Vanquish® Water Vapor Ablation System

Software Version 3.0

User Manual

Electronic version available at www.francismedical.com/documents

IMPORTANT: Carefully read and understand all instructions, indications, warnings, precautions, and directions for use before using any Vanquish System component. Failure to do so could result in compromised patient safety, patient complications, and/or insufficient treatment.

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1 General Information

1.1 Purpose

This manual provides comprehensive information on the system functions and components. It details the instructions for setting up, using, transporting, processing, and storing the Vanquish Water Vapor Ablation System, hereafter referred to as the 'Vanquish System'.

1.2 Manufacturer

The Vanquish System is manufactured by:

Francis Medical, Inc.
7351 Kirkwood Lane N, Suite 130
Maple Grove, MN 55369 USA
Website: www.francismedical.com
Phone: +1 763-951-0370

1.3 General Information Disclaimer

This manual contains information specific to the Vanquish System and is not intended as medical advice. It does not endorse or promote any particular medical procedure, product, or surgical method.
Clinical decision-making, including the selection of treatment approach, equipment, and sterile technique, remains the sole responsibility of the treating physician. Francis Medical does not make recommendations regarding individual patient care.

1.4 Prescription Device - Rx Only

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

1.5 Copyright and Trademark

1.6 Indications for Use / Intended Use

The Vanquish Water Vapor Ablation System is indicated for the thermal ablation of targeted prostate tissue via a transurethral approach.

1.7 Terminology

To maintain clarity, the terms listed below may be used in place of one another.

Line / Tubing: These terms are used interchangeably to refer to the flexible conduit that transports fluid between system components.

Vanquish System / Vanquish Water Vapor Ablation System / The System: All three terms refer to the complete device system used for water vapor ablation procedures. Vanquish System is a shortened form used throughout this manual for readability.

Clark Clamp / Clark Socket: These terms refer to the same clamping mechanism used to attach accessories to OR bed rails.

Vapor Activation Button / Vapor Delivery Button: Both terms refer to the button on the controller that activates vapor delivery after the Needle has been deployed.

Transducer / Probe: Both terms refer to the BK E14CL4b transducer used with the transrectal ultrasound.

1.8 Contraindications

The Vanquish System is contraindicated for use in the following patients:

- Patients with an active urinary tract infection
- Patients with acute bacterial prostatitis
- Patients who have an artificial urinary sphincter implant
- Patients with inaccessible prostatic urethra
- Patients contraindicated for transrectal ultrasound

1.9 Intended Use Environment

The Vanquish System is intended for use by trained healthcare professionals in controlled clinical environments such as hospitals and ambulatory surgery centers (ASCs). It is not intended for use in home settings or mobile environments.

1.10 Symbols in Labeling

The symbols in **Table 1** may appear in this manual, on the reusable and disposable product labeling and/or packaging. Some of the symbols represent standards and compliances associated with the Vanquish System and its use.

Table 1: Symbols in Labeling

Symbol	Description	Symbol	Description
	Medical Device		Video Output
	Type BF applied part		Locking, general
	Caution		Unlocking
	Fragile; handle with care		Power Connection Port
	Temperature limit		Serial interface
	Do not re-use		Keep away from sunlight
	Consult instructions for use		Keep dry
	Batch code		Date of manufacture
	Catalogue number		Packaging unit
	Serial number		Universal Serial Bus (USB), port/plug
	Sterilized using ethylene oxide		Refer to instruction manual/booklet
	Do not use if package is damaged and consult instructions for use		No access for people with active implanted cardiac devices

Symbol	Description	Symbol	Description
	Use by date		No sitting
	Do not resterilize		No stepping on surface
	Humidity limitation		Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Manufacturer		Power off (circle)
	Repackaging		Power on (vertical line)
	Single sterile barrier system with protective packaging inside	IPXX	Degrees of ingress protection provided by enclosure
	Fuse		Shelf/drawer max load
	Protective earth; protective ground		Downward force prohibition
	Direct current		EO Exposure indicator
	Alternating current		Do not touch. Moving parts
	Electrostatic sensitive devices		General warning

1.11 Reporting of Serious Incidents

Any serious incident that has occurred in relation to the device should be reported to Francis Medical and to FDA.
Serious incident means any incident that directly or indirectly led, might have led, or might lead to any of the following:

- The death of a patient, user or other person,
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- A serious public health threat.

1.12 Responsibility of the User

All personnel who operate, maintain, or service the Vanquish System must read and understand this manual to ensure the safety of patients, users, and the equipment. The user specified within this manual may refer to the trained physician and/or procedure support staff under physician supervision.

To ensure safe and effective use, users must:

- Operate the device only as instructed and for its intended purpose
- Be properly trained and qualified
- Follow all safety warnings and precautions
- Perform routine maintenance and inspections as specified
- Use only approved accessories and replacement parts

- Report any malfunctions, unusual performance, or adverse events
- Avoid unauthorized repairs or modifications
- Comply with all applicable regulations and facility protocols

⚠ **WARNING – Training:** Do not operate the Vanquish System without completing Francis Medical-provided physician training. Untrained operation of the device may lead to improper use. Improper use can result in patient injury or equipment malfunction.

1.13 Initial System Assembly

Initial assembly of the Vanquish Cart and Monitor should be conducted by Francis Medical or an authorized representative.

2 Warnings and Cautions

The symbol and signal words shown below identify potential hazard categories. The definition of each category is as follows:

⚠ **WARNING –** This alert identifies hazards that may cause serious personal injury or death.

⚠ **CAUTION –** This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

■ **NOTE:** Indicates information considered important but not hazard-related.

2.1 ⚠ Warnings

WARNING – Training: Do not operate the Vanquish System without completing Francis Medical-provided physician training. Untrained operation of the device may lead to improper use. Improper use can result in patient injury or equipment malfunction.

WARNING – Transport (within facility): Do not transport the Cart with the Monitor Arm fully extended. Transporting the Cart in this state may cause it to tip. This can lead to equipment damage or personal injury.

WARNING – Fuses: Always disconnect the Generator from its power source before replacing fuses. Changing fuses while the Generator is powered may expose users to electrical hazards. This may result in electric shock or damage to the equipment.

WARNING – Servicing: Do not attempt to service the system except for fuse replacement. User servicing beyond fuse replacement may compromise device safety. This may lead to equipment malfunction or personal injury.

WARNING – Excessive Treatments: Take care when delivering multiple treatments in a single location. Excessive treatments in one area can lead to unintended thermal spread to adjacent tissue. This may lead to patient injury.

WARNING – Proper Needle Placement: Ensure the Needle is placed within the prostate before delivering vapor. Delivering vapor outside the prostate can damage surrounding tissue. This may lead to serious patient injury.

WARNING – Compromised Ultrasound Visibility: Do not proceed with treatment if ultrasound visibility of the needle or vapor plume is compromised. Poor visibility may prevent accurate verification of needle position or vapor delivery, which can result in unintended tissue ablation and patient injury.

WARNING – Power Supply: Always connect the system to an appropriate supply mains source with protective earth. Do not operate the system if such a power source is unavailable or improperly grounded.

An inadequate or ungrounded power supply may disrupt system performance. This can result in device malfunction, electric shock, or patient injury.

WARNING – Multiple Socket Outlet: Do not connect equipment other than what is specified to the Multiple Socket Outlet (MSO). Connecting unspecified equipment may affect system safety. This may result in degraded safety and potential patient or user harm.

WARNING – Electromagnetic Compatibility and Interference: Follow all electromagnetic compatibility (EMC) precautions and instructions for Vanquish System and surrounding equipment. High levels of electromagnetic interference (EMI) may disrupt system performance. This may cause display distortion, erratic readings, or unsafe operation.

WARNING – Electromagnetic Interference (EMI): This device may be affected by nearby 5G radios, especially from indoor 5G base stations with higher transmission power. Keep the device away from high-power 5G transmitters to avoid potential interference.

WARNING – Damaged Components: Do not use the system if any hardware components or connectors are damaged. Damaged parts may interfere with system performance. This may lead to inaccurate output or potential injury.

WARNING – Damaged Cables: Do not bend, kink, or use damaged cables. Damaged or improperly handled cables may disrupt signal integrity. This can result in inaccurate data or personal injury.

WARNING – Disconnect Before Cleaning: Disconnect all equipment before cleaning. Cleaning powered equipment can create hazards. Failure to do so may lead to shock or injury.

WARNING – Unauthorized Accessories: Do not use unauthorized cables or accessories. Unapproved components may interfere with performance or safety. This may result in degraded system function or injury.

WARNING – Proximity of Field Generators: Do not operate a Field Generator within 10 m (33 ft) of another operating Field Generator. Proximity can result in interference between tracking systems. This may lead to inaccurate navigation and patient injury.

WARNING – Field Generator Cable Placement: Do not place the Field Generator cable inside the measurement volume or wrap it around the Field Generator. This configuration may cause magnetic interference and may result in tracking errors and potential injury.

WARNING – Coiling of Field Generator Cable: Do not coil the Field Generator cable during use. Coiling induces a magnetic field that may disrupt tracking. This may lead to inaccurate tracking and patient injury.

WARNING – Objects on Field Generator: Do not place metallic, conductive, or magnetic objects on the Field Generator. These materials may interfere with the Field Generator's magnetic field and disrupt tracking accuracy. Inaccurate tracking can result in improper needle placement or treatment delivery. This may lead to patient injury. Only non-metallic items, such as surgical drapes, should be placed on the Field Generator.

WARNING – Field Generator Movement During Treatment: Do not move the Field Generator during treatment. Movement may disrupt spatial tracking references. If the Field Generator is moved, re-establish all required spatial references before continuing. Failure to do so may result in inaccurate system output and patient injury.

WARNING – Unverified Electromagnetic Environments: Do not operate the system in environments not evaluated for electromagnetic compatibility. Such environments may introduce magnetic interference. This may cause tracking inaccuracy and potential injury.

WARNING – Proximity to Implanted Devices: Do not operate the Field Generator within 20 cm (8 in) of an implanted pacemaker or similar device. The magnetic field may interfere with implant function. This can cause serious health complications and tracking errors.

WARNING – Use During Defibrillation: Do not use the system during or immediately after cardiac defibrillation. System performance has not been validated under these conditions. Use may result in unexpected behavior or injury.

WARNING – Exposure to MRI: Do not expose the system to strong magnetic fields like MRI. Exposure may alter internal sensor calibration. This may lead to inaccurate readings and potential injury.

WARNING – Presence of External Magnetic Fields: Do not operate the system in the presence of external magnetic fields. Such fields may interfere with system tracking. This can result in incorrect device operation and injury.

WARNING – Proximity to RF Equipment: Keep portable RF communications equipment at least 30 cm (12 in) away from the Field Generator and cables. Closer proximity may degrade performance. This can lead to inaccurate tracking and patient risk.

WARNING – Dropping the Field Generator: Do not drop or impact the Field Generator. Impact may alter calibration. This may cause inaccurate tracking and personal injury.

WARNING – Disconnecting Field Generator While Powered: Do not disconnect the Field Generator while the Generator is powered on. Disconnecting under power may cause electrical arcing. This can result in sparks or personal injury.

WARNING – Proper Mounting of Field Generator: Ensure the Field Generator is mounted at least 20 cm (8 in) away from the ferromagnetic segment of the Mounting Arm. Close proximity to ferromagnetic material may distort magnetic field. This can result in inaccurate tracking and potential patient injury.

WARNING – Ethylene Oxide Exposure: This product contains ethylene oxide, a chemical known to the State of California to cause cancer and birth defects or other reproductive harm. Use may result in exposure to this chemical. For more information, go to www.p65Warnings.ca.gov. Please ensure that anyone who may come in contact with this product is advised of this warning.

2.2 ⚠ Cautions

CAUTION – Bladder Overfilling: Monitor the amount of saline instilled during the procedure using the Generator display. Failure to empty the bladder as needed may result in bladder overfilling, potentially causing patient discomfort or procedural complications.

CAUTION – Delivery Device Insertion: Advance the Delivery Device shaft slowly and under direct visualization to avoid creating a false passage in the prostatic urethra. A false passage can cause urethral trauma or bleeding. If a false passage is observed or suspected, immediately stop advancement and carefully withdraw the device before attempting re-insertion.

CAUTION – Patient Movement: If anesthesia lightens and the patient moves or begins to awaken, immediately stop the procedure and withdraw both instruments—first the Delivery Device, then the TRUS probe—to avoid mechanical trauma to the urethra or rectum, which can result in bleeding or tissue injury.

CAUTION – Needle Retraction: Always confirm the Needle is fully retracted before repositioning or removing the Delivery Device. Moving the device with the Needle extended may harm the patient. This can lead to internal tissue damage.

CAUTION – Room Temperature Saline: Use only room temperature saline during treatment. Using cold saline may result in insufficient treatment and compromised therapy delivery.

CAUTION – Saline Line Positioning: Ensure saline lines are correctly oriented as indicated on the Generator. Incorrect placement may prevent saline from flowing during treatment, resulting in inadequate cooling and increased risk of tissue injury.

CAUTION – Air Bubbles in Water Line or Syringe: Remove air bubbles from the Auto-Refill Syringe and water line before use. Trapped air may result in insufficient treatment and compromised therapy delivery.

CAUTION – Urethral Saline Delivery: Ensure continuous urethral saline flow and monitor saline levels throughout the procedure. Interrupted saline delivery or an empty saline source may result in inadequate cooling, potentially causing urethral discomfort or thermal injury to the urethra.

CAUTION – Disposal: Handle and dispose of used components as potential biohazardous waste, in accordance with local, state, and federal medical waste regulations. Failure to do so may pose infection or environmental risks.

CAUTION – User Responsibility to Avoid PHI/PII Upload: Do not upload Protected Health Information (PHI) or Personally Identifiable Information (PII) via the USB port or third-party equipment. The system does not detect or block such data. Uploading PHI/PII may lead to unauthorized disclosure and compromise patient privacy.

CAUTION – Syringe Purging: Do not purge the sterile-water syringe while the needle is deployed in the prostate. Purging with the needle deployed in the prostate can force fluid into unintended tissue and cause injury or insufficient treatment. Fully retract the needle before initiating a purge.

CAUTION – Aerosol Sprays: Do not use aerosol sprays near the system. Aerosols can damage internal circuitry and impair system performance.

CAUTION – Approved Cleaning Methods: Use only the cleaning and disinfection procedures described in this document. Unapproved cleaning methods may damage the equipment or compromise safety.

CAUTION – Weight on Connectors: Avoid placing heavy objects on connectors. Excessive weight may damage connector integrity and lead to system malfunction.

CAUTION – Connector Placement: Do not leave connectors in areas where they may be stepped on, crushed, or otherwise damaged. Damaged connectors can cause system failures or inaccurate function.

CAUTION – Unauthorized Modification: Do not modify any part of the system without explicit authorization from Francis Medical. Unauthorized modifications can damage the equipment and void the warranty.

CAUTION – Connector Stress in Tight Spaces: Avoid pushing or pulling connectors in confined areas. Doing so may damage the cable or connector and disrupt system operation.

CAUTION – Proper Disconnection Technique: Disconnect cables by gripping the connector housing, not the cable. Pulling on the cable may damage internal wiring and impair device function. Never force a connection or disconnection.

CAUTION – Autoclaving Prohibited: Do not autoclave the Field Generator. Autoclaving will damage internal components and render the equipment unusable.

3 System Overview

3.1 Method of Operation

The Vanquish Water Vapor Ablation System delivers stored thermal energy in the form of sterile water vapor to ablate targeted prostate tissue. In a minimally invasive transurethral outpatient procedure performed under transrectal ultrasound (TRUS) guidance, sterile water is heated within the system and converted into vapor. This vapor is then delivered through small emitter holes at the distal end of a transurethral needle into the prostate tissue.

The vapor travels convectively through the interstitial spaces of the prostate, when emitted at pressure slightly greater than that of the interstitial tissue. As it condenses back into liquid, the stored thermal energy (latent heat of vaporization) is rapidly released onto cell membranes, causing thermal damage and subsequent cell death. The ablated tissue is then naturally resorbed by the body.

The emitted vapor is delivered at a pressure sufficient to displace interstitial fluid but not typically high enough to traverse densified tissue structures such as the prostate capsule and surgical capsule. These natural anatomical barriers generally inhibit the movement of vapor, helping confine the thermal effect to the targeted zones within the prostate. This containment is intended to reduce exposure to adjacent structures, such as the external sphincter and neurovascular bundles, thereby minimizing the potential for extraprostatic thermal damage.

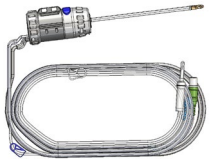
3.2 Compatibility

Only use instruments specified by Francis Medical. Using unauthorized instruments may adversely affect safety and/or effectiveness of the system.

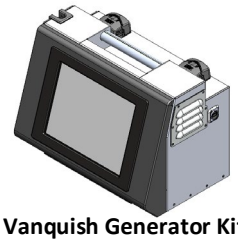
⚠ **WARNING – Unauthorized Accessories:** Do not use unauthorized cables or accessories. Unapproved components may interfere with performance or safety. This may result in degraded system function or injury.

⚠ **CAUTION – Unauthorized Modification:** Do not modify any part of the system without explicit authorization from Francis Medical. Unauthorized modifications can damage the equipment and void the warranty.

3.2.1 Vanquish System Compatibility

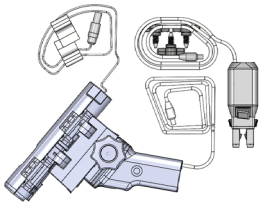


Vanquish Delivery Device:
- Standard (STD): 4570-001
- Peripheral Zone (PZ): 4571-001
- Retreatment (RTX): 5257-001

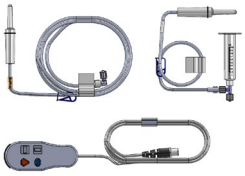


Vanquish Generator Kit:
- 4751-001 (SW Version 3.0)

Vanquish Cart and Monitor:
- 4741-001

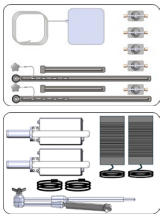


Vanquish Stabilizer Kit:
- 4573-001



Vanquish Accessory Kit:
- 4572-001

Sterile Water for Injection*:
- 4839-001 (250 mL bag)



Vanquish Capital Mounts Kit:
- 4752-001

Vanquish Stabilizer Arm Kit:
- 5536-001

Saline Catheter Needle:
- 10 cm Length: 4840-001
- 15 cm Length: 5245-001

Third-Party Equipment Required for Compatibility:

Ultrasound:
- BK Medical bkSpecto Ultrasound System (FW Version: Distribution Build 6.68.20636.49, Software Version 6.6.8; Live Dual Mode)
- BK Medical E14CL4b (9048) Endocavity Biplane Transducer

Cystoscope:
- Cystoscopy System (User-selected; Any compliant with IEC 60601-1 and IEC 60601-2-18)
- Karl Storz Cystoscope Lens (4 mm, 30 degree, 30 cm)

Operating Room (OR) Table:
- Equipped with North American standard surgical table side rails measuring 1 ⅛” x ⅜”

Saline:
- 0.9% Injectable Grade Saline (1 L, 2 L, 3 L, 4 L, 5 L flexible bag)

*** Use of Third-Party Sterile Water**

If Francis Medical-supplied sterile water is unavailable, users may supply sterile water from a third party, provided it meets all of the following conditions:
- Labeled as Sterile Water for Injection, USP (or equivalent injection-grade designation)
- Packaged in a 250 mL or 1 L flexible bag (not a rigid container)
- No antimicrobial or other substance has been added
- pH: 5.5 (5.0-7.0)
- Nonpyrogenic
- Not made with natural rubber latex, PVC, or DEHP
- Includes a standard IV-compatible spike port
- Stored and used at room temperature (20–25°C)

Use of sterile water that does not meet all of the above criteria may impair device performance or compromise patient safety. It is the responsibility of the user to verify that all conditions are met before use.

3.3 Main Components

The main components of the Vanquish System are shown below (**Figure 3-1**). The system is presented in position for use in an operating room.

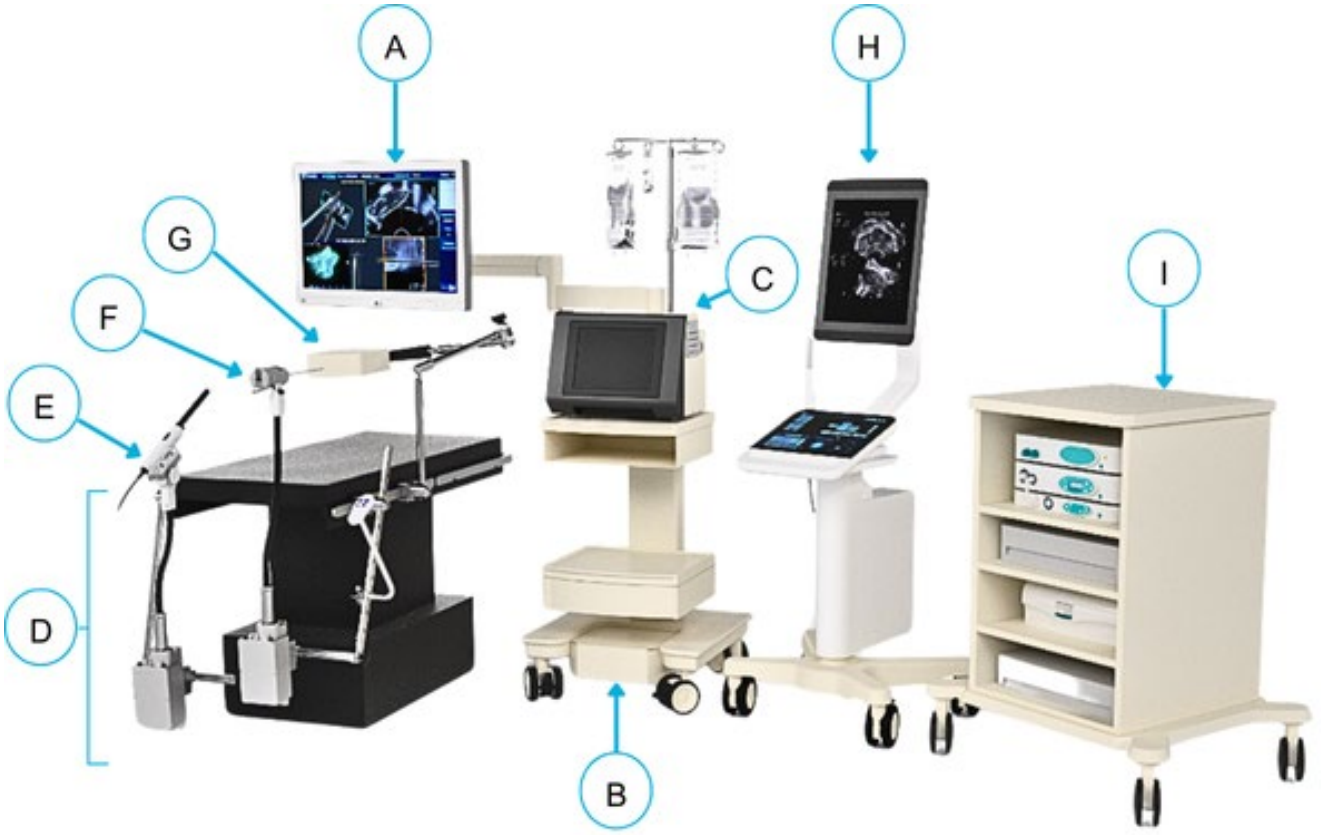


Figure 3-1: Main Components of the Vanquish System

The main function of the Vanquish System is to ablate prostate tissue. To accomplish this, the main components of the system function as described in **Table 2:**

Table 2: Vanquish System Components Functional Description

Label	Component	Functional Description
A	Monitor	The Monitor, mounted above the patient, displays the Physician User Interface (PUI) which shows critical treatment metrics together with live Ultrasound, Cystoscopy, and NGS images for real-time guidance.
B	Cart	The Cart securely houses the Generator and Monitor and incorporates an integrated IV pole to hang the sterile-water and saline sources, enabling convenient system positioning and fluid management.
C	Generator	The Generator is the central processing for the system and is used with the Delivery Device for the ablation of prostate tissue. The Generator displays the Operator User Interface (OUI) controls and monitors the process.
D	Stabilizer System	The Stabilizer System holds functional components of the System in place to allow a single user to move safely and easily between components. It is also designed to minimize device movement during treatments for optimal therapeutic effect.
E	TRUS Cradle	The TRUS Cradle holds the TRUS (Transrectal Ultrasound) Probe and contains a button to engage and disengage the Stabilizer Arm.

Label	Component	Functional Description
F	Delivery Device	The Delivery Device is inserted into the prostatic urethra, positioned and rotated for alignment, deploys and advances a Needle to the targeted treatment area, and creates and delivers water vapor.
G	Field Generator	The Field Generator generates an electromagnetic field which, together with sensors on the Delivery Device and TRUS Cradle, provide navigation aids to the user to enable optimal Needle placement prior to vapor delivery.
H	Ultrasound	The Ultrasound provides the primary means of imaging guidance during the procedure. Using a TRUS probe, the prostate is viewed live in both the transverse (axial) and sagittal views during Delivery Device positioning, Needle advancement, and vapor delivery.
I	Cystoscopy	The Cystoscopy system is used together with a rigid Storz lens to provide viewing of the urethra during Delivery Device insertion and the prostatic urethra during device positioning and vapor treatment.

3.4 Software Interface Overview

The Vanquish System features a user-friendly software interface designed to provide intuitive control of the Generator and real-time guidance and visualization for the physician. The interface is comprised of two main functional areas:

3.4.1 Operator User Interface (OUI)

Figure 3-2: Operator User Interface (OUI)

The Operator User Interface (OUI) is located on the Generator and is used to assist with system setup, configuration, and intra-procedural support (**Figure 3-2**). The OUI provides access to both informational displays and adjustable system settings. Through the OUI, users can verify setup status, configure system preferences, adjust operational parameters, and monitor system connections. In addition, the OUI enables access to treatment-related functions that correspond with those shown on the Physician User Interface (PUI).

3.4.2 Physician User Interface (PUI)

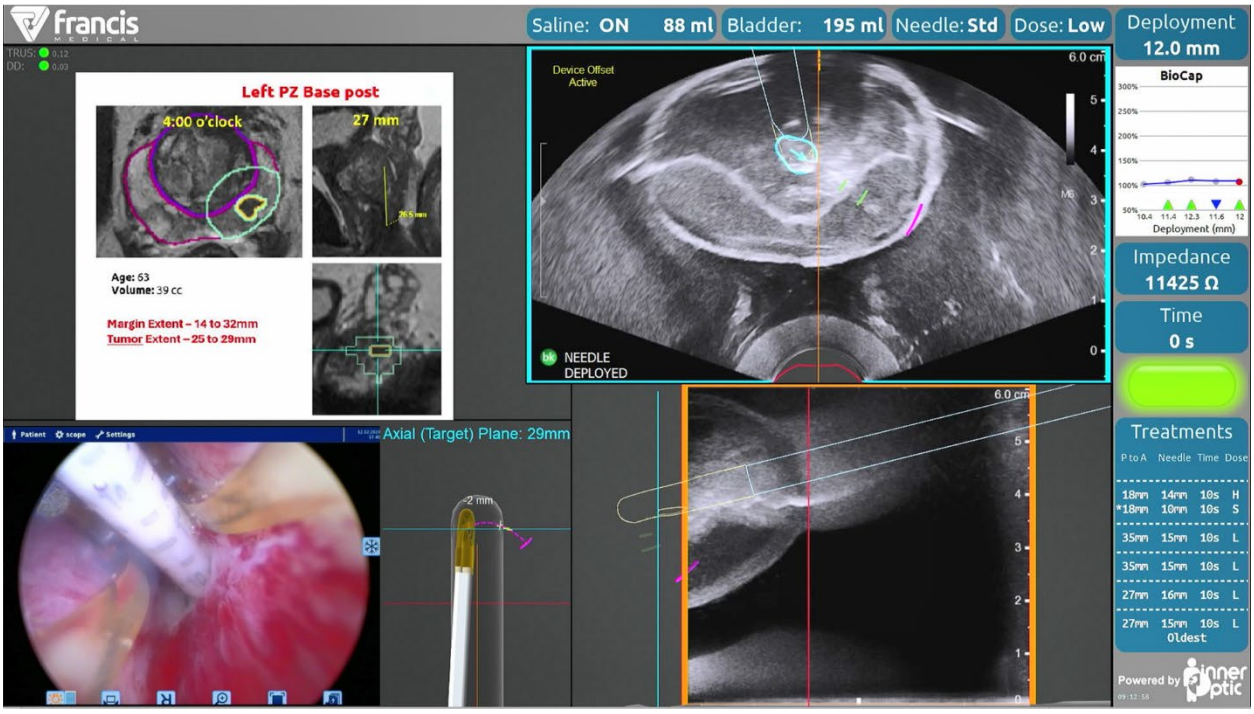


Figure 3-3: Physician User Interface (PUI)

The Physician User Interface (PUI) is displayed on the system monitor above the patient and is used during treatment to support image-guided navigation, device positioning, and procedural decision-making. The PUI consolidates real-time imaging, procedural feedback, system status indicators, and navigation cues into a single interface designed to enhance clinical workflow and safety (**Figure 3-3**).

4 Vanquish Performance

4.1 Vanquish System Performance

The performance of the Francis Medical Vanquish Water Vapor Ablation System has been evaluated through bench testing, adherence to applicable standards, and clinical studies. The key performance claims for the system are detailed throughout these Instructions for Use and are summarized below:

- **Clinical Performance**: The claimed clinical safety and effectiveness of the system for the thermal ablation of targeted prostate tissue are detailed in **Section 4.2**, Vanquish Clinical Performance. This section includes specific data on biopsy results, prostate volume reduction, and PSA reduction.
- **Technical and Operational Performance**: The system's claimed operational parameters, physical characteristics, precision, and accuracy are specified in **Section 17.3**, Technical Specifications.
- **Essential Safety Performance**: Key performance claims related to basic safety, including physiological effects and temperature of applied parts, are described in **Section 17**, IEC 60601 Basic Safety and Essential Performance.
- **Electromagnetic Compatibility (EMC) Performance**: The system's claimed performance regarding its immunity to and emission of electromagnetic energy within a professional healthcare environment is detailed in **Section 17.1.3**, Electromagnetic Compatibility (EMC) and Immunity (EMI).

- **Cybersecurity:** The system incorporates cybersecurity measures to ensure safe and secure operation. These measures are described in **Section 17.2**, Cybersecurity.
- **Biocompatibility, Sterilization, and Validation:** The Vanquish System and its components have undergone biocompatibility testing, sterilization validation, and software verification and validation to ensure they meet all safety and performance requirements.

4.2 Vanquish Clinical Performance

Study Design

The performance of the Francis Medical Vanquish Water Vapor Ablation System is supported by the manufacturer sponsored VAPOR 2 (NCT05683691) pivotal study, a prospective, single-arm clinical study of an intermediate risk prostate cancer patient population to evaluate the safety and effectiveness of the Vanquish System to ablate targeted prostate tissue per the FDA Guidance Clinical Investigations for Prostate Tissue Ablation Devices.

A total of 235 patients were treated with the Vanquish System at 26 sites in the United States from July 2023 to February 2025. A pre-specified analysis of the first 110 patients with 6-month effectiveness and 12-month safety was completed and summarized below.

Key Inclusion Criteria

- ≥50 years of age; with life expectancy of ≥10 years
- 20-80cc prostate size measured by MRI
- PSA ≤15 ng/ml
- Cancer stage ≤T2c
- Historic mpMRI fusion biopsy indicating a single PI-RADS 3 or 4 lesion with biopsy confirmed Gleason Grade Group (GGG) 2 cancer
- Less than 34% of systematic biopsy cores are positive for GGG 1 or 2 disease
- Qualifying lesion <15mm in diameter

Key Exclusion Criteria

- MRI evidence of extracapsular extension of lesion
- Prior prostate or bladder neck interventions
- Rectal pathology, anomaly, or previous treatment that could change properties of rectal wall or insertion and use of TRUS
- Active urinary tract infection
- Allergy to medication such as MRI contrast or anesthesia

Efficacy Results

The VAPOR 2 study effectiveness endpoints per FDA Guidance are reported as follows using an intent-to-treat (ITT) lesion plus 1 cm margin, treatment approach in 110 subjects:

- Biopsy Results: using multiple imputation, 74.8% of subjects show negative biopsy at six months.
- Prostate Volume Reduction: average prostate volume reduction at 6-months for 110 subjects as measured by MRI is 20.6% (±12.5% standard deviation).
- PSA Reduction for 108 subjects at 12-months is 52.2% (± 27.6% standard deviation).

Safety Results

The VAPOR 2 study interim safety results are summarized as follows for 110 treated subjects:

- No reported unanticipated adverse device effects (UADE).
- Nearly all reported adverse events (94%) were non-serious.
- Nearly all device and/or procedure-related adverse events (96%) were mild to moderate (CTCAE Grade 1 or 2).
- No reported serious device-related adverse events.
- 5 reported serious procedure-related adverse events; all resolved prior to 12 months and are expected with a transurethral procedure or general anesthesia:

Table 3: Serious Procedure-Related Adverse Events

Event(s)	Adjudication to procedure	CTCAE Grade
Thromboembolic Event	Probable	Moderate
Peripheral Ischemia	Possible	Life Threatening
Myocardial Infarction	Possible	Life Threatening
Urinary tract Infection	Probable	Severe
Hyponatremia	Possible	Severe

Other Procedure-Related Events of Interest

Ongoing procedure-related events at 12-months with highest frequency include ejaculatory dysfunction, erectile dysfunction, and urinary incontinence. These events are anticipated for a prostate intervention.

Table 4: Ongoing Procedure-Related Events at 12-Months with Highest Frequency

Event	Grade	CTCAE Grade Definition	n	%
Erectile Dysfunction (n=18/110)	Grade 1	No intervention indicated	2	1.8%
	Grade 2	Medication/interventions successfully manage symptoms	11	10.0%
	Grade 3	Medication/intervention not successful	5	4.5%
Ejaculation Disorder (n=18/110)	Grade 1	Diminished ejaculation	7	6.4%
	Grade 2	Anejaculation or retrograde ejaculation	11	10.0%
Urinary Incontinence (n=8/110)	Grade 1	No pads indicated	5	4.5%
	Grade 2	Spontaneous leakage with pad use	3	2.7%
	Grade 3	Intervention indicated (e.g. clamp, artificial sphincter)	0	0.0%

Conclusion

The VAPOR 2 study confirms that the Vanquish System is safe and effective for the ablation of targeted prostate tissue. The device can be safely used as a minimally invasive treatment approach for this intermediate risk prostate cancer patient population and use of the proposed device does not result in any new concerns about safety or effectiveness based on the predicate device.

5 Vanquish System Capital and Reusable Components

The capital and reusable components of the Vanquish System are described in this section.

5.1 Cart and Monitor

The Vanquish Cart and Monitor (4741-001) is a component of the Vanquish System designed to support and power essential devices during procedures. This powered cart features two shelves and drawers for the Vanquish Generator and related accessories. It also includes a monitor on an adjustable arm and an IV pole to facilitate an efficient and ergonomic workflow.

The Vanquish Cart and Monitor (4741-001) includes the following components (not detachable):

- Monitor – Qty: 1
- Cart Base – Qty: 1
- IV Pole – Qty: 1

The Vanquish Cart and Monitor and its functional components are shown in **Figure 5-1** and described in **Table 5**.

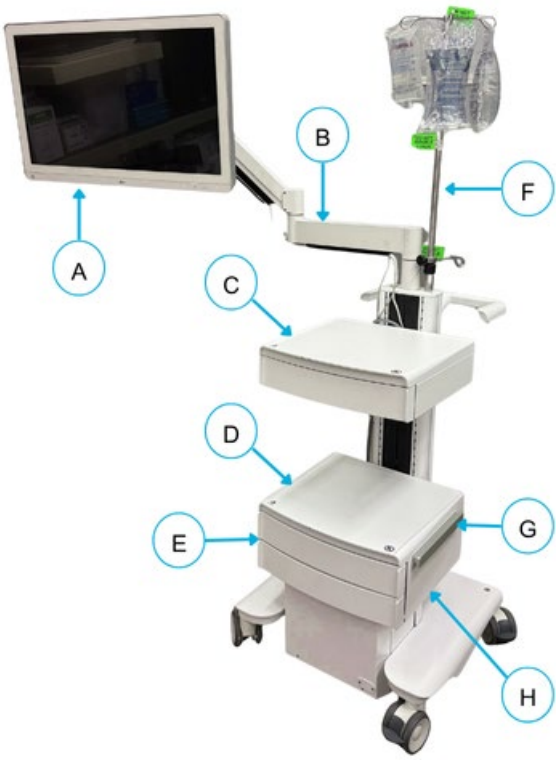


Figure 5-1: Vanquish Cart

Table 5: Vanquish Cart Functional Description

Label	Name	Functional Description
A	Monitor	The Monitor, mounted above the patient, displays the Physician User Interface (PUI) which shows critical treatment metrics together with live Ultrasound, Cystoscopy, and NGS images for real-time guidance.
B	Monitor Arm	Allows the physician to adjust the monitor position for optimal viewing during the procedure.

Label	Name	Functional Description
C	Shelf	Supports and securely holds the Vanquish Generator during use.
D	Bottom Shelf	Provides space for placement of ancillary tools or equipment.
E	Drawers	Used to store procedure supplies or reusable Stabilizer Arms when not in use.
F	IV Pole	Holds fluid bags used during treatment, including Perineal Saline, Urethral Saline, and Sterile Water.
G	Rails	Provides a place for Clark Clamps to be attached when not in use.
H	Multi Socket Outlet (MSO)	Provides six power outlets and a power cord to connect the Cart to a wall outlet; located at the base on the back side of the Cart.

5.2 Generator

The Vanquish Generator is a core component of the Vanquish System, responsible for powering and controlling key procedural functions. It interfaces directly with the Delivery Device and other system components to support accurate, efficient treatment delivery. The Generator also integrates seamlessly with imaging systems, fluid management, and accessory components—providing essential functionality for successful operation.

Primary Functions:

- Powers and communicates with the Delivery Device
- Controls the delivery of sterile water for vapor generation
- Manages urethral saline flush delivery
- Provides perineal saline irrigation
- Processes tool tracking data from the Needle Guidance System (NGS) system
- Displays real-time treatment and Delivery Device status information

The Vanquish Generator Kit (4751-001) includes the following subcomponents:

- Vanquish Generator (4731-001) – Qty: 1
- Power Cord – Qty: 1
- HDMI Cable – Qty: 1
- DVI Cable – Qty: 1
- DVI to HDMI Cable – Qty: 1
- Serial Cable DB9 – Qty: 1
- DVI to HDMI Adapter – Qty: 1
- Software Version 3.0

The Vanquish Generator and its functional components are shown in **Figure 5-2, Figure 5-3,** and **Figure 5-4** are described in **Table 6**.

Figure 5-2: Vanquish Generator, Front View

Figure 5-3: Vanquish Generator, Back View

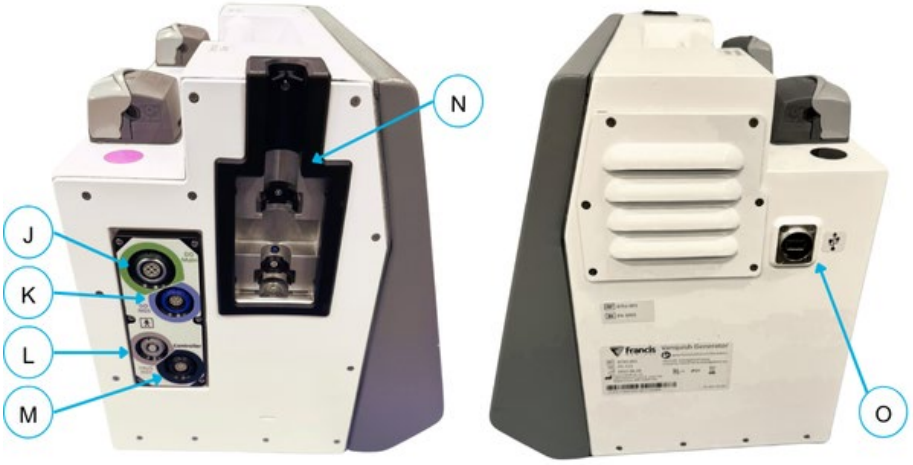


Figure 5-4: Vanquish Generator, Side Views

Table 6: Vanquish Generator Functional Description

Label	Name	Functional Description
A	Screen	Touchscreen display used to view the Operator User Interface (OUI) and interact with the Generator.
B	HDMI Ports	Transmits video signals from the Generator to the Monitor.
C	Field Generator Port	Connects the Field Generator to the Generator for electromagnetic tracking.
D	Power Switch	Turns the Generator ON or OFF.
E	Power Cord	Provides electrical power to the Generator.
F	DVI Port	Connects the Ultrasound to the Generator using an HDMI-to-DVI cable.
G	Monitor Port (IOIOI)	Connects the Monitor to the Generator to control the PUI viewing mode.
H	Perineal Saline Pump	Pumps saline through the Saline Needle Tubing to the Saline Catheter Needle. The Saline Needle Tubing is loaded into the pump via the Perineal Saline Pump Door, guided by matching color indicators on the Generator and tubing.
I	Urethral Saline Pump	Pumps saline through the tubing to the Delivery Device. The Urethral Saline line is loaded into the pump via the Urethral Saline Pump Door, guided by matching color indicators on the Generator and tubing.
J	Delivery Device Main Port	Connection point for the green end of the Delivery Device split cable, enabling the Delivery Device controls from the Generator and providing power to the Delivery Device.
K	Delivery Device NGS Port	Connection point for the blue end of the Delivery Device split cable, enabling NGS tracking of the Delivery Device.
L	TRUS NGS Port	Connection point for the TRUS Cradle cable, enabling NGS tracking of the TRUS Probe.
M	Controller Port	Connects the Controller to the Generator for input control and power.
N	Syringe Cradle	Holds the Auto-Refill Syringe in place during sterile water delivery and refill.
O	USB Port	Supports user-generated Treatment Plan import and system log export using a USB flash drive.

5.3 Capital Mounts

The Vanquish Capital Mounts Kit holds the functional components of the Vanquish System in place to allow a single user to move safely and easily between components. It is also designed to minimize device movement during treatments for optimal therapeutic effect.

- Attaches to standard surgical table bed rails
- Supports both locked and free-motion states for positioning and stability of the TRUS probe and Delivery Device
- Facilitates single-user operation across multiple components
- Reduces the risk of inadvertent motion following deployment of the Needle

The Vanquish Capital Mounts Kit (4752-001) includes the following subcomponents:

- Vanquish Motor Control Box (4736-001) — Qty: 2
- Stabilizer Mount, Horizontal — Qty: 2
- Stabilizer Mount, Vertical — Qty: 2
- Field Generator — Qty: 1
- Field Generator Arm — Qty: 1
- Clark Clamp — Qty: 5
- Power Supply, Motor Control Box — Qty: 2
- DC Power Cord, Motor Control Box — Qty: 2

5.3.1 Field Generator

The Field Generator produces the electromagnetic field used, together with sensors on the Delivery Device and TRUS Cradle, to generate the NGS navigation aids.

The Field Generator and adjustable Field Generator Arm are subcomponents of the Vanquish Capital Mounts Kit (4752-001).

The Field Generator Arm is connected to the OR Bed Rail with a Clark Clamp. The Field Generator Arm holds the Field Generator in place over the patient during a procedure, and the Adjustment Knob allows for loosening and repositioning of the Field Generator as needed.

The Field Generator and its functional components are shown in **Figure 5-5** and described in **Table 7**.

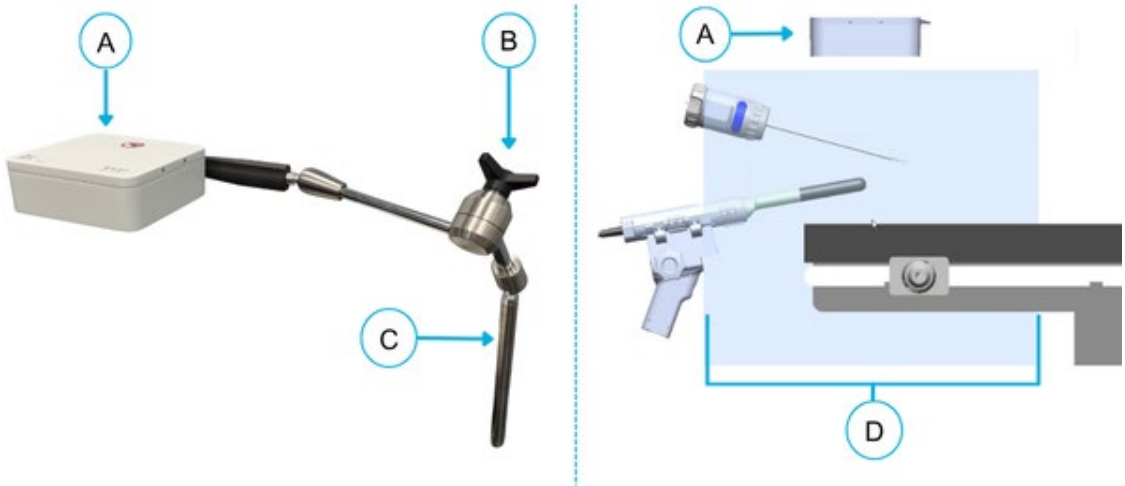


Figure 5-5: Field Generator

Table 7: Field Generator Functional Description

Label	Name	Functional Description
A	Field Generator	Generates the electromagnetic field used by the NGS for real-time tracking of the Delivery Device and TRUS Probe.
B	Field Generator Adjustment Knob	Loosens or tightens the Field Generator Arm to allow repositioning or maintain stability.
C	Field Generator Arm	Attaches to the OR table via a Clark Clamp and holds the Field Generator in position over the patient.
D	Field	50mm offset from field generator, Cubic Volume 500mm x 500mm x 500mm.

5.4 Stabilizer Arm Kit

The Vanquish Stabilizer Arm Kit (5536-001) includes the following subcomponents:

- Delivery Device Stabilizer Arm (Long) — Qty: 1
- TRUS Stabilizer Arm (Short) — Qty: 1
- Controller Arm and Knob — Qty: 1

The Vanquish Stabilizer System and its functional components are shown in **Figure 5-6** and described in **Table 8**.

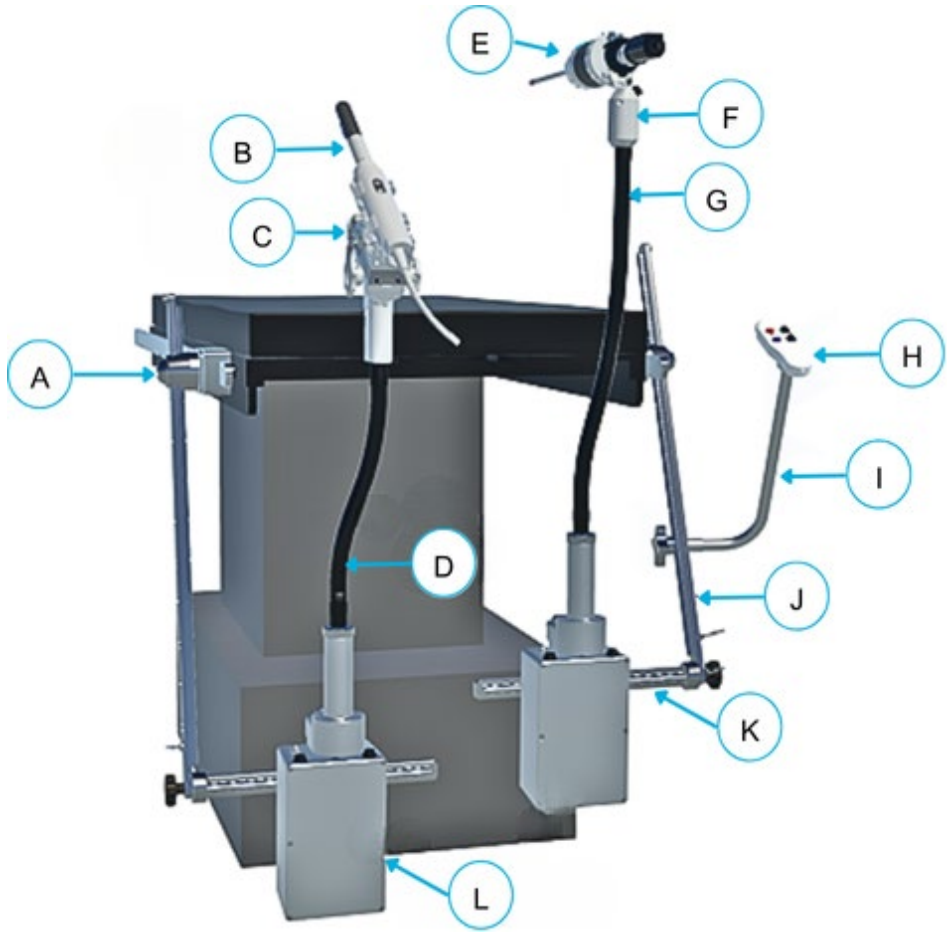


Figure 5-6: Vanquish Stabilizer System (Capital Mounts, Stabilizer Arm Kit, and Accessories)

Table 8: Vanquish Stabilizer System Functional Description

Label	Name	Functional Description
A	Clark Clamp	Secures accessories (e.g., Field Generator Arm, Capital Mounts) to the side rails of a standard OR bed. Also known as a Clark Socket.
B	TRUS Probe	Transrectal ultrasound probe which is placed in the TRUS Cradle and connected to the Ultrasound system for imaging.
C	TRUS Cradle	Holds the TRUS Probe and includes a button to engage or disengage the TRUS Stabilizer Arm.
D	TRUS (Short) Stabilizer Arm	Locks the TRUS Cradle and Probe in place when engaged and allows free movement when disengaged.
E	Delivery Device	The Delivery Device is inserted into the prostatic urethra, positioned and rotated for alignment, deploys and advances a Needle to the targeted treatment area, and creates and delivers water vapor.
F	Delivery Device Attachment	Connects the Delivery Device to the Delivery Device Stabilizer Arm and includes a switch to engage or disengage the arm.
G	Delivery Device (Long) Stabilizer Arm	Locks the Delivery Device in place when engaged and allows free movement when disengaged.
H	Controller	Provides the user interface for executing treatment functions; magnetically attaches to the Controller Arm when not in use.
I	Controller Arm	Holds the Controller via magnetic attachment and can be repositioned for convenient access.
J	Vertical (Long) Stabilizer Mount	Attaches to the bed rails and supports all Stabilizer System components.
K	Horizontal (Short) Stabilizer Mount	Connects to the Vertical Mount and provides a mounting point for the Motor Control Boxes at the foot of the bed.
L	Motor Control Box	Controls the engagement and disengagement of the Stabilizer Arms.

6 Vanquish System Single-Use (Disposable) Components

The Vanquish System includes single-use components available from Francis Medical:

6.1 Stabilizer Kit

The Vanquish Stabilizer Kit (4573-001) includes the following subcomponents:

- TRUS Cradle — Qty: 1
- Delivery Device Attachment — Qty: 1
- Thumb Screw — Qty: 3

6.1.1 Transrectal Ultrasound (TRUS) Cradle

The TRUS Cradle is a component of the Vanquish System that connects to the TRUS Stabilizer Arm and holds the TRUS Probe. The TRUS Cradle contains a button to engage and disengage the TRUS Stabilizer Arm and incorporates mechanisms for fine longitudinal and rotational adjustments of the probe position during the procedure. A TRUS Cradle cable connects to the Motor Control Box, supplying power to the TRUS Stabilizer Arm, and a second cable connects to the Generator to enable NGS communication.

The TRUS Cradle and Thumb Screw is provided sterile. The TRUS Cradle and its functional components are shown in **Figure 6-1** and **Figure 6-2** and are described in **Table 9**.

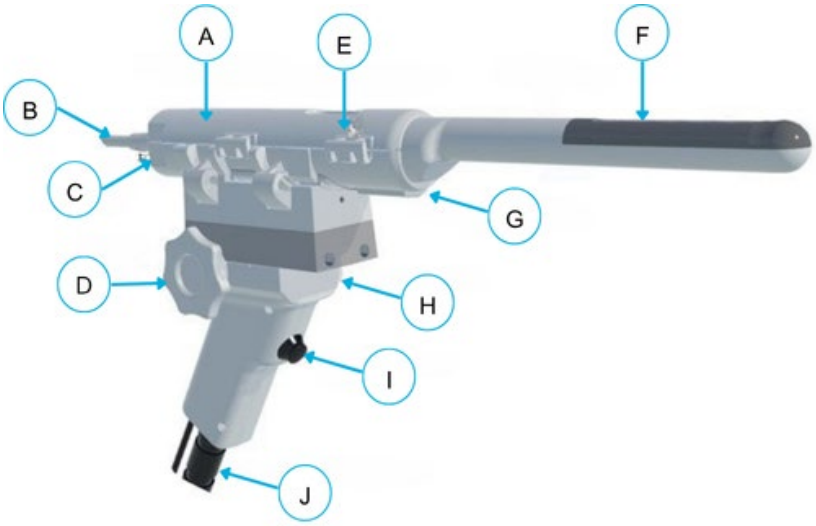


Figure 6-1: TRUS Cradle and Probe

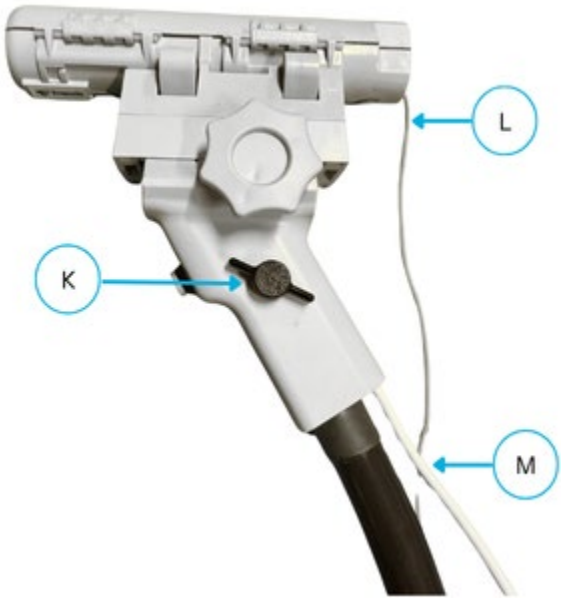


Figure 6-2: TRUS Cradle view 2

Table 9: TRUS Cradle Functional Description

Label	Name	Functional Description
A	TRUS Sleeve Holder	Holds the TRUS probe in place when locked.
B	TRUS Cable	Connects the TRUS probe to the Ultrasound system.
C	Rotational Adjustment	Allows for manual rotation of the TRUS Cradle and probe.
D	Fine Axial Adjustment	Allows for manual longitudinal adjustment of the TRUS Probe.
E	Locking Mechanism	Secures the TRUS Probe within the TRUS Cradle using two latches.
F	TRUS Probe	Transrectal ultrasound probe used with the TRUS Cradle and Ultrasound system.

Label	Name	Functional Description
G	TRUS NGS Sensor	Provides position data for the TRUS Probe within the electromagnetic field.
H	Handle	Holds the TRUS Probe and includes the button to engage or disengage the Stabilizer Arm.
I	Stabilizer Power Button	Engages or disengages the Stabilizer Arm to allow positioning or locking.
J	TRUS Stabilizer (Short) Arm	Adjustable arm that positions and holds the TRUS Cradle in place when locked.
K	Thumb Screw	Secures the TRUS Cradle to the TRUS Stabilizer Arm.
L	TRUS NGS Cable	Connects the TRUS NGS Sensor to the Generator for positional data.
M	TRUS Cradle Cable	Connects to the Motor Control Box to enable locking/unlocking via the Stabilizer Power Button.

6.1.2 Delivery Device Attachment

The Delivery Device Attachment is a component of the Vanquish System that connects to the Delivery Device Stabilizer Arm and holds the Delivery Device. The Delivery Device Attachment contains a switch to engage and disengage the Delivery Device Stabilizer Arm. A Delivery Device cable connects to the Motor Control Box, supplying power to the Delivery Device Stabilizer Arm.

The Delivery Device Attachment and Thumb Screw is provided sterile.

The Delivery Device Attachment and its functional components are shown in **Figure 6-3** are described in **Table 10**.

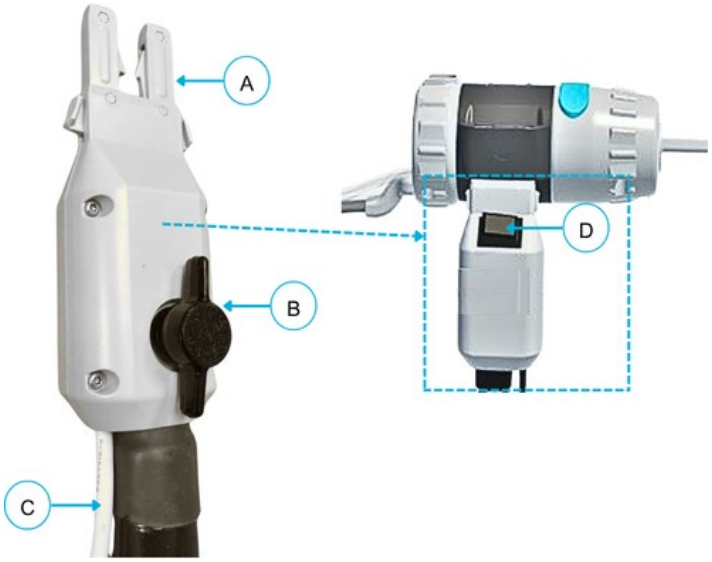


Figure 6-3: Delivery Device Attachment

Table 10: Delivery Device Attachment Description

Label	Name	Functional Description
A	Delivery Device Attachment	Attaches the Delivery Device to the Delivery Device Stabilizer Arm and includes the button to engage or disengage the arm.
B	Thumb Screw	Secures the Delivery Device Attachment to the Delivery Device Stabilizer Arm.
C	Delivery Device Attachment Cable	Connects to the Motor Control Box to enable locking/unlocking of the Delivery Device Stabilizer Arm.
D	Delivery Device Attachment Switch	Unlocks the Stabilizer Arm for repositioning or locks it for Delivery Device stability.

6.2 Delivery Device

The Vanquish Delivery Device is a component of the Vanquish System. During the procedure, the Delivery Device is inserted into the prostatic urethra, positioned and rotated for alignment, deploys and advances a Needle to the targeted treatment area, and creates and delivers water vapor.

The Delivery Device is provided sterile.

There are three Vanquish Delivery Devices with different Needle configurations. Selection is based on the predetermined treatment plan. The Needle configurations are shown in **Figure 6-4** and are described in **Table 11**.

- Vanquish Delivery Device – Standard (STD) (4570-001)
- Vanquish Delivery Device – PZ (4571-001)
- Vanquish Delivery Device – Retreatment (RTX) (5257-001)

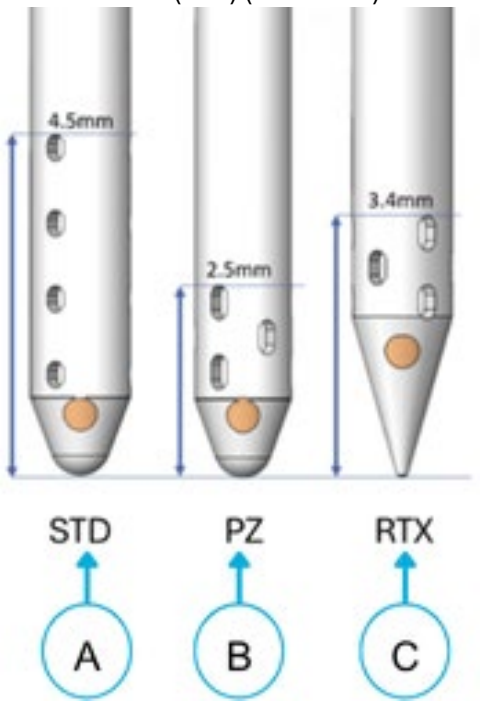


Figure 6-4: Delivery Device Needle Configurations

Table 11: Delivery Device Needle Configurations

Label	Name	Functional Description
A	Standard (STD) Needle	The STD Needle can be used in the majority of prostates. It has 12 vapor emitter holes, with the most proximal emitter holes being 4.5 mm from the tip of the Needle. The minimum treatment depth is 6 mm for the Standard Needle.
B	Peripheral Zone (PZ) Needle	The PZ Needle has nine emitter holes, with the most proximal holes being 2.5 mm from the tip of the Needle. The PZ Needle may be needed in prostates with a very narrow peripheral zone or other small treatment areas. The minimum treatment depth is 4 mm for the PZ Needle.
C	Retreatment (RTX) Needle	The RTX Needle, like the PZ Needle, has nine emitter holes, with the most proximal holes being 3.4 mm from the tip of the Needle. The RTX Needle incorporates a sharper Needle tip that can be used in cases where challenging anatomy might make movement of the Needle all the way to the target more difficult. An example would be performing retreatment of a previously treated prostate, where the remaining tissue can become more unyielding. The minimum treatment depth is 5 mm for the RTX Needle.

All Delivery Devices have the same design and features, except for the Needle tip. The Vanquish Delivery Device and its functional components are shown in **Figure 6-5** and **Figure 6-6** and described in **Table 12**.

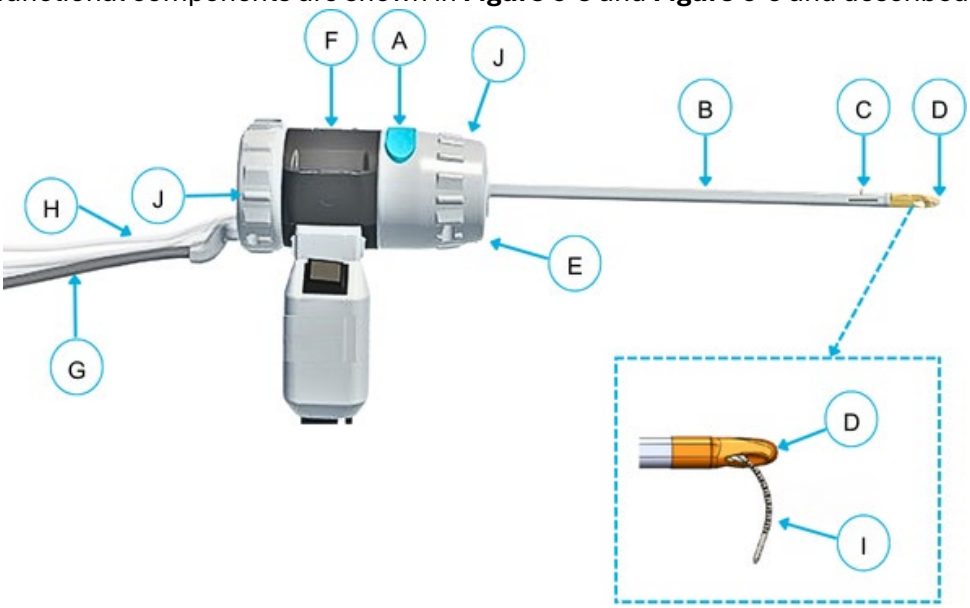


Figure 6-5: Vanquish Delivery Device

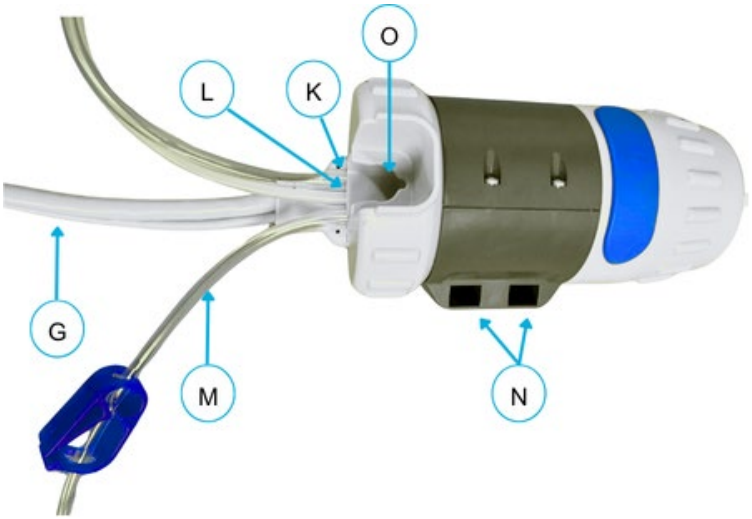


Figure 6-6: Vanquish Delivery Device Lines and Delivery Device Attachment

Table 12: Vanquish Delivery Device Functional Description

Label	Name	Functional Description
A	Flush Activation/Saline Flush Button	Activates urethral saline flush; supports both normal and turbo flush modes.
B	Shaft	Houses the needle, rigid cystoscope lens, and irrigation pathways.
C	NGS Sensor	Reports the Delivery Device's position within the electromagnetic field for navigation tracking.
D	Shaft Tip	Distal end of the shaft where the needle is deployed into target tissue.
E	Pullout Pin	Enables manual needle retraction in the event of Delivery Device failure.
F	Non-Rotating Member	Fixed, non-rotating portion of the Delivery Device connected to the Delivery Device Attachment.

Label	Name	Functional Description
G	Delivery Device Split Cable	Connects to the Generator and provides power and signal communication to the Delivery Device.
H	Saline and Water Paired Tubing	Saline line provides urethral irrigation; water line delivers sterile water into the Delivery Device.
I	Needle	Deploys from the shaft and is inserted into the prostate to deliver vapor therapy.
J	Rotating Members	Allows clockwise or counterclockwise rotation of the Delivery Device to align the Needle trajectory with the targeted tissue.
K	Saline Line	Transports saline from the urethral saline bag, through the Urethral Saline Pump on the Generator, to the Delivery Device.
L	Water Line	Transports sterile water from the Generator to the Delivery Device for vapor generation.
M	Drain Line	Provides a pathway to drain fluid from the bladder when unclamped.
N	Delivery Device Attachment Connection	Mechanical interface where the Delivery Device Attachment connects to the Delivery Device.
O	Rigid Cystoscope Lens Port	Entry point for inserting the rigid cystoscope lens into the Delivery Device.

6.3 Accessory Kit

The Vanquish Accessory Kit (4572-001) includes the following subcomponents:

- Controller — Qty: 1
- Auto-Refill Syringe and Tubing Set — Qty: 1
- Saline Needle Tubing Set — Qty: 1

6.3.1 Controller

The Controller is the primary interface for operating the Delivery Device during treatment. It allows the user to deliver vapor, control needle movement, and manage saline flushes.

The Controller is provided sterile.

The Vanquish Controller is a component of the Vanquish Accessory Kit (4572-001).

The Controller and its functional components are shown in **Figure 6-7** and described in **Table 13**.

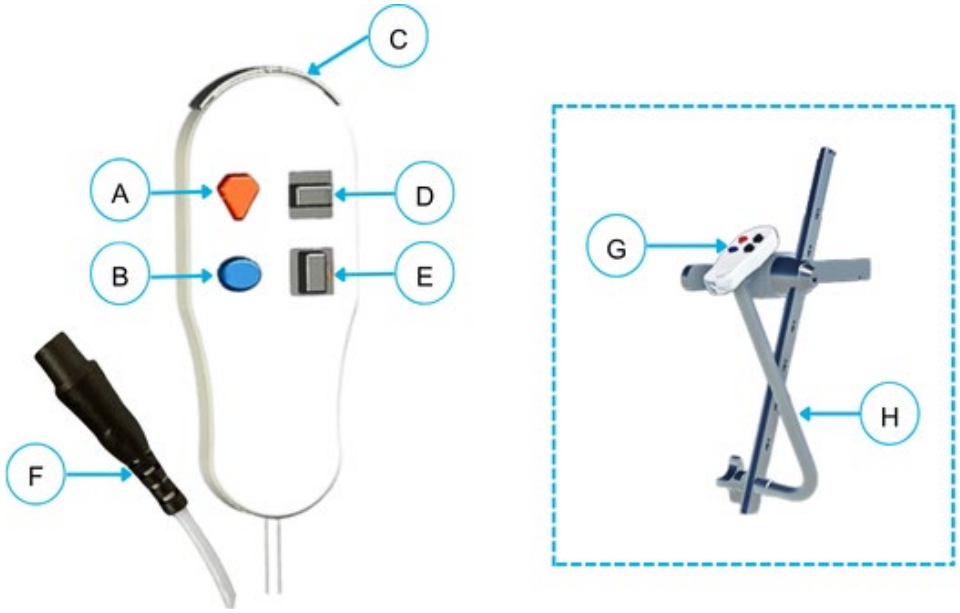


Figure 6-7: Controller

Table 13: Controller Functional Description

Label	Name	Functional Description
A	Vapor Delivery Button	Activates vapor delivery after the Needle has been deployed.
B	Urethral Saline Flush Button	Delivers saline flush through the Delivery Device for urethral irrigation.
C	Perineal Saline Flush Button	Delivers turbo saline flush to the periprostatic space.
D	Needle Advance/Retract Button	Deploys and advances or retracts the Needle to reach the treatment target or return it to the Delivery Device.
E	Needle Deployment Length Button	Sets the initial Needle deployment length and controls instant replay.
F	Controller Cable	Connects the Controller to the Generator and supplies power.
G	Controller	User interface for activating treatment functions via buttons described in A–E. Magnetically attaches to the Controller Arm when not in use.
H	Controller Arm	Adjustable arm with magnetic holder for storing the Controller when not in use.

6.3.2 Auto-Refill Syringe and Tubing Set

The Auto-Refill Syringe and Tubing Set connects the sterile water supply to a syringe pump on the System Generator, designed to deliver sterile water at a pre-defined rate to the Delivery Device for the generation of water vapor.

The Auto-Refill Syringe and Tubing Set is provided sterile.

The Auto-Refill Syringe and Tubing Set and its functional components are shown in **Figure 6-8** and described in **Table 14**.

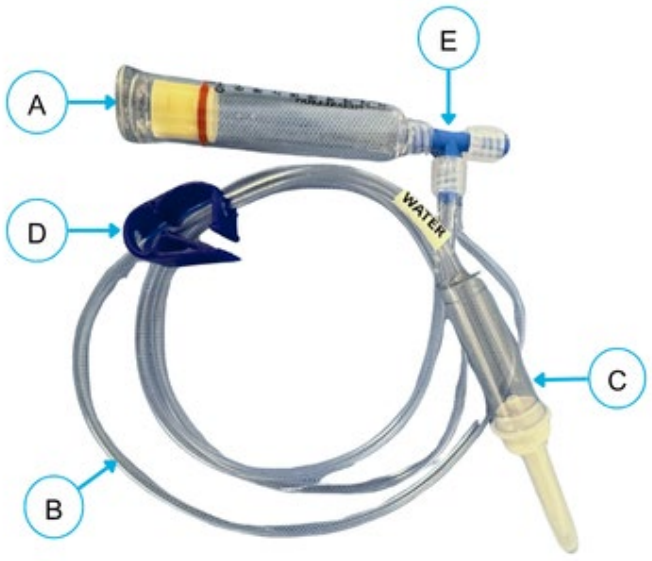


Figure 6-8: Auto-Refill Syringe and Tubing Set and Sterile Water Bag

Table 14: Auto-Refill Syringe and Tubing Set Functional Description

Label	Name	Functional Description
A	Syringe	Holds sterile water that is pumped into the Delivery Device to generate vapor. Housed in the Generator Syringe Cradle.
B	Auto-Refill Syringe Tubing	Connects the Syringe to the sterile water bag on the IV pole.
C	Spike	Connects the tubing and Syringe to the sterile water bag.
D	Clamp	Controls the flow of water through the tubing.
E	Check-Valve	Valve to control fluid flow direction. Allows fluid in the sterile water bag to flow into the Syringe and from the Syringe to the Delivery Device.

6.3.3 Saline Needle Tubing Set and Saline Catheter Needle

The Saline Needle Tubing Set is used to connect the Saline Catheter Needle to a 0.9% Injectable Grade Saline bag.

The Transperineal Saline Catheter Needle is used for the insertion of saline into the periprostatic space between the rectum and prostate during vapor treatments. This provides additional safety by lifting the prostate up and away from the rectum and a cooling effect to structures outside the prostate capsule.

The Saline Needle Tubing Set and Saline Catheter Needle are provided sterile.

The Saline Catheter Needle can be purchased in two sizes, 10 cm or 15 cm.

- 10 cm Saline Catheter Needle (4840-001)
- 15 cm Saline Catheter Needle (5245-001)

The Saline Needle Tubing Set and Saline Catheter Needle and their functional components are shown in **Figure 6-9** and described in **Table 15**.

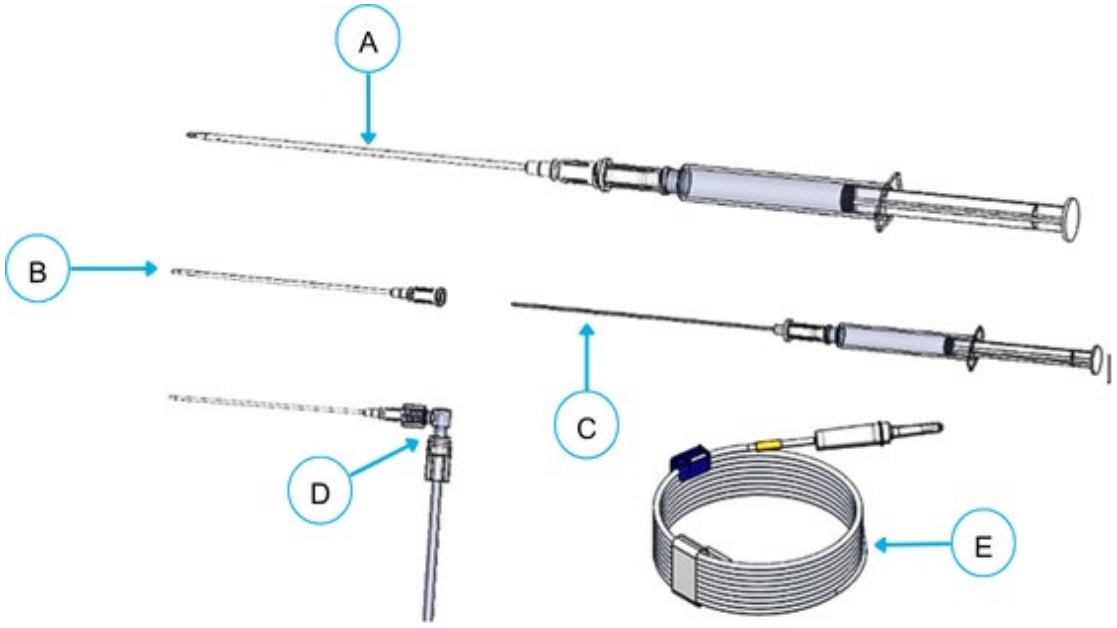


Figure 6-9: Transperineal Saline Catheter Needle and Saline Needle Tubing Set

Table 15: Transperineal Saline Needle and Tubing Set Functional Description

Label	Name	Description
A	Saline Catheter Needle and Catheter Sheath Assembly	Combines a Catheter Needle and a preloaded Catheter Sheath with Luer Hubs, allowing for single-unit insertion.
B	Catheter Sheath	Slides over the Catheter Needle. Remains in place after needle removal and connects to the Saline Catheter Tubing via the Luer Hub.
C	Saline Catheter Needle	Used to insert the assembly into the periprostatic space. Removed after positioning to leave the Catheter Sheath in place.
D	Saline Catheter Tubing Luer Hub	Connects the Saline Catheter Sheath to the Saline Needle Tubing.
E	Saline Needle Tubing	Connects the Saline Catheter to a 0.9% sterile saline bag.

6.4 Sterile Water Bag

The Sterile Water Bag functions as the primary source of sterile water for water vapor generation. The vapor generated in the Delivery Device is delivered through the Delivery Device Needle to the target tissue for ablation.

The Sterile Water Bag is available for purchase from Francis Medical (**Figure 6-10**):

- Sterile Water Bag, 250 mL (4839-001)

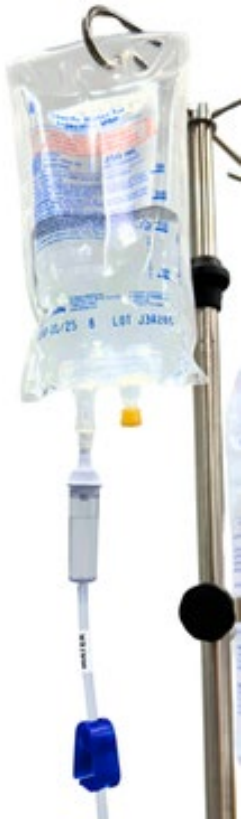


Figure 6-10: Sterile Water Bag

6.5 Non-Francis Medical-Supplied Components

The following equipment and supplies are required for system operation or clinical workflow but are not supplied by Francis Medical. These items must be sourced by the user or coordinated through Francis Medical customer service and meet the compatibility and safety requirements outlined in the Vanquish System Compatibility section of this manual (see **Section 3.2**).

- Ultrasound:
  - BK Medical bkSpecto Ultrasound System (FW Version: Distribution Build 6.68.20636.49, Software Version 6.6.8; Live Dual Mode)
  - BK Medical E14CL4b (9048) Endocavity Biplane Transducer
- Cystoscopy System:
  - Cystoscopy Tower/System (must be IEC 60601-1 and IEC 60601-2-18 compliant)
  - Karl Storz Cystoscope Lens (4 mm diameter, 30° angle, 30 cm length)
- Operating Room Table:
  - Surgical table equipped with North American standard side rails (1 ⅛ in x ⅜ in)
- Sterile Accessories:
  - 0.9% Injectable Grade Saline (1 L, 2 L, 3 L, 4 L, 5 L flexible bag at room temperature)
  - 10cc or 15cc disposable syringe with luer lock
  - Lidocaine gel anesthetic or water-soluble lubricating gel
  - Arm Sheath (Sheathing Technologies Inc. 50040-74244 or similar equivalent)
  - Camera Drape (DeRoyal 28-0401 or similar equivalent)
  - Underbuttocks Drape (Medline DYNJP6006 or similar equivalent)
  - Foley Catheter
  - Hemostat

7 Operator User Interface (OUI)

7.1 Description

The Operator User Interface (OUI), located on the Generator, is used to support system setup, configuration, and intra-procedural operation. It provides access to both system status displays and adjustable settings. Through the OUI, users can verify setup status, configure system preferences, adjust operational parameters, and monitor hardware connections. The OUI also enables access to treatment-related functions that correspond with those displayed on the Physician User Interface (PUI) (**Section 8**).

7.2 Navigation

The system software interface is designed for navigation using a combination of touchscreen and button-based controls. Users interact with on-screen menus to perform system setup, adjust settings, and access treatment-related functions.

7.2.1 Key Screens and Menus

The following screens and menus are accessible via the Operator User Interface (OUI) (**Table 16**):

Table 16: OUI Key Screens and Menus Description

Corresponding Section	Description
7.5 System Setup Screen	Used to manage system connections and complete required setup tasks**.**
7.6 Options Menu	Provides access to operational functions, including fluid management and device removal.
7.7 System Information Screen	Displays software version details, date/time settings, and log export options.

Corresponding Section	Description
7.8 Settings Menu	Allows configuration of therapy settings and Physician User Interface (PUI) preferences.
7.9 Extended Settings Menu	Used to configure supplemental features not displayed on the primary Settings screen.
7.10 Treatment Session Screen	Provides access to real-time treatment data and system status during the procedure.
7.11 Operating Condition Screen	Displays system performance and diagnostic data for service personnel.

7.2.2 Navigation Controls

The system uses the following standard navigation controls:

- **Arrows:** Used to increment or decrement values (e.g., date, time, settings).
- **Buttons:** Tapped to select menu items, confirm actions, or exit screens. A green outline indicates the currently selected button.
- **Checkboxes:** Used to enable or disable specific options.

7.2.3 Returning to Previous Screens

Users can return to previous screens or close menus using the following controls:

- Select **[Cancel]** or **[Close]** to exit the current screen without saving changes.
- Select **[Options]** or **[Settings]** to open or close their respective menus.

7.3 Audible Tones

The system uses audible tones to provide real-time audio feedback during operation. These tones alert the user to key actions, system status changes, and warnings. Descriptions and tone patterns are summarized in **Table 17**.

Table 17: Audible Tones Description

Tone Type	Description	Tone Pattern
Success Tone	Played when: • Pre-treatment is successfully completed • A full treatment is successfully completed • Volume is adjusted	Short, high-pitched chime with a clear, glass-like tone.
Treatment Ready	Played when the system is ready to perform a treatment.	Three medium-pitch tones in a short, evenly spaced sequence.
Treatment	Played once per second: • During pre-treatment • While treatment is actively in progress	Repeating series of steady, medium-pitch tones with uniform rhythm and pauses.
Partial Treatment	Played when the Vapor Activation Button is released before completing a full treatment.	Two medium-pitch tones with a brief pause, conveying interruption or incompletion.
Treatment Warning	Played when an alert appears in the Alert Window.	Single medium-pitch tone with a sharp start and soft fade.
Error Message	Played when an informational or non-critical error is reported.	Single sharp, high-pitch tone with a sudden start and no fade.
Critical Message	Played when a critical error is reported.	Repeating series of sharp, high-pitch tones with regular spacing and abrupt start.
Key Click	Played when an on-screen button is pressed, except for the volume adjustments (which trigger the Success tone).	Brief, low-pitch click with a crisp, tactile feel.

7.4 Pop-Up Messages and Errors

The system displays color-coded pop-up messages to communicate informational updates and error conditions. These messages appear as overlays on the screen and are categorized based on severity. For details on specific error codes, causes, and messages, refer to the **Troubleshooting** section in **Appendix A: Troubleshooting**.

7.4.1 Informational Messages

Informational messages appear with a blue border (see **Figure 7-1**).

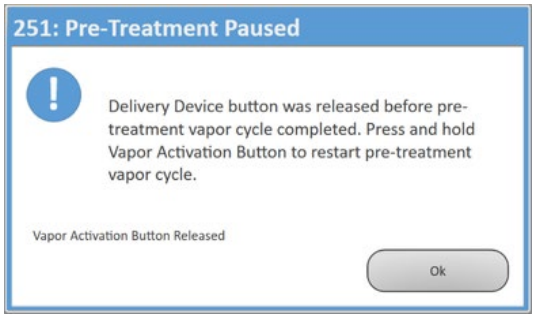


Figure 7-1: Informational Messages

7.4.2 Non-Critical Errors

Non-critical errors appear with an orange border (see **Figure 7-2**).

Figure 7-2: Non-Critical Errors

7.4.3 Critical Errors

Critical errors appear with a red border and represent system conditions that may prevent continued operation or require immediate user action (see **Figure 7-3**).

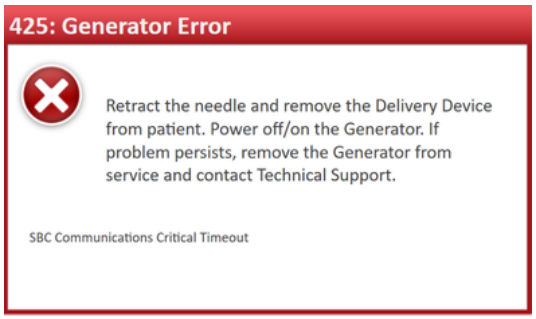


Figure 7-3: Critical Errors

7.5 System Setup Screen

The System Setup screen (**Figure 7-4**) provides access to key setup tasks and system information required before beginning a procedure. Users can view the status of system connections, complete mandatory setup steps, configure the default therapy dose, and enter system-specific parameters to ensure proper operation (see **Table 18**).

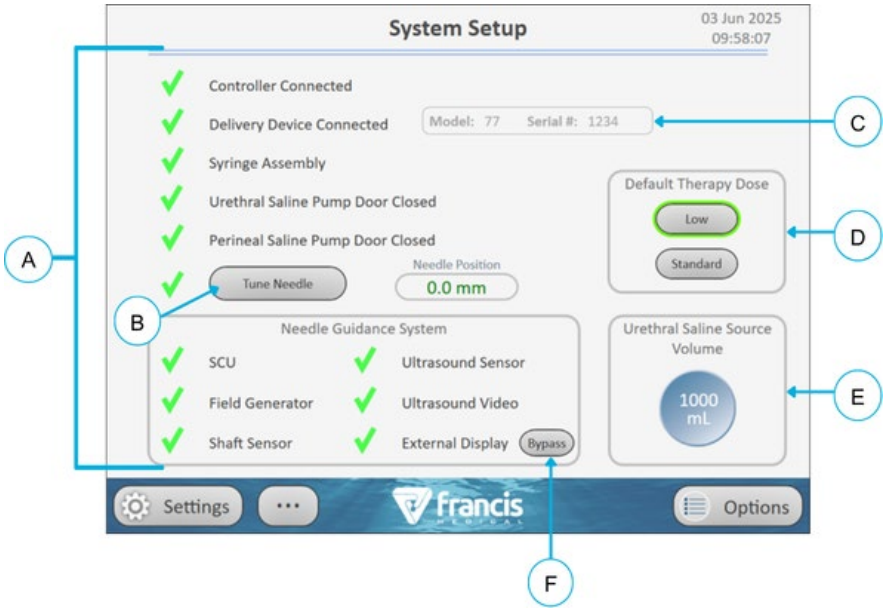


Figure 7-4: System Setup Screen

Table 18: Double : System Setup Screen Description

Label	Name	Description
A	System Setup Checklist	Displays the status of all required system connections and interlocks that must be verified before use.
B	Tune Needle Button	Initiates the needle tuning process, which is required during system setup.
C	Connected Delivery Device Information	Displays the model and serial number of the Delivery Device currently connected to the Generator.
D	Default Therapy Dose Selection	Allows the user to set the default therapy dose. After each full treatment (≥7 seconds), the system automatically reverts to the default dose. Users can override this setting on a per-treatment basis.
E	Urethral Saline Source Volume	Enables the user to enter the starting volume of the urethral saline source. The system uses this information to provide alerts when replacement is needed.

Label	Name	Description
F	External Display Bypass Button	Bypasses the external monitor interlock when the RS232 serial cable is not detected. When bypassed, changing views on the PUI will be unavailable. ■ **NOTE:** physical buttons on the monitor may be used in the event bypass is required.

7.6 Options Menu

The Options Menu is a pop-up menu that provides access to key system functions related to fluid management, device removal, and system information. Users can perform tasks such as saline flush and replacement, bladder drain confirmation, sterile water syringe refill or purge, and view system information.

To access the Options Menu:

Select **[Options]** in the bottom-right corner of the Generator screen (**A**). The Options Menu will appear along the right side of the screen (**B**) (see **Figure 7-5**).

The Options menu allows the user to select (see **Table 19**).

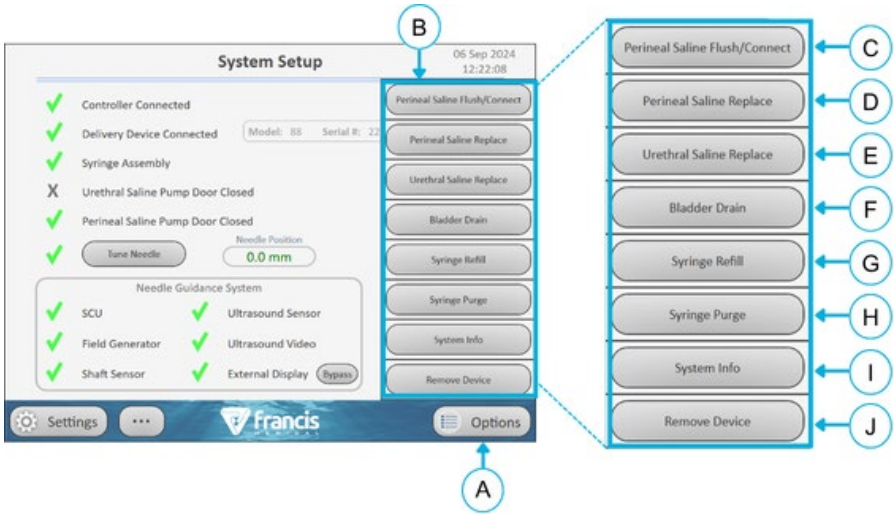


Figure 7-5: Options Menu

Table 19: Options Menu Description

Label	Name	Description
A	Options Button	Opens the Options Menu from the Generator screen.
B	Options Menu	Displays a list of available system functions for fluid management, device handling, and system information.
C	Perineal Saline Flush/Connect	Opens the screen for flushing or connecting the perineal saline needle tubing (see **Section 7.6.1**).
D	Perineal Saline Replace	Opens the screen to replace the perineal saline source (see **Section 7.6.2**).
E	Urethral Saline Replace	Opens the screen to replace the urethral saline source (see **Section 7.6.3**).
F	Bladder Drain	Opens the screen to confirm the completion of bladder drainage (see **Section 7.6.4**).
G	Syringe Refill	Opens the screen for refilling the sterile water syringe used for delivery of sterile water to the Delivery Device for vapor generation (see **Section 7.6.5**).
H	Syringe Purge	Opens the screen for purging air from the sterile water syringe system (see **Section 7.6.6**).

Label	Name	Description
I	System Info	Opens the screen displaying Generator software version and hardware information (see **Section 7.7**).
J	Remove Device	Opens the screen for removing or replacing the Delivery Device (see **Section 7.6.8**).

7.6.1 Perineal Saline Flush/Connect

The **Perineal Saline Flush/Connect** option allows the user to manage perineal saline flow for tubing flush or for connection to the transperineal Saline Catheter Needle. Selecting this option opens the Perineal Saline Flush/Connect screen (see **Figure 7-6** and **Table 20**).

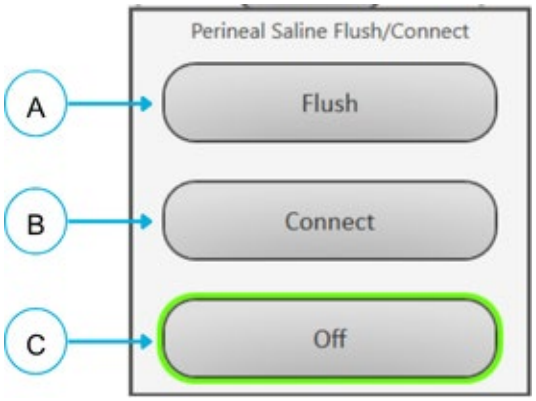


Figure 7-6: Perineal Saline Flush/Connect

Table 20: Perineal Saline Flush/Connect Description

Label	Name	Description
A	Flush	Activates saline flow at normal flush rate to prime the Saline Needle Tubing Set and remove air bubbles.
B	Connect	Activates saline flow at a slower rate to prevent air from entering the needle during connection.
C	Off	Stops perineal saline flow.

7.6.2 Replace Perineal Saline Source

The Perineal Saline Replace option allows the user to enter the replacement volume for the perineal saline source. Selecting **Confirm** clears any related alerts for low saline volume (see **Figure 7-7**).

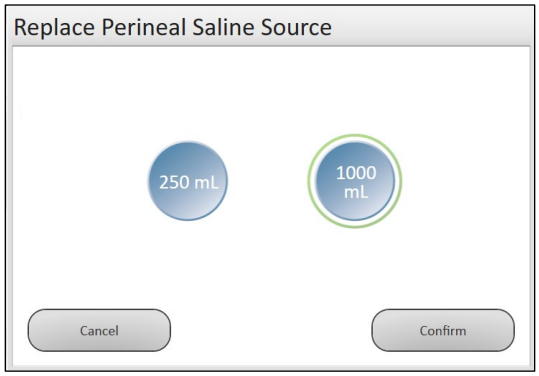


Figure 7-7: Replace Perineal Saline Source

7.6.3 Replace Urethral Saline Source

The Urethral Saline Replace option allows the user to enter the replacement volume for the urethral saline source. Selecting **Confirm** clears any related alerts for low saline volume (see **Figure 7-8**).

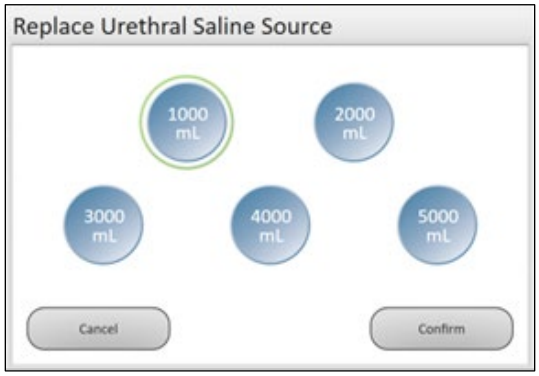


Figure 7-8: Replace Urethral Saline Source

7.6.4 Confirm Bladder Drain

The Bladder Drain option allows the user to confirm that the bladder has been manually drained by the physician. Selecting **Confirm** resets the tracked volume of instilled saline (see **Figure 7-9**).

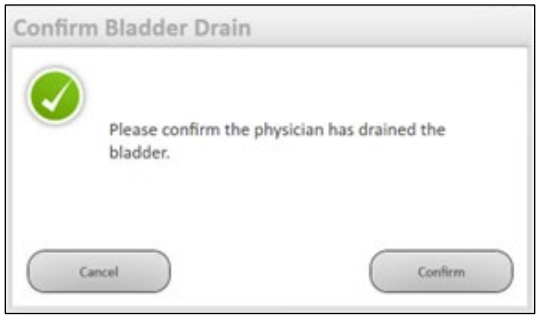


Figure 7-9: Confirm Bladder Drain

7.6.5 Confirm Syringe Refill

The Syringe Refill option allows the user to initiate a refill of the sterile water syringe by selecting **Confirm** (see **Figure 7-10**).

Figure 7-10: Confirm Syringe Refill

7.6.6 Confirm Syringe Purge

The Syringe Purge option allows the user to purge and then refill the sterile water syringe. This function is typically used to remove air bubbles from the syringe or connected tubing (**Figure 7-11**). Selecting **Confirm** initiates the syringe purge.

Figure 7-11: Confirm Syringe Purge

7.6.7 System Information

The System Info option allows the user to view key system information, including software version numbers, and access functions for setting the date and time or exporting system logs.
For full details, see **Section 7.7** System Information Screen.

7.6.8 Remove Device

The Remove Device option allows the user to initiate the Delivery Device removal process, either for device replacement or to end the procedure. Selecting **Confirm** (see **Figure 7-12**) opens the Remove Device screen (see **Figure 7-13**).

Figure 7-12: Confirm Device Removal

The Remove Device screen displays the connected device information, a summary of the procedure, and available actions for how to proceed (see **Figure 7-13**). Selecting the ? button next to each action displays the corresponding confirmation prompt described in **Table 21**.

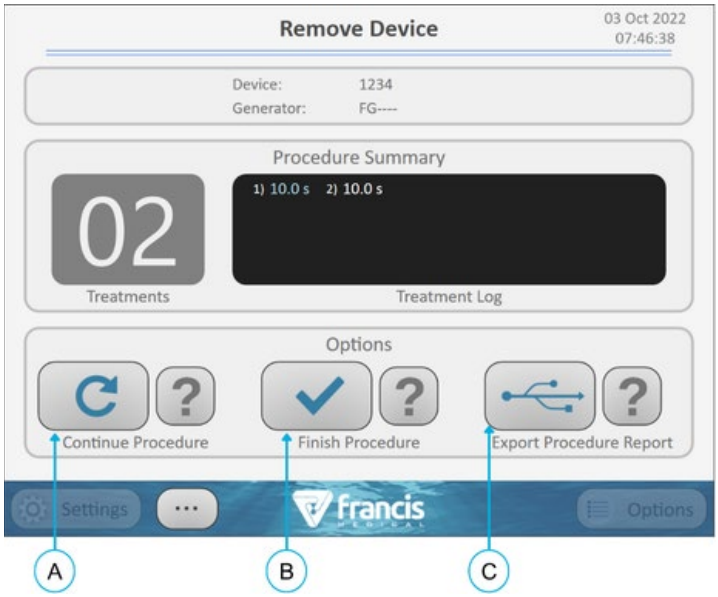


Figure 7-13: Remove Device Screen

Table 21: Remove Device Screen Description

Label	Name	Description
A	Continue Procedure	Continue with the current procedure using another Delivery Device.
B	Finish Procedure	Close the current procedure. No more therapy is intended.
C	Export Procedure Report	Save a report of the current procedure to a USB drive.

7.7 System Information Screen

The System Information screen provides access to key system details, including software versions, system configuration data, and utility functions such as setting the date and time or exporting logs. This screen is accessed from the Options Menu on the Generator screen.

From the System Information screen you can select a new date and time and export system logs (**Figure 7-14** and **Table 22**).

Figure 7-14: System Information Screen

Table 22: System Information Screen Description

Label	Name	Description
A	Set Date/Time	Opens the screen for adjusting the Generator's internal date and time.
B	Export Logs	Opens the screen for exporting system logs to an external USB drive.
C	Close the Screen	Closes the System Information screen and returns to the Generator home screen.

7.7.1 Select New Date and Time

The **Set Date/Time** option allows the user to set or update the Generator's internal date and time (**Figure 7-15**).

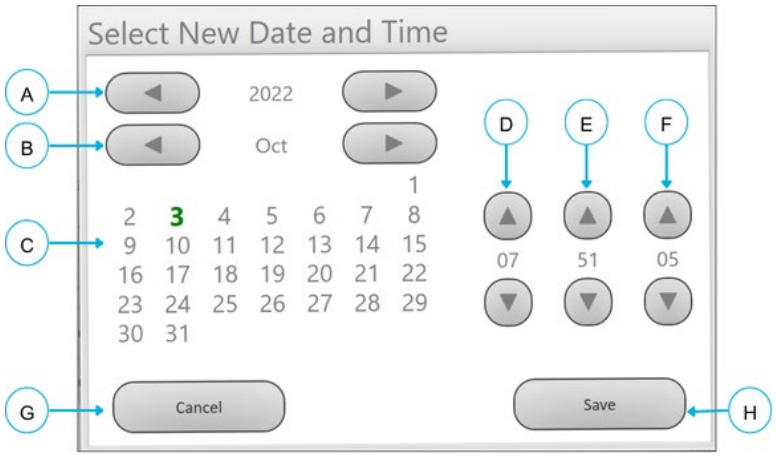


Figure 7-15: Select New Date and Time Window

To set the date:

1. Select **[Options]** on the Generator screen, then select **[System Info]** to open the System Information screen.
2. Select [Set Date/Time].
   - The Select New Date and Time window appears (**Figure 7-15**)
3. Use the navigation arrows to update the following values:
   - **Year** (A): Left/right arrows adjust the year.
   - **Month** (B): Left/right arrows adjust the month.
   - **Day** (C): Select the day from the calendar. The selected day is highlighted in bold green.

To set the time:

1. Use the [up/down arrows] to adjust the:
   - **Hour** (D)
   - **Minutes** (E)
   - **Seconds** (F)

To save or cancel:

1. Select **[Save]** (H) to confirm and apply the new date and time.
   - Select **[Cancel]** (G) to exit without saving.

7.7.2 Export Logs

The Export Logs option allows the user to save system log data to a USB drive. Logs can be filtered by time range, and video/image files may be excluded to reduce export time and file size (**Figure 7-16**).

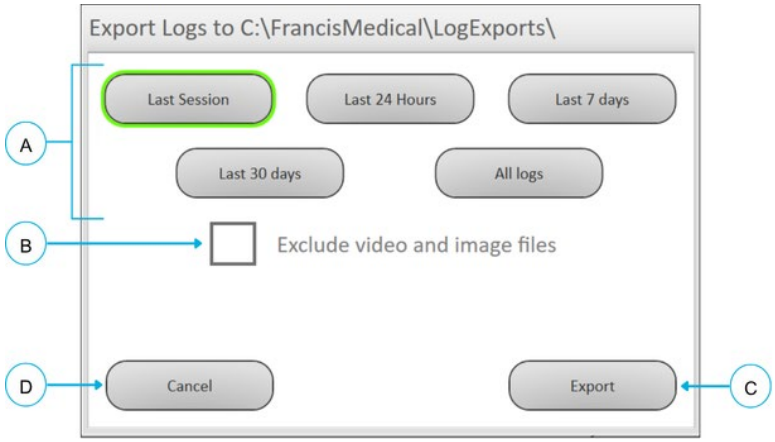


Figure 7-16: Export Logs window

To export logs:

1. Insert a USB Drive into the USB Port on the Generator.
2. Select **[Options]**, then select **[System Info].**
3. On the System Information screen, select **[Export Logs].**
   - The Export Logs window is displayed (**Figure 7-16**)
4. Select the desired time range (A). The selected option will be highlighted in green:
   - **Last Session** – Logs from the last power cycle
   - **Last 24 Hours** – Logs from all cases run in the last 24 hours
   - **Last 7 Days** – Logs from all cases run in the last 7 days
   - **Last 30 Days** – Logs from the past 30 days
   - **All Logs** – All logs stored on the system
5. **(Optional)** Select the Exclude video and image files checkbox (B) to exclude large media files.
6. Select **[Export]** (C) to save the selected logs to a USB drive.
   - When complete, the screen will display: “File(s) Exported Successfully!”
7. Select **[Cancel]** (D) to exit without exporting.
8. Remove the USB drive.

7.8 Settings Menu

The Settings menu (**Figure 7-17**) is accessed by selecting **[Settings]** in the lower corner of the Generator screen. It provides access to key procedural configuration options and visualization controls (see **Table 23**).

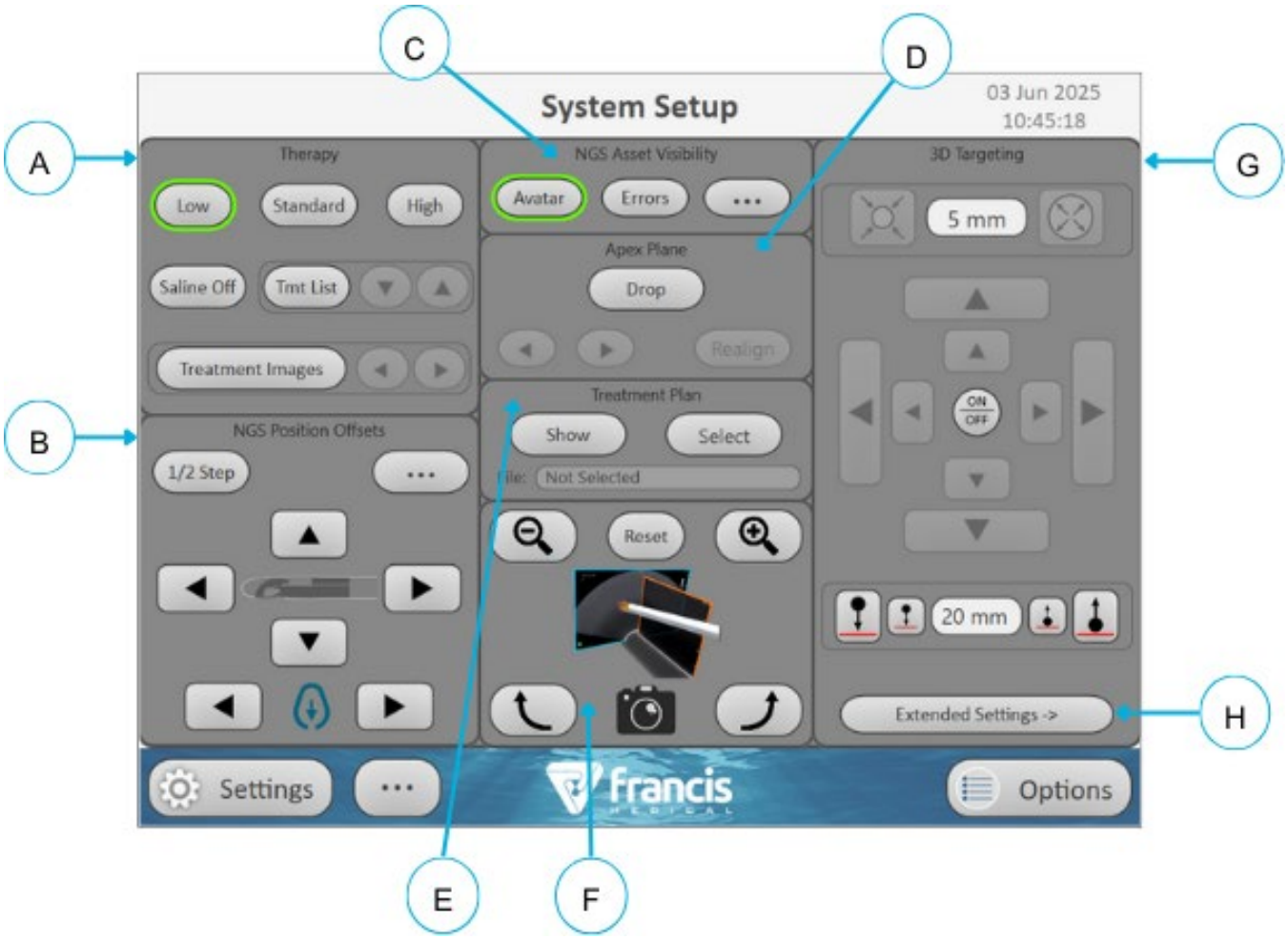


Figure 7-17: Settings Menu

Table 23: Settings Menu Description

Label	Name	Description
A	Therapy Menu	Provides controls for therapy dose selection, saline toggling, and treatment review.
B	NGS Position Offsets Menu	Adjusts offsets for NGS assets displayed on the PUI.
C	NGS Asset Visibility Menu	Toggles visibility of NGS assets on the PUI.
D	Apex Plane Menu	Drops and adjusts the Apex Plane position.
E	Treatment Plan Menu	Imports and displays a custom treatment plan image on the PUI.
F	3D View Menu	Controls the viewing angle and zoom level of the 3D view.
G	3D Targeting Menu	Resizes and repositions the 3D target.
H	Extended Settings button	Opens additional system settings not shown on the primary Settings screen.

7.8.1 Therapy Menu

The Therapy Menu (**Figure 7-18**) allows the user to configure therapy-related settings and view prior treatment data or images on the Physician User Interface (PUI) (see **Table 24**).

To access the Therapy menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the Therapy menu on the Settings screen (**Figure 7-18**).

Figure 7-18: Therapy Menu

Table 24: Therapy Menu Description

Label	Name	Description
A	Therapy Dose	Allows the operator to select one of three dose levels: for the subsequent vapor treatment, Low, Standard, or High, each corresponding to a different vapor energy delivery rate (calories per second).
B	Saline Off	Toggles perineal saline delivery ON/OFF for the subsequent vapor treatment: • **On** – saline is flowing (button not outlined in green) • **Off** – saline is stopped (button outlined in green) When active, saline automatically flows at a normal rate through the Saline Catheter Needle. ▪ **NOTE** : This can be overridden by controller commands.
C	Tmt List	Opens a list of all completed treatments lasting 4 seconds or longer on the PUI (see **Section 8.1.7** Treatment List). While displayed: • Needle advancement and vapor delivery are disabled • The NGS Position Offsets Menu is disabled • Needle retraction remains available Use the Up/Down Arrows to scroll through the list (disabled if the list fits on one page).
D	Treatment Images	Displays image snapshots of previous treatments on the PUI. Each image reflects the state of the PUI at the end of a treatment. • Treatment images are indicated by a tan border • Device Serial Number, Track, and Treatment Number appear at the bottom of the window While displayed: • Needle advancement and vapor delivery are disabled • The NGS Position Offsets and 3D View Menus are disabled • Needle retraction remains available Use the Left/Right Arrows to scroll through the images.

7.8.2 NGS Position Offsets Menu

The NGS Position Offsets Menu (**Figure 7-19**) allows the user to make visual calibration adjustments to the Delivery Device avatar on the PUI relative to the ultrasound images. This can be helpful to ensure spatial alignment when necessary (see **Table 25**).

To access the NGS Position Offsets menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the NGS Position Offsets menu on the Settings screen (**Figure 7-19**).

Figure 7-19: NGS Position Offsets Menu

Table 25: NGS Position Offsets Menu Description

Label	Name	Description
A	[½ Step] Button	Enables smaller incremental adjustments. Outlined in green when active.
B	[...] Button	Opens the NGS Offset Position popup menu (see **Section 7.8.3**).
C	Avatar Offset Controls (Sagittal Plane)	Adjusts the position of the Delivery Device avatar vertically and longitudinally within the Sagittal Plane.
D	Avatar Offset Controls (Axial Plane)	Adjusts the position of the Delivery Device avatar laterally within the Axial Plane.

7.8.3 NGS Position Offset Options Popup Menu

The **NGS Position Offset Options** (**Figure 7-20**)popup menu allows the user to toggle between pre- and post-offset views of the Delivery Device avatar (see **Table 26**).

To access the NGS Position Offset Options menu:

1. Select **[Settings]** on the Generator screen.
2. Select the **[...]** button on the NGS Position Offsets menu (see **Figure 7-20**).

Figure 7-20: NGS Position Offsets Options Menu

Table 26: NGS Position Offsets Menu Description

Label	Name	Description
A	Suspend	Toggles between pre-offset and post-offset settings.
B	Clear	Resets all offset settings.
C	Close	Closes the menu and returns to the main Settings screen.

7.8.4 NGS Asset Visibility Menu

The NGS Asset Visibility Menu allows users to toggle visibility of tracking and display assets associated with the Delivery Device and TRUS probe (see **Table 27**).

To access the NGS Asset Visibility menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the NGS Asset Visibility icon on the Settings screen (**Figure 7-21**).

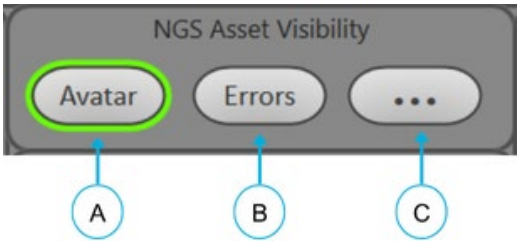


Figure 7-21: NGS Asset Visibility Menu

Table 27: NGS Asset Visibility Menu Description

Label	Name	Description
A	Avatar	Toggles the display of the Delivery Device avatar on the PUI.
B	Errors	Toggles the display of the numerical tracking quality next to the TRUS and Delivery Device status indicators.
C	[...]	Opens the Additional NGS Asset Visibility Options popup (**Section 7.8.5).**

7.8.5 Additional NGS Asset Visibility Options Popup Menu

The Additional NGS Asset Visibility Options menu, accessed from the Settings screen, allows the user to toggle the visibility of specific NGS visual assets on the PUI.

To access the Additional NGS Asset Visibility Options popup menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the NGS Asset Visibility menu on the displayed Settings screen.
3. Select the **[...]** button on the NGS Asset Visibility menu.
4. The Additional NGS Asset Visibility Options popup menu will be displayed (**Figure 7-22**).

Descriptions of each NGS asset listed in **Table 28** can be found in **Section 8**: Physician User Interface (PUI).

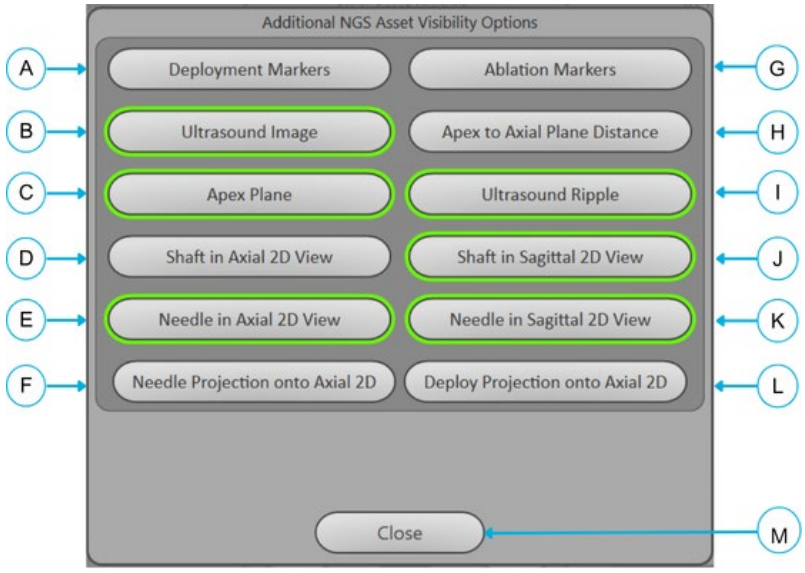


Figure 7-22: Additional NGS Asset Visibility Popup Menu

Table 28: Additional NGS Asset Visibility Popup Menu Description

Label	Name	Description
A	Deployment Markers	Toggles visibility of deployment marker locations on the PUI.
B	Ultrasound Image	Toggles projection of ultrasound image planes onto the 3D and Top-Down 2D Views.
C	Apex Plane	Toggles visibility of the user-defined Apex Plane.
D	Shaft in Axial 2D View	Toggles visibility of the shaft avatar on the Axial ultrasound image.
E	Needle in Axial 2D View	Toggles visibility of the predicted needle trajectory on the Axial image.
F	Needle Projection onto Axial 2D	Toggles visibility of the projected needle trajectory on Axial image.
G	Ablation Markers	Toggles visibility of full vapor treatment locations.
H	Apex to Axial Plane Distance	Toggles visibility of the yellow line showing distance between planes.
I	Ultrasound Ripple	Toggles visibility of the yellow projected intersection on the Axial view.
J	Shaft in Sagittal 2D View	Toggles visibility of the shaft avatar in the Sagittal view.
K	Needle in Sagittal 2D View	Toggles visibility of the predicted needle trajectory in the Sagittal view.
L	Deploy Projection onto Axial 2D	Toggles visibility of the projected deployment distance on Axial image.
M	Close	Closes the Additional NGS Asset Visibility Options popup menu.

7.8.6 Apex Plane Menu

The Apex Plane menu allows the user to drop and adjust the Apex Plane on the PUI (see **Table 29**).

To access the Apex Plane menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the Apex Plane menu on the displayed Settings screen (**Figure 7-23**).

Figure 7-23: Apex Plane Menu

Table 29: Apex Plane Menu Description

Label	Name	Description
A	Drop	The Drop button places the Apex Plane on the PUI and changes its appearance from a dashed red line to a solid red line. The button is outlined in green on the OUI when active.
B	Left/Right Arrows	The Left/Right Arrows adjust the position of the dropped Apex Plane within the Sagittal ultrasound view.
C	Realign	The Realign button repositions the Apex Plane to align it parallel to the Axial Plane.

7.8.7 Treatment Plan Menu

The Treatment Plan menu allows the user to display a custom treatment plan image on the PUI. The selected image must be in .png or .jpg format and under 2 MB in size. When enabled, the treatment plan appears in the upper-left corner of the PUI (see **Table 30**).

To access the Treatment Plan menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the Treatment Plan menu on the displayed Settings screen (see **Figure 7-24).**

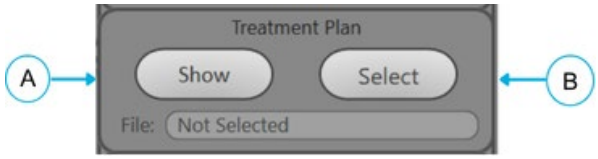


Figure 7-24: Treatment Plan Menu

Table 30: Treatment Plan menu

Label	Name	Description
A	Show	Displays the selected treatment plan image on the PUI. If no image is available, the message “No Treatment Plan Image Is Available” is shown. When unselected, the image is hidden, and the Show button is no longer highlighted in green.
B	Select	Allows the user to choose a treatment plan image from a USB drive connected to the Generator. If no valid images are available, the message “No Treatment Plan Images Are Available” is displayed.

7.8.8 3D View Menu

The 3D View menu allows the user to control the orientation and zoom level of the 3D View displayed on the PUI. This feature is helpful for adjusting the visualization of the Delivery Device and anatomical reference planes during the procedure (see **Table 31**).

To access the 3D View menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the 3D View menu on the displayed Settings screen (see **Figure 7-25**).

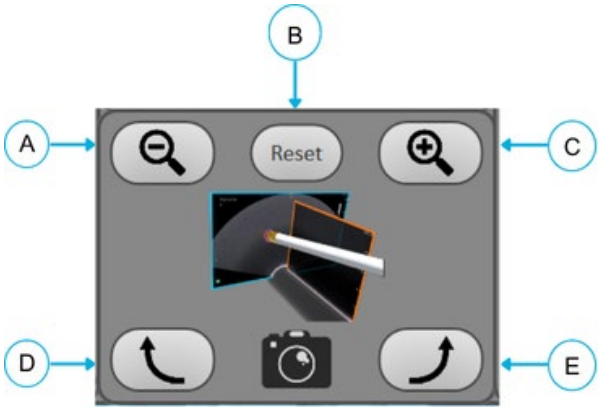


Figure 7-25: 3D View Menu

Table 31: 3D View Menu Description

Label	Name	Description
A	Zoom Out	Decreases the zoom level of the 3D View on the PUI.
B	Reset	Resets the 3D View to the default orientation, aligned along the axis of the TRUS probe shaft.
C	Zoom In	Increases the zoom level of the 3D View on the PUI.
D	Rotate Clockwise	Rotates the 3D View clockwise.
E	Rotate Counterclockwise	Rotates the 3D View counterclockwise.

7.8.9 3D Targeting Menu

The **3D Targeting** menu allows the user to resize and reposition the 3D target displayed on the PUI. This feature supports visual alignment of tools and anatomical targets during treatment (see **Table 32**).

To access the 3D Targeting menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the **3D Targeting** menu on the displayed Settings screen (see **Figure 7-26).**
3. Toggle the **ON/OFF** button to **On** (outlined in green) to enable adjustments.

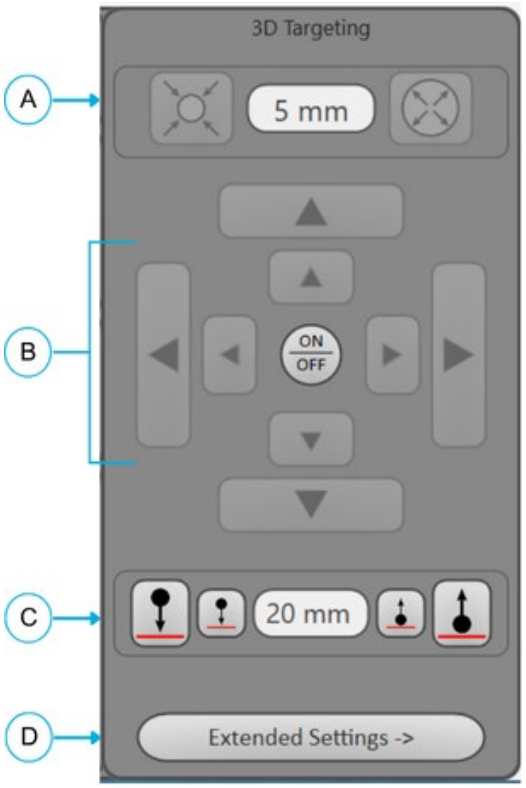


Figure 7-26: 3D Targeting Menu

Table 32: 3D Targeting Menu Description

Label	Name	Description
A	Target Size Controls	Adjust the size of the 3D target:  **Left Button:** Decreases target size in 1 mm increments  **Right Button:** Increases target size in 1 mm increments  **Center Display:** Shows the current target diameter (in mm)
B	Target Position Controls (Axial Plane)	Adjust the target's position within the axial plane: **Outer Ring Arrows (Up/Down/Left/Right):** Move the target in 5 mm increments **Inner Ring Arrows (Up/Down/Left/Right):** Move the target in 1 mm increments **ON/OFF Toggle:** Enables or disables the 3D target on the PUI
C	Target Depth Controls (Into/Out of Plane)	Adjust the depth of the target along the sagittal plane:  Left Buttons: **Move the target closer to the Apex Plane in 5 mm or 1 mm increments**  **Right Buttons:** Move the target further from the Apex Plane in 5 mm or 1 mm increments  Center Display: **Shows the current depth relative to the Apex Plane (in mm)**
D	Extended Settings Menu	Opens the Extended Settings menu for additional options not shown on the main Settings screen (see **Section 7.9**).

7.9 Extended Settings Menu

The Extended Settings menu is accessed from the Settings screen and is used to configure supplemental features not displayed on the primary Settings screen (see **Table 33**).

To access the Extended Settings menu:

1. Select **[Settings]** on the Generator screen.
2. Locate the **3D Targeting** menu on the displayed **Settings** screen.
3. Select **[Extended Settings →]** on the **3D Targeting** menu.
   - The **Extended Settings** pop-up menu will be displayed (see **Figure 7-27**).

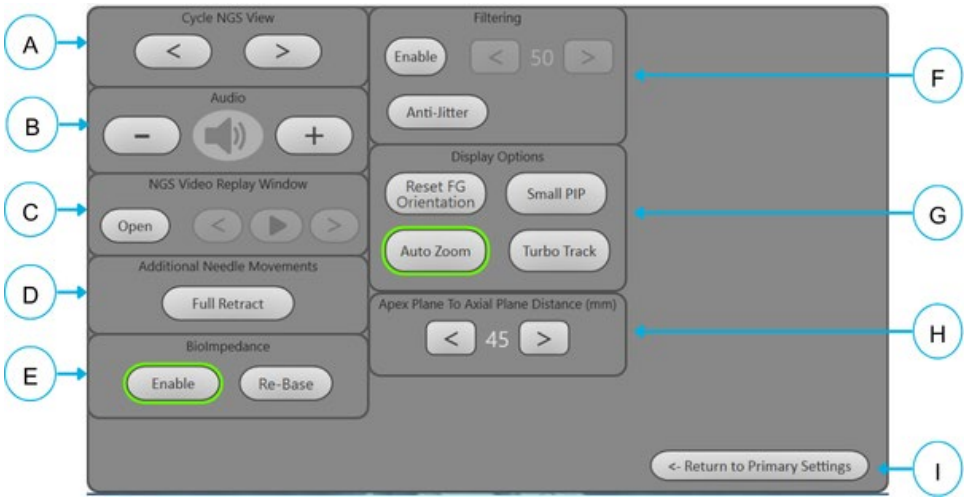


Figure 7-27: Extended Settings Popup Menu

Table 33: Extended Settings Popup Menu Description

Label	Name	Description
A	Cycle NGS View	Left/Right arrows cycle the PUI layout to enlarge a selected viewing window. Cycling order: All View → Axial Ultrasound → Sagittal Ultrasound → 3D View → Cystoscope View.
B	Audio	Allows adjustment of Generator volume using **[–]** and **[+]** buttons. The current level is shown on a volume indicator.
C	NGS Video Replay Window	Displays a replay of the most recent treatment. Shown in a yellow-outlined PUI window with **"Replay"** flashing in the corner. Use Left/Right arrows to rewind or fast-forward.
D	Additional Needle Movements	**Full Retract**: When enabled, the next needle retraction via the Controller performs a full retraction.
E	BioImpedance	**Enable**: Toggles BioCap and the real-time impedance graph on the PUI. When disabled, "BioCap Disabled" appears. **Re-Base**: Resets the baseline impedance measurement.
F	Filtering	**Enable**: Toggles signal filtering for improved NGS tracking. **Anti-Jitter**: Suppresses rapid oscillations in NGS tracking.
G	Display Options	**Reset FG Orientation**: Reorients the PUI so the TRUS probe appears upright toward the Axial view. **Small PIP**: Enables a small cystoscope picture-in-picture view on the PUI. **Auto Zoom**: Automatically zooms the Top-Down 2D View to include the Delivery Device, Apex Plane, Axial Plane, and 3D Target. **Turbo Track**: Adjusts Field Generator operating frequency for noise compensation (may impact performance).

Label	Name	Description
H	Axial Plane to Apex Plane Distance (mm)	Sets the default distance between Apex and Axial Planes (0–70 mm). Cannot be adjusted once the Apex Plane is dropped.
I	Return to Primary Settings	Returns the user to the primary Settings menu.

7.10 Treatment Session Screen

The Treatment Session screen (**Figure 7-28**) is displayed on the Generator after System Setup is complete. This screen provides real-time visual feedback and procedural data during treatment delivery, including vapor delivery status, treatment logs, saline usage, and bioimpedance measurements.

The Treatment Session screen includes the interface elements described in **Table 34**.

Figure 7-28: Treatment Session Screen

Table 34: Treatment Session Screen Description

Label	Name	Description
A	System Status Window	Displays system status related to vapor delivery, including a color-coded readiness indicator light, a progress bar showing vapor delivery and refill, and a timer that counts the duration of active vapor delivery.
B	Treatment Summary Panel	Consolidates treatment and alert information, including a running count of full treatments (≥7 seconds), a color-coded log of all vapor deliveries, and a display of active system alerts.
C	Needle Position	Displays the current needle deployment depth and initial deployment settings in real time.
D	Saline Usage	Displays the instilled and remaining volume for Urethral and Perineal saline.
E	Bio Impedance	Displays real-time measurements from the BioCap system.

7.10.1 System Status Window

The System Status Window (see **Figure 7-29**) provides real-time visual indicators related to vapor delivery readiness and progress. It includes three key components: the Status Indicator Light, which reflects the system's current state; the Status Bar, which shows progress during vapor delivery and syringe refill; and the Vapor Delivery Timer, which tracks the elapsed time of each vapor delivery in seconds. Together, these elements give the user clear, immediate feedback to support safe and effective treatment delivery (see **Table 35**).

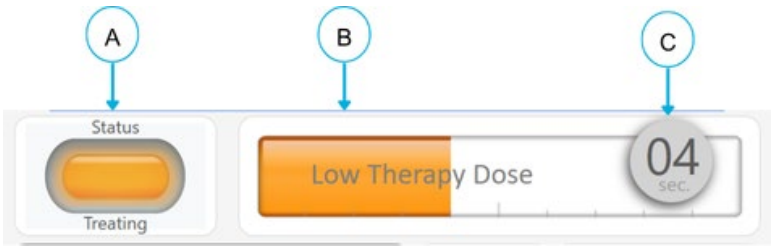


Figure 7-29: System Status Window

Table 35: System Status Window Description

Label	Name	Description
A	Status Indicator Light	Displays a color-coded signal indicating the system's readiness to deliver vapor. **Green (Ready):** Indicates the system is ready for vapor delivery. "Ready" is displayed below the indicator. **Orange (Treating):** Indicates the system is actively delivering vapor. "Treating" is displayed below the indicator. **Gray (Waiting):** Indicates the system is temporarily unavailable while the syringe refills and the coil reheats. "Waiting" is displayed below the indicator.
B	Status Bar	Provides visual feedback during vapor delivery and displays the selected therapy dose. During vapor delivery, an orange bar fills from left to right to indicate progress. After delivery, the message "Refilling Syringe" is displayed while the system automatically refills the syringe.
C	Vapor Delivery Timer	Displays the elapsed vapor delivery time, in seconds, up to a maximum of 10 seconds. The value is shown in real time inside the circular timer at the end of the Status Bar. The system emits one audible tone per second during delivery. The timer resets when the Vapor Delivery Button is released or after a full 10-second treatment. Vapor delivery automatically stops after 10 seconds.

7.10.2 Treatment Summary Panel

The Treatment Summary Panel (**Figure 7-30**) tracks all vapor deliveries and displays a cumulative count of full treatments delivered (≥7 seconds). The Treatment Log is displayed on the Treatment Session Screen and includes system alerts relevant to the treatment session (see **Table 36**).

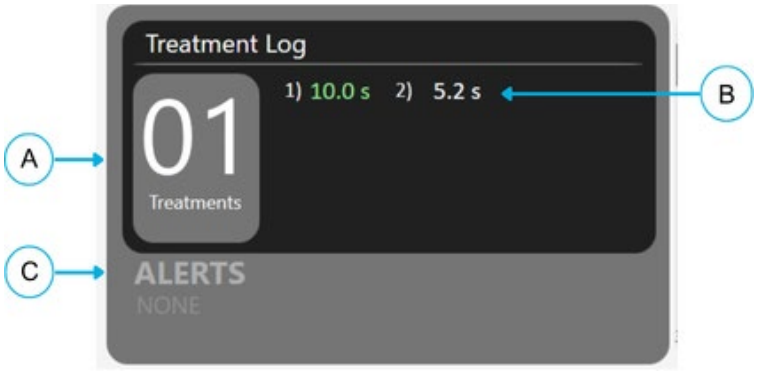


Figure 7-30: Treatment Log

Table 36: Treatment Log Description

Label	Name	Description
A	Treatments Counter	Displays the number of full treatments (≥7 seconds) delivered.
B	Treatment Log	Records all vapor deliveries, including duration and dose. Entries are numbered sequentially and color-coded by dose: Green (Low), White (Standard), Blue (High).
C	Alert Window	Displays applicable alerts during treatment. Alerts appear in-line with the log and are automatically cleared when resolved.

7.10.3 Needle Position

The Needle Position display (**Figure 7-31**) provides real-time feedback on the initial deployment and current needle deployment distance during treatment. This information is shown both numerically and graphically on the Generator Treatment Session screen (see **Table 37**).

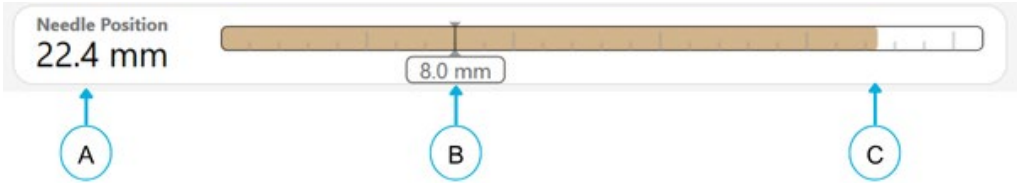


Figure 7-31: Needle Position

Table 37: Needle Position Description

Label	Name	Description
A	Needle Position	Numeric display (in mm) of the current deployment length.
B	Initial Deployment	Default initial deployment length is 8 mm, adjustable from 5 mm to 22 mm.
C	Graphical Indicator	Visual representation of the current needle position relative to travel limits.

After initial deployment, the needle can be advanced up to a maximum deployment length of **26.0 mm** using the Controller.

7.10.4 Saline Usage

The Saline Usage display (**Figure 7-32**) shows real-time tracking of saline volumes during the treatment session. Two bar graphs—one for urethral saline and one for perineal saline—indicate the amount of saline delivered and the remaining volume (see **Table 38**).

■ **NOTE**: Initial volumes are based on the amounts selected during System Setup.

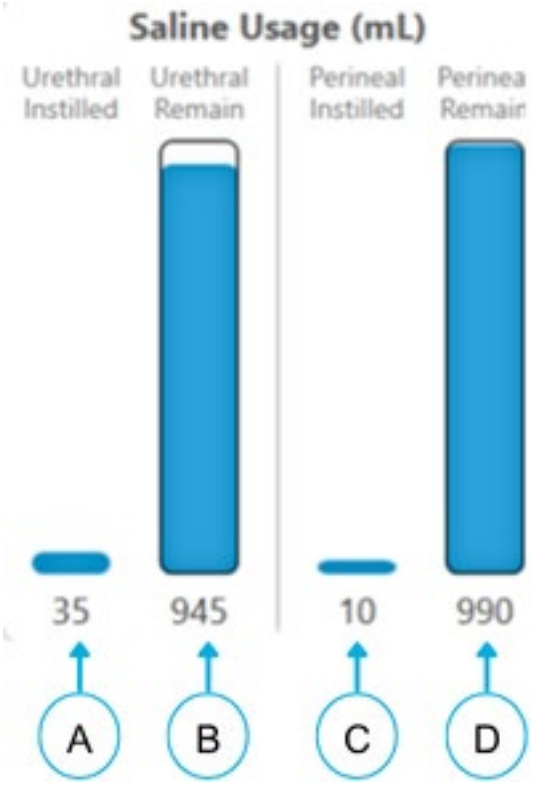


Figure 7-32: Saline Usage Graphs

Table 38: Saline Usage Graphs Description

Label	Name	Description
A	Urethral Instilled	Volume (mL) of saline delivered since bladder drain or pre-treatment completion.
B	Urethral Remain	Volume (mL) of saline remaining in the urethral saline source.
C	Perineal Instilled	Volume (mL) of saline delivered since the start of the procedure.
D	Perineal Remain	Volume (mL) of saline remaining in the perineal saline source.

7.10.5 Bio-Impedance

The Bio-Impedance display (**Figure 7-33**) presents real-time measurement data from the BioCap system on the Treatment Session Screen. BioCap calculates the electrical response of tissue to an externally applied current, providing values that support clinical assessment during vapor delivery.

The System displays BioCap information, as described in **Table 39**.

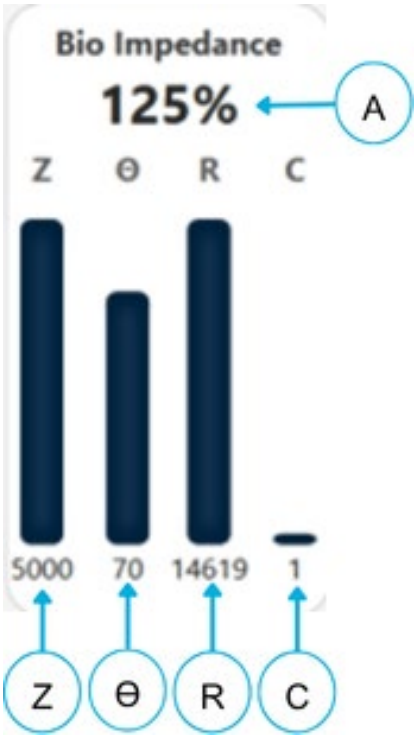


Figure 7-33: BioImpedance Display

Table 39: Bio-Impedance Display Description

Label	Name	Description
A	Percentage	Displays the BioCap impedance measurement normalized to the baseline value (100%) taken within 1 second after initial needle deployment. If a short, open circuit, or disabled state is detected, displays “Short Detected,” “Open Detected,” or “Disabled,” respectively.
Z	Impedance	Total opposition to electrical current flow through tissue; includes both resistance and capacitance (Ohms).
Θ	Phase Angle	Balance between resistance and capacitance (Degrees).
R	Resistance	Opposition to current flow through tissue fluids (Ohms).
C	Capacitance	Ability of tissue to store electrical charge (Farads).

7.11 Operating Condition Screen

The Operating Condition screen (**Figure 7-34**) displays real-time system operating data used for diagnostics and service support. This screen is not intended for routine clinical use, and no user-adjustable settings are available. However, the information may be requested by a Service Technician during maintenance or troubleshooting.

Figure 7-34: Operating Conditions

To view the Operating Condition screen:

1. Locate and press the **[...]** button on the Generator screen (**Figure 7-35**)
2. Continue holding the button to display the Operating Conditions screen.
3. Release the button to exit the screen.

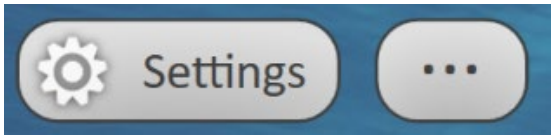


Figure 7-35: Operating Conditions Button

8 Physician User Interface (PUI)

The Physician User Interface (PUI) is displayed on the Monitor positioned over the patient and provides real-time feedback, imaging, and system status indicators to support accurate treatment delivery and informed clinical decision-making throughout the procedure (see **Figure 8-1**).

The PUI can be configured to display one of several viewing modes via the Generator settings: **All View**, **Axial View**, **Sagittal View**, **3D View**, and **Cystoscope View**.

- **All View** is the default mode and presents a multi-panel layout, with each display area serving a specific function, as described in this chapter.
- **Axial View** displays the Axial Ultrasound Image as the primary view across the interface (see **Section 8.1.1** Axial (Transverse) Ultrasound Image)
- **Sagittal View** displays the Sagittal Ultrasound Image as the primary view (see **Section 8.1.1** Sagittal (Longitudinal) Ultrasound Image)
- **3D View** shows the 3D model prominently on the interface (see **Section 8.1.5**)
- **Cystoscope View** displays the live cystoscope feed as the primary image (see **Section 8.1.4**)

Each view mode is designed to optimize visualization and workflow based on user preference or the specific stage of the procedure. However, **All View** is recommended as the primary viewing mode, as it provides a comprehensive layout with simultaneous access to key imaging and system data.

8.1 Display Overview

The key features of the Physician User Interface Display are illustrated in **Figure 8-1** and detailed in **Table 40**.

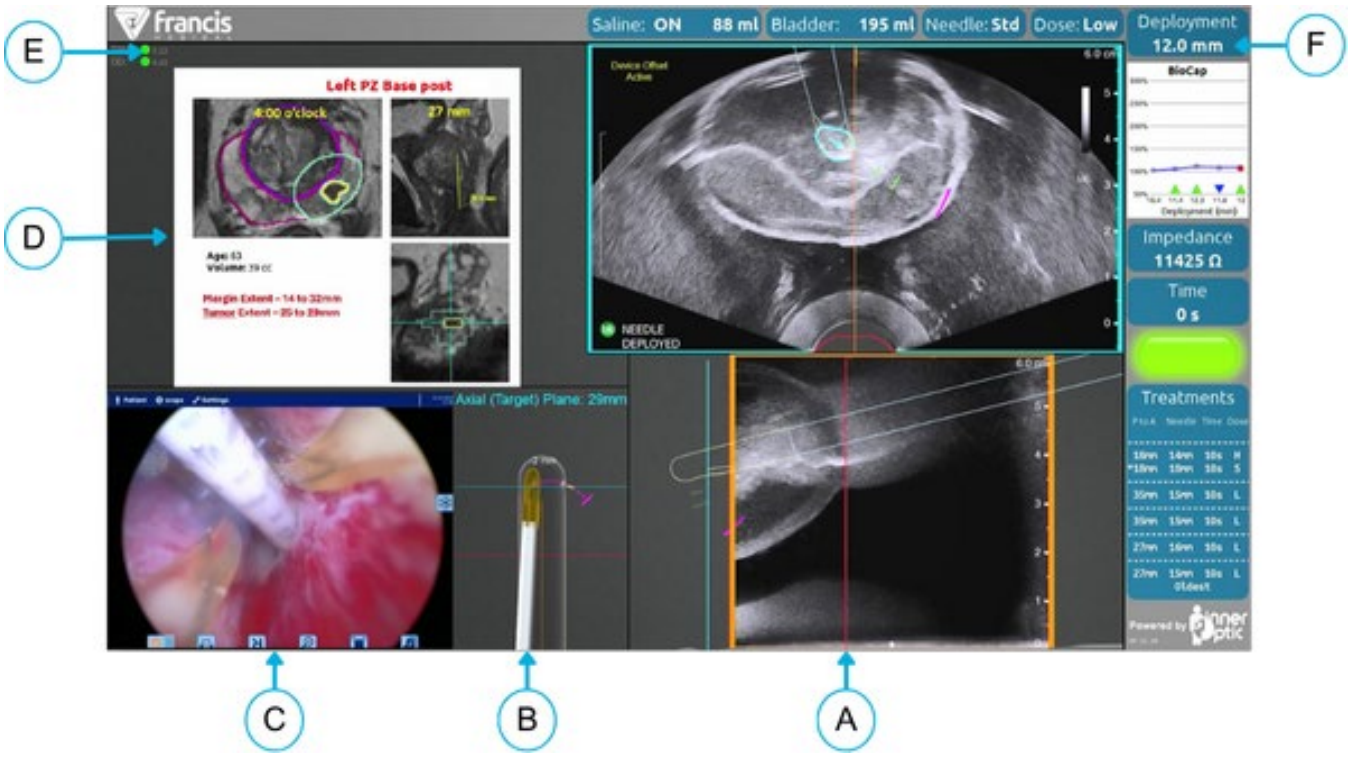


Figure 8-1: Physician User Interface (PUI) Display

Table 40: Physician User Interface (PUI) Display Description

Label	Name	Description
A	Ultrasound Views	Displays real-time axial and sagittal ultrasound images for anatomical visualization and needle guidance.
B	Top-Down 2D View	Shows a top-down representation of the TRUS Probe and Delivery Device relative to the Apex and Axial planes.
C	Cystoscope View	Displays the live video feed from the cystoscope.
D	3D and Treatment Plan View	Displays either a 3D view of the TRUS Probe, Delivery Device, and ultrasound planes or an imported user-generated image.
E	NGS Sensor Status	Indicates the tracking quality of NGS-tracked components and Field Generator alignment.
F	Treatment Information Pane	Consolidates key procedural data, alerts, and system indicators during treatment.

8.1.1 Ultrasound Views

Ultrasound Views display real-time axial and sagittal ultrasound images to assist with needle positioning, anatomical visualization, and treatment planning. These views are continuously updated and form the foundation for image-guided navigation during the procedure (see **Figure 8-2** and **Table 41**).

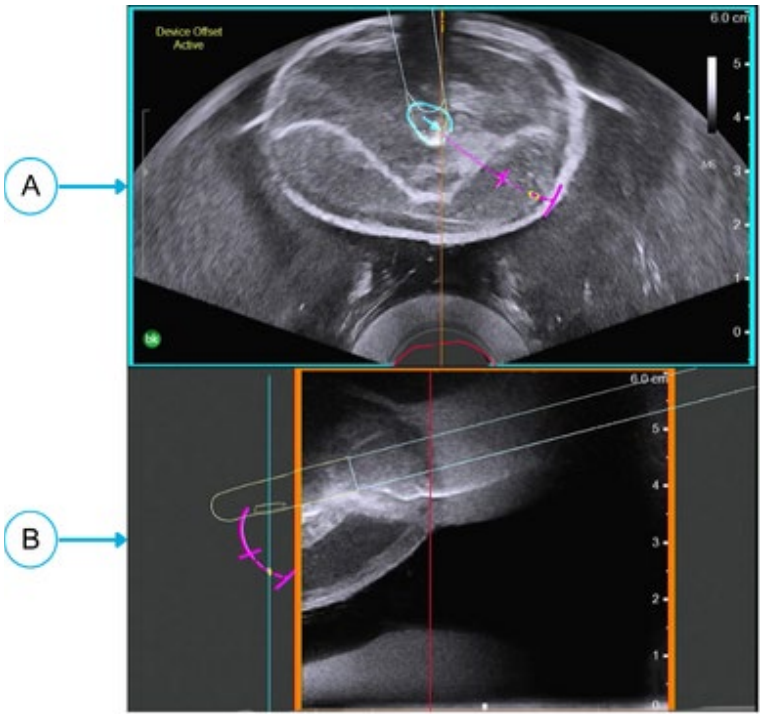


Figure 8-2: Ultrasound Views on the PUI

Table 41: Ultrasound Views on the PUI Description

Label	Name	Description
A	Axial (Transverse) Ultrasound Image	Displays a real-time cross-sectional scan perpendicular to the sagittal plane; outlined in blue.
B	Sagittal (Longitudinal) Ultrasound Image	Displays a real-time vertical scan parallel to the probe's long axis; outlined in orange.

Axial (Transverse) Ultrasound Image

The Axial Ultrasound Image (**Figure 8-3**) displays a two-dimensional, cross-sectional view of the anatomy perpendicular to the sagittal plane. It is outlined in blue and corresponds to the blue reference lines in the Top-Down 2D View (**Section 8.1.3**) and the Sagittal Ultrasound Image (**Section 8.1.1**).

Optional visual guidance cues can be toggled in this view (see **Section 8.2**).

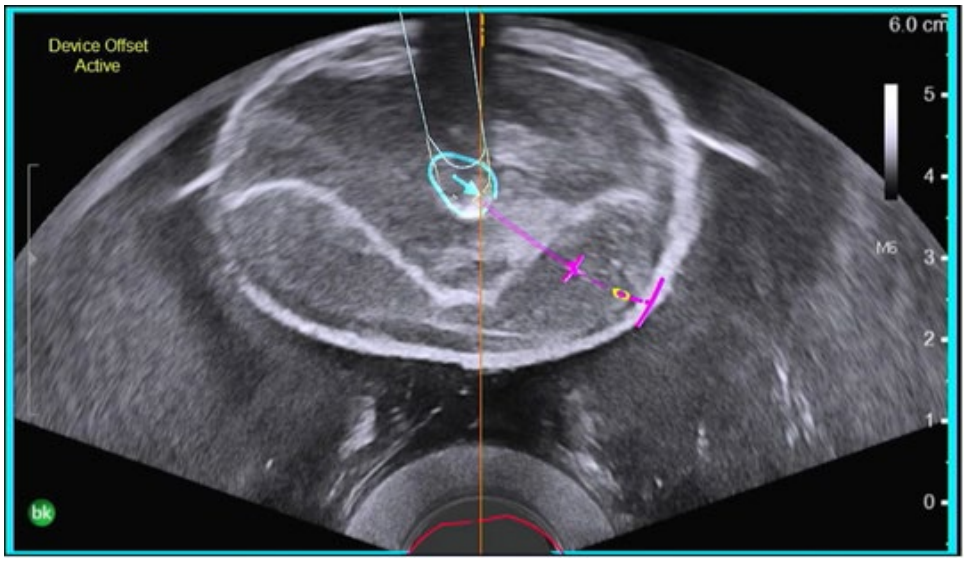


Figure 8-3: Axial (Transverse) Ultrasound Image

Sagittal (Longitudinal) Ultrasound Image

The Sagittal Ultrasound Image **(Figure 8-4)** displays a vertical view along the midline of the TRUS probe, parallel to its long axis. It is outlined in **orange** and corresponds to the orange reference lines in the Top-Down 2D View (see **Section 8.1.3**) and the Axial Ultrasound Image (**Section 8.1.1**).

Optional visual guidance cues can be toggled in this view (see **Section 8.2**).

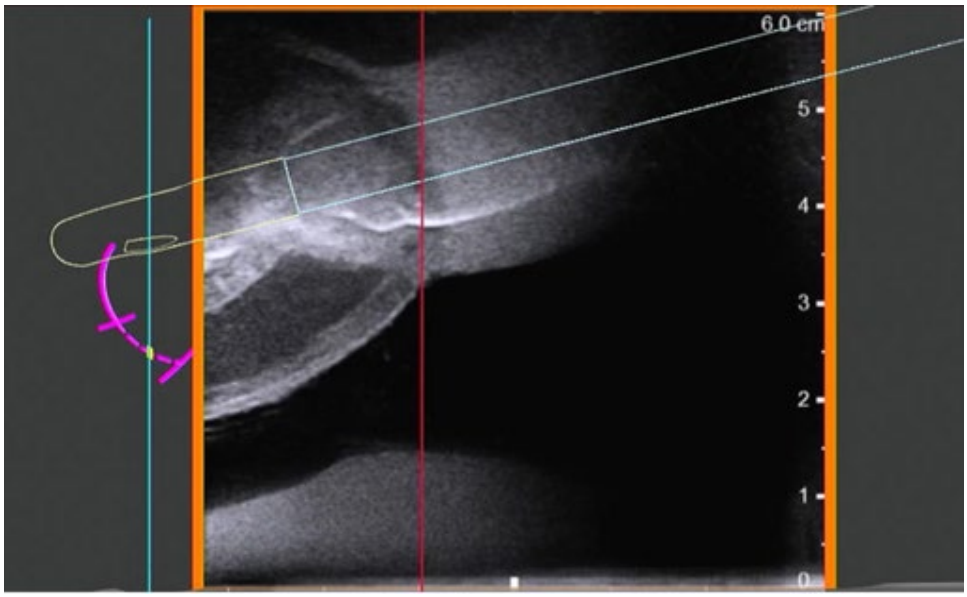


Figure 8-4: Sagittal (Longitudinal) Ultrasound Image

8.1.2 Snowflake Icon

The Snowflake Icon (**Figure 8-5**) appears when the ultrasound image is frozen using the ultrasound system controls. When shown, it indicates that real-time imaging is paused and a static image is being displayed.

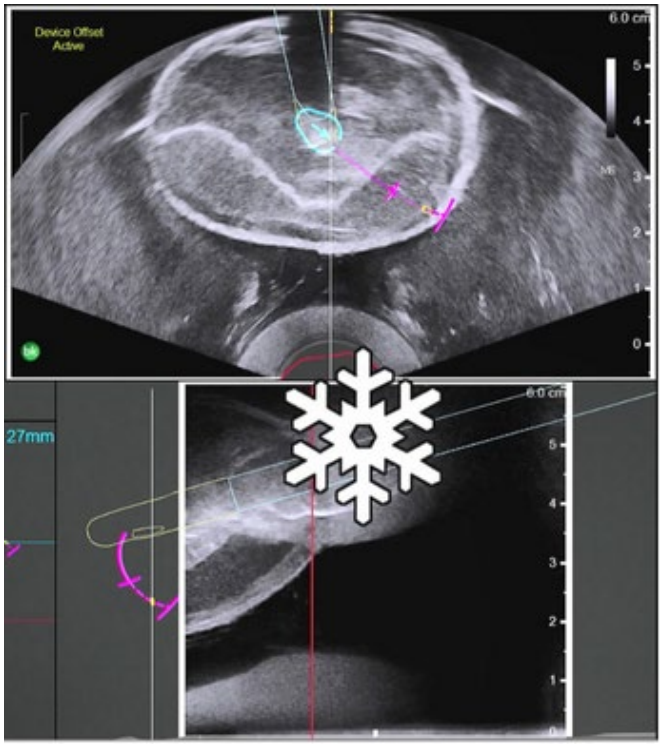


Figure 8-5: Snowflake Icon

8.1.3 Top-Down 2D View

The Top-Down 2D View provides an orthogonal, top-down visualization of the spatial relationship between the Delivery Device and the TRUS probe, as seen from above (see **Figure 8-6**). This view includes the distance between the Ultrasound Axial Plane and the point where the needle exits the Delivery Device shaft. Optional visual guidance cues can be enabled in this view (refer to **Section 8.2**).

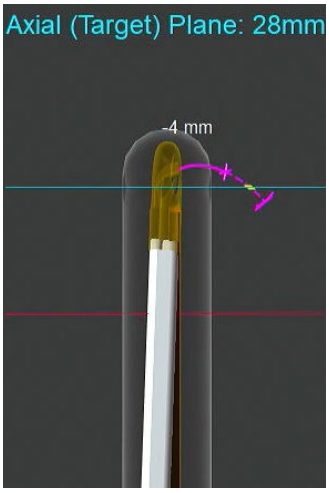


Figure 8-6: Top-Down 2D View

8.1.4 Cystoscope View

The Cystoscope View displays a live endoscopic image captured by the cystoscope lens inside the Delivery Device (see **Figure 8-7**). This real-time video feed assists with visualization during insertion of the Delivery Device and positioning within the prostatic urethra.

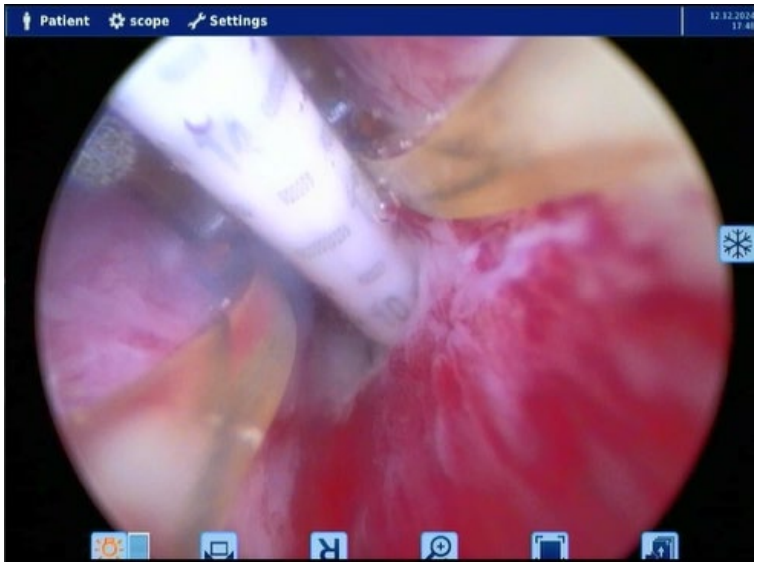


Figure 8-7: Cystoscope View

8.1.5 Treatment Plan and 3D View

This window can be toggled between two display modes:

- **Treatment Plan View (Figure 8-8)** displays a pre-planned treatment map or other user-generated image imported via USB. This view is intended to support procedural planning and intraoperative reference.
- **3D View (Figure 8-9)** provides a three-dimensional visualization of the Delivery Device's position and orientation relative to the TRUS probe and ultrasound imaging planes. Optional visual guidance cues can be enabled in this view (refer to **Section 8.2**).

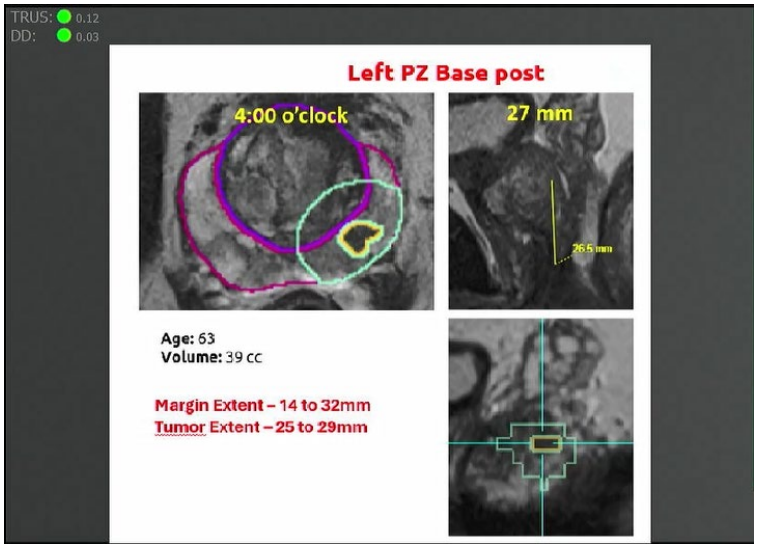


Figure 8-8: Treatment Plan View

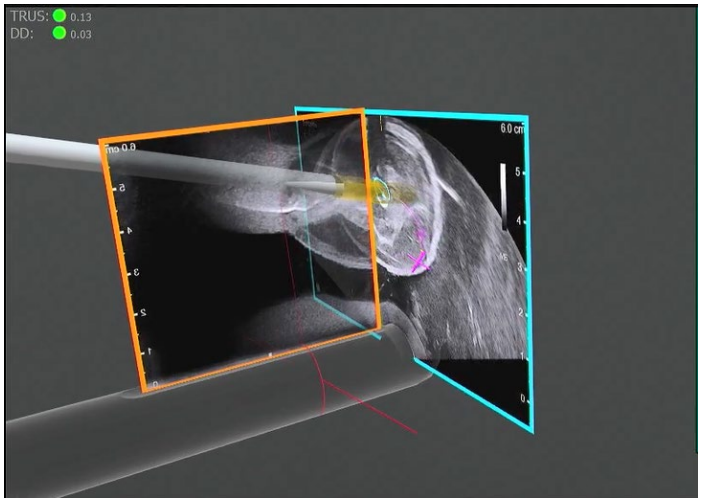


Figure 8-9: 3D View

8.1.6 NGS Sensor Status

The NGS Sensor Status display provides real-time feedback on the tracking quality of key system components, including the Transrectal Ultrasound (TRUS) Probe, Delivery Device (DD), and Field Generator (FG). These components are labeled in the interface as shown in **Figure 8-10** and described in **Table 42**.

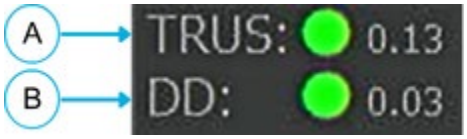


Figure 8-10: NGS Sensor Status Indicators

Table 42: NGS Sensor Status Indictors Description

Label	Name	Description
A	TRUS	Transrectal Ultrasound Probe.
B	DD	Delivery Device.
Not Pictured	FG	Field Generator (appears during Generator startup).

Tracking Quality Indicators

Each component listed in the NGS Sensor Status area is accompanied by a color-coded circle that reflects its tracking quality:

Colored status circles next to each component name indicate the current tracking quality (see **Figure 8-10** and **Table 43**):

Table 43: Status Circle Color Description

Color	Status
Green	Good tracking quality.
Yellow	Near edge of volume.
Red	Out of volume, poor tracking quality, or disconnected.

In addition to the color indicators, numerical error values may be displayed to assist with optimal Field Generator placement and alignment.

8.1.7 Treatment Information Pane

The Treatment Information Pane consolidates key real-time data and system status indicators relevant to the procedure. These components are labeled in the interface as shown in **Figure 8-11** and described in **Table 44**.

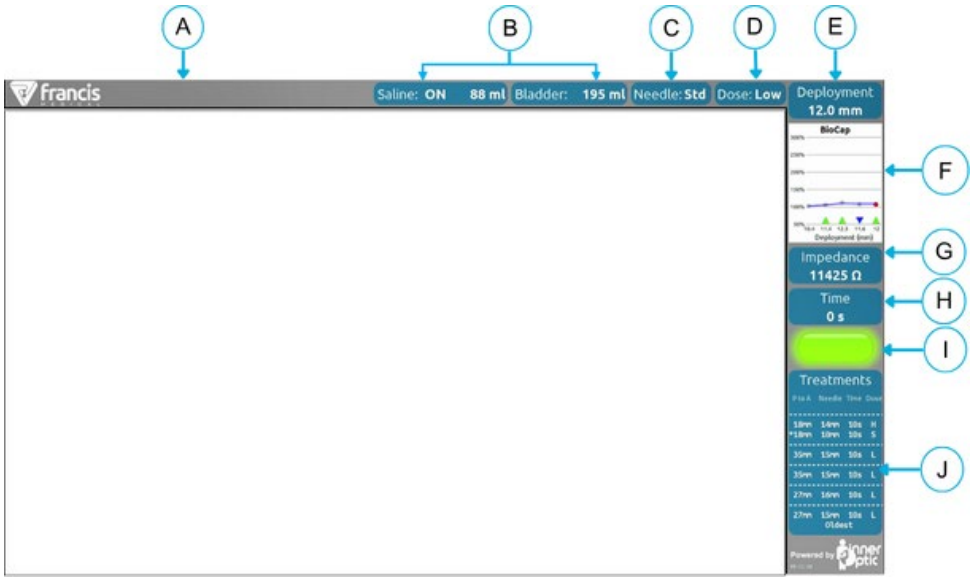


Figure 8-11: Treatment Information Pane

Table 44: Treatment Information Pane Description

Label	Name	Description
A	Alert Window	Displays alerts and procedural messages. Mirrors alerts shown on the Generator OUI.
B	Saline Volume Indicators	Displays the status of perineal and bladder saline volumes (see details below).
C	Delivery Device Needle Type	Displays the connected needle type: Std, Pz, or Rtx.
D	Selected Therapy Dose	Displays the selected vapor dose: Low, Std, or High.
E	Needle Deployment Distance	Displays the current needle deployment distance in millimeters.
F	BioCap Graph	Displays a real-time graph of impedance levels measured at the needle tip.
G	BioCap Impedance	Displays the real-time impedance value (in Ohms) measured at the needle tip.
H	Treatment Time	Displays the elapsed time (in seconds) during active vapor delivery.
I	System Status Indicator	Displays a color-coded indicator reflecting the current system state.
J	Treatment List	Displays a list of completed treatments.

Alert Window

The Alert Window displays procedural alerts and messages relevant to the treatment (see **Figure 8-12**). These alerts mirror those shown in the Alerts window on the Operator User Interface (OUI) of the Generator.

Figure 8-12: Example Alert Window Message

Saline Volume Indicators

The Saline Volume Indicators display operational status and fluid volumes for both the perineal and bladder saline systems.

Perineal Saline Indicator

The Perineal Saline Indicator displays the ON/OFF status of the perineal saline pump and the total volume of saline instilled through the Saline Catheter Needle and Saline Needle Tubing Set (see **Figure 8-13).**

Figure 8-13: Perineal Saline Indicator

Bladder Instilled Volume Indicator

The Bladder Instilled Volume Indicator (**Figure 8-14**) displays the volume of saline currently instilled in the bladder via the Delivery Device. The text color changes based on the instilled volume:

- **White**: ≤ 600 mL
- **Yellow**: > 600 mL and ≤ 700 mL
- **Red**: > 700 mL and ≤ 750 mL
- **Flashing Red**: > 750 mL

Figure 8-14: Bladder Instilled Volume Indicator

Delivery Device Needle Type

The Delivery Device Needle Type display shows the type of needle currently connected to the Delivery Device. This field is labeled **Needle** in the interface (see **Figure 8-15**). Possible values include:

- **Std**: Standard
- **Pz**: Peripheral Zone
- **Rtx**: Retreatment

Figure 8-15: Delivery Device Needle Type

Selected Therapy Dose

The Selected Therapy Dose display shows the vapor dose currently chosen for treatment. This field is labeled **Dose** in the interface (see **Figure 8-16**). Possible values include:

- Low
- Std (Standard)
- High

Figure 8-16: Selected Therapy Dose

Needle Deployment Distance

The Needle Deployment Distance display shows the real-time needle deployment distance, in millimeters, measured from the fully retracted position (see **Figure 8-17** and **Table 45**). This measurement assists with procedural control and accuracy during treatment.

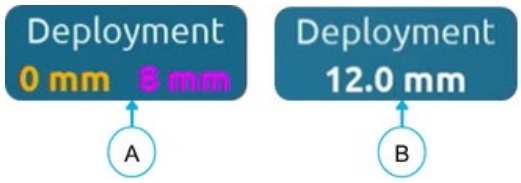


Figure 8-17: Needle Deployment Distance

Table 45: Needle Deployment Distance Description

Label	Name	Description
A	Pre-Deployment Distances	Visual indicators of needle deployment: • Yellow (left): Indicates current needle deployment distance • Magenta (right): Indicates setting for initial deployment distance
B	Post-Deployment Distance	Displays the current needle deployment distance in millimeters once the needle has been deployed.

BioCap Graph

The BioCap Graph displays a real-time graph of impedance levels measured at the needle tip (see **Figure 8-18** and **Table 46**). It includes both current and historical BioCap values.

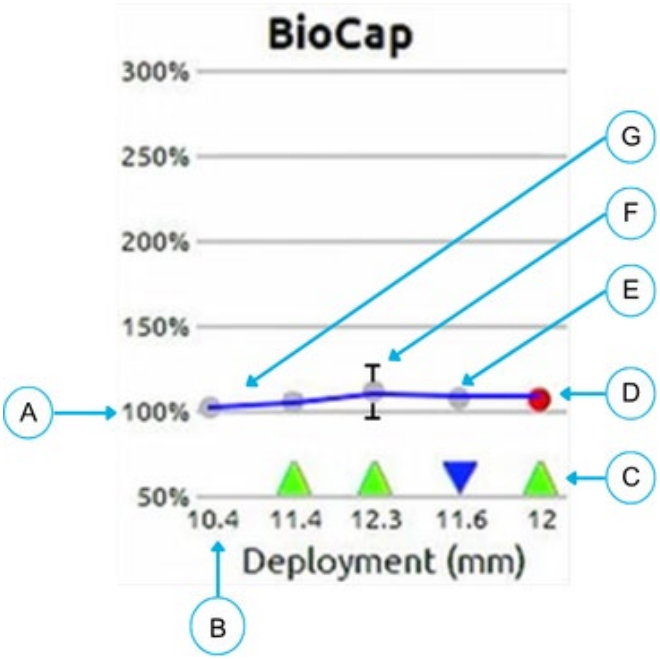


Figure 8-18: BioCap Graph

Table 46: Bio Cap Graph Description

Label	Name	Description
A	Baseline BioCap (%)	Displays the relative BioCap measurement (as a percentage) recorded at the time of initial needle deployment (baseline = 100%).
B	Deployment Distance (mm)	Indicates the needle deployment distance in millimeters at the time of each BioCap measurement.
C	Deployment Indicator Arrows	Shows directional arrows indicating needle movement and impedance changes: • **Green upward arrow** – needle advanced from previous position • **Blue downward arrow** – needle retracted from previous position • **Orange arrow** – BioCap measurement at this position exceeds 300%
D	Current BioCap Value	Displays the current, live BioCap measurement at the needle tip.
E	Prior Exit Value	Shows the BioCap value recorded when the needle was last retracted or advanced away from the current position.
F	Range of Values at Position	Displays the full range of BioCap values measured while the needle remained at the same deployment distance.
G	Entry Value	Shows the BioCap value recorded when the needle was first advanced or retracted into the current position.

Alternate BioCap Messages

The BioCap graph may be replaced by alternate messages depending on system state:

- *"Vapor Active"* – Displayed during vapor delivery
- *"BioCap Sensor Short Detected"* – Displayed if a short is detected in the BioCap circuit
- *"BioCap Sensor Open Detected"* – Displayed if an open is detected in the BioCap circuit

BioCap Impedance

The Impedance display shows the real-time electrical impedance measured at the needle tip, labeled 'Impedance' (see **Figure 8-19**). This value provides feedback on tissue conductivity characteristics and may support procedural decision-making.

Figure 8-19: BioCap Impedance

Treatment Time

The Treatment Time display shows the elapsed duration (in seconds) of the active vapor delivery, labeled 'Treatment' (see **Figure 8-20**). It provides real-time feedback to assist with monitoring and control of vapor application.

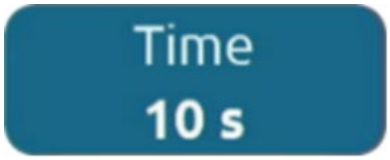


Figure 8-20: Treatment Time

System Status Indicator

The System Status Indicator displays a color-coded signal on the monitor to indicate the current state of the system (see **Figure 8-21**and **Table 47**).

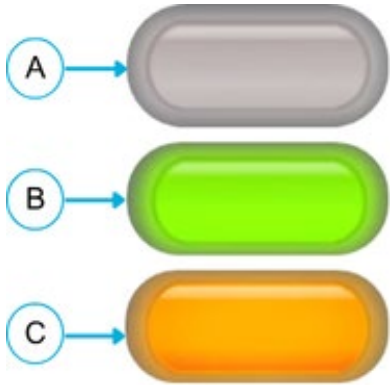


Figure 8-21: System Status Indicator Lights

Table 47: System Indicator Light Colors Description

Label	Status	Description
A	Waiting	The system is temporarily unavailable while the syringe refills and the coil reheats following vapor delivery.
B	Ready to Deliver Vapor	The system is fully primed and ready to initiate vapor delivery.
C	Vapor Delivery in Progress	The system is actively delivering vapor.

Treatment list

The Treatment List displays a chronological record of completed treatments lasting 7 seconds or longer, labeled 'Treatments' (see **Figure 8-22** and **Table 48**). The most recent entry appears at the top. A dashed line indicates a new needle deployment after full retraction.

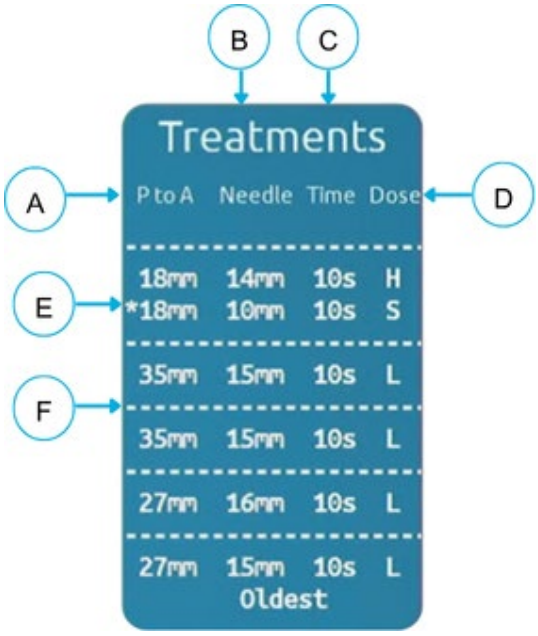


Figure 8-22: Treatment List

Table 48: Treatment List Description

Label	Name	Description
A	P to A	Distance from the Axial Ultrasound Plane to the Apex Plane at the time of vapor delivery.
B	Needle	Deployment distance when vapor was delivered.
C	Time	Duration of vapor delivery.
D	Dose	Therapy dose delivered, H, S, or L.
E	Asterisk	Indicates the Apex Plane was adjusted prior to treatment.
F	Dashed Line	Indicates a new needle deployment after full retraction.

8.2 Visual Guidance Cues (NGS Assets)

Visual guidance cues, also referred to as NGS Assets, can be enabled or disabled using the Generator interface (see **Section 7.8.4**). The cues displayed on the PUI vary depending on whether the needle is deployed.

- Guidance cues displayed ***prior to needle deployment*** are described in **Table 49** and **Figure 8-23**.
- Guidance cues displayed ***after needle deployment*** are described in **Table 50** and **Figure 7-24**.

8.2.1 Prior to Needle Deployment

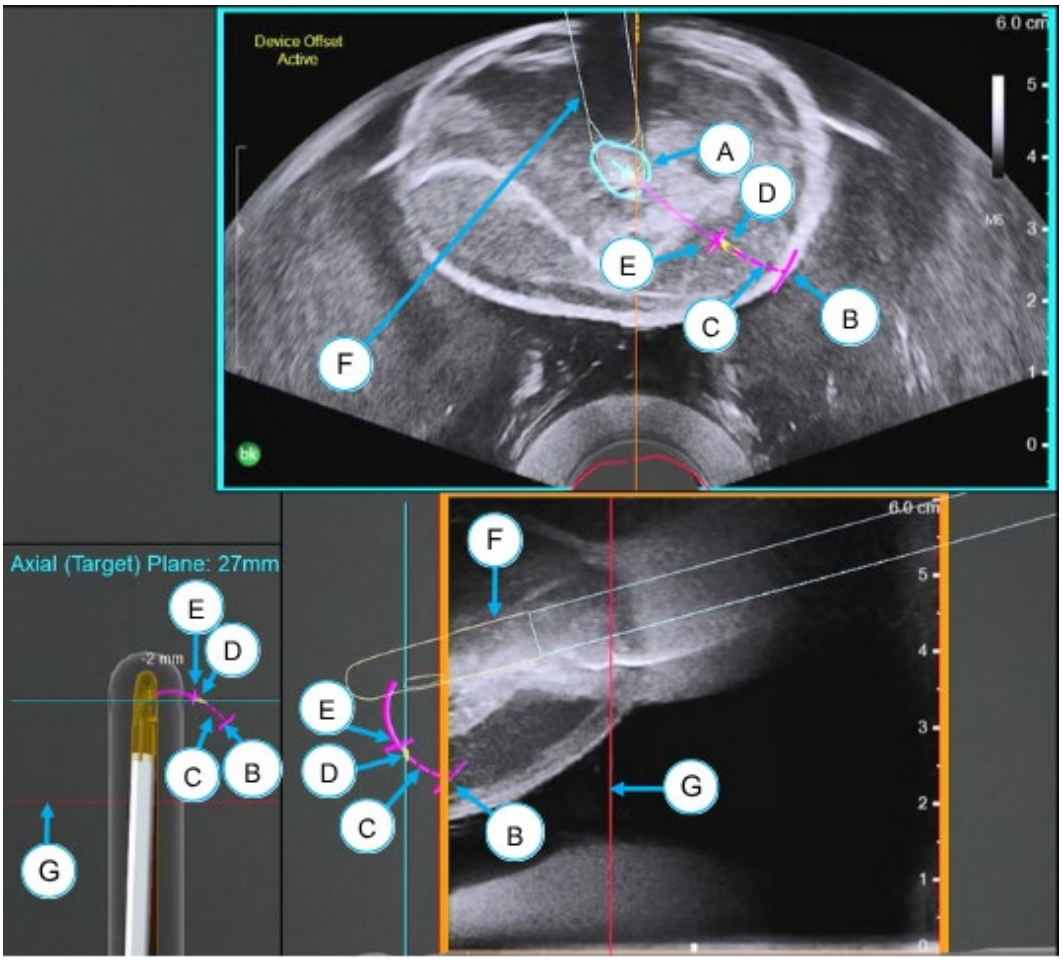


Figure 8-23: Visual Guidance Cues Prior to Needle Deployment

Table 49: Descriptions of Visual Guidance Cues Prior to Needle Deployment

Label	Name	Description
A	Shaft Projection	Displays a blue projection of the Delivery Device shaft on the ultrasound plane. The arrow indicates the direction in which the needle will deploy.
B	Shaft Projection Maximum Deployment Arc	Displays a solid magenta arc representing the maximum possible needle deployment distance.
C	Predicted Needle Trajectory Arc	Displays a dashed magenta arc representing the predicted path of the deployed needle.
D	Ultrasound Ripple	Displays a yellow projection at the intersection of the predicted needle trajectory with the axial ultrasound plane.
E	Initial Deploy Distance Indicator	Displays a solid magenta line along the predicted needle path, representing the programmed initial deployment distance.
F	Shaft Avatar	Displays the Delivery Device shaft's position and orientation relative to the ultrasound planes.
G	Apex Plane	Displays a red line on the Sagittal Ultrasound Image, 3D View, and Top-Down 2D View. A dashed red line indicates the plane is unset (“picked up”); a solid red line indicates it is set (“dropped”).

8.2.2 After Needle Deployment

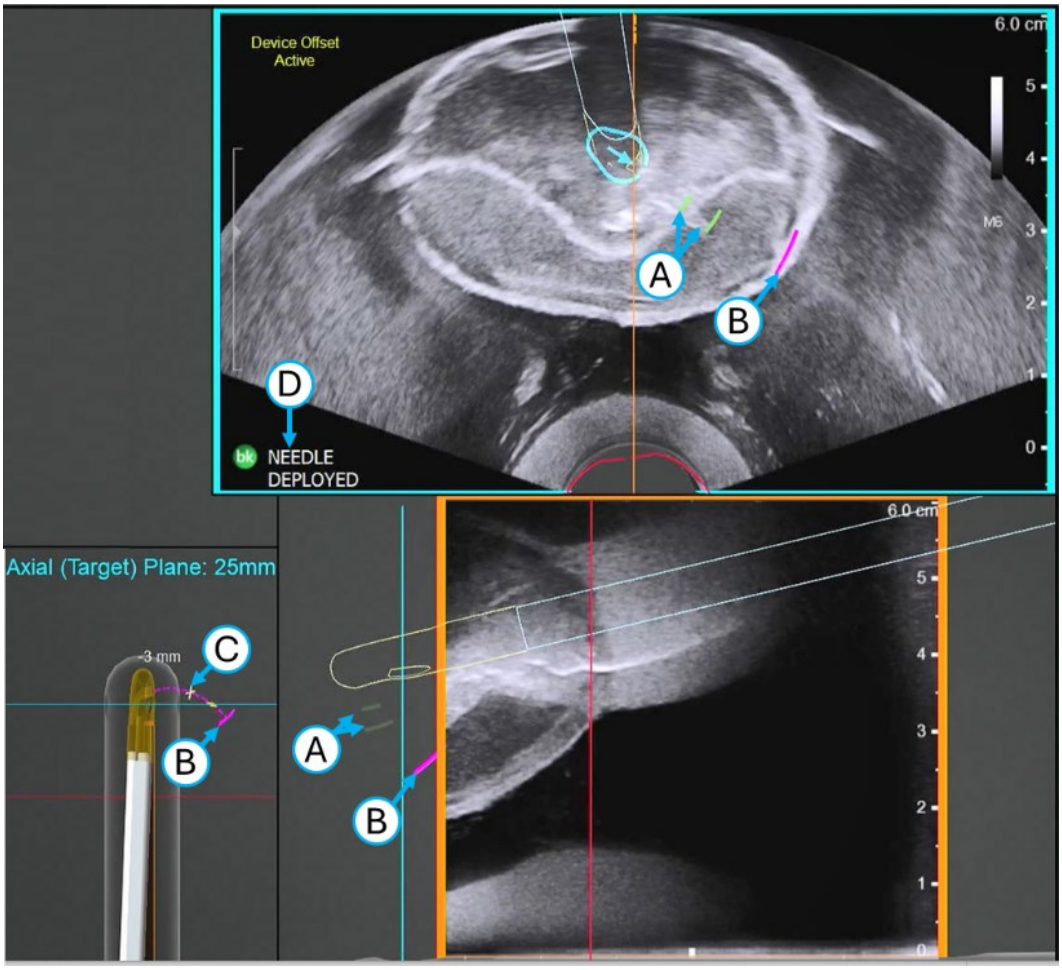


Figure 7-24: Visual Guidance Cues After Needle Deployment

Table 50: Visual Guidance Cues After Needle Deployment

Label	Name	Description
A	Needle Emitter Hole Arcs	Displays two solid green arcs representing the estimated needle position. The proximal arc corresponds to the most proximal emitter holes and the distal arc corresponds to the needle tip.
B	Maximum Needle Deployment Arc	Displays a solid magenta arc indicating the maximum needle deployment length.
C	Needle Tip Position Crosshairs	Displays crosshairs on the Top-Down 2D View to indicate the estimated position of the needle tip.
D	Needle Deployed Indicator	Displays a “NEEDLE DEPLOYED” message while the needle is deployed. The message flashes after a full treatment is delivered.

8.2.3 Additional Visual Guidance Cues Controlled via the Generator OUI

Target Sphere

The Target Sphere displays a user-defined sphere in 3D space to assist with tool positioning. This feature can be enabled and configured using the 3D Targeting menu on the Generator OUI (see **Section 7.8.9** 3D Targeting). The Target Sphere is overlaid on the ultrasound image planes and changes color based on alignment:

- **Orange** indicates that the needle trajectory does **not** intersect the sphere (see **Figure 7-25**A).
- **Green** indicates that the needle trajectory **does** intersect the sphere (see **Figure 7-25**B).

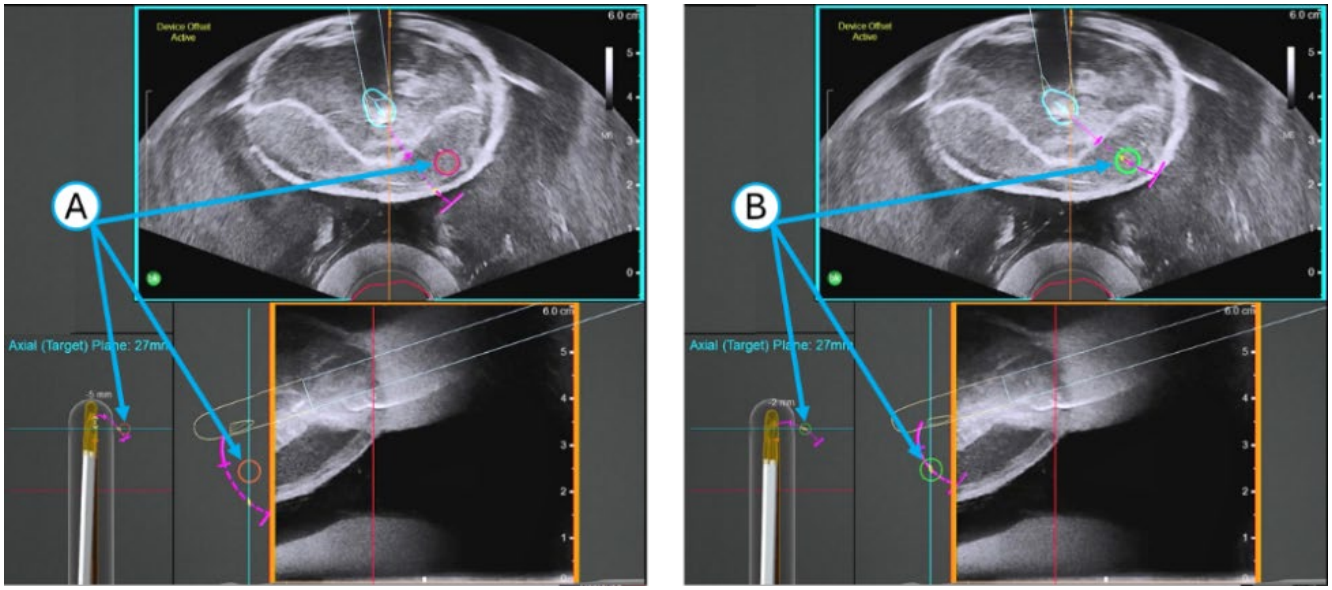


Figure 7-25: Target Sphere visualization.
A) Projected needle trajectory does not intersect the sphere.
B) Projected needle trajectory intersects the sphere

Deployment Markers

The Deployment Markers display magenta markers and directional vectors indicating where needle deployments occurred. This feature can be enabled and configured using the Additional NGS Asset Visibility Options popup menu on the Generator OUI (see **Section 7.8.5** Additional NGS Asset Visibility Options Popup Menu). These markers appear in both the 3D View (see **Figure 8-26**A) and Top-Down 2D View (see **Figure 8-26**B).

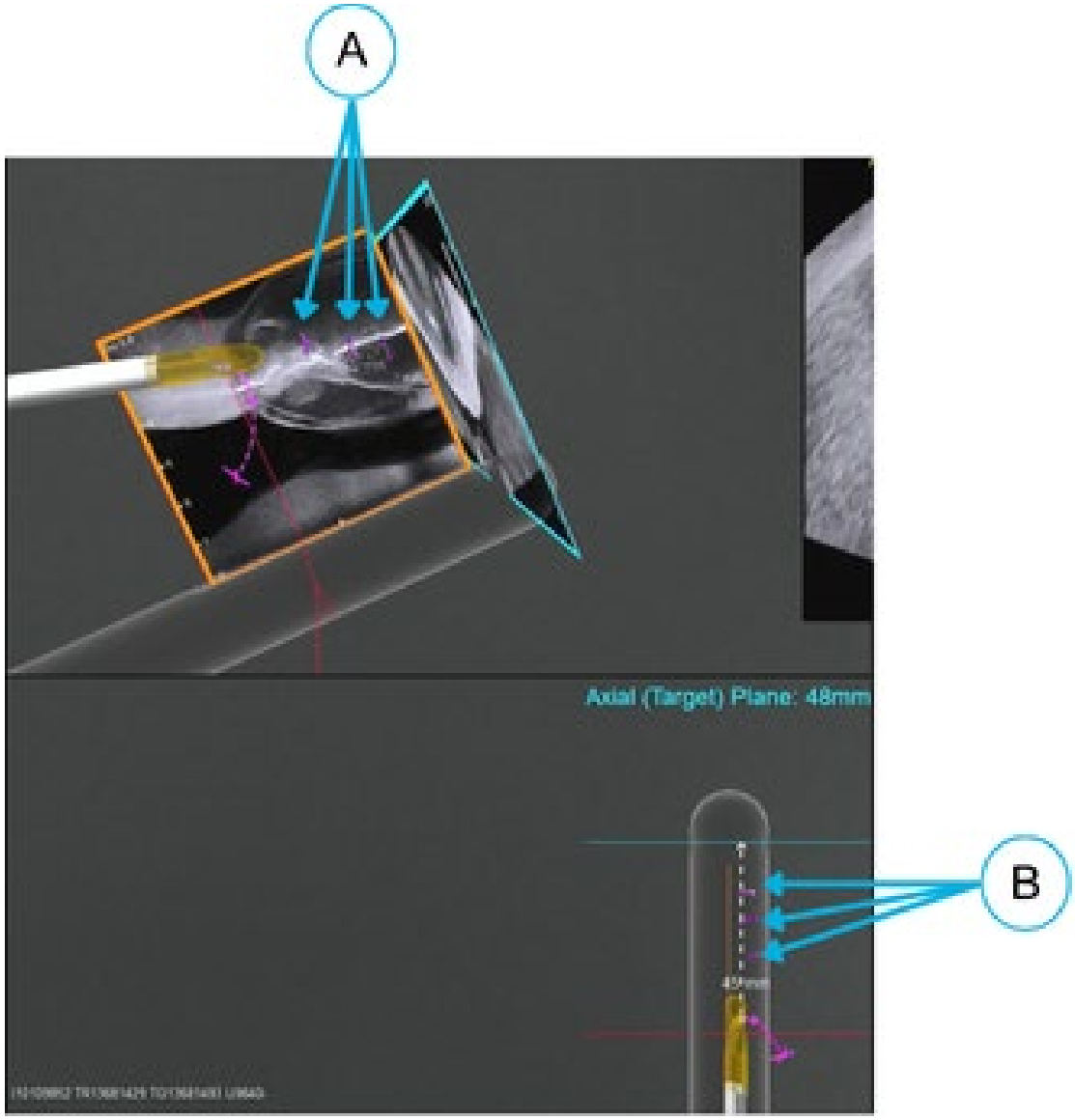


Figure 8-26: Deployment Markers displayed in A) the 3D View and B) the Top-Down 2D View

Ablation Markers

The Ablation Markers display yellow circular markers indicating where full vapor treatments were delivered based on estimated trajectory. This feature can be enabled and configured using the Additional NGS Asset Visibility Options popup menu on the Generator OUI (see **Section 7.8.5** Additional NGS Asset Visibility Options Popup Menu). These markers appear in both the 3D View (see **Figure 8-27**A) and Top-Down 2D View (see **Figure 8-27**B).

■ **NOTE:** If intraprocedural movement of the Field Generator or prostate occurs, the accuracy of the deployment and ablation markers may be compromised.

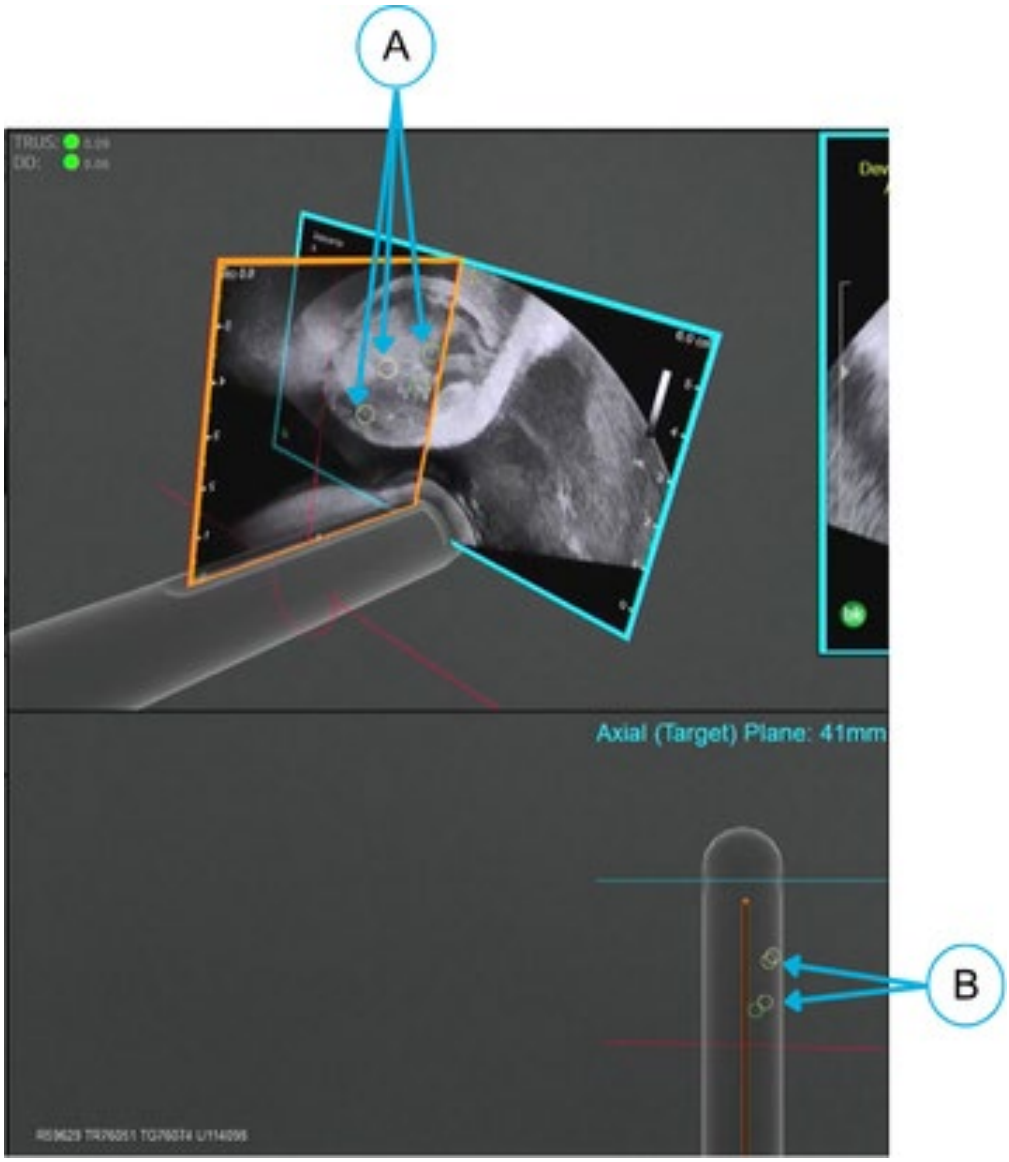


Figure 8-27: Ablation Markers displayed in A) the 3D View and B) the Top-Down 2D View

Ultrasound Image in 3D View

The Ultrasound Image in 3D View projects the Axial and Sagittal ultrasound images into the 3D and Top-Down 2D Views to provide spatial context during navigation and treatment (see **Figure 8-28**). This feature can be enabled and configured using the Additional NGS Asset Visibility Options popup menu on the Generator OUI (see **Section 7.8.5** Additional NGS Asset Visibility Options Popup Menu).

Apex to Axial Plane Distance

The Apex to Axial Plane Distance displays a yellow line between the Apex and Axial Planes in the 3D View and Top-Down 2D View to indicate their spatial separation. This feature can be enabled and configured using the Additional NGS Asset Visibility Options popup menu on the Generator OUI (see **Section 7.8.5** Additional NGS Asset Visibility Options Popup Menu).

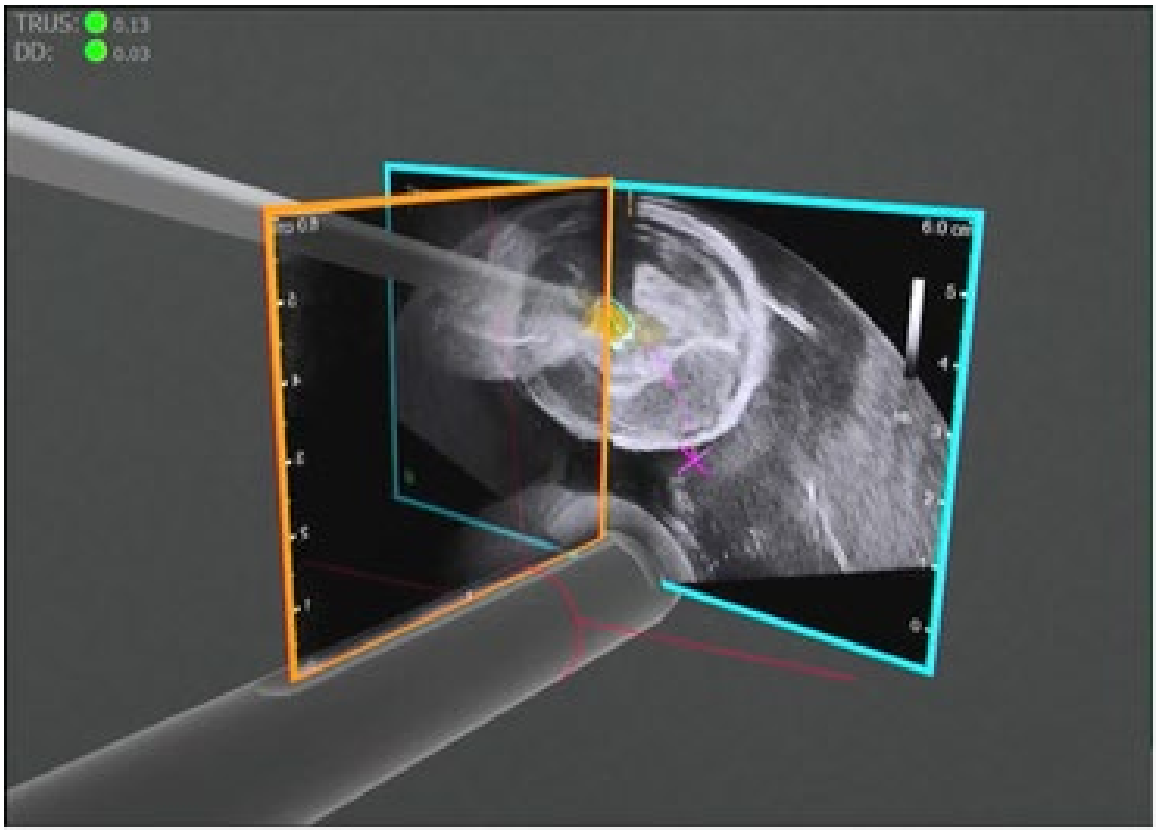


Figure 8-28: Ultrasound Image in 3D view

Apex Plane
The Apex Plane displays a red line in the 3D View, Top-Down 2D View, and Sagittal Ultrasound Image. A solid red line indicates the plane has been dropped, while a dashed red line indicates the plane has been picked up. This feature can be enabled and configured using the Additional NGS Asset Visibility Options popup menu on the Generator OUI (see **Section 7.8.5** Additional NGS Asset Visibility Options Popup Menu).

Needle Projection onto Axial 2D
The Needle Projection onto Axial 2D displays a dashed magenta line representing the estimated needle trajectory projected onto the Axial Ultrasound Image. This feature can be enabled and configured using the Additional NGS Asset Visibility Options popup menu on the Generator OUI (see **Section 7.8.5** Additional NGS Asset Visibility Options Popup Menu).

Deploy Projection onto Axial 2D
The Deploy Projection onto Axial 2D displays a solid magenta line representing the projected initial deployment distance onto the Axial Ultrasound Image. This feature can be enabled and configured using the Additional NGS Asset Visibility Options popup menu on the Generator OUI (see **Section 7.8.5** Additional NGS Asset Visibility Options Popup Menu).

Full Treatment List
The Full Treatment List (**Figure 8-29)** displays a comprehensive list of all vapor treatments lasting 4 seconds or longer. Each entry includes key procedural details to support retrospective review and documentation (see **Table 51**). The treatment list can be opened via the Settings menu on the Generator OUI (see **Section 7.8.1** Therapy Menu).

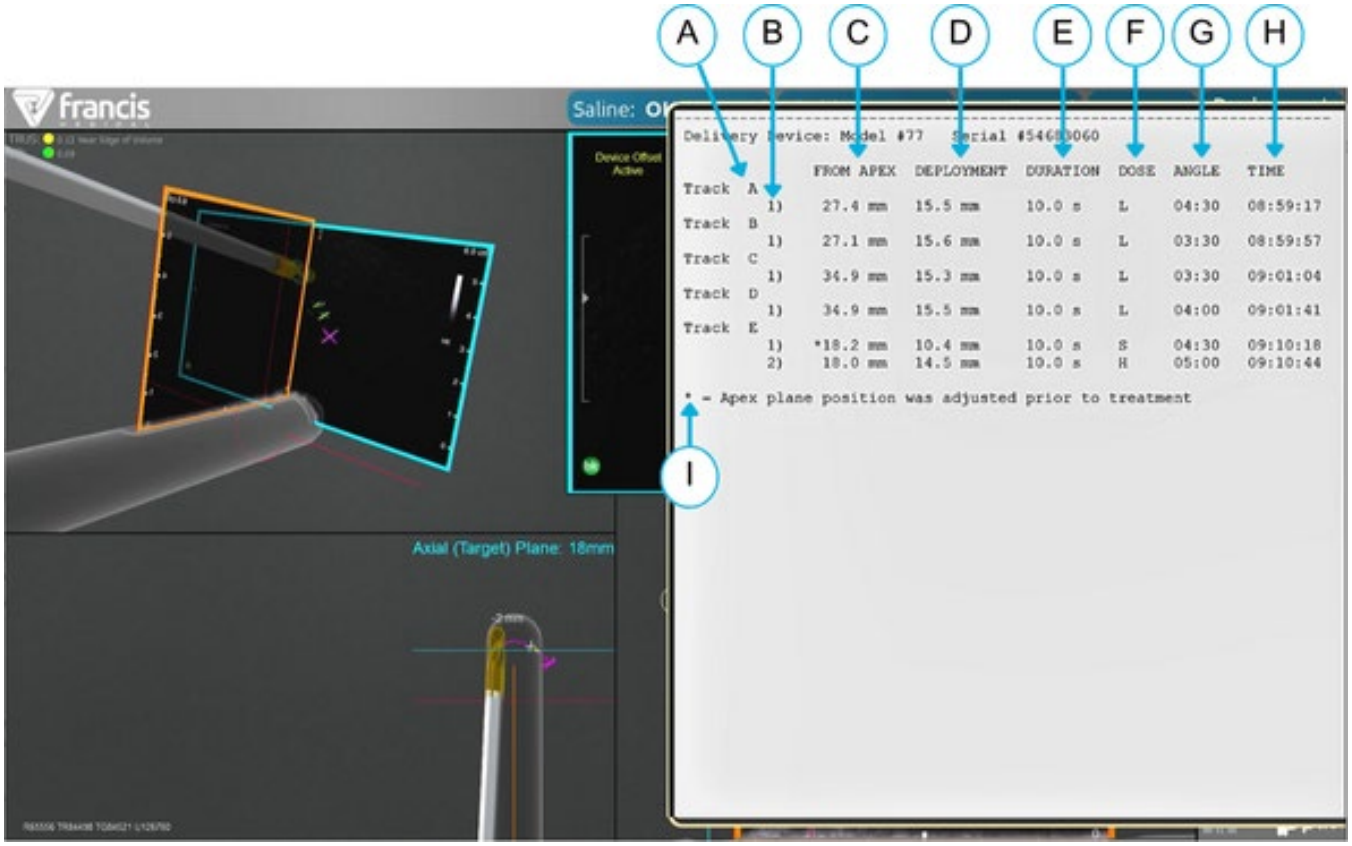


Figure 8-29: Full treatment list

Table 51: Full Treatment List Description

Label	Name	Description
A	Track Label	Indicates the start of a new needle track following full retraction and subsequent deployment.
B	Treatment Number	Sequential identifier for each treatment within the same deployment.
C	From Apex	Distance between the Apex Plane and Axial Plane at treatment time.
D	Deployment	Needle deployment distance at the start of the treatment.
E	Duration	Duration of vapor delivery, in seconds.
F	Dose	The vapor dose delivered (L = low, S = standard, H = high).
G	Angle	Needle orientation at the time of treatment, shown using clock-face format (e.g., 12:00 = vertical upward).
H	Time	Generator time stamp (24-hour format) indicating when the treatment began.
I	(*) Asterisk	Indicates that the Apex Plane position was adjusted prior to treatment.

9 Planning a Procedure

Procedure planning should be done using available imaging, biopsy, or other diagnostic information to determine the target location(s) for treatment within the prostate and the extent of intended ablation.

■ **NOTE** : A static, user-generated image of a treatment plan can be imported to the Generator via the USB port for placement on the Treatment Plan/3D View section of the PUI (see **Section 10.9**).

10 System Setup and Start-Up

⚠ **WARNING – Damaged Components:** Do not use the system if any hardware components or connectors are damaged. Damaged parts may interfere with system performance. This may lead to inaccurate output or potential injury.

■ **NOTE:** The Cart (with IV Pole) and Monitor require assembly by Francis Medical personnel or an authorized representative prior to first use.

1. Perform visual inspection of the single-use sterile components cartons and sterile barriers before transporting them to procedure environment:
   - Verify the products are not expired.
   - Verify the sterile barriers are undamaged and unopened.
   - If present, verify the EO Exposure Indicator label is green. If it is not green, sterility may be compromised.
   - If any of the visual inspections above are not satisfied, do not use the product, replace the product, and report to Francis Medical Customer Service.
2. Perform visual inspection of the reusable components before use:
   - Carefully inspect components for stress or physical damage.
   - Inspect all external connections for loose connectors.
   - Inspect all external cables for damage or cracking.
   - Inspect the display for marks, scratches, or other damage.
   - Verify that the Safety label on the device is clearly legible and present.
   - After the visual inspection, if reusable components are damaged, take them out of service, replace the components, and report to Francis Medical Customer Service.
3. Disinfect the following reusable equipment before the procedure (see **Section 15.2**):
   - Cart/Monitor
   - Generator
   - Field Generator
   - Capital Mounts
   - Stabilizer Arm Kit

10.1 Patient Preparation

Prior to the procedure:

1. Anesthetize the patient.
   - It is important that the patient does not move throughout the procedure.
2. Empty the patient's bladder.
3. Place the patient in the lithotomy position.
4. Prepare and drape the patient using standard cystoscopy guidelines.

■ **NOTE:** Ensure buttocks are resting at the edge of the OR table to provide adequate access to the anatomy with the treatment tools.

10.2 Positioning the Cart and Monitor

⚠ **WARNING – Transport (within facility):** Do not transport the Cart with the Monitor Arm fully extended. Transporting the Cart in this state may cause it to tip. This can lead to equipment damage or personal injury.

■ **NOTE:** The power cord to the rear of the generator is used for mains power disconnection (isolation). If there is a need to isolate the Generator from AC mains power, disconnect the AC cord from the power inlet connection at the rear of the Generator.

■ **NOTE:** The Vanquish System is designed to be used only with the Francis Medical Monitor.

1. When moving the Cart and Monitor, utilize the transport configuration outlined in **Figure 10-1**:
   - Fold the Monitor Arm in with the Monitor positioned above the Cart (A)
   - Position the Monitor perpendicular to the handle grip (B) location
   - Place the Generator on the top shelf (C)
   - Load the drawers and shelves (D) to the marked rating or less
   - Unlock all wheels (E)

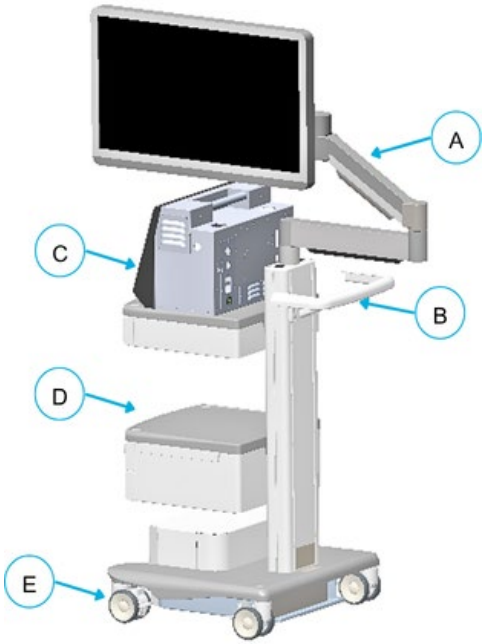


Figure 10-1: Cart and Monitor Transport Position

2. Position the Cart and Monitor:
   - On the same side of the OR bed as the Cystoscopy and Ultrasound systems, within reach of an electrical outlet
   - Outside the sterile field, approximately 1 m (3 ft) from the patient, between the patient's arm and leg close to the abdomen
   - For easy removal of the power cord and uninhibited access to the power switches for the Cart and Generator
3. Lock all wheels

10.3 Cable Connections

⚠ **WARNING – Power Supply:** Always connect the system to an appropriate supply mains source with protective earth. Do not operate the system if such a power source is unavailable or improperly grounded. An inadequate or ungrounded power supply may disrupt system performance. This can result in device malfunction, electric shock, or patient injury.

⚠ **WARNING – Multiple Socket Outlet:** Do not connect equipment other than what is specified to the Multiple Socket Outlet (MSO). Connecting unspecified equipment may affect system safety. This may result in degraded safety and potential patient or user harm.

⚠ **WARNING – Damaged Cables:** Do not bend, kink, or use damaged cables. Damaged or improperly handled cables may disrupt signal integrity. This can result in inaccurate data or personal injury.

⚠ **WARNING – Electromagnetic Compatibility and Interference:** Follow all electromagnetic compatibility (EMC) precautions and instructions for Vanquish System and surrounding equipment. High levels of electromagnetic interference (EMI) may disrupt system performance. This may cause display distortion, erratic readings, or unsafe operation.

⚠ **CAUTION – Weight on Connectors:** Avoid placing heavy objects on connectors. Excessive weight may damage connector integrity and lead to system malfunction.

⚠ **CAUTION – Connector Placement:** Do not leave connectors in areas where they may be stepped on, crushed, or otherwise damaged. Damaged connectors can cause system failures or inaccurate function.

⚠ **CAUTION – Connector Stress in Tight Spaces:** Avoid pushing or pulling connectors in confined areas. Doing so may damage the cable or connector and disrupt system operation. This section describes all the cable connections for the Vanquish System. Cables can be connected in any order.

⚠ **CAUTION – Aerosol Sprays:** Do not use aerosol sprays near the system. Aerosols can damage internal circuitry and impair system performance.

■ **NOTE:** The system should not be unplugged after the system has been turned on.

■ **NOTE:** Do not force the cable into the port when trying to connect them. Use the design of the connectors to guide the correct orientation.

■ **NOTE:** Only use the cables supplied with the system.

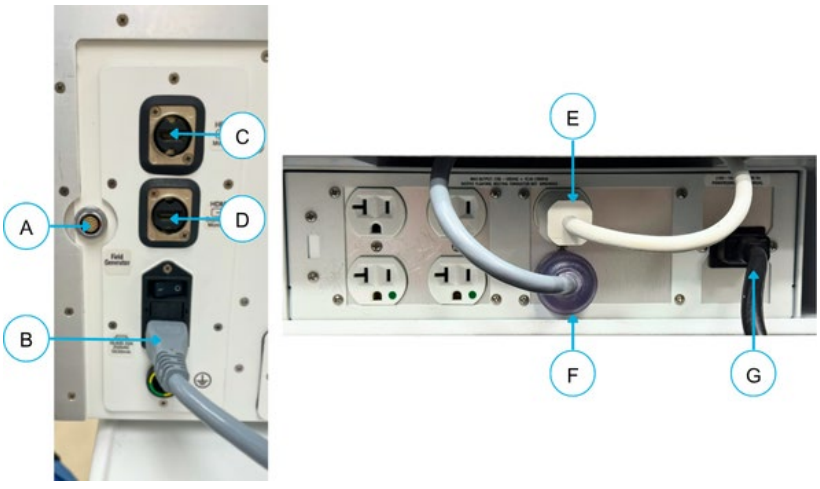


Figure 10-2: Generator to Cart Connections

1. Ensure the **Monitor power cord** is plugged into a Multiple Socket Outlet (MSO) at the base of the Cart (**E**) (see **Figure 10-2)**.
2. Plug the female end of the **Vanquish Generator power cord** into the back of the Vanquish Generator (**B**) (**see Figure 10-2)**.
3. Plug the **Vanquish Generator power cord** into the Multiple Socket Outlet at the base of the Cart (**F**) (see **Figure 10-2)**.
4. Plug the **Cart power cord** (**G**) into an Operating Room outlet (see **Figure 10-2**).
5. Use the **Serial Cable DB9** to connect the Vanquish Generator to the Monitor (see **Figure 10-4**).
   - Generator port (**M**) labeled 'IOIOI Monitor'
   - Monitor port (**H**) labeled 'RS-232C'

■ **NOTE:** Ensure that the power cable for the monitor is connected to the DC-IN port (**I** in **Figure 10-4**).

6. Use the **HDMI to HDMI cable** to connect the Generator to the Monitor (see **Figure 10-3** and **Figure 10-4**).
   - Generator HDMI port (**C** or **D**)
   - Monitor HDMI port (**K**) labeled 'HDMI IN'

■ **NOTE:** The Generator has two HDMI ports (**C, D**); either port can be used.

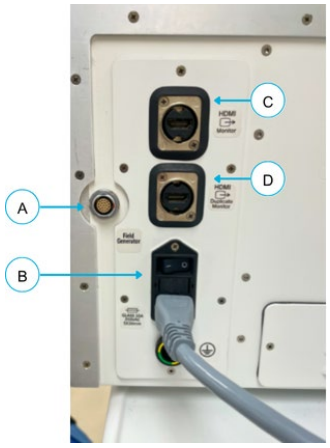


Figure 10-3: Generator Ports

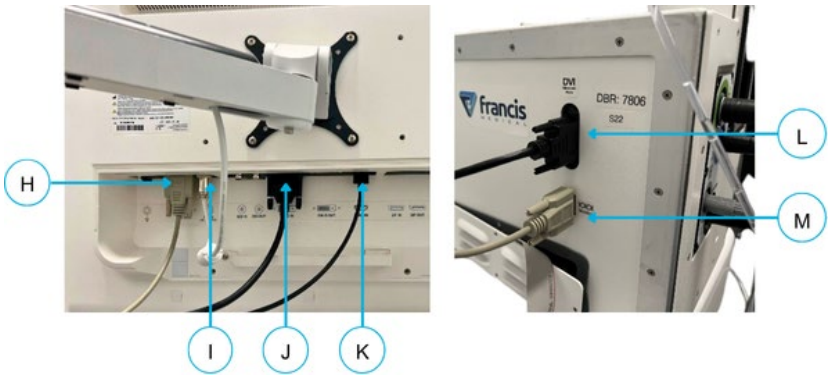


Figure 10-4: Figure: Generator to Monitor Connections

7. Use the **DVI cable** to connect the Monitor to Cystoscopy.
   - Monitor port (**J**) labeled 'DVI-D IN' (**Figure 10-4**)
   - Cystoscopy system: Connect to the appropriate Digital Output DVI port (**N**) (**Figure 10-5**).

■ **NOTE:** Some Cystoscopy systems may require use of the HDMI Adapter, provided with the Cart and Monitor Assembly or Generator Kit.

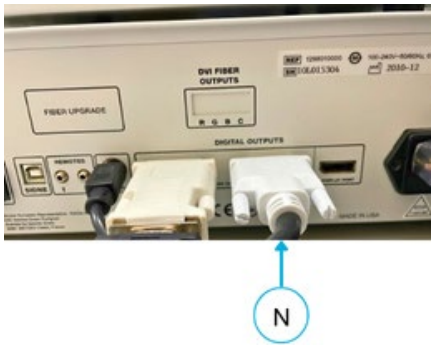


Figure 10-5: Cystoscopy Connections

8. Use the **HDMI to DVI cable** to connect the Ultrasound (HDMI) to the Vanquish Generator (DVI) (**Figure 10-6**).
   - Ultrasound HDMI port (**O**)
   - Generator port (**L**) labeled 'DVI Ultrasound Video'
9. Plug the **Ultrasound power cord** into an Operating Room outlet.

■ **NOTE**: The Ultrasound power cord is not rated to plug into Cart MSO.

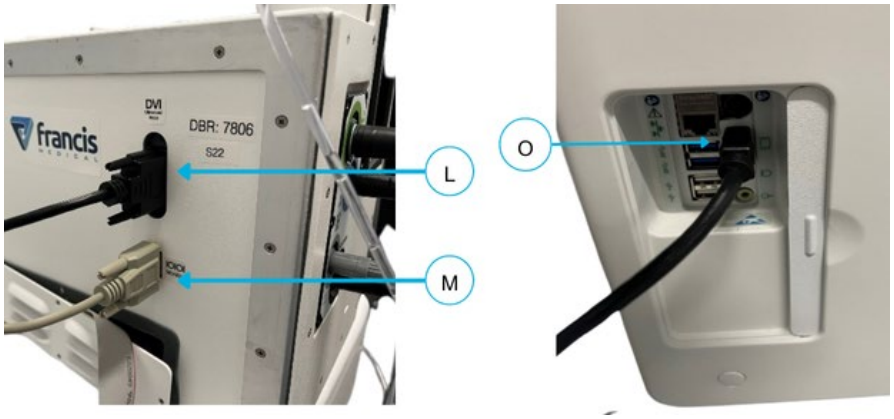


Figure 10-6: Generator to Ultrasound Connections

10. Use the **Field Generator cable** to connect the Field Generator to the Generator.
    - Generator port (**A**) labeled Field Generator' (**Figure 10-7**)
    - This connection may have already been made when setting up the Field Generator

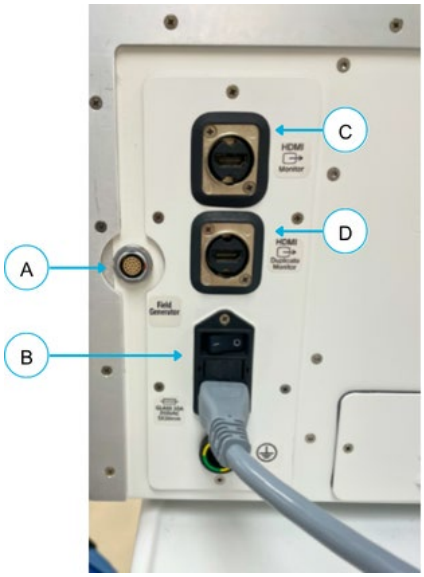


Figure 10-7: Generator Connections, Back View

10.4 Starting the System

10.4.1 Turn on the Generator

1. Flip the power switch on the back of the Generator (labeled O/-) to the **ON** position (**B**) (**Figure 10-3**).
   - The Generator screen will power on and automatically complete a self-test (**Figure 10-8**)
   - The display will show Self-Test progress

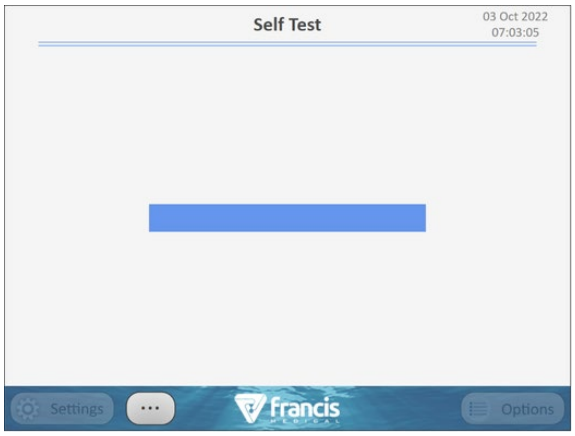


Figure 10-8: Self-Test Screen

2. Once the Self-Test is complete, the system will display the System Setup screen with no connections (**Figure 10-9**).

10.4.2 Generator System Setup Overview

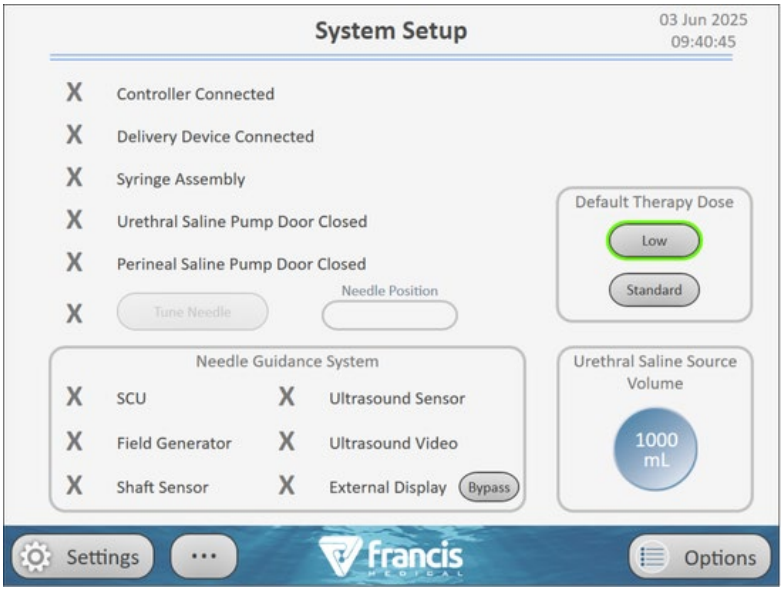


Figure 10-9: Initial Generator System Setup Screen

Before starting treatment, all required system connections must be established. The **System Setup** screen (**Figure 10-9**) provides a visual status of each connection, ensuring proper setup before proceeding.

- A **gray X** appears next to any disconnected component
- Once properly connected, the **gray X turns into a green checkmark**

- Treatment **cannot begin** until all required connections are established

When all connections are complete, the System Setup screen will display green check marks next to each component (**Figure 10-10**).

Figure 10-10: Completed Generator System Setup Screen

10.4.3 Turn on the Monitor

1. Press the Monitor power switch located on the bottom edge of the monitor on the lower right side.
2. Verify that the **gray X** next to "External Display" changes to a **green checkmark** (**Figure 10-11**), indicating a successful connection.
3. Verify that there is signal displayed on the Monitor from both the Generator and Cystoscopy.

Figure 10-11: Green Completion Check Mark

■ **NOTE**: The Bypass button allows the user to bypass the NGS system check. Under normal operating conditions this button should not be used. Only press this button under direction of Technical Support. Bypass disables the ability to change the PUI view with the OUI.

■ **NOTE**: The Generator is in an inactive state until a valid Delivery Device is connected.

10.5 System Setup

10.5.1 Set Up the Stabilizer System

1. Inspect the OR bedrail for compatibility and damage before transferring the Stabilizer System to the bedrail.
2. Attach one Clark Clamp on the rail of OR bed opposite Generator.
   - Position the Clark Clamp (**A**) next to the stirrup clamp (**B**) (**Figure 10-12**)

■ **NOTE:** The stirrup clamp should be placed **as close to the end of the bedrail as possible**.

■ **NOTE:** Ensure the clamp is not placed over a notch in the rail to maintain a secure attachment.

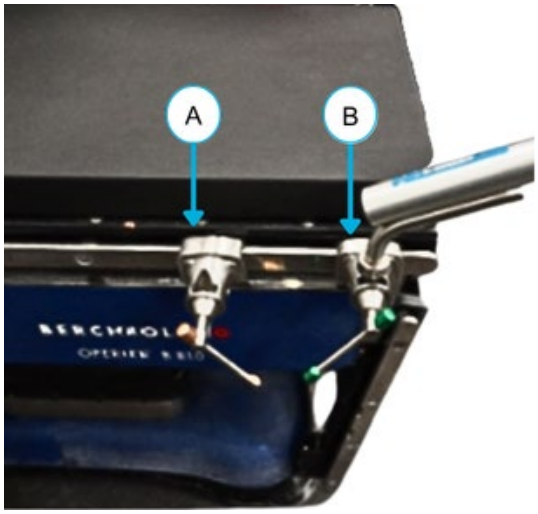


Figure 10-12: Clark Clamp Position

3. Attach two Clark Clamps on the rail of the OR bed closest to the Generator.
   - Attach the First Clamp (**D**) next to the stirrup clamp (**E**) (**Figure 10-13**)
   - Position the second Clark Clamp (**C**) approximately **15-45 cm** (**6–18 in**) past the first clamp (**D**) (towards the head of the bed)

■ **NOTE:** Ensure the clamp is not placed over a notch in the rail to maintain a secure attachment.

■ **NOTE:** The stirrup clamp should be placed **as close to the end of the bedrail as possible**.

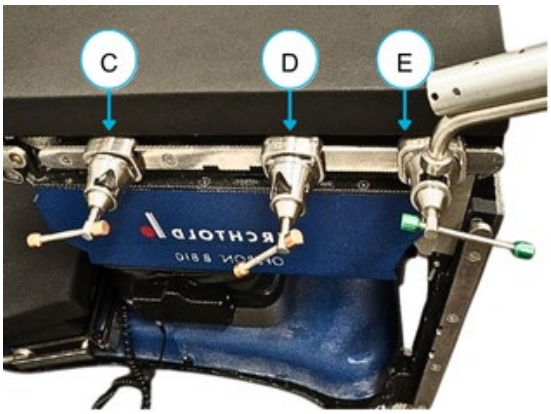


Figure 10-13: Clark Clamp Positions

4. Place one Vertical (long) Stabilizer Mount (**G**) into the Clark Clamp (**F**) (**Figure 10-14**) next to the stirrup clamp (**Figure 10-13**).

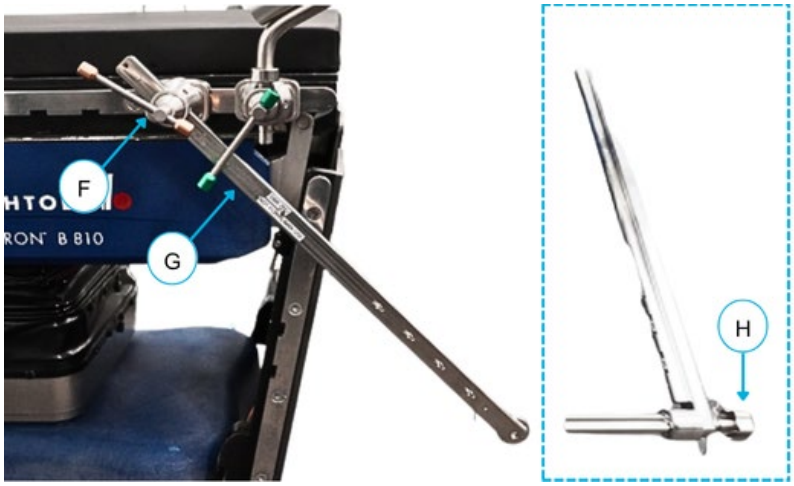


Figure 10-14: Vertical (long) Stabilizer Mounts Attachment

5. Position the Vertical Stabilizer Mount in the Clark Clamp at approximately a 45-degree angle from the OR bed, with knob end (**H**) towards the floor.
6. Repeat Steps **4** and **5**, on the other side of the OR bed, so both sides have a Vertical (long) Stabilizer Mount attached.
7. Attach one Horizonal (short) Stabilizer Mount to the Vertical (long) Stabilizer Mount using attached knob (**I**) (**Figure 10-15**).
   - Ensure ridged edges of Horizonal (short) Stabilizer Mounts are facing outwards (**J**)
   - The flat side of the Horizontal (short) Stabilizer Mounts should face the bed and be perpendicular to the floor

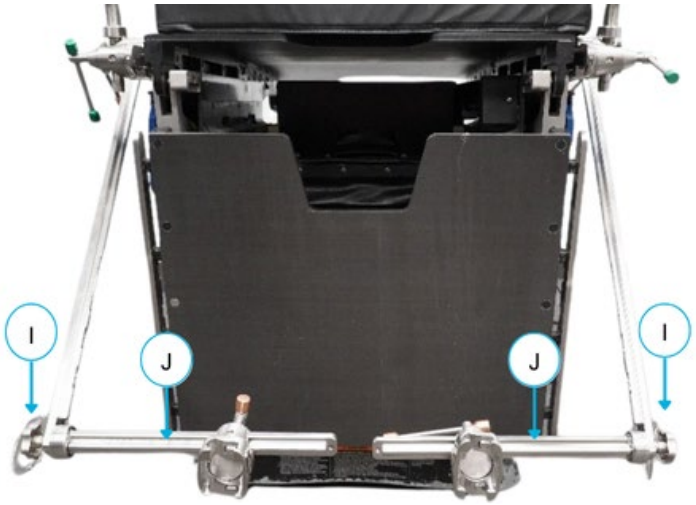


Figure 10-15: Horizontal (short) Stabilizer Mounts Attachment

8. Repeat Steps **6** and **7**, on the other side of the OR bed, so both sides have a Horizontal (short) Stabilizer Mount attached.
9. Attach one Clark Clamp to each Horizontal (short) Stabilizer Mount.
   - Attach through the triangular hole (**K**) on the Clark Clamp (**Figure 10-16**)
   - The flat edge of the Clark Clamp faces away from the end of the OR bed (**L**) (**Figure 10-16**)

■ **NOTE:** Alternatively, the Clark Clamps can be placed on the Horizontal Stabilizer Mounts prior to attachment. This can be helpful if the tips of the Horizontal Stabilizer Mounts are in close proximity.

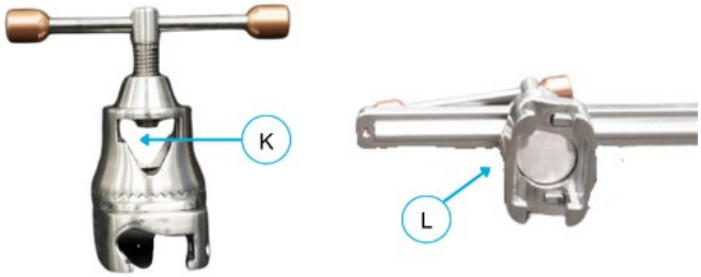


Figure 10-16: Motor Control Box Clark Clamp Side View, and Facing Out

10. Plug the silver cylindrical connector ends (**M**) of the power cords from the Motor Control Box power bricks into the bottom of the Motor Control Boxes (**N**). The two red dots indicate correct alignment (**Figure 10-17**).

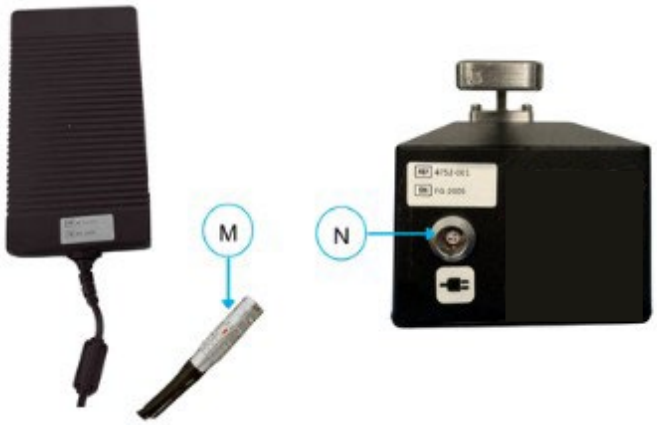


Figure 10-17: Plugging in the Motor Control Box

11. Plug Motor Control Box power bricks (black power cords) into the Multiple Socket Outlet (MSO) at the base of the Cart.
    - Check that the indicator lights are ON (**O**) to confirm power (**Figure 10-18**)

■ **NOTE:** For ease of setup, plug in the Control Boxes before placing them on the Clark Clamps.

Figure 10-18: Motor Control Box Indicator Light

Attach the Stabilizer Arms

12. Place Motor Control Box slide arms into Clark Clamps on Horizontal (short) Stabilizer Mounts with:
    - Plug facing towards floor (**Figure 10-19**)
    - Posts facing upwards (**P**)

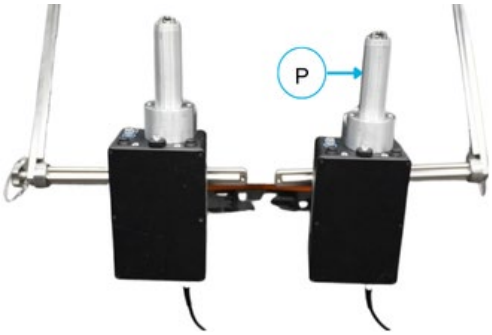


Figure 10-19: Motor Control Box Position

13. Lock the Clark Clamp to hold the Motor Box in place.
14. Confirm the Motor Control Box light (**O**) is solid blue. If not, hold the Unlock button (**S**) until the light stops flashing.

■ **NOTE:** Do not allow the rigid portion of the plug to rest on the floor. This puts strain on the connection and can lead to equipment damage. As needed, raise the OR bed height to provide clearance.

15. Slide the metallic connector pin end of the TRUS (short) Stabilizer Arm (**R**) into the slot (**Q**) on top of the left Motor Control Box (**Figure 10-20**).

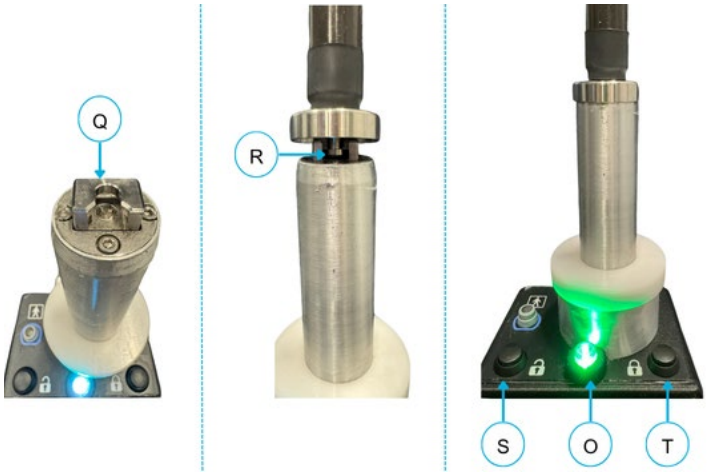


Figure 10-20: Motor Control Box and Stabilizer Arm Connection

16. Press and Hold the black **Lock** button (**T**) to engage and lock arm (**Figure 10-20**).
    - The Motor Control Box will pull the connector pin until the Arm is fully seated
    - The light (**O**) will slowly flash green when locked

■ **NOTE**: If the slot at the top of the Motor Control Box has insufficient room for insertion of the connector pin, press and hold the **Unlock** (**S**) button until the slot is sufficiently large for insertion.

17. Slide the metallic connector pin end of the Delivery Device (long) Stabilizer Arm (**R**) into the slot (**Q**) on top of the right Motor Control Box (**Figure 9-20**).
18. Press and Hold the black **Lock** button (**T**) to engage and lock the Stabilizer Arm.
    - The Motor Control Box will pull the connector pin until the Stabilizer Arm is seated and locked into place and the light (**O**) will blink green when locked

■ **NOTE**: **Refer to the Motor Control Box Indicator Lights table** (**Table 52**) whenever an indicator light on the control box begins flashing or changes to a color that does not match the indicated expected status.

Table 52 provides a quick reference to understand the meaning of each Motor Control Box Indicator Light color and flashing pattern, along with the recommended action to take. Checking this table can help facilitate diagnosis and issue resolution, ensure proper setup, and maintain safe operation of the device.

Table 52: Motor Control Box Indicator Lights

Color	Color	Meaning	Recommended Action
Blue	Slow Flash	Needs to be returned to the home position.	Press and hold the unlock button until the blue light stops flashing.
Blue	Solid	Reached the home position.	None.
Green	Fast Flash	Stabilizer Arm is loaded and the Stabilizer Attachment Cable is plugged into the Motor Control Box, but the connection failed.	Replace the TRUS Cradle or Delivery Device Attachment.
Green	Slow Flash	Stabilizer Arm is loaded, but the Stabilizer Attachment Cable is not plugged into the Motor Control Box.	Plug the Stabilizer Attachment Cable into the Motor Control Box.
Green	Solid	Ready for use. Stabilizer Arm is loaded and Stabilizer Attachment Cable connection is good.	None.
Magenta	Fast Flash	Lower travel limit has been reached.	Unload the Stabilizer Arm and reload. If this does not resolve the issue, replace the stabilizer arm.
Magenta	Slow Flash	Jam detected.	Press and hold the unlock button to clear jam.
Magenta	Solid	Stabilizer Arm cabling has stretched. The Stabilizer Arm will still function but should be replaced as soon as convenient.	Replace as soon as convenient.

Adjust the Motor Control Box Height

The height of the Motor Control Box can be adjusted as needed to ensure the TRUS Cradle and Delivery Device are positioned correctly for the procedure.

19. Adjust the height of the Motor Control Box attached to the TRUS Stabilizer Arm.
    - Extend the TRUS Stabilizer Arm fully
    - Adjust Motor Control Box height so the top of the TRUS Stabilizer Arm is the same height as the OR Bed
    - Loosen the Clark Clamp while holding the Motor Control Box in place
    - Lift or lower the Motor Control Box to the desired height and hold in place
    - Tighten the Clark Clamp to lock the position
20. Adjust the height of the Motor Control Box attached to the Delivery Device Stabilizer Arm.
    - Adjust the Delivery Device Motor Control Box height so it is approximately 5 cm (2 in) higher than the Motor Control Box attached to the TRUS Stabilizer Arm

■ **NOTE**: If the Motor Control Box is not held in place, it will drop when the Clark Clamp is loosened.

■ **NOTE**: Remove the Delivery Device and TRUS Probe from the patient before adjusting the Motor Control Box height during a procedure.

Attach the Controller Arm

The Controller Arm is attached to the Vertical (long) Stabilizer Mount using the Controller Arm Knob.

■ **NOTE:** The Controller Arm should be placed on the same side of the Mount as the Delivery Device Stabilizer Arm (typically toward the dominant hand), at a convenient height for easy access.

■ **NOTE:** The Controller Arm can be placed either inward or outward from the Stabilizer Mount with the Controller Knob on the opposite side of the Stabilizer Mount.

21. Determine Position:
    - At a convenient height for easy Controller access
    - On the side nearest to the Generator
22. Align the notches on the end of the Controller Arm (**V**) with the 'keyhole' slots (**U**) on the side of the Vertical (long) Stabilizer Mount (**Figure 10-21**).

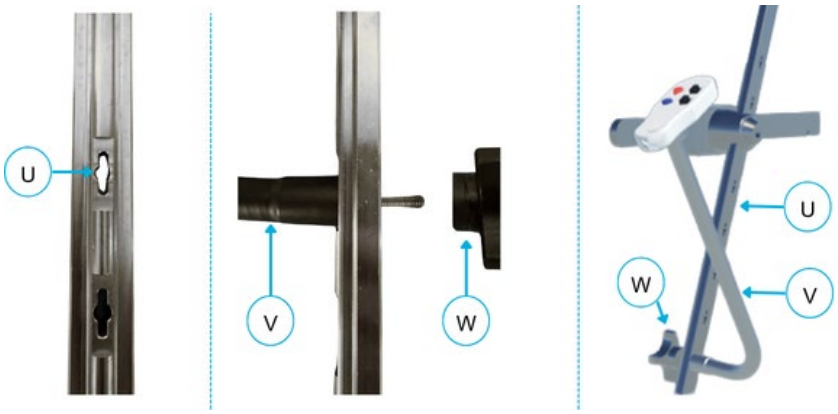


Figure 10-21: Controller Connection to Stabilizer Mount

23. Tighten the Controller Arm Knob (**W**) until secure.

■ **NOTE:** Disinfect all Stabilizer Arms after setting up and prior to use (see **Section 15.2**).

24. Cover the TRUS Stabilizer Arm (**X**), Delivery Device Stabilizer Arm (**Y**), and Controller Arm (**Z**) with a sterile sheath prior to attaching sterile components (**Figure 10-22**).

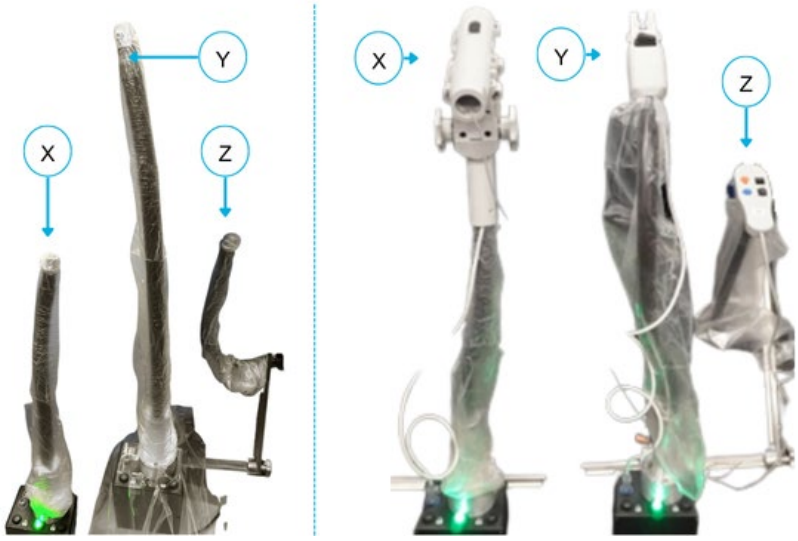


Figure 10-22: Covered Stabilizer Arms with and without Components Attached

10.5.2 Set Up the Field Generator and Needle Guidance System (NGS)

⚠ **WARNING – Proximity of Field Generators:** Do not operate a Field Generator within 10 m (33 ft) of another operating Field Generator. Proximity can result in interference between tracking systems. This may lead to inaccurate navigation and patient injury.

⚠ **WARNING – Field Generator Cable Placement:** Do not place the Field Generator cable inside the measurement volume or wrap it around the Field Generator. This configuration may cause magnetic interference and may result in tracking errors and potential injury.

⚠ **WARNING – Coiling of Field Generator Cable:** Do not coil the Field Generator cable during use. Coiling induces a magnetic field that may disrupt tracking. This may lead to inaccurate tracking and patient injury.

⚠ **WARNING – Objects on Field Generator:** Do not place metallic, conductive, or magnetic objects on the Field Generator. These materials may interfere with the Field Generator's magnetic field and disrupt tracking accuracy. Inaccurate tracking can result in improper needle placement or treatment delivery. This may lead to patient injury. Only non-metallic items, such as surgical drapes, should be placed on the Field Generator.

⚠ **WARNING – Field Generator Movement During Treatment:** Do not move the Field Generator during treatment. Movement may disrupt spatial tracking references. If the Field Generator is moved, re-establish all required spatial references before continuing. Failure to do so may result in inaccurate system output and patient injury.

⚠ **WARNING – Unverified Electromagnetic Environments:** Do not operate the system in environments not evaluated for electromagnetic compatibility. Such environments may introduce magnetic interference. This may cause tracking inaccuracy and potential injury.

⚠ **WARNING – Proximity to Implanted Devices:** Do not operate the Field Generator within 20 cm (8 in) of an implanted pacemaker or similar device. The magnetic field may interfere with implant function. This can cause serious health complications and tracking errors.

⚠ **WARNING – Use During Defibrillation:** Do not use the system during or immediately after cardiac defibrillation. System performance has not been validated under these conditions. Use may result in unexpected behavior or injury.

⚠ **WARNING – Exposure to MRI:** Do not expose the system to strong magnetic fields like MRI. Exposure may alter internal sensor calibration. This may lead to inaccurate readings and potential injury.

⚠ **WARNING – Presence of External Magnetic Fields:** Do not operate the system in the presence of external magnetic fields. Such fields may interfere with system tracking. This can result in incorrect device operation and injury.

⚠ **WARNING – Proximity to RF Equipment:** Keep portable RF communications equipment at least 30 cm (12 in) away from the Field Generator and cables. Closer proximity may degrade performance. This can lead to inaccurate tracking and patient risk.

⚠ **WARNING – Dropping the Field Generator:** Do not drop or impact the Field Generator. Impact may alter calibration. This may cause inaccurate tracking and personal injury.

⚠ **WARNING – Disconnecting Field Generator While Powered:** Do not disconnect the Field Generator while the Generator is powered on. Disconnecting under power may cause electrical arcing. This can result in sparks or personal injury.

⚠ **WARNING – Proper Mounting of Field Generator:** Ensure the Field Generator is mounted at least 20 cm (8 in) away from the ferromagnetic segment of the Mounting Arm. Close proximity to ferromagnetic material may distort magnetic field. This can result in inaccurate tracking and potential patient injury.

⚠ **CAUTION – Autoclaving Prohibited:** Do not autoclave the Field Generator. Autoclaving will damage internal components and render the equipment unusable.

1. Attach Field Generator to Field Generator Arm (**B**) using black knob (**A**) (**Figure 10-23**).
   - Twist knob (**B**) until the Field Generator is securely connected to the Field Generator Arm

■ **NOTE:** Ensure Heart symbol (**C**) on the Field Generator top faces upwards.

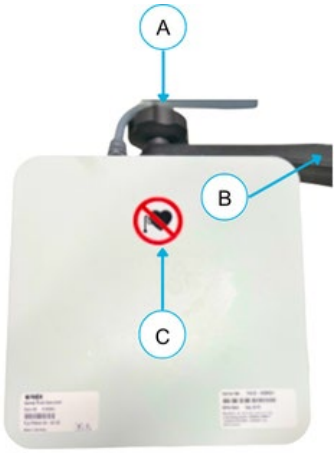


Figure 10-23: Field Generator Orientation

2. Place the end of the Field Generator Arm in the Clark Clamp (**D**) on side of bed closest to Generator (**Figure 10-24**).
   - The Field Generator should be placed in the Clark Clamp furthest from the stirrup clamp (**F**), next to the Stabilizer System Clark Clamp (**E**)
   - Ensure the clamp is not placed over a notch in the OR bed rail to maintain a secure attachment

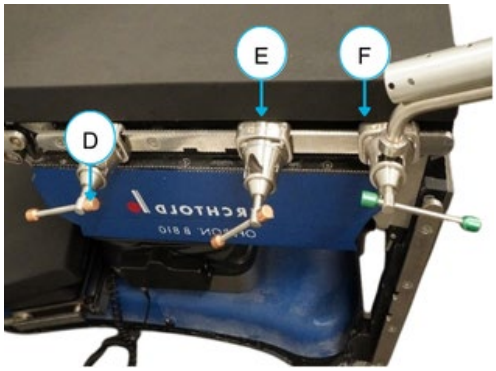


Figure 10-24 : Field Generator Arm Clark Clamp

3. Secure the Arm in the Clark Clamp.
4. Place the Field Generator approximately **15 cm (6 in)** over the patient's lower abdomen.
   - Ensure that the entire prostate is directly beneath the Field Generator
5. Position the Field Generator on the OR bed with the cable oriented toward the head end of the bed.

■ **NOTE**: Final positioning of the Field Generator will be completed after insertion of the Delivery Device into the patient.

6. Plug the **Field Generator cable** into the port (**A**) labeled 'Field Generator' on the back of the Generator (**Figure 10-25**).

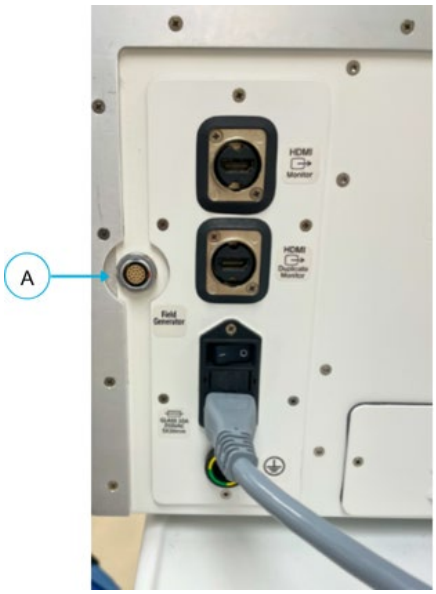


Figure 10-25: Field Generator to Generator Connection

7. **(OPTIONAL)**: A sterile drape can be used to cover the Field Generator to allow for easier adjustments during the procedure.

■ **NOTE**: All ferromagnetic metal should be kept outside of the Field Generator tracking field and off the Field Generator.

■ **NOTE**: The Field Generator only provides tracking guidance when the tip of the Delivery Device and TRUS Cradle are within the tracking field.

■ **NOTE**: The Field Generator along with the Delivery Device and TRUS Cradle must be correctly connected to use the Needle Guidance System (NGS). If tracking is lost due to sensor damage on a component, it must be replaced with a component of the same type to continue use of guidance.

10.5.3 Select Delivery Device

Based on the predetermined treatment plan, select the Delivery Device:

- Standard (STD)
- PZ
- Retreatment (RTX)

■ **NOTE:** Optimal treatment requires that all of the vapor emitter holes are within a single zone of the prostate. The PZ Needle has fewer holes and a shorter zone of emission than the Standard Needle and may be needed in prostates with a very narrow peripheral zone or other small treatment areas.

■ **NOTE:** The RTX Needle incorporates a sharper needle tip that can be used in cases where challenging anatomy might make movement of the Needle all the way to the target more difficult. An example would be performing retreatment of a previously ablated prostate where the remaining tissue can be more pliable.

10.5.4 Unpack Sterile Components and Accessories

1. Prior to opening all products, inspect the integrity of the sterile barrier packaging.
   - Do not use if the package is damaged
2. Using sterile technique, open the Tyvek® tray, and:
   - Remove the Stabilizer Kit from the tray and place on a table in the sterile field
   - Remove the Delivery Device from the tray and place on a table in the sterile field
   - Remove the Accessory Kit components, and place on a table in sterile field
3. Using sterile technique, open the Saline Catheter Needle and place on a table in sterile field.

10.5.5 Connect the Controller

1. Identify the cord extending from the Controller (**A**).
2. Pass the connector end of the Controller cord outside the sterile field to the Generator.
3. Locate the black port (**B**) labeled "Controller" on the Generator (**Figure 10-26**).

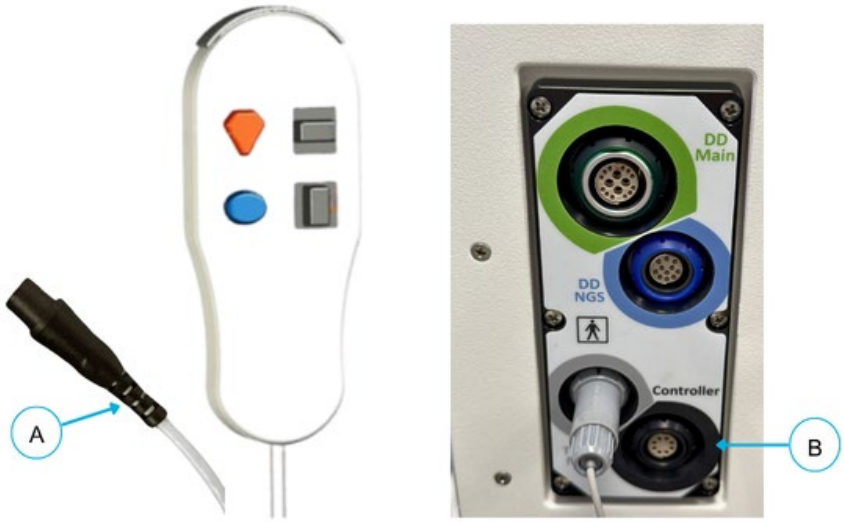


Figure 10-26: Controller Connection to Generator

4. Firmly plug the Controller cord into the black port (**B**) until it is fully seated.
   - A green checkmark will appear next to 'Controller Connected' on the Generator Setup screen
5. Place the Controller (**C**) on the Controller Arm (**D**) (**Figure 10-27**), connecting the magnet on the back of the Controller with the magnet on the end of the Controller Arm.
   - The two magnets will automatically attach to each other
6. Ensure a secure connection.
   - The Controller should be firmly attached and should not wobble or detach easily

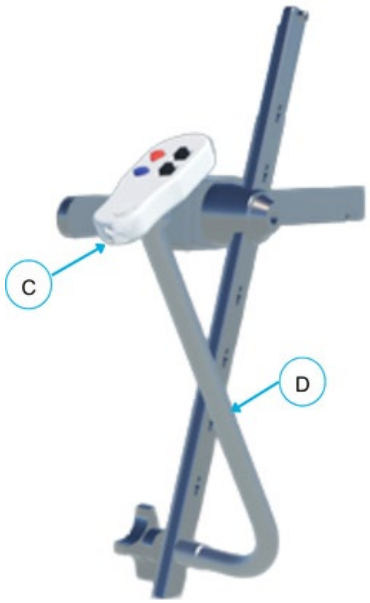


Figure 10-27: Controller Connection to Controller Arm

10.5.6 Set Up the TRUS Cradle

■ **NOTE**: The TRUS Cradle is attached to the (shorter) TRUS Stabilizer Arm.

1. Align the hole in the side of the TRUS Cradle (**A**) with the hole in the end of the Stabilizer Arm (**B**) (**Figure 10-28**).
2. Twist the Thumb Screw (**C**) through the holes until the TRUS Cradle is secure on the Stabilizer Arm.

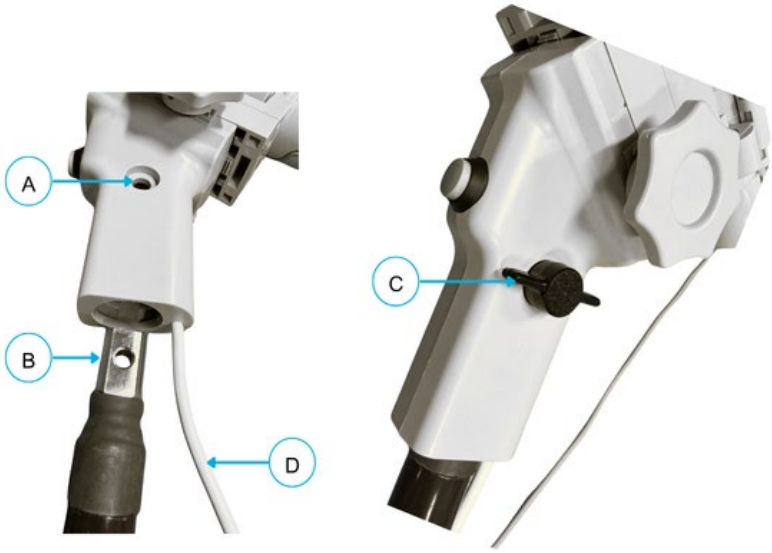


Figure 10-28: TRUS Cradle Attachment to Stabilizer Arm

■ **NOTE:** The Motor Control Box is **not sterile**. Touching it while connecting the cable may compromise glove sterility. If contact occurs, change gloves before proceeding.

3. Identify the cord (**D**) extending from the TRUS Cradle.
4. Locate the cable connection port (**E**) on the top left corner of the Motor Box (**Figure 10-29**).

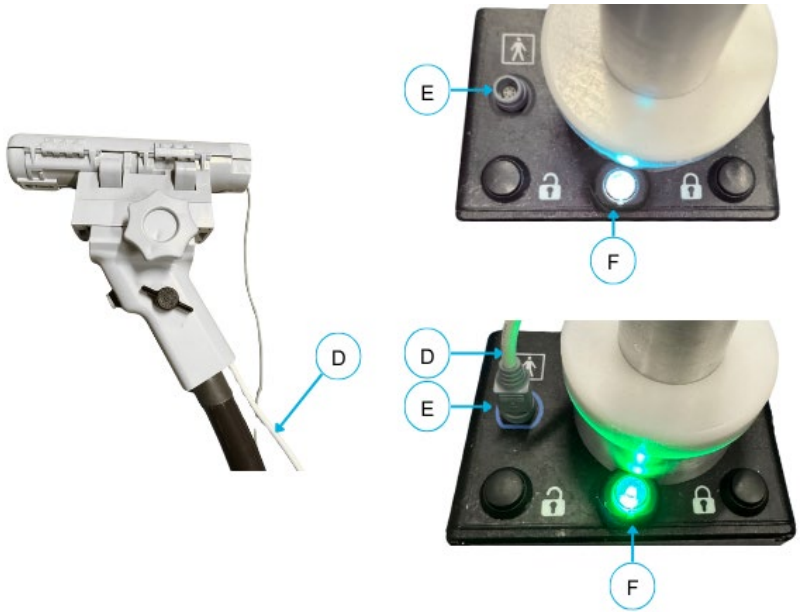


Figure 10-29: TRUS Cradle Cable Connection

5. Plug the larger white TRUS Cradle cable (**D**) into the cable connection port (**E**) until firmly seated.
   - The blinking indicator light (**F**) will turn solid green
   - Refer to **Table 52: Motor Control Box Indicator Lights** if the indicator light is not solid green
6. Pass the connector end of the small gray TRUS NGS cable (**G**) outside the sterile field to the Generator.
7. Locate the gray port (**H**) labeled "TRUS NGS" on the Generator (**Figure 10-30**).
8. Firmly plug the TRUS NGS cable into the gray port (**H**) until it is fully seated.
   - A green checkmark will appear next to 'Ultrasound Sensor' on the Generator Setup screen

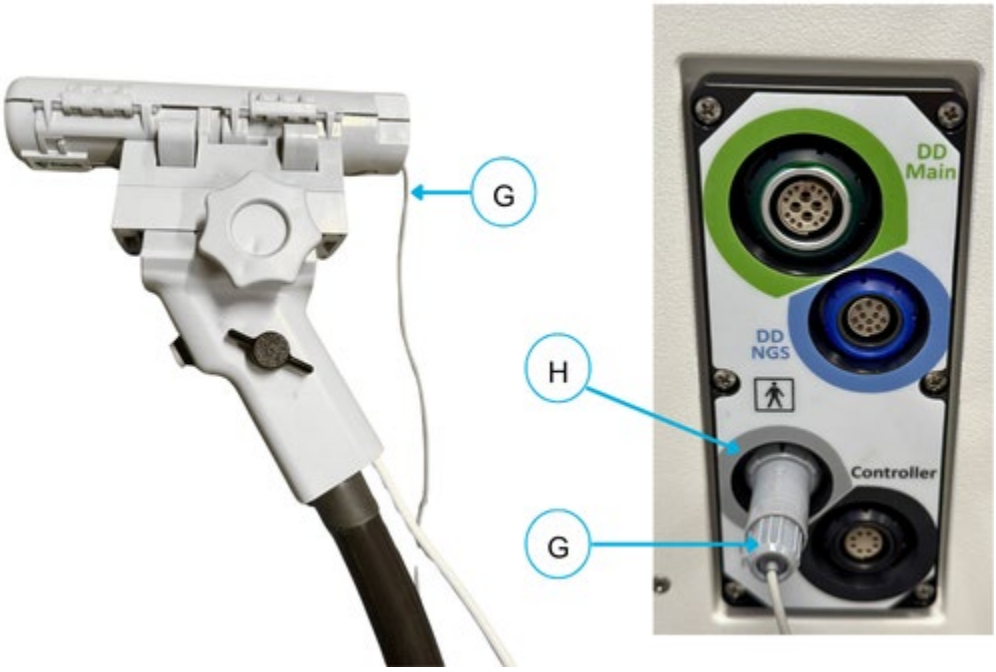


Figure 10-30: TRUS Cradle NGS Connection to Generator

10.5.7 Connect the Delivery Device Attachment

■ **NOTE**: The Delivery Device is attached to the longest Stabilizer Arm.

1. Align the hole in the Delivery Device Attachment (**B**) with the hole at the top of the Stabilizer Arm (**A**) (**Figure 10-31**).
2. Twist the provided Thumb Screw (**C**) until the Delivery Device Attachment is secure on the Stabilizer Arm.

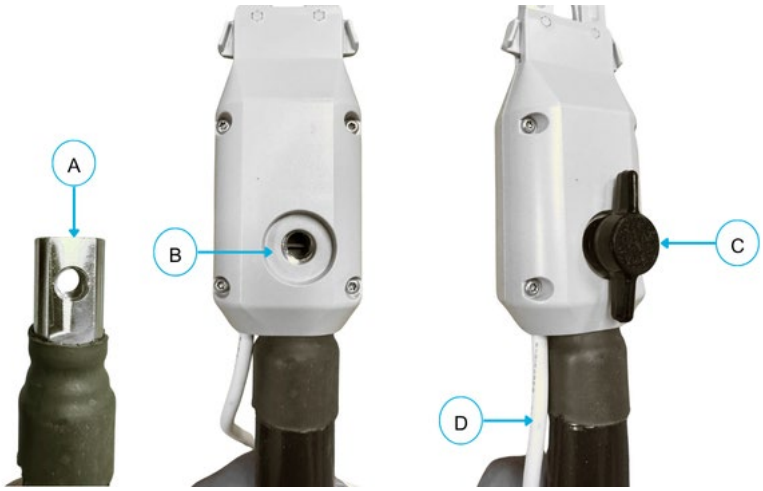


Figure 10-31: Delivery Device Attachment

■ **NOTE:** The Motor Control Box is **not sterile**. Touching it while connecting the cable may compromise glove sterility. If contact occurs, change gloves before proceeding.

3. Identify the electrical cable extending from the Delivery Device Attachment (**D**).
4. Locate the cable connection port (**E**) on top left corner of the Motor Control Box (**Figure 10-32**).

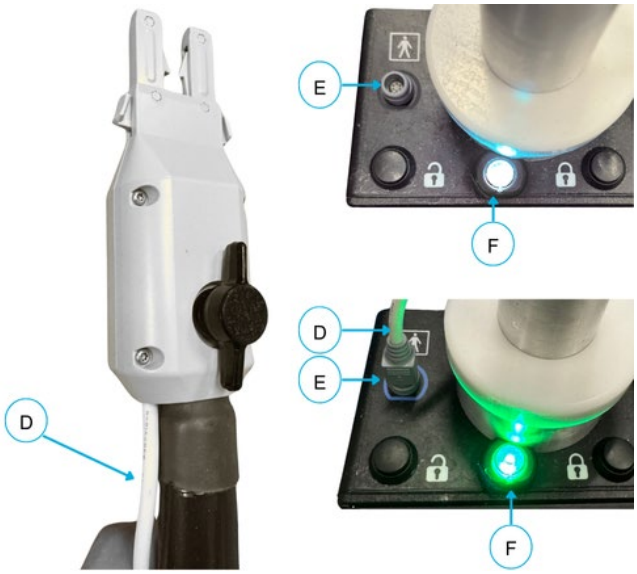


Figure 10-32: Delivery Device Attachment Electrical Cable Connection

5. Plug the Delivery Device Attachment cable (**D**) into the cable connection port (**E**) until firmly seated.
   - The blinking indicator light (**F**) will turn solid green
   - Refer to **Table 52**: **Motor Control Box Indicator Lights** if indicator light is not solid green

10.6 Set Up the Ultrasound

The Vanquish System treatment is designed to be used with the bkSpecto Ultrasound and BK E14CL4b Transducer.

1. Power up the Ultrasound.
2. Prepare the Ultrasound per the bkSpecto_Instructions for Use (IFU).

■ **NOTE:** Disable the Auto-Sleep feature on the bkSpecto Ultrasound.

■ **NOTE:** The bkSpecto Ultrasound should be placed in **Live Dual mode** to operate effectively with the navigation system.

3. Ensure the Ultrasound is connected to the Generator using HDMI output on Ultrasound to DVI input on Generator.
4. When the Ultrasound is initially powered up, the Monitor will display:
   - US Video Initiating: DO NOT DISCONNECT CABLE

■ **NOTE:** Ensure the Ultrasound is in **Live Dual mode** throughout the case.

5. Prepare the Ultrasound probe per standard TRUS protocol.
6. Place the TRUS Probe (**B**) in the TRUS Cradle (**A**) (**Figure 10-33**).
   - Ensure that the guiding pin (**C**) is fully seated in the slot at the front edge of cradle before closing

Figure 10-33: TRUS Cradle and TRUS Probe

7. Close the top of the cradle over the probe, ensuring that both latching mechanisms are fully secured.
8. Insert the TRUS Probe per ultrasound standard of practice and optimize image.

■ **NOTE:** Depressing the Stabilizer Power Button on the TRUS Cradle handle allows for full freedom of movement of the TRUS probe and cradle. Releasing the Stabilizer Power Button locks the probe in place. Once locked, the probe can be moved in and out using the Fine Adjustment Knobs on the side of the Cradle.

■ **NOTE:** In addition to providing visualization of the prostate to guide vapor treatment, the Ultrasound image is also needed for optimal placement of the Saline Catheter Needle as outlined in section **11.2.2.**

10.7 Prepare the Sterile Saline Bags

⚠ **CAUTION – Room Temperature Saline:** Use only room temperature saline during treatment. Using cold saline may result in insufficient treatment and compromised therapy delivery.

■ **NOTE:** The outside of the Sterile Saline Bag is not sterile and should not be placed in the sterile field.

1. Hang two new bags of 0.9% injectable grade saline fluid on IV pole.

■ **NOTE:** 1000 mL - 5000 mL volume options are compatible with the Delivery Device.

■ **NOTE:** 1000 mL is the preferred size for the Transperineal Saline Catheter Needle, but a smaller size (as little as 250 mL) is also an option.

2. On the Generator screen:
   - Select the [**Saline Source Volume**] icon
   - Select the volume associated with the size of the urethral saline bag
   - Select [**Confirm**]

■ **NOTE:** Bag spikes are NOT needed. Spikes are pre-attached to the Urethral Saline Line Tubing and Saline Needle Tubing.

10.8 Connect the Auto-Refill Syringe and Tubing Set

1. Hang Sterile Water Bag on IV pole.
2. Gather the Auto-Refill Syringe and Tubing Set, connect the syringe to the tubing set, and pass outside the sterile field to be connected to Generator.
3. Keeping the Auto-Refill Syringe (**B**) connected to the Auto-Refill Tubing (**C**), insert the syringe into the syringe cradle (**A**) of the Generator (**Figure 10-34**).
   - A green checkmark will appear next to 'Syringe Assembly' on the Generator Setup screen

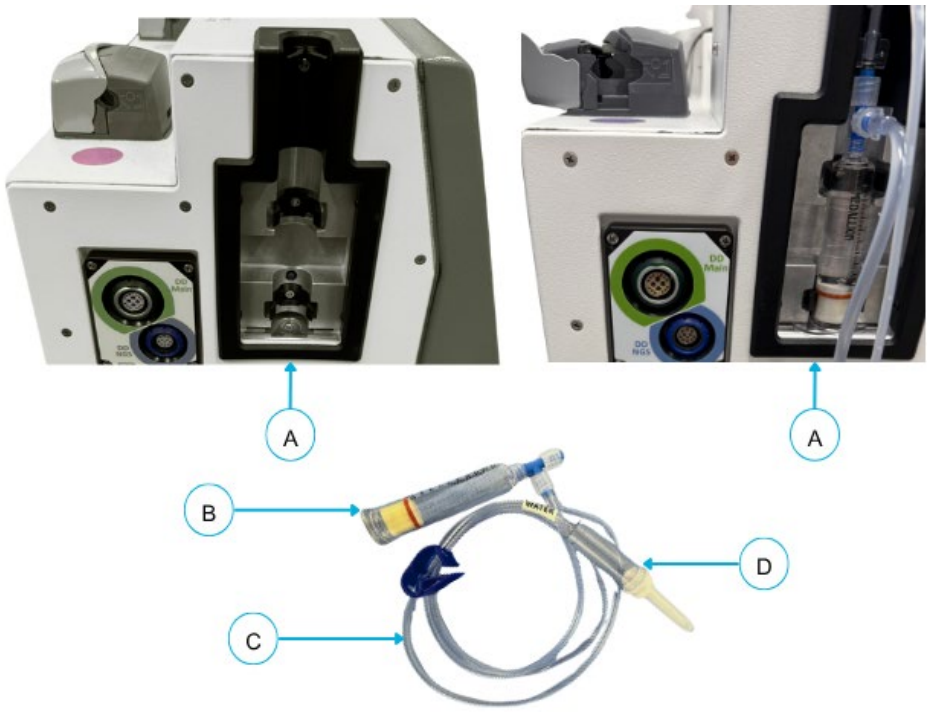


Figure 10-34: Generator Syringe Cradle

4. Remove protective cover from the Spike (**D**) and insert into Sterile Water Bag.

■ **NOTE**: Ensure that the Sterile Water Bag is not dripping into the drip chamber at initial set up. A slow drip is expected during refill operations. If there is a drip at initial set up check that connections to the Auto-Refill Syringe are tight.

10.9 User Generated Image Import

⚠ **CAUTION – User Responsibility to Avoid PHI/PII Upload:** Do not upload Protected Health Information (PHI) or Personally Identifiable Information (PII) via the USB port or third-party equipment. The system does not detect or block such data. Uploading PHI/PII may lead to unauthorized disclosure and compromise patient privacy.

The custom image file name should be in .png or .jpg format and be under 2 MB and the File must be saved to the USB drive in the following subfolder: USB DISK: /Treatment

■ **NOTE**: If the USB port is unavailable, the treatment plan image may instead be viewed on a laptop or other external display.

10.9.1 Import the Treatment Plan

1. Insert the USB drive into the USB Port on the right side of the Generator.
   - The Treatment Plan is automatically imported

10.9.2 Display the Treatment Plan on the PUI

1. Select **[Settings]** on the Generator screen.
2. Locate the **Treatment Plan** menu on the displayed Settings screen (see **Figure 10-35**).

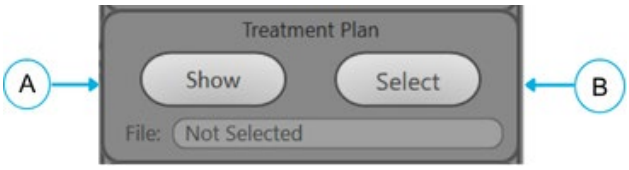


Figure 10-35: Treatment Plan menu

3. Choose Show or Select as described in **Table 53** below.

Table 53: Treatment Plan Menu Description

Label	Name	Description
A	Show	Displays the selected treatment plan image on the PUI. If no image has been selected, the message “No Treatment Plan Image Is Available” is shown. When unselected, the image is hidden and the **Show** button is no longer highlighted in green.
B	Select	Allows the user to select a treatment plan image (.png or .jpg format under 2 MB) from the USB connected to the Generator. If no treatment plan images are available, the message “No Treatment Plan Images Are Available” is displayed.

11 Prepare the System

The Vanquish System walks the user through a series of steps to prepare the system for Treatment. Once System Setup and Preparation are complete, the Readiness Checklist is provided as a tool to ensure everything is ready for treatment.

11.1 Connect the Saline Needle Tubing Set (Perineal Saline)

⚠ **CAUTION – Saline Line Positioning:** Ensure saline lines are correctly oriented as indicated on the Generator. Incorrect placement may prevent saline from flowing during treatment, resulting in inadequate cooling and increased risk of tissue injury.

1. Gather the Saline Needle Tubing Set from the table in the sterile field.
2. Pass the capped spiked end of the tubing outside the sterile field.
3. Place the Saline Needle Tubing line in the Perineal Saline Pump (**A**) on the top back side of the Generator (**Figure 11-1**).
   - Match the Yellow (**C**) and Black (**B**) color indicators on the Generator and Saline Needle Tubing to guide placement

■ **NOTE**: Ensure that the Saline Needle Tubing is seated such that the pump door can close smoothly.

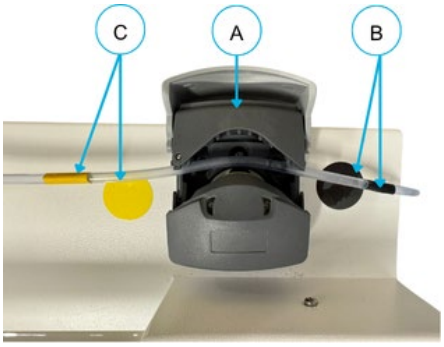


Figure 11-1: Perineal Saline Color Indicators

4. Close the Perineal Saline Pump door prior to attaching the Saline Needle Tubing spike to the Saline bag.
   - A green checkmark will appear next to 'Perineal Saline Pump Door Closed' on the Generator Setup screen

■ **NOTE**: If the Saline Needle Tubing spike is attached to Saline bag prior to placing the Saline Flush Line in the Saline Pump and closing the Saline Pump door, saline may leak.

5. Remove the cap from the tip of the Saline Needle Tubing spike and attach to a 1000 mL saline source.
   - Ensure that the clamp on the Saline Needle Tubing and the vent on the Drip Chamber are open
6. Select **[Options]** on the Generator screen.
7. Select **[Perineal Saline Flush/Connect]**.
8. Select **[Flush]**.
   - Run flush until saline runs from the end of the tubing and all air bubbles are removed
9. Select **[Off]** to terminate Saline Flush.

11.2 Transperineal Saline Catheter Needle Insertion

The purpose of the Saline Catheter Needle (**Figure 11-2**) is to lift the prostate away from the rectum during vapor treatments. It also provides cooling to the periprostatic space.

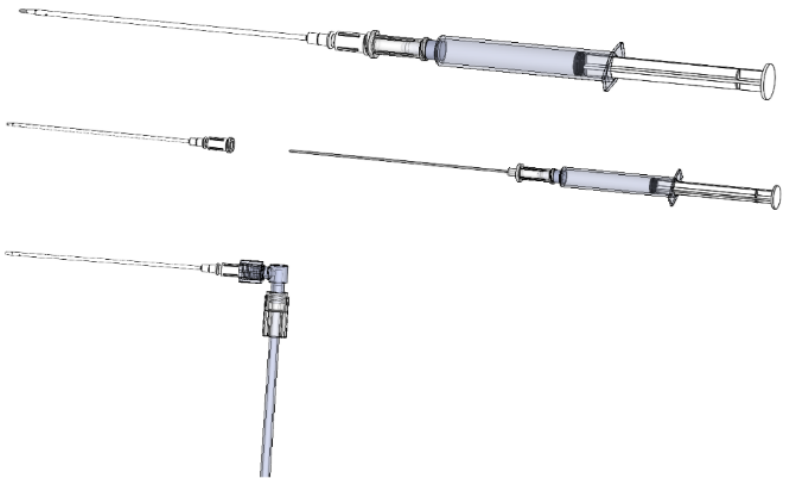


Figure 11-2: Saline Catheter Needle

11.2.1 Prime the Saline Catheter Needle:

1. Retrieve previously unpacked Saline Catheter Needle from the table in the sterile field.
2. Remove plug from the back of the Saline Catheter Needle and discard.
3. Fill a 10 cc or 15 cc syringe with injectable grade saline.
   - Remove any air bubbles from the syringe by gently tapping and pushing out the air
4. Attach the 10 cc or 15 cc Syringe to the Saline Catheter Needle.
5. Securely connect the Saline Catheter Needle to the syringe using the Luer-lock.
   - Ensure a tight seal to avoid leakage
6. Prime the Saline Catheter Needle to ensure that no air obscures the TRUS image.
   - Ensure that there are no air bubbles in the syringe. Air bubbles can impair the visualization of the ultrasound
   - Slowly depress the syringe plunger to push saline through the needle
   - Continue until you see a steady stream of saline exiting the needle tip
   - Check for and eliminate any remaining air bubbles

11.2.2 Insert the Saline Catheter Needle

1. Under TRUS guidance in the sagittal plane, insert the Saline Catheter Needle into the perineum at the desired location between the prostate and rectum, and advance into the periprostatic space.
2. Advance needle to the apex of the prostate inside the periprostatic space.
3. Inject small volumes of saline into the periprostatic space.
4. Observe under Ultrasound guidance the fluid separating and expanding the space between the rectum and the prostate as the needle advances.
5. Continue to advance the Saline Catheter Needle until positioned near the intended area of treatment.
6. Withdraw the insertion needle, leaving the catheter in place.
7. In the Options Menu on the Generator, select **[Perineal Saline Flush/Connect]**.
8. Then select **[Connect]**.
9. As saline slowly drips from the Saline Needle Tubing, connect the luer from the tubing to the hub of the catheter.
10. Once connected, select **[Off]** on the Generator to terminate connecting flush.
11. **(OPTIONAL)** The Saline Needle Tubing can be taped to a drape to prevent inadvertent movement of the sheath during the procedure.

11.3 Setup the Delivery Device

1. Align the two prongs on the Delivery Device Attachment (**D**) with the slots on the side of the Delivery Device (**E**) (**Figure 11-3**).

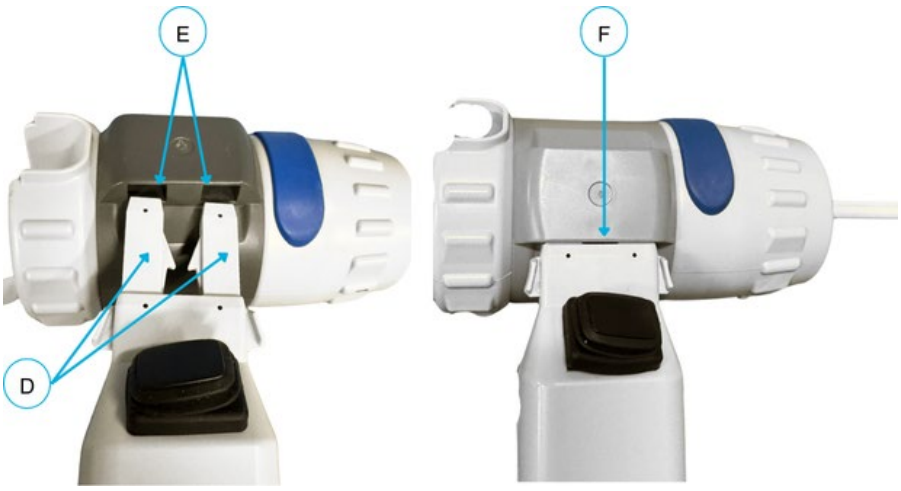


Figure 11-3: Connection of the Delivery Device to the Delivery Device Attachment

2. Press together until the posts are fully inserted into the slots on the Delivery Device (**F**).
3. Pass the cables and tubing (excluding the drain line) outside the sterile field.
4. Initiate connection of the three lines from the Delivery Device (**Figure 11-4**):
   - Saline Flush Line (**G**)
   - Water Line (**H**)
   - Drain Line (**I**)

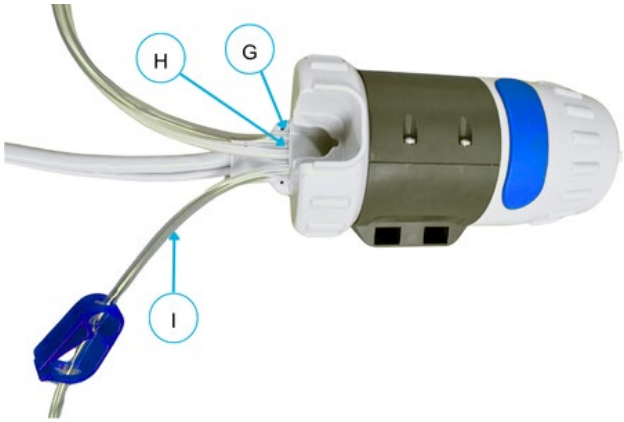


Figure 11-4: Delivery Device Lines

11.3.1 Connect the Urethral Saline Flush Line

⚠ **CAUTION – Saline Line Positioning:** Ensure saline lines are correctly oriented as indicated on the Generator. Incorrect placement may prevent saline from flowing during treatment, resulting in inadequate cooling and increased risk of tissue injury.

1. Place the **Saline Flush Line** in the Urethral Saline Pump (**K**) on the top of the Generator (**Figure 11-5**).
   - Match the green (**J**) and purple (**L**) color indicators on the Generator and Saline Flush Line to guide placement

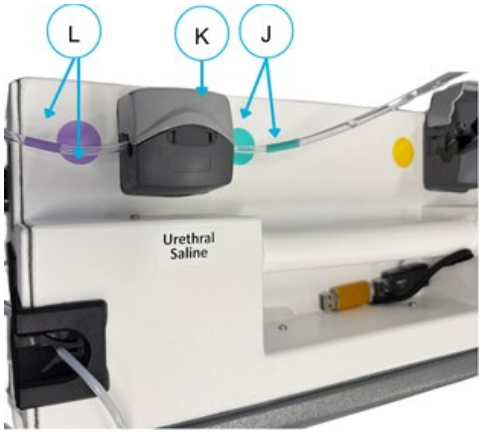


Figure 11-5: Urethral Saline Color Indicators

2. Ensure that the Saline Flush Line is seated such that the pump door can close smoothly.
3. Close the pump door prior to attaching the Saline Flush Line Spike to the Saline bag.
   - A green checkmark will appear next to 'Urethral Saline Pump Door Closed' on the Generator Setup screen

■ **NOTE**: If the Saline Flush Line tip is attached to Saline bag prior to placing the Saline Flush Line in the Saline Pump and closing the Saline Pump door, saline may leak.

4. Remove the cap from the tip of the Saline Flush Line spike and attach to the saline source.
   - Ensure that the clamp on the Saline Flush Line is open

11.3.2 Connect the Delivery Device Water Line

1. Remove the Auto-Refill Syringe (**O**) from the Generator cavity to help make the Water Line connection (**Figure 11-6**).

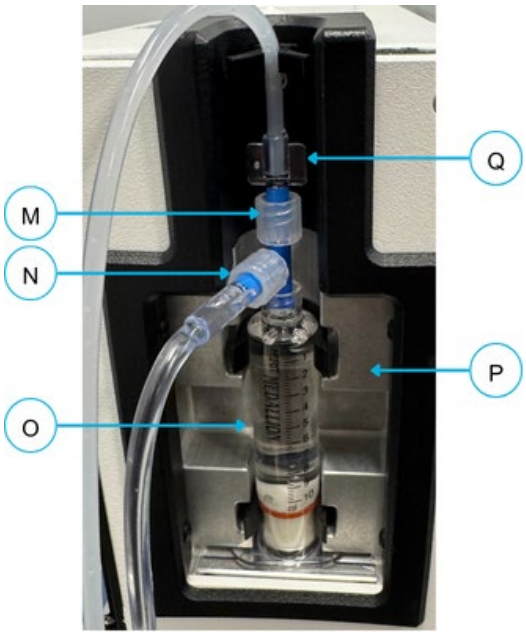


Figure 11-6: Auto-Refill Syringe Connections

2. Remove the cap from the Water Line luer.
3. Connect the Water Line from the Delivery Device to the Auto-Refill Syringe (**M**).
   - Twist to tighten

4. Confirm that the water line to the Sterile Water Bag is tightly connected (**N**).
5. Replace the Auto-Refill Syringe into the Syringe Cradle of the Generator (**P**).
   - A green checkmark will appear next to 'Syringe Assembly' on the Generator Setup screen
6. Clip the waterline into the syringe housing.

11.3.3 Close Clamp on the Delivery Device Drain Line

1. Move the blue clamp (**B**) on the Drain Line (**A**) approximately **15 cm (6 in)** from the Delivery Device.
2. Close the clamp (**B**) to ensure that saline flows through the Delivery Device during the procedure (**Figure 11-7**).

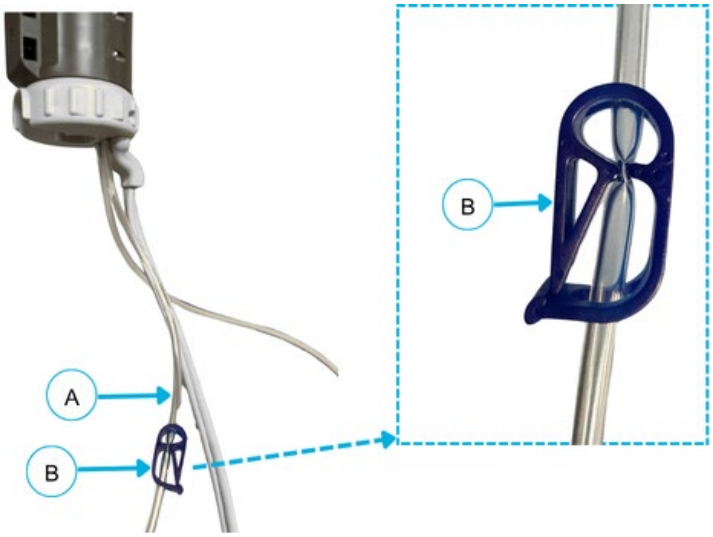


Figure 11-7: Delivery Device Drain Line

3. Place the end of the Drain Line into a reservoir to capture fluid drained from the bladder during the procedure.

11.3.4 Connect the Delivery Device to the Generator

1. Connect the two ends of the split cable to the side of the Generator (**Figure 11-8**).
2. Plug the **Green** end (**E**) of the split cable into the Green port (**A**) labeled 'DD Main.'
3. Plug the **Blue** end (**F**) of the split cable into the Blue port (**C**) labeled 'DD NGS.'
   - A green checkmark will appear next to 'Delivery Device Connected' on the Generator Setup screen once both cables are connected

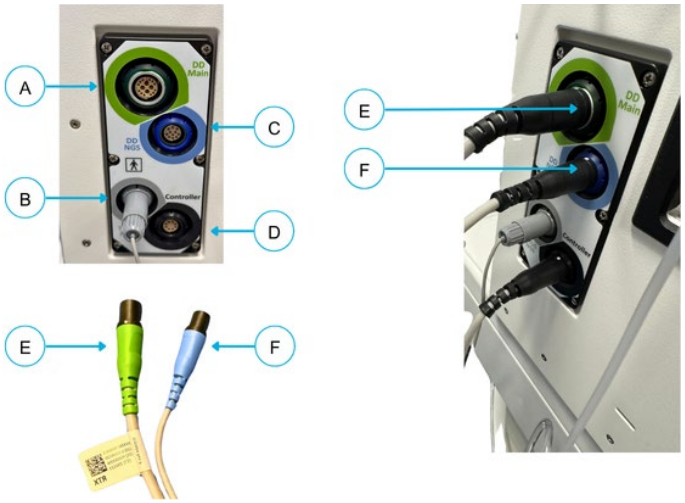


Figure 11-8: Delivery Device to Generator Connections

11.3.5 Perform Needle Tuning

Needle Tuning ensures that the Delivery Device Needle travel range is characterized and ready for use. When Needle Tuning is initiated, the Needle will fully extend and retract. This motion allows the system to verify needle performance and positioning.

1. Place the Delivery Device on the Stabilizer Arm.
2. Ensure that the shaft is pointing away from any object and the Needle is pointing down.
3. Select **[Tune Needle]** on the Generator screen (**Figure 11-9**).
   - The Needle will fully extend and retract
   - A green checkmark will appear next to 'Tune Needle' on the Generator Setup screen when Needle Tuning is complete

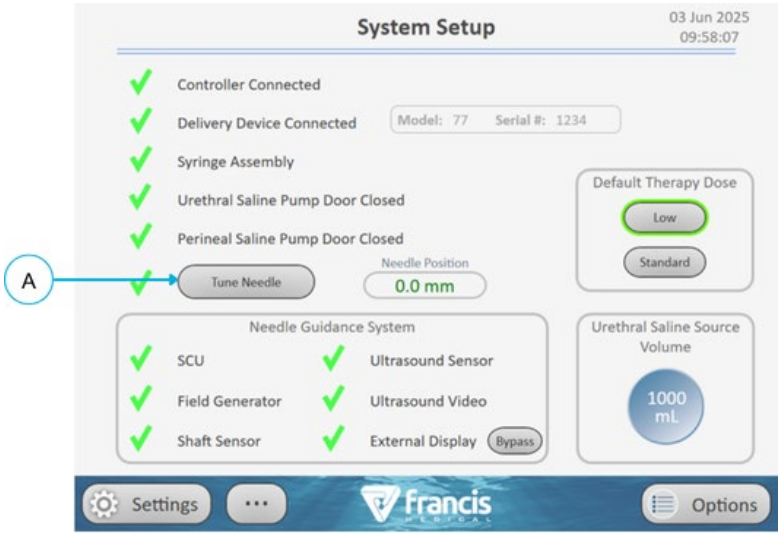


Figure 11-9: Tune Needle

■ **NOTE**: If the **[Tune Needle]** button is selected again, the Confirm Needle Tuning box will appear (**Figure 11-10**).

- Select [**Cancel**] to exit without Re-Tuning the Needle (**B**) (**Figure 11-10**)
- Select [**Confirm**] to Re-Tune (**C**)

Figure 11-10: Confirm Needle Tuning

11.4 Perform Auto-Syringe Fill

The *Syringe Auto Fill* function automatically fills the Auto-Refill Syringe with sterile water from the connected Sterile Water Bag.

⚠ **CAUTION – Air Bubbles in Water Line or Syringe:** Remove air bubbles from the Auto-Refill Syringe and water line before use. Trapped air may result in insufficient treatment and compromised therapy delivery.

■ **NOTE**: This step will cause the Needle to drip sterile water.

1. Place the tip of the Needle over a liquid waste collection container.
   - Ensure that the tip remains sterile
2. With all interconnections complete on the screen (indicated by green checkmarks):
   - The Generator displays: "Perform a syringe autofill operation?" (**Figure 11-11**)
   - Ensure that the Auto-Refill Syringe Tubing connects the Auto-Refill Syringe and Sterile Water Bag

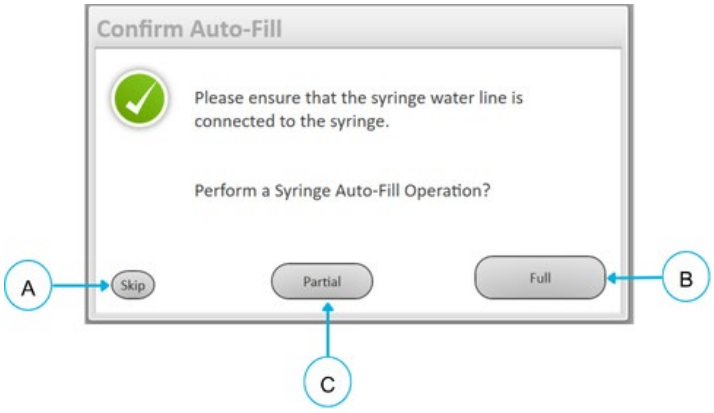


Figure 11-11: Perform Syringe Auto-Refill Operation Screen

3. Select **[Full]** (**B**).
   - The Auto-Refill Syringe will begin the automated process of filling
   - The Screen will display "Auto-Filling…" with a status bar (**Figure 11-12**)
   - The Auto-Filling process will take approximately 1-2 minutes

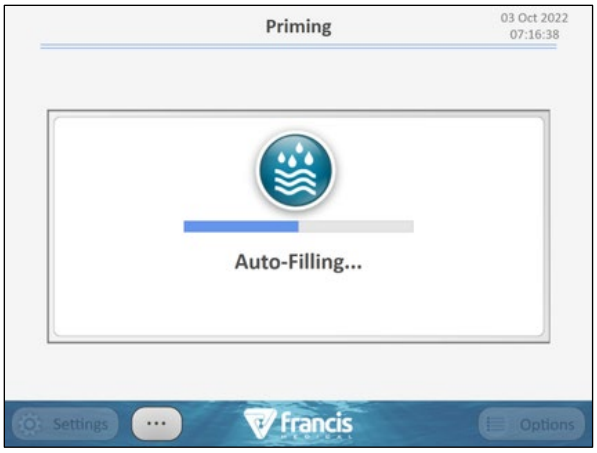


Figure 11-12: Auto-Refilling Screen

■ **NOTE**: If an additional needle tune is performed and the Syringe is already partially filled with Sterile Water, select **[Partial]** (**C**) to fully fill Syringe. If the Syringe is full, select **[Skip]** (**A**) and no further action is necessary (see **Figure 11-11**).

11.5 Syringe Purge

If air bubbles are observed in the Auto-Refill Syringe or Tubing, the *Syringe Purge* function can be used to remove trapped air bubbles.

⚠ **CAUTION – Syringe Purging:** Do not purge the sterile-water syringe while the needle is deployed in the prostate. Purging with the needle deployed in the prostate can force fluid into unintended tissue and cause injury or insufficient treatment. Fully retract the needle before initiating a purge.

1. Check the Auto-Refill Syringe and Tubing for trapped air bubbles.
2. If trapped bubbles are found, select **[Options]** followed by **[Syringe Purge]** on the Generator screen.
   - The 'Confirm Syringe Purge' pop-up will display (**Figure 11-13**)

Figure 11-13: Confirm Syringe Purge Screen

3. Select **[Confirm]** to proceed with the Syringe Purge (**B**).
   - Select **[Cancel]** to exit without performing Syringe Purge (**A**)
4. Repeat as necessary until all bubbles are purged from the system.

11.6 Insert the Rigid Cystoscope Lens

The Delivery Device is compatible with a 4 mm, 30-degree, 30 cm length Storz lens. The lens provides direct or video display visualization to help the physician position the Delivery Device Needle within the prostatic urethra.

1. Prior to use, inspect the camera, lens, and light cable to ensure they are cleaned, sterile, and prepared according to manufacturer's instructions.
2. Coat the lens shaft near the lens tip with lidocaine gel anesthetic or water-soluble lubrication to ensure smooth insertion into the Delivery Device.

■ **NOTE:** Do not coat the lens itself. This may impede visualization.

3. Insert the lens (**C**) into the lens port (**A**) (**Figure 11-14**).

■ **NOTE**: The lens should be initially rotated 90 degrees (light post at 3 or 9 o'clock) and inserted straight into the lens port (not at an angle) to avoid damage to the lens or Delivery Device (**B**).

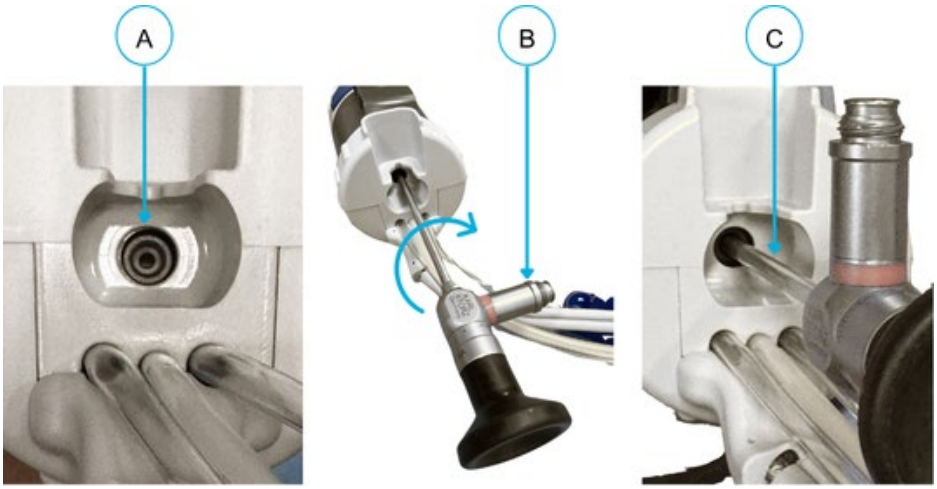


Figure 11-14: Insert the Rigid Cystoscope Lens

4. Rotate to 12 o'clock and advance until the lens snaps into place.
5. Attach cystoscopy camera to lens (**D**) (**Figure 11-15**).

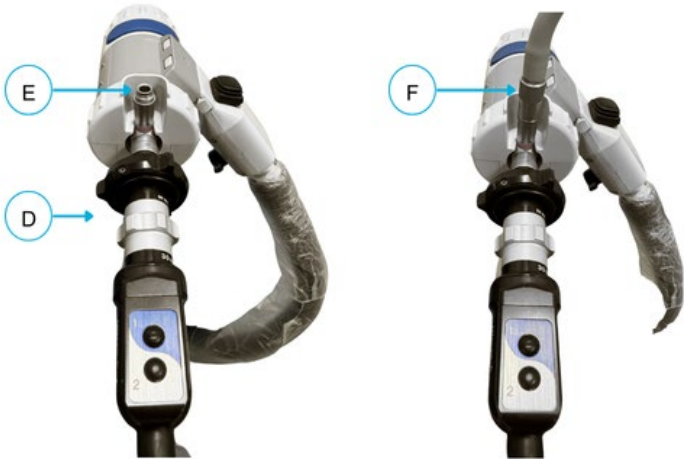


Figure 11-15: Cystoscopy Camera and Light

6. Attach cystoscopy light (**F**) to the lens light port (**E**) (**Figure 11-15**).

11.7 Perform the Pre-Treatment Vapor Cycle

When all connections have been made, Needle tuned, and Auto-Refill Syringe filled, the Generator will display 'Setup Complete' and prompt the user to perform a Pre-Treatment Vapor Cycle (**Figure 11-16**).

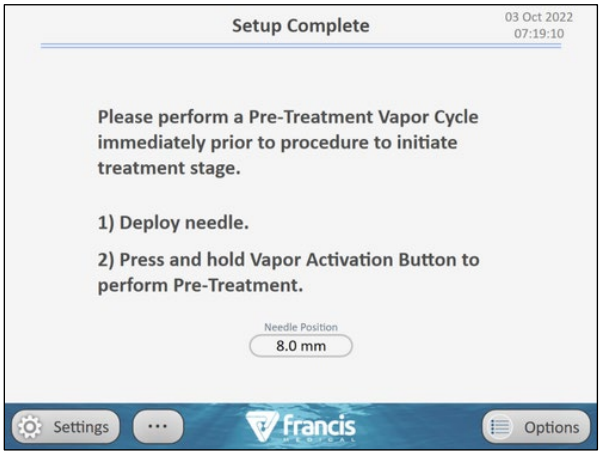


Figure 11-16: Setup Complete Screen

■ **NOTE:** The Pre-Treatment Vapor Cycle should only be performed outside the patient immediately prior to beginning treatment. Performing too early causes liquid to run through the device.

■ **NOTE: Running a Pre-Treatment Vapor Cycle activates the idle feature.** The idle feature heats the coil to keep it in a ready state so that vapor delivery is immediate.

1. Place the tip of the Needle over a liquid waste collection container.

■ **NOTE:** Ensure that the tip of the Needle remains sterile.

2. With the Delivery Device held firmly or attach to the Stabilizer Arm.
   - Ensure that the shaft is pointing away from any object
3. Push upward on the Needle Advance/Retract Button (**B**) on the Controller to deploy the Needle (**Figure 11-17**).

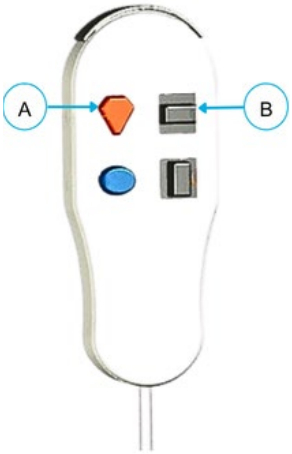


Figure 11-17: Controller Buttons

4. Press Vapor Delivery Button on the Controller (**A**) and hold.
   - The system emits a single beep per second while vapor is being released
   - The Generator screen will display "Pre-Treatment…" and a status bar **(Figure 11-18**)

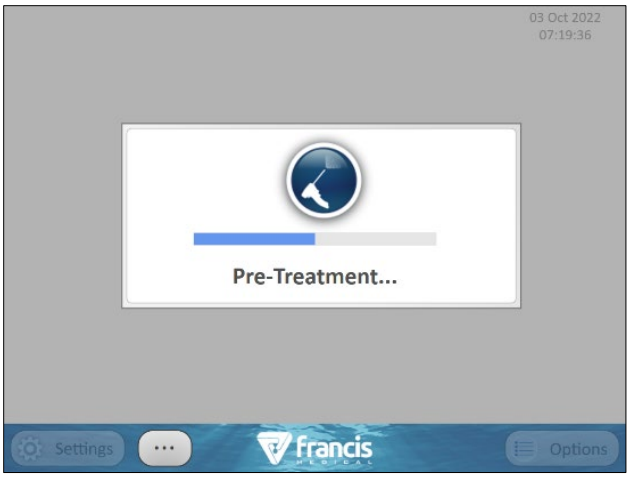


Figure 11-18: Pre-Treatment Status

5. When the Pre-Treatment Vapor Cycle is complete, release the **Vapor Delivery Button** (**A**). Confirm that there is no dripping from the drip chamber. If there is dripping, check that connections to the Auto-Refill Syringe are tight and do not proceed until dripping is resolved.
   - After Pre-Treatment Vapor Cycle is complete, the Needle will automatically retract
6. When the Pre-Treatment Vapor Cycle is complete, the screen will prompt: "Please confirm perineal tubing and needle have been primed and connected." (**Figure 11-19**).

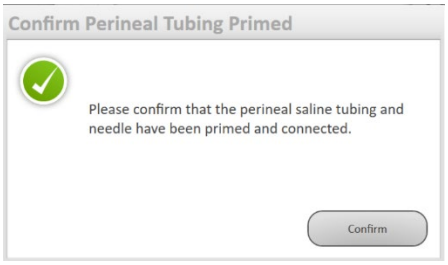


Figure 11-19: Confirm Perineal Tubing Primed

7. Select **[Confirm]** to continue to the Treatment Session screen.
8. At this stage, Status Ready indicator turns green on the Treatment Session screen (**Figure 11-20**).

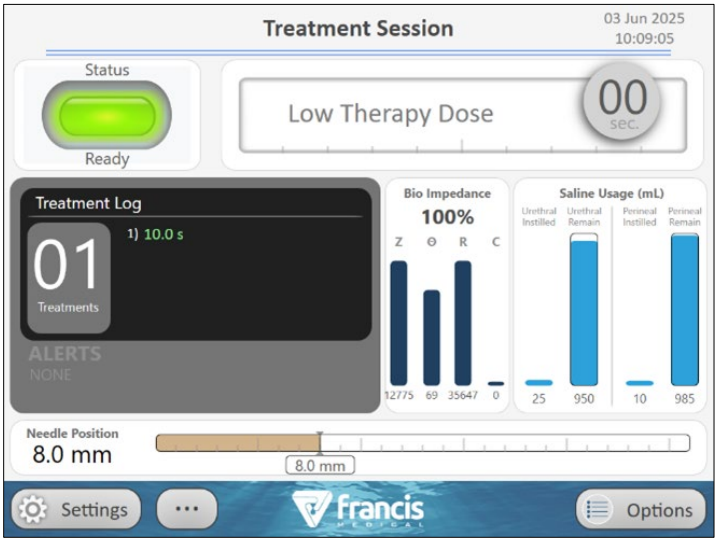


Figure 11-20: Status Ready Indicator

11.8 Readiness Checklist (Pre-Operative Checklist)

- Stabilizer System attached
- Cart and Monitor in position
- Generator and Monitor powered on
- NGS Field Generator in position
- Transrectal Ultrasound (TRUS) prepared
- Two bags of sterile saline and one bag sterile water hung
- Delivery Device connected
- Controller connected
- Saline Catheter Needle in place
- Needle tuning performed
- Auto syringe fill performed
- Cystoscopy lens inserted, camera, and light cable attached
- Urethral and Perineal tubing connected and primed
- Pre-treatment vapor cycle performed

12 Intraoperative Use

12.1 Perform Vapor Ablation Treatment

12.1.1 Insert the Delivery Device

⚠ **CAUTION: Delivery Device Insertion –** Advance the Delivery Device shaft slowly and under direct visualization to avoid creating a false passage in the prostatic urethra. A false passage can cause urethral trauma or bleeding. If a false passage is observed or suspected, immediately stop advancement and carefully withdraw the device before attempting re-insertion.

⚠ **CAUTION – Bladder Overfilling:** Monitor the amount of saline instilled during the procedure using the Generator display. Failure to empty the bladder as needed may result in bladder overfilling, potentially causing patient discomfort or procedural complications.

⚠ **CAUTION – Patient Movement:** If anesthesia lightens and the patient moves or begins to awaken, immediately stop the procedure and withdraw both instruments—first the Delivery Device, then the TRUS probe—to avoid mechanical trauma to the urethra or rectum, which can result in bleeding or tissue injury.

1. Confirm that the Generator display shows the Treatment Session Screen and the Status Indicator Light is Green (**Figure 12-1**).

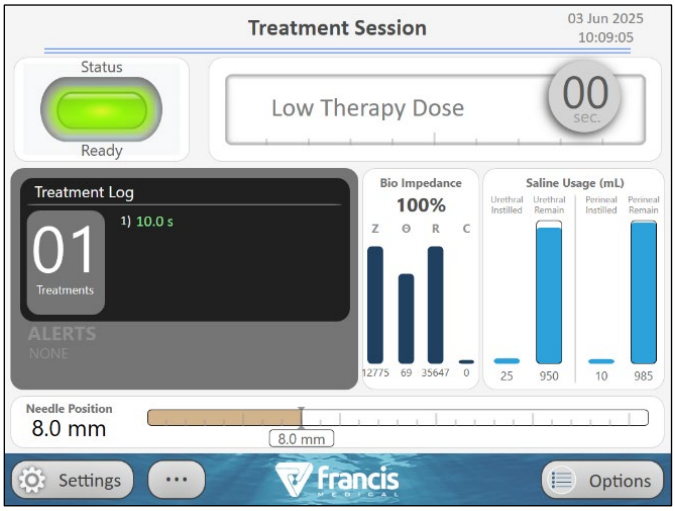


Figure 12-1: Status Indicator Light Ready

2. Detach the Delivery Device from the Delivery Device Stabilizer Arm.
3. Coat the shaft of the Delivery Device with water-soluble lubricating or anesthetizing gel.
4. Press the **Saline Flush Button** on the Delivery Device to activate the saline flush.
   - Saline will flow from the tip of the Delivery Device
5. Carefully insert the Delivery Device into the urethra through the meatus using Cystoscopy visualization.
6. Advance the Delivery Device until the distal tip of the device is in the bladder.
7. Reattach Delivery Device to the Delivery Device Stabilizer Arm.

12.1.2 Position the Field Generator

■ **NOTE:** The Field Generator (**A**) tracks positioning sensors on the Delivery Device (**C**) and TRUS Cradle (**B**) (**Figure 12-2**).

■ **NOTE:** Sensors (**B, C**) (**Figure 12-2**) must be within the tracking volume—50 cm x 50 cm x 50 cm (20 in x 20 in x 20 in) - to be located and their avatars displayed on the monitor.

■ **NOTE:** When sensors are on the edge, or out of volume, the on-screen avatars can “jitter” or “flicker”.

■ **NOTE:** The cause of flickering images is different to the cause of moving/drifting images. Drifting generally occurs when ferrous/magnetic materials, such as a cell phone or some metallic instruments, are passed through the Field Generator tracking volume.

■ **NOTE:** The Field Generator is placed in its final position **after** insertion of the Delivery Device.

■ **NOTE:** Once the Field Generator is in place, any movement can negatively impact the accuracy of the Guidance System.

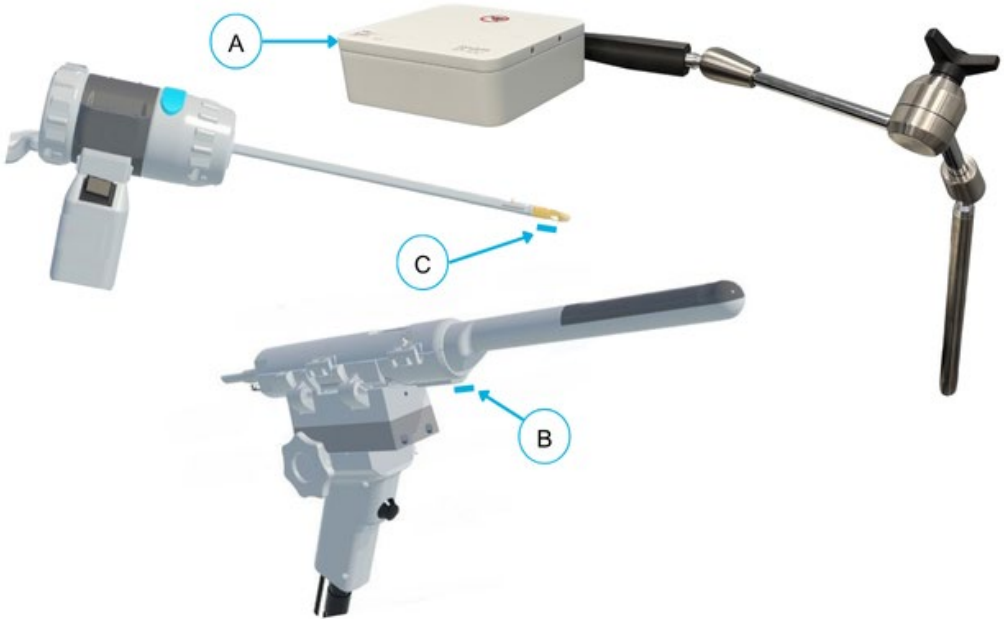


Figure 12-2: Field Generator, TRUS, and Delivery Device Sensors

12.1.3 Position Field Generator over Patient

If the adjustment takes place after the Field Generator has been covered with a sterile drape, it will require two people to perform the adjustment:

- One in the sterile field to hold and move the Field Generator
- One to loosen and tighten the Field Generator Arm Adjustment Knob

If adjustment takes place without a sterile covering, it is possible for one person to adjust, but using two people is highly recommended for additional stability.

1. Hold the Field Generator (**A**) firmly. Ideally, with both hands (**Figure 12-3**).
2. Loosen the Field Generator Adjustment Knob (**B**) until there is freedom of movement of the Field Generator.

■ **NOTE:** Continue to hold firmly until the Field Generator is in the desired position.

3. Place the Field Generator over the patient's pelvis with the front edge of the Field Generator 2-5 cm (1-2 in) over the edge of the surgical bed and patient's perineum.

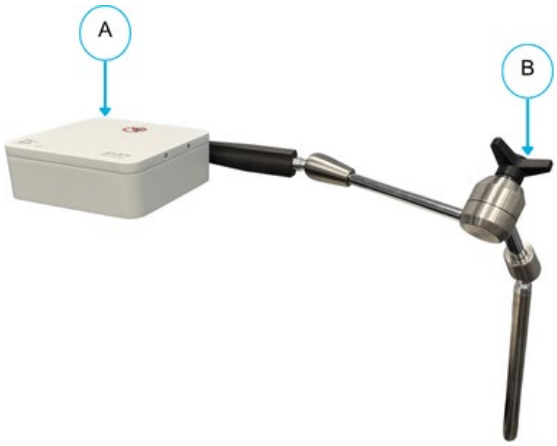


Figure 12-3: Field Generator

4. Adjust so the Field Generator is tilted slightly (~3 degrees) towards the physician.
5. Verify the TRUS (**C**) and DD (**D**) NGS Sensor error values on the PUI are less than 0.20 (ideally <0.10), and the indicator lights are green (**Figure 12-4**).
   - Ensure no magnetic material is within the Field Generator tracking volume.

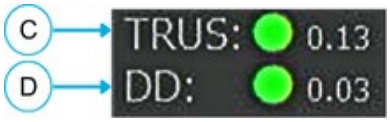


Figure 12-4: Physician User Interface - NGS Sensor Error Values

6. If the NGS Sensor errors are greater than 0.2, perform the following adjustments:
   - Ensure the delivery device rotating member is not directly over TRUS NGS Sensor
   - Ensure TRUS Cradle is within the Field Generator tracking volume
   - Lower the Field Generator if possible
   - Tilt the Field Generator slightly towards the physician user
   - Move the Field Generator until the NGS Sensor error values are as low as possible (ideally <0.10) and the indicator lights are green
   - Check for other potential sources of interference
7. Tighten the Field Generator Adjustment Knob firmly.
8. Slowly release hold of the Field Generator, confirming that it remains firmly in place.

12.1.4 Adjust the Needle Guidance System (NGS)

1. Using both the Axial and Sagittal ultrasound views, adjust the NGS Delivery Device shaft Avatar (**Figure 12-5**) as needed to correspond to the live ultrasound image using the **[NGS Position Offsets]** buttons on the Settings menu on the Generator (**Figure 12-6**).

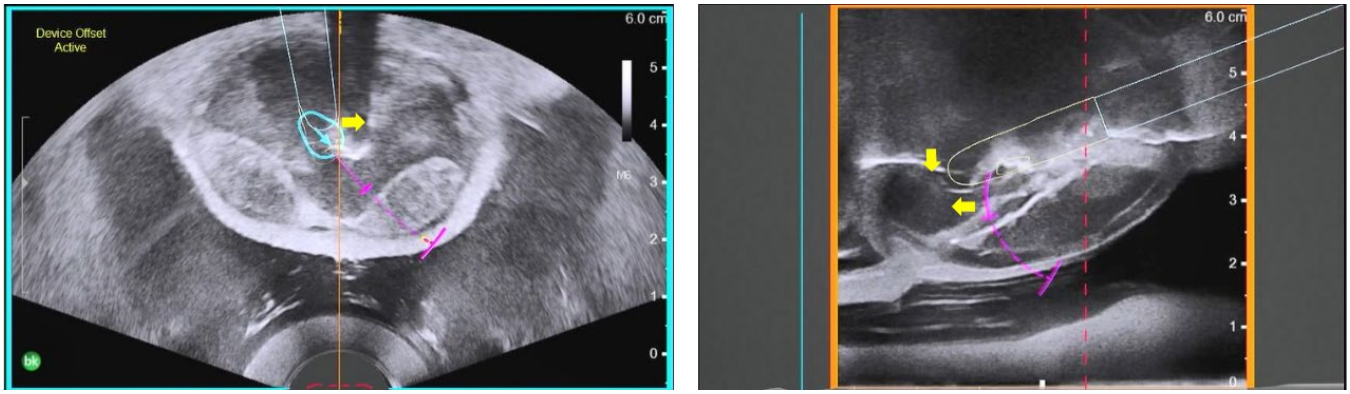


Figure 12-5: NGS Adjustment Under Ultrasound

Figure 12-6: NGS Position Offsets

12.1.5 Position the Apex Plane

1. Roll the ultrasound probe in or out to place the Apex Plane (dashed red line) at the tip of the apex (**A**) in the sagittal view (**Figure 12-7**).
2. Drop the Apex Plane by selecting the **[Drop]** button (**Figure 12-8**) on the Settings menu on the Generator.
   - The dashed red line will turn solid (**B**) (**Figure 12-7**)

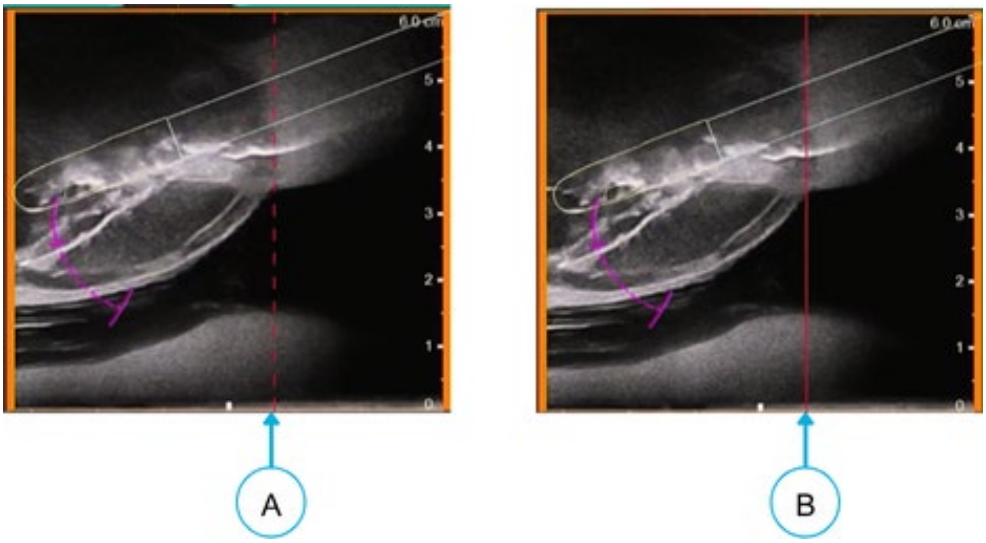


Figure 12-7: Apex Plane

Figure 12-8: Drop the Apex Plane

■ **NOTE:** The Apex Plane, once a solid red line, remains at a fixed location in space and will no longer move with the ultrasound probe. It can then be used as a measurement tool showing the distance from the tip of the apex to the Axial (Transverse) ultrasound plane (**Figure 12-9**).

■ **NOTE:** If there is movement of the prostate after the solid red line is placed, use the Apex Plane arrow buttons on the Settings menu to move the solid red line to the tip of the apex (**Figure 12-10**).

■ **NOTE:** If the TRUS Cradle is moved so that the solid red line is no longer perpendicular in the sagittal view (parallel to the blue axial plane line), press the **[Realign]** button in the Apex Plane menu on the Settings menu (**Figure 12-10**).

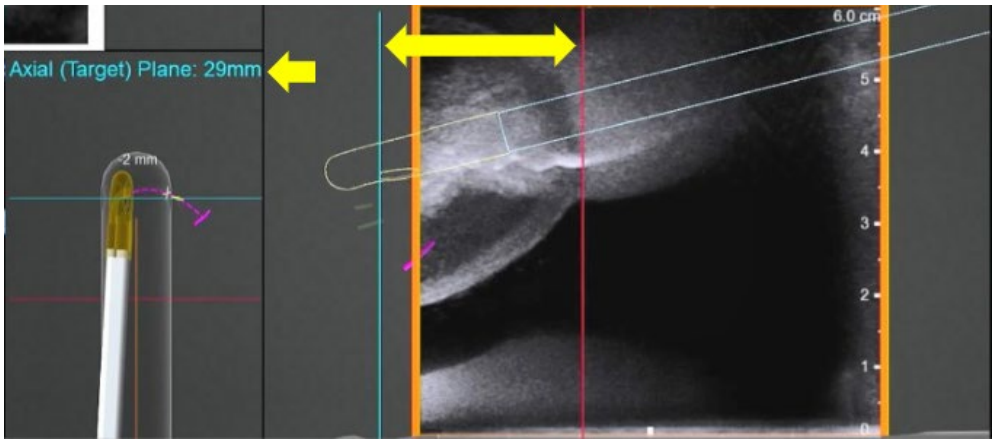


Figure 12-9: Apex Plane Measurement

Figure 12-10: Adjust the Apex Plane

3. Position ultrasound at the Target Pane.
4. Roll the ultrasound probe in or out to position the axial plane at the desired treatment plane.

■ **NOTE**: If predetermined MRI measurements have been made of the distance from the apex to the target treatment plane, those measurements can be used to optimize placement of the Axial Plane.

12.1.6 Move the Delivery Device into the Target Plane

1. Press the Stabilizer Power Switch (**D**) to allow movement of the Delivery Device Stabilizer Arm (**Figure 12-11**).
2. Move the Delivery Device to the treatment (Axial) plane previously established with positioning of the ultrasound probe. In the Axial (**A**), Top-Down (**B**), and Sagittal (**C**) views, the NGS projected Needle path will be seen crossing the blue Axial Plane (**Figure 12-12**).
3. Press the Stabilizer Power Switch on the Delivery Device Attachment to lock the Stabilizer Arm in place.

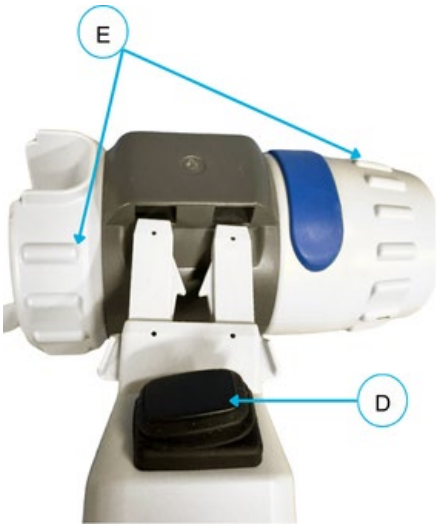


Figure 12-11: Delivery Device Rotating Members

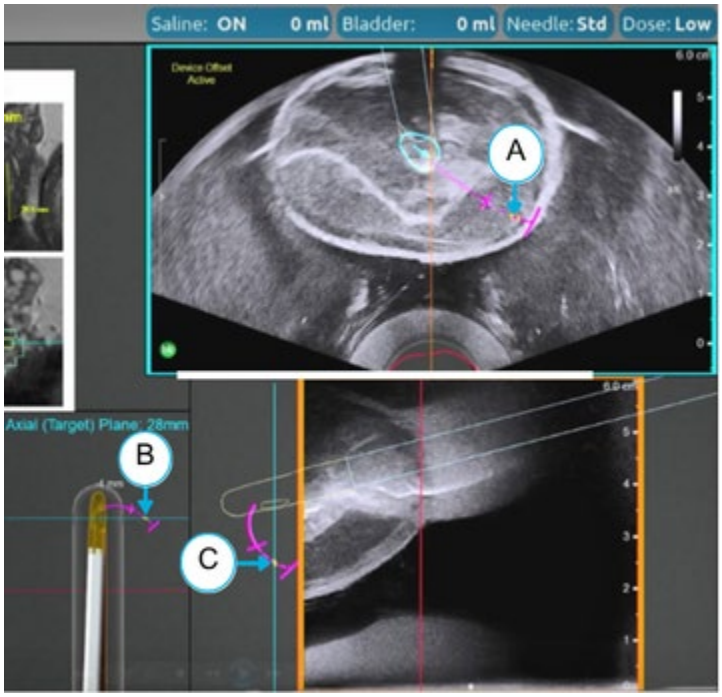


Figure 12-12: Projected Needle Path Crossing the Axial Plane

12.1.7 Adjust the Needle Delivery Angle

1. Rotate the Delivery Device using the light gray sections of the device body (**E**) to achieve the desired Needle delivery angle (**Figure 12-11**).

■ **NOTE**: In the Axial Ultrasound view, the Needle Guidance System provides information as to the range of potential Needle pathways if the Needle were deployed at a chosen angle. This range is represented as a magenta-colored arch (**A**) at the maximum deployment length. A dotted line (**B**) depicts the most likely Needle path with a solid section (**C**) depicting the initial deployment length (**Figure 12-13**).

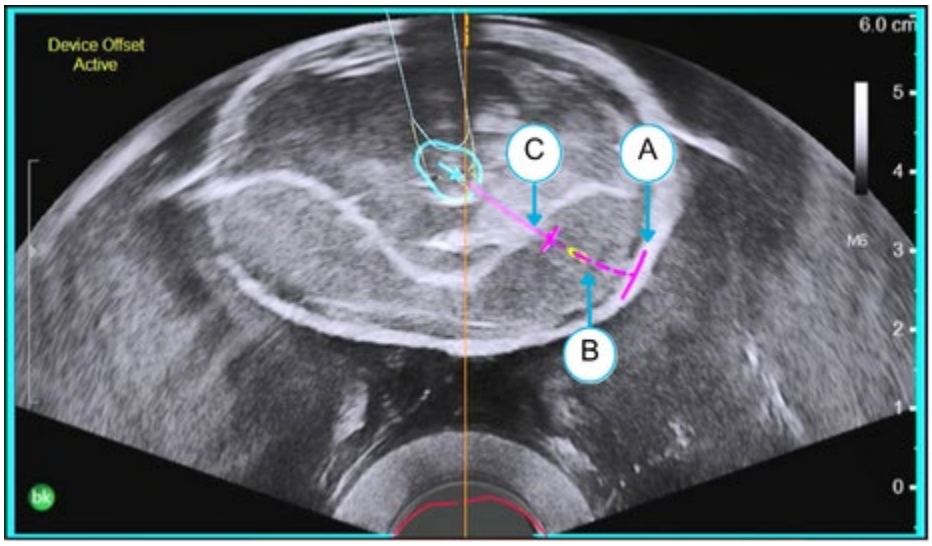


Figure 12-13: Projected Needle Path and Initial Deployment Length

2. Press the Delivery Device Attachment **Stabilizer Power Switch** (**D**) to unlock the Delivery Device Stabilizer Arm.
3. Place the distal tip of the Delivery Device shaft against the lateral urethral wall.
4. Move the device in or out as needed so that the projected Needle path crosses the Axial Plane at the target location. A yellow dot will indicate this location on the Axial Plane (**Figure 12-14**).

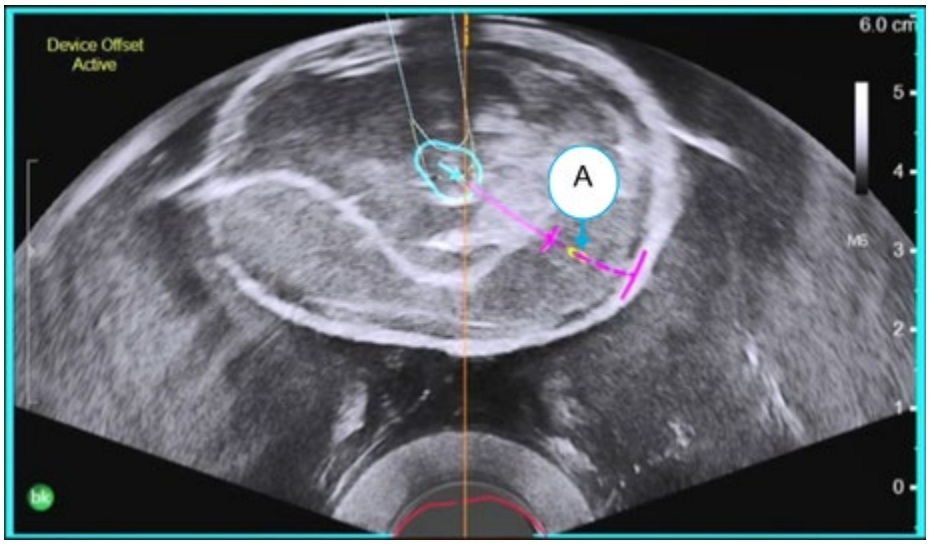


Figure 12-14: Projected Needle Path Crossing the Axial Plane

5. Press the Delivery Device **Stabilizer Power Switch (D) (Figure 12-11)** to relock the Stabilizer Arm in place.

12.1.8 Deploy the Needle

⚠ **WARNING – Proper Needle Placement:** Ensure the Needle is placed within the prostate before delivering vapor. Delivering vapor outside the prostate can damage surrounding tissue. This may lead to serious patient injury.

1. Confirm the Delivery Device is at the desired urethra location and angle for Needle deployment.
2. Adjust initial Needle Deployment to the desired length using the **Needle Deployment Length Button** on the Controller.

■ **NOTE:** The Needle will deploy to an initial length of approximately **8 mm** unless adjusted.

■ **NOTE:** The initial deployment length will display a solid line representing the distance along the predicted Needle trajectory (**A**). The initial deployment length will also be displayed in mm on the PUI in the upper right corner (**B**) (**Figure 12-15**).

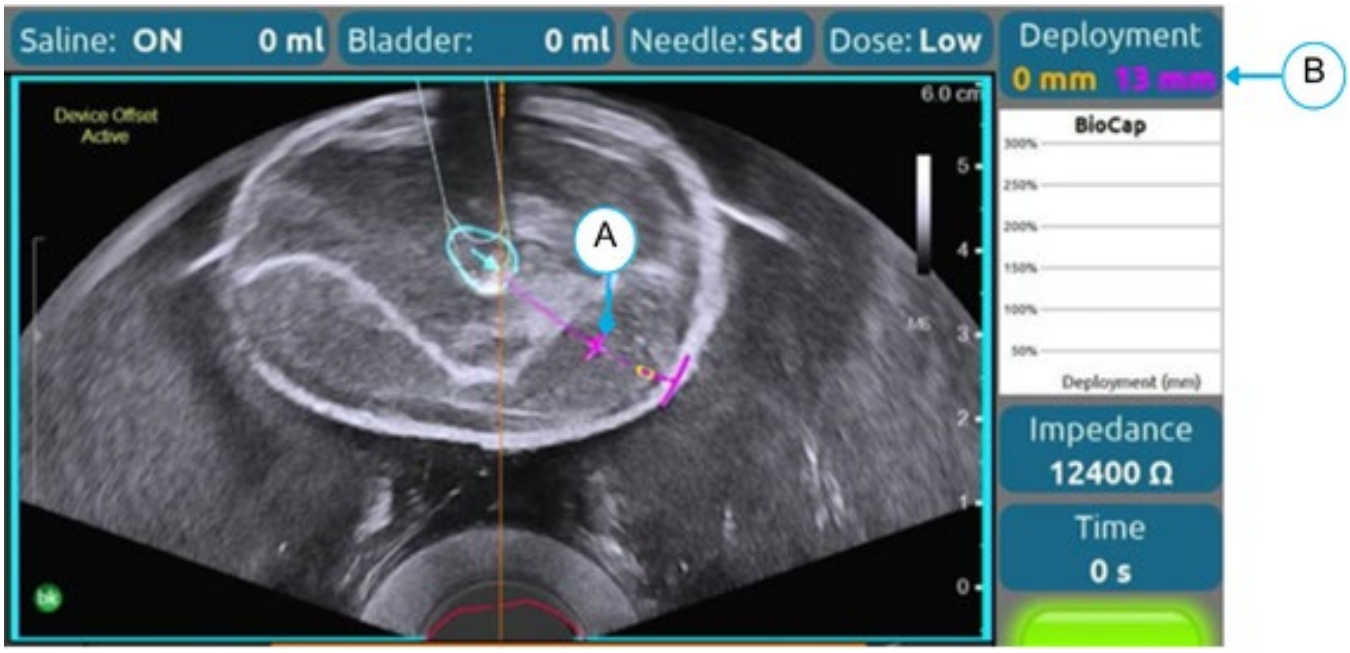


Figure 12-15: Initial Deployment Length

3. Push upward on the Controller **Needle Advance/Retract Button** to deploy the Needle.

■ **NOTE:** Once deployed, the magenta-colored projected needle path changes to two green arches. The most distal green arch (**A**) depicts the estimated location of the Needle tip, and the proximal arch (**B**) depicts the estimated location of the most proximal emitter holes. Vapor will be emitted between the two green arches (**Figure 12-16**).

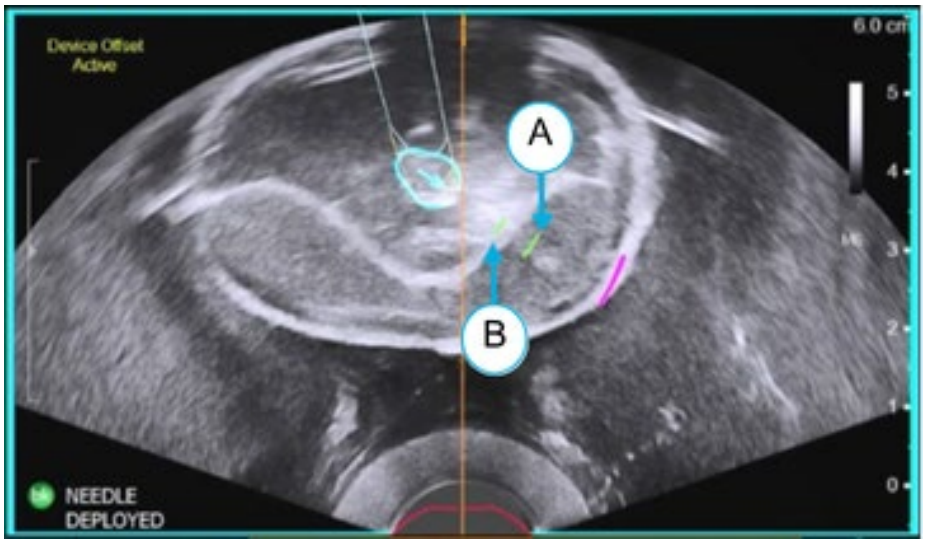


Figure 12-16: Location of Vapor Emitter Holes

4. Advance the Needle to the desired location.
   - After the initial deployment, the Needle can be advanced or retracted in 1 mm increments
   - Push upward on the Needle Advance/Retract Button repeatedly to advance to the desired location

■ **NOTE:** If the Needle does not move after 6 advancement attempts, a Stuck Needle alert will be issued by the Generator.

■ The Needle deployment distance is displayed on the **Treatment Session Screen** on the Generator (**F**) (**Figure 12-17**) and the upper right corner of the PUI (**A**) (**Figure 12-18**).

■ Although the Needle Guidance System provides information as to the estimated location of the Needle tip, this is an estimate only and **visual confirmation of the Needle tip location under ultrasound** should be made prior to making a vapor treatment.

■ The BioCap reading provides information as to the capacitance of the prostatic tissue the Needle tip is touching. As the Needle approaches the prostate capsule this reading typically increases. If the Needle is inadvertently moved through the capsule, the capacitance reading typically shows a significant decline.

Figure 12-17: Needle Deployment Length on OUI

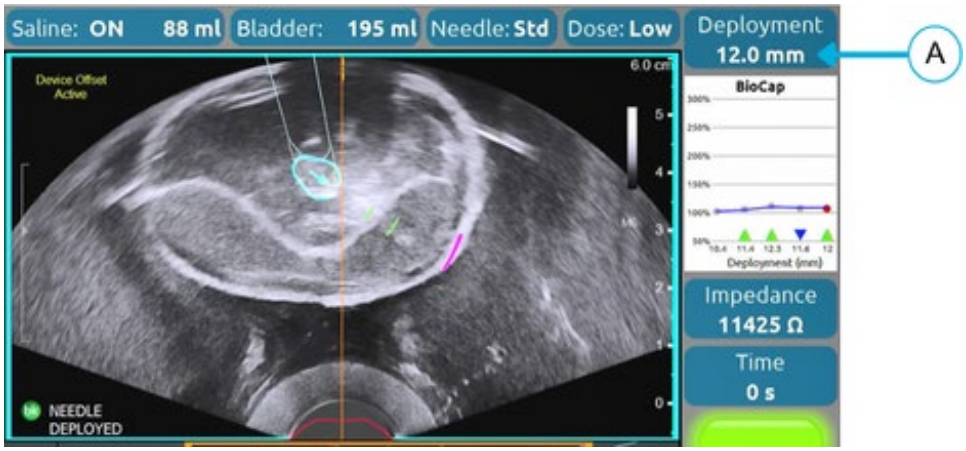


Figure 12-18: Needle Deployment Distance on PUI

5. Visually confirm via Ultrasound that the Needle has been advanced to the desired location.

■ **NOTE:** Optimal treatment requires that all the vapor emitter holes are within a single zone of the prostate. The PZ and RTX Needles have fewer holes and a shorter zone of emission and may be needed in prostates with a very narrow peripheral zone or other small treatment areas.

■ **NOTE:** The minimum treatment depth is 4 mm for PZ Needle, 5 mm for the RTX Needle and 6 mm for the Standard Needle.

12.1.9 Verify the Therapy Dose

The Therapy Dose is adjusted on the Treatment Session menu.

1. Prior to delivering vapor, verify the Therapy Dose.
   - The Therapy Dose is displayed on both the Treatment Session screen on the Generator (**A**) (**Figure 12-19**) and on the PUI (**B**) (**Figure 12-20**)

Figure 12-19: Therapy Dose on Generator

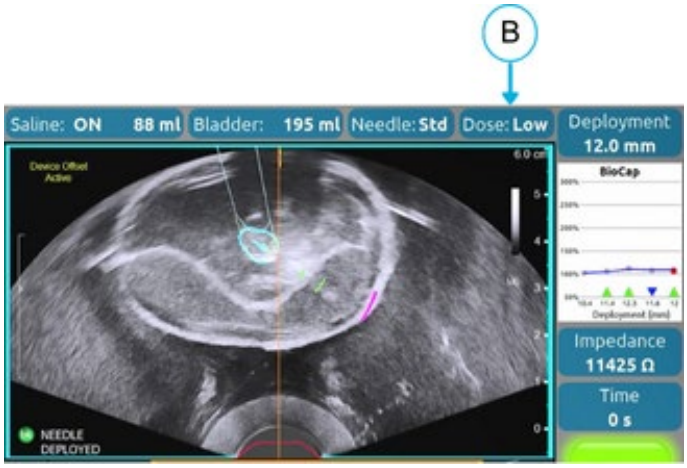


Figure 12-20: Therapy Dose on PUI

2. To adjust the Therapy Dose:
   - The Therapy Dose is adjusted on the Settings menu
   - Select **[Settings]**
   - Select the desired dose to **[Low]**, **[Standard]** or **[High]** (**Figure 12-21**)

Figure 12-21: Therapy Dose

■ **NOTE**: The default Therapy Dose is set at startup. After each full treatment, the Therapy Dose will revert to the default setting.

12.1.10 Deliver Vapor

Vapor is delivered when the **Vapor Delivery Button** on the Controller is pressed and held. Vapor delivery stops when the **Vapor Delivery Button** is released or after vapor has been delivered for 10 seconds.

⚠ **WARNING – Compromised Ultrasound Visibility:** Do not proceed with treatment if ultrasound visibility of the needle or vapor plume is compromised. Poor visibility may prevent accurate verification of needle position or vapor delivery, which can result in unintended tissue ablation and patient injury.

⚠ **WARNING – Excessive Treatments:** Take care when delivering multiple treatments in a single location. Excessive treatments in one area can lead to unintended thermal spread to adjacent tissue. This may lead to patient injury.

1. Verify under ultrasound visualization that the Needle emitter holes are in the desired location.
2. Verify that the Status Indicator Light is green (**B**) (**Figure 12-22**).
   - Status of vapor delivery is shown on the Generator screen and PUI
3. Press the **Vapor Delivery Button** (**D**) and hold down until treatment is complete (**Figure 12-23**).
   - During vapor treatment the Status Indicator Light is orange (**C**) (**Figure 12-22**)
   - The system emits one beep per second during vapor delivery
   - The maximum vapor treatment time is 10 seconds
   - When the full treatment of 10 seconds is complete, the vapor will stop automatically, the Generator will beep, and the Status Indicator Light will turn gray to indicate Status Waiting (**A**)

■ **NOTE**: To terminate vapor treatment prior to 10 seconds, release the **Vapor Delivery Button (D).**

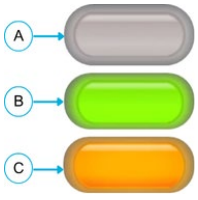


Figure 12-22: Status Indicator Light

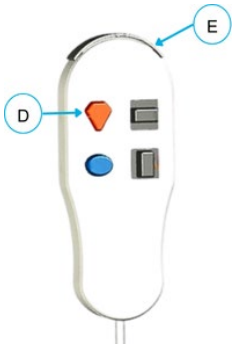


Figure 12-23: Controller Vapor Delivery Button and Perineal Saline Flush Button

4. After completion of a full 10 second treatment, the **Vapor Delivery Button (D)** should be released.

■ **NOTE**: At any time, extra saline can be injected through the Transperineal Saline Catheter Needle into the periprostatic space by pressing the **Perineal Saline Flush Button (E)** at the top of the Controller (**Figure 12-23**).

■ **NOTE**: During vapor delivery, confirm via Ultrasound that vapor is being delivered fully within a single zone of the prostate. If vapor is being delivered across zones, terminate the treatment by releasing the **Vapor Delivery Button** and reposition fully within a single zone.

■ **NOTE**: After vapor delivery, an instant replay of the most recent treatment can be viewed on the Monitor by selecting **[Open]** in the **Video Replay** section under the Settings menu on the Generator.

■ **NOTE**: It is important to utilize full 10 second treatments to ensure adequate ablation.

■ **NOTE**: The Treatment Log on the Generator screen displays each individual treatment time and a count of the number of full treatments (longer than 7 seconds) completed. Each entry is numbered, notes delivery duration (in seconds), and is color-coded by dose (**Green** = Low, **White** = Standard, **Blue** = High).

■ **NOTE**: The system is programed to deliver a maximum of 75 full 10 second treatments. When the treatment limit is reached, the Delivery Device will become permanently disabled. The Generator will emit a warning tone and an error message will be displayed: Error 220: Expired Delivery Device.

5. The Needle can be advanced or retracted along the same Needle pathway as desired in 1 mm increments for additional treatments.
   - See Section **12.1.12** for additional information on adjacent treatments

12.1.11 Retract the Needle

When all treatments have been completed along the Needle pathway, the Needle can be fully retracted by pushing downward and holding the **Needle Advance/Retract Button (F)** or by selecting the **[Full Retract]** option on the Generator screen (**Figure 12-24**).

⚠ **CAUTION – Needle Retraction:** Always confirm the Needle is fully retracted before repositioning or removing the Delivery Device. Moving the device with the Needle extended may harm the patient. This can lead to internal tissue damage.

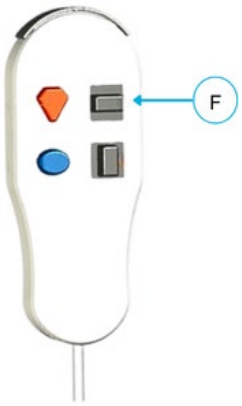


Figure 12-24: Controller Needle Advance/Retract Button

1. Press downward and hold the **Needle Advance/Retract Button** (**F**) on the Controller until the Needle is fully retracted (**Figure 12-24**).
2. Or, select **[Full Retract]** on the Generator screen. Then the next press downward on the **Needle Advance/Retract Button (F)** will fully retract the Needle.

3. Prior to moving the Delivery Device, confirm that the Needle is fully retracted.

12.1.12 Perform Additional Treatments

⚠ **CAUTION – Urethral Saline Delivery:** Ensure continuous urethral saline flow and monitor saline levels throughout the procedure. Interrupted saline delivery or an empty saline source may result in inadequate cooling, potentially causing urethral discomfort or thermal injury to the urethra.

1. Repeat steps **12.1.6** to **11.1.11** to reposition the Needle and deliver additional treatments according to the predetermined treatment plan.

■ **NOTE**: A single vapor treatment in unencumbered space will cover a radius of 8-10 mm (0.3-0.4 in) (**Figure 12-25**). Therefore, adjacent treatments should be placed approximately 8-10 mm (0.3-0.4 in) apart to allow for overlap of the ablation zones and full coverage of the targeted tissue (**Figure 12-26** and **Figure 12-27**).

■ **NOTE**: Since the movement of vapor is inhibited by the natural boundaries of the prostate (i.e. prostate capsule and surgical capsules), it is important to assess each treatment under ultrasound visualization to confirm the desired location of adjacent treatments.

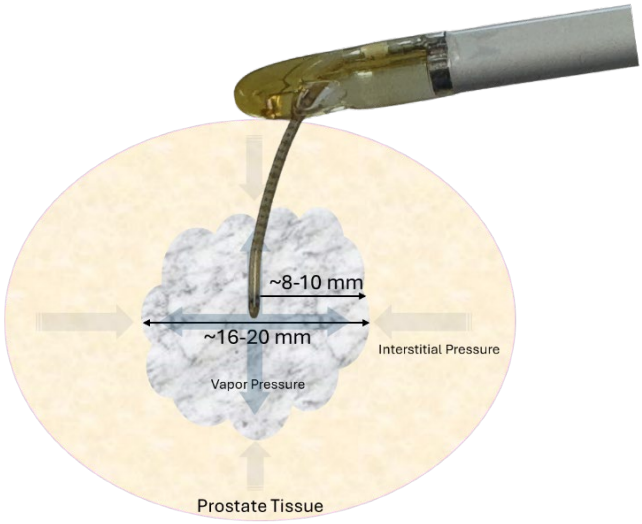


Figure 12-25: Approximate Size of a Single Vapor Treatment in Unencumbered Space

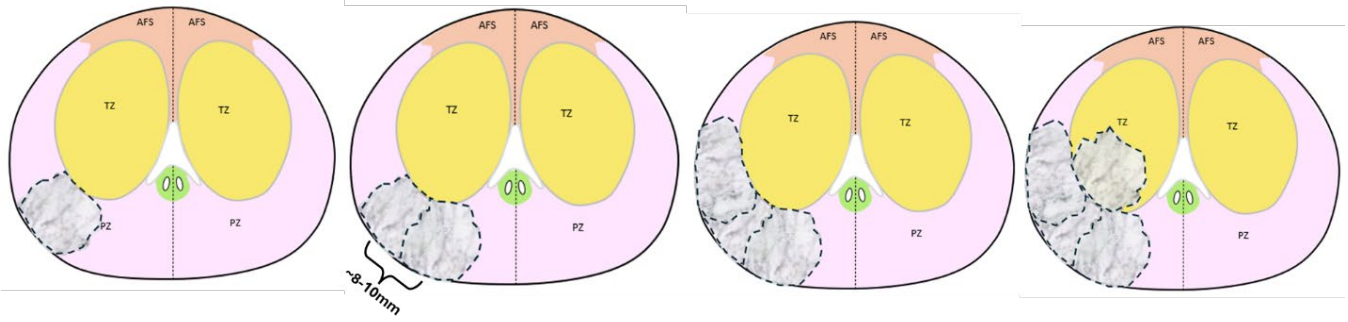


Figure 12-26: Overlapping Treatments in the Axial (Transverse) Plane

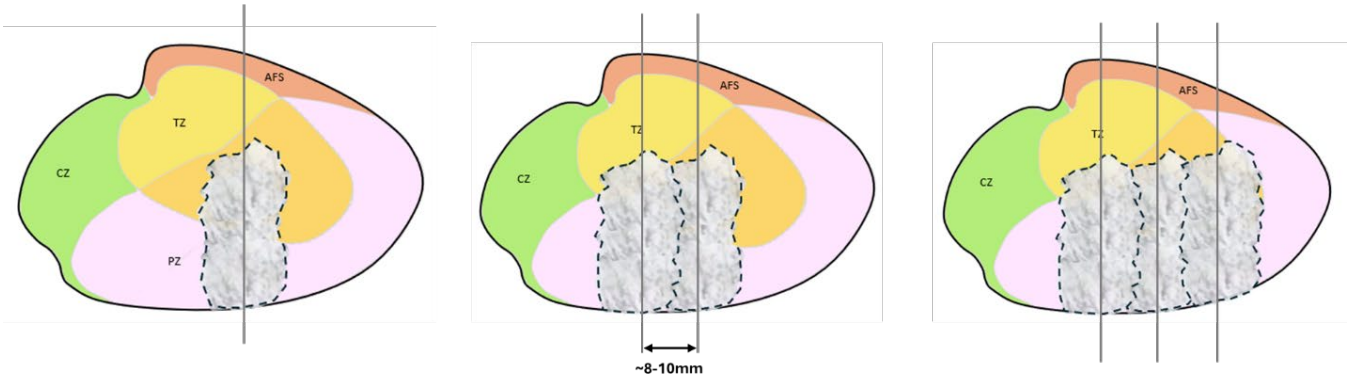


Figure 12-27: Overlapping Groups of Treatments in the Sagittal Plane

12.2 Complete the Procedure

12.2.1 Remove System Components from the Patient

1. The Needle should be fully retracted before removing the Delivery Device from the patient.
   - Confirm the Needle is fully retracted by ensuring the Deployment distance on the Generator screen reads 0.0 or by viewing the Needle in a fully retracted position through the cystoscopy lens
2. With the scope lens in place, an optional visual inspection of the urethra and bladder can be conducted at the conclusion of treatments.
3. Withdraw the Delivery Device from the urethra.
   - The Delivery Device can be removed while remaining attached to the Delivery Device Stabilizer Arm
4. When the Delivery Device is fully removed from the urethra, lock the Delivery Device Stabilizer Arm.
5. Drain the bladder.

Remove Ultrasound

1. Unlock the TRUS Stabilizer Arm.
2. Remove Ultrasound Probe from the patient.
3. Lock the TRUS Stabilizer Arm.

Remove Saline Catheter Needle

1. Remove Saline Catheter Needle from the patient.
2. Disconnect from the Saline Needle Tubing and discard.

13 Post-Procedure Workflow

13.1 Disconnect Disposable Components

1. Confirm the Delivery Device has been removed from the patient as described in **Section 12.2.1**.
2. Remove the Cystoscope lens from the Delivery Device and place in the sterile field.
3. Select **[Options]** on the Generator screen.
4. Select **[Remove Device]** from the Options menu.
5. Select **[Release]** on the Remove Device menu.
   - The Confirm Device Removal popup is displayed (**Figure 13-1**)

Figure 13-1: Confirm Device Removal

6. Select **[Confirm]** to remove the Delivery Device (**B**).
   - Select **[Cancel]** to exit without removing the Delivery Device (**A**)
7. Select **[Finish] (A)** on the **Remove Device** screen to complete the case (**Figure 13-2**).

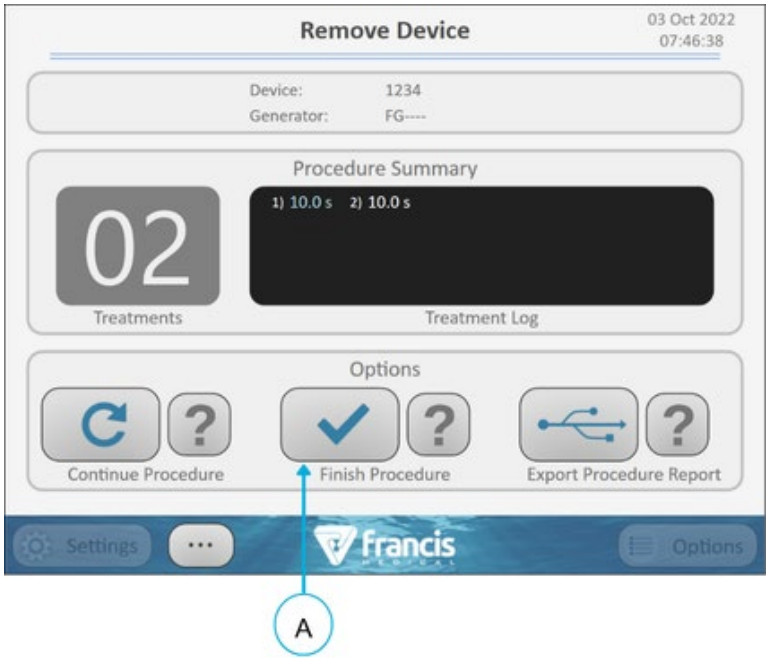


Figure 13-2: Remove Delivery Device Screen

8. Clamp all tubing sets.
9. Disconnect the Water Line between the Syringe and the Delivery Device.
10. Disconnect the Delivery Device split electrical cable from the Generator.
    - Remove the cable from the Blue 'DD NGS' port
    - Remove the cable from the Green 'DD Main' port
11. Open both Generator roller pump doors.
12. Remove the Saline Flush Line from the pump.
13. Remove Saline Needle Tubing Set from the pump.
14. Remove the Auto-Refill Syringe and Water Line from the Syringe Cradle on the Generator.
15. Remove the Delivery Device Attachment and TRUS Cradle from the Stabilizer Arms.
    - Twist to remove the attached thumb screws
16. Discard all Vanquish System disposable components according to **Section 15.1**.

13.2 Disconnect Reuseable Components

⚠ **CAUTION – Proper Disconnection Technique:** Disconnect cables by gripping the connector housing, not the cable. Pulling on the cable may damage internal wiring and impair device function. Never force a connection or disconnection.

1. Remove the Stabilizer Arms from the Motor Control Boxes.
   - Hold the Stabilizer Arm so it does not fall when released
   - Press and Hold the black 'Unlock' button on the Motor Control Box to disengage the Stabilizer Arm
2. Remove the Motor Boxes from the Stabilizer System.
3. Disconnect Motor Box power supplies from MSO.
4. Remove Field Generator and Stabilizer System components from the bed rails and disassemble.
5. Turn off the Generator using the power switch on the back.
6. Disconnect the Field Generator from the back of the Generator.
7. Disconnect the Generator power cord from the Generator.
8. Power off the Monitor to protect it from damage.
9. Disconnect the Cart power cord from the electrical outlet.
10. Clean and disinfect all reusable components after use according to **Section 15.2** and store according to **Section 16**.

14 Supplemental Instructions

This section includes instructions on occasionally used procedure steps.

14.1 To Change the Delivery Device and Continue Procedure

1. Confirm the Delivery Device has been removed from the patient as described in **Section 12.2.1**.
2. Remove the Cystoscope from the Delivery Device and place in the sterile field.
3. Select **[Options]** on the Generator screen.
4. Select **[Remove Device]** from the Options menu.
5. Select **[Release]** on the Remove Device menu.
   - The Confirm Device Removal popup is displayed (**Figure 14-1**)

Figure 14-1: Confirm Device Removal

6. Select **[Confirm]** to remove the Delivery Device (**B**).
7. To continue the procedure with a new Delivery Device, select **[Continue Procedure]** (**C**) on the Remove Device screen on the Generator (**Figure 14-2**).

Figure 14-2: Continue Procedure

8. The New Delivery Device Window is displayed (**Figure 14-3**).
   - Select **[New]** (**D**) to start a new procedure with a new Delivery Device
   - Select **[Continue]** (**E**) to continue the current procedure with a new Delivery Device

Figure 14-3: New Delivery Device window

9. With a new Delivery Device perform each of the following steps as if beginning a new procedure:
   - Delivery Device Setup (see **Sections 10.5.3, 10.5.7, 11.3**)
   - Needle Tuning (see **Section 11.3.5**)
   - Insert Cystoscope (see **Section 11.6**)
   - Pre-Treatment Vapor Cycle (see **Section 11.7**)

14.2 Drain Bladder

If necessary, the bladder can be drained during treatment through the Delivery Device.

1. Ensure the Needle is fully retracted.
2. Place the tip of the Delivery Device in the bladder to drain.
3. Unclamp the drain line.
4. Remove Cystoscope lens to expedite draining of the bladder.
5. Select **[Options]** on the Generator screen.
6. Select **[Drain Bladder]** from the Options menu.
   - The “Confirm Bladder Drain” screen will be displayed (**Figure 14-4**)

Figure 14-4: Confirm Bladder Drain

7. Allow the bladder to drain fully.
8. When the bladder is drained, re-clamp the drain line.

■ **NOTES**: Be sure to completely drain the bladder. The Generator assumes an empty bladder after Drain Bladder is activated. Failure to do so will invalidate the saline volume monitor.

■ **NOTES**: Alternatively, the Delivery Device can be removed from the patient and the bladder drained with a Foley Catheter.

9. Select **[Confirm]** on the 'Confirm Bladder Drain' popup menu to reset the saline instilled (**A**).
10. Select **[Cancel]** to exit or if the bladder was not drained (**B**).

14.3 Clearing Visual Field (Turbo Flush)

To clear bubbles from the field of vision and/or to remove a clot, activate the Turbo Flush feature by double tapping and holding the **Flush Activation Button** on either the Controller or Delivery Device.

1. Double tap and hold the **Flush Activation Button** on the Controller (**A**) or Delivery Device (**B**) to activate the Turbo Flush feature (**Figure 14-5**).
   - This leads to accelerated delivery of saline down the Delivery Device shaft to facilitate clearing of the visual field

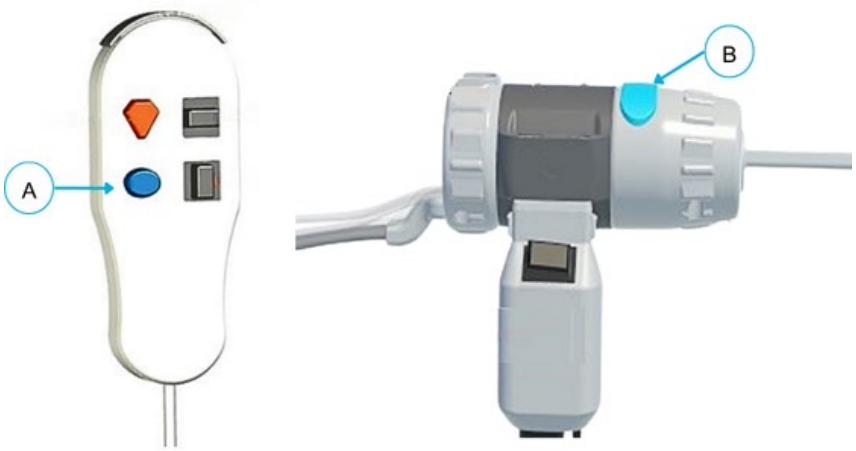


Figure 14-5: Flush Activation Button on the Controller and Delivery Device

2. Hold the Flush Activation Button until visualization is cleared.
3. When visualization is cleared, release the **Flush Activation Button**.
   - Flush will run at the normal rate the next time the **Flush Activation Button** is engaged

14.4 Method for Manual Needle Retraction

In the event the Needle retraction button fails to retract the Needle fully into the Delivery Device shaft, follow these steps to manually retract the Needle before removing the Delivery Device from the urethra. A hemostat or similar device is required.

■ **NOTE**: This should not occur under normal use and is designed only as a backup in case of device malfunction.

1. Disconnect the **Delivery Device electrical cable** from the Green DD Main and Blue NGS Main ports on the Generator.
2. Remove the Cystoscope lens from the Delivery Device and place in the sterile field.
3. Using a hemostat or other device, pull down and remove the Pullout Pin (**A**) located below the nose cone to disengage the shaft assembly from the Delivery Device (**Figure 14-6**).

Figure 14-6: Delivery Device Pullout Pin

4. Hold the shaft firmly in position and withdraw the Delivery Device just sufficiently to draw the Needle into the shaft tip (26 mm (1 in) minimum).
5. While maintaining the Needle tip within the shaft, remove the shaft and Delivery Device from patient.
6. If treatment is incomplete, re-start procedure with new Delivery Device (**Section 14.1** To Change Delivery Device and Continue Procedure) and complete procedure.
7. Report all incidences of manual Needle retraction to Francis Medical customer service.

14.5 Replace Urethral Saline Source

When the Urethral Saline volume level becomes low, the system shows an alert on the PUI “Urethral saline remining is low”. The alert is also displayed on the Generator Treatment Session screen as “Urethral saline source volume remaining is low”.

1. Hang a new bag of 0.9% injectable grade saline fluid on IV pole.
2. Remove the Saline Flush Line spike from the empty Saline bag and attach it to the new Saline bag.
3. On the Generator screen (**Figure 14-7**):
   - Select **[Options]**
   - Select **[Urethral Saline Replace]**
   - On the Replace Urethral Saline Source window, select the volume associated with the size of the Urethral saline bag **(A)**
   - Select **[Confirm] (B)**

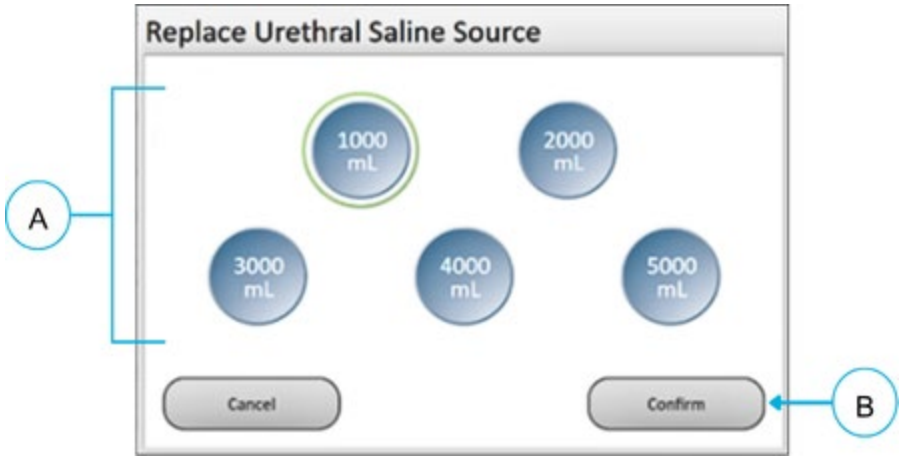


Figure 14-7: Replace Urethral Saline Source Window

14.6 Replace Perineal Saline Source

When the Perineal Saline volume level becomes low, the system shows an alert on the PUI "Perineal saline remining is low". The alert is also displayed on the Generator Treatment Session screen as "Perineal saline source volume remaining is low".

1. Hang a new bag of 0.9% injectable grade saline fluid on IV pole.
2. Remove the Saline Needle Tubing spike from the empty Saline bag and attach it to the new Saline bag.
3. On the Generator screen (**Figure 14-8**):
   - Select **[Options]**
   - Select **[Perineal Saline Replace]**
   - On the Replace Perineal Saline Source window, select the volume associated with the size of the new Saline bag **(A)**
   - Select **[Confirm] (B)**

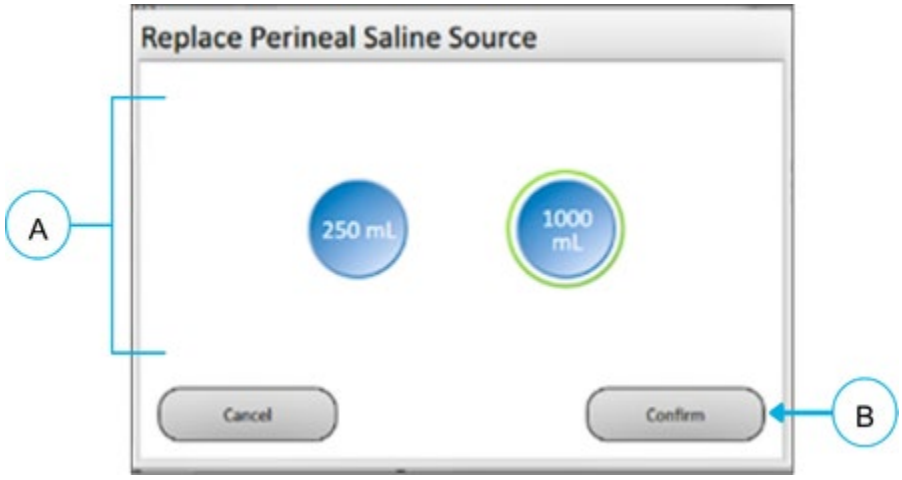


Figure 14-8: Replace Perineal Saline Source Window

14.7 Monitor Adjustments

14.7.1 Monitor Support Arm Position

The Monitor Support Arm will hold its position once the tension of the Monitor Arm Joint hex screw is properly adjusted.

Adjust Monitor Support Arm position

Before Adjusting:

1. Position the monitor so that the Support Arm is parallel to the floor.
2. Observe whether the arm drifts:
   - If the arm drifts **upward**, the hex screw is **too tight**
   - If the arm drifts **downward**, the hex screw is **too loose**

Figure 14-9: Monitor Support Arm Position

If the Arm Drifts Up (Too tight)

1. Locate the Monitor Arm Joint hex screw (see points **B** and **C** in **Figure 14-9**).
2. Insert a **7/32" Allen wrench** into the hex screw.
3. Turn the wrench **counterclockwise** to loosen.

■ **NOTE:** It may take several turns before the arm maintains position.

4. Test the arm's movement and adjust as needed.
5. The arm should remain in place when positioned.

If the Arm Drifts Down (Too loose)

1. Locate the Monitor Arm Joint hex screw (see points **B** and **C** in Figure 14-9).
2. Insert a **7/32" Allen wrench** into the hex screw.
3. Turn the wrench **clockwise** to tighten.
4. Continue adjusting until the arm holds its position when moved.

■ **NOTE:** It may take several turns before the arm maintains position.

■ **NOTE:** Do **not overtighten**, as this may damage the internal mechanism or restrict movement.

Verify Adjustment

1. Verify the Monitor is securely positioned and does not tilt or drift during use after Monitor Arm adjustment.

14.7.2 Monitor Alignment

The Monitor may tilt forward if the hex screw at the back of the Monitor becomes loose.

Adjust Monitor Alignment

1. Locate the Monitor Arm Joint hex screw.
2. Manually return the Monitor back into the correct position and hold in place.
3. Insert a **7/32" Allen wrench** into the hex screw at the base of the Monitor Support Bracket on the back of the Monitor (**A** on **Figure 14-10**).
4. Turn the wrench **clockwise** until the Monitor holds position.

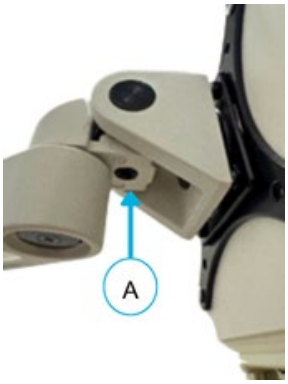


Figure 14-10: Monitor Alignment

14.8 Export Procedure Report

The Generator allows you to export a report containing treatment data for documentation or review using the USB port. This report can be exported from the Remove Device screen after a Delivery Device is removed.

Figure 14-11: Export Procedure Report

1. Insert a USB flash drive in the USB port on the side of the Generator.
2. Select **[Export Procedure Report]** on the Options menu of the Remove Device screen (**Figure 14-11**) **(A)**.
3. Select **[Complete]** when prompted.
   - The system displays “Report Exported Successfully” when done (**Figure 14-12**)
4. Select **[OK]** to close **(A)**.
5. Export Logs.

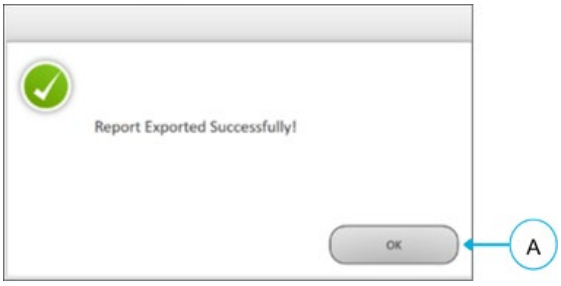


Figure 14-12: Report Exported Successfully Window

■ **NOTE:** Logs can be exported from the system at any time, or at the end of the case by selecting Export Logs from the System Information screen. The System Information screen is accessed from the Options menu. This process is described in **Section 7.7.2**.

15 Device Handling After Use

15.1 Expected Service Life and Disposal of Products

Below is the expected service life and disposal requirements for the Vanquish System and its components (**Table 54**). Dispose of all single-use products, accessories, and packaging materials in accordance with hospital, administrative and/or local government policy.

■ **NOTE**: It is the sole responsibility of the end user/equipment owner to monitor, schedule servicing, and track the number of uses for each component, in accordance with the specified service life.

Table 54: Expected Service Life and Disposal of Products

Component	Equipment Type	Expected Service Life	Disposal Guidance
Vanquish Generator Kit (4751-001)	Capital (multiple patient multiple use)	The Vanquish Generator Kit is expected to remain safe and effective for up to 5 years, provided it continues to pass visual inspection prior to use (see **Section 16**), annual inspections and maintenance performed by Francis Medical or authorized service personnel.	Contact Francis Medical.
Vanquish Capital Mounts Kit (4752-001)	Capital (multiple patient multiple use)	The Vanquish Capital Mounts Kit is expected to remain safe and effective for up to 2 years, provided it continues to pass visual inspection prior to use, annual inspections and maintenance performed by Francis Medical or authorized service personnel.	
Vanquish Cart and Monitor (4741-001)	Capital (multiple patient multiple use)	The Vanquish Cart and Monitor is expected to remain safe and effective for up to 5 years, provided it continues to pass visual inspection prior to use, annual inspections and maintenance performed by Francis Medical or authorized service personnel.	
Vanquish Stabilizer Arm Kit (5536-001)	Reusable (multiple patient multiple use)	The Vanquish Stabilizer Arms are designed for reuse. Prior to use, test the arms for flexibility and rigidity and perform visual inspection. Replace the arms if they are not flexible or not rigid enough to support the weight of the devices or if they fail visual inspection. See **Section 20**: Stabilizer Arm Reuse.	Contact Francis Medical.
Vanquish Stabilizer Kit (4573-001)	Disposable (single-use)	Single use. Refer to the expiration date on packaging.	Dispose of in accordance with local biohazardous waste regulations.
Vanquish Accessory Kit (4572-001)	Disposable (single-use)		
Vanquish Delivery Device – Standard (4570-001)	Disposable (single-use)		
Vanquish Delivery Device – PZ (4571-001)	Disposable (single-use)		
Vanquish Delivery Device – RTX (5257-001)	Disposable (single-use)		
10 cm Saline Catheter Needle (4840-001)	Disposable (single-use)		
15 cm Saline Catheter Needle (5245-001)	Disposable (single-use)		
Sterile Water Bag 250mL (4839-001)	Disposable (single-use)		

15.2 Cleaning, Disinfection, and Sterilization

15.2.1 Proper Care and Cleaning for each component

The following procedure reflects the physical design and intended use of the **Vanquish System**, as well as the typical soiling and contamination expected during clinical use.

⚠ **WARNING – Disconnect Before Cleaning:** Disconnect all equipment before cleaning. Cleaning powered equipment can create hazards. Failure to do so may lead to shock or injury.

⚠ **CAUTION – Approved Cleaning Methods:** Use only the cleaning and disinfection procedures described in this document. Unapproved cleaning methods may damage the equipment or compromise safety.

15.2.2 Intended Level of Contamination

Vanquish components are intended for indirect contact with intact skin. These components may:

- Be exposed to splatters of body fluids due to proximity to the patient
- Become contaminated by soiled hands of patient caregivers
- Be subject to unexpected or accidental contamination events

15.2.3 Required Materials

- Unused pre-moistened quaternary ammonium/isopropanol cleaning wipes, such as CaviWipe® (Metrex Research)
- Appropriate PPE for handling disinfectants (refer to facility protocols)

■ **NOTE:** Discard used wipes appropriately after each step.

■ **NOTE:** Do not spray or dump cleaning solutions directly onto equipment. Use a pre-moistened wipe or spray disinfectant on a wipe and apply it to equipment.

■ **NOTE:** Do not submerge equipment.

15.2.4 Cleaning Process

1. Thoroughly wipe and remove all gross visible soil from surfaces to be cleaned
2. Repeat thorough wiping of surfaces to be cleaned for a minimum of 2 minutes to ensure adequate mechanical removal of soil
3. Inspect for remaining visible soil
4. If any visible soil remains, repeat steps 1 through 3 until the surfaces are visibly clean

15.2.5 Intermediate-Level Disinfection Process

1. Thoroughly wipe surfaces to be disinfected ensuring they remain wet for at least 30 seconds
2. Repeat thorough wiping of all surfaces keeping the surfaces wetted with the disinfection chemistry for a minimum of 2 minutes 30 seconds. Total wet contact time is 3 minutes
3. Allow surfaces to air dry completely under ambient conditions. Do not manually dry or rinse

15.2.6 Reusable Device Re-Processing

The following components must be reprocessed after each use according to the guidelines in **Sections 15.2.4 and 15.2.5.** Reprocess the components immediately after the procedure to prevent soil drying. Unless otherwise specified, use an **Intermediate Level Disinfectant** that is compatible with the device materials and approved for use in your facility.

■ **NOTE:** Follow manufacturer's instructions for **High-Level** disinfection or sterilization of the TRUS Probe. Methods should align with hospital infection control policy and probe compatibility.

Table 55: Reusable Device Re-Processing

Component	Reprocessing Method
Generator	Clean and Disinfect with Intermediate Level disinfectant
Cart Assembly	Clean and Disinfect with Intermediate Level disinfectant
Field Generator	Clean and Disinfect with Intermediate Level disinfectant
Capital Mounts	Clean and Disinfect with Intermediate Level disinfectant
Stabilizer Arms	Clean and Disinfect with Intermediate Level disinfectant
Ultrasound	Clean and Disinfect according to manufacturer's instructions
TRUS Probe	Clean and **High Level** disinfect or sterilize (see ■ **NOTE** above)

16 Storage, Service and Maintenance

16.1 Storage

16.1.1 Storage of Capital and Reusable System Components

When not in use, all capital and reusable system components should be stored in a cool, dry, location out of direction sunlight (10 to 40°C, 10% to 85% Relative Humidity (non-condensing), and pressure 70kPa to 106kPa). The capital mounts kit and generator kit should be stored in their original packaging. The cart and monitor should be stored in the transport configuration. The stabilizer arm kit components should be stored together in a manner to prevent unintentional damage. If the components are exposed to prolonged storage conditions beyond these conditions, perform normal inspection and set-up process.

Perform visual inspection of the capital and reusable components before and after use.

- Carefully inspect components for stress or physical damage
- Inspect all external connections for loose connectors
- Inspect all external cables for damage or cracking
- Inspect the display for marks, scratches, or other damage
- Verify that the Safety label on the device is clearly legible and present
- Passes power-on self-test (Generator indicated by on screen on OUI and motor control box LED status) – See **Section 10.4** and **Section 10.5**

After the visual inspection, if reusable components are damaged or a message indicates to not use, take them out of service and call Francis Medical Customer Service.

16.1.2 Storage of Single-Use System Components

Always handle Disposable Components with care. Store in a well-ventilated area, protected from extreme temperatures and humidity (10 to 40°C, 10% to 85% Relative Humidity (non-condensing), and pressure 70kPa to 106kPa). If these components are exposed to prolonged storage conditions beyond these conditions, visually assess the sterile barrier per **Sections 10** and **10.5.4**.

Do not remove the Disposable Components from their carton/packaging until ready for use. The carton / packaging keeps the device from sunlight and UV light. If these components are inadvertently removed from the carton, visually assess the sterile barrier per **Sections 10** and **10.5.4**.

16.2 Service and Maintenance

All capital components require service on an annual basis.

The only field-serviceable components in the system are the fuses in the Generator. There are two fuses in the power inlet module slide out drawer adjacent to the power cord connection on the rear of the Generator. The fuse type is T10AH250V.

All other service and maintenance should be performed by qualified Francis Medical personnel only. Contact Francis Medical: +1 763-951-0370

No service or maintenance activities shall be performed while the device is in use with a patient.

⚠ **WARNING – Servicing:** Do not attempt to service the system except for fuse replacement. User servicing beyond fuse replacement may compromise device safety. This may lead to equipment malfunction or personal injury.

⚠ **WARNING – Fuses:** Always disconnect the Generator from its power source before replacing fuses. Changing fuses while the Generator is powered may expose users to electrical hazards. This may result in electric shock or damage to the equipment.

17 Electrical Safety, Cybersecurity, and Technical Specifications

This section describes the safety and technical characteristics of the Vanquish System.

17.1 Electrical Safety

Table 56: Basic Safety and EMC Standards

Standards	
Basic Safety	IEC 60601-1, Edition 3.2
EMC	IEC 60601-1-2, Edition 4.1

17.1.1 Physiological Effects

The system produces sterile water vapor at temperatures between 100°C and 110°C to deliver therapeutic treatment. When used as intended, the vapor ablates targeted tissue. Unintentional delivery of vapor outside the intended treatment area may result in thermal injury to adjacent tissues.

17.1.2 Temperature of Applied Parts

The patient-contacting portion of the Delivery Device (the applied part) is designed and controlled to maintain a temperature below 41°C during use. This limit is established to prevent thermal injury to the patient in accordance with IEC 60601 safety standards. Adherence to the instructions for use is essential to ensure that the temperature of the applied part remains within safe limits. Improper use or failure to follow instructions may result in unintended tissue injury due to excessive heat exposure.

17.1.3 Electromagnetic Compatibility (EMC) and Immunity (EMI)

Electromagnetic Emissions
The Vanquish System is intended for use in the electromagnetic environment below (**Table 57**). The customer or the user should ensure that the system is used accordingly.

Table 57: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Vanquish System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Vanquish System is suitable for use in a Professional Healthcare Facility environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Conducted Emissions CISPR 11	Class A	■ **NOTE:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Current Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	

Electromagnetic Immunity

Table 58: Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2, 4, 8, 15 kV Air	Complies	Relative humidity should be at least 5%.
Radiated Immunity IEC 61000-4-3	≥ 3 V/m 80 MHZ to 2.5 GHz	Complies	Portable and mobile RF communications equipment should be used no closer to any part of the Generator, including power cord and Delivery Device cable, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. See the table for Recommended Separation Distances. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[a]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Electrical Fast Transients (EFT) and Burst Immunity IEC 61000-4-4	±2 kV mains ±1 kV I/O	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge Immunity IEC 61000-4-5	±0.5, 1, 2 kV differential mode ±0.5, 1, 2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted Immunity IEC 61000-4-6	3V rms 0.15 MHz to 80 MHz 6 V rms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic Field Immunity IEC 61000-4-8	30 A/m 60 Hz	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Magnetic Field Immunity – Proximity Fields IEC 61000-4-39	65 A/m 134.2 kHz	Complies	Magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Avoid placing the device in very close proximity to strong magnetic field sources such as large motors, power distribution equipment, or RFID security gates.
Voltage Dips and Interruptions (VDI) Immunity IEC 61000-4-11	Three 100% dips each at phase angles of 0,45,90,135,180,225,270,315 degrees Thirty 30% dips each at a phase angle of 0 degrees	Complies	Mains power quality should be that of a typical commercial or hospital environment.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Generator is used exceeds the applicable RF compliance level listed in the “Test Level” column, the Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Generator.			

Recommended Separation Distances

The Vanquish System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Vanquish System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Vanquish System.

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

Table 59: Guidance and Manufacturer's Declaration – Electromagnetic Immunity to RF Wireless

Test Frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation, 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM, ± 5 kHz deviation, 1 kHz sine	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation, 217 Hz	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation, 18 Hz	28
1,720 1,845 1,970	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation, 217 Hz	28
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation, 217 Hz	28
5,240 5,500 5,785	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation, 217 Hz	9

17.2 Cybersecurity

17.2.1 Cybersecurity Controls

The system is designed as a closed, non-networked medical device and does not support connection to external systems or networks. As such, recommended cybersecurity controls (e.g., anti-malware software, firewalls, or user password policies) are not applicable to its intended use environment. Routine clinical use of the system does not require user authentication. Access to service mode, which is intended only for authorized service personnel, is restricted using multi-factor authentication (**Figure 17-1**).

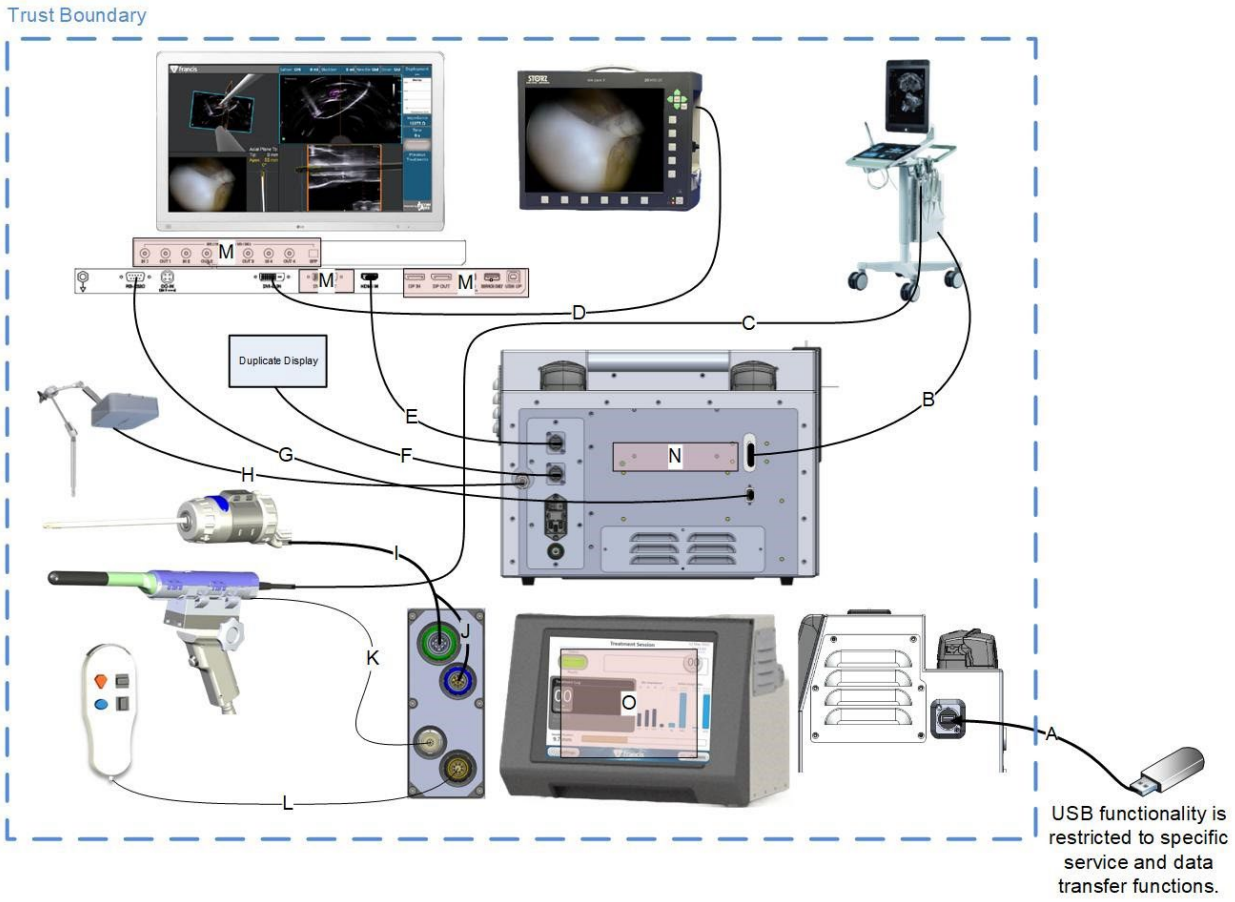


Figure 17-1: System Design

17.2.2 Network Ports and Other Interfaces

The Vanquish System is designed with deliberate restrictions to limit networking capabilities and external communication. The system does not support internet connectivity, network-based communication, or wireless communication, and does not include any capability for remote access. Additionally, external USB devices are restricted to specific service and data transfer functions. Unauthorized software execution or network communication is not supported.

The following interfaces are present on the system and are limited in function (**Table 60**).

Table 60: Network Ports and Other Interfaces

Diagram Label	Interface	Format/Protocol[1]	Direction	Functionality	Approved Endpoint(s)
A	USB Port	USB 3.1	In/Out	Imports treatment plans and exports system logs.	Authorized USB storage device, Logitech Pointer
B	HDMI to DVI (Ultrasound to Generator)	DVI (HDMI Video Compatible)	In	Transfers ultrasound video from the ultrasound system to the Generator.	Ultrasound system, Connect only to BK Specto
C	TRUS Probe	BK Proprietary	In	Connected through ultrasound system for real-time imaging.	TRUS probe via ultrasound system
D	DVI Input (from Cystoscope System)	DVI	In	Inputs cystoscope video into the physician monitor.	Cystoscope system
E	HDMI Output (Physician Monitor)	HDMI 2.0a	Out	Sends visual data from the Generator to the Physician User Interface (PUI) on the physician monitor.	Physician monitor
F	HDMI Output (Duplicate Display)	HDMI 2.0a	Out	Sends duplicate video signal from the Generator to a second display, if present.	Duplicate monitor
G	RS-232 Monitor Connection	RS-232	In/Out	Provides serial communication between the Generator and the physician monitor.	Physician monitor
H	Electromagnetic Field Generator Connection	NDI Proprietary	In/Out	Connects the EM tracking Field Generator to the Generator.	EM field generator
I	Delivery Device Main Connector	Francis Proprietary	In/Out	Connects the Delivery Device to the Generator for therapy delivery and control.	Delivery Device
J	Delivery Device NGS Connector	NDI Proprietary	In	Connects the Delivery Device electromagnetic tracking sensor to the Generator for tool tracking via the Needle Guidance System (NGS).	Delivery Device NGS sensor
K	TRUS Probe NGS Connector	NDI Proprietary	In	Connects the TRUS probe electromagnetic tracking sensor to the Generator for tool tracking via the Needle Guidance System (NGS).	TRUS probe NGS sensor
L	Controller	Francis Proprietary	In/Out	Connects the handheld physician controller to the Generator. Used by the physician to control needle movement, vapor delivery, and display settings.	Handheld physician controller
M	Unused Digital Video Inputs (Monitor)	Varied; See LG 32HL714S Specification	N/A	Present but not connected or used in standard operation.	None
N	SBC Ethernet Ports (Physically Inaccessible)	Disabled (also internal and not user facing).	N/A	Present on internal hardware but not accessible without	None

Diagram Label	Interface	Format/Protocol[1]	Direction	Functionality	Approved Endpoint(s)
				disassembly. No networking functionality supported.	
O	Operator User Interface (OUI)	LVDS (internal connection, not user facing)	In/Out	Allows interaction with system settings, images, and workflow.	Generator-integrated touchscreen UI

[1]For standard protocol specifics, see respective protocol specifications. All interfaces verified with select compatible components or cables during verification testing, including EMC/EMI. Time synchronization is handled by the system, protocol, or unneeded – no user synchronization required. For interfaces that require user interaction, the intended user is the trained physician and/or procedure support staff under physician supervision.

17.2.3 Supporting Infrastructure Requirements

The Vanquish System does not rely on external networking infrastructure for operation, servicing, or configuration. No network connectivity is supported, and no internet or intranet access is required. As a result, there are no technical requirements for secure deployment within a networked environment.

17.2.4 Software Bill of Materials (SBOM)

The SBOM for the Vanquish System is available upon request. Contact your Francis Medical representative for the most current version.

17.2.5 Software Maintenance

System software and firmware are not distributed to users and cannot be updated by users. All updates are performed exclusively by authorized Francis Medical service personnel. Users will not receive update notifications and are not expected to download or install any software or firmware components.

17.2.6 System Configurations

The system does not support alternate configurations or user-configurable settings. Upon power cycling, the device automatically restores to its original, authenticated default configuration.

17.2.7 Protection of Critical Functionality

The system is designed to protect critical functionality through layered security measures and architectural controls. These include:

- Isolation from External Networks: The system does not support network or internet connectivity, reducing exposure to remote attacks.
- Restricted Interface Access: External interfaces are limited and tightly controlled to prevent unauthorized access or modification.
- Service Mode Controls: Access to advanced system functions is restricted to authorized personnel using secure service procedures.
- Data Protection Measures: Security features are in place to protect the confidentiality and integrity of sensitive data.
- System Restoration: The system is designed to revert to its intended configuration upon restart, minimizing the risk of persistent changes due to anomalous behavior.

These protections help ensure the system continues to operate safely and effectively, even in the presence of attempted unauthorized access or anomalous events.

17.2.8 Security Event Response

The Vanquish System is designed to minimize the risk of persistent anomalous conditions through the use of a write-protected operating environment. Specifically, the system employs the Windows Unified Write Filter (UWF), which prevents permanent changes to the operating system partition. Any unauthorized modifications or abnormal system behavior are cleared upon a system power cycle.
The system does not support network connectivity or remote access, reducing exposure to security events such as network anomalies, login attempts, or data transmissions to unknown endpoints. The system does not log security-specific events, as its architecture is designed to eliminate persistence of changes and to restrict avenues for attacks.

For more information on system servicing or recovery from anomalous conditions, contact your Francis Medical representative.

17.2.9 Cybersecurity End of Support and End of Life

This system uses an operating system with a currently published end-of-support (EOS) date of 2029. After this date, the OS vendor is no longer expected to provide security patches or updates for the operating system. Users who choose to operate the system beyond the OS EOS date or beyond its designated service life assume responsibility for managing any associated cybersecurity risks.

The manufacturer will make reasonable efforts to provide updated information regarding support timelines as it becomes available. Customers are encouraged to contact their Francis Medical representative for the most current information.

17.2.10 Securely Decommissioning the Vanquish System

Before disposing of or decommissioning the Vanquish System, it is important to consider both physical and cybersecurity aspects of system retirement. This includes the proper removal or sanitization of any stored data as well as the physical disposal of reusable and capital equipment.

For detailed guidance on secure decommissioning procedures — including data sanitization, component disposal, and documentation — please contact your Francis Medical representative.

17.2.11 Manufacturer Disclosure Statement and Security Documentation

A revision-controlled Manufacturer Disclosure Statement for Medical Device Security (MDS2) is available upon request to support risk assessments and procurement processes. This document provides detailed information about the system's cybersecurity capabilities and responsibilities.

To request the MDS2 or other cybersecurity-related documentation, contact your Francis Medical representative.

17.2.12 Data Privacy and Information Disclosure

To avoid potential security-based, unintended information disclosure, Francis Medical recommends that users do not upload or display patient-identifying information within the uploaded treatment plan image, ultrasound system, or cystoscope system during procedures involving the Vanquish System. These images may be recorded or temporarily cached within the Generator's file structure. Users are responsible for managing patient data privacy in accordance with institutional protocols and applicable regulations.

17.2.13 Use of Cystoscope Output During Procedure

If the cystoscope output to the physician monitor is unavailable, the procedure may continue by using the display available on the compatible cystoscope system, if available. If both outputs are unavailable,

continuation of the procedure is at the discretion of the treating physician, based on clinical judgment and institutional policy.

17.2.14 Loss of Treatment Plan Display on Physician Monitor

In the event that the imported treatment plan cannot be viewed on the physician monitor, users may access the plan using an alternative device (e.g., an external laptop).

17.2.15 Display Troubleshooting

If the monitor display is not functioning as intended, users should attempt to use the physical control buttons on the monitor to adjust settings, including picture-in-picture sizing and display toggling. Refer to the monitor manufacturer's instructions for further guidance on display control.

17.3 Technical Specifications

Table 61: Technical Specifications

Parameter	Value				
Classifications and Ratings					
Applied Part Type	**BF**				
Patient Contacting Components	Delivery Device Shaft Delivery Device Shaft Tip Delivery Device Needle Delivery Device Needle Tip	See **Figure 6-4** and **Figure 6-5**			
Ingress Protection	IP21 Unless Marked Otherwise Exceptions: Monitor Front IP35 Monitor Except for Front IP32 Stabilizer System Power Supplies IP22				
	System	**Generator**			
Class of Protection Against Electric Shock	Class I	Class I			
Input Voltage	100-120 V AC Max	100-120 V AC Max			
Input Current	12.0 A Max	6.0 A Max			
Input Frequency	50/60 Hz Max	50/60 Hz Max			
Output Voltage	100-120 V AC Max	Not applicable			
Output Current	12.0 A Max	Not applicable			
Output Frequency	50/60 Hz Max	Not applicable			
Standards					
Basic Safety	IEC 60601-1, Edition 3.2				
EMC	IEC 60601-1-2, Edition 4.1				
Essential Performance					
Needle Movement	There will be no unintended forward movement of the Needle.				
Vapor Generation	There will be no uncommanded vapor delivered by the system.				
Essential performance parameters are monitored by the system and errors are reported and operation halted when detected by the system.					
Operating Environmental Conditions					
Temperature	18°C - 24°C (65°F - 75°F)				
Relative Humidity	30% - 60% RH				
Atmospheric Pressure	70 kPa – 106 kPa				
Physical Characteristics					
Cart Weight (unloaded)	295 lbs (134 kg)				
Cart Weight (loaded)	440 lbs (200 kg)				
Generator Weight	28 lbs (13 kg)				
Monitor	30 lbs (14 kg)				
Cart Shelf Max Load Rating	35 lbs (16 kg)				
Cart Drawer Max Load Rating	10 lbs (4.5 kg)				
Precision and Accuracy					
Name	Lower	Upper	Accuracy	Precision	Units
Perineal Saline Volume Instilled	0	1000	± 20%	1	mL
Bladder Saline Volume Instilled	0	750	± 20%	1	mL
Needle Deploy Length	0.0	26.0	± 2.0	0.1	mm
Time	0	10	± 0.1	0.1	seconds
Previous Treatments Time	0	10	± 0.1	0.1	seconds
Axial Plane to Apex	0	500[1]	± 1	1	mm
Dose (Low)	160		± 16	1	Cal/second

Parameter	Value				
Name	Lower	Upper	Accuracy	Precision	Units
Dose (Standard)	230		± 20	1	Cal/second
Dose (High)	330		± 26	1	Cal/second
Impedance	0	13125	±25%	1	Ohms
DD Error[2]	0	1.00	NA	.01	Unitless
TRUS Error[2]	0	1.00	NA	.01	Unitless

[1] Defined by the Field Generator Tracking Volume

[2] These are unitless values supplied by the NDI Tracking system that provide an indication of tracking quality. Lower is better.

18 Glossary

AC: Alternating Current
DVI: Digital Visual Interface
EMC: Electromagnetic Compatibility
EMI: Electromagnetic Interference
ESD: Electrostatic Discharge
FG: Field Generator
GUI: Graphical User Interface
HDMI: High-Definition Multimedia Interface
IFU: Instructions for Use
IV: Intravenous
MCU: Micro Controller Unit
MRI: Magnetic Resonance Imaging
MSO: Multiple Socket Outlet
NGS: Needle Guidance System
PZ: Peripheral Zone
RTX: Retreatment
STD: Standard
TRUS: Transrectal Ultrasound
USB: Universal Serial Bus

19 Appendix A: Troubleshooting

Troubleshooting error messages and associated troubleshooting steps.

19.1 Informational Error Messages

The Generator uses **Informational Error Messages** to communicate minor issues, status updates, or actions that require user awareness but do not interrupt device operation. These messages are intended to assist with smooth use and quick troubleshooting. Refer to **Table 62** whenever an informational message appears.

All informational messages appear on the Generator screen in a box with a **BLUE** outline, and an exclamation point, indicating that they are non-urgent and do not affect the overall function of the device (**Figure 19-1**).

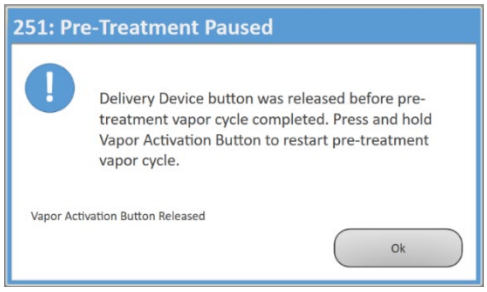


Figure 19-1: Informational Error Message Window

Each informational message includes:

- A **Code** to help identify the issue
- A **Title** for quick reference
- The **Cause** of the message
- A clear **Message** describing the appropriate user response

Table 62: Informational Error Messages

Code	Title	Cause	Informational Error Message
251	Pre-Treatment Paused	Vapor Activation Button Released	Delivery Device button was released before pre-treatment vapor cycle completed. Press and hold Vapor Activation Button to restart pre-treatment vapor cycle.
252	Needle Deployment Insufficient	Vapor Activation Button Pressed	Needle deployment is insufficient for vapor delivery.
41000	Export Error	USB Drive Not Present or Invalid	Re-insert USB flash drive and try again. If problem persists, replace USB flash drive.
41002	Export Error	USB Drive Export Error	Insert a valid USB flash drive with sufficient available memory.

19.2 Non-Critical Error Messages

Non-Critical Error Messages indicate issues that require user action to continue operation but do **not** pose an immediate safety risk or system failure. These messages alert the user to problems with components like the Controller, Delivery Device, or saline systems that may impact treatment delivery if not resolved.

Refer to **Table 63** to identify and respond to non-critical errors appropriately. In many cases, issues can be resolved by reconnecting cables, replacing components, or adjusting saline lines and syringes.

Each non-critical message is displayed on the Generator screen in a box with an **ORANGE** outline and warning symbol, visually identifying it as a **non-critical issue** that must be addressed to proceed (**Figure 19-2**).

Figure 19-2: Non-Critical Error Message Window

Each message includes:

- A **Code** for quick reference
- A **Title** that summarizes the issue
- A brief **Cause** of the error
- A detailed **Message** with instructions to resolve it

Table 63: Non-Critical Error Messages Description

Code	Title	Cause	Non-Critical Error Message
200	Faulty Controller	Unable to Read from Controller Memory	Remove and reconnect Controller electrical cable. If problem persists, replace Controller.
201	Faulty Delivery Device	Unable to Read from Delivery Device Memory	Remove and reconnect Delivery Device electrical cable. If problem persists, replace Delivery Device.
205	Faulty Controller	Unable to Write to Controller Memory	Remove and reconnect Controller electrical cable. If problem persists, replace Controller.
206	Faulty Delivery Device	Unable to Write to Delivery Device Memory	Remove and reconnect Delivery Device electrical cable. If problem persists, replace Delivery Device.
210	Faulty Delivery Device	Faulty Delivery Device Thermocouple	Replace Delivery Device.
211	Faulty Delivery Device	Faulty Delivery Device Signals	Replace Delivery Device.
215	Faulty Delivery Device	Invalid Model Number or Therapy Code	Remove and reconnect Delivery Device electrical cable. If problem persists, replace Delivery Device.
216	Faulty Controller	Invalid Model Number	Remove and reconnect Controller electrical cable. If problem persists, replace Controller.
218	Faulty Delivery Device	Delivery Device Vapor Coil Impedance Error	Replace Delivery Device.
219	Faulty Delivery Device	Delivery Device Solenoid Impedance Error	Replace Delivery Device.
220	Expired Delivery Device	Maximum Full Treatments Exceeded	Replace Delivery Device.
225	Faulty Delivery Device	Delivery Device is Permanently Disabled	Replace Delivery Device.
226	Faulty Controller	Controller is Permanently Disabled	Replace Controller.
230	Expired Delivery Device	Maximum Vapor Time Exceeded	Replace Delivery Device.
242	Pre-Treatment Failed	Low Water Pressure (Pre-Treatment)	Check syringe and water line for bubbles or leaks. If bubbles are found, release and replace syringe, and reprime Delivery Device. If leaks are found, replace Delivery Device. If no bubbles or leaks are observed, replace Delivery Device.
243	Pre-	High Water Pressure	Check water line for kinks. Resume Pre-Treatment Vapor Cycle. If

Code	Title	Cause	Non-Critical Error Message
	Treatment Failed	(Pre-Treatment)	problem persists, replace Delivery Device.
244	Pre-Treatment Failed	Low Temperature (Pre-Treatment)	Replace Delivery Device.
245	Pre-Treatment Failed	High Temperature (Pre-Treatment)	Check syringe and water line for bubbles or leaks. If bubbles are found, release and replace syringe, and reprime Delivery Device. If leaks are found, replace Delivery Device. If no bubbles or leaks are observed, replace Delivery Device.
262	Treatment Halted	Low Water Pressure (Treatment)	Check syringe and water line for bubbles or leaks. If bubbles are found, release and replace syringe, and reprime Delivery Device. If leaks are found, replace Delivery Device. If no bubbles or leaks are observed, replace Delivery Device.
263	Treatment Halted	High Water Pressure (Treatment)	Check water line for kinks. Resume treatment. If problem persists, replace Delivery Device.
264	Treatment Halted	Low Temperature (Treatment)	Retract the needle and remove the Delivery Device from patient. Replace Delivery Device.
265	Treatment Halted	Elevated Coil Temperature	Partial treatment delivered. Check syringe and water line for bubbles or leaks. If no bubbles or leaks are found, resume treatment. If problem persists, replace Delivery Device. If bubbles are found, replace syringe and reprime Delivery Device. If leaks are found, replace Delivery Device.
275	Auto-Fill/Refill Failed	Water Pressure Not Detected	Check water line for kinks or leaks and inspect syringe. Retry operation. If problem persists, replace Delivery Device.
276	Auto-Fill/Purge Failed	High Water Pressure	Check water line for kinks. Retry operation. If problem persists, replace Delivery Device.
283	Faulty Delivery Device	High Water Pressure (Idling)	Replace Delivery Device.
285	Faulty Delivery Device	High Temperature (Idling)	Replace Delivery Device.
295	Faulty Delivery Device	Needle Retraction Error	Reattempt needle retraction. If problem persists, retract needle manually and replace Delivery Device.
300	Urethral Saline Pump Error	Urethral Saline Pump Encoder Error	Ensure Delivery Device urethral saline line is correctly inserted into urethral saline pump and pump door is closed. If problem persists, contact Technical Support.
325	Confirm Bladder Drain	Urethral Saline Instilled Limit Exceeded	Urethral Saline instilled limit exceeded. Please confirm the physician has drained the bladder, or acknowledge and continue without draining.
326	Confirm Bladder Drain	Urethral Saline Instilled Limit Exceeded	Urethral saline instilled limit exceeded. Please confirm the physician has drained the bladder.
330	Perineal Saline Pump Error	Perineal Saline Pump Encoder Error	Ensure perineal saline line is correctly inserted into perineal saline pump and pump door is closed. If problem persists, contact Technical Support.
340	Syringe Pump Error	Syringe Pump Encoder Error	Ensure syringe is correctly inserted into syringe pump. If problem persists, contact Technical Support.
342	Pre-	Power Tolerance	Retract the needle and remove the Delivery Device from patient.

Code	Title	Cause	Non-Critical Error Message
	Treatment Paused	Failure	Replace Delivery Device. If problem persists, remove the Generator from service and contact Technical Support.
343	Treatment Halted	Power Tolerance Failure	Retract the needle and remove the Delivery Device from patient. Replace Delivery Device. If problem persists, remove the Generator from service and contact Technical Support.
344	Device Failure	Power Tolerance Failure	Retract the needle and remove the Delivery Device from patient. Replace Delivery Device. If problem persists, remove the Generator from service and contact Technical Support.

19.3 Critical Error Messages

Critical Error Messages indicate serious system malfunctions that require **immediate action** to protect patient safety and prevent potential device damage. When a critical error occurs, the system may halt operation and display an alert on the Generator screen in a box with a **RED** outline and a red 'X' that signifies the issue is critical and must be addressed without delay (**Figure 19-3**).

Use **Table 64** to quickly interpret and respond to critical messages.

Critical error messages typically involve internal Generator faults, communication failures, or essential component errors.

Figure 19-3: Critical Error Message Window

What to Do When a Critical Error Appears

- **Immediately retract the needle** (if applicable) (see **Section 12.1.11**)
- **Remove the Delivery Device from the patient** (see **Section 12.2.1**)
- **Follow the on-screen instructions** and refer to the table below for detailed guidance
- If the issue persists, **remove the Generator from service and contact Technical Support:** +1 763-951-0370

Each message includes:

- A **Code** for identifying the issue
- A **Title** summarizing the error type
- The **Cause** describing what triggered the error
- A clear **Message** with required next steps

Table 64: Critical Error Messages Description

Code	Title	Cause	Critical Error Message
400	Generator Error	Internal Communications Error	Retract the needle and remove the Delivery Device from patient. Power off/on the Generator. If problem persists, remove the Generator from service and contact Technical Support.
425	Generator Error	SBC Communications Critical Timeout	Retract the needle and remove the Delivery Device from patient. Power off/on the Generator. If problem persists, remove the Generator from service and contact Technical Support.

Code	Title	Cause	Critical Error Message
435	Generator Error	MCU Processing Error	Retract the needle and remove the Delivery Device from patient. Remove the Generator from service and contact Technical Support.
436	Generator Error	MCU Reset Detected	Power off/on the Generator. If problem persists, contact Technical Support.
455	Generator Error	Urethral Saline Pump Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
456	Generator Error	Perineal Saline Pump Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
457	Generator Error	Syringe Pump Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
460	Generator Error	Syringe Retract Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
465	Generator Error	Water Pressure Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
475	Generator Error	Software Compatibility Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
480	Generator Error	Sensor Interface Error	Retract the needle and remove the Delivery Device from patient. Power off/on the Generator. Replace Delivery Device. If problem persists, remove the Generator from service and contact Technical Support.
481	Generator Error	Power Supply Error	Retract needle manually and remove the Delivery Device from patient. Power off/on the Generator. Replace Delivery Device. If problem persists, remove the Generator from service and contact Technical Support.
485	Generator Error	Internal Generator Temperature Error	Retract the needle and remove the Delivery Device from patient. Power off the Generator and allow it to cool before using again.
35000	Generator Error	GUI Program Files Corrupted	Power off/on the Generator. If problem persists, contact Technical Support.
35001	Generator Error	Unexpected GUI Program Exit	Power off/on the Generator. If problem persists, contact Technical Support.
35002	Generator Error	Unable to Start GUI Program	Power off/on the Generator. If problem persists, contact Technical Support.
40000	Generator Error	GUI Unable to Communicate with MCU	Power off/on the Generator. If problem persists, contact Technical Support.

19.4 System Alerts

The Treatment Screen and Pending-Ready Screen contain an Alert Window that displays “NONE” or one of the following messages corresponding to the highest priority alert condition (**Table 65**).

■ **NOTE:** Priority of system alerts in **Table 65** is from highest (top) to lowest (bottom).

Table 65: System Alerts Description

Alert Condition	System Alert Text Displayed
Vapor Activation Button not released following vapor operation	Please release the Vapor Activation Button to continue.
Needle position insufficient for vapor	Needle deployment is insufficient for vapor delivery.
Stuck needle	Stuck Needle Detected.
700 mL of Urethral Saline instilled	Bladder may be full. Please consider draining the bladder.
600 mL of Urethral Saline Instilled	Bladder may be full. Please consider draining the bladder.

Alert Condition	System Alert Text Displayed
100 mL of Urethral Saline remaining	Urethral Saline Source volume remaining in low.
1000 mL Perineal Saline Installed	Perineal Saline instilled exceeds 1000 mL.
100 mL Perineal Saline remaining	Perineal Saline source volume remaining is low.
Remaining treatment time < 50	XX second(s) of treatment time remaining in Delivery Device.
(setpoint > (full deploy + 2 mm)) or (position > (full deploy – 2 mm))	Needle near end of travel.
Vapor attempted but is disabled	Vapor disabled.

19.5 Detailed Emergency Instructions

⚠ **CAUTION – Needle Retraction:** Always confirm the Needle is fully retracted before repositioning or removing the Delivery Device. Moving the device with the Needle extended may harm the patient. This can lead to internal tissue damage.

In rare cases where electrical power is lost during a procedure, follow the appropriate steps below based on the system's power recovery status.

19.5.1 Power Loss with System Power Restored

1. Wait for the system to complete self-test.
2. Confirm the Delivery Device Needle is fully retracted.
   - If not retracted, retract the Delivery Device Needle with the Controller
3. Detach the Delivery Device from the Stabilizer System and remove the Delivery Device from the patient.
4. Remove the TRUS Probe from the TRUS Cradle.
5. Remove the TRUS Probe from the patient.
6. Navigate to the System Setup screen and repeat all required setup steps. Refer to **Section 10.5** for detailed instructions on re-establishing system readiness before proceeding with treatment.

19.5.2 Power Loss without Return of Power (e.g., facility-wide outage)

If power cannot be restored and the needle is deployed:

1. Confirm the Delivery Device Needle is fully retracted.
   - If not retracted, proceed with manual needle retraction and removal of the Delivery Device as described in **Section 14.4**
2. If retracted, detach the Delivery Device from the Stabilizer System and remove the Delivery Device from patient.
3. Remove the TRUS Probe from the TRUS Cradle.
4. Remove the TRUS Probe from the patient.
5. Do not resume use of the system until power is restored and full setup with a new Delivery Device is re-verified.

20 Appendix B: Stabilizer Arm Reuse

The Stabilizer Arms are designed for reuse. Prior to reuse, they should be tested to ensure:

- Flexibility of the arms is not compromised
- When the arms are locked in place, they have sufficient rigidity to support the weight of the Delivery Device, TRUS Cradle, and Probe

If there is a failure of either of these tests, the Stabilizer Arms should be replaced prior to use.

21 Appendix C: Warranty

Francis Medical, Inc. (“Francis Medical”) warrants that reasonable care was used in the design and manufacture of this device. **THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY EXPRESSLY DISCLAIMED.** Handling, storage, cleaning and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, and other matters beyond Francis Medical’s control directly affect the device and the results obtained from its use. This warranty does not cover damage resulting from misuse, abuse, accident, or unauthorized alterations. Francis Medical’s obligation under this warranty is limited to the repair or replacement of this device and Francis Medical shall not be liable for any incidental, special, consequential or other indirect loss, damage or expense directly or indirectly arising from the use of this device, whether a claim is based upon warranty, contract, tort, or otherwise. Francis Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. **FRANCIS MEDICAL ASSUMES NO LIABILITY WITH RESPECT TO DEVICES REUSED, REFURBISHED, REPROCESSED OR RESTERILIZED AND MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO SUCH DEVICES**.

22 Manufacturer Information

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