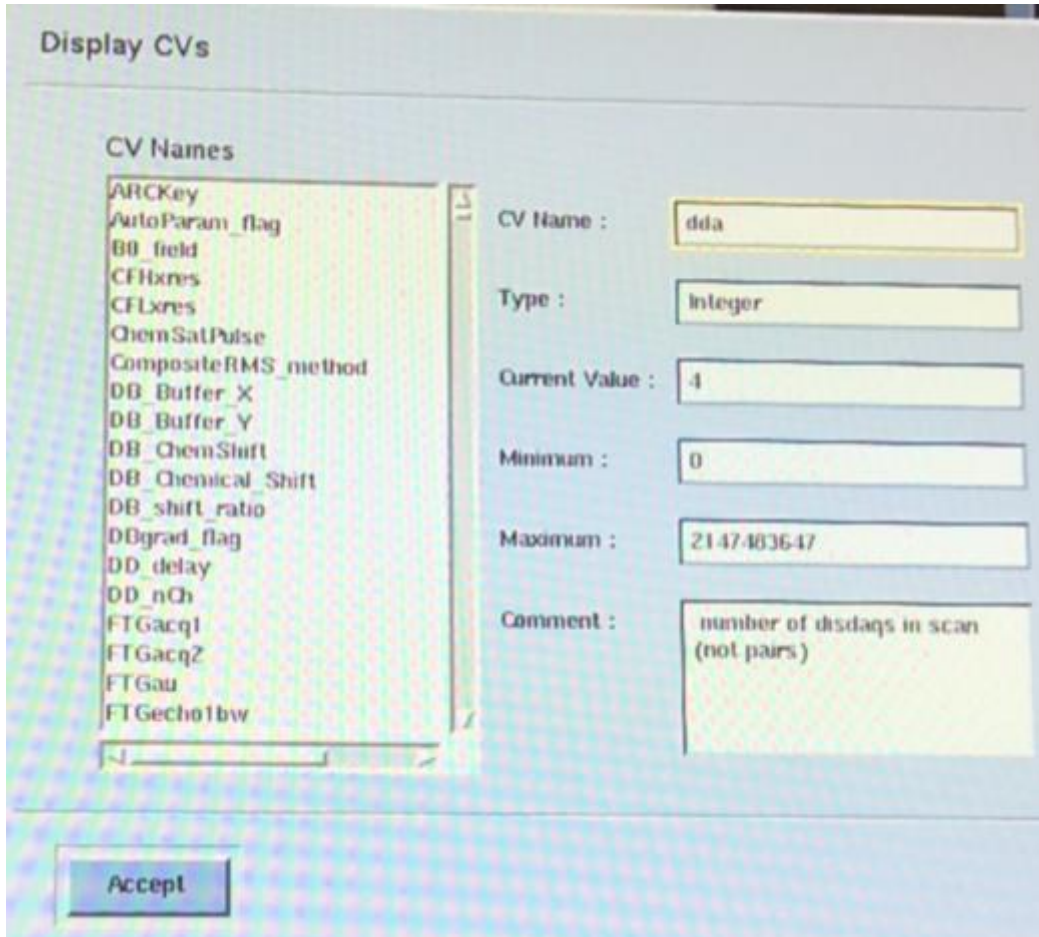


Figure 38: Editing Research CVs for AX THERM scan

9. Run AX THERM by clicking **Scan**. TDC will automatically receive the thermometry images. As the thermometry scans are received, the Magnitude and Temperature Uncertainty views will be displayed to facilitate treatment planning (*Figure 39*).
4. **MRI Technologist:** Prescribe and run the AX T2 sequence:
 - a. Open AX T2.
 - b. Manually prescribe the **Start / End Locations** using the coordinates listed by TDC for the R/L, P/A, and I/S directions.
 - c. Acquire the scan and send it to TDC.
 - d. If instructed by the Radiologist, repeat these steps to prescribe and run the AX DWI sequence (" mpMRI Vision" on page 55).
5. **Radiologist:** Click **Load ... Scan** to load the AX T2 images. Afterwards, you will have the option to also load DWI images .

9. Treatment Planning

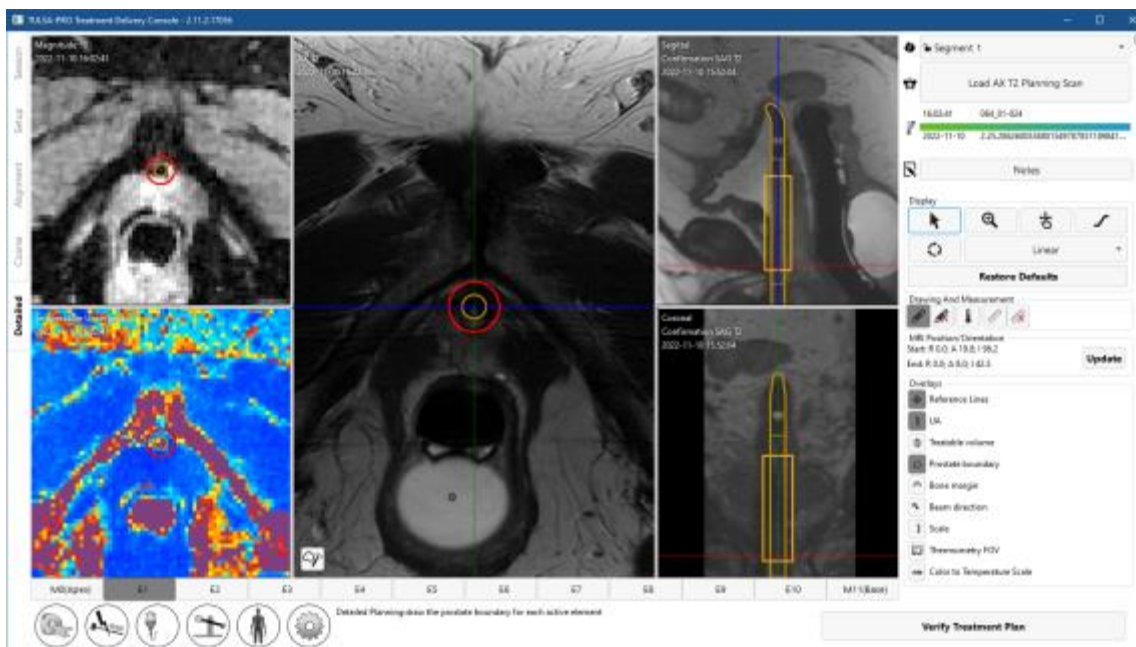


Figure 39: Detailed Planning workspace with Thermometry Magnitude and Temperature Uncertainty

9.e.ii How to draw prostate boundaries

1. Radiologist: Before drawing boundaries, ensure that the UA center overlay on the AX THERM is aligned with the UA center on the images. Because of geometrical distortion on AX THERM, it is possible that the first UA center alignment is incorrect and needs to be readjusted manually. To adjust the UA center, click and drag the UA center overlay on the Magnitude AX THERM image.

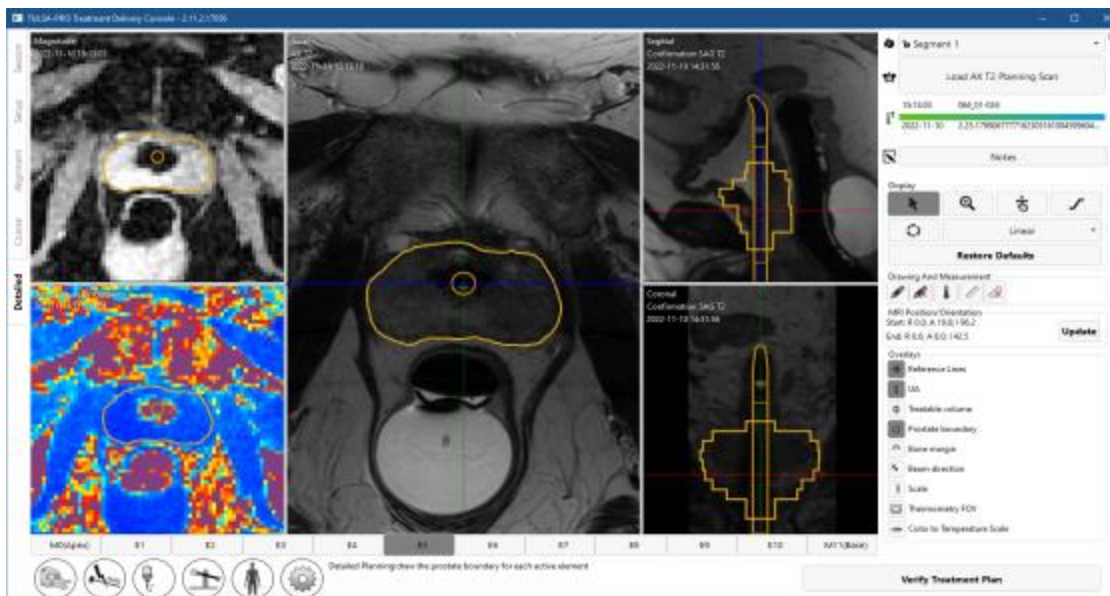


Figure 40: Detailed Planning after drawing boundaries

2. To draw the prostate boundary, select the drawing tool and outline the tissue to be ablated on each slice based on the corresponding AX T2 and THERM magnitude images (Figure 40). You can select individual slices by clicking on the numbered tab at the bottom of the screen or by pressing

9. Treatment Planning

the left and right arrow keys on the keyboard. Use the sagittal and coronal views of the SAG T2 images to verify the intended ablation zone in three dimensions.



NOTE: If the displayed slice is not part of the treatable volume, the drawing cursor will be disabled. If you need to draw on this slice, return to Coarse Planning, click **Unlock**, and add this slice to the treatable volume.



NOTE: When drawing the boundary for a current slice or re-positioning the UA center, you can restore (undo [CTRL+z]) the boundary to a previous drawing or restore a new boundary change [redo (CTRL+y)], as much as needed. When you work with a new slice, you cannot undo changes on previous slices.

The color of the prostate boundary indicates possible conditions:

- A gold boundary is a valid boundary.
- A pink boundary is valid and ultrasound will be directed to those areas, but it extends beyond the expected maximum treatable radius and thermal coagulation might fall short of the prostate boundary in those areas.
- A red boundary represents an area that is excluded from the target prostate volume because it is too close to the UA.



NOTE: You can progress to **Treatment** if parts of the boundary are red, but ultrasound energy will not be directed to those areas.

- A purple boundary represents an invalid boundary because the boundary was drawn on a region with high temperature uncertainty.



NOTE: You cannot progress to **Treatment** if parts of the boundary are purple.



A warning icon is displayed next to each region where there is high temperature uncertainty on the calculated control boundary.

3. When all planning steps are completed and verified, continue by clicking **Verify Treatment Plan**.

9.e.iii Treatment planning guidelines

Radiologist: The prostate boundary should be drawn on all AX T2 images that contain prostate tissue intended to be treated. On each slice with a boundary, the prostate boundary must contain the UA center. The location of the UA center should be the same on all slices. Slices that do not have any defined prostate boundary will not be active during treatment delivery (in other words, no ultrasound power will be delivered by that element). Boundaries drawn too close to the UA will appear red and will not be treated.



NOTE: The prostate boundary should not be drawn outside of the prostate gland and should not include urine or important peri-prostatic anatomy such as the rectum, neurovascular bundles, external urinary sphincter, bladder wall, or pelvic bone. Including urine or important peri-prostatic anatomy within the prostate boundary could result in thermal damage to structures outside the prostate, which could lead to treatment-related harms that may include rectal fistula, other bowel complications,

9. Treatment Planning

erectile dysfunction, retrograde ejaculation, urinary incontinence, other urinary complications, or damage to the pelvic bone and/or nerves adjacent to the pelvic bone.



NOTE: Bone has significantly higher ultrasound attenuation and absorption than soft tissue, which can result in significant heating of bone and adjacent soft tissue. Since the pelvic bone can tolerate some small amount of thermal damage and soft tissues adjacent to the pelvic bone are often of little concern, the volume/area of at-risk pelvic bone and its proximity to other important structures (such as nerves) should be considered carefully.



NOTE: Anomalies in the prostate should be identified (including but not limited to cysts and calcifications) on the treatment planning images. The prostate boundary should be at least 5 mm away from these anomalies. The risk of heating in sectors containing cysts is overtreatment outside the prostate due to their low ultrasound attenuation/absorption.



NOTE: For partial gland ablation, contour the entire prostate in **Detailed Planning**. During treatment **Delivery**, use the start angle to define where the ablation should begin, and then stop treatment when thermal coverage of the desired angular segment has been achieved.




NOTE: Temperature uncertainty is expected to be uniformly low (blue on the temperature-uncertainty color scale) within the prostate and in the muscles lateral to the gland. Large amounts of intermediate (yellow-red) or severe (purple) temperature uncertainty in these regions can indicate thermometry artifacts that could affect patient treatment. If you suspect thermometry artifacts, check for the following before proceeding to treatment:

- tissue abnormalities within the gland
- patient motion due to breathing or contraction of pelvic floor muscles
- incorrect imaging coil placement
- incorrect UA or ECD placement
- air or feces within the rectum
- incorrect prescription of THERM scan.

9.e.iv mpMRI Vision

Radiologist: When prescribing the treatment volume, use the mpMRI Vision feature in *Detailed Planning* to load a set of axial diffusion weighted images (DWI), which can be used to visualize intraprostatic differences in prostate tissue to help select tissue intended for ablation (*Figure 41*).

9. Treatment Planning

1. **MRI technologist:** Acquire an AX DWI scan. Several output scans will be created automatically. Send either the apparent diffusion coefficient (ADC) map or the calculated high b-value DWI to the TDC, based on physician preference.
2. **Radiologist:** Click **Load ... Scan** and double-click the new AX DWI scan to import it. The DWI scan will replace the existing AX T2 scan in the transverse view. Toggle between viewing the AX DWI and AX T2 scans by clicking the mpMRI button () in the top right of the transverse view.

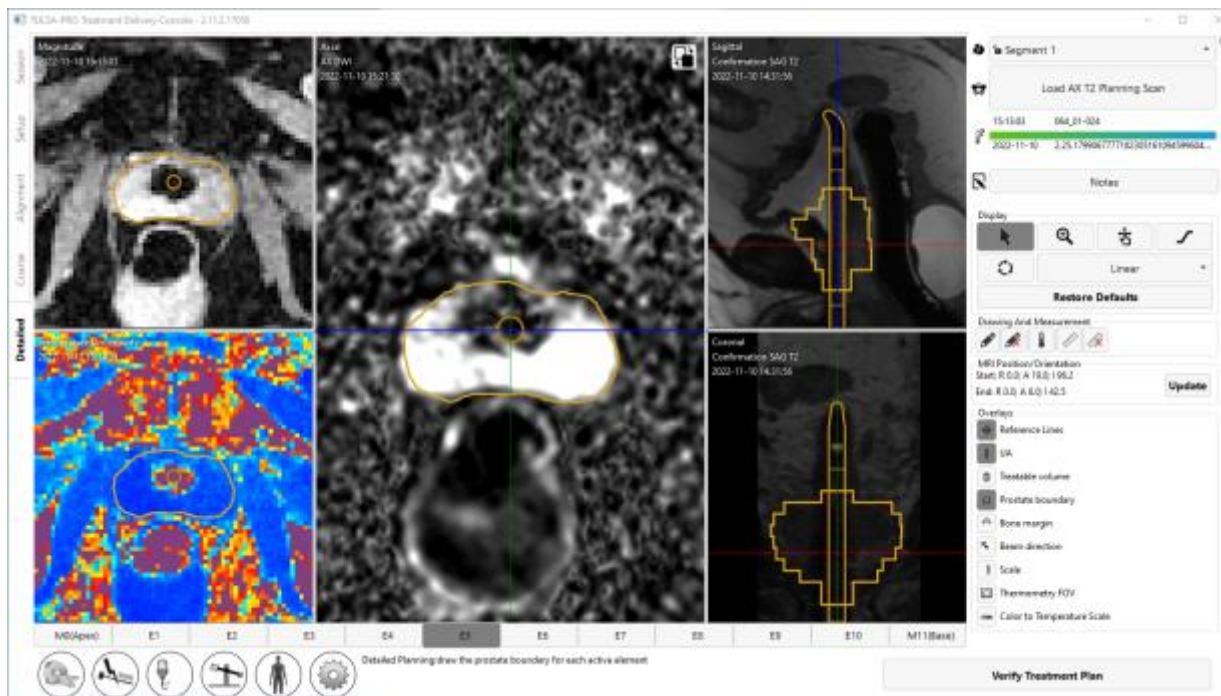



Figure 41: Using mpMRI vision in Detailed Planning to visualize intraprostatic differences in tissue properties on an AX DWI scan and select tissue intended for ablation

9.e.v Contouring Assistant

Radiologist: Your TULSA-PRO installation might include the Contouring Assistant feature. In Detailed Planning, this feature allows the physician to apply a software-assisted contour on a selected slice as a starting point for drawing the prostate boundary. The physician is then able to modify the boundary to prescribe and verify the appropriate treatment plan. Software-assisted contours are disabled by default and must be manually applied one slice at a time.

1. To apply a software-assisted contour on a selected slice in Detailed Planning, click the Contouring Assistant button () in the bottom left of the transverse view. If prostate tissue is detected on that slice, a software-assisted contour will appear.
2. Modify the boundary to prescribe an appropriate treatment plan for that slice.
3. Repeat steps on additional slices as desired.

9. Treatment Planning

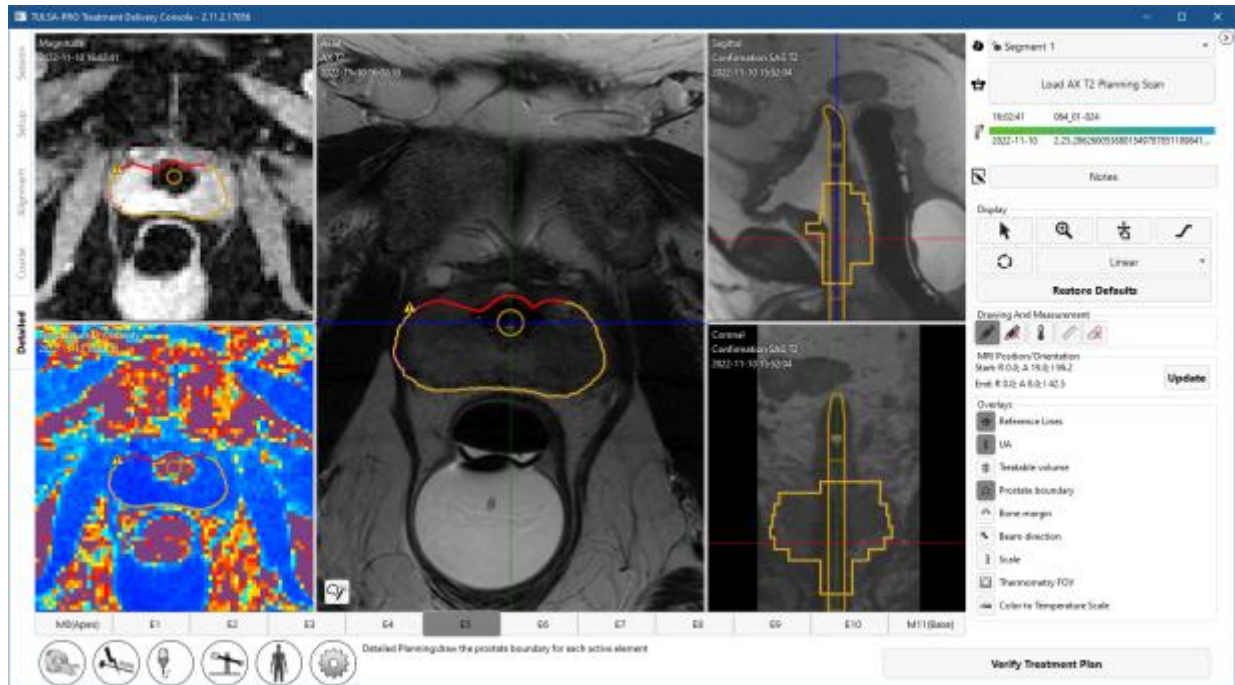


Figure 42: Using the Contouring Assistant feature in Detailed Planning to apply a software-assisted prostate boundary as a starting point for treatment planning on a selected slice

10. Delivery


Radiologist: Start prostate ablation according to the treatment plan defined in **Detailed Planning**. Confirm the treatment plan with the **Urologist**, notify the Anesthesiologist to prepare the patient for treatment, and instruct the **MRI Technologist** to initiate MR thermometry.

The *Delivery* workspace displays information from 12 axial slices in real time: 10 slices corresponding to the elements (E1-E10) that can deliver heating, and two additional slices corresponding to the Monitoring Elements, M0 and M11 (*Figure 43*). Images are updated every 5 to 7 seconds during treatment as new images from the MR scanner are processed into temperature information.

In the main viewport, the enlarged image on the left, shows either Current or Maximum Temperature from a selected slice. The enlarged image on the right shows the same slice in one of several selected display modes.

Above the main viewport, smaller (thumbnail) views of all slices are displayed in two rows of 12 images. The top row shows all slices in the display mode selected for the left enlarged image. The second row shows all slices in the display mode selected for the right enlarged image. Click on any slice in the top rows to show the corresponding slice enlarged below. You can also move between individual slices by pressing the left and right arrow keys on the keyboard.

The following display modes are available for the right enlarged image:

1. **Current temperature** view displays a color map of the most recently acquired thermometry image.
2. **Maximum temperature** view displays a color map of the maximum temperature from the start of treatment.
3. **Dose** view displays a color map of the cumulative, quantitative measure of thermal dose.
4. **Motion** view displays the difference between the most recently acquired magnitude image and the first reference image.
5. **Anatomy** view displays the most recently acquired thermometry magnitude image.
6. **Planning** view displays the most recently acquired AX T2 and AX DWI planning images. Toggle between AX T2 and AX DWI by clicking the mpMRI button ().

NOTE: Planning images are not dynamically acquired during treatment delivery and might not reflect the current anatomical configuration if motion has occurred during treatment.

10. Delivery

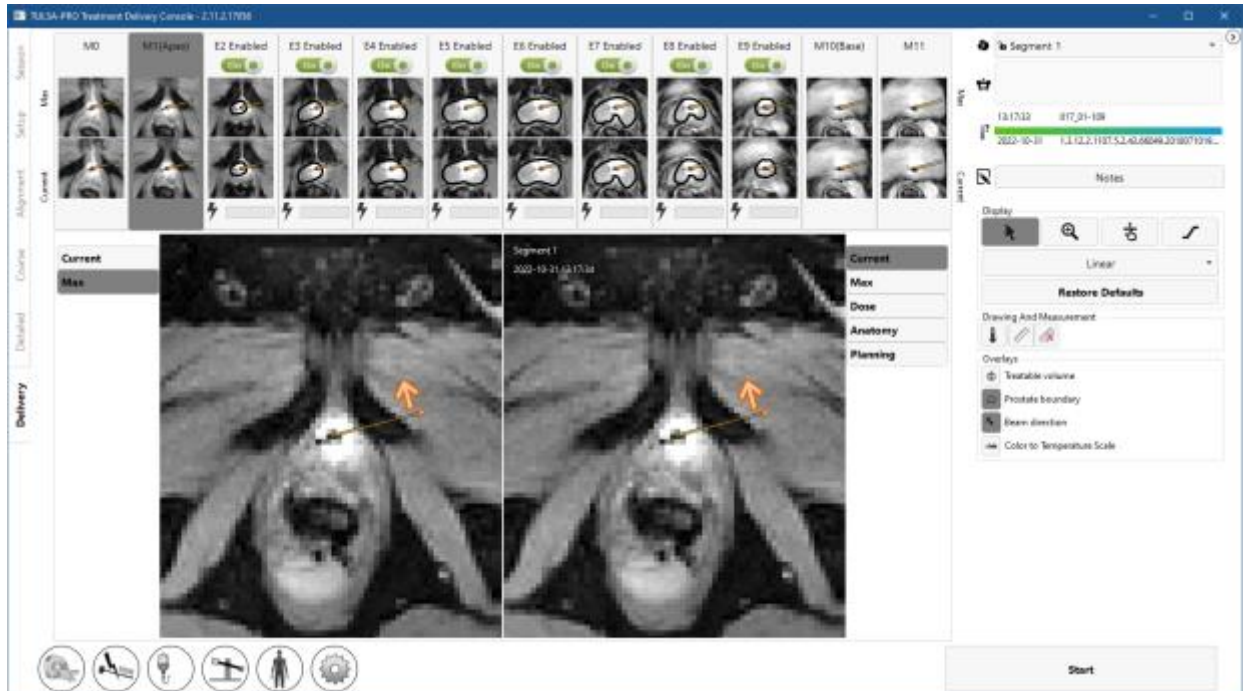


Figure 43: Delivery workspace of TDC software - Drag the orange dot to define the starting UA angle, and click the orange arrow to define the direction of rotation

10.a Starting position and direction of rotation

Radiologist: Before initiating treatment, adjust the starting position and direction of the UA rotation in the TDC *Delivery* tab. Avoid starting ablation therapy with the UA pointed at sensitive structures, such as the neurovascular bundles or rectum. Click on the orange arrow once to change the intended clockwise or counter-clockwise direction of UA travel at the start of treatment. Adjust the starting position of the UA by clicking and dragging on the orange dot beside the arrow (*Figure 43*). When the desired UA position and rotation direction is set, click the **Rotate to ###min** button to execute the command. Alternatively, click the **Reset** button to cancel the command.



NOTE: When ablation begins, the controller rapidly rotates through the first 15 angular degrees and may rotate further before heat initially builds up to the target boundary depending on target radius. Consider this angular margin when defining the start angle.

10.b Treatment Initialization for GE

Radiologist: When you have finished planning and are ready to start treatment, instruct the Anesthesiologist to administer a second dose of GI anti-spasmodic drug if appropriate. This will reduce GI peristalsis during treatment delivery and help maintain stable temperature maps.

1. **MRI Technologist:** Duplicate and open the AX THERM sequence on the MRI console.
2. **MRI Technologist:** In the **Multi-Phase** tab, change **Total Phases** to 1500 or as instructed by the Radiologist.

10. Delivery

- Download the scan to the magnet by clicking the dropdown arrow next to the **Scan** button. Click **Research > Download**. Click the dropdown again and select **Auto Prescan**. The previously entered Research CVs will automatically apply. **Do not run the scan until instructed by the physician.**
- Radiologist:** Click **Start treatment** on TDC. A window will prompt you to verify the core body temperature using an external temperature measurement device before proceeding (10). Enter the temperature in degrees Celsius and click **Confirm**. The software will enter the **Treatment Initialization** state where it will wait to receive thermometry images (Figure 44).



NOTE: Core body temperatures outside the normal range of 35-39°C will require an additional confirmation.

If the core body temperature is less than 30°C or higher than 40°C, treatment is not allowed.

- MRI Technologist:** Run AX THERM on the MR Host by clicking **Scan**.

The first 26 imaging dynamics are received during the **Treatment Initialization** state, where all hardware is configured to prepare for heat delivery. During this step, the Radiologist should closely monitor the magnitude and thermometry images and click **Stop Initialization** if there is evidence of severe thermometry artifacts or patient motion that could affect treatment.

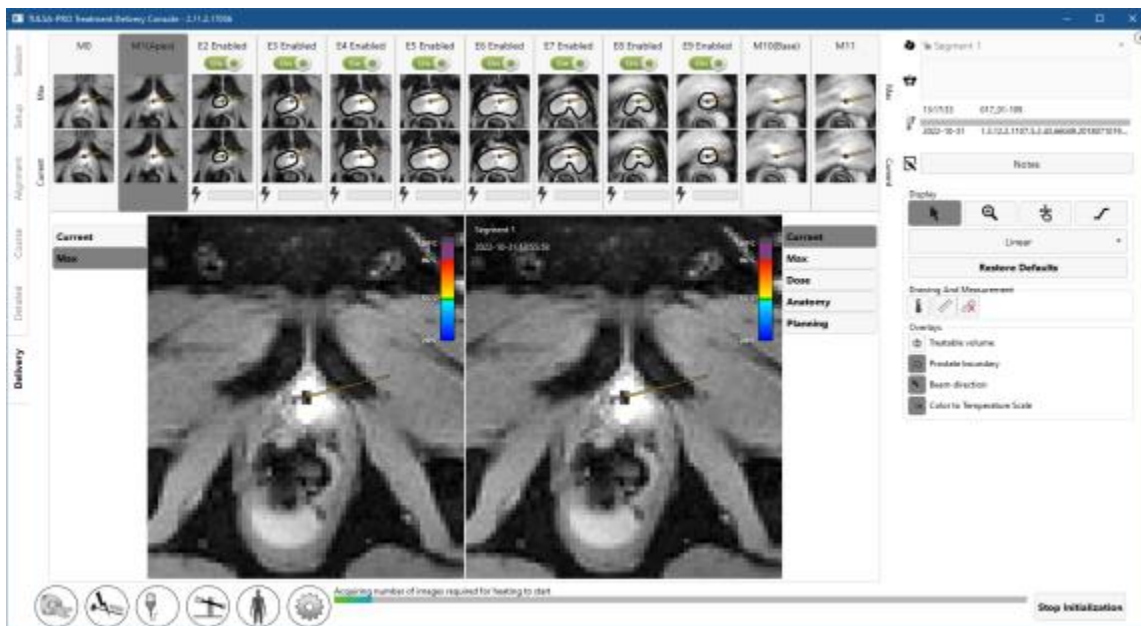


Figure 44: Treatment Initialization state

10.b.i Monitoring Treatment Delivery

Radiologist: After receiving 26 thermometry dynamics, heating begins (Figure 45). Throughout the ablation, actively monitor real-time treatment images on all slices, ensuring that:

- The observed heating pattern on the Current Temperature display matches the expected heating direction and depth. The Current Temperature image is used by the software to automatically adjust treatment parameters.

10. Delivery

- There are no erroneous temperature measurements in unheated regions of the prostate due to artifacts caused by gross patient motion, excessive prostate swelling, contraction of the pelvic floor muscles, displacement of gas in the rectum, bladder filling, or RF interference.

If unintended heating or gross patient motion is suspected, click **Pause** to temporarily disable heating on all elements without stopping MRI thermometry, giving you time to evaluate the situation.

The following subsections describe the use of software features to fine-tune parameters during treatment delivery.

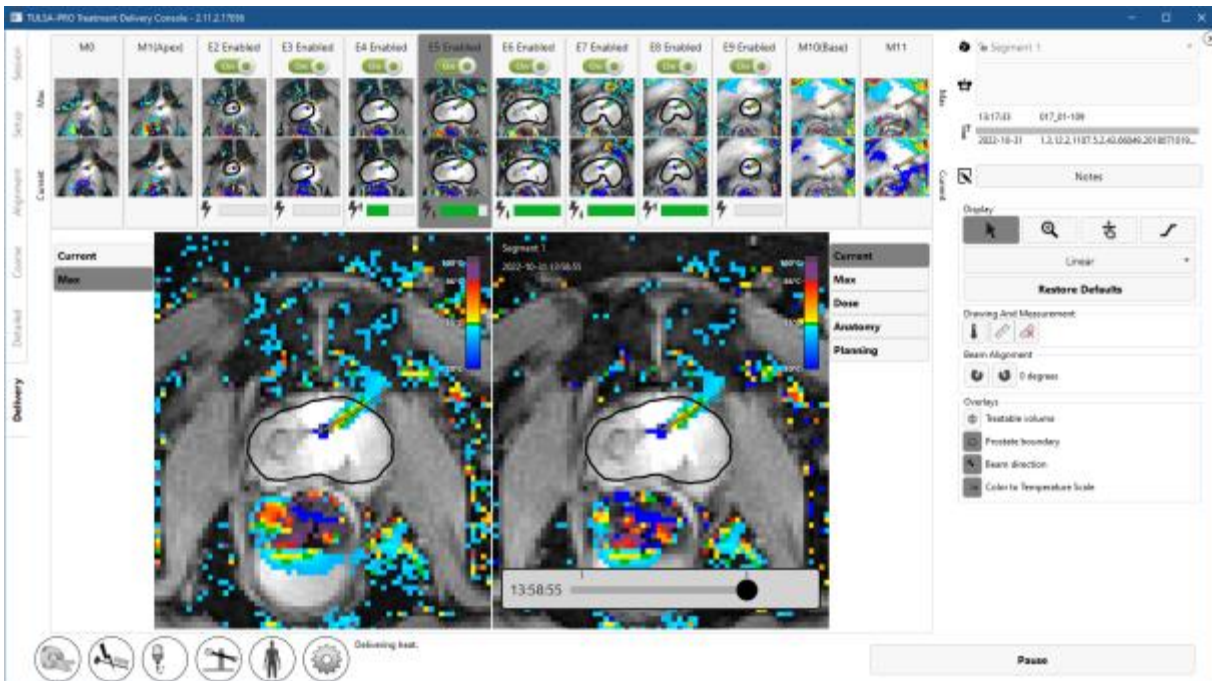


Figure 45: Ultrasound heating has begun

10.c Toggling Power to One or More Treatment Elements

Radiologist: The power and frequency delivered on each active element is shown for each slice in real-time; power is shown by a solid, green bar. Hover the cursor over the power bar to display the actual value of the frequency and delivered power.

If unintended heating of important structures outside the prostate is observed at any time, unselect the switch to disable power to that element (*Figure 46*).

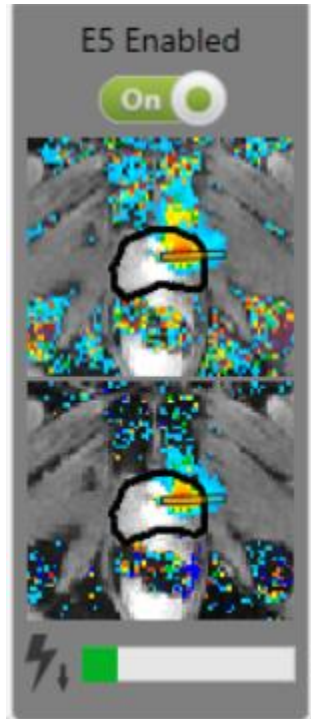


Figure 46: Active element in the Delivery workspace
(Green bar shows power is being delivered from this element.
Down-arrow indicates element is operating at low frequency.)

10.d Adjusting Beam Alignment during Treatment

Radiologist: To execute a successful TULSA-PRO® treatment, the actual direction of ultrasound heating must correspond to the heating direction expected in the TDC software. You can determine the actual direction of ultrasound heating directly by examining the heat pattern on the MRI Thermometry image during ablation.

The expected heating direction in the TDC software is represented by a feature called the **UA Beam Angle** (*Figure 47*), which is a visual overlay over the MRI Thermometry image and represented as a line extending radially outwards from the UA center.

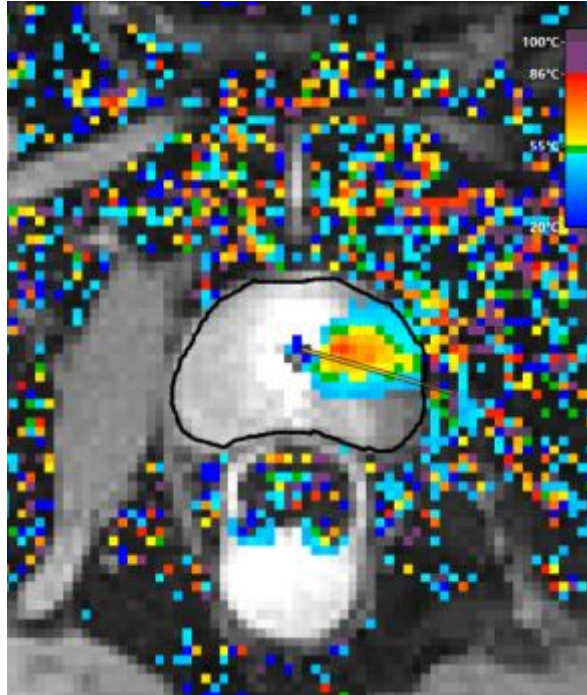


Figure 47: UA beam orientation overlay

It is the Radiologist's responsibility to ensure that the actual direction of ultrasound heating as observed in the temperature maps corresponds with the UA beam angle at the start of delivery.



During treatment delivery, if it is observed that the direction of ultrasound heating and the UA beam angle do not correspond or align with each other on the Current Temperature view (Figure 48), adjust the beam angle. If the adjustment does not resolve the problem, click Pause and create a new treatment segment (see *Creating a new Treatment Segment*) to suspend ultrasound delivery and thermometry acquisition. Enter the MRI magnet room to ensure the UA is properly mated to the PS. If the problem persists, contact a Profound Medical authorized service representative.

10. Delivery

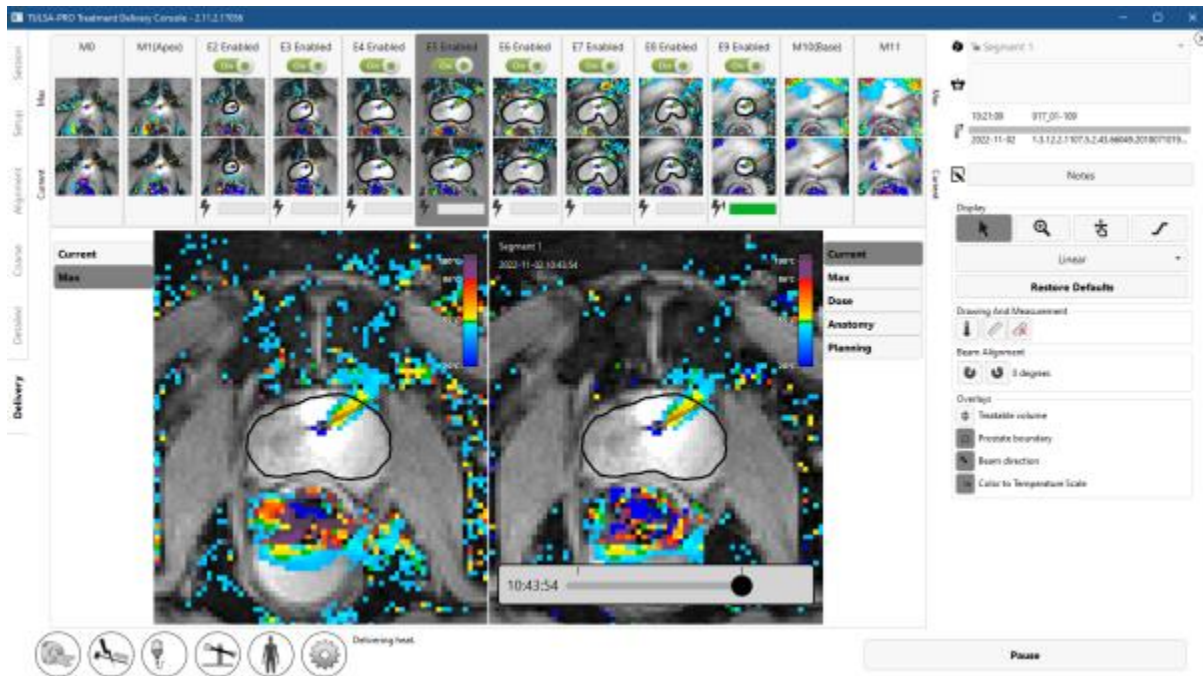



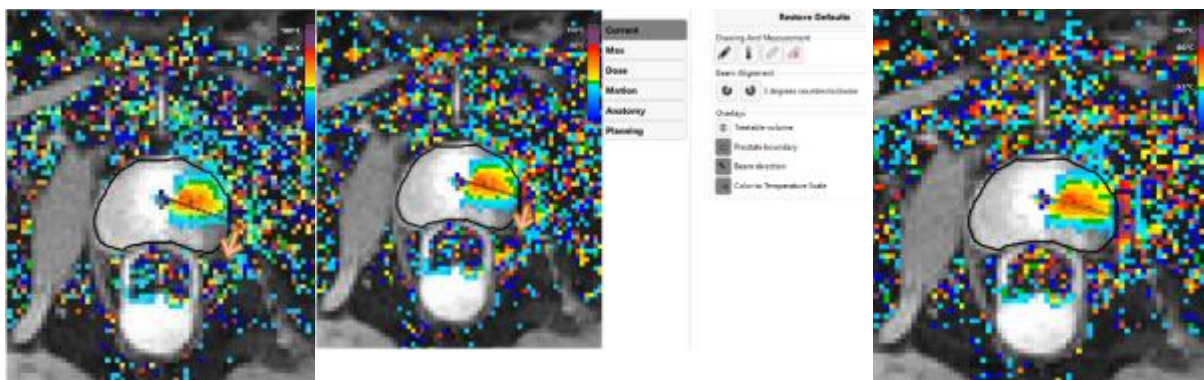


Figure 48: Misaligned ultrasound heating and UA beam angle

To adjust the UA beam angle at any time, expand the right panel in the Delivery workspace to access the

beam angle adjustment buttons . Click the buttons to adjust the UA beam angle in 1-degree increments in either clockwise  or counter-clockwise  directions, up to a maximum of 5 degrees in either direction. It is recommended to perform beam alignment near the start of treatment when the heating pattern from the UA is a developing narrow beam. As treatment progresses, since the UA rotates while delivering heat, previously heated tissue can still appear hot and make it difficult to identify where the heat is currently being delivered. As an example, *Figure 49* shows a UA beam angle that is offset from the heating pattern of the temperature map. Next, the beam angle adjustment buttons are used to rotate the UA beam angle back toward the center of the heating pattern. After the adjustment is complete, the UA beam angle is positioned more centrally within the heating pattern.



The UA is treating in the clockwise direction and the UA beam angle leads

The **Beam Alignment** buttons are used to adjust the beam angle in increments of 1 degree each time it is clicked. In this image

The beam angle is now positioned more accurately as it is situated more centrally in

10. Delivery

the heating pattern of the temperature map. the counter-clockwise button has been clicked the area where the heating pattern or temperature is highest.

Figure 49: Beam angle adjustment

10.e Delivery Paused

Radiologist: At any time during Delivery, click **Pause** in the bottom-right corner of the screen (see *Figure 45*). While in the paused state, all heating from the UA is suspended while thermometry acquisition continues (*Figure 50*).

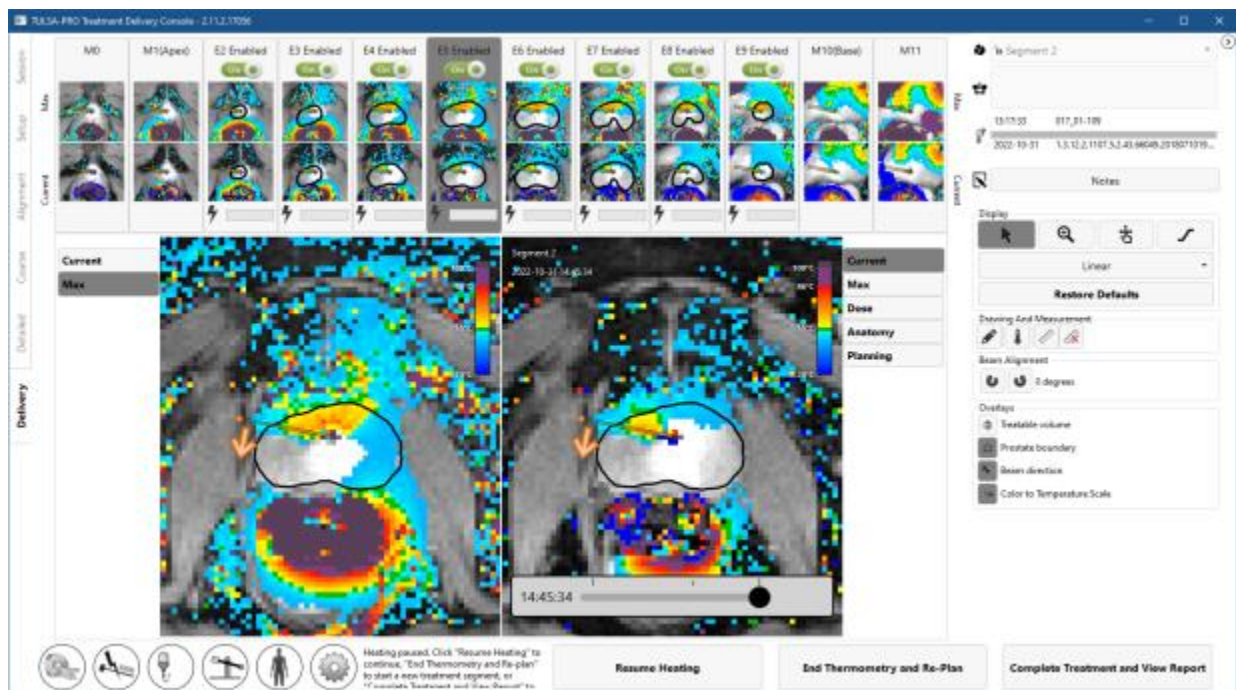


Figure 50: Delivery workspace with treatment and heating paused

Pausing treatment enables the following options:

- **Rotate the UA to a new position and/or change the direction of treatment rotation.** In some instances, you might want to set the UA to a new position and/or change the treatment rotation direction. To execute this command, follow the steps in the *Starting position and direction of rotation* section and when the system is ready to resume treatment, click **Resume Heating**.
- **Edit the prostate boundaries.** In some instances, the patient anatomy may deviate from the originally planned target volume over time. Editing the prostate boundaries allows you to make minor changes to target volume to better reflect the current anatomy. See *Editing the Prostate Boundary during Treatment*.
- **Start a new treatment segment.** In some instances, the temperature maps are no longer valid due to, for example, large motion artifacts. In such cases, you must end the current treatment segment by clicking the **End Thermometry and Re-plan** button. This will stop cooling of the UA and ECD; you can choose to wait up to 4 minutes before taking this step. After ending the segment, the TULSA-PRO® system enforces a minimum wait period of 20 minutes before heat

10. Delivery

delivery can resume, to allow for tissues to reach baseline temperature again. During this time, you can update the treatment plan before creating a new segment. See *Creating a new Treatment Segment* for more information.



During treatment delivery, if you see that the temperature maps are no longer valid (such as due to patient motion), you must end the treatment segment to acquire new reference images for MR thermometry.

- **Continue treatment delivery.** When you want to resume treatment delivery (such as after rotating the UA to a new position or editing the prostate boundaries), click the **Resume Heating** button to exit the Pause state and resume treatment in the Delivery state.
- **End the treatment.** When you are satisfied with the heat delivered to the target volume, click **Complete Treatment and View Report**. After pressing this button, the TULSA-PRO system will continue acquiring thermometry images and pumping cooling fluid through the UA and ECD during the post-delivery cooldown period (which can last up to 4 minutes). Afterward, the TDC software will enter review mode, allowing you to review the previous workspaces (Setup, Alignment, Coarse Planning, Detailed Planning, and Delivery), but not the ability to unlock them for editing.

MRI Technologist: If the MRI is still acquiring thermometry images after the treatment segment and the post-delivery cooldown has ended in TDC, stop the current AX THERM scan on the MR console.



NOTE: Stopping the AX THERM scan on the MR console will interrupt treatment and the post-delivery cooldown.

10.f Editing the Prostate Boundary during Treatment

Radiologist: In some instances during treatment delivery, the patient anatomy may change from the originally planned target volume over time. For minor changes, the prostate boundaries can be modified while thermometry acquisition continues. To do this:

1. Pause the treatment delivery.
2. Once delivery is paused, expand the right panel in the Delivery workspace to select the prostate boundary drawing tool (*Figure 51*).

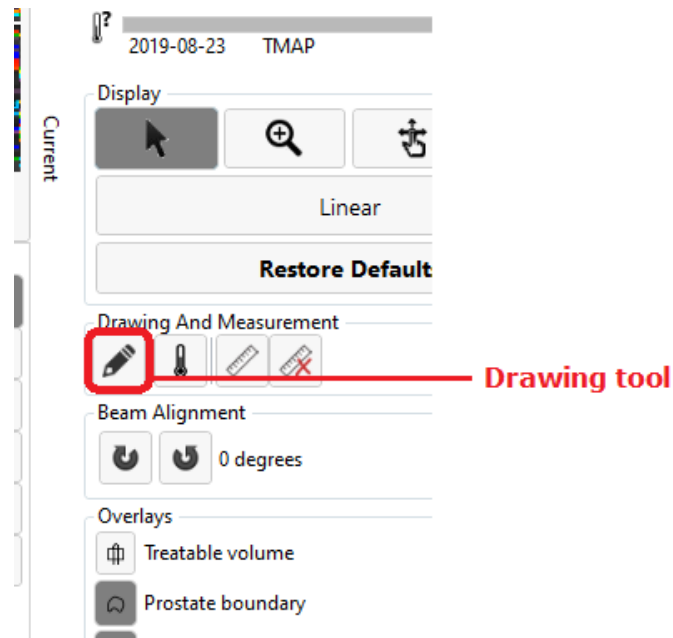
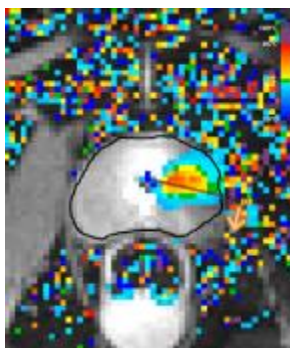
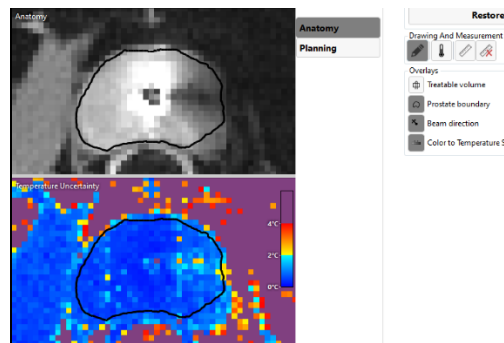


Figure 51: Prostate-boundary 'Drawing' tool on Delivery screen

3. Click the drawing tool. The TDC displays a new pane showing the prostate boundary contour and the temperature uncertainty for the selected slice (*Figure 52*).
4. Modify the boundary as needed on each slice. As with the thermometry uncertainty images in Detailed Planning, avoid drawing the boundary through high-temperature uncertainty regions.
5. If satisfied with the modified boundaries on all slices, click **Apply**. The TDC will validate the changes to the boundary and then you can click **Resume Heating** to resume treatment delivery. Otherwise, click **Discard Changes** to start editing from the current boundaries again. If none of the changes are acceptable, then create a new treatment segment by clicking **End Thermometry and Re-plan**.



The prostate boundary does not match the prostate in the image.



Treatment is paused, and the prostate boundary is changed with the drawing tool.

Figure 52: Editing the prostate boundary

10.g Creating a new Treatment Segment

Radiologist: Sometimes during treatment delivery, the current temperature maps may no longer be valid. In other words, temperature measurements near the target boundary are not accurate enough to deliver an effective treatment. This could be caused by large motion artifacts such as bulk patient motion, artifacts from uncleared bubbles between the ECD and rectal wall, or even motion of the rectum into planned target volume. Alternatively, it could be observed that heat is accumulating in unexpected regions (for example, in the wrong direction or on the wrong slices).

1. **Radiologist:** In these cases, you must recognize the situation and click **End Thermometry and Re-plan** to create a new treatment segment.



NOTE: Ending thermometry also turns off cooling of the UA and ECD.

After ending a treatment segment, wait a minimum period of 20 minutes is imposed to allow tissue temperatures to reach baseline again before initiating a new thermometry acquisition and resuming the delivery of heat. This is necessary because the current thermometry sequence will be interrupted and a new set of reference images (at baseline temperature) must be acquired.

2. **MRI Technologist:** If the MRI is still acquiring thermometry images after the treatment segment has been ended in TDC, stop the current AX THERM scan on the MR console.
3. **MRI Technologist:** Before re-acquiring treatment planning images, home the rotation of the ultrasound applicator so that it can be visualized correctly during re-planning. In the Setup workspace, click the Unlock button in the bottom right corner, and then click **Home** (🏠). The system will rotate the UA clockwise and counter-clockwise to find the home position of the UA, so that the UA window is facing downwards (6:00).
4. **MRI Technologist:** Duplicate the MRI planning sequences into the queue and follow the instructions from that point in the workflow (from section *Gross Positioning* through *Delivery*).
5. **Radiologist:** Repeat the instructions from *Gross Positioning* through *Delivery*. For each step, ensure that a new set of images is being used to update the treatment plan. When the treatment re-planning is complete and at least 20 minutes has elapsed since the previous treatment segment was ended, proceed to *Delivery*.

10.h History Slider

Use the History Slider to display treatment images from previous timepoints in order to assess:

- patient motion and thermometry artifacts in the current treatment segment, and
- ablation coverage in previous segments.

The History Slider appears at the bottom of the right viewport in the Delivery workspace (*Figure 53*), and is accessible during live treatment delivery, when treatment is paused, and after treatment is completed.

To use the history slider:

1. Select the desired slice and display mode (Current Temperature, Maximum Temperature, Dose, Motion, or Anatomy).

10. Delivery

2. Click-and-drag the History Slider until the desired timepoint is displayed on both the right viewport and the corresponding second row of thumbnail images.
3. Rapidly scroll through sequential images in either on Anatomy or Current Temperature view helps to identify the occurrence of gross patient motion and the movement of gas or stool in the rectum.
4. Scroll further to the left to see Maximum Temperature or Dose views, which help to assess ablation coverage from previous treatment segments.



NOTE: When viewing images from previous timepoints, a frame around the right viewport shows that the latest images are not being viewed (*Figure 54*). A dashed line shows where the beam angle was at the previous timepoint. To return to the current timepoint, click **See live** or drag the History Slider until the framed message disappears.

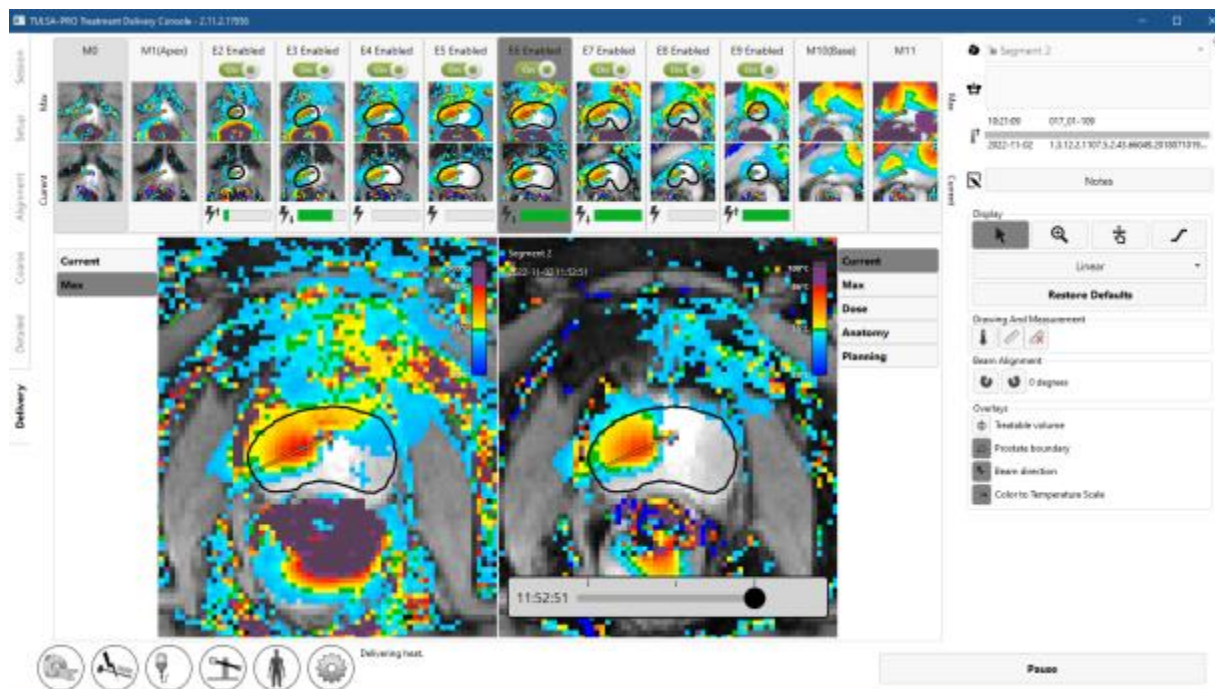


Figure 53: History slider in Delivery workspace

5. To return to the current dynamic, click **See Live** or drag the history slider until the message that reads “You are not viewing the latest image” disappears.

10. Delivery

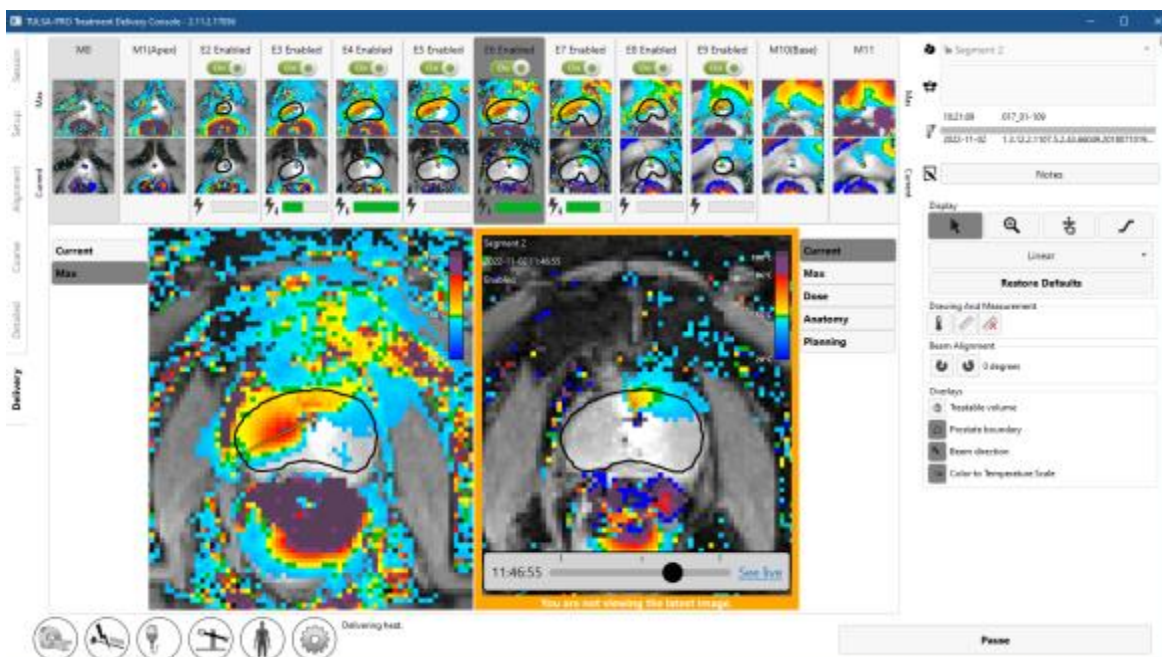


Figure 54: “You are not viewing the latest image” message below history slider

10.i Thermal Boost

Radiologist: If your TULSA-PRO installation includes Thermal Boost, you can use it to optimize the reliability of heating to the target boundary.

Figure 1 shows the maximum temperature view in a case where Thermal Boost was applied on one slice and not on the other.



Figure 55: Max temperature maps of the same target boundary treated with boost (left) and without (right).



NOTE: Thermal Boost can help to ablate target tissue when a desired target boundary is invalid due to high thermometry uncertainty at the edge of the gland. In areas with invalid boundaries, reduce the target radius by 1-2 mm into areas of lower thermometry uncertainty, and then apply Thermal Boost during Delivery to achieve the intended ablation extent.

10. Delivery



NOTE: Thermal Boost remains activated until turned off by the physician. Thermal Boost should not be used to heat important peri-prostatic anatomy such as the rectum, neurovascular bundles, external urinary sphincter, bladder wall, or pelvic bone. Targeting important peri-prostatic anatomy with Thermal Boost could result in thermal damage to structures outside the prostate, which could lead to treatment-related harms that may include rectal fistula, other bowel complications, erectile dysfunction, retrograde ejaculation, urinary incontinence, other urinary complications, or damage to the pelvic bone and/or nerves adjacent to the pelvic bone.

To boost an element during treatment:

1. Make sure the individual element is Enabled (switch is set to **On**). For example, in Figure 2, elements 5 to 9 are enabled.



Figure 56: Enabled elements

2. Click on the double-chevron to activate the **boost**. When Boost is activated, the element's label will change from **Enabled** to **Boost**, its Boost icon will turn yellow, and the Thermal Boost control parameters will remain in effect for that element until deactivated. For example, in Figure 3, heating is Enabled on elements 5, 7, 8, 9, and Boost is activated on Element 5.



Figure 57: Thermal Boost enabled

3. To disable Thermal Boost, click on the double-chevron again and the element will return to the planned treatment delivery boundary.

11. Post-Treatment Imaging and Reports

After the post-delivery cooldown period, the TDC software will advance to the *Reports* workspace where the MRI Technologist acquires post-treatment images, generates treatment reports, and exports treatment session data.

11.a Post-treatment Imaging

MRI Technologist: Acquire Contrast-Enhanced (CE)-MR images to evaluate the extent of acute thermal coagulation using the following steps from the MRI console:

1. In the MRI sequence protocol, open the AX T1 sequence.
2. Enter in the slice prescription manually using the prescription given in TDC. These should match the prescription used for the AX T2 scans.
3. Click **Save Rx** and run AX T1 pre by clicking **Scan**.
4. After AX T1 pre is complete, inject contrast agent into patient under direction of the treating physician.
5. Approximately 2 minutes after injection, repeat steps to acquire a matching set of post-contrast images (AX T1 post).
6. End the MRI exam.

11.b Entering Treatment Milestones

MRI Technologist: Use the Treatment Milestones panel in the *Reports* workspace (*Figure 58*) to record:

- The time when the Urologist removed the ultrasound applicator (UA), and
- The time when the patient was transferred from the MRI magnet room to the recovery area.

After saving each Treatment Milestone, the area will turn gray and the **Save** button will be replaced by **Edit**.

Recording these timepoints allows for better estimates of total procedure time and total anesthesia time.

11. Post-Treatment Imaging and Reports

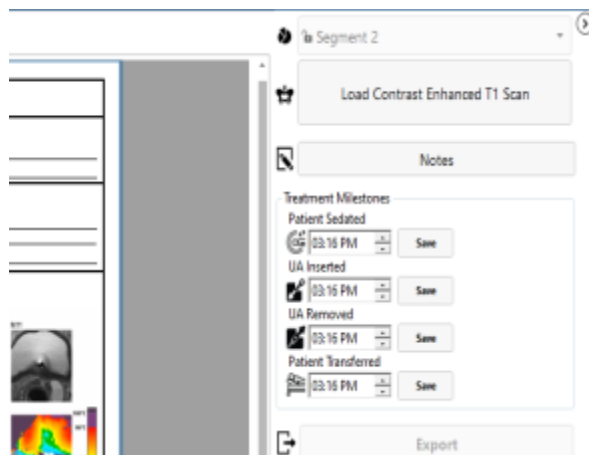


Figure 58: Treatment Milestones panel in Reports workspace

11.c Treatment Reports

When the Treatment Delivery Console (TDC) enters the *Reports* workspace, users see a brief summary of the treatment session (Figure 59). At the same time, the TDC starts to generate videos of the treatment, which might take several minutes.

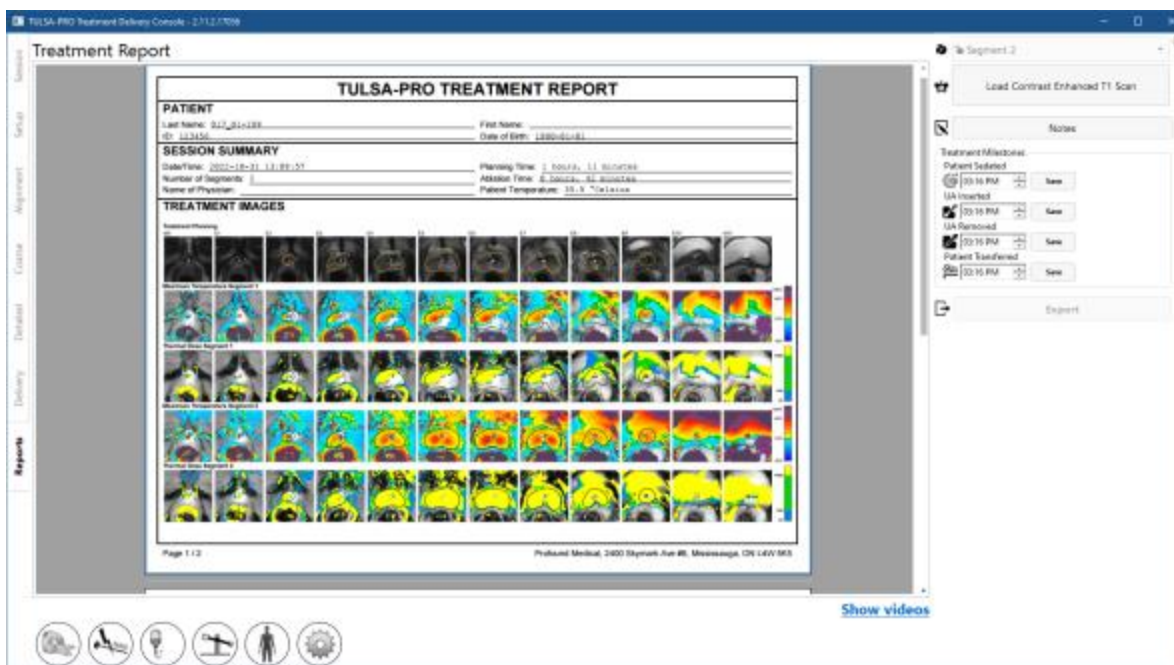


Figure 59: TDC Reports tab

The **PATIENT** section includes the patient's name, ID, and birthdate.

The **SESSION SUMMARY** gives an overview of the treatment performed, including:

- the session date and time
- the number of treatment segments (which will include any segments on which no treatment was performed)

11. Post-Treatment Imaging and Reports

- the physician's name (if entered for the MRI scans)
- an estimate of the total time spent on the treatment, separated into two timeframes:
 - o **Ablation Time:** An estimate of time spent in treatment delivery, over all the segments.
 - o **Planning Time:** The remainder of the time spent between the beginning of planning (alignment) and ending the treatment
 - o the patient temperature at the start of the last segment treated.

The **TREATMENT IMAGES** section shows the AX T2 scan for each slice, as used for planning, followed by the maximum temperature observed in each treatment segment and the estimated thermal dose. If there was more than one treatment segment, there will be one series of maximum temperature images and thermal dose images for each segment.

The report also shows any **NOTES** made throughout the entire session.

From the **Reports** tab, you can import post-treatment, contrast-enhanced images to include in the report.



NOTE: The TDC can only import axial images and only within 12 hours after treatment.

MRI Technologist: To import images, follow the same instructions as Section *Pushing planning images from the MRI to TDC*.

In the *Reports* workspace, you can review images by selecting the tab for any step of the treatment, including *Session*, *Setup*, *Alignment*, *Coarse Planning*, *Detailed Planning*, and *Delivery*. If you change the treatment notes on any tab, the treatment report will be updated with your changes.

You can also view the *Reports* workspace when reviewing old treatment sessions. The TDC software can generate a treatment report for sessions performed with previous versions of the software; however, some fields might not be shown for old sessions if the data was not saved.

11.c.i Viewing treatment videos

When TDC has finished generating the treatment videos, the [Show videos](#) link will be available at the bottom of the *Reports* workspace. Click [Show videos](#) and the report region of the display will show the treatment videos (*Figure 60*).

11. Post-Treatment Imaging and Reports



Figure 60: Treatment video displayed in Reports workspace

You can play (▶) the video for the treatment segment (or if the session had multiple segments, use the segment selector (Figure 60) to choose an individual segment) and choose to see the anatomy with an overlay of the current temperature, maximum temperature, or thermal dose. Each video also shows the prostate boundary, the direction of the beam at each moment, and the intensity of heating.

11.c.ii Exporting reports and videos

You can also save the treatment report and videos to the computer hard drive or any storage medium. Attach the appropriate storage device and click **Export**. The system displays a window where you can choose a location to store the files and whether to export a PDF file of the report and videos with overlays (Thermal Dose, Maximum Temperature, Current Temperature, or Anatomy) (Figure 61).

As an option, you can exclude the patient's personal data from the PDF report to protect their privacy. To exclude patient data from the export, select **Anonymize patient data**.

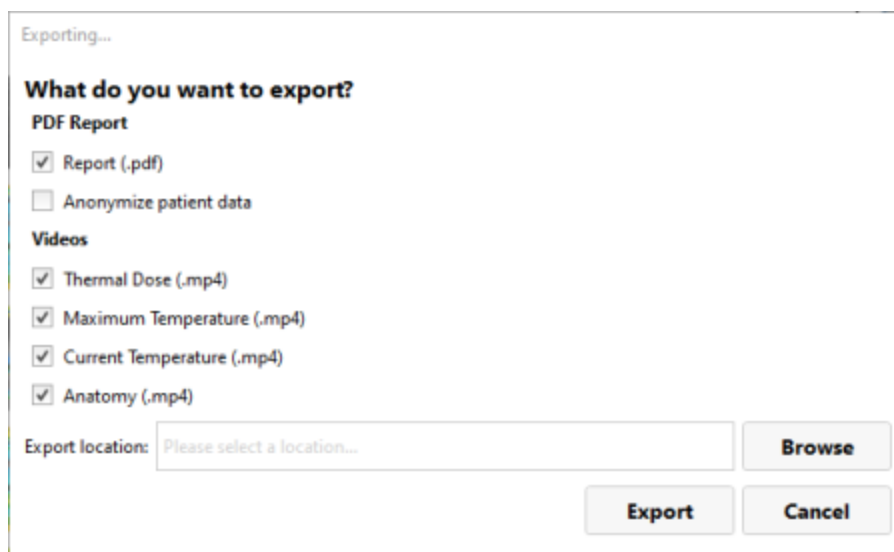


Figure 61: Exporting treatment session reports and videos

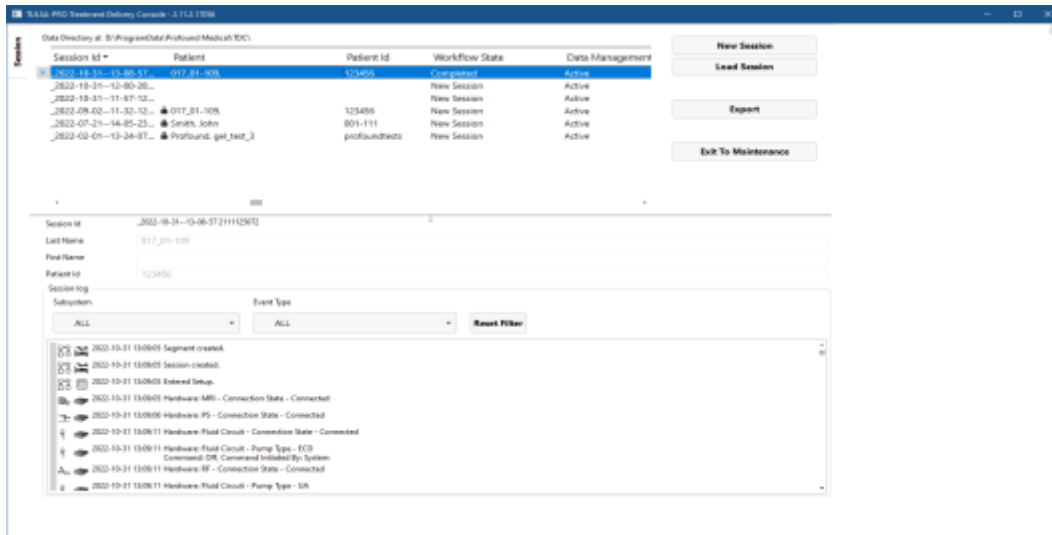
11.d Post-treatment Session Export

MRI Technologist: From the Treatment Delivery Console (TDC), you can export a patient’s session data in order to:

- send session data to Profound Medical for help with troubleshooting problems
- back up the session information for future retrieval and use.

To export a patient session:

1. On the TDC **Session** screen, click **Export**.



The **Export Wizard** screen opens.

2. On the **Export Wizard**, complete the **Session Export Options**:

The screenshot shows the 'Export Wizard' screen with the 'Session Export Options' section. It contains the following options:

- Split session ZIP file into chunks:
- Include all treatment therm images:
- Anonymize patient data:
- Patient alias (first name):
- Patient alias (last name):
- Export location:

At the bottom of the form are two buttons: 'Export' and 'Cancel'.

- i. You can export the session software logs and related data. In addition, you can export the temperature map images during treatment. To include images in the export, select **Include all treatment therm images**.

NOTE: If you do not select **Include all treatment therm images**, only the last image will be exported.

11. Post-Treatment Imaging and Reports

- ii. As an option, you can *anonymize*, or remove, the patient's personal data to protect his privacy. To exclude patient data from the export, select **Anonymize patient data**.
- iii. If you choose to anonymize patient data, you must enter:
 - **Session alias**, or reference name
 - **Patient alias (first name)**
 - **Patient alias (last name)**
- iv. Enter an **Export location** on your computer hard drive where you want to store the session data. Click **Browse** to find a folder where you want to store the session.
- v. Click **Export**.

12. Device Removal and Patient Recovery

After treatment and all post-treatment imaging is complete, the MRI technologist leads equipment dismantling, the Urologist removes the UA and ECD and examines the patient, and the Anesthesiologist recovers the patient.

12.a Device Removal

1. MRI Technologist: Switch off the System Electronics.
2. MRI Technologist: Move the MRI table out of the magnet bore.
3. MRI Technologist: Disconnect the UA cable.
4. MRI Technologist: Close the line clamps on the UA and ECD tube sets near the UA and ECD.
5. MRI Technologist: Withdraw saline from the ECD balloon using a syringe.
6. MRI Technologist: Disconnect the fluid tube sets from the UA and ECD, taking care as some water might leak. Prevent further leaks on the UA, ECD, and tube sets by connecting their respective male and female fittings together.
7. MRI Technologist: Prepare a biohazard bag for disposing the UA and ECD as described in *Device Removal and Patient Recovery*.
8. MRI Technologist: Without moving the patient, release the UA Clamp to detach the UA from the PS.
9. Urologist: Wearing sterile gloves, hold on to the UA handle while the MRI technologist moves the PS.
10. MRI Technologist: Unlock and lower the PS, then slide the PS back, away from the UA. Disconnect the PS, remove the PS and PSIB from the base plate, and place them on the work surface in the MRI magnet room.
11. Urologist: Remove the UA and ECD from the patient and place in the biohazard bag.
12. MRI Technologist: Detach and remove the anterior imaging coil and any straps placed around the patient.

12.b Patient Recovery

1. MRI Technologist: With help from the clinical team, transfer the patient from the MRI table to an MRI-compatible gurney or undock and use the transportable MRI table (site-specific).
2. Urologist: Examine the patient for any signs of positioning-related injury.
3. Urologist: If a supra-pubic catheter was used, it should be kept in place after treatment for a period of 1 to 4 weeks. If no supra-pubic catheter was used, insert a Foley catheter using sterile technique, to be kept in place for several days. Catheters (suprapubic or urethral) should only be removed after a successful voiding trial at the discretion of the prescribing physician.
4. Anesthesiologist: Transfer the patient to the patient preparation area and follow patient recovery procedures according to anesthesia standard of care.

12.c Equipment dismantling

1. MRI Technologist: Remove the base plate and patient pad.
2. If desired, copy or back up the MR images from the MRI console computer.
3. Terminate the MRI exam (close patient).
4. Turn off all the TULSA-PRO® equipment: shut down the TDC computer.
5. Pass tube sets back through the waveguide into the equipment room or control room.
6. Remove the tube sets from the System Cart and dispose as described in *Disposables*.
7. Coil up any disconnected cables, remove all TULSA-PRO® equipment from the MRI magnet room, and move the System Cart to its storage location. The Filter Box can be left in place, attached to the penetration panel. If for any reason the Filter Box needs to be removed, cover the opening in the penetration panel with the provided cover plate.
8. Wipe down the MR bed and clean TULSA-PRO equipment following the instructions in *Reusable Equipment Cleaning & Disinfection* and then store them in the designated storage case.

13. Cleaning and Disposal

13.a Disposables

The Ultrasound Applicator (UA) and Endorectal Cooling Device (ECD) will touch the patient during treatment and will be contaminated with body fluids.

13.a.i Ultrasound Applicator (UA)

- Wear gloves when handling a used UA to avoid contamination with body fluids.
- The UA is intended for single use only. Do not attempt to re-use the UA.
- Dispose in biohazard garbage.

13.a.ii Endorectal Cooling Device (ECD)

- Wear gloves when handling a used ECD to avoid contamination with body fluids.
- The ECD is intended for single use only. Do not attempt to re-use the ECD.
- Dispose in biohazard garbage.

13.a.iii Fluid Tubing

Fluid circuit tubing is designed for single use. Dispose of tubing in regular garbage. If any section of tubing is visibly soiled with body fluids, dispose in biohazard garbage.

13.b Reusable Equipment Cleaning & Disinfection

13.b.i General Cleaning and Disinfection

Reusable equipment should be cleaned thoroughly before the first use and after each patient treatment. Disinfect devices that come into contact with bodily fluids or that touch the patient's skin. After cleaning and/or disinfecting using the instructions in this section, visually inspect for cleanliness and repeat as required.

Other medical devices that are used along with TULSA-PRO should be cleaned based on manufacturer instructions.

The following equipment might contact intact skin and should be cleaned and disinfected after each patient use:

- Base Plate and Patient Pad
- Leg supports
- Straps

13. Cleaning and Disposal



NOTE: Dispose of straps if soiling occurs. Contact Profound Service for replacements.

The following equipment is not intended to contact intact skin and should be cleaned and disinfected after each patient use:

- Positioning System (PS)
- Positioning System Interface Box (PSIB)
- UA cable and PS cable

The following equipment will not become contaminated during use as they are located in an alternate room. Therefore, they do not need to be disinfected. However, wipe them down until visually clean to prevent dust and other debris from accumulating:

- System Cart and System Electronics
- other system cables
- TDC computer

13.b.ii General Cleaning Reagents, Methods, and Tools

Cleaning Reagents

TULSA-PRO components that are intended for reprocessing, excluding the computer, are compatible with only Cavicide wipes or solutions as cleaning and disinfection reagents. Profound Medical has not evaluated the use of other cleaning or disinfection reagents; avoid using them.



Do not use hydrogen peroxide based cleaners for cleaning, because they will corrode copper, zinc, and brass, which are present on the equipment.

Cleaning Tools and Methods

- Perform all cleaning using pre-wet wipes and/or a soft-bristled brush.
- Cavicide solution in a spray bottle is recommended for cleaning some components.
- Prepare all cleaning and disinfection agents according to manufacturer guidelines for water conditions and concentrations.
- Discard and replace straps, pads, and other components that become soiled and cannot be cleaned. Contact Profound Service to order replacement straps or pads.

Pre-cleaning Preparation

1. Ensure you put on all personal protective equipment recommended by the manufacturer of the cleaner.
2. Ensure there is a stable surface to work on and a separate clean area is available to place cleaned modules.
3. Ensure system is powered OFF.

13. Cleaning and Disposal

4. Immediately after use, wipe any visible soil or contaminants from the surfaces of these components using a damp cloth or cleaning wipe to prevent drying of contaminants.

If you must transport soiled components to a designated cleaning area, ensure individual closed containers are available to limit cross contamination.



Always wear gloves and other applicable personal protective equipment when cleaning the device and handling cleaning chemicals.



Do not use abrasive tools. Do not spray the cleaning reagents on the system components, modules, accessories, or peripherals unless directed.



No method of automated cleaning or disinfecting has been validated for the TULSA-PRO System. None of the reusable modules are sterilizable or autoclavable.



Power off and unplug the system before reprocessing. Ensure connectors and cable ends do not become wet. Allow all components to fully dry before re-powering.



Do not fully immerse any components in cleaning fluid unless directed.

13.b.iii Performing Manual Cleaning and Disinfection

This section covers the cleaning methods for:

- PSIB
- UA cable
- PS cable
- Patient pad
- Leg supports
- Straps

The methods for cleaning the Positioning System and base plate are described in " Positioning System – Cleaning and Disinfection Instructions" on page 83 and " Base Plate – Cleaning and Disinfection Instructions" on page 84, respectively.

Steps:

1. Wipe the surfaces of each device using a disinfecting wipe to remove visible soil.
2. Wipe around cables, edges, cracks, crevices, corners, hard-to-reach areas.
3. Repeat steps 1 and 2 as necessary until all surfaces and hard-to-reach areas are visibly clean.

13. Cleaning and Disposal

4. Use a fresh disinfecting wipe to thoroughly wet all external surfaces of the device, ensuring all surface areas have been in contact with the wipe, and allow them to remain visibly wet for the manufacturer-specified contact time.
5. Complete a rinse set by wiping all surfaces with a lint-free cloth dampened with distilled water to remove cleaner residue.
6. Wipe the area with a dry, lint-free cloth. Ensure that the area is dry to the touch.
7. Allow devices to air dry before storing in designated storage cases.

13.b.iv Positioning System – Cleaning and Disinfection Instructions

Clean and disinfect all outer surfaces of the positioning system (PS) following the instructions in "Performing Manual Cleaning and Disinfection" on page 82. Move the PS through all its ranges of motion to ensure all surfaces are reached. Disassemble the PS by following these steps:

1. Remove the PS from its notched base plate by partially unscrewing the thumbscrew located on the rear of the PS base and depressing the horizontal adjustment lever through the Z channel at the rear of the PS base (*Figure 62*).

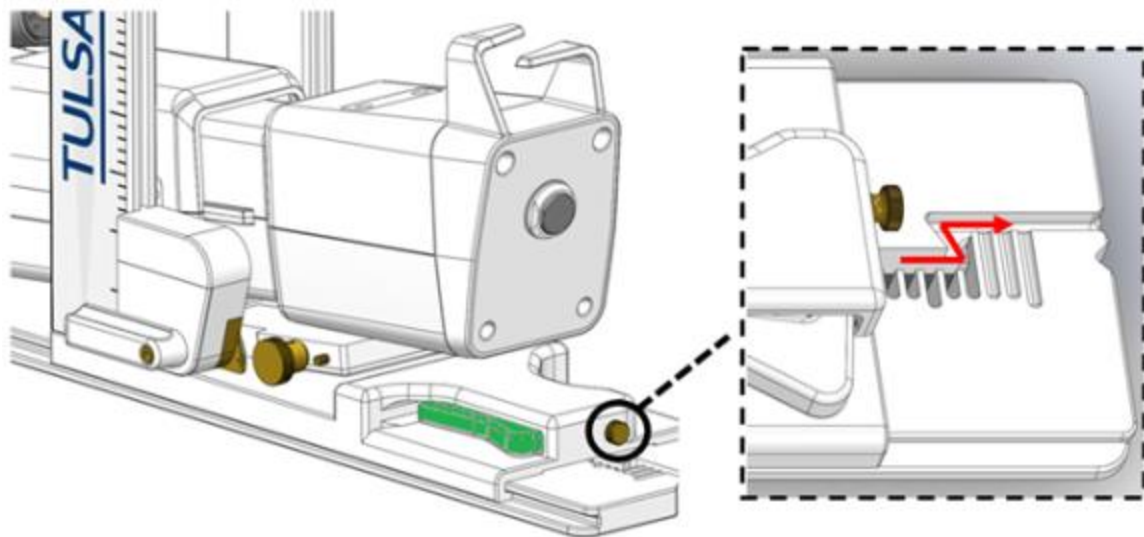


Figure 62: Removing PS from base plate

2. Detach the PS Nose by depressing the brass buttons.
3. If you see soiling in either the PS Base or PS Nose area, perform these steps:
 - a. Using a spray disinfectant, saturate the entire gripper area, focusing on the gear area or anywhere with visible soiling. Allow to remain wet for, at minimum, the manufacturer's specified contact time.
 - Ensure all edges, cracks, crevices, corners, and hard-to-reach areas are wetted with the spray disinfectant.
 - b. Use a wipe to loosen and brush away gross soil, then wipe all surfaces of gripper again using a fresh wipe.
 - c. Repeat steps 1 and 2 as necessary until no visible soiling remains, closely inspecting the areas around the gripper and gear (*Figure 63*).

13. Cleaning and Disposal

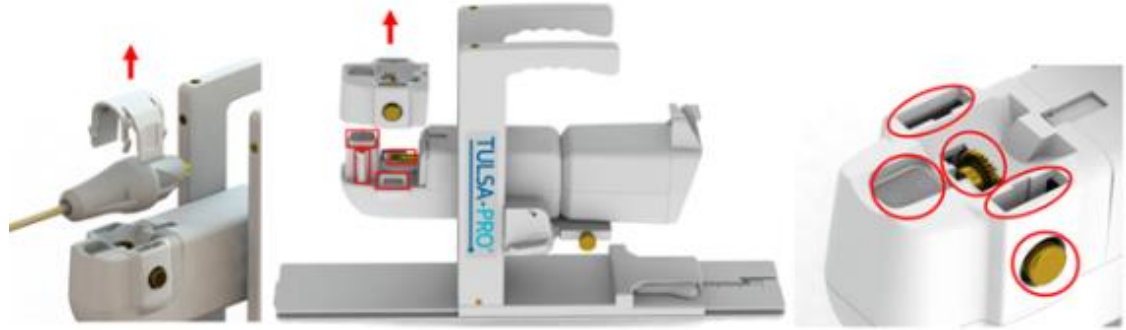


Figure 63: Inspecting the Positioning System

4. Once visually clean, use a fresh, disinfecting wipe to thoroughly wet all external surfaces, ensuring all surface areas have been in contact with the wipe, and allow to remain visibly wet for the manufacturers specified contact time.
 - If necessary, use a pointed swab to access hard to each areas.
5. Complete a rinse step by wiping all surfaces with a lint-free cloth, dampened with distilled water, and remove cleaner residue. Alternatively, rinse the UA mount by holding it above a basin and pouring water directly over the device and into the basin.
 - For any parts of the PS that might have contacted the patient's skin, repeat the rinse step a second time.
6. Allow the device to air dry. Ensure that the area is dry to the touch before re-attaching the PS nose component and subsequently storing or using the device in a procedure.
7. If soiling cannot be removed through this cleaning procedure, contact Profound Service.

13.b.v Base Plate – Cleaning and Disinfection Instructions

Clean and disinfect the easily accessible surfaces of the Base Plate following the instructions in "Performing Manual Cleaning and Disinfection" on page 82. For any grooves, recesses, or hard to reach areas, such as the leg support rails, latch, or handles, follow these steps:

1. Using a spray disinfectant, saturate any recesses, grooves, or areas that contain soiling. Focus on areas like the leg support rails, strap attachment points, the PS latch, and any edges or grooves. Allow to remain wet for the minimum manufacturer specified contact time.
2. Wipe inside the recesses and grooves that were sprayed with a disinfecting wipe to remove gross soil and absorb disinfectant.
 - If necessary, use a pointed swab to access hard to reach areas.
3. Repeat steps 1 and 2 as necessary until no visible soiling remains, closely inspecting all hard-to-reach areas. Use a soft bristle brush to loosen or brush away remaining soil.
4. Once visually clean, perform a final wipe of all surfaces, recesses, and grooves of the base plate ensuring surfaces remain visibly wet for the manufacturer's recommended contact time.
5. Complete a rinse step by wiping all surfaces with a lint-free cloth, dampened with distilled water, and remove cleaner residue.

13. Cleaning and Disposal

- For any parts of the Base Plate that might have contacted the patient's skin, repeat the rinse step a second time.
6. Allow the device to air dry before storage or subsequent use in a procedure.

14. Software Alarms

14.a Alarm Indicators







An area at the bottom-left of the Treatment Delivery Console (TDC) screen shows alarm indicators when a session is in progress (*Figure 64*).



Figure 64: Alarm indicators (all indicators are clear)

The following table lists and describes the alarm indicators:

Table 1: Alarm indicators

INDICATOR	ALARM AND INFORMATION RELATED TO...	ALARM CLASSIFICATION
	...communications with and functionality of the connected MRI system, or to show there is no MRI connected.	Technical
	...the Radio Frequency circuit.	Technical
	...Fluid Circuits.	Technical
	...the Positioning System (PS).	Technical
	...the state of the MRI field of view relating to observed and predicted temperatures in the patient's treated region.	Physiological
	...the state of the Treatment Delivery Console (TDC) computer.	Technical

14.b Description of Alarm Conditions

Though the TDC software has five indicators associated with distinct hardware components and a single indicator associated with physiological parameters of the patient under treatment, each indicator can have multiple conditions classified as *information* or *warning*.

An **information condition** happens when the corresponding subsystem detects a minor deviation from normal functionality. Information conditions do not affect normal setup, planning, or treatment workflow of TDC; they only draw attention to a potential problem.

A **warning condition** happens when there is a major deviation in a hardware or physiological parameter, which requires quick intervention. Depending on the condition and current system workflow state, a warning condition can affect normal TDC workflow.

Each information and warning condition has an error code, which is shown at the end of the error message displayed on the TDC. The *Appendix, Software Alarms*, provides detailed specifications of warning conditions, their delays, effects on TDC workflow, and troubleshooting tips. The TDC warning messages show the error code with a hyperlink; click on the link to open the related troubleshooting section in the Appendix.

If there is no information or warning condition associated with a subsystem, the corresponding subsystem alarm indicator stays clear (*Figure 64*).

If a subsystem detects an **information** condition, the background color of the corresponding indicator changes to **light blue** and an additional icon (i) is shown at the top-right of the indicator (*Figure 65*).

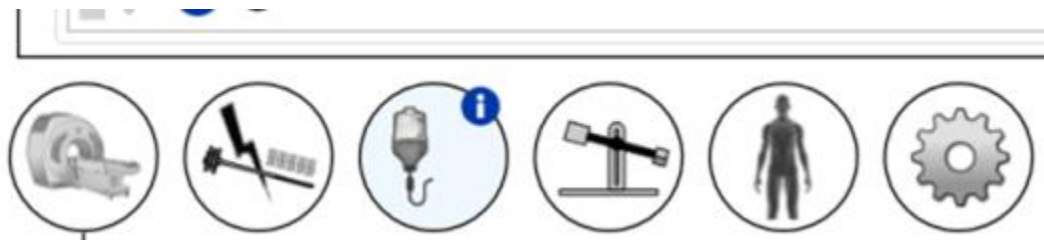


Figure 65: Example of Information condition

When a subsystem detects a **warning** level condition, the background color of the corresponding indicator changes to **orange** and an additional icon (!) is shown at the top-right of the indicator (*Example of Warning condition*).

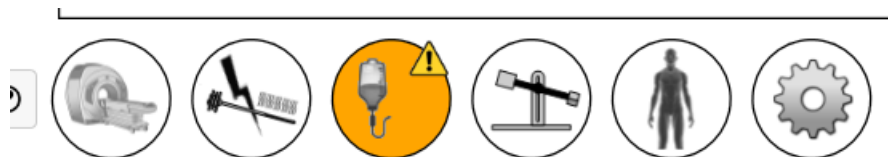


Figure 66: Example of Warning condition

Both Information and Warning level conditions detected by TDC are *Non-Latching*, which means the condition indicator will clear once the corresponding problem is fixed. However, the condition indicator will show its message for 10 seconds, even if the problem is fixed during that time. For example, if the system detects abnormally high pressure in a fluid circuit caused by a physical flow obstruction, the

system shows the corresponding fluid circuit alarm. As soon as you remove the obstruction and the system detects pressure normalization, the alarm indicator returns to a normal, or clear, state.



NOTE: Though operators do not need to interact with the TDC software to clear the alarm and corresponding condition, you might need to return the TDC system to normal workflow. If the scenario discussed above happened during Treatment Delivery, the system would stop Ultrasound Applicator (UA) rotation and heat. After clearing the flow obstruction, the alarm will clear, but heat and rotation **will not start** until you click **Resume Heating** on TDC.

In addition to a change in the background color of an alarm indicator, a pop-up message containing details shows beside the indicator (*Example of message with Alarm condition details*). The message stays on the screen for 10 seconds. To see the pop-up message again, hover the cursor over the alarm indicator.

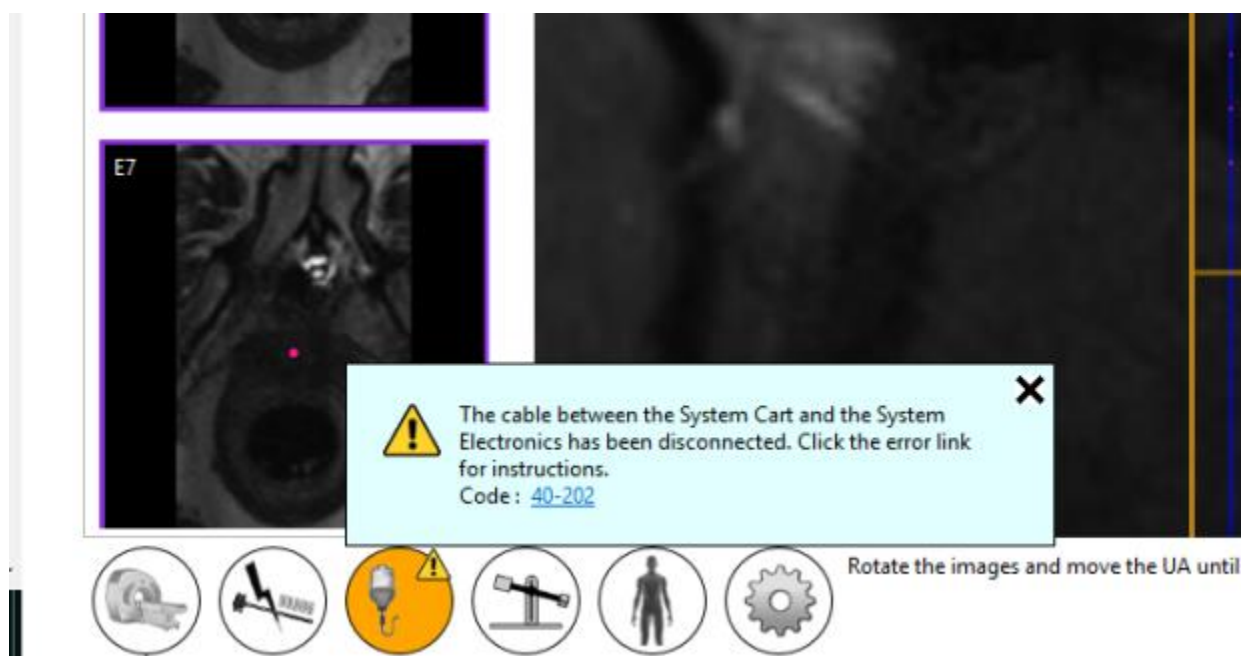


Figure 67: Example of message with Alarm condition details



14.c Multiple Alarm Conditions

A subsystem might detect multiple information-level and warning-level conditions. The following table describes the behaviour of the subsystem alarm indicator depending on condition levels.

Table 2: Example of multiple subsystem conditions

SUBSYSTEM CONNECTED	AT LEAST ONE WARNING-LEVEL CONDITION PRESENT	AT LEAST ONE INFORMATION-LEVEL CONDITION PRESENT	BACKGROUND OF THE INDICATOR	STATUS ICON
Yes	No	No	Default system	No icon
Yes	No	Yes	Light Blue	

14. Software Alarms

Yes	Yes	No	Orange	
Yes	Yes	Yes	Orange	

The corresponding subsystem pop-up message will contain all condition messages (*Multiple condition messages in the pop-up message*).

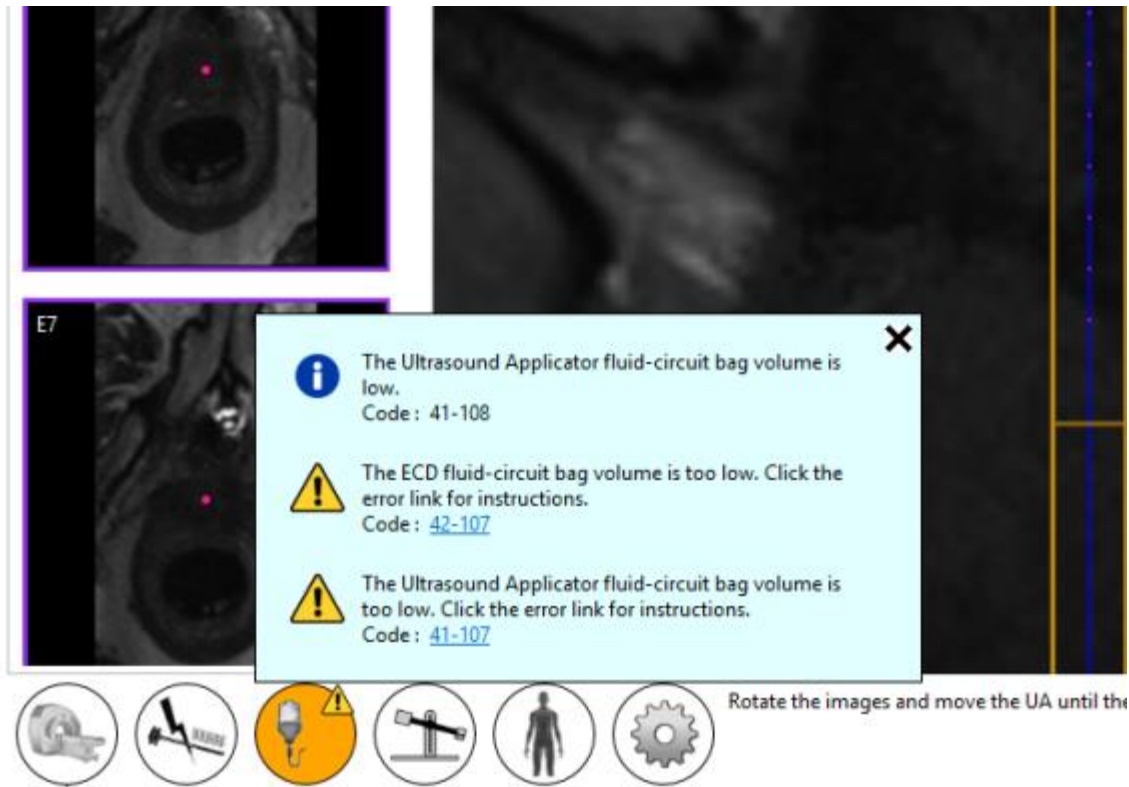


Figure 68: Multiple condition messages in the pop-up message

14.d Alarm Condition Log

Each warning or information condition detected in a session is registered in the session's Audit Log and can be reviewed any time during the session by switching to the *Session* workspace. You can see the conditions of each remote hardware subsystem (MRI, RF, FC and PS) individually by switching to the *Setup* workspace at any time during the session. The conditions will be shown in the corresponding subsystem log.



NOTE: The host-system hard drive creates an audit log immediately after any warning or information condition is detected for any subsystem.

Appendix A. TULSA-PRO® MRI Troubleshooting Tips

Patient motion concerns

The MR Thermometry of the prostate is adversely affected by any motion. Here are the motions of concern and how to address them:

MOTION CONCERN	TO ADDRESS THIS CONCERN...
Respiratory	Tightly strap the coils down.
Pulsation of vessels or arteries	Reposition the patient to change the angle or location of the vessel or artery.
Bladder filling	Install a supra-pubic catheter into the patient before treatment.
Fecal build-up	Ensure the patient follows a pre-treatment bowel preparation.
Peristalsis	Administer anti-spasmodic drugs to the patient.
Passing of gas	

Thermometry and temperature uncertainty

To adequately display temperature changes in the prostate, the tissue must be non-moving and show a low fat-to-water ratio. Also, the signal-to-noise ratio must be high enough in the regions of interest or the temperature in the MR thermometry images could be assessed incorrectly. Use the MR thermometry temperature-uncertainty map during treatment planning to assist in selecting regions of sufficiently high signal.

1. Fat protons do not contribute to changing the MR thermal signal. Therefore, the MR thermometry sequence uses a fat saturation technique, which is specified in the MR protocol. Consequently, TULSA-PRO® cannot measure the temperature in regions outside of the prostate that are made up of mostly fatty tissue.
2. Incorrect temperature measurements can be caused by an absence of MR thermometry signal, image distortions due to magnetic field variations, or other artifacts. The TDC software monitors the temperature during Treatment Planning and during Treatment. If temperature uncertainty measurements are outside the acceptable range during the validation of target boundaries, an error will show when you define the target boundary during Planning or when you change the target boundary during Treatment.
3. Temperatures within an MR thermometry voxel (in-plane resolution and slice thickness) are averaged. The MR thermometry spatial resolution is carefully selected to ensure accurate

temperature measurements. The MRI Protocol specifies a resolution of 2x2mm² in-plane and a slice thickness of 4mm.

4. Temperature changes are integrated over the MR thermometry image acquisition time. To ensure accurate temperature measurements, the MR Protocol specifies the image acquisition time, which can range from 5 to 6.5 seconds.
5. Ultrasound heating in the presence of large cysts and calcifications has not been validated using the TULSA-PRO®. Do not treat patients with the TULSA-PRO® System if they have cysts or calcifications within the target prostate tissue volume that are larger than 1 cm. You can treat prostates with smaller cysts or calcifications if these structures are in the interior of the gland and not at the periphery where temperature feedback measurements are calculated. Be careful and vigilant when treating tissue near these abnormalities.

Access to User Documentation from TDC

On any TDC screen and during any step—except during Treatment Delivery—you can press F1 on your keyboard to open and review the *TULSA-PRO® Operator's Manual*. Click **X** in the top corner to close the document window.

Appendix B. Troubleshooting Guide

Alarm Signals

This section explains how to resolve issues that can interfere with or stop a patient's treatment.

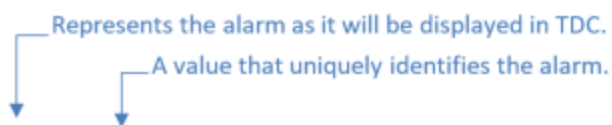


It is important that all users review this section to ensure that patients are not injured accidentally during a troubleshooting process.

Here is what typically occur when the Treatment Delivery Console (TDC) detects a problem:

1. A **condition** is detected that warrants an alarm being raised.
2. The **alarm message** shows on the TDC display.
3. The **TULSA-PRO® System responds** by taking the appropriate action.
4. User **addresses the cause** to resolve the issue.
5. User takes any **additional steps** to resume normal operation.

When an alarm shows on the TDC display, look for the appropriate table in this section to identify how to resolve the problem.



Alarm [00-000]

Condition	Describes why the alarm has been raised.
Error Code	The TDC-generated software-code associated with the condition. This code is used by Profound Medical authorized service representatives in addressing complex issues
Delay	Represents the period of time from when the issue began, to when the alarm was raised.
System Response	Describes the actions that are automatically taken by TDC when the alarm is raised. During treatment, TDC will typically: <ul style="list-style-type: none"> ▪ Pause Treatment – all heating and motion will stop, or ▪ Interrupt Treatment – all heating and motion is stopped, and subsequent thermometry dynamics are ignored.
Address the Cause	Describes the steps required to clear the alarm. When troubleshooting, it is recommended that you try the recommendations in the order they are presented. For example: <ol style="list-style-type: none"> 1. Try this action first. If this does not clear the alarm, then... 2. Try this action.

Steps After Addressing the Cause	Describes any additional steps to continue normal TULSA-PRO® operation.
----------------------------------	---

After resolving the issue, you might need to proceed through the TDC workflow to *Delivery* to start a new treatment segment.

If you can resolve the issue without leaving the *Delivery* workspace, then you need to decide how to proceed:

- **If Treatment is Paused:**
 - i. *Resume Heating* treatment with the current segment.
 - ii. *End Thermometry and Re-plan* the treatment by creating a new segment.
 - iii. *Complete Treatment and View Report* for the current session.
- **If Treatment is Interrupted:**
 - *Resume Heating* treatment with the current segment.
 - *Complete Treatment and View Report* for the current session.

For additional help, contact a Profound Medical authorized service representative as directed in the 'Service and Maintenance' section of the *TULSA-PRO® Instructions For Use*.

Fluid Cart

40-201: TDC lost a network connection to the System Cart

Condition	The System Cart has lost network connection to the TDC computer.	
Error Code	40-201	
Delay	Immediate	
System Response	<p>Setup: UA & ECD purging will be cancelled. RF test cannot be performed.</p> <p>Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>	
Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> Ensure the thermometry sequence is running on the MRI, and that enough dynamics have been selected for the thermometry scan you are trying to run. <ul style="list-style-type: none"> GE: 26 dynamics for Detailed, 1500 dynamics minimum for Delivery Ensure the MRI and TDC Computer are still able to communicate through their network connection by checking the status of the MRI subsystem in <i>Setup</i> workspace. Ensure that the appropriate TULSA-PRO® sequence and parameters is being used for thermometry acquisition. 	
Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received.
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> Click Start on the TDC. Re-enter the patient's core temperature. Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received.
	DELIVERY - ABLATION	<ol style="list-style-type: none"> Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment. Stop the MRI Thermometry Sequence on the MRI Console. Click Start on the TDC. Re-enter the patient's core temperature.

5. Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received.

40-202: The cable between the System Cart and the System Electronics has been disconnected

Condition	The cable connecting the System Cart (SC) to the System Electronics (SE) is not connected.	
Error Code	40-202	
Delay	Immediate	
System Response	<p>Setup: UA and ECD purging will be cancelled. RF test cannot be performed.</p> <p>Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>	
Address the cause	<p>At any stage:</p> <ol style="list-style-type: none"> 1. Ensure the cable is connected between the System Cart to the System Electronics. 2. If the alarm still does not clear, unplug the cable from the System Electronics and the System Cart. Re-attach, and wait one minute. Verify if alarm disappears. 	
Steps After Addressing the Cause	SETUP	<ol style="list-style-type: none"> 1. Address the cause of the alarm so that the message disappears. 2. Perform another UA and ECD purge after the alarm has been resolved.
	ALIGNMENT	Address the cause of the alarm so that the message disappears. Proceed through the normal workflow.
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Stop the MRI Thermometry Sequence on the MRI Console. 2. Address the cause of the alarm so that the message disappears. 3. Click Start on the TDC. 4. Re-enter the patient's core temperature. 5. Relaunch the MRI Thermometry Sequence on the MRI Console.
DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment. 2. Stop the MRI Thermometry Sequence on the MRI Console. 	

3. Address the cause of the alarm so that the message disappears.
4. Click **Start** on the TDC.
5. Re-enter the patient's core temperature.
6. Relaunch the MRI Thermometry Sequence on the MRI Console.

40-206: The room temperature for the System Cart is too high

Condition	The System Cart temperature is greater than or equal to 37°C	
Error Code	40-206	
Delay	Immediate	
System Response	<p>Setup, Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>	
Address the Cause	<p>Reduce the temperature of the room where the System Cart is located. For example:</p> <ol style="list-style-type: none"> 1. Ensure the air conditioning in the room where the System Cart is located is turned on. 2. Ensure there is air ventilation near the System Cart. 	
Steps After Addressing the Cause	SETUP	Address the cause of the alarm so that the message disappears. Although the alarm will not prevent you from moving to the next phase of treatment, you will be prevented from performing an ablation.
	ALIGNMENT	
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Stop the MRI Thermometry Sequence on the MRI Console. 2. Address the cause of the alarm so that the message disappears. 3. Click Start on the TDC. 4. Re-enter the patient's core temperature. 5. Relaunch the MRI Thermometry Sequence on the MRI Console.
DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment. 2. Stop the MRI Thermometry Sequence on the MRI Console. 3. Address the cause of the alarm so that the message disappears. 4. Click Start on the TDC. 5. Re-enter the patient's core temperature. 6. Relaunch the MRI Thermometry Sequence on the MRI Console. 	

41-107: The Ultrasound Applicator fluid-circuit bag volume is too low

Condition	The volume in the Ultrasound Applicator (UA) circuit is less than or equal to 400 mL.
Error Code	41-107
Delay	Immediate
System Response	<p>Setup: UA purging will be cancelled. RF test cannot be performed.</p> <p>Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>
Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> 1. Visually inspect the UA tubing, and all Luer Lock connections for leaks between the fluid reservoir, the pump, and the UA. 2. Ensure the UA's fluid reservoir contains a minimum of 500mL of fluid. <ul style="list-style-type: none"> • If necessary, add fluid to the reservoir.

NOTE: This may require a new 1L Sterile Water Bag to be opened.

Steps After Addressing the Cause	SETUP	<ol style="list-style-type: none"> 1. Address the cause of the alarm so that the message disappears. 2. Perform another UA purge. 3. After purging, perform an RF Test.
	ALIGNMENT	Address the cause of the alarm so that the message disappears. Proceed through the normal workflow.
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Stop the MRI Thermometry Sequence on the MRI Console. 2. Address the cause of the alarm so that the message disappears. 3. Click Start on the TDC. 4. Re-enter the patient's core temperature. 5. Relaunch the MRI Thermometry Sequence on the MRI Console.
DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment. 2. Stop the MRI Thermometry Sequence on the MRI Console. 3. Address the cause of the alarm so that the message disappears. 	

4. Click **Start** on the TDC.
5. Re-enter the patient's core temperature.
6. Relaunch the MRI Thermometry Sequence on the MRI Console.

41-109: The Ultrasound Applicator fluid-circuit pump pressure is too low

- Condition
- During Ultrasound Applicator (UA) Purging: The UA pressure is less than or equal to 3 psi after the purging cycle is completed.
 - During normal operation: The UA pressure is less than or equal to 3 psi, with the pumps on for at least 20 seconds.

Error Code	41-109	
Delay	Immediate	
System Response	<p>Setup: UA purging will be cancelled. RF test cannot be performed.</p> <p>Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Initialization stops.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>	
Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> 1. Verify that the UA pressure sensor is connected to the System Cart. 2. Ensure the UA fluid reservoir contains more than 400mL of fluid. This can be checked by looking at the UA Circuit – Volume in the <i>Setup</i> tab of TDC <ul style="list-style-type: none"> • If necessary, add fluid to the reservoir (should be filled to minimum of 500ml). NOTE: <i>This may require a new 1L Sterile Water Bag to be opened.</i> 3. Visually inspect the UA tubing, and all Luer Lock connections for leaks between the fluid reservoir, the pump, and the UA. 4. Check the connection of the UA pressure sensor on the Fluid Cart is properly seated. Remove the UA pressure sensor from the System Electronics, and re-insert, making sure it is fully seated in the connector slot. 	
Steps After Addressing the Cause	SETUP	<ol style="list-style-type: none"> 1. Address the cause of the alarm so that the message disappears. 2. Perform another UA purge. 3. Afterward the purge, perform an RF Test.
	ALIGNMENT	Not applicable.
	COARSE	
	DETAILED	
DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Stop the MRI Thermometry Sequence on the MRI Console. 2. Address the cause of the alarm so that the message disappears. 3. Click Start on the TDC. 	

	<ol style="list-style-type: none">4. Re-enter the patient's core temperature.5. Relaunch the MRI Thermometry Sequence on the MRI Console.
DELIVERY - ABLATION	<ol style="list-style-type: none">1. Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment.2. Stop the MRI Thermometry Sequence on the MRI Console.3. Address the cause of the alarm.4. Click Start on the TDC.5. Re-enter the patient's core temperature.6. Relaunch the MRI Thermometry Sequence on the MRI Console.

41-110: The Ultrasound Applicator fluid-circuit pump pressure is too high

- Condition
- During Setup (purging): The Ultrasound Applicator (UA) pressure is greater than or equal to 30 psi after the purging cycle is completed.
 - During Delivery (Initialization or Ablation): The UA pressure is greater than or equal to 30 psi, with the pumps on for at least 20 seconds.

Error Code 41-110

Delay Immediate

System Response

Setup (purging): UA purging will be cancelled. RF test cannot be performed.

Alignment, Coarse, Detailed: No system response.

Delivery - Initialization: Ablation will not start.

Delivery - Ablation: Ablation will be paused.

- Address the Cause
- At any stage:
1. Visually inspect the UA tubing for obstructions between the fluid reservoir, the pump, and the UA. For example:
 - Ensure all fluid line clamps near the UA are open.
 - Ensure the tubing is loaded correctly, and not kinked, in the UA pump roller head.
 - Ensure that the UA tubing is not caught beneath a fluid-cart wheel or any other equipment in the MRI/Technical/Control Rooms.
 2. Consider raising the temperature of the room where the System Cart is located. Although *uncommon*, it is possible for this alarm to occur if the room temperature where the System Cart is located is cold.

Steps After Addressing the Cause	SETUP	If the UA purge has not been completed, perform another UA purge. If the purge has been completed, but the RF test has not yet been completed, initiate the RF test.
	ALIGNMENT	
	COARSE	Not applicable.
	DETAILED	
	DELIVERY - INITIALIZATION	Click Resume Heating on the TDC to resume treatment.
	DELIVERY - ABLATION	

42-107: The ECD fluid-circuit bag volume is too low

Condition	The volume in the ECD circuit is less than or equal to 400 mL.
Error Code	42-107
Delay	Immediate
System Response	<p>Setup: ECD purging will be cancelled. RF test cannot be performed.</p> <p>Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>
Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> Inspect the ECD fluid line and all in-line Luer Lock connections for leaks between the fluid reservoir, the pump, and the ECD. Ensure that the ECD fluid reservoir contains a minimum of 500mL of fluid <ul style="list-style-type: none"> If additional fluid is required in the fluid reservoir, ensure a correlated amount of MnCl and Span/Tween is also added to the fluid reservoir. NOTE: This may require a new Span/Tween and MnCl bottle and 1L Sterile Water Bag to be opened.

Steps After Addressing the Cause	SETUP	<ol style="list-style-type: none"> Address the cause of the alarm so that the message disappears. Perform another ECD purge.
	ALIGNMENT	Address the cause of the alarm so that the message disappears. Proceed through the normal workflow.
	COARSE	
	DETAILED	
DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> Stop the MRI Thermometry Sequence on the MRI Console. Address the cause of the alarm so that the message disappears. Click Start on the TDC. Re-enter the patient's core temperature. Relaunch the MRI Thermometry Sequence on the MRI Console. 	
DELIVERY - ABLATION	<ol style="list-style-type: none"> Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment. Stop the MRI Thermometry Sequence on the MRI Console. Address the cause of the alarm so that the message disappears. 	

4. Click **Start** on the TDC.
5. Re-enter the patient's core temperature.
6. Relaunch the MRI Thermometry Sequence on the MRI Console.

42-109: The ECD fluid-circuit pump pressure is too low

- Condition
- During ECD Purging: The ECD pressure is less than or equal to 13 psi after the purging cycle is completed.
 - During normal operation: The ECD pressure is less than or equal to 13 psi, with the pumps on for at least 20 seconds.

Error Code	42-109	
Delay	Immediate	
System Response	<p>Setup: ECD purging will be cancelled.</p> <p>Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>	
Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> 1. Verify the ECD pressure sensor is connected to the System Cart. 2. Visually inspect the ECD fluid line for leaks between the fluid reservoir, the pump, and the ECD. 3. Ensure that the ECD fluid reservoir contains a minimum of 500mL of fluid. If additional fluid is required in the fluid reservoir, ensure a correlated amount of MnCl and Span/Tween is also added to the water at the same time. <i>NOTE: This may require a new Span/Tween and MnCl bottle and 1L Sterile Water Bag to be opened.</i> 3. Check the connection of the ECD pressure sensor on the Fluid Cart. Remove the ECD pressure sensor, and re-insert, making sure it is fully seated in the connector slot. 	
Steps After Addressing the Cause	SETUP	<ol style="list-style-type: none"> 1. Address the cause of the alarm so that the message disappears. 2. Perform another ECD purge after the alarm has been resolved.
	ALIGNMENT	Address the cause of the alarm so that the message disappears. Proceed through the normal workflow.
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Stop the MRI Thermometry Sequence on the MRI Console. 2. Address the cause of the alarm so that the message disappears. 3. Click Start on the TDC. 4. Re-enter the patient’s core temperature. 5. Relaunch the MRI Thermometry Sequence on the MRI Console.

DELIVERY -
ABLATION

1. Click **End Thermometry and Re-plan** on the TDC to create a new Treatment Segment.
2. Stop the MRI Thermometry Sequence on the MRI Console.
3. Address the cause of the alarm so that the message disappears.
4. Click **Start** on the TDC.
5. Re-enter the patient's core temperature.
6. Relaunch the MRI Thermometry Sequence on the MRI Console.

42-110: The ECD fluid-circuit pump pressure is too high

- Condition
- During ECD Purging: The ECD pressure is greater than or equal to 37 psi after the purging cycle is completed.
 - During normal operation: The ECD pressure is greater than or equal to 37 psi, with the pumps on for at least 20 seconds.

Error Code	42-110
Delay	Immediate
System Response	<p>Setup: ECD purging will be cancelled.</p> <p>Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be paused.</p>

- Address the Cause
- At any stage:
1. Visually inspect the ECD tubing for obstructions between the fluid reservoir, the pump, and the ECD. For example:
 - Ensure all fluid line clamps near the ECD are open.
 - Ensure the fluid tubing is loaded correctly, and not kinked, in the ECD pump head.
 - Ensure that the ECD tubing is not caught beneath a fluid cart wheel or any other equipment in the MRI/Technical/Control Rooms
 2. Ensure the ECD fluid and additives are adequately mixed in the ECD reservoir.
 3. Consider raising the temperature of the room where the System Cart is located.

Although uncommon, it is possible for this alarm to be raised if the room temperature where the System Cart is located is cold.

Steps After Addressing the Cause	SETUP	<ol style="list-style-type: none"> 1. Address the cause of the alarm until the message disappears. 2. Perform another ECD purge after the alarm has been resolved.
	ALIGNMENT	Address the cause of the alarm so that the message disappears. Proceed through the normal workflow.
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Click Stop Initialization on the TDC. 2. Stop the MRI Thermometry Sequence on the MRI Console. 3. Address the cause of the alarm so that the message disappears.

	<ol style="list-style-type: none">4. Click Start on the TDC.5. Re-enter the patient's core temperature.6. Relaunch the MRI Thermometry Sequence on the MRI Console.
DELIVERY - ABLATION	<ol style="list-style-type: none">1. Address the cause of the alarm so that the message disappears.2. Click Resume Heating on the TDC to resume treatment.

Magnetic Resonance Imaging

50-201: The IP address or port for the MRI cartridge is wrong or in use

Condition	The IP Address and Port specified by the MRI cartridge is being used by another program.
Error Code	50-201
Delay	Immediate
System Response	At any stage, the TDC will not receive thermometry images from the MRI.
Address the Cause	<p>At any stage:</p> <ul style="list-style-type: none"> • Close the TDC application and reboot the TDC computer. • Ensure that no other MRI client computer is turned on. • Contact your on-site IT support team for assistance: • Ensure no additional programs have been installed on the TDC which are trying to communicate with the MRI Host • Open <i>Maintenance Mode</i> in TDC and ensure the appropriate <i>MRI Configuration</i> values are being used.
Steps After Addressing the Cause	Proceed through the normal workflow.

50-202: TDC lost network connection to the MRI

Condition	The TDC has lost the network connection to the MRI.
Error Code	50-202
Delay	Immediate
System Response	<p>Setup, Alignment, Coarse: User cannot load a SAG T2 image.</p> <p>Detailed: User cannot load AX T2 images. TDC will not be able to receive TUV images.</p> <p>Delivery - Initialization: It will not be possible to start initialization or initialization will stop.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>
Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> 1. Ensure the TDC computer is connected to the appropriate switch via an Ethernet cable. 2. Ping from the TDC Computer to the MRI Host and verify there is a network connection. 3. Unplug the Ethernet cable connecting the TDC to the switch, reconnect, and wait one minute before continuing. 4. If all else fails, reboot the MRI.
Steps After Addressing the Cause	At any stage, proceed through the normal workflow.

50-203: There is a delay in receiving the thermometry image

Condition	The thermometry image is being received slower than normal (longer than typical 5-6 seconds).
Error Code	50-203
Delay	1.3x MR sampling period
System Response	Setup, Alignment, Coarse: No system response. Detailed: TDC will stop processing thermometry images from the MRI Delivery - Initialization: Ablation will not start. Delivery - Ablation: Ablation will be paused.
Address the Cause	At any stage: <ol style="list-style-type: none"> 1. Ensure that the TDC application and the MRI host has access to enough computer resources by terminating all non-essential programs or operations such as antivirus programs, Windows Updates, web browsers, or image querying. 2. <i>For Philips MRI's, ensure both TDC and MRI host are isolated from the main hospital network. To verify, try exporting the planning image to PACS and verify if it fails.</i> 3. Ensure that the appropriate TULSA-PRO® sequence and parameters is being used for thermometry acquisition.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	<ol style="list-style-type: none"> 1. Stop the MRI. 2. Re-launch the Thermometry sequence with the appropriate dynamic number. The alarm will clear when the next thermometry scan is received.
DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Stop initialization and the MRI. 2. Click Start on the TDC. 3. Re-enter the patient's core temperature. 4. Relaunch the MRI Thermometry Sequence on the MRI Console. 	
DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Click Resume Heating to resume treatment. The alarm will clear when the next thermometry scan is received. 	

50-204: TDC has not received new thermometry images in the last 30 seconds

Condition A new thermometry image has not been received in the last 30 seconds or so.

Error Code 50-204

Delay 5x MR sampling period

System Response **Setup, Alignment, Coarse:** No system response.
Detailed: TDC will stop processing thermometry images from the MRI
Delivery - Initialization: TDC will stop processing thermometry images from the MRI and Initialization will be terminated.
Delivery - Ablation: Ablation will be interrupted.

Address the Cause At any stage:

1. Ensure the thermometry sequence is running on the MRI, and that sufficient dynamics have been selected for the thermometry scan you are trying to run.
 - o GE: 26 dynamics for Detailed, 1500 dynamics minimum for Delivery
2. Ensure the MRI and TDC computer are still able to communicate through their network connection by checking the status of the MRI subsystem in *Setup* workspace.
3. Ensure that the appropriate TULSA-PRO® sequence and parameters is being used for thermometry acquisition.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received.
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Click Start on the TDC. 2. Re-enter the patient’s core temperature. 3. Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received.
	DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment. 2. Stop the MRI Thermometry Sequence on the MRI Console. 3. Click Start on the TDC. 4. Re-enter the patient’s core temperature.

5. Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received.

50-209: The thermometry images cannot be used

Condition The thermometry images have become corrupted and can no longer be used. Patient motion or an MRI artifact is suspected.

Error Code 50-209

Delay Immediate

System **Setup, Alignment, Coarse:** Not applicable. Condition and alarm will not occur.

Response **Detailed:** TDC will stop processing thermometry images from the MRI
Delivery – Initialization: TDC will stop processing thermometry images from the MRI and Initialization will be terminated.
Delivery – Ablation: Ablation will be interrupted.

Address At any stage:

- the Cause**
1. Check magnitude THERM images for tissue displacement outside of the treatment volume (e.g. bladder filling, bowel movement, gas).
 2. Ensure the patient has not moved during Delivery. Consult with the anesthesiologist to confirm the patient has received the correct medication, dosage, and the timing of drug administration. Anesthesiologist will decide if a top up medication is necessary.
 3. Ensure there is no RF noise in the MRI images (for example, non-MRI Compatible equipment in the technical room, intermittent electrical connection)
 4. Check the magnitude THERM images for phase wrap in the A>P direction.

The alarm will clear once new thermometry images are received.

Steps After Addressing the Cause	SETUP	Not applicable.	
	ALIGNMENT		
	COARSE		
	DETAILED	Acquire a new thermometry scan.	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Click Start on the TDC. 2. Re-enter the patient's core temperature. 3. Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received. 	
	DELIVERY - ABLATION	If you suspect any patient motion, tissue motion, bladder filling, bowel gas or bowel movement:	If the source of MRI noise was RF:
	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan. 2. Return to <i>Alignment</i>. 3. Unlock the UA. 	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan. 2. Return to <i>Detailed Planning</i>. 	

- | | |
|--|---|
| <ol style="list-style-type: none">4. Re-acquire a new SAG T2 Image.5. Proceed through the normal workflow to <i>Delivery</i>. | <ol style="list-style-type: none">3. Re-acquire a new TUV.4. Proceed through the normal workflow to <i>Delivery</i>. |
|--|---|

In either situation, the alarm will clear after you click **End Thermometry and Re-plan**.

50-211: The thermometry scan does not match the prescribed image position or orientation

Condition There is a disagreement between where the thermometry scan was acquired and where the TDC thinks the thermometry scan should have been acquired.

Error Code 50-211

Delay Immediate

System Response **Setup, Alignment, Coarse:** No system response.

Detailed: TDC will stop processing thermometry images from the MRI

Delivery - Initialization: TDC will stop processing thermometry images from the MRI and Initialization will be terminated.

Delivery - Ablation: Not applicable.

Address the Cause Ensure that thermometry position & orientation information for the thermometry scan to the MRI have been correctly setup.

NOTE: This Alarm only appears when using TULSA-PRO® with a Siemens MRI.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	<p>Confirm the last Scan run on the MRI is the same as the last Scan imported into TDC Coarse Planning.</p> <p style="text-align: center;"><i>1. If not done correctly:</i></p> <ol style="list-style-type: none"> 1. Import the latest SAG T2 in the <i>Alignment Planning</i> tab of TDC. 2. If necessary, adjust the UA Position by selecting Unlock UA. Proceed through the normal workflow. 3. Open the THERM scan on the MRI Software. 4. Copy the Table Position from the most recent SAG T2 Scan acquired. 5. Click Update in <i>Detailed Planning</i>. 6. Set the number of dynamics to 1. 7. Run the thermometry sequence. 8. Repeat the sequence, changing the number of dynamics 26. 9. Ensure the coils activated between the Reference Scan (1 dynamic) and the larger dynamic scan are identical. <p>The alarm will clear when the images with the correct THERM position and orientation is received.</p>

<p>DELIVERY - INITIALIZATION</p>	<ol style="list-style-type: none"> 1. Open the THERM scan on the Siemens MRI Software. 2. Copy the Table Position from the most recent SAG T2 Scan acquired. 3. Click Update in <i>Delivery</i> workspace. 4. Set the number of dynamics to 1. 5. Run the thermometry sequence. 6. Repeat the sequence, changing the number of dynamics to the maximum available. 7. Ensure the coils activated between the Reference Scan (1 dynamic) and the larger dynamic scan are identical. 8. Click Start on the TDC. 9. Re-enter the patient's core temperature. 0. Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received.
<p>DELIVERY - ABLATION</p>	<p>Not applicable.</p>

50-212: Someone changed the thermometry sequence parameters and they are out of range

Condition The thermometry sequence parameters have been modified and are no longer the default value.

Error Code 50-212

Delay Immediate

System **Setup, Alignment, Coarse:** No system response.

Response **Detailed:** TDC will stop processing thermometry images from the MRI

Delivery - Initialization: TDC will stop processing thermometry images from the MRI and Initialization will be terminated.

Delivery - Ablation: Not applicable.

Address the Cause At any stage:

1. Reload the sequence from the exam card to restore original default values.
2. If the problem continues, contact a Profound Medical authorized service representative.
3. If using a GE MRI, check that the Research CV 'dda' has been set correctly.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	Re-run the MRI Sequence. The alarm will clear once the first image from the correct sequence is received.
	DELIVERY - INITIALIZATION	
	DELIVERY - ABLATION	Not applicable.

50-213: The thermometry images cannot be used

Condition The image shift calculated after 100 dynamics is greater than 1 mm in the frequency-encoding direction or 2 mm in the phase-encoding direction for any slice.

Error Code 50-213

Delay Every 100 imaging dynamics

System Response **Setup, Alignment, Coarse, Detailed, Delivery - Initialization:** No system response.

Delivery – Ablation: Ablation will be interrupted.

Address the Cause At any stage:

1. Check magnitude THERM images for tissue displacement outside of the treatment volume (e.g. bladder filling, bowel movement, gas).
2. Ensure the patient has not moved during Delivery. Consult with the anesthesiologist to confirm the patient has received the correct medication, dosage, and the timing of drug administration. Anesthesiologist will decide if a top up medication is necessary.
3. Ensure there is no RF noise in the MRI images (for example, non-MRI Compatible equipment in the technical room, intermittent electrical connection)
4. Check the magnitude THERM images for phase wrap in the A>P direction.

The alarm will clear once new thermometry images are received.

Steps After Addressing the Cause	SETUP	Not applicable.	
	ALIGNMENT		
	COARSE		
	DETAILED	Acquire a new thermometry scan.	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Click Start on the TDC. 2. Re-enter the patient's core temperature. 3. Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received. 	
	DELIVERY - ABLATION	<p>If you suspect any patient motion, tissue motion, bladder filling, bowel gas or bowel movement:</p> <ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan. 2. Return to <i>Alignment</i>. 3. Unlock the UA. 	<p>If the source of MRI noise was RF:</p> <ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan. 2. Return to <i>Detailed Planning</i>. 3. Re-acquire a new TUV.

4. Re-acquire a new SAG T2 Image.
5. Proceed through the normal workflow to *Delivery*.

4. Proceed through the normal workflow to *Delivery*.

In either situation, the alarm will clear once you click **End Thermometry and Re-plan**.

50-214: The anatomy scan required for alignment is older than 2 hours.

Condition Only when **not** in **Delivery - Ablation**: The SAG T2 treatment planning image used to establish the Ultrasound Applicator (UA) position cannot be trusted. A new SAG T2 image is required to confirm the location of the UA in the MRI Image.

Error Code 50-214

Delay Immediate

System Response **Setup, Alignment, Coarse, Detailed:** No system response.
Delivery – Initialization: It will not be possible to start initialization.
Delivery – Ablation: Not applicable. Condition and alarm will not occur.

Address the Cause

1. Unlock the *Alignment* workspace, acquire a new SAG T2 Scan, and then import it into the TDC.
2. Realign if necessary. **NOTE:** If you need to realign, then you will be forced to acquire new TUV and AX T2 scans during **Detailed** planning.

The alarm will clear once the new SAG T2 image is loaded into the TDC.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	Continue through the normal workflow.
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	
	DELIVERY - ABLATION	Not applicable.

50-215: Check that the patient is in a head-first, supine position

Condition	The Patient Orientation is not head-first, supine and was set incorrectly during patient registration.	
Error Code	50-215	
Delay	Immediate	
System Response	<p>Setup, Alignment, Coarse: No system response.</p> <p>Detailed: TDC will stop processing thermometry images from the MRI</p> <p>Delivery – Initialization: TDC will stop processing thermometry images from the MRI and Initialization will be terminated.</p> <p>Delivery – Ablation: Not applicable. Condition and alarm will not occur.</p>	
Address the Cause	The patient will need to be re-registered on the MRI console with the correct Patient Position Orientation (Head First – Supine) or the MRI configuration will need to be adjusted.	
Steps After Addressing the Cause	SETUP	Continue through the normal workflow.
	ALIGNMENT	
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	
	DELIVERY - ABLATION	Not applicable.

Positioning System

10-102: TDC lost the network connection to the Positioning System Interface Box

Condition The Positioning System Interface Box (PSIB) network connection has been lost and the TDC can no longer communicate with the PSIB.

Error Code 10-102

Delay Immediate

System Response **Setup:** User will not be able to proceed to Alignment.

Alignment: No system response.

Coarse: User will not be able to translate the Ultrasound Applicator (UA) with the robotic linear axis.

Detailed: User will not be able to rotate the UA with the robotic rotational axis. User can still proceed to Delivery.

Delivery - Initialization: Ablation will not start.

Delivery - Ablation: Ablation will be paused.

Address the Cause At any stage:

1. Ensure the System Electronics (SE) is plugged into a power outlet and the power switch is turned ON. Verify if the connection is re-established.
2. Ensure there is an Ethernet cable connecting the TDC to the SE. Verify if the connection is re-established.
3. Ensure both RF cables (System Electronics-to-Filter Box and Filter Box-to-PSIB) are connected. Check that the connection is re-established.
4. Unplug the Ethernet cable connecting the TDC to the SE, reconnect, and wait one minute before continuing. Verify if the connection is re-established.
5. Turn the SE power off. Disconnect the white RF cable at the PSIB, wait one minute, and re-connect. Turn on the SE power. Verify if the connection is re-established.

Steps After Addressing the Cause	SETUP	Proceed through the normal workflow.
	ALIGNMENT	Check if the UA rotational axis is still homed. If homing was lost, repeat the UA homing procedure in the <i>Setup</i> workspace. Proceed through the normal workflow.
	COARSE	Perform the required linear move of the UA with the robotic linear axis (if needed) and proceed to the <i>Detailed Planning</i> .
	DETAILED	Check if the UA rotational axis is still homed. If homing was lost, repeat the UA homing procedure in the <i>Setup</i> workspace. Proceed through the normal workflow.
	DELIVERY - INITIALIZATION	

DELIVERY -
ABLATION

Click **Resume Heating** on the TDC to resume treatment.

20-102: The cable between the Positioning System (PS) and PS Interface Box is disconnected

Condition	The Positioning System (PS) cable is disconnected from the PS Interface Box (PSIB).	
Error Code	20-102	
Delay	Immediate	
System Response	<p>Setup: User will not be able to Test PS or Home UA</p> <p>Alignment: No system response.</p> <p>Coarse: User will not be able to adjust the linear position of UA with the robotic linear axis.</p> <p>Detailed: No system response.</p> <p>Delivery - Initialization: It will not be possible to start initialization or initialization will stop.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>	
Address the Cause	At any stage, verify the PS cable is firmly seated in the PSIB. Verify if the connection is restored. If it still does not show a connection, remove the PS cable, wait one minute, and then re-insert.	
Steps After Addressing the Cause	SETUP	Proceed through the normal workflow.
	ALIGNMENT	<ol style="list-style-type: none"> 1. Return to <i>Setup</i>. 2. Unlock UA. 3. Home the UA. 4. Load the latest SAG T2 image acquired into Alignment. 5. Align the UA. 6. Proceed through the normal workflow.
	COARSE	<ol style="list-style-type: none"> 1. Return to <i>Setup</i>. 2. Unlock the UA. 3. Home the UA. 4. Load the latest SAG T2 image acquired into <i>Alignment</i>. The UA will be auto-registered by the software. 5. Select Register UA. 6. Proceed through the normal workflow.
	DETAILED	<ol style="list-style-type: none"> 1. Return to <i>Setup</i>. 2. Unlock the UA. 3. Home the UA. 4. Load the latest SAG T2 image acquired into Alignment. The UA will be auto-registered by the software. 5. Select Register UA. Do not move the UA in <i>Coarse Planning</i>; instead, select Accept Position.

	<ol style="list-style-type: none"> 6. Proceed through the normal workflow.
<p>DELIVERY - INITIALIZATION</p>	<ol style="list-style-type: none"> 1. Return to <i>Setup</i>. 2. Unlock the UA. 3. Home the UA. 4. Load the latest SAG T2 image acquired into Alignment. The UA will be auto-registered by the software. 5. Select Register UA. 6. Do not move the UA in <i>Coarse Planning</i>; instead, select Accept Position. 7. Confirm treatment planning. You will not need to re-acquire new TUV or AX T2 images. 8. Proceed through the normal workflow.
<p>DELIVERY - ABLATION</p>	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan. 2. Return to <i>Setup</i>. 3. Unlock the UA. 4. Home the UA. 5. Load the latest SAG T2 image acquired into Alignment. The UA will be auto-registered by the software. 6. Select Register UA. 7. Do not move the UA in <i>Coarse Planning</i>; instead, select Accept Position. 8. Confirm treatment planning. You will not need to re-acquire new TUV or AX T2 images. 9. Proceed through the normal workflow.

20-201: There is a problem with the rotary motion

Condition	A rotary motion fault occurred.
Error Code	20-201
Delay	Immediate
System Response	<p>Setup: PS Test or Rotary Home will stop.</p> <p>Alignment, Coarse: Not applicable. Condition and alarm will not occur.</p> <p>Detailed: The Ultrasound Applicator (UA) will not reach the intended starting position.</p> <p>Delivery - Initialization: Not applicable. Condition and alarm will not occur.</p> <p>Delivery - Ablation: Ablation will be paused.</p>

Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> Ensure nothing is preventing the Positioning System (PS) from rotating the UA freely. Possible causes include: <ul style="list-style-type: none"> The UA and/or ECD fluid lines have become wrapped around the PS. One of fluid lines are impeded by table drapes or other accessories. The UA cable is too tight and is not allowing the UA to rotate freely. To remove tension from the UA cable, disconnect the UA cable at the PSIB end, un-wind the cable, and then re-connect it.
-------------------	---

Steps After Addressing the Cause	SETUP	Proceed through the normal workflow.
	ALIGNMENT	Not applicable.
	COARSE	
	DETAILED	Re-attempt the rotary motion. Proceed through the normal workflow.
	DELIVERY - INITIALIZATION	
	DELIVERY - ABLATION	

20-202: The TDC computer is busy and cannot process thermometry images fast enough

Condition The Positioning System (PS) is receiving new hardware commands slower than usual, because TDC is not processing images fast enough.

Error Code 20-202

Delay 8 seconds

System Response **Setup, Alignment, Coarse, Detailed, Delivery - Initialization:** Not applicable. Condition and alarm will not occur.

Delivery - Ablation: Ablation will be paused.

Address the Cause At any stage, ensure that the TDC has access to enough computer resources by closing all non-essential programs, such as antivirus programs, Windows Updates, or web browsers.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	
	DELIVERY - ABLATION	Click Resume Heating on the TDC. The alarm will clear and treatment will resume.

20-203: Something went wrong with the Positioning System communications

Condition There was a Positioning System Interface Box (PSIB) communication failure with a motion controller, which has stopped motion.

Error Code 20-203

Delay Immediate

System Response **Setup, Alignment, Coarse, Detailed:** No system response.

Delivery - Ablation: Ablation will be paused.

Delivery – Initialization: Ablation will not start.

Address the Cause At any stage, the TDC automatically corrects the issue. You do not need to perform any action.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	
	DELIVERY - ABLATION	Click Resume Heating on the TDC. The alarm will clear and treatment will resume.

21-201: The Positioning System's linear axis moved unexpectedly

Condition The Positioning System (PS) linear axis has unexpectedly moved and the Ultrasound Applicator (UA) is no longer registered to the MRI Image.

Error Code 21-201

Delay Immediate

System Response **Setup, Alignment, Coarse, Detailed:** No system response.

Delivery - Initialization: It will not be possible to start initialization or initialization will stop.

Delivery - Ablation: Ablation will be interrupted.

Address the Cause At any stage, the automated linear axis has unexpectedly moved from its last-requested linear position. The UA is no longer registered to the MRI Image.

1. Ensure that there is no additional force being applied on the robotic linear axis of the PS.
2. Ensure the patient is not moving.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	<ol style="list-style-type: none"> 1. Re-acquire a new SAG T2. 2. From the Anatomy selector, select the new SAG T2 to align the UA a second time. The alarm will clear once the new SAG T2 image has been acquired. 3. Proceed through the normal workflow to return to <i>Delivery</i>.
	COARSE	<ol style="list-style-type: none"> 1. Unlock the UA in the <i>Alignment</i> tab.
	DETAILED	<ol style="list-style-type: none"> 2. Re-acquire a new SAG T2.
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 3. Go to the Anatomy selector and select the new SAG T2 to align the UA a second time. The alarm will clear once the new image is acquired. 4. Proceed through the normal workflow to return to <i>Delivery</i>.
DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Create a new segment. 2. Unlock the UA in the <i>Alignment</i> tab. 3. Re-acquire a new SAG T2. 4. Go to the Anatomy selector and select the new SAG T2 to align the UA a second time. The alarm will clear once the new image is acquired. 5. Proceed through the normal workflow to return to <i>Delivery</i>. 	

22-201: The Positioning System is not rotating the Ultrasound Applicator at the expected rate

Condition	The Positioning System (PS) is not rotating the Ultrasound Applicator (UA) at the expected rate.
Error Code	22-201
Delay	Immediate
System Response	Setup, Alignment, Coarse, Detailed, Delivery - Initialization: Not applicable. Condition and alarm will not occur. Delivery - Ablation: Ablation will be paused.
Address the Cause	At any stage: <ol style="list-style-type: none"> Ensure nothing is preventing the PS from rotating the UA freely. Possible reasons include: <ul style="list-style-type: none"> The UA and/or ECD fluid lines have become wrapped around the PS. One of the fluid lines is impeded by table drapes or other accessories. The UA cable is too tight and not allowing the UA to rotate freely. <ul style="list-style-type: none"> To remove tension from the UA cable, disconnect the UA cable at the PSIB end, un-wind the cable, and then re-connect it. Although <u>uncommon</u>, the alarm could be raised due to malfunctioning hardware. If you continue to receive this alarm, contact PMI support.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	
	DELIVERY - ABLATION	Click Resume Heating on the TDC. The alarm will clear and treatment will resume.

22-202: The rotary home position has been lost

Condition The Ultrasound Applicator (UA) is not properly seated in the Positioning System (PS) gripper or the PS Interface Box (PSIB) lost power, which caused the known position to be lost.

Error Code 22-202

Delay Immediate

System Response **Setup, Alignment, Coarse:** No system response.
Detailed: User will not be able to rotate the UA with the robotic rotational axis. User can still proceed to Delivery.
Delivery - Initialization: It will not be possible to start initialization or initialization will stop.
Delivery - Ablation: Ablation will be interrupted.

Address the Cause At any stage:

1. Ensure the UA is properly seated within the PS gripper. If necessary, open the PS Gripper and reattach the UA.
2. Ensure that the PS can communicate with the PSIB by checking the UA attached status in the *Setup* workspace. If necessary, unplug the cable connecting the PS to the PSIB, reconnect, and wait one minute.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	1. Navigate to the <i>Setup</i> workspace and select Unlock UA . Home the UA. The alarm will clear.
	COARSE	If the UA became disengaged from the PS:
	DETAILED	
	DELIVERY - INITIALIZATION	
	DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Create a new segment. 2. Navigate to the <i>Setup</i> workspace and select Unlock UA. 3. Home the UA. The alarm will clear. <p>If UA became disengaged from PS:</p> <ol style="list-style-type: none"> 1. Acquire a new SAG T2 scan. 2. Load the latest SAG T2 sequence in the Anatomy selector. 3. Proceed through the normal workflow.

22-206: The Ultrasound Applicator (UA) has rotated too far in one direction

Condition	The Ultrasound Application (UA) has rotated too far in one direction. The UA must be unwound to proceed with heating.	
Error Code	22-206	
Delay	Immediate	
System Response	<p>Setup, Alignment, Coarse, Detailed: No system response.</p> <p>Delivery – Initialization: It will not be possible to start initialization.</p> <p>Delivery - Ablation: Ablation will be paused.</p>	
Address the Cause	<p>In Delivery: The UA has rotated too far in one direction. Clicking the <i>Unwind UA</i> button will unwind the UA. Once it has finished unwinding, it allows you to continue treatment in the same treatment direction.</p> <p>In Initialization: Using the <i>Delivery</i> workspace, manually move the center position of the UA <u>slightly on the THERM TUV magnitude</u>. The TDC application will recognize that it has reached the UA rotation limit and will take the necessary steps to correct the problem.</p>	
Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	Not applicable.
	COARSE	Not applicable.
	DETAILED	Not applicable.
	DELIVERY - INITIALIZATION	Not applicable.
	DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Click Unwind UA to unwind the UA. 2. Once the unwinding procedure has completed, click Resume Heating to proceed with treatment. The alarm will clear once the UA has finished unwinding.

22-208: The Positioning System's rotary axis moved unexpectedly

Condition	The Positioning System (PS) rotary axis has unexpectedly moved and the UA beam may point in an unintended direction.	
Error Code	22-208	
Delay	Immediate	
System Response	<p>Setup, Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: It will not be possible to start initialization.</p> <p>Delivery - Ablation: Not applicable. Condition and alarm will not occur.</p>	
Address the Cause	<p>At any stage, the automated rotary axis has unexpectedly moved from its last-requested rotary position.</p> <ol style="list-style-type: none"> 1. Ensure that there is no additional force being applied on the robotic rotary axis of the PS. 2. Ensure the patient is not moving. 	
Steps After Addressing the Cause	SETUP	Repeat the PS rotary homing procedure in the <i>Setup</i> workspace.
	ALIGNMENT	<ol style="list-style-type: none"> 1. Navigate to the <i>Setup</i> workspace and select Unlock UA. 2. Perform PS rotary homing again. 3. Proceed through the normal workflow.
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	

Radio Frequency

30-201: Emergency switch button has been activated

Condition	Someone pressed the emergency switch on the System Electronics.
Error Code	30-201
Delay	Immediate
System Response	<p>Setup: Linear and rotary axes will turn off, ultrasound power for all elements will turn off, UA and ECD fluid pumps will turn off.</p> <p>Alignment: No system response.</p> <p>Coarse: User can not adjust the UA linear position with the robotic linear axis.</p> <p>Detailed: User can not adjust the UA rotational position with the robotic rotational axis.</p> <p>Delivery - Initialization: It will not be possible to start initialization or initialization will stop.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>
Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> 1. Resolve the situation that required the emergency button to be pushed. 2. To clear the alarm, press-and-hold the emergency switch button, located on the front side of the SE, for five seconds.
Steps After Addressing the Cause	At any stage, proceed through the normal workflow.

30-202: The TDC computer is busy and cannot process thermometry images fast enough

Condition The System Electronics (SE) have not received a new power-update command in the last 8 seconds, because the TDC is not processing images fast enough.

Error Code 30-202

Delay 8 seconds

System Response
Setup, Alignment, Coarse, Detailed: Not applicable. Condition and alarm will not occur.
Delivery-Initialization: Ablation will not start.
Delivery - Ablation: Ablation will be paused.

Address the Cause At any stage, ensure that the TDC application has enough computer resources by terminating all non-essential programs, such as antivirus programs, Windows Updates, and web browsers.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	When the Resume Heating button is available on the TDC, click it to continue treatment.
	DELIVERY - ABLATION	Continue treatment.

31-201: The System Electronics amplifiers are overheating

Condition One or more amplifiers inside the System Electronics (SE) are overheating.

Error Code 31-201

Delay Immediate

System Response **Setup, Alignment, Coarse, Detailed:** No system response.
Delivery - Initialization: It will not be possible to start initialization or initialization will stop.
Delivery - Ablation: Ablation will be interrupted.

Address the Cause At any stage:

1. Ensure the front and rear vents on the SE are unobstructed and the fans are running. Allow the amplifiers to cool before continuing.
2. Consider moving the SE (without disconnecting the SE power cable or fluid tubes), to a more open space in the room to maximize airflow.
3. Consider decreasing the temperature in the room where the SE is located.

Steps After Addressing the Cause	SETUP	Not applicable.
	ALIGNMENT	
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Stop the MRI Thermometry Sequence on the MRI Console. 2. Click Start on the TDC. 3. Re-enter the patient's core temperature. 4. Relaunch the MRI Thermometry Sequence on the MRI Console.
	DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment. 2. Stop the MRI Thermometry Sequence on the MRI Console. 3. Click Start on the TDC. 4. Re-enter the patient's core temperature. 5. Relaunch the MRI Thermometry Sequence on the MRI Console.

31-202: The System Electronics amplifiers have turned off

Condition	One or more amplifiers inside the System Electronics (SE) have switched off unexpectedly.										
Error Code	31-202										
Delay	Immediate										
System Response	<p>Setup, Alignment, Coarse, Detailed: Not applicable. Condition and alarm will not occur.</p> <p>Delivery – Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be paused.</p>										
Address the Cause	Ensure the TDC application has enough computer resources by terminating all non-essential programs, such as antivirus programs, Windows Updates, and web browsers.										
Steps After Addressing the Cause	<table border="1"> <tr> <td>SETUP</td> <td rowspan="4">Not applicable.</td> </tr> <tr> <td>ALIGNMENT</td> </tr> <tr> <td>COARSE</td> </tr> <tr> <td>DETAILED</td> </tr> <tr> <td>DELIVERY - INITIALIZATION</td> <td>Once the Resume Heating button is available on the TDC, click it to continue treatment.</td> </tr> <tr> <td>DELIVERY - ABLATION</td> <td>Continue treatment.</td> </tr> </table>	SETUP	Not applicable.	ALIGNMENT	COARSE	DETAILED	DELIVERY - INITIALIZATION	Once the Resume Heating button is available on the TDC, click it to continue treatment.	DELIVERY - ABLATION	Continue treatment.	
SETUP	Not applicable.										
ALIGNMENT											
COARSE											
DETAILED											
DELIVERY - INITIALIZATION	Once the Resume Heating button is available on the TDC, click it to continue treatment.										
DELIVERY - ABLATION	Continue treatment.										

32-102: TDC lost the network connection to the System Electronics

Condition	The System Electronics (SE) network connection has been lost.	
Error Code	32-102	
Delay	Immediate	
System Response	<p>Setup: UA and ECD purging will be cancelled. RF test cannot be performed.</p> <p>Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: It will not be possible to start initialization or initialization will stop.</p> <p>Delivery - Ablation: Ablation will be interrupted.</p>	
Address the Cause	<p>At any stage:</p> <ol style="list-style-type: none"> 1. Ensure the SE is plugged into a power outlet and the power switch is turned ON. Verify if the connection is re-established. 2. Ensure there is an Ethernet cable connecting the TDC to the SE. Verify if the connection is re-established. 3. Unplug the Ethernet cable connecting the TDC to the SE, reconnect, and wait one minute. Verify if the connection is re-established. 4. Consider replacing the Ethernet cable that connects the TDC to the SE. 	
Steps After Addressing the Cause	SETUP	<p>If the UA purge has <u>not</u> been completed, perform another UA purge.</p> <p>If the purge has been completed, but the RF test has not yet been completed, initiate the RF test.</p>
	ALIGNMENT	Proceed through the normal workflow.
	COARSE	
	DETAILED	
	DELIVERY - INITIALIZATION	<ol style="list-style-type: none"> 1. Stop the MRI Thermometry Sequence on the MRI Console. 2. Click Start on the TDC. 3. Re-enter the patient's core temperature. 4. Relaunch the MRI Thermometry Sequence on the MRI Console.
DELIVERY - ABLATION	<ol style="list-style-type: none"> 1. Click End Thermometry and Re-plan on the TDC to create a new Treatment Segment. 2. Stop the MRI Thermometry Sequence on the MRI Console. 3. Click Start on the TDC. 4. Re-enter the patient's core temperature. 	

5. Relaunch the MRI Thermometry Sequence on the MRI Console. The alarm will clear once the new image is received.

System

71-202: There is not enough hard-drive storage space to complete this session

Condition	There is not enough storage space on the TDC hard drive. At least 6 GB of space are required.
Error Code	71-202
Delay	Immediate
System Response	<p>Setup, Alignment, Coarse, Detailed: No system response.</p> <p>Delivery - Initialization: Ablation will not start.</p> <p>Delivery - Ablation: Ablation will be paused.</p>
Address the Cause	Contact an authorized Profound Medical service representative.
Steps After Addressing the Cause	At any stage, follow the instructions from the authorized Profound Medical service representative.