Vanquish® Water Vapor Ablation System

Instructions for Use

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. Copyright

2. Manufacturer

The Vanquish System is manufactured by:

Francis Medical, Inc.
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3. Symbols, Acronyms, Terminology, Glossary

3.1 Symbols in Labeling

The symbols in **Table 1** may appear in this manual, on the reusable and disposable 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

Symbol	Description	Symbol	Description
	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
	Use by date		No sitting
	Do not resterilize		No stepping on surface
	Humidity limitation	Rx Only	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

3.2 Acronyms

DVI: Digital Visual Interface
EMC: Electromagnetic Compatibility
EMI: Electromagnetic Interference
ESD: Electrostatic Discharge
HDMI: High-Definition Multimedia Interface
IFU: Instructions for Use
IV: Intravenous
MRI: Magnetic Resonance Imaging
MSO: Multiple Socket Outlet
NGS: Needle Guidance System
PZ: Peripheral Zone
RTX: Retreatment
SCU: System Control Unit
STD: Standard
TRUS: Transrectal Ultrasound
USB: Universal Serial Bus

3.3 Terminology

To ensure clarity throughout these Instructions for Use (IFU), the following terms are used consistently:

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.

4. Document Scope and Intended Use

4.1 Scope

These Instructions for Use (IFU) provide information necessary to safely and effectively perform procedures with the **Vanquish Water Vapor Ablation System** by **Francis Medical** in a clinical setting. It is intended for trained healthcare professionals.

Detailed instructions on system setup, operation, and maintenance are provided in the **Vanquish Water Vapor Ablation System User Manual**.

4.2 Prescription Device - Rx Only

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

4.3 Intended Use

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

4.4 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.

4.5 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.

5. 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 an inaccessible prostatic urethra
- Patients contraindicated for transrectal ultrasound

6. 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.

6.1 ⚠ 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.

6.2 ⚠ 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.

7. Vanquish System Overview

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.

7.1 Vanquish System

The Vanquish System components (without tubing and cables) are figured in **Figure 7-1**.

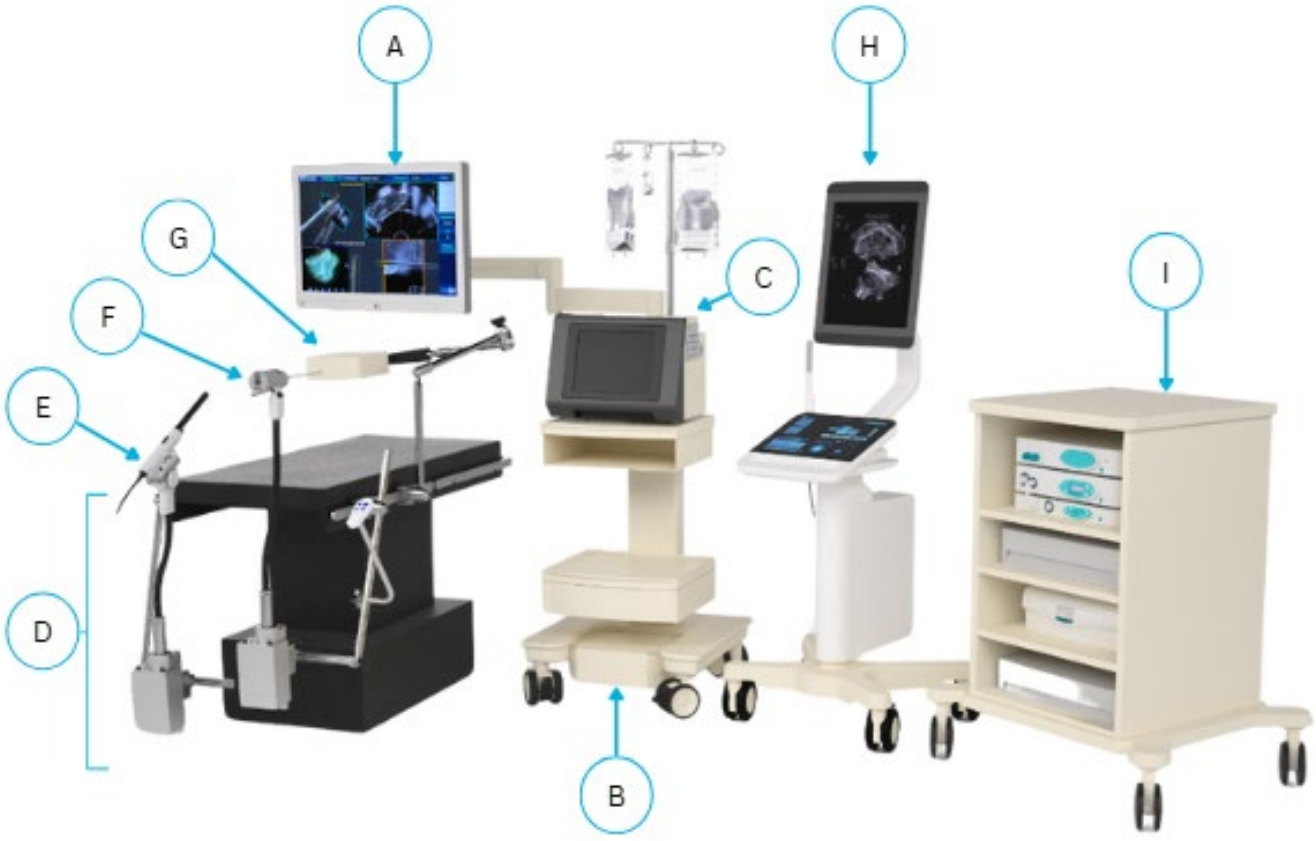

Figure 7-1: Vanquish System

Table 2: Functional Description of Vanquish System

Label	Component	Functional Description
A	Monitor	The Monitor is positioned directly over the patient and displays critical treatment information as well the Ultrasound, Cystoscopy, and NGS images utilized during the procedure.
B	Cart	The Vanquish System Cart provides a location for placement and easy movement of the System Generator and a Monitor.
C	Generator	The Vanquish Generator is used with the Delivery Device for the ablation of prostate tissue. The Generator Operator User Interface (OUI) controls and monitors the process.
D	Stabilizer System	The Stabilizer System holds the functional components of the Vanquish System in place to allow a single user to move safely and easily between components. It also is designed to minimize device movement during treatments for optimal therapeutic effect.
E	TRUS Cradle	Holds the TRUS (Transrectal Ultrasound) Probe and contains the button to engage and disengage the Stabilizer Arm.
F	Delivery Device	The Delivery Device is inserted into the prostatic urethra, rotated for alignment, deploys and advances a Needle to the targeted area of the prostate, and creates and delivers water vapor.
G	Field Generator	The Field Generator's Needle Guidance System (NGS) utilizes an electromagnetic field along with sensors on the Delivery Device and Ultrasound Cradle to provide navigation aids to the user to enable optimal Needle placement prior to vapor delivery.
H	Ultrasound	The Ultrasound provides the primary means of visual guidance during the procedure. Using the TRUS probe the prostate is viewed live in both the transverse (axial) and sagittal views.
I	Cystoscopy	The Cystoscopy system is used together with a rigid Stortz lens to provide viewing of the urethra during Delivery Device insertion and the prostatic urethra during device positioning and vapor treatment.

7.2 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 7.3**, 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 12**, Technical Specifications.
- **Essential Safety Performance**: Key performance claims related to basic safety, including physiological effects and temperature of applied parts, are described in **Section 14**, 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 15**, Electromagnetic Compatibility (EMC) and Immunity (EMI).
- **Cybersecurity:** The system incorporates cybersecurity measures to ensure safe and secure operation. These measures are described in **Section 13**, 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.

7.3 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-Relate 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.

7.4 User Supplied Materials

Other materials that are typically required for the Vanquish System procedure include, but are not limited to, the following items:

Sterile / High-Level Disinfected

- BK Medical E14CL4b (9048) Endocavity Biplane Transducer
- Lidocaine gel anesthetic or water-soluble lubricating gel
- 0.9% Injectable Grade Saline supply at room temperature (1L, 2L, 3L, 4L, 5L)
- 4mm, 30 degree, 30cm Storz cystoscope lens
- Foley Catheter
- Hemostat
- 10cc or 15cc disposable syringe
- 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)

Non-Sterile

- Cystoscopy System (must be IEC 60601-1 and IEC 60601-2-18 compliant)
- BK Medical bkSpecto Ultrasound System

8. Procedure Planning

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.

9. Procedure Steps

For detailed procedure steps, refer to the Vanquish Water Vapor Ablation System User Manual (4272-008).

1. **Prepare the Patient**
2. **Set Up**
   - 2.1. For sterile components:
     - 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
   - 2.2. Clean, disinfect, and visually inspect the following non-sterile components prior to use (see **Section 10** and **Section 11.2**):
     - Cart/Monitor
     - Generator
     - Ultrasound
     - Field Generator
     - Stabilizer Capital Mount
     - Stabilizer Arms
   - 2.3. Unpack the Stabilizer Kit

2.4. Attach the Stabilizer System
2.5. Position the Cart and Monitor
2.6. Power Up the Vanquish Generator and Monitor
2.7. Position the NGS Field Generator
2.8. Set Up the Transrectal Ultrasound (TRUS)
   - **NOTE:** The Vanquish System is designed to be used with the bkSpecto Transrectal Ultrasound and BK E14CL4b Transducer
2.9. Prepare the Sterile Saline and Sterile Water Bags
2.10. Unpack Delivery Device Components
2.11. Unpack The Accessory Kit
2.12. Unpack the Saline Catheter Needle
2.13. Connect The Controller
2.14. Connect the Auto Refill Syringe, and Tubing Set
2.15. Connect the Saline Needle Tubing Set
2.16. Set Up the Vanquish System Delivery Device
2.17. Perform Needle Tuning
2.18. Perform Syringe Auto Fill
2.19. Insert the Rigid Cystoscope Lens
   - **NOTE:** The Delivery Device is compatible with a 4mm, 30 degree, 30cm length Storz lens.
2.20. Perform the Pre-Treatment Vapor Cycle
2.21. Confirm the Readiness/Pre-Operative Checklist (see Vanquish Water Ablation System User Manual 4272-008 for details)
2.22. Successfully performing the steps above confirms that all automated quality control procedures are complete
2.23. Insert the Transperineal Saline Catheter Needle

3. Perform the Transurethral Vapor Ablation Treatment

3.1. Confirm that the Generator display shows the Treatment Session Screen and the Status Indicator Light is Green.
3.2. Coat the shaft of the Delivery Device with water-soluble lubricating or anesthetizing gel.
3.3. Detach Delivery Device from the Stabilizer System and insert into prostatic urethra.
3.4. Use Saline Flush as needed to clear the visual field
3.5. Reattach the Delivery Device to the Stabilizer System.
3.6. Using the cystoscope, ultrasound and The Needle Guidance System (NGS), position the Delivery Device to the desired position within the urethra.
3.7. Rotate the Delivery Device to achieve the desired delivery angle.
3.8. Deploy and advance the Needle to the desired location, confirming via ultrasound.
3.9. Deliver the vapor treatment.
3.10. To deliver additional treatments along the same pathway, the Needle can be advanced or retracted in 1 mm increments.
3.11. When all treatments have been completed along the Needle pathway, fully retract the Needle.
3.12. Repeat steps 3.6 through 3.10 of this section for additional treatments.

4. Conclude Procedure

4.1. Remove and dispose (according to local regulations) of disposable components
4.2. Clean, disinfect, visually inspect and store reusable components

10. Cleaning and Disinfecting Reusable Components

The following cleaning and disinfecting method reflects the physical design of the Vanquish System and intended use, and the soiling and contamination to which the device will be subject during clinical use. The Vanquish components to be cleaned and disinfected contact only intact skin via indirect patient contact and may be subject to splatter of body fluids because of proximity to the patient, or these components may be subject to contamination during use from contact with soiled hands of patient caregivers or be subject to contamination by unexpected or accidental events. The Vanquish components to be cleaned and disinfected must be reprocessed after each use. Reprocess the components immediately after the procedure to prevent soil drying.

Required Materials

- Unused pre-moistened quaternary ammonium / isopropanol cleaning wipes ("cleaning wipes") such as CaviWipe® from Metrex Research (validated chemistry).
- 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.

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

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

Failure to thoroughly clean reusable components may result in contamination and infection.

Carefully read labels and instructions including warnings, precautions, and proper disposal for all cleaning materials. Detailed information on the reprocessing requirements of specific system components can be found in the Vanquish Water Ablation System User Manual (4272-008).

11. Storage, Maintenance, and Handling

11.1 Expected Service Life and Disposal of Products

Table 5 contains the expected service life and disposal requirements for the Vanquish System and its components:

Table 5: 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 11.2**), 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 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.	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)		
10cm Saline Catheter Needle (4840-001)	Disposable (single-use)		
15cm Saline Catheter Needle (5245-001)	Disposable (single-use)		
Sterile Water Bag 250 mL (4839-001)	Disposable (single-use)		

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

11.2 Storage and Maintenance of Vanquish System Capital and Reusable Components

Storage Requirements

When not in use, all capital and reusable system components should be stored in a cool, dry, location away from direction sunlight (10-40°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 Vanquish Water Ablation System User Manual (4272-008) **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.

Maintenance Requirements

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. Detailed information on the service life of specific system components can be found in the Vanquish Water Ablation System User Manual (4272-008).

11.3 Storage and Maintenance of Vanquish System Single-Use Components

Storage Requirements

Always handle Disposable Components with care. Store in a well-ventilated area, protected from extreme temperatures and humidity (10-40°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.

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.

12. Technical Specifications

Table 6: 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** in **Vanquish Water Ablation System User Manual (4272-008).**			
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

Parameter	Value				
Name	Lower	Upper	Accuracy	Precision	Units
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
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

13. Cybersecurity

The Vanquish System is a closed, non-networked medical device that does not support internet, wireless, or network-based communication. This design significantly reduces exposure to common cybersecurity threats by limiting external connectivity and access points. Routine clinical use does not require user authentication, and USB ports are restricted to approved functions such as importing treatment plans and exporting logs.

System software and firmware are not user-accessible and may only be updated by authorized Francis Medical service personnel. The device operates in a write-protected environment, automatically restoring to its validated configuration after each power cycle to help prevent persistent unauthorized changes.

Patient-identifying information should not be entered or displayed on the system, as images from external sources (e.g., ultrasound, cystoscope) may be cached temporarily. For additional information, refer to the Vanquish Water Vapor Ablation System User Manual or contact Francis Medical.

14. IEC 60601 Basic Safety and Essential Performance

14.1 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.

14.2 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.

15. Electromagnetic Compatibility (EMC) and Immunity (EMI)

15.1 Electromagnetic Emissions

The Vanquish System is intended for use in the electromagnetic environment below. The customer or the user should ensure that the system is used accordingly (see **Table 7**).

Table 7: 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. **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.
Conducted Emissions CISPR 11	Class A	
Harmonic Current Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	

15.2 Electromagnetic Immunity

Table 8: 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.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
			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.
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.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
[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.			

15.3 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 9: Guidance and Manufacturer's Declaration – Electromagnetic Immunity to RF Wireless Communications Equipment

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